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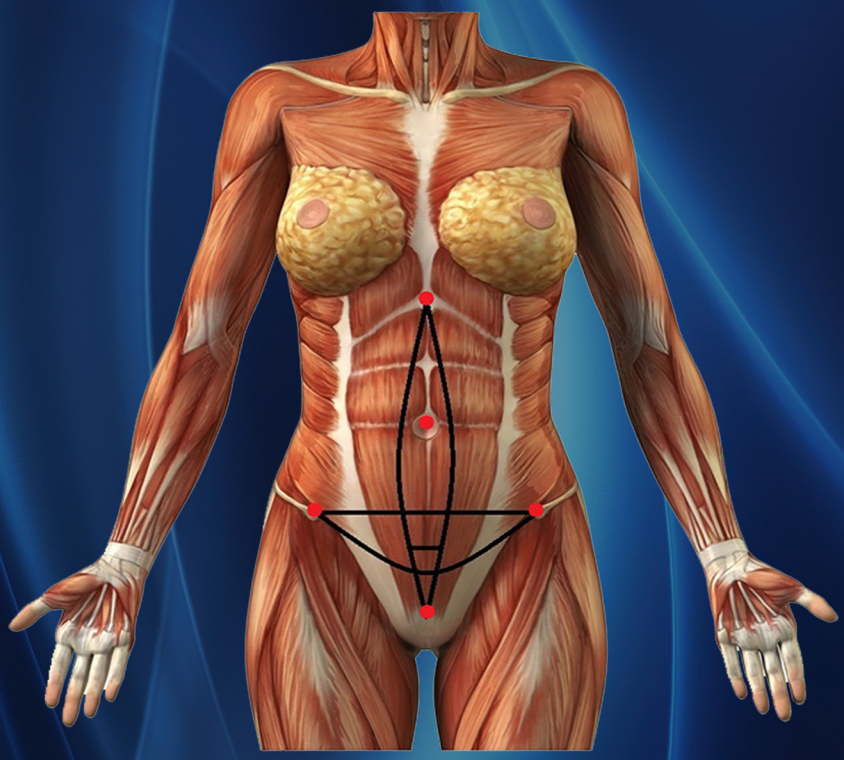

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REVISTA BRASILEIRA DE CIRURGIA PLÁSTICA

BRAZILIAN JOURNAL OF PLASTIC SURGERY

Jan/Feb/Mar - 2019 - Volume 34, Issue 1

REVISTA BRASILEIRA DE CIRURGIA PLÁSTICA
BRAZILIAN JOURNAL OF PLASTIC SURGERY

INSTRUCTIONS TO AUTHORS

The Brazilian Journal of Plastic Surgery is the official publication of the Brazilian Society of Plastic Surgery (BSPS). It is a quarterly journal, and has been regularly published since 1986. The Brazilian Journal of Plastic Surgery is indexed in the Latin American and Caribbean Health Sciences Literature (LILACS) database.

The aim of the Brazilian Journal of Plastic Surgery is to record scientific developments in Reconstructive and Aesthetic Plastic Surgery, to promote research, and to support and inform professionals in this specialty, as well as to report new investigations, surgical experiments, and other original contributions.

Manuscripts submitted for publication in the Brazilian Journal of Plastic Surgery must cover topics related to plastic surgery and related areas. The journal publishes the following types of articles: Editorials, Original Articles, Review Articles, Case Reports, Ideas and Innovations, Special Articles, and Letters to the Editor.

Articles for advertising or commercial purposes will not be accepted.

The authors are responsible for the content and information in their manuscripts. The Brazilian Journal of Plastic Surgery strongly condemns plagiarism and self-plagiarism; such manuscripts will be immediately excluded from the evaluation process.

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Editorial - These are generally articles published in each issue of the Brazilian Journal of Plastic Surgery, selected for their importance to the scientific community. These are written either by the Editorial Board or by renowned specialists in their subject areas. The Editorial Board may consider publishing editorials that are spontaneously submitted.

Original Article - This category includes controlled and randomized trials and observational studies, as well as basic investigations using animal experimentation. Original articles must contain the following sections: Introduction, Objective, Methods, Results, Discussion, Conclusion, References, Summary, and Abstract. The length of the text should not exceed 3,000 words, excluding tables, references, summary, and abstract. The number of references should not exceed 30, and the number of figures or figure parts should be limited to 20. There should be no more than 4 tables.

Review Article - These are critical and organized evaluations of the literature related to a specific subject of clinical importance. Review articles should be limited to 3,000 words, excluding references and tables, and a maximum of 6 figures or figure parts. References should have been recently published, preferably in the last 5 years. The maximum number allowed is 40.

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Prior to publication, all articles submitted to the Brazilian Journal of Plastic Surgery undergo a review and arbitration process, in order to ensure quality and appropriateness in the selection of articles to be published. Initially, articles are evaluated by the office secretary, to determine whether they comply with publication standards and are complete. All manuscripts are then submitted to peer review by at least three reviewers, who are selected from among the members of the Editorial Board. Article acceptance is based on originality, significance, and scientific contribution. The reviewers fill out a form that provides a rigorous appraisal of all items of an article. At the end, the reviewers make general comments about the work and express their opinion as to whether it should be published or revised according to recommendations. Based on this information, the editor makes a final decision. In case of discrepancies between the reviewers, an additional opinion may be requested for a better assessment. When reviewers suggest modifications, these are then forwarded to the corresponding author, and a revised manuscript is subsequently sent to reviewers to determine whether suggestions/requirements were met. In exceptional cases, when required by the subject of the manuscript, the Editor can request the opinion of a professional who is not part of the Editorial Board, for an evaluation. This entire process is carried out through the submission and management system for online publication (GNPapers). The evaluation is double-blinded, ensuring anonymity throughout the process. The decision on the acceptance of the article for publication will occur, whenever possible, within 3 months from the date of its receipt. The dates for receiving and approving the manuscript for publication are reported in the article published, in order to respect the priority interests of the authors. The Brazilian Journal of Plastic Surgery asks its reviewers to follow the Committee on Publication Ethics (COPE) Ethical Guidelines for Peer Reviewers, available at: http://publicationethics.org/files/Ethical_guidelines_for_peer_reviewers_0.pdf

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Research on Humans and Animals

Studies involving human research should comply with the Declaration of Helsinki (http://www.wma.net/en/30publications/10policies/b3/) and Resolution 466/2012 of the National Health Council (http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf). Authors are reminded of the need to complete an informed consent form for all participants in the research. Two copies should be signed, one remaining with the participant and the other with the researcher. Research carried out by consulting medical records or databases requires the written consent of the legally responsible individual or the clinical director of an institution, to obtain documents.

Animal investigations must be carried out in accordance with rules applicable to such procedures, as specified in the Basel Declaration (www.basel-declaration.org) and the Guide for the Care and Use of Laboratory Animals (Institute of Laboratory Animal Resources, National Academy of Sciences, Washington, D.C., USA). The Editorial Board of the Journal may decline articles that do not strictly comply with ethical principles of research, whether involving humans or animals. The authors should accurately identify all drugs and chemicals used, providing the names of active ingredients, dosages, and routes of administration. They should also avoid using commercial or proprietary names.

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The Brazilian Journal of Plastic Surgery supports the clinical trial registration policies of the World Health Organization (WHO) and International Committee of Medical Journal Editors (ICMJE), recognizing the importance of these initiatives for the international registration and dissemination of information on open access clinical trials. Thus, clinical trials are only acceptable if duly registered before the start of data collection on www.clinicaltrials.gov or an equivalent international repository. The identification number should be recorded at the end of the abstract.

Within this context, the Brazilian Journal of Plastic Surgery adopts the definition of a clinical trial recommended by the WHO, summarized as follows: "any research that prospectively designates humans for one or more interventions aimed at assessing their effects on health-related outcomes. Interventions include drugs, cells and other biological products, surgical procedures, radiological, devices, behavioral therapies, changes in care processes, preventive care, etc".

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We suggest that authorship criteria for articles be adopted according to the recommendations of the ICMJE. Thus, only those individuals who have contributed directly to the intellectual content of the work should be listed as authors.

The authors should meet all the following criteria, in order to have public responsibility for the work content:

1. Having conceived and planned the activities that led to the final work, or interpreted the results of these activities, or both;
2. Having written the work or revised successive versions and taken part in the review process;
3. Having approved the final version.

Individuals who do not meet the aforementioned requirements or whose participation consists of purely technical or general support may be mentioned in the Acknowledgments section.

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The Journal adheres to the Vancouver Requirements - Uniform Requirements for Manuscripts Submitted to Biomedical Journals, as organized by the *ICMJE* - "Vancouver Group", available at www.icmje.org. Compliance with the instructions is mandatory for the study to be considered for review.

Identification
The manuscript should include the title of the work, written in a concise and descriptive manner, in Portuguese and English, the full names of the authors and their respective titles, as well as the institution where the study was carried out. These should be followed by the name of the corresponding author, along with the author's address, telephone, and e-mail. If the work was presented at a conference, the name of the event, place, and date of the presentation should be mentioned. Potential conflicts of interest and funding sources should be stated.
The maximum number of authors permitted for an article is 8, and the contribution of each author must be specified. Authors are considered those who have: contributed substantially to the design and planning, and/or analysis and interpretation of the data; contributed significantly to the draft or critical review of the content; and participated in the approval of the final version of the manuscript.

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Text
Articles should be divided in accordance with the category to which they belong. References should be cited numerically in order of appearance in the text, using superscript numerals.

Introduction - This section should discuss the purpose of the article and the rationale for the study. It must establish the theoretical premise that led the authors to investigate the topic. The Introduction should explain why the topic should be studied, clarifying flaws or inconsistencies in the literature and/or difficulties in clinical practice that make the work interesting to the specialist.

Objective - This section must describe the purpose of the work clearly and objectively in one paragraph.

Methods - This section should clearly describe the basis for selection of observation and experimental elements, such as patients, laboratory animals, and controls. Where appropriate, inclusion and exclusion criteria should be described. This section should provide sufficient detail to allow reproduction and use in other works. Methods that have already been published, but about which little is generally known, must be accompanied by a bibliographical reference; new techniques should be described in detail. Similarly, the time and place of study, statistical methods, and any computer programs should be described.
The authors should state in this section that the study was approved by the Ethics Committee of the institution where the work was carried out, providing the registration number in the text.

Results - Tables and illustrations should be presented in a logical sequence in the text. The information in tables or figures should not be repeated in the text.

Discussion - In this section, the author is expected to demonstrate personal knowledge and critical thinking in relation to the work, by comparing the results obtained with those in the literature. Comments should be related to the scope, position, and correlation of the study with respect to other literature and should include limitations and future prospects.

Conclusions - These should be concise and address only the proposed objectives.

Acknowledgments - If desired, these should be presented at the end of the text, mentioning the names of participants who contributed intellectually or technically in any phase of the work, but did not meet the requirements for authorship. Any funding agency that supported the research that resulted in the published article should also be mentioned.

References
References should be cited when actually consulted, in Arabic superscript numerals and numbered in the order of citation in the text. All authors up to 6 should be cited; if the authors exceed 6, the first 6 should be cited, followed by et al. The presentation should be based on the "Vancouver Style" format and the titles of the journals should be abbreviated according to the style presented in the List of Journals Indexed in Index Medicus, of the National Library of Medicine. The following are some examples of the main types of bibliographic references; other examples can be consulted at the website of the National Library of Medicine (http://www.nlm.nih.gov/bsd/ uniform_requirements.html).

Journal Article
Quintas RC, Coutinho AL. Risk factors for the commitment of surgical margins in basal cell carcinomas resections. Rev Bras Cir Plást. 2008;23(2):116-9.

Book Chapter
D'Assumpção EA. Problems and solutions in rhytidoplasty. In: Melega JM, Baroudi R, eds. Plastic surgery fundamentals and art: cosmetic surgery. Rio de Janeiro: Medsi; 2003. p. 147-65.

Book
Saldanha O. Lipoabdominoplasty. Rio de Janeiro: Di Livros; 2004.

Thesis

Freitas RS. Jaw bone elongation using internal device: quantitative analysis of results [Doctoral thesis]. São Paulo: University of São Paulo, School of Medicine; 2003. 97p.

Events

Carreirão S. Reduction mammoplasty. In: XXXVI Brazilian Conference of Plastic Surgery; 2001 Nov 11-16; Rio de Janeiro, Brazil.

Tables

The numbering of tables should be sequential, using Arabic numerals, in the order in which they are cited in the text. All tables (maximum of 4) should have a title and header for columns and should be cited in the text. The table footer should include the legend for abbreviations and statistical tests used.

The tables should be presented only as necessary for the effective understanding of the work, and should not repeat information already mentioned in the text.

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All figures (graphs, photographs, illustrations) should be numbered sequentially, in Arabic numerals, following their order of citation.

The figures must be accompanied by their respective legends, but these should not be included within the image. Abbreviations used in the figures must be spelled out in the legends.

The number of figures must not exceed 20 (twenty) for original articles, and each image attached to the study is considered a figure; for example, Figure 1 (A, B, C, D), will correspond to 4 of the 20 allowed figures.

Photos of patients should have a uniform background, especially when color is used, and without showing any foreign objects, e.g., doorknobs, lamps, etc. The field photographed should be strictly of the area of interest. In pictures of the face, use resources to prevent patient identification; however, if identification is possible, the author should enclose an individual authorization.

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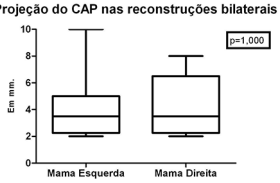
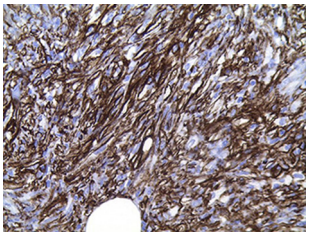
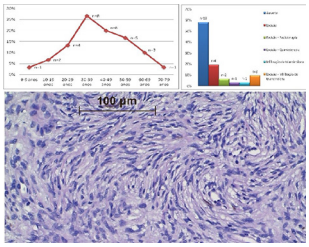
Line art	Image consisting of lines and text that does not contain shading or shaded areas		tif, png, jpg	1-bit monochrome or RGB	300 dpi
Medium shade	Continuous photo shade that does not contain text		tif, png, jpg	RGB or grayscale	300 dpi
Combination	Containing halftone image plus text or line-art elements		tif, png, jpg	RGB or grayscale	300 dpi

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• Shade example taken from: Alves JC, Fonseca RP, Silva Filho AF, Andrade Filho JS, Araujo IC, Almeida AC, et al. Ressecção alargada no tratamento do dermatofibrossarcoma protuberante. Rev Bras Cir Plást. 2014;29(3):395-403.

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Manuscripts must be submitted electronically at www.rbcp.org.br. Authors must register before submitting the work, following the guidelines that appear on the website. Texts, figures, and tables should be inserted in the respective fields in the electronic submission system.

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Once accepted for publication, a sample of the article for publishing (PDF format) will be sent to the corresponding author for evaluation and final approval.

CHECKLISTS

Prior to the submission of a manuscript, the authors should use the checklist corresponding to the category of the article:

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- STARD (Standards for Reporting of Diagnostic Accuracy) checklist and flowchart for studies of diagnostic accuracy, available at: http://www.stard-statement.org/
- PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) checklist and flowchart for systematic reviews, available at: http://www.prisma-statement.org/
- STROBE checklist for observational studies in epidemiology, available at: http://www.strobe-statement.org/index.php?id=strobe-home

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Brazilian Journal of Plastic Surgery

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EDITORIAL / EDITORIAL

ORIGINAL ARTICLES / ARTIGOS ORIGINAIS

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REVIEW ARTICLE / ARTIGO DE REVISÃO

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SPECIAL ARTICLE / ARTIGO ESPECIAL

Editorial

The Authority of the Impact Factor

A autoridade do Fator de Impacto

The impact factor is the most commonly cited measure used to evaluate the quality of a journal and reflects the ratio of the number of citations of a journal to its number of published articles, based on the previous two years[1-2]. The impact factor is proportionally higher in journals with a high number of readers and consequently underestimates the importance of articles published in journals that are more specific and directed to subspecialties. As it directly reflects the number of citations and consequently accesses, more generalist journals often have a higher impact factor. Compare the impact factor of the *New England Journal of Medicine* – NEJM (72.4) with *Plastic and Reconstructive Surgery* (3.78); certainly, a publication in NEJM will have a greater chance of being read by a general reader. On the other hand, it is more likely that a plastic surgeon will first read an article of interest published in the journal of their specialty. Thus, in the author's point of view, it is essential to define whether the goal is to disseminate a study in order to gain visibility in general or influence peers with the results obtained, even when publishing in journals of lesser circulation, but of high quality, such as specialized journals. The role of doctors and researchers is to disseminate their results for the well-being of their patients, implementing improvements in diagnosis, management, and therapy outcome. It is essential to understand the limitations of the impact factor to encourage submission to journals of lesser specialties that are also impactful[1,3].

There is clear pressure in the academic environment to publish in journals with high impact to ensure the best performance indices for the service of origin, in addition to requirements in graduate courses and higher chances of obtaining funding. The exclusive use of the impact factor as a tool to classify journals in our country should be reassessed. This does not relate exclusively to our specialty, but to all specialized areas of medicine that coexist with the dilemma between publishing for appearance and publishing to disseminate science. Of course, a publication in a high-impact, well-known journal does not merit debate, but there are many less-qualified journals with much higher impact rates than specialist journals. These situations should be evaluated. How can we explain that the world's leading plastic surgery journal does not merit the highest classification in Qualis-Capes? This is not unique to our specialty, as discussed earlier.

New methodologies should be implemented to classify journals, nationally and internationally. Publishers' associations have sought to provide justifications and stimuli for publishers in order to increase the evaluation metric to assess the readability of an article. Open access is one way, as it allows greater scope in terms of readers. This dissemination of medical knowledge to a broader audience not yet evaluated or accounted for by the impact factor should become the main path for change.

DOV GOLDENBERG
Editor-in-Chief of the RBCP

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2. Mohamed NS, Gwam CU, Etcheson JI, George NE, Piuzzi NS, Rosas S, et al. Impact factors of orthopaedic journals between 2010 and 2016: trends and comparisons with other surgical specialties. Ann Transl Med. 2018;6(7):114. DOI: https://doi.org/10.21037/atm.2018.03.02
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DOI: 10.5935/2177-1235.2019RBCP0001

Original Article

Perioperative systematization for the prevention of hematomas following face-lift procedures: a personal approach based on 1,138 surgical cases

Sistematização perioperatória para prevenção de hematomas em face-lifts: abordagem pessoal após 1.138 casos operados

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Conflicts of interest: none.

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■ **ABSTRACT**

Introduction: Hematoma, the most frequent complication of face-lift procedures, may require a second surgical approach, which delays patient recovery. In the literature, its incidence ranges from 0.2% to 8%, and further studies are essential to standardize preventive measures. The objective is to present a proposal of perioperative systematization for effectively prevention of hematoma formation after rhytidectomies. **Methods:** We analyzed the medical records of 594 patients who underwent operation by the author between 2011 and 2018 to compare the incidence of hematomas before and after the systematization implemented in 2015. **Results:** From July 2011 to December 2014, before the adoption of the systematization, the incidence of hematomas was 3.43% in 233 cases. After its adoption, the incidence decreased to 1.66% in 361 cases. The last 177 consecutive cases did not have this complication. **Conclusion:** We observed a significant reduction in the incidence of hematomas following rhytidectomy after the use of the proposed standardization. None of the measures would be effective alone; thus, their combined adoption is essential in preventing this serious complication.

Keywords: Rhytidectomy; Hematoma; Protocols; Postoperative complications.

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■ **RESUMO**

Introdução: O hematoma, complicação mais frequente do *face-lift*, pode exigir reabordagem cirúrgica e atrasar a recuperação do paciente. Na literatura, sua incidência varia entre 0,2 e 8%, sendo fundamentais novos estudos para padronização das medidas de prevenção. O objetivo é apresentar uma proposta de sistematização perioperatória que previna eficientemente a formação de hematomas em ritidoplastias. **Métodos:** Foram analisados 594 prontuários de pacientes operados pelo autor entre os anos de 2011 a 2018 a fim de se comparar as incidências de hematomas anteriores e posteriores à sistematização implementada no ano de 2015. **Resultados:** De julho de 2011 a dezembro de 2014, antes da adoção da sistematização, houve uma incidência de hematomas de 3,43% em 233 casos. Após sua adoção, houve uma queda para 1,66% em 361 casos realizados. Os últimos 177 casos consecutivos não apresentaram a complicação. **Conclusão:** Observamos redução expressiva da incidência de hematomas pós-ritidoplastias após o uso da padronização proposta. Nenhuma das medidas adotadas seria eficiente isoladamente, sendo o conjunto essencial na prevenção desta grave complicação.

Descritores: Ritidoplastia; Hematoma; Protocolos; Complicações pós-operatórias.

INTRODUCTION

Initially, attempts to treat wrinkles were based on resections of skin bands associated with broad tissue detachment, with short-term results and poor-quality scars[1-4]. Indeed, superficial muscular aponeurotic system (SMAS) treatments represent a wide evolution in face-lift surgery, with more lasting and natural results than other treatments[1-4].

The search for more efficient operative techniques or tactics with better results, always associated with greater safety and lower incidence of complications in the short and long term, continues until today[1,3-5].

Despite the ongoing improvement, the most frequent complication of face-lift surgery continues to be hematoma, which when of large proportions, may compromise flap vascularization, for which another urgent surgical approach is required (expansive and/or voluminous case), significantly delaying patient recovery. It can also prolong the time of edema and ecchymoses, with risks of developing necrosis, dyschromia, and irregularities in the skin after healing[6-9].

According to the literature, the incidence of hematomas following face-lift procedures ranges from 0.2% to 8%, and in men, the incidence can reach 12.9%[8-10] (Table 1).

Several measures have been taken to reduce the incidence of hematomas, such as blood pressure (BP) control in the perioperative and postoperative periods, dressings, drains, fibrin glue, and platelet gel[7,9,10]. Nevertheless, hematoma persists as the main complication of face-lift procedures, with the constant analysis and study of cases being essential for better standardization of preventive measures for this significant complication (Figures 1A and 1B).

OBJECTIVES

This study aimed to present a proposal of perioperative and postoperative systematization for the prevention of hematoma formation after rhytidectomies by analyzing current literatures, a series of cases, and the author's personal experience.

METHODS

The author has been performing face-lift procedures since 1992. Over the years, several changes in approaches have been proposed to improve results and reduce complications. Since 2015, the author has been using complete systematization, which is presented below and in Chart 1. The data of all the cases analyzed in this article were collected from medical records of the institution, whose clinical director is the main author. The study was conducted in accordance with the principles of the Declaration of Helsinki.

All the face-lift procedures were performed in a hospital environment, with the patient under general

Table 1. Incidence of hematomas requiring surgical evacuation following rhytidectomy in women and men*

Authors	Year	No. of cases of hematoma		Incidence (%)
Before 1980†				
Serson-Nesto	1964	170	2	1.2
Galozzi et al.	1965	100	3	3.0
Conway	1970	325	21	6.6
McGregor and Greenberg	1971	524	42	8.0
McDowell	1972	105	3	2.9
Webster	1972	221	2	0.9
Pitanguy et al.	1972	1600	89	5.5
Rees et al.	1973	806	23	2.9
Barker	1974	163	2	1.3
Black	1976	1804	48	2.7
Baker et al.	1977	1500	46	3.0
Stark	1977	500	13	2.6
Leist et al.	1977	324	19	5.9
Straith et al.	1977	500	8	1.6
Thompson and Ashley	1978	922	44	5.0
Lemmon and Hamra	1980	577	5	0.8
Total		10141	370	3.6
After 1980†				
Matsunaga	1981	427	1	0,2
Fodor	1982	100	1	1,0
Owsley	1983	435	6	1,4
Lemmon	1983	1445	8	0,5
Shirakabe	1988	738	9	1,2
Rees et al.	1994	1236	23	1,9
Marchac and Sandor	1994	412	17	4,2
Heinreichs and Kaidi	1999	200	2	1,0
Kamer and Song	2000	451	10	2,2
Grover et al.	2001	1078	45	4,2
Total		6522	122	1,9

*Compilation of major series in the world literature; †Without blood pressure control or monitoring; ‡With blood pressure control or monitoring.

anesthesia and with noninvasive BP monitoring and indwelling urinary catheterization.

Approximately 100 mL of 0.375% lidocaine solution was infiltrated by hemiface, with adrenaline at 1:600,000. Although some authors avoid such infiltration because of the risk of vasodilation rebound after the use of adrenaline solution[10], we believe that this approach facilitates detachment and visualization of the appropriate surgical plan, in addition to minimizing intraoperative bleeding and facilitating definitive hemostasis[7,8].

The surgical time for hemostasis is never <20 minutes for each hemiface and is always performed with systolic pressure values of ≥130 mmHg. Definitive hemostasis should never be performed in hypotension.

In all the cases, we used quilting sutures with absorbable stitches between the detached flap and the SMAS, similar to Baroudi's stitches in abdominoplasties[11,12]. Generally, eight stitches were distributed in each hemiface to hinder the expansion of an eventual hematoma, besides reducing the dead space and facilitating the adhesion of the flap (Figure 2).

We routinely used fibrin glue (Tessel®) in the detached area of the face and neck with the intention of improving flap adhesion, enhancing hemostasis, and preventing hematomas (Figure 3).

We did not use a drain, and the dressing was made with a low compressive elastic mesh and compresses soaked in cold saline solution, which were renewed every hour. Moreover, we placed frozen gel bags on the compresses, which were also renewed systematically every hour. The objective was to generate vasoconstriction in the first hours and inhibit bleeding.

All the dressing was removed the next morning at the time of discharge, and the patients continued to use

Figure 1. A: Significant postoperative hematoma; **B:** Significant postoperative hematoma

the frozen gel bags over the hemifaces (always with the skin protected) at home, 30 minutes at a time and with intervals of 1 hour for a total period of 48 hours (except at night to sleep).

During hospitalization, all the patients were instructed to remain with their heads held at approximately 30°. We also prescribe medications with a fixed schedule for the prevention of vomiting, and we maintained strict BP control with reevaluations every hour. When the systolic BP reached 140 mmHg, we initiated antihypertensive treatment, usually with intravenous clonidine.

As the patients were probed, they were not allowed to get up during the entire hospitalization, not even to go to the bathroom, because we believe that immobilization reduces the risk of bleeding. To reduce the risk of deep vein thrombosis, all the patients wore intermittent compression boots throughout the surgery and hospitalization. Moreover, they started using low-weight heparin the morning after the surgery, before discharge from the hospital.

All the patients stayed overnight in the hospital, were discharged in the morning after the surgery, and were reevaluated at the physician's clinic 48 hours after discharge, when lymphatic drainage by the physiotherapy team already started.

For didactic purposes, we considered as hematomas only those cases that required drainage for hematomas, even small ones, during, for example, suture removal or new incisions, in a hospital environment in patients undergoing surgical interventions. They cause significant distortions in the face, threaten the integrity of the skin flaps due to the great distension they cause, and require prompt emptying. The small blood collections that eventually form during the postoperative period in a localized manner and without causing harm to the flap were disregarded. Usually, they are benign occurrences that are drained in the physician's clinic with punctures, commonly after the 10th day, when they are liquefied.

RESULTS

From January 1992 to March 2018, a period longer than 26 years, the author performed 1,138 face-lifts procedures, a number close to that performed by Rohrich in a 23-year analysis[4,8]. Since August 2013, the author has been working exclusively with facial plastic surgery.

Reliable records on the occurrence of hematomas have been available since July 2011. Therefore, all data from the medical records dated since then were included in the analysis.

From July 2011 to December 2014, the period prior to the adoption of systematization, 233 patients underwent face-lift procedures, of whom 8 had a hematoma (incidence of 3.43%).

Since January 2015, we used the aforementioned systematization and had, until March 2018, 6 cases of hematomas in 361 surgeries (incidence, 1.66%). All the bruises occurred in the first 48 hours after surgery.

Thus, with the introduction of the new measures, we obtained a 48.4% reduction in our hematoma rates. The Fischer exact test did not show statistical significance for these results ($p > 0.05$).

The set of measures used seems to have led to this significant reduction, which we observed to be continually occurring. In the last 19 months included in the analysis, 177 consecutive face-lift procedures were performed, in which no occurrence of this complication was observed.

Figure 4 shows the significant decrease in the incidence of hematomas after the beginning of the use of systematization, despite the progressive increase in the

Chart 1. Systematization used for preventing hematomas following face-lift procedures.

Preoperative measures
Hospital environment Long-term indwelling urinary catheterization (until hospital discharge)
Intraoperative measures
General anesthesia Pneumatic compression of LL (for DVT prophylaxis) Infiltration of approximately 100 mL of 0.375% + lidocaine solution in each hemiface Adrenaline at 1:600,000 Definitive hemostasis – ≥ 20 minutes per hemiface Under SBP ≥ 130 mmHg (never under hypotension) Reduction of dead space: eight Baroudi sutures + use of fibrin glue
Postoperative measures
Maintain the head high Dressing using low-compression elastic mesh Cold saline solution compresses + frozen gel bag (1/1h) Administration of antiemetics at fixed times Rigorous BP control (1 h/1 h) – Intravenous administration of clonidine if SBP ≥ 140 mmHg Pneumatic compression of the LL during the entire hospitalization LMWH - start the morning after surgery Do not walk in the first 24 hours (during hospitalization) Hospital discharge only in the morning following surgery and if BP is under control Outpatient reevaluation within 48 hours

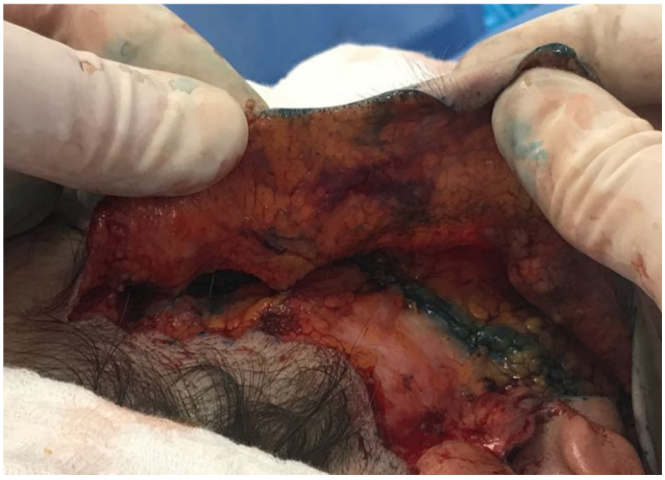

Figure 2: Quilting sutures between the detached flap and the SMAS.

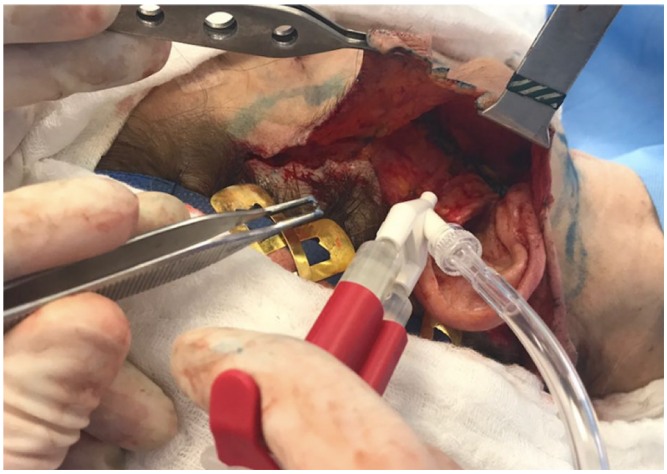

Figure 3. Use of fibrin glue on facial and cervical detached tissues.

number of surgical cases in the same period. The number of cases increased from 52 in 2012 to 114 cases in 2017. To avoid distortions, the graph included only the years when data were collected over the 12 months (Figure 4).

DISCUSSION

Several factors are associated with the formation of hematomas following face-lift procedures, including the type of anesthesia, age, sex, surgical technique, the combination of procedures, use of drains, and BP[9]. We observed that the data were not enough to determine the specific cause responsible for the formation of hematomas following rhytidectomy[9,10]. Therefore, a set of measures is necessary for its prevention.

Adequate techniques and anesthesia care are vital components to prevent preoperative and postoperative complications. Specifically, in the prevention of hematomas after rhytidectomy, the control of BP, heart rate, anxiety, analgesia, and vomiting are essential[13].

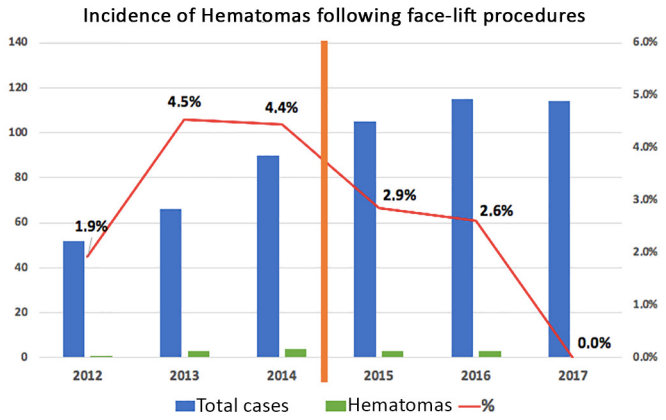

Figure 4: Incidence of hematomas following face-lift procedures The orange line represents the beginning of the use of systematization.

In the immediate preoperative period, the patients received benzodiazepines to reduce anxiety and enhance the effect of the sedative medication. Despite the good results achieved by some authors with the use of local anesthesia associated with intravenous sedation[9], we chose to always perform these surgeries under general anesthesia, as we believe that patients remain better monitored and controlled, with airways assured during head movements and a closed system for oxygen delivery, which allow safe use of electrocautery[8,13].

During the preparation for surgery, we infiltrated a 0.375% lidocaine solution with adrenaline at 1:600,000 in each hemiface; some authors prefer not to perform this procedure because of the potential risk of rebound vasodilatation[10]. However, like most surgeons, we believe that this approach optimizes the detachment and visualization of the appropriate surgical plan, in addition to minimizing intraoperative and postoperative bleeding, which greatly facilitates definitive hemostasis[6-13].

Of all the factors responsible for the formation of hematomas following rhytidectomy, hypertension is certainly the main factor, a fact well documented by several authors such as Baker, Knize, Ramanadham, and Rohrich[7-13]. Regardless of the perioperative approach proposed by each author, agreement is always reached that strict control of intraoperative and postoperative pressures is associated with the reduction of the incidence rates of hematomas following face-lift[7-13]. Baker reported in his study on hematomas in men that strict BP control reduced the incidence from 8.7% in 1977 to 3.97% in 2005[9,13,14].

BP just below normal or even mild hypotension is tolerated during facial flap detachment to minimize perioperative bleeding. However, definitive hemostasis under hypotension should never be performed because of the risk of masking injured perforating vessels that could bleed significantly in the postoperative period after the expected rebound increase in BP[7-16]. Routinely, we perform hemostasis after the systolic BP reaches ≥130 mmHg.

Rohrich et al. recommend the use of 0.1- to 0.2-mg transdermal clonidine adhesive per day before entering the operating room, with maintenance for up to 7 days in the postoperative period[4,7,8,13,14]. Rohrich justifies this prolonged use on the basis of the observation that hypertensive peaks are more common in the postoperative period than in the intraoperative or immediate postoperative period[8].

In our routine, we use intravenous clonidine during hospitalization when the systolic BP reaches 140 mmHg. We consider that the constant use of a transdermal clonidine adhesive increases the risk of hypotension in the first postoperative days and, consequently, increases the risk of falls and consequent trauma.

Furthermore, other factors such as anxiety, pain, urinary retention, nausea, and vomiting are directly associated with increased BP and, consequently, the formation of hematomas[7-15]. They must be adequately prevented. In our routine practice, antiemetic medication is used at a fixed time, starting even before the patient's anesthetic awakening, a protocol also adopted by Baker and Rohrich[9,13,14]. All the patients received indwelling urinary catheterization during the entire hospitalization.

In all the cases, we used quilting sutures between the dermis of the detached flap and the SMAS; we consider this step important for reducing dead space (improving flap adhesion) and limiting the dissemination of any hematoma that may form. These sutures are similar to Baroudi's sutures in abdominoplasties and have already been described in rhytidectomies by the same surgeon[11,12].

In addition to these quilting sutures, we used fibrin glue (Tessel®) to provide better adhesion to the detached and pulled flap, besides preventing the formation of hematomas. The use of fibrin glues and other flap adhesion mechanisms is controversial. Fibrin sealants have demonstrated good efficacy in controlling slow and focal bleeding or diffuse bleeding[9,17,18]. While some authors such as Marchac and Sándor[19] reported that after the use of fibrin glue in aerosol under the detached flap, they observed a decrease in the incidence of hematomas. Others such as Fezza et al.[20] reported only a reduction in edema and ecchymosis, without statistically significant differences in the incidence of hematomas. The platelet-based sealing gel is an alternative, but further studies are needed to define its potential in the prevention of hematomas[17].

Still in the operating room, soon after surgery, the patients were positioned with their head elevated to 30° and received cold compresses on their face, which were systematically changed every 30 minutes, to generate vasoconstriction. After hospital discharge, we

recommended strict maintenance of ice therapy every 30 minutes for 48 to 72 hours.

According to the literature, the incidence of hematomas following face-lift is 0.2% to 8%, and in men, this incidence can reach 12.9%[8-16].

Before the adoption of the systematization in 2015, we observed an incidence of 3.43%, and after implementation, the incidence became 1.66%, which represents a decrease of approximately 48.4%. The current index is close to the lower limits reported in the literature. With the data analyzed, we did not reach statistical significance. However, it is important to emphasize that the incidence has been decreasing, as the last 177 cases analyzed showed no incidence of hematomas.

CONCLUSION

After analyzing our series of cases and the data in the literature, we observed a significant reduction in the incidence of hematomas following rhytidectomy over the years with the use of the proposed standardization. The set of proposed measures acts synergistically to reduce the incidence of this serious complication. In our opinion, none of these measures alone would be able to achieve such a reduction in hematoma index.

Although the sample size was insufficient to prove statistical significance ($p > 0.05$), we are convinced that the numbers are promising. Despite that hematoma is the most frequent complication in face-lift surgery, the number of surgeries was relatively small, which makes the expansion of the series of cases essential to obtain more robust data. However, it is important to emphasize that systematization has been progressively consolidated in our service, and consistency must be maintained in the application of the protocol, and the adequate data must be collected, always with the aim of obtaining the best possible outcome for the patient.

COLLABORATIONS

TCTC Analysis and/or data interpretation, conception and design study, conceptualization, data curation, final manuscript approval, investigation, methodology, project administration, realization of operations and/or trials, resources, supervision, visualization, writing - original draft preparation, writing - review & editing.

WFFJ Analysis and/or data interpretation, conception and design study, final manuscript approval, investigation, project administration, visualization, writing - original draft preparation, writing - review & editing.

CEGL Analysis and/or data interpretation, conception and design study, final manuscript approval, methodology, project administration, supervision, writing - review & editing.

FXC Analysis and/or data interpretation, conception and design study, data curation, final manuscript approval, formal analysis, writing - original draft preparation, writing - review & editing.

LML Analysis and/or data interpretation, conception and design study, data curation, final manuscript approval, formal analysis, writing - review & editing.

LRL Analysis and/or data interpretation, conception and design study, data curation, final manuscript approval, formal analysis, writing - review & editing.

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Original Article

Zygomatic-palpebral flap: an optional technique for lower eyelid reconstruction

Retalho zigomático-palpebral: uma técnica opcional para a reconstrução da pálpebra inferior

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■ **ABSTRACT**

Introduction: Lower eyelid reconstruction represents a unique challenge to plastic surgeons, since it involves a facial region of aesthetic and functional importance. The objective is to present an optional technique for the reconstruction of lower eyelid defects using zygomatic-palpebral skin flap. This technique represents an alternative in cases of scleroatrophic skin in older patients, and for young people who do not have an upper eyelid skin redundancy, which prevents, for example, the use of upper eyelid grafts or flaps such as those of Fricke or Tripier. **Methods:** The authors describe the flap used in cases of cicatricial ectropion and reconstruction after resection of neoplasms and association with other flaps, such as those of Hughes, or for coverage of cartilage grafts. The flap consisted of a transposition flap made up of skin and underlying subcutaneous tissues, randomized . The technique was based on the use of a local flap with highly similar characteristics to the defect area, which allowed it to mimic functions, while being safe and feasible. **Results:** The immediate and late results in terms of aesthetics and function were satisfactory and well accepted by patients and the surgical team, with adequate eyelid occlusion and preserved ocular lubrication. **Conclusion:** The advantages of the zygomatic-palpebral flap are its ease of execution, minimal bleeding, low morbidity of the donor area, and the use of local anesthesia. The reconstruction of eyelid defects aims to restore anatomy and function. This can be a challenging task, especially in cases with larger defects that may be present after oncologic procedures both in young and old patients presenting with scleroatrophic skin and minimal tissue laxity.

Keywords: Eye; Eyelids; Conjunctiva; Eyelid diseases; Reconstructive surgical procedures; Flaps.

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Conflicts of interest: none.

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■ **RESUMO**

Introdução: A reconstrução de pálpebra inferior representa um desafio peculiar ao cirurgião plástico, uma vez que traduz uma região facial de importância estética e funcional. O objetivo é apresentar uma técnica opcional para a reconstrução de defeitos da pálpebra inferior com o retalho cutâneo zigomático-palpebral. Esta técnica mostra uma alternativa nos casos de pele escleroatrófica de pessoas idosas, bem como para pessoas jovens, que não apresentam redundância da pele palpebral superior, impossibilitando por exemplo o uso de enxertos de pálpebra superior ou retalhos como o de Fricke ou Tripier. **Métodos:** Os autores mostram a indicação do retalho em casos de ectrópio cicatricial, reconstrução após ressecção de neoplasias, associação com outros retalhos como de Hughes ou para cobertura de enxertos cartilaginosos. É um retalho de transposição composto por pele e subcutâneo, randomizado. A técnica baseia-se no uso de retalho local, de características muito semelhantes à área do defeito, o que permite mimetização, segurança e exequibilidade. **Resultados:** Os resultados imediatos e tardios são satisfatórios e bem aceitos pelos pacientes e pela equipe cirúrgica em termos estéticos e funcionais, com oclusão palpebral adequada e lubrificação ocular preservada. **Conclusão:** O retalho zigomático-palpebral apresenta como vantagens a simplicidade de execução, sangramento mínimo, baixa morbidade de área doadora e feito sob anestesia local. O objetivo de reconstruir defeitos da pálpebra é restaurar a anatomia e função. Esta pode ser uma tarefa desafiadora, especialmente em defeitos maiores que podem estar presentes nos procedimentos oncológicos em jovens e em idosos com pele escleroatrófica e mínima frouxidão.

Descritores: Olho; Pálpebras; Túnica conjuntiva. Doenças palpebrais; Procedimentos cirúrgicos reconstrutivos; Retalhos.

INTRODUCTION

Reconstruction of eyelid defects focuses on two major targets: restoring the anatomy and eyelid function. This can be a challenging task, especially in larger defects, such as those occurring after oncologic procedures in young people with minimal tissue laxity and elderly patients with scleroatrophic skin, and in cases of trauma or burns with significant tissue loss.

Several reconstructive techniques have been developed and the surgical choice usually depends on the affected portion of the eyelid and the extent of the defect. Reconstructive procedures must maintain the function and integrity of the periorbital structures while seeking adequate aesthetic repair. The objectives of eyelid reconstruction should consider the following aspects:

1. Smooth and soft internal conjunctival mucosa - eye lubrication;
2. A stable eyelid margin with rigid support such as the tarsus in order to ensure shape and stability;
3. Eyelid stiffness in the canthal ligaments;
4. Functionally active muscles that allow tonus;
5. Adequate eyelid occlusion to maintain eye protection;
6. Acceptable aesthetic result in terms of facial symmetry.

In this study, the authors presented the use of zygomatic-palpebral flap, a technique initially described by Hermann Eduard Fritze in 1845, which despite its antiquity has proven to be a safe and versatile option with good results for lower eyelid reconstruction.

OBJECTIVES

This study aimed to present an optional technique for the reconstruction of defects of the anterior lamella of the lower eyelid using the zygomatic-palpebral skin flap. This technique is an excellent alternative in cases of scleroatrophic skin in elderly patients, as well as in young people not presenting upper eyelid skin redundancy, which prevents, for example, the use of upper eyelid grafts

or flaps such as that of Fricke or Tripier. Moreover, this technique is also indicated for retraction due to burns, trauma or in association with other techniques.

METHODS

The flap was indicated in cases of ectropion, reconstruction after resection of neoplasms, and in association with other flaps, such as those of Hughes, in order to cover cartilage grafts and retractions caused by burns. It consisted in a transposition flap composed of skin and underlying subcutaneous tissues, randomized. This technique is based on the use of local flaps with highly similar characteristics to the defect area, allowing it to mimic functions while being safe and feasible.

The procedure for creating the flap was the same in all cases. The limits of the receiving area were evaluated (Figure 1A), and based on the extent of the defect, the donor area was delimited in the ipsilateral malar region. Then, the flap was marked in the zygomatic region (Figure 1B) from the lateral corner of the eyelid, descending perpendicularly to 90° in relation to the lower ciliary margin. The skin flap was raised along with a sufficient thick layer of subcutaneous tissue in order to fill the defect entirely (Figures 1C, 1D). Subsequently, the transposition process took place, followed by closure of the donor and receiving areas using deep subdermal stitches (4-0 polydioxanone) and simple separated stiches (6-0 monofilament nylon) superficially (Figure 1E).

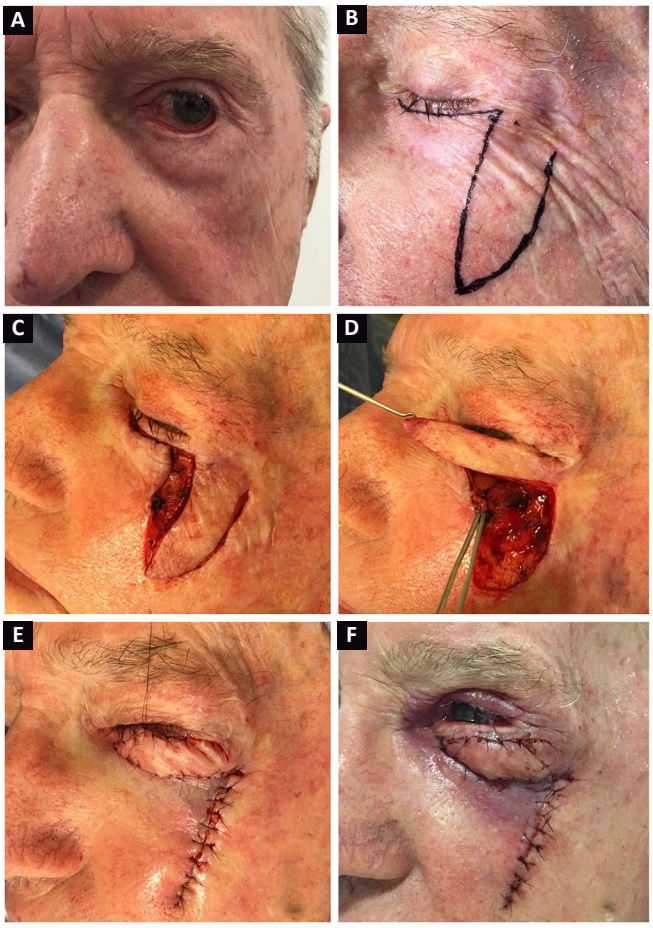

Figure 1. Technique sequence of the zygomatic-palpebral flap procedure used for correction of senile ectropion. **A:** Ectropion; **B:** Flap design; **C:** Incision and dissection; **D:** Flap transposition; **E:** Immediate postoperative period; **F:** Second postoperative day.

RESULTS

The zygomatic-palpebral flap for lower eyelid reconstruction allowed the restoration of height and palpebral vertical length, preventing and correcting ectropion. The immediate results (Figure 1F) and late results in terms of aesthetics, scar quality and function were satisfactory and well accepted by both patients and surgical team, with adequate eyelid occlusion and preserved eye lubrication.

Lymphatic edema of the flap was the greatest complaint in operated cases, but it resolved spontaneously within approximately 6 months. Infection, surgical dehiscence, hematomas, and other complications were not recorded. Figures 2 and 3 present cases of reconstruction of the lower eyelid due to a skin cancer in a young and in an elderly patient, respectively. Moreover, correction of a scar ectropion in a burn victim is presented in Figure 4.

DISCUSSION

The eyelids cover and protect the eyes. Their function is to protect the eyes against excessive light, trauma, or dryness. Moreover, they contain glands that produce mucus, lubricants, and lipids that make up the tear film. Eyelids are divided into three lamellae. The anterior lamella contains skin and muscle, the middle lamella contains the orbital septum, and the posterior lamella contains tarsus, tarsal plates, and the retractor muscles of the eyelid and conjunctiva. The skin of the eyelids is extremely thin, and the skin of the upper eyelid is thinner than that of the lower eyelid, since there is little subcutaneous fat at the base of the eyelid skin.

Eyelid reconstruction techniques involve the restoration of all lamellae, with at least one of these layers having to be well vascularized. Flaps are preferable when compared to grafts due to the like-to-like phenomenon - similarity with the adjacent skin in texture, color, thickness, and elasticity, besides having intrinsic blood supply, maintenance of tactile sensation, the same surgical field, and durability. However, for partial thickness defects, skin grafts may be highly recommended. A satisfactory reconstruction of the lower eyelid should allow juxtaposition of the eyelid to the eyeball in order to prevent the onset of ectropion.

The eyelid reconstruction technique is chosen

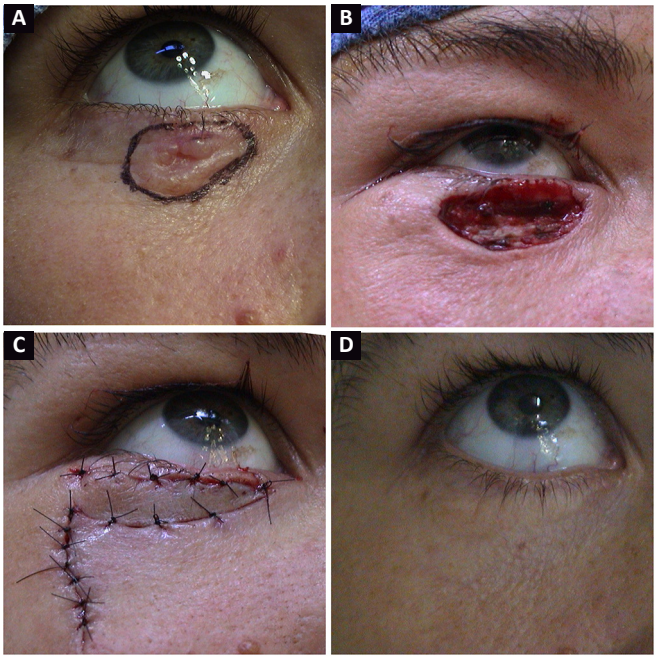

Figure 2. Basal cell carcinoma of the lower eyelid. **A:** Marking of the lesion; **B:** Defect greater than 50% of the anterior lamella in a young patient without excess skin; **C:** Immediate postoperative; **D:** Sixmonth postoperative result.

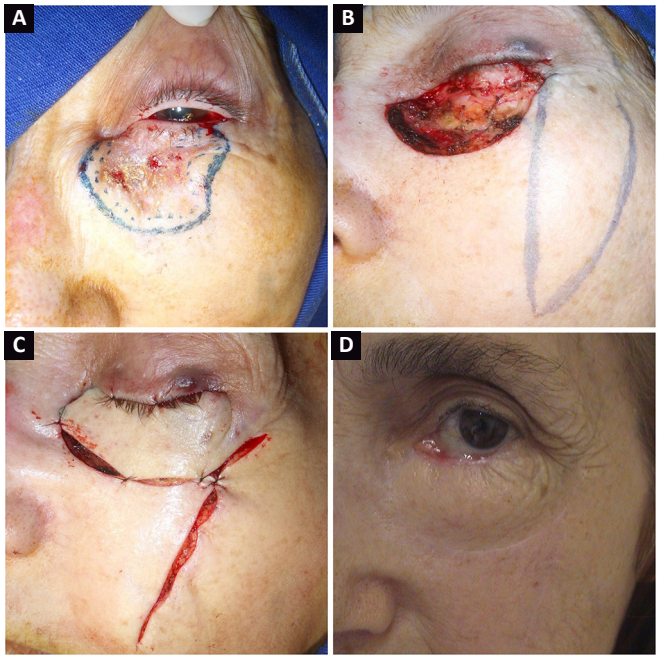

Figure 3. Squamous cell carcinoma of the lower eyelid. **A:** Marking of lesion and surgical margin of resection in total plane; **B:** Reconstruction of posterior and middle lamella with Hughes flap; **C:** Positioning of the zygomatic-palpebral flap for reconstruction of the defect and closure of the donor area; **D:** Sixmonth postoperative result.

based on the thickness and extent of the defect. Direct closure techniques can be used in defects of up to 30% in young patients, and up to 45% in elderly patients. In borderline cases, a lateral cantholysis may provide additional relaxation for wound closure.

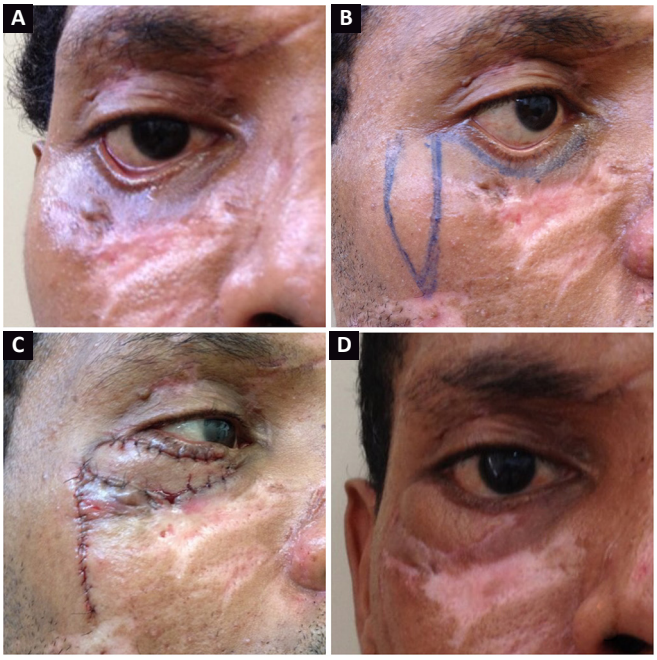

Figure 4. Thermal burn seizure. **A:** Cicatricial ectropion; **B:** Marking the flap and the extension of the receiving area; **C:** Immediate postoperative; **D:** Sixmonth postoperative result.

Local and regional flaps are useful for reconstruction of the lamella. Flaps, as described previously by Tenzel, Hughes, Mustardé, and Cutler, are well known among plastic surgeons and are useful for reconstruction of large defects, as well as cartilage grafts[1-6]. Tarsus with free margin associated with myocutaneous flap can be used for reconstruction of the posterior lamella.

A literature review showed that the choice of the technique for lower eyelid reconstruction varied according to the skin texture, scars adjacent to the recipient area, patient's age, probable aesthetic result, size of the defect, and already used alternatives. The zygomatic-palpebral flap technique has some advantages, including the ease of execution, minimal bleeding, low morbidity of the donor area, and the ability to perform it under local anesthesia. Although some authors questioned that the flap design did not consider any of the aesthetic subunits of the face (this being the greatest reservation found in the literature), the scars along the malar region are usually considered as aesthetically acceptable by the patients and surgical teams.

CONCLUSION

Zygomatic-palpebral flap is an alternative technique that can be used in cases of scleroatrophic skin in elderly patients and young patients without sufficient tissue to reconstruct major defects.

COLLABORATIONS

AGM Analysis and/or data interpretation, conception and design study, data curation, project administration, writing - original draft preparation, writing - review & editing.

MPSN Analysis and/or data interpretation, data curation, project administration.

LRCCT Data curation, writing - original draft preparation.

MTRC Data curation.

CRRC Data curation.

VAP Data curation.

JPRP Data curation.

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Original Article

Complications of lipoabdominoplasty without Scarpa fascia preservation versus classic abdominoplasty: a prospective blind study

Comparação entre as complicações da lipoabdominoplastia sem preservação da fáscia de Scarpa com abdominoplastia clássica: um estudo prospectivo cego

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■ **ABSTRACT**

Introduction: Abdominoplasty is among the most commonly performed surgical procedures. Seroma is the most common local complication associated with abdominoplasty, with an average incidence of 10%. The highest incidence of postoperative (PO) seroma occurs on the eleventh postoperative day (POD). Abdominal ultrasound is the method of choice for diagnosing seroma after abdominoplasty. New techniques have emerged aiming to improve aesthetic results with fewer complications, such as lipoabdominoplasty described by Saldanha. However, recent anatomical studies have questioned the need for Scarpa fascia preservation recommended in the lipoabdominoplasty technique, describing that around 90% of the abdominal lymphatic system is in the subdermal plane, while the other 10% is in a deep lymphatic system near the abdominal aponeurosis. The objective is to compare the incidence of seroma in lipoabdominoplasty without Scarpa fascia preservation to that in classic abdominoplasty. **Methods:** Prospective blinded cohort in which 40 consecutive patients who underwent abdominoplasty without associated liposuction (n = 20) or lipoabdominoplasty (n = 20) at the Hospital de Clínicas of Porto Alegre between April 2016 and May 2017 were analyzed. All patients underwent abdominal wall ultrasonography on the tenth POD. **Results:** The incidence of seroma was 5% (n = 1) in the classic abdominoplasty group and 10% (n = 2) in the lipoabdominoplasty group, with no statistical difference. **Conclusion:** These results showed no statistically significant intergroup difference in seroma development.

Keywords: Abdominoplasty; Seroma; Lipectomy; Lipodystrophy; Body contouring.

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■ **RESUMO**

Introdução: Abdominoplastia é um dos procedimentos cirúrgicos estéticos mais realizados. Seroma é a complicação local mais comum associada com abdominoplastia, com uma incidência média de 10%. A maior incidência de seroma pós-operatório (PO) ocorre no décimo primeiro dia PO. Ecografia abdominal é o método de escolha para o diagnóstico de seroma após abdominoplastia. Novas técnicas surgiram ao longo dos anos na tentativa de trazer melhores resultados estéticos com menos complicações, como lipoabdominoplastia descrita por Saldanha. Porém, estudos anatômicos recentes questionam a necessidade da manutenção da fáscia de Scarpa descrita na técnica de lipoabdominoplastia, descrevendo que em torno de 90% do sistema linfático abdominal está no plano subdérmico e 10% em um sistema linfático profundo justa-aponeurose abdominal. O objetivo é comparar a incidência de seroma na lipoabdominoplastia sem preservação da fáscia de Scarpa com a abdominoplastia clássica. **Métodos:** Coorte prospectiva, cega na qual serão analisados 40 pacientes consecutivos que realizaram abdominoplastia sem lipoaspiração associada (n = 20) ou lipoabdominoplastia (n = 20) no Hospital de Clínicas de Porto Alegre entre abril de 2016 e maio de 2017. Todos foram submetidos à ecografia de parede abdominal no 10o dia PO. **Resultados:** A incidência de seroma foi de 5% (n = 1) no grupo de abdominoplastia clássica e de 10% (n = 2) no grupo de lipoabdominoplastia, sem diferença estatística. **Conclusão:** Estes resultados, neste grupo de pacientes, mostram que não houve diferença estatística entre os dois grupos.

Descritores: Abdominoplastia; Seroma; Lipectomia; Lipodistrofia; Contorno corporal.

INTRODUCTION

Abdominoplasty was the fourth most commonly performed aesthetic surgical procedure in 2014 in Brazil and worldwide according to the International Society of Aesthetic Plastic Surgery[1]. Patients with pronounced excess skin or sagging of the abdominal aponeurotic muscle system with or without hernia or excess abdominal fat are considered suitable candidates for abdominoplasty[2,3].

Seroma is the most common local complication associated with abdominoplasty, with incidence rates of 1–57% and a mean incidence of 10%[4,5]. The highest incidence of postoperative seroma occurs on the eleventh postoperative day, most commonly at the iliac fossa[6].

Abdominal ultrasonography is the method of choice for diagnosing seroma development after abdominoplasty[5]. To reduce the high seroma rate in the postoperative period, some preventive measures were described: minimal skin flap manipulation, progressive tension sutures, reduced surgical time, use of drains, and use of compression garments for 30 days in the postoperative period[7-8].

The most widely publicized were the dead space obliteration sutures described by Baroudi & Ferreira[9] and the use of drains. However, the simultaneous use of the 2 methods does not offer any advantage; when compared, they have the same incidence of seroma[10].

New techniques of aesthetic correction of the abdomen have emerged over the years in an attempt to improve aesthetic results with fewer complications, such as liposuction and lipoabdominoplasty described by Saldanha[11,12]. However, recent anatomical studies questioned the need for Scarpa fascia preservation recommended in the lipoabdominoplasty technique, describing that around 90% of the abdominal lymphatic system is in the subdermal plane and 10% is in a deep lymphatic system near the abdominal aponeurosis[13-15].

OBJECTIVE

This study aimed to compare the incidence of seroma in lipoabdominoplasty without Scarpa fascia

preservation to that in classic abdominoplasty as well as the final aesthetic result, surgery time, time required for Baroudi sutures, and postoperative complications in our service.

METHODS

This prospective study included 40 consecutive patients who underwent abdominoplasty or lipoabdominoplasty and whose data were analyzed at the Hospital de Clínicas of Porto Alegre, RS, between April 2016 and May 2017. All patients provided written informed consent. The research followed the principles of Helsinki. The inclusion criterion in the lipoabdominoplasty group was supraumbilical lipodystrophy indicated for improving body contour.

Exclusion criteria were post-bariatric status or a body mass index (BMI) above 35 kg/m^2. During surgery, the time at incision, end of the surgery (time of liposuction was not computed), time of beginning of the Baroudi and the final sutures (encompassing the time of the omphaloplasty) as well as their quantity were recorded. All patients were hospitalized for 24 hours after surgery and allowed to take a bath 48 hours post-surgery. No patient received postoperative antibiotic therapy; a compressive mesh was placed in the operating room and maintained for 30 days postoperatively.

After discharge, the patients were reassessed at 13 days, 20 days, 30 days, 2 months, 3 months, and 6 months, during which times photos were taken. All patients underwent abdominal wall ultrasonography on the tenth POD, and cases in which fluid of 20 mL or more was collected were identified as having seroma. All examinations were performed by the same professional, an ultrasound expert radiologist, who was blinded to the surgical technique. The final aesthetic result will be evaluated during the follow-up visit at 6 months using photos taken on the same day by a plastic surgeon blinded to the technique performed.

During the follow-up, the medical records of these patients were analyzed for the following: age, BMI, incidence of seroma, infection, comorbidities, operative complications, smoking, time to perform the Baroudi technique, and total surgery time (excluding liposuction time in the lipoabdominoplasty group). All data were entered in an Excel table.

Descriptive evaluations were performed of the variables using SPSS version 18.0.3 at the Hospital de Clínicas of Porto Alegre. Age is shown as mean and standard deviation.. Quartile distribution was used for quantitative variables. Absolute and relative frequency were used to describe qualitative variables. The Shapiro-Wilk test was used to check the distribution of the variables and to classify them as parametric or non-parametric. Age, the only parametric variable, was analyzed by the t test. For the other variables, the Mann-Whitney test was used. Fisher's chi-square test was used to evaluate the qualitative variables.

Surgical Technique – Classic Abdominoplasty

Markings were made according to the classic technique; cefazolin 2 g was administered preoperatively. An incision was made according to the upper marking to produce limited detachment up to the xiphoid process only for plication; a thin layer of loose areolar tissue near the abdominal muscle aponeurosis, the deep lymphatic tissue, was preserved[13-15] (Figure 1).

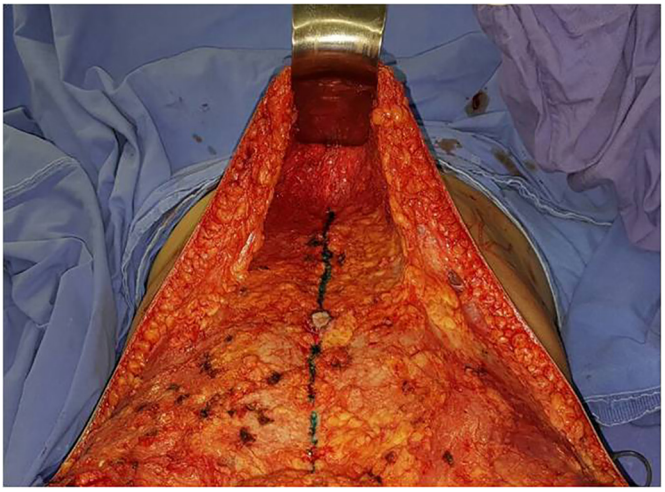

Figure 1. Detachment with preservation of the loose areolar tissue.

In the Fowler's position, the surplus skin was resected and the neo-navel was created using the diamond technique. Diastasis plication of the rectus abdominis muscle was performed with Prolene 0 sutures from the xiphoid process to the umbilical scar and below the umbilical scar to the pubis.

The anterior rectus abdominis aponeurosis was fixed to the umbilical scar with Mononylon 3.0 sutures. Baroudi stitches were made using Vicryl 3.0 (4 on the midline above the umbilical scar, 2 bilaterally on the upper portion of the flap). Below the umbilical scar, 4 more stitches were placed in the midline and 4 more lateral bilaterally to pull the flap to the medial position to improve the body contour. A mean 20 stitches were placed. The surgical site was closed with 3-plane Monocryl 3.0 sutures and the intradermal layer was closed with Monocryl 4.0 sutures. No drains were used. Antithrombotic prophylaxis was used in each case according to the routine service protocol.

Surgical Technique – Lipoabdominoplasty

The surgery began with liposuction and solution for infiltration (Ringer Lactate 1 L) with an ampoule of adrenaline. A mean 500 mL of fluid was infiltrated into the abdominal flap plus 250 mL for each flank when needed. Deep liposuction was performed with the machine at a pressure of 600 mmHg; final liposuction control was performed using the pinch test. Subsequently, superficial liposuction was performed in the muscle transitions to create a better body contour that favors the appearance of muscle definition. The rest of the process was performed according to the classic abdominoplasty technique. Drains were not used in any case.

RESULTS

The postoperative complication rates (occurrence of seroma) were compared between groups on imaging. Of our 40 patients, 20 underwent classic abdominoplasty (Figures 2 and 3) and 20 underwent lipoabdominoplasty (Figures 4–6). All patients were female. No patient with a history of bariatric surgery or a BMI above 35 kg/m^2 was included in the study. The patients' mean age was 39.8 years, while the mean BMI was 24.3 kg/m^2. Of the total number of patients, only 10% were smokers, while 17% had other comorbidities.

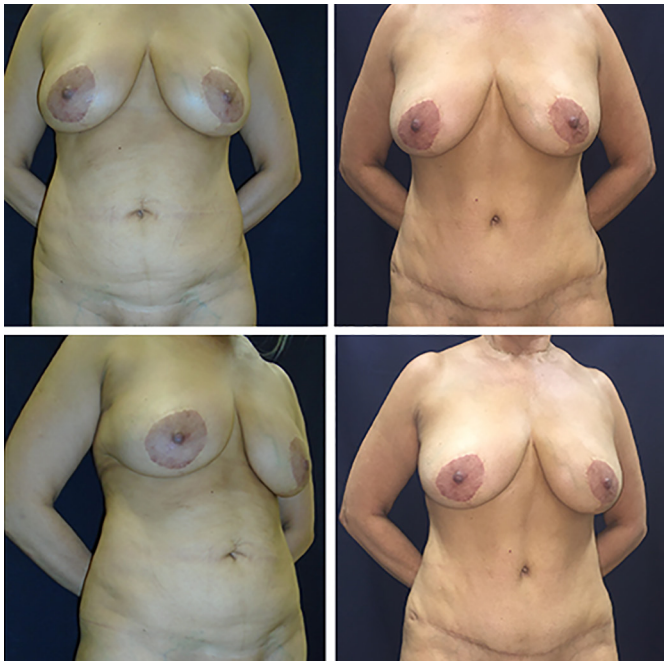

Figure 2. Patient from the classic abdominoplasty group.

The classic abdominoplasty and lipoabdominoplasty groups had a homogeneous distribution in terms of the variables above; there were no significant

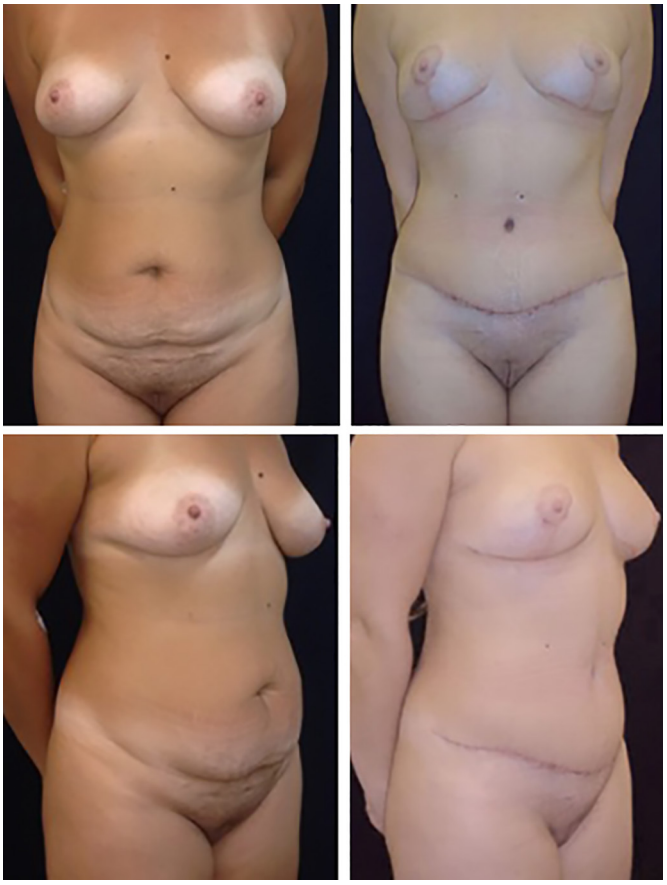

Figure 3. Patients from the classic abdominoplasty group.

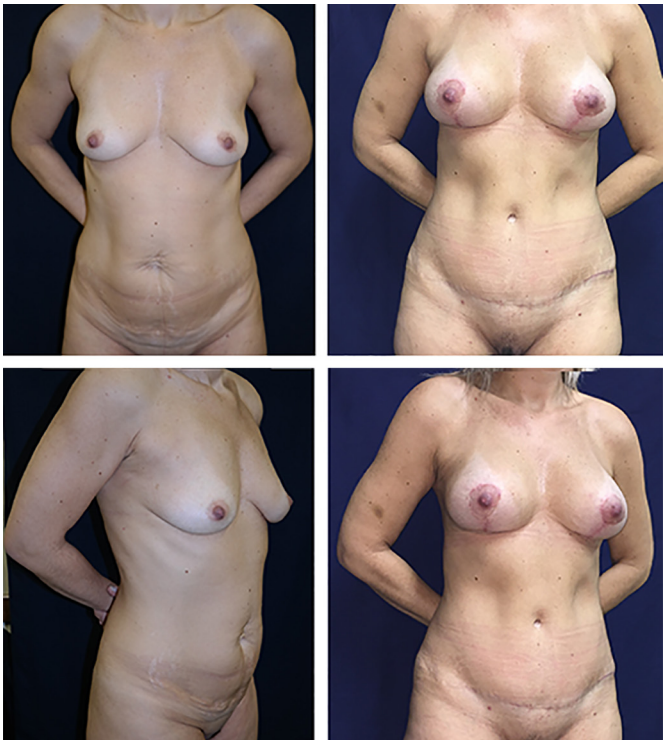

Figure 4. Patients from the lipoabdominoplasty group without Scarpa fascia preservation.

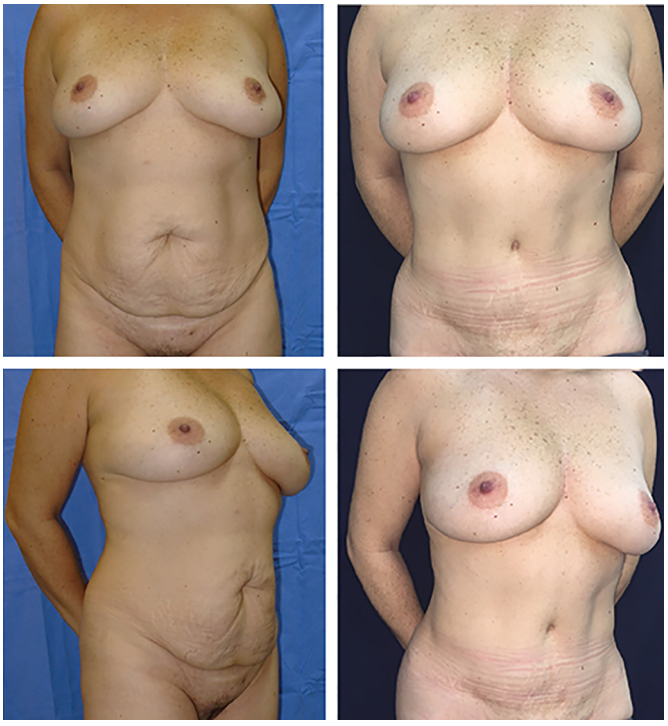

Figure 5. Patient from the lipoabdominoplasty group without Scarpa fascia preservation.

intergroup differences. The mean ages and BMI values were 36.5 and 43.5 years and 24.16 and 24.5 kg/m^2, respectively (Table 1).

Abdominal ultrasonography revealed that the incidence of seroma (fluid collection > 20 mL) was 5% in the classic abdominoplasty group and 10% in the lipoabdominoplasty group, with the iliac fossa being the most common site described by the radiologist. Cases of seroma were treated with needle drainage in the doctor's office; no other procedures were needed.

The surgical wound infection incidence was 15% in the classic abdominoplasty group (versus 0% in the lipoabdominoplasty group), occurring on average on the tenth POD, with improvement after the initiation of outpatient oral antibiotic therapy and no need for another procedure.

No other postoperative complications requiring pharmacological or surgical intervention occurred

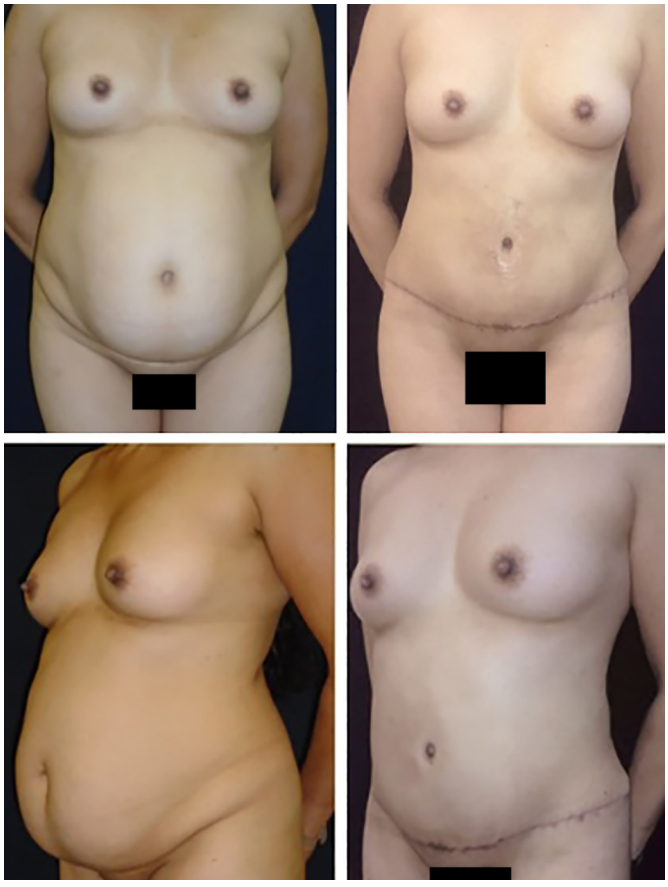

Figure 6. Patient from the lipoabdominoplasty group without Scarpa fascia preservation.

during the 6-month postoperative period. The intergroup differences in the incidence of seroma or surgical wound infection were not statistically significant ($p > 0.05$). There were no cases of flap necrosis, hematoma, venous thromboembolism, pulmonary dysfunction, or other complications in the postoperative evaluation (Table 2).

The plastic surgeon who evaluated the 6-month postoperative photos was blinded to which technique was used and identified better body contour in the lipoabdominoplasty group than in the classic abdominoplasty group. There was no significant

Table 1. Patients' clinical characteristics.

	Classic abdominoplasty (n = 20)	Lipoabdominoplasty (n = 20)	Total (N = 40) ($p > 0.05$)
Mean age, years	36.5	43.5	39.8
Mean body mass index	24.16	24.5	24.3
Smokers, %	10	10	10
Other comorbidities (subarachnoid hemorrhage, diabetes mellitus, dyslipidemia), %	20	15	17

BMI: Body mass index.

Table 2. Incidence of major postoperative complications.

	Classic abdominoplasty	Lipoabdominoplasty	Total ($p > 0.05$)
Seroma	5%	10%	7%
Surgical wound infection	15%	0%	7%
Hematoma	0%	0%	0%
Deep vein thrombosis	0%	0%	0%
Flap necrosis	0%	0%	0%

intergroup difference in the number of Baroudi sutures used (mean, 20 per patient).

There was also no significant intergroup difference in time required to place the Baroudi sutures, with the average being 42 minutes per patient (including the time for omphaloplasty, which occurs between the upper and lower Baroudi sutures). There was also no difference in total surgical time, with a mean of 2 hours and 30 minutes in both groups; liposuction time in the lipoabdominoplasty group was not computed. All patients were discharged by 24 hours postoperatively.

DISCUSSION

The lipoabdominoplasty, classic abdominoplasty, and isolated liposuction techniques have been the subject of comparative studies of their efficacy, risk factors for complications, and patient satisfaction. In a prospective study comparing the 3 techniques in 2012, Swanson[15] described a high satisfaction rate with all options, with the discomfort associated with classic abdominoplasty being similar to that with lipoabdominoplasty and the highest degree of satisfaction after lipoabdominoplasty.

Factors such as age, BMI, and male sex were demonstrated as isolated risk factors for major postoperative complications[16,17]. Associated surgeries also showed higher complication rates than isolated procedures, with a higher incidence of surgical wound infections, higher rate of deep vein thrombosis, and higher rate of postoperative pain[16]. These factors are responsible for a higher rate of hospital readmissions, especially in patients with previous cardiac or pulmonary comorbidities[18].

To reduce the rate of seroma, the complication with the highest incidence in abdominoplasty, Baroudi & Ferreira[9] described using sutures to obliterate dead space; later, Polock & Polock[8] classified them as progressive tension sutures because, in addition to reducing the dead space, they reduced the tension in the surgical wound, improving the final quality of the infraumbilical scar.

In a randomized double-blind clinical trial, Andrades et al.[10] compared the efficacy of progressive tension sutures with the use of drains or the combination of the 2 techniques and concluded that progressive tension sutures increase surgical time, reduce the amount of drainage, and have the same frequency of seroma incidence compared to the use of drains alone, either clinically or when evaluated by abdominal ultrasonography. The combined use of the 2 methods adds no advantage.

As an important point of lipoabdominoplasty, Saldanha advocated a more superficial flap dissection than in the classic approach that preserved the Scarpa fascia. According to Saldanha, this option allows the surgeon to keep the network of abdominal lymphatics that are predominantly below the Scarpa intact, reducing seroma rates and preventing greater bleeding since it preserves the inferior perforating vessels. In addition, Saldanha justified preservation as a way of giving more homogeneous support to the upper flap, which is naturally thinner in its caudal portion[11,12].

Costa-Ferreira et al.[19] published in 2013 a randomized clinical trial about the safety and efficacy of Scarpa fascia preservation. This study evidenced that Scarpa fascia preservation reduces the amount of secretion drainage by 65.5% and that drains can be removed 3 days sooner than in the group without preservation. Long periods with drain use (>6 days) were eliminated and the seroma rate was reduced by 86.7%. In addition to the results obtained, preservation of the Scarpa fascia was considered not to compromise the final aesthetic results[19].

However, preservation of the Scarpa fascia has been the subject of discussion in the scientific community. Tourani et al.[13] and Razzano et al.[14] published anatomical studies in 2015 and 2016, respectively, questioning the need to preserve the Scarpa fascia with the objective of preserving the abdominal lymphatic system.

Tourani et al.[13], based on a radiographic map of the lymphatic vessels of the abdominal wall in cadavers, described that the main lymphatic drainage medium occurs by superficial cutaneous collectors that originate in a subdermal plane in the abdomen and run superficially to the Scarpa fascia and are responsible for about 90% of the abdominal lymphatic system,

while juxta-aponeurosis of the abdominal muscles in a loose areolar tissue are the deep lymphatic vessels, which are responsible for about 10% of the abdominal lymphatic system.

Razzano et al.[14], through the histopathological analysis of abdominoplasty pieces, reported` findings similar to those of Tourani et al.[13]. Both described that there would be no need to keep all adipose tissue below the Scarpa fascia to preserve the abdominal lymphatic system.

Tourani et al.[13], Razzano et al.[14], and Swanson[15] agreed that the most important factor in the prevention of postoperative seroma is maintaining this thin layer of loose areolar tissue, attempting to reduce dead space, and performing reduced lateral detachment of the abdominal flap. The maintenance of this juxta-aponeurotic tissue in abdominoplasties was first described by Avelar & Illouz in 1986[20]. Therefore, preservation of the Scarpa fascia alone would not justify the reduction in the seroma rate found by Costa-Ferreira et al.[19].

The results obtained here were equivalent to those in the literature. The seroma rate in the literature is 1–57%, with an average of 10% accepted by most authors[6]. In our analysis, both procedures provided acceptable aesthetic surgical correction of the abdomen. Classic abdominoplasty had a higher but not statistically significant rate of surgical wound infection; all cases were treated with oral antibiotics and none required reoperation. The most prevalent site of fluid collection was in the iliac fossa as reported by previous studies[6].

Mean patient age was higher in the lipoabdominoplasty group, which is described in the literature as a risk factor for seroma; all other evaluated characteristics were homogeneous. In this study, age was not a decisive factor for an increase in seroma rate in the lipoabdominoplasty group, which highlights the need to evaluate a set of risk factors rather than one in isolation.

The importance of prospective studies for the analysis of complications and patient satisfaction in aesthetic procedures is well recognized[15]. The experience reported by the patient and the analysis of the results are more reliable and preferable in these studies[15]. This type of study allowed us to better evaluate the patients in the postoperative period. The importance of the same sonographer performing the analysis contributed to the greater reliability of the sample evaluated and the maintenance of a standard sonographic analysis.

The internal suture placed using the Baroudi technique allows reduction of the dead space and could be responsible for the low seroma rate[21]. The sum of abdominal flap dissection keeping this thin layer of loose tissue juxta-aponeurosis of the abdominal muscles with the Baroudi sutures and the use of compressive mesh for 30 days postoperatively agree with the findings of the recent systematic review conducted by Janis et al.[22] on strategies for preventing postoperative seroma.

This low incidence of complications suggests that lipoabdominoplasty is as safe as abdominoplasty, not adding risk to the procedure even without Scarpa fascia preservation. However, it provides a greater aesthetic refinement in cases of supraumbilical lipodystrophy and can be performed safely using a surgical routine similar to that of classic abdominoplasty. A limitation of the study is that the total liposuction time in the lipoabdominoplasty group was not evaluated, which may have created bias in the evaluation of the general complications and seroma rates.

CONCLUSION

Our results in this group of patients show that it is possible to perform lipoabdominoplasty without Scarpa fascia preservation and maintain an incidence of seroma similar to those described in the national and international literature. Other complications did not differ significantly between the groups. There were no significant differences in recovery times. The associated liposuction allows refinement in cases of localized lipodystrophy.

COLLABORATIONS

JM	Analysis and/or data interpretation, conception and design study, formal analysis, investigation, methodology, project administration, realization of operations and/or trials, writing - original draft preparation, writing - review & editing.
ACO	Analysis and/or data interpretation, conceptualization, final manuscript approval, project administration, supervision.
CPP	Analysis and/or data interpretation, project administration, writing - review & editing.
MF	Realization of operations and/or trials.
MR	Data curation, investigation.
TS	Data curation.
DD	Analysis and/or data interpretation, data curation, realization of operations and/or trials.
MVMC	Analysis and/or data interpretation, conception and design study, conceptualization, final manuscript approval, project administration, supervision, visualization

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Original Article

Abdominal wall treatment with plication using the crossbow technique

Tratamento da parede abdominal com plicatura em Crossbow

ISRAEL SOARES FILHO [1,2]*

■ **ABSTRACT**

Introduction: Owing to the need to deliver results with greater definition in abdominoplasties, techniques must evolve. The objective of this study was to introduce the crossbow technique for plication along with its three variants that reinforces the concept of vertical and horizontal alignments of the aponeurosis of the rectus and oblique abdominis muscles at the same time, promotes 2 different traction vectors, and culminates in a greater definition of the abdominal wall, mainly in the hypogastrium and iliac fossa regions. **Methods:** From January 2016 to February 2018, 22 surgeries were performed exclusively with the types l, ll, or lll crossbow technique, both in esthetic surgery cases and post-bariatric patients. **Results:** The results were favorable both from the esthetic point of view, with greater definition of the hypogastrium, and from a clinical point of view, as none of the patients showed signs or symptoms different from those of the conventional techniques. **Conclusion:** The crossbow technique is a simple and reproducible tool in the medical armamentarium to improve abdominal esthetics. Although it promotes the strengthening of the hypogastric region, both for primary and secondary treatments of this region, only a sample size increase can demonstrate the possible advantages of the method.

Keywords: Abdominoplasty; Abdominal muscles; Abdominal wall; Reconstructive surgical procedures; Aponeurosis.

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■ **RESUMO**

Introdução: A necessidade de oferecer resultados com maior definição nas abdominoplastias nos compele a evoluir tecnicamente. O objetivo deste trabalho é apresentar a técnica de plicatura em Crossbow com suas três variantes, reforçando o conceito de aproximação vertical e horizontal da aponeurose dos músculos retos e oblíquos abdominais ao mesmo tempo, promovendo dois vetores diferentes de tração, culminando em uma maior definição da parede abdominal, principalmente na região do hipogastro e fossas ilíacas. **Métodos:** No período entre janeiro de 2016 e fevereiro de 2018, foram realizadas 22 cirurgias exclusivamente com a técnica Crossbow em seus tipos I, II e III, tanto em pacientes estéticos como pós-bariátricos. **Resultados:** Os resultados foram favoráveis tanto do ponto de vista estético, com maior definição do hipogastro, como do ponto de vista clínico, uma vez que nenhum paciente apresentou sinais ou sintomas diferentes de técnicas convencionais. **Conclusão:** A técnica Crossbow é simples e reprodutível, sendo mais um agregante na armamentária para melhorar a estética abdominal. Apesar de promover o reforço da região hipogástrica, tanto para tratamento primário como secundário desta região, só o aumento da casuística poderá demonstrar as possíveis vantagens do método.

Descritores: Abdominoplastia; Músculos abdominais; Parede abdominal; Procedimentos cirúrgicos reconstrutivos; Aponeurose.

INTRODUCTION

The aesthetic demand for a perfect abdomen compels the plastic surgeon to constantly develop innovative surgical techniques. By contrast, it is imperative that the patient understand that not all variables that involve abdominal protrusion are susceptible to surgical correction. Bad posture, sedentary lifestyle, and obesity should, preferably, be corrected prior to surgery. Excess visceral fat, variation in collagen type with stronger or more fragile aponeuroses[1,2], and the associated bone structure in the abdominal polygon[3] can also change the outcome.

The crossbow technique was conceived by the present author from his experience in abdominal wall plication. Before developing this technique, the author used horizontal shortening of the rectus abdominis muscles[3-6] and sometimes the rectus and oblique abdominis muscles[4,5]. The results showed large variations in the lower abdominal region, from excellent rectifications to residual bulging that required a second intervention to correct the bulging.

In an attempt to fix the residual bulging of the lower abdomen, from observations over time, the author moved the vectors of these plicatures until a vertical position was attained, which provided better retrusion of the region between the iliac fossa and the hypogastrium.

When migrating from secondary correction to primary indication, the conventional plicature (correction of the diastasis of the rectus abdominis and oblique abdominis muscles in the semilunar line) must be incorporated to the transverse arc plicature in the lower floor of the abdomen. This fusion gave rise to the crossbow technique with its variations, which appeared in all the samples. The types were defined as follows: type I, xiphopubic plication of the rectus abdominis (Figure 1, 2A); type II, mini-abdominoplasties and restriction of the detachment to the umbilical scar (Figure 2B); and type III, plication of the semilunar line concomitant with plication of the diastasis of the rectus abdominis muscles (Figure 2C).

The crossbow technique is indicated for patients who exhibit diastase of the linea alba, a semilunar line, and multidirectional enlargement, mainly in the lower floor of the abdomen, where we observed bulging containing only by the inguinal ligament and upper edge of the pubis, demonstrating esthetic failure in the containment of abdominal volume.

Studies using vertical or mixed abdominal wall traction vectors (Figure 3) were initially conducted by Jackson and Downie[7] in 1978. Their cruciform plication

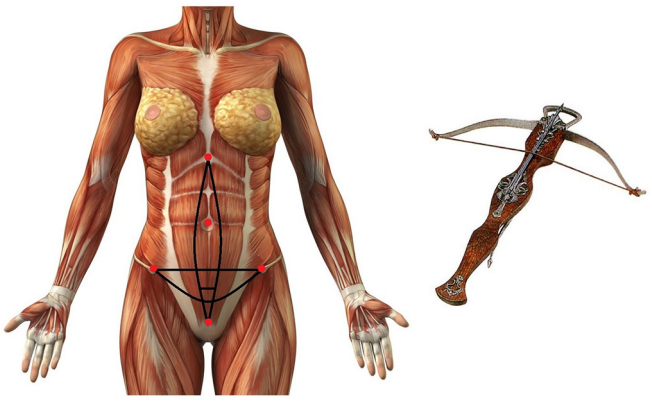


Figure 1. Marking in Crossbow type I, reference points in red. Acquired and modified from: iStock-160085304..

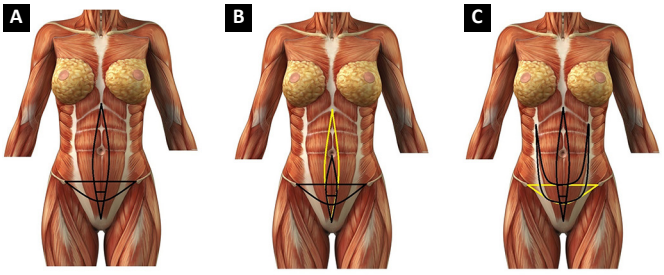


Figure 2. Variations of marking in Crossbow. **A:** type I; **B:** Type II and **C:** Type III. Acquired and modified from: iStock-160085304.

technique foresaw plication of the diastasis of the rectus abdominis muscles and, at the same time, another plication with a transverse spindle, with the umbilical scar as the center of the intersection.

In 1999, Abramo et al.[8] proposed a plication in the form of a horizontal "H" involving a small arciforme plication in the epigastrium, another arciforme plication in the lower region of the abdomen, and plication of the rectus abdominis muscles. In 2001, Ferreira et al. used a triangular suture in the aponeurosis of the rectus abdominis, in the epigastric region, promoting vertical and horizontal shortening that prevented residual epigastric bulging[1]. For mini abdominoplasties, Cárdenas Restrepo and Munoz Ahmed, in 2002[9], indicated a detachment limited to the umbilicus and preparation of a horizontal semilunar plication in the aponeurosis of the lower abdomen.

Cárdenas Restrepo and García Gutiérrez, in 2004[10], published a new technique with plicature in the anchor with the closing spindle of the diastasis of the rectus abdominis muscles and plication in a recurved horizontal arc in the lower floor of the abdomen, without the intersection of the 2 drawings. Villegas, in 2011[11], demonstrated his TULUA technique at the Vancouver Ipras World Congress, where he more broadly defended the systematic amputation of the umbilical stump and the confection of a large

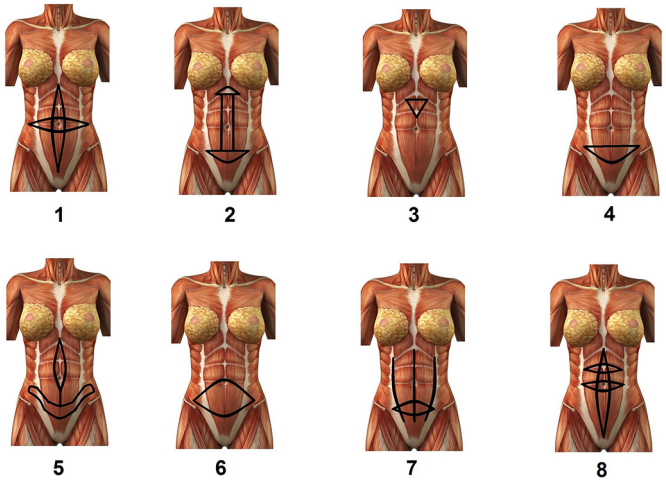


Figure 3. Techniques that compose horizontal plications. 1 - Jacson I, 1967; 2 - Abramo AC, 1999; 3 - Ferreira LM, 2001; 4 - Cardenas R, 2002; 5 - Cardenas, 2004; 6 - Villegas F, 2011; 7 - Bozola AR, 2013; 8 - Gonzales HO, 2016.

horizontal spindle in the aponeurosis throughout the lower abdomen, this being the only plication, promoting remarkable vertical shortening of the abdominal wall.

In 2013, Dr. Pamella Verissimo, at the Federal University of São Paulo, guided by Dr. Fabio Nahas, presented the study entitled, "Plication of the anterior lamina of the rectus abdominis sheath with the triangular suture technique"[12]. This work proved the maintenance of vertical shortening by imaging tests accompanied by metallic clips inserted in the abdominal wall. In 2013, Antônio Roberto Bozola, in his publication entitled, "27 years of observation by the author"[4], exposed the need for a complementary horizontal spindle plication between the iliac fossae in cases of bulging in the hypogastrium.

More recently, in 2016, Gonzalez published his technique called smile plication[13], which provides for the plication of the diastasis of the rectus abdominis muscles, concomitant to horizontal plication in the tendinous intersections of the rectus abdominis, aiming at an abdomen with more muscular appearance.

OBJECTIVE

The objective of this study was to demonstrate the plication using the crossbow technique and its variations, identify complications and conduct a double-blind comparative assessment, and observe the lower abdomen of these patients and other patients who received only plication of the rectus abdominis muscles.

METHODS

From January 2016 to February 2018, the author performed surgery with type I, II, or III crossbow plication in 22 patients (Table 1). In the preoperative

period, the patients were evaluated with clinical and laboratory examinations, and an assessment of their cardiac surgical risk was performed by the anesthetic team. The patients' ages ranged from 29 to 59 years; of the 22 patients, 21 were female and 1 was male.

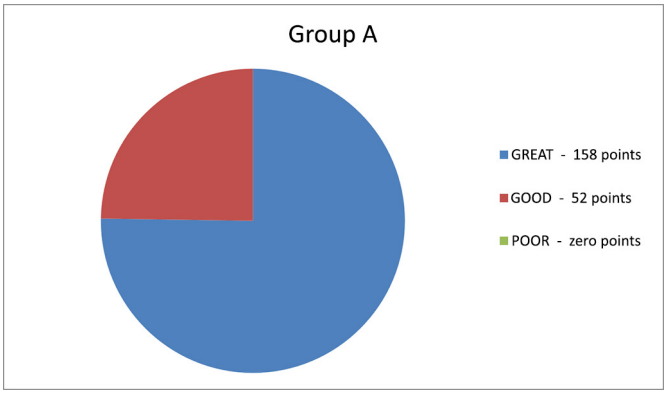
The patients were chosen according to the following criteria: underwent bariatric surgery with a body mass index (BMI) of <30 kg/m^2, had an indication for anchor dermolipectomy, esthetic cases with a BMI of <28 kg/m^2, had a history of multiparity, had no desire to conceive again, and had bulging of the lower abdomen. The exclusion criteria were relative and cover primiparous patients, patients who still had doubts about conceiving, and patients with clinical contraindication. In these cases, the plication were restricted conventionally to the rectus abdominis diastasis.

The study followed the principles of the Declaration of Helsinki.

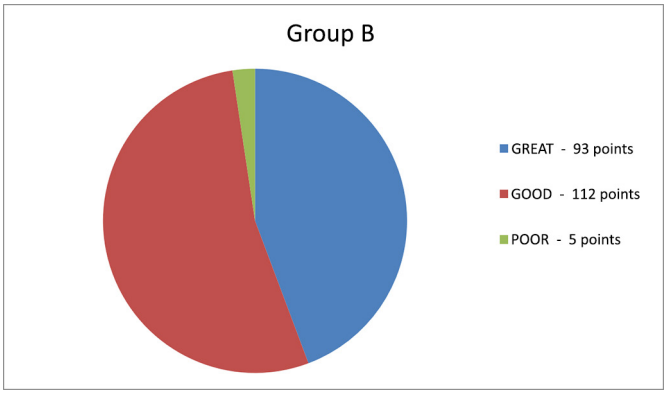
As rigid anthropometric measurements would be complex in relation to the abdomen owing to the number of variables, the author opted for an empirical evaluation and a double-blind study to compare 10 lipoabdominoplasty patients who underwent plication using the crossbow technique (group A) and 10 lipoabdominoplasties patients by the author, with an isolated plication of the diastase of the rectus abdominis muscles (group B).

The assessment took into account the observation of the horizontal distance of the anterosuperior iliac spine from the edge of the abdominal silhouette in the lateral view of the patient in the orthostatic position, with arms outstretched to the front at a 90° angle. Results were considered excellent when this distance was almost tangential, good when this distance did not exceed a harmonic silhouette (abdominal lyre), and poor when there was greater and inadequate distance and residual bulging of the hypogastrium.

By assigning 1 point for each vote of the 21 observers, we arrived at 210 points, and the following graphs were constructed (Graphics 1, 2 and Table 1):



Graph 1. Patients with crossbow plication.



Graph 2. Patients with plication of the rectus abdominis only.

Surgical procedure

At the surgical center, the patients received antibiotic prophylaxis and care to prevent venous thrombosis according to the modified Sandri protocol. All the patients underwent operation under routine epidural anesthesia with a catheter.

Type I crossbow plication was most frequently used (Figure 1, 2A). This technique begins with the patient in the dorsal decubitus position, and when indicated, liposuction is performed before abdominoplasty in the same procedure. After the due suprafascial detachment in the tunnel, similar to that recommended by Saldanha[6], the following reference points are identified: the xiphoid appendix, upper edge of the pubis bone, right and left anterior superior iliac spines, and umbilical scar (Figura 1).

The marking begins by tracing the conventional zone for the treatment of the diastasis of the rectus

Table 1. Correlation between the types of surgery and crossbow plication.

Plication type / Surgery type	Type I	Type II	Type III	Total no of Patients
Abdominoplasty	3		1	4
Mini lipoabdominoplasty		2		2
Lipoabdominoplasty	11		1	12
Anchor dermolipectomy	4			4
Total	18	2	2	22

abdominis muscles and, most often, the xiphoid appendix to the upper edge of the pubis (Figura 4). Then, a straight line is drawn that connects the anterosuperior right iliac spine to the left anterosuperior iliac spine, which we call the cord.

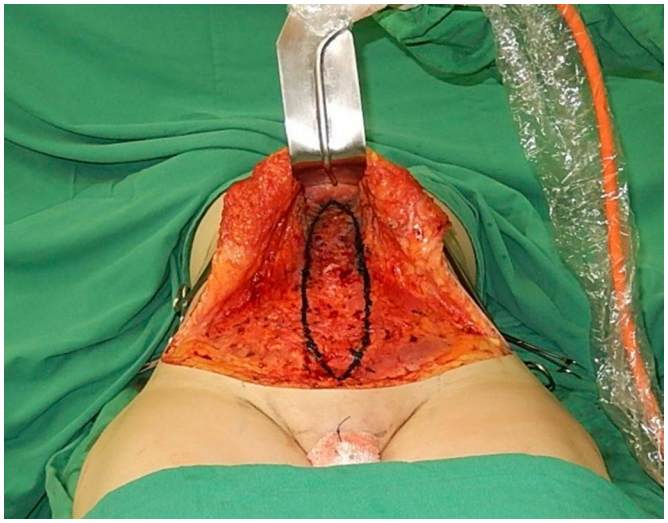


Figure 4. Marking of the xiphobic rubric for plication of the rectus abdominis muscles and identification of the anterior superior iliac spines.

At this time, the space between the cord and the upper edge of the pubis is divided into three equal parts, within the marking of the plication of the rectus abdominis muscles. A second line, in the form of an arc, connects the anterior superior iliac spines, with the lowest point of this arc tangent to the second pubic cord space (Figure 5). The importance of this marking is the protection of the critical structures that border the inguinal region (Figure 6), avoiding their sequestration with the plicature (Figure 7).

With the patient in the supine position, we begin plication of the rectus abdominis muscles from the xiphoid appendix to near the points of intersection of the drawing, just below the umbilical scar. A more vigorous figure-8 polypropylene suture (Prolene 0 or similar suture) is applied in a figure-8 pattern, joining the four intersection sutures of the drawing, which facilitates the observation of the level of tension of this suture, the main suture of the technique. We then continue in the lower direction to plicate the pyramidal muscles with 2 or more sutures.

The next step is the horizontal plication of the aponeurosis of the external oblique muscle, from the center of the drawing outward until the anterosuperior iliac spines are reached. Sutures are all performed in shaped 8 pattern with the knot inverted, using Prolene 0 or a similar suture. Additional interrupted running sutures with Vicryl 0 (polyglactin) are also used as reinforcement on top of the Prolene sutures.

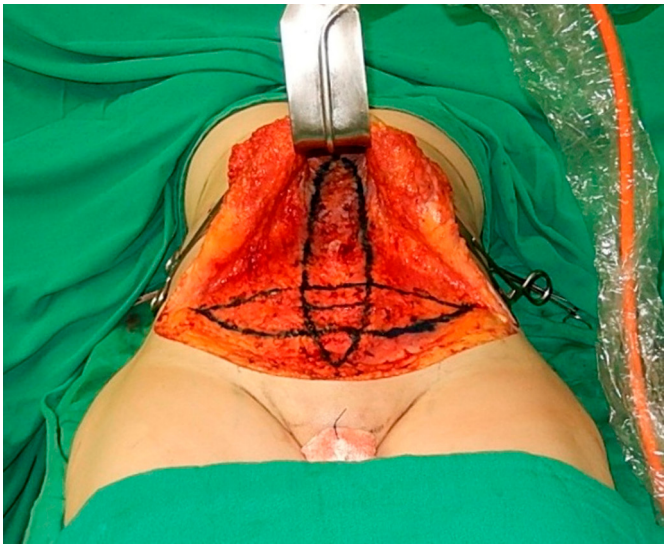


Figure 5. Marking the rope and the bow.

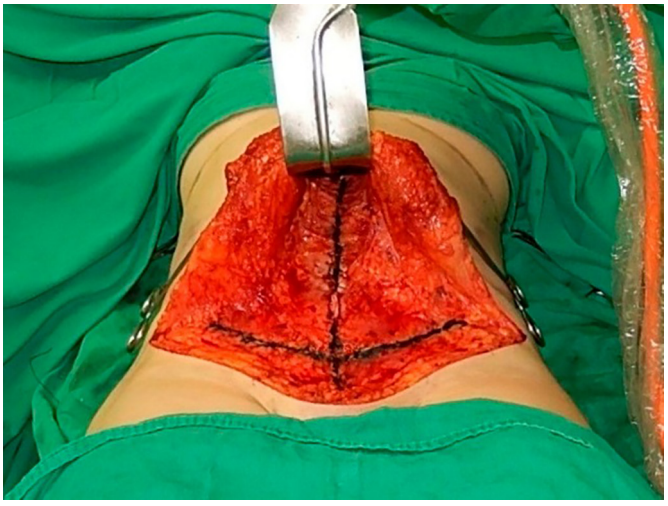


Figure 6. Complete type I plication.

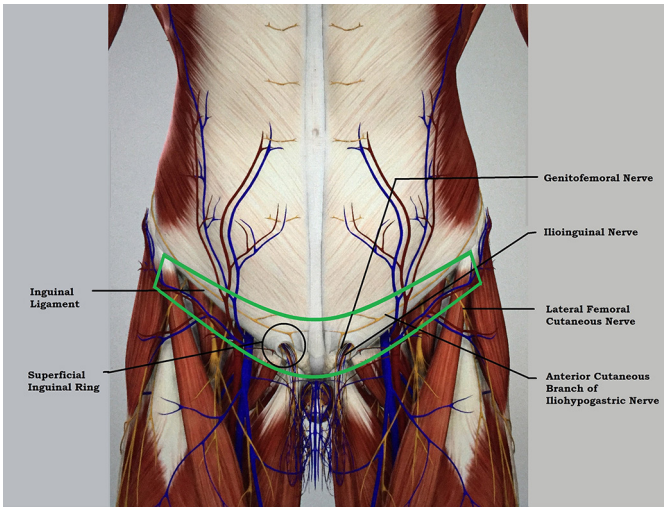


Figure 7. Delimited in green - area below the marking arch that should not be included in the plicature. modified from: C Anatomy 'application image 18.

The surgery continues with the resection of skin and subcutaneous tissue flaps, introduction of a suction drain, fixation of the umbilicus with Vicryl 0, closure of the fascia of Scarpa with Monocryl 3-0, subdermal sutures also with Monocryl 3-0, and micropore dressing.

Most cases will be solved with this technique, in Crossbow type 1 (Figure 8).

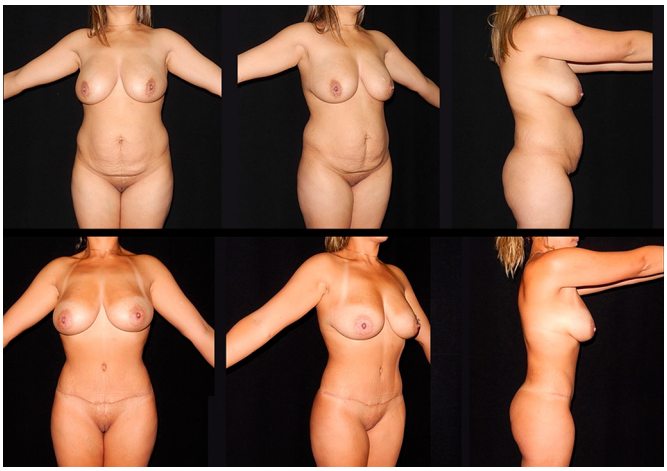


Figure 8. Pre and post-operative of 6 months; lipoabdominoplasty with type I plication.

Special attention must be paid to patients with naturally low implantation of the umbilicus because vertical shortening of the abdomen causes the umbilical stump to be too low. In these cases, one must amputate the umbilical stump and prepare a new umbilicus in a higher position (Figure 9).

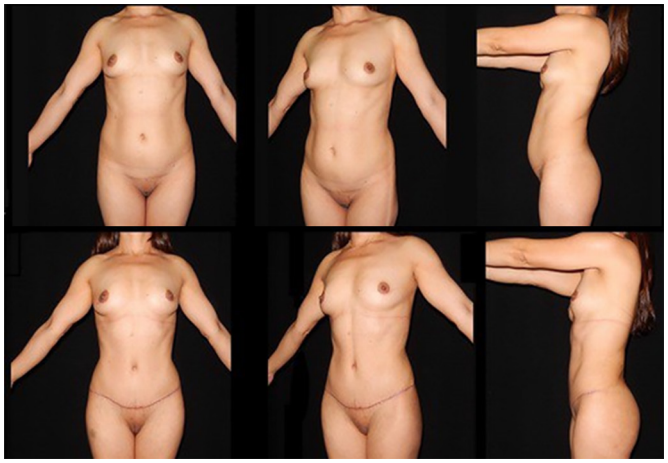


Figure 9. Pre-and post-operative of three months. Lipoabdominoplasty, Type I Plication, amputation of the umbilical stump and creation of neo-navel in the highest position.

The technique can adapt to the need of a mini abdomen, with the detachment restricted to the umbilicus, only a small vertical spindle that connects the umbilicus to the pubis, and the conventional marking of the cord and arc (Figure 10).

In cases that need plication of the diastase of the semilunar line concomitant to plication of the rectus abdominis, we select the vertical spindle of the closure of the rectus abdominis, arc, and cord. However, the 2 ends of the arc should bend and follow the semilunar line, and no longer the anterosuperior iliac spines (Figure 11).

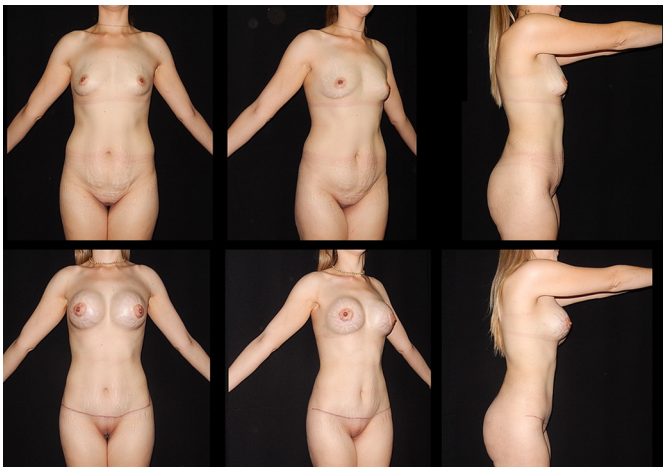


Figure 10. Pre and post-operative 6 months. Minilipoabdominoplasty with scar extended by great skin flaccidity and detachment restricted to umbilical scar. Plicature type II.

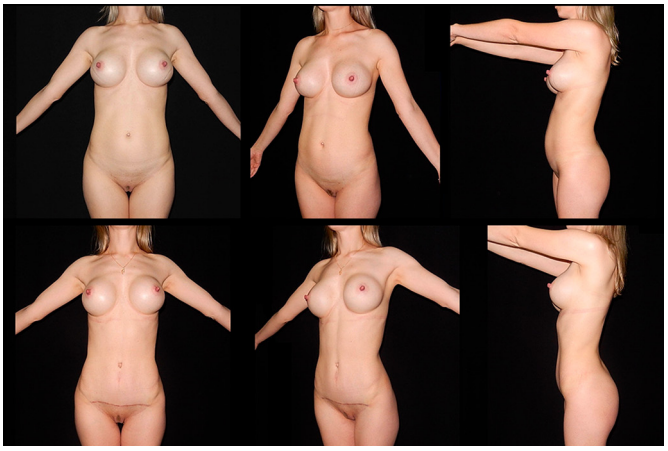


Figure 11. Pre-and postoperative of 6 months; abdominoplasty plicature type III.

RESULTS

With regard to complications, one case of slight hematoma occurred in a patient with dermolipectomy in anchor, which was drained in the postoperative period. In a patient who underwent lipoabdominoplasty, persistent pain occurred in the right inguinal region but was resolved in 3 months. Two small sacral seromas (liposuction) and one seroma occurred in the lower abdomen but was resolved with puncture

and compression. Another patient had a keloid after abdominoplasty. So far, reintervention to correct residual convexities in the lower abdominal region has never been required with this technique.

According to the comparative double-blind assessment, 5 observers classified the concept as poor in only three patients from group B (conventional plication) and in none of the patients in group A (crossbow). Group A attained a higher number of points for excellent concept than group B, whose major concept was classified as poor.

DISCUSSION

We know from previous studies that decreased waist and abdominal protrusions hold a direct relationship with the diastasis of the rectus[14] and oblique abdominis muscles. Factors such as volumetric increase, type of collagen[1,2] and distension of the musculoaponeurotic fibers also induce this protrusion. Thus, in some patients who underwent lipoabdominoplasties, a residual bulging was observed in the lower abdomen in the postoperative period, despite the plication of the rectus and oblique abdominis muscles[4]. The hypothesis is that the increase in the musculoaponeurotic wall area was caused not only by the diastases of the linea alba and semilunar line but also by the multidirectional distention of its fibers[9,12-14].

Below the arcuate line, only the transversalis fascia is observed, next to the inner surface of the rectus abdominis muscles[15]. These areas are susceptible to pressure and the weight of the abdominal contents, and to the effects of pregnancy, predisposing the patients toward greater flaccidity and protrusion. The use of vertical and horizontal traction vectors is assumed to attain both shortening and reinforcement of this region, thereby preventing or minimizing residual bulging[7,8,10-13].

As the transversalis fascia does not offer as much resistance as the posterior aponeurosis of the rectus abdominis muscles, below the arcuate line, the rectus abdominis muscles can adapt without risk of compartmental syndrome. In this context, in the subcutaneous level, it is important to approximate the superficial fascia at the time of occlusion of the flaps before subdermal closure to prevent its retraction and subsequent division, which would increase the suprapubic bulging[4-6,16].

The crossbow technique was initially developed for secondary abdomens and, subsequently, introduced in primary abdomens to prevent myofascial bulging in the hypogastrium.

Multiparous, post-bariatric patients, or those with a large distension on the lower floor of the abdomen are ideal indications for this technique.

The consequences of gestation in the patients who underwent crossbow plicature were not evaluated; thus, it is recommended that patients undergo this procedure only after they have given birth and if they do not wish to conceive further.

CONCLUSION

The crossbow technique is simple, standardized, and reproducible. Possible complications are the same as those of the conventional techniques. According to the author's preliminary assessment, in principle, the technique contributes to the shortening and strengthening of the abdominal wall, improving the contour of the iliac fossa and hypogastric region. According to the observers, none of the 10 patients with crossbow plication had a residual bulging in the hypogastrium. The expectation is that with the increase in the sample size, a conclusion can be reached about the possible advantages of the method and its applicability.

COLLABORATIONS

ISF Analysis and/or data interpretation, conception and design study, conceptualization, data curation, final manuscript approval, formal analysis, investigation, methodology, project administration, realization of operations and/or trials, resources, supervision, validation, visualization, writing - original draft preparation, writing - review & editing.

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Original Article

Prospective assessment of the repercussions on the lipid profile of surgeries involving liposuction and dermolipectomies

Avaliação prospectiva das repercussões no perfil lipídico das cirurgias que envolvem lipoaspiração e dermolipectomias

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ABSTRACT

Introduction: Liposuction associated with dermolipectomies is the most commonly performed surgical procedure in plastic surgery. Although regarded as an extremely safe surgery, some considerations must be taken on the possible metabolic effects of these surgeries. The development of the tumescent technique in liposuction allowed the safer removal of large amounts of fat. The objective is to compare lipid profile variations in the early and late postoperative period in patients undergoing liposuction and dermolipectomies. **Methods:** Between October 2006 and June 2012, 40 female patients who were candidates for surgeries involving liposuction and dermolipectomies were prospectively followed, and the lipid profile was analyzed through preoperative and postoperative examinations. The surgeries performed were mammoplasty + liposuction, abdominoplasty + liposuction, and lipoabdominoplasty + mammoplasty. **Results:** Of the 40 female patients who were followed, 20 were selected (after applying the exclusion criteria). In agreement with our study, in 1996, Cazes showed that there were no changes in the lipid profile of patients 12 months after lipoabdominoplasty. **Conclusion:** After a preoperative and postoperative analysis of 20 patients, it was observed that there were no statistically significant changes in the lipid profile and that the measurements after 1 year were close to those obtained in the preoperative period.

Keywords: Lipid metabolism disorders; Lipid A; Abdominoplasty; Lipectomy; Triglycerides.

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■ **RESUMO**

Introdução: Lipoaspiração associada a dermolipectomias é o procedimento cirúrgico mais comumente realizado em cirurgia plástica. Apesar de ser considerada uma cirurgia extremamente segura, algumas considerações devem ser levantadas a respeito dos possíveis efeitos metabólicos que essas cirurgias possam causar. O desenvolvimento da técnica tumescente de lipoaspiração permitiu a remoção de grande quantidade de gordura de modo mais seguro. O objetivo é comparar as variações do perfil lipídico em pós-operatório precoce e tardio de pacientes submetidos à lipoaspiração e dermolipectomias. **Métodos:** Entre outubro de 2006 e junho de 2012, 40 pacientes do sexo feminino candidatas a cirurgias que envolviam lipoaspiração e dermolipectomias foram acompanhadas prospectivamente e o perfil lipídico foi analisado por meio de exames no pré-operatório e no pós-operatório. As cirurgias realizadas foram: mamoplastia + lipoaspiração, abdominoplastia + lipoaspiração e lipoabdominoplastia + mamoplastia. **Resultados:** Das 40 pacientes que foram acompanhadas no estudo, 20 pacientes do sexo feminino foram selecionadas (após a aplicação dos critérios de exclusão). Em consonância com nosso estudo, Cazes, em 1996, demonstrou que após 12 meses de pós-operatório de lipoabdominoplastia não houve alteração do perfil lipídico das pacientes. **Conclusão:** Após análise pré- e pós-operatória de 20 pacientes, observamos que não há alterações estatísticas significantes em relação ao perfil lipídico com tendência de equilíbrio das aferições em um ano em patamares próximos aos observados no pré-operatório.

Descritores: Transtornos do metabolismo dos lipídeos; Lipídeo A; Abdominoplastia; Lipectomia; Triglicerídeos.

INTRODUCTION

In plastic surgery, body-contouring surgery is currently becoming increasingly popular due to the appreciation of a well-toned body in modern times. Liposuction associated with lipectomy is one of the most performed surgical procedures in plastic surgery. Although regarded as a safe surgery, considerations should be taken on its possible metabolic effects[1].

It is presently known that the subcutaneous tissue acts as an endocrine organ that produces adipocytokines that help maintain homeostasis. Based on this, some plastic surgeons have assessed the metabolic effects of liposuction on fat reduction. Another associated procedure that removes fat from the subcutaneous tissue is dermolipectomy[2].

The development of the tumescent technique for liposuction allowed a safer removal of large amounts of fat. With the knowledge that the adipose tissue is an endocrine organ, this alternative led researchers to believe that liposuction could be a viable method for improving the metabolic profile through immediate loss of body fat mass, a possible coadjuvant in the treatment of obesity and comorbidities[3], associated with physical activity and lifestyle changes.

Studies in humans suggest that large-volume liposuction can increase the proportion of visceral adipose tissue compared to abdominal tissue, and this leads us to think of possible metabolic complications related to the procedure[4].

Does liposuction have repercussions on the lipid profile of patients undergoing body-contouring surgery? In medical literature, there are several studies that show dissonant and sometimes contradictory conclusions regarding alterations in the lipid profile of patients undergoing liposuction and dermolipectomies[3,4].

OBJECTIVE

The objective of this study was to compare the lipid profile variations in the early and late postoperative period in patients undergoing liposuction and dermolipectomy.

METHODS

Between October 2006 and June 2012, the lipid profile of 40 female patients undergoing liposuction and dermolipectomy was analyzed through preoperative and postoperative examinations.

The surgeries performed were mammoplasty + liposuction, abdominoplasty + liposuction, and lipoabdominoplasty + mammoplasty. The patients were divided into 2 groups:

- Group 1: Ten patients underwent examinations in the preoperative period, and these were repeated 3 months postoperatively.
- Group 2: Thirty patients underwent examinations in the preoperative period, and these were repeated 1 year postoperatively.

A comparative analysis of total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL), and triglycerides was performed for the groups. Three comparisons were performed: In group 1, the results of the preoperative examinations were compared to the 3-month postoperative results. In group 2, the results of the preoperative examinations were compared to the 1-year postoperative results. After this analysis, the 3-month postoperative results of group 1 were compared to the 1-year postoperative results of group 2.

All patients in the study were aware of the need to return periodically to the clinic in the postoperative period to undergo blood tests and clinical assessments.

The inclusion criteria were as follows: participation and willingness to undergo complementary examinations relevant for the study in predetermined times; volume of liposuction not exceeding 5–7% of the body weight as recommended by Resolution No. 1711 of December 10, 2003, of the Brazilian Federal Council of Medicine (Conselho Federal de Medicina), use of the tumescent technique[5] and surgical risk ASA I or II. The exclusion criteria were as follows: body mass index (BMI) > 30 kg/m^2 before dietary re-education and weight reduction, associated with physical activity; gastroplasty; surgeries combined with another specialty; gigantomastia (estimated weight of the resection > 800–1000 g) associated with abdominal apron (estimated weight of resections > 2000 g) and lipodystrophy of the flanks and dorsum (large volume and area liposuctions were estimated), except if patients agree to undergo only lipoabdominoplasty and liposuction of the flanks in the first procedure and mammoplasty in the future; changes in their physical condition in the 1-year postoperative period or increase of ≥ 2 kg/m^2 in the BMI; pregnancy after surgery; and dyslipidemia with medication use for such a pathology.

Operations in all patients were performed by a single plastic surgeon using the same surgical technique and from private practice. The laboratory tests were performed in the pre- and postoperative period in the same laboratory.

Statistical tests were performed with significance level set at a *P*-value < 0.05. All patients were advised about the postoperative period and importance of performing physical activity pre- and postoperatively.

RESULTS

Of the 40 patients who were followed in the study, 20 were selected (after applying the exclusion criteria).

Of the 20 excluded patients, 7 showed changes in the BMI; 6 patients were not present in the follow-up consultation and did not undergo postoperative examinations; 5 showed changes in physical condition; and 2 patients were excluded as they had dyslipidemia and were using statin.

The analyzed patients were aged between 30 and 59 years and had BMI < 30 kg/m^2, with an average of 26.4 kg/m^2 (SD = 2.2). The mean liposuction volume was 3,415 mL (SD = 1.024). The patients had a mean total cholesterol level of 197.7 mg/dL (SD = 34.3), LDL level of 118.4 mg/dL (SD = 24.6), HDL level of 51.3 mg/dL (SD = 10.7), and triglyceride level of 127.2 mg/dL (SD = 60.8). All patients underwent lipoabdominoplasty and liposculpture surgeries, and 7 (35%) also underwent breast surgery (Table 1).

Table 1. General profile of the sample in the preoperative period (n = 20)

	Mean	SD	Min	Max
Age	43	9	30	59
BMI	26.4	2.2	22.3	30.0
Liposuction volume	3,415	1,024	1,050	4,800
Total cholesterol	197.7	34.3	124.0	260.0
LDL	118.4	24.6	80.0	174.2
HDL	51.3	10.7	36.0	73.0
TRIG	127.2	60.8	39.0	277.0
Surgeries Performed			N	%
Lipoabdominoplasty and liposuction			7	35%
Lipoabdominoplasty, liposuction, and mammoplasty			13	65%

BMI, body mass index; LDL, low-density lipoprotein; HDL, high-density lipoprotein; TRIG, triglyceride

Table 2 shows data on the profile of selected patients and preoperative data in each group. Although there are no preoperative parameters that distinguish groups 1 and 2, this analysis had to evaluate the homogeneity between groups to subsequently compare the 3-month and 1-year postoperative measurements.

As it can be observed, the groups did not show statistically significant differences ($p > 0.05$) regarding the analyzed variables (age, BMI, liposuction volume, and preoperative total cholesterol, LDL, HDL, and triglyceride levels) and can therefore be considered a single sample.

The subsequent analyses compared the pre- and postoperative lipid measurements, and group 1 was assessed 3 months postoperatively and group 2 was assessed 1 year postoperatively.

The analysis in group 1 showed a decrease in the mean total cholesterol and LDL levels and an increase in HDL and triglyceride levels. However, no significant differences ($p > 0.05$) were found between the preoperative and 3-month postoperative measurements (Table 3).

Contrary to group 1, the analysis in group 2 showed an increase in the mean total cholesterol and LDL levels and a decrease in HDL and triglyceride levels. However, no significant differences ($p > 0.05$) were found between the preoperative and 1-year postoperative measurements (Table 4).

The subsequent analysis compared the 3-month postoperative measurements of group 1 with the 1-year postoperative measurements of group 2. This analysis was possible as the groups showed homogeneous preoperative measurements. However, because the measurements do not belong to the same group of patients in the two analyzed periods, the Mann-Whitney U test was used to determine whether the postoperative cholesterol measurements differ between the groups (Table 5).

The measurements showed no statistically significant differences, but there was a trend in the increase in total cholesterol and LDL levels and decrease in HDL and triglyceride levels.

Figure 1 shows the mean cholesterol measurements at the three analyzed periods. Although the comparison between the periods was not statistically conclusive, there is a trend for alterations in the 3-month postoperative measurements and equilibrium in the 1-year postoperative measurements with values close to those observed in the preoperative period.

Table 3. Group 1 cholesterol data (n = 10)

	Preoperative		Postoperative (3 months)		Wilcoxon signed rank test (*P*-value)
	Mean	SD	Mean	SD	
Total cholesterol	195.70	42.02	192.80	23.87	0.799
LDL	118.04	31.53	117.18	21.00	0.721
HDL	50.80	10.17	53.54	7.67	0.333
TRIG	112.60	61.19	113.40	40.24	0.646

LDL, low-density lipoprotein; HDL, high-density lipoprotein; TRIG, triglyceride

Table 4. Group 2 cholesterol data (G1, n = 10; G2, n = 10).

	Preoperative		Postoperative (1 year)		Wilcoxon signed rank test (*P*-value)
	Mean	SD	Mean	SD	
Total cholesterol	199.70	26.61	202.70	20.69	0.721
LDL	118.70	16.87	122.00	34.02	0.314
HDL	51.80	11.66	47.90	7.08	0.138
TRIG	141.70	59.96	135.60	33.96	0.760

LDL, low-density lipoprotein; HDL, high-density lipoprotein; TRIG, triglyceride

The next analysis is aimed at identifying possible correlations between liposuction volume and cholesterol measurements.

Correlation analysis was conducted to measure the degree of association between two variables. Spearman's coefficient was used in this analysis.

A significance test was then performed with the initial hypothesis that there is no association between the variables. *P*-values < 0.05 indicate a significant association (Table 6).

The following correlations indicate that the difference between the preoperative and 3-month

Table 2. Preoperative profile of patients per group (G1, n = 10; G2, n = 10).

	Group 1				Group 2				Mann-Whitney U test (*P*-value)
	Mean	SD	Min	Max	Mean	SD	Min	Max	
Age	43	10	30	59	43	10	32	57	0.9710
BMI	26.7	2.2			26.0	2.3			0.3930
Liposuction volume	3,555	993	1,050	4,800	3,275	1,088	1,400	4,600	0.4810
Total cholesterol	195.7	42.0	160.0	241.0	199.7	26.6	124.0	260.0	0.6840
LDL	118.0	31.5	97.0	148.0	118.7	16.9	80.0	174.2	1.0000
HDL	50.8	10.2	37.0	73.0	51.8	11.7	36.0	64.0	1.0000
TRIG	112.6	61.2	66.0	277.0	141.7	60.0	39.0	221.0	0.2180

BMI, body mass index; LDL, low-density lipoprotein; HDL, high-density lipoprotein; TRIG, triglyceride

Table 5. Groups 1 (3 months) and 2 (1 year) cholesterol data (n = 20).

	Postoperative (3 months)		Postoperative (1 year)		Wilcoxon signed rank test (*P*-value)
	Mean	SD	Mean	SD	
Total cholesterol	192.80	23.87	202.70	20.69	0.9120
LDL	117.18	21.00	122.00	34.02	0.6840
HDL	53.54	7.67	47.90	7.08	0.1900
TRIG	113.40	40.24	135.60	33.96	0.2180

LDL, low-density lipoprotein; HDL, high-density lipoprotein; TRIG, triglyceride

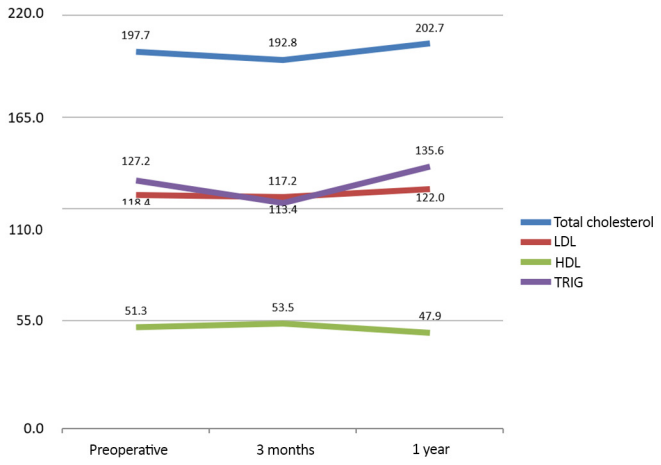

Figure 1. Preoperative and postoperative mean cholesterol measurements.

postoperative triglyceride levels has a direct association with liposuction volume, although inconclusive (p = 0.0793). Conversely, there was no trend in the 1-year postoperative values (p = 0.4667). Thus, considering the 3-month postoperative period, higher liposuction volumes lead to greater decreases in triglyceride levels. Moreover, 1 year postoperatively, the liposuction volume no longer influences the triglyceride levels.

In other cholesterol measurements, no statistically significant correlations were observed. However, for HDL, both the 3-month and 1-year coefficients were negative, indicating that there is a trend, although inconclusive, and that higher liposuction volumes lead to less pronounced decreases in HDL levels.

DISCUSSION

Removal of a significant volume of fat from the subcutaneous tissue through liposuction creates a visible change in body composition through a rapid decline in subcutaneous adipose tissue. There are beneficial effects on traditional forms of weight loss, in which both subcutaneous and intra-abdominal adipose tissues are reduced. However, physiological and metabolic effects that result only from subcutaneous fat loss are still not well established.

The subcutaneous fat has different metabolic implications compared to visceral adipose tissue and is the main source of energy and free fatty acids.

Although experimental animal studies have shown that fat elimination from the body improves serum lipid levels, some studies in humans suggested that large-volume liposuction can increase the proportion of visceral adipose tissue, which raises the concern of possible metabolic complications related to liposuction and increases the risk of cardiovascular diseases[4]. Matarasso et al.[5] assessed the impact of liposuction on body fat and concluded that although large-volume liposuction removes a small amount of fat from the body, this significantly increases the proportion of visceral fat.

Samdal et al.[6] assessed patients undergoing large-volume liposuction and their lipid profiles in the preoperative and postoperative periods (1, 9, and 12 months after surgery). The major finding of the study was a significant increase in HDL level in all patients. Based on the mean HDL level increase of 0.2 mm/L, the authors showed that large-volume liposuction can reduce the risk of cardiovascular disease by up to 30%. In our case series, there was no improvement in HDL levels 1 year postoperatively.

Capla and Rubin[7] prospectively analyzed 322 patients who underwent liposuction and/or abdominoplasty and the impact on the lipid profile after 3 months. The study showed a significant reduction in triglyceride

Table 6. Correlation of the pre- and postoperative cholesterol differences with liposuction volume (G1, n = 10; G2, n = 10)

Correlation	G1, postoperative (3 months)		G2, postoperative (1 year)	
	Spearman's coefficient	*P*-value	Spearman's coefficient	*P*-value
Liposuction volume × total cholesterol	0.11	0.3814	0.05	0.4433
Liposuction volume × LDL	0.17	0.3186	-0.21	0.2769
Liposuction volume × HDL	-0.34	0.1717	-0.34	0.1710
Liposuction volume × TRIG	0.48	0.0793	0.03	0.4667

LDL, low-density lipoprotein; HDL, high-density lipoprotein; TRIG, triglyceride

levels and no changes in cholesterol levels. In our study, it was observed that at 3 months postoperatively, LDL and total cholesterol levels improved and triglyceride levels worsened, but these changes were not statistically significant.

In agreement with our study, Cazes, in 1996, showed that there were no changes in the lipid profile of patients undergoing lipoabdominoplasty 12 months postoperatively. Associated with this, the study also showed the efficacy of physical exercise on the lipid profile of patients, which reduces the lipogram after the metabolic stress caused by liposuction[8,9].

CONCLUSION

After the preoperative and postoperative analyses of 20 patients undergoing liposuction and dermolipectomies, no statistically significant changes were observed in the lipid profile, with a trend to equilibrium 1 year postoperatively to levels close to that observed in the preoperative period.

COLLABORATIONS

LDPB Analysis and/or data interpretation, conception and design study, conceptualization, data curation, final manuscript approval, formal analysis, funding acquisition, investigation, methodology, project administration, realization of operations and/or trials, resources, software, supervision, validation, visualization, writing - original draft preparation, writing - review & editing.

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Original Article

Omphaloplasty based on an isosceles triangle with double fixation in abdominoplasty

Onfaloplastia em triângulo isósceles e com dupla fixação na abdominoplastia

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■ **ABSTRACT**

Introduction: In conventional abdominoplasty, the creation of a new umbilical scar is challenging. Several surgical techniques and approaches have previously been described and applied, but not always with satisfactory results. The objective is to demonstrate the applicability and satisfaction with omphaloplasty based on an isosceles triangle with double fixation in abdominoplasty. **Methods:** The study included 97 female patients aged between 25 and 65 years. All underwent classic abdominal dermolipectomy with moderate abdominal liposuction of the entire anterior abdomen and flanks by the same surgeon and were evaluated at 90, 180, and 360 days postoperatively. **Results:** Patients were satisfied with the umbilicus in most cases (92.8%). Some umbilical scars had contracted (3.1%) and others appeared unsightly (4.1%). No necrosis was observed. **Conclusion:** This technique was effective and easy to perform, with satisfactory umbilical scar aesthetic outcomes in abdominal dermolipectomy.

Keywords: Liposuction; Abdominoplasty; Abdomen; Umbilicus; Scar.

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■ **RESUMO**

Introdução: Na abdominoplastia convencional, a cicatriz do novo umbigo representa o ponto de maior desafio. Em sua execução, já foram descritas e utilizadas várias técnicas e táticas cirúrgicas, com resultados nem sempre satisfatórios, sob o ponto de vista do paciente e também do médico. O objetivo é demonstrar a aplicabilidade e satisfação com a onfaloplastia em triângulo isósceles e com dupla fixação na abdominoplastia. **Métodos:** Foram selecionadas 97 pacientes do sexo feminino, com idades entre 25 e 65 anos. Todas foram submetidas à dermolipectomia abdominal clássica associada à lipoaspiração moderada de todo abdome anterior e flancos e avaliadas com 90, 180 e 360 dias pós-operatórios, pelo mesmo cirurgião. **Resultados:** Observou-se um índice de resultados satisfatórios das cicatrizes umbilicais na maioria dos casos (92,8%). Algumas cicatrizes umbilicais apresentaram estenoses (3,1%) e outras, cicatrizes inestéticas (4,1%). Não se observaram necroses. **Conclusão:** A utilização desta técnica demonstrou ser eficaz, de fácil execução e com resultados muito satisfatórios na estética da cicatriz umbilical nas dermolipectomias abdominais.

Descritores: Lipoaspiração; Abdominoplastia; Abdome; Umbigo; Cicatriz.

INTRODUCTION

Abdominoplasty or abdominal dermolipectomy was described by Kelly[1] in 1899 and is among the most common plastic surgery procedures.

Liposuction combined with abdominal dermolipectomy was described by Avelar[2] in 1998 and has subsequently been accepted as a routine procedure by other authors[3-6].

Despite advances in various techniques and adaptations of this procedure, there is still no unanimous agreement on the creation of an umbilical scar, which remains a major challenge in abdominal plastic surgery.

The umbilical scar divides the human body exactly in the middle, according to Marcus Vitruvius[7], a Roman architect, and this concept was perfected by Leonardo da Vinci in 1490. The evolution of omphaloplasty began in 1924, when Frist[8] performed the first transposition of the umbilicus. Since then, many variations have been used in an attempt to approximate the appearance of the original umbilicus.

In the 1970s, Baroud[9] and Regnaut[7] used horizontal incisions in the abdominal flap, while in 1978, Avelar[10] used a star-shaped incision.

Several techniques have been described: Juri et al.[11] proposed the use of a V-shaped incision, Massiha et al.[12] added a circular umbilical incision and a triangular incision in the abdominal flap, Malic et al.[13] used an inverted U-shaped incision in the flap, and Castillo et al.[14] used Y-shaped de-epithelized skin flaps.

Several authors[2,7,8,9,13,15] have used various geometric shapes (Mercedes star, lozenge, ellipse, cross, rectangle, shield shape, infinity logo, and y-shape) in an attempt to obtain a more natural result in the creation of the umbilicus, but there is still no consensus on the best technique.

OBJECTIVE

To demonstrate the applicability and satisfaction with omphaloplasty based on an isosceles triangle with double fixation in abdominoplasty.

METHODS

This study included 97 female patients, with a mean age of 45 years (range, 25 to 65 years) who underwent omphaloplasty between January 2014 and December 2015.

The surgeries were performed at the STK-Plastic Surgery Center in Belo Horizonte, MG, by the same surgeon.

All patients received the same pre-, intra-, and postoperative care.

The guidelines of the principles of Helsinki were followed.

Surgical technique

The abdominal flap was freed using an isosceles triangular incision, with an upper base measuring 2 cm and sides measuring 2.5 cm (Figure 1A and B).

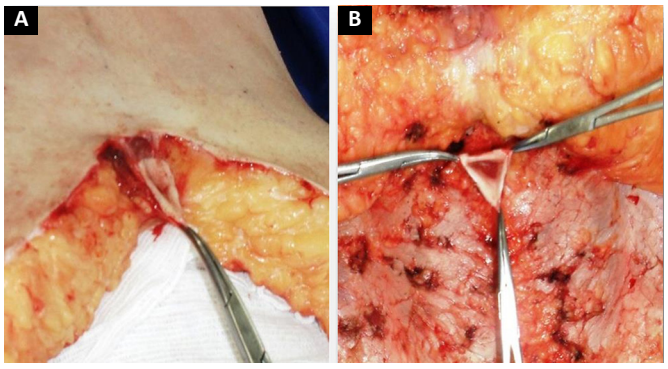

Figure 1. A: Demarcation of the umbilicus still fixed to the abdominal flap; **B:** Upper base of the umbilicus measuring 2 cm, with sides measuring 2.5 cm.

The abdominal flap was provisionally fixed in the suprapubic region (Figure 2).

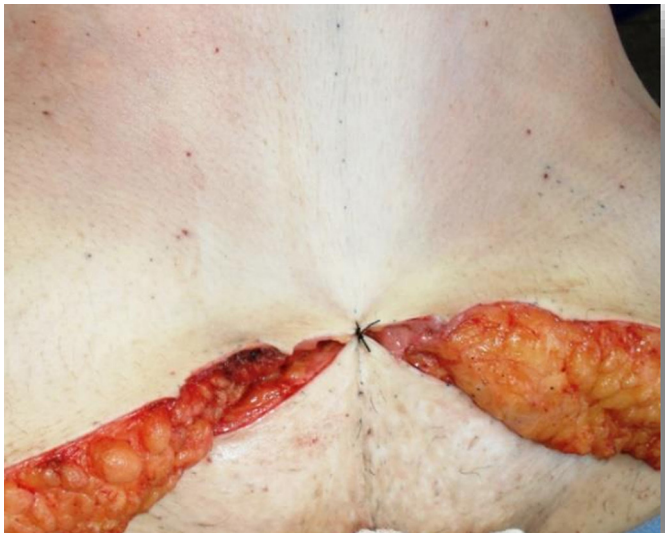

Figure 2. Provisional fixation of the dermal-fat flap in the pubic area.

The demarcation of the new umbilical implantation site began with a linear, 2-cm horizontal incision in the abdominal flap in place of the original projection of the umbilicus in the skin (Figure 3).

A triangle measuring approximately 0.5 cm was then removed from the middle third of the lower border of this incision (Figure 4 A and B).

Once the skin incision was made at the new umbilical site, the flap fixation site was released to the suprapubic region. This flap was lifted to expose the detachment area and umbilicus. Fixation was performed with 3-0 monofilament nylon between the medial region of the upper edge of the new umbilical incision and the aponeurosis of the rectus abdominis at the upper base of the umbilical pedicle (Figures 5 and 6).

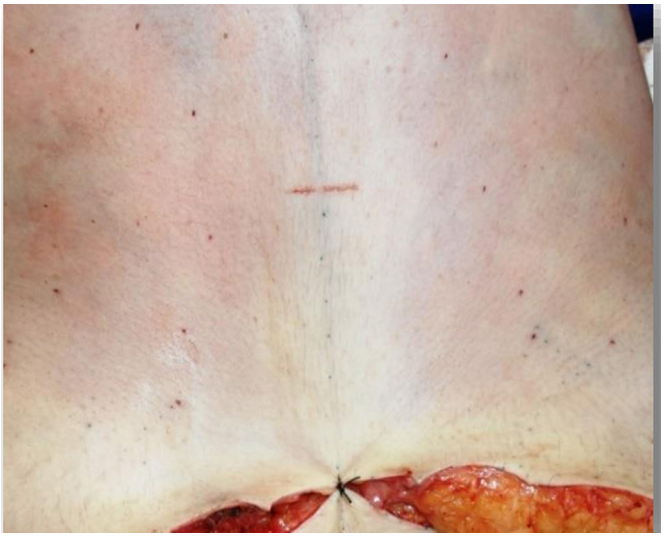

Figure 3. Linear, horizontal, 2-cm incision on the abdominal flap at the level of the projection of the original umbilicus in the skin.

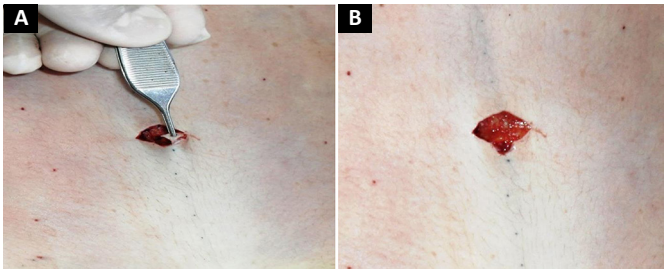

Figure 4. A and **B:** Removal of a triangle measuring approximately 0.5 cm from the middle third of the lower edge of this incision.

Next, the upper portion of the new umbilical incision was attached with a transcutaneous U-point to the upper portion of the umbilicus (Figure 7), with the knot buried in the umbilicus.

The umbilicus was transferred through the incision in the abdominal flap (Figure 8).

The angles of the umbilical triangle correspond to the angles of the flap incision and are fixed with 4-0 nylon monofilament (Figure 9).

Suturing of the umbilicus at the new site was completed with interrupted U sutures, using 4-0 monofilament nylon with knots buried in the umbilicus (Figure 10).

Finally, the inferior portion of the new umbilical incision was fixed in the abdominal flap to the aponeurosis of the rectus abdominis in the caudal portion of the umbilical pedicle, avoiding displacement of the umbilicus in the postoperative period and minimizing traction on the umbilical scar (Figure 11).

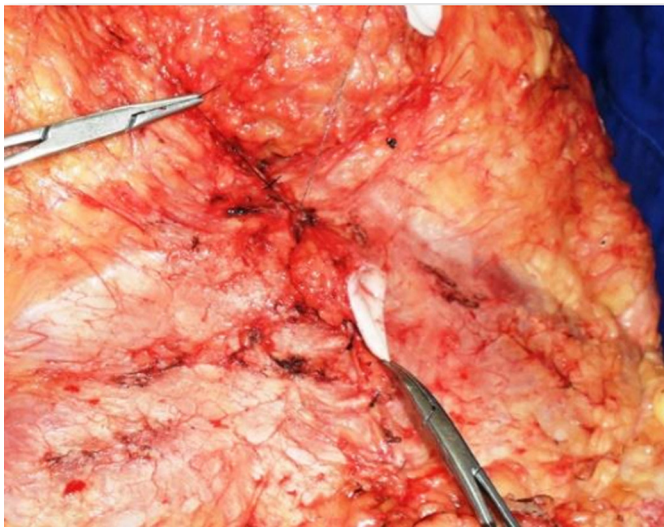

Figure 5. Suture fixation with 3-0 monofilament nylon between the medial region of the dermis in the upper portion of the umbilical incision with the aponeurosis of the rectus abdominis.

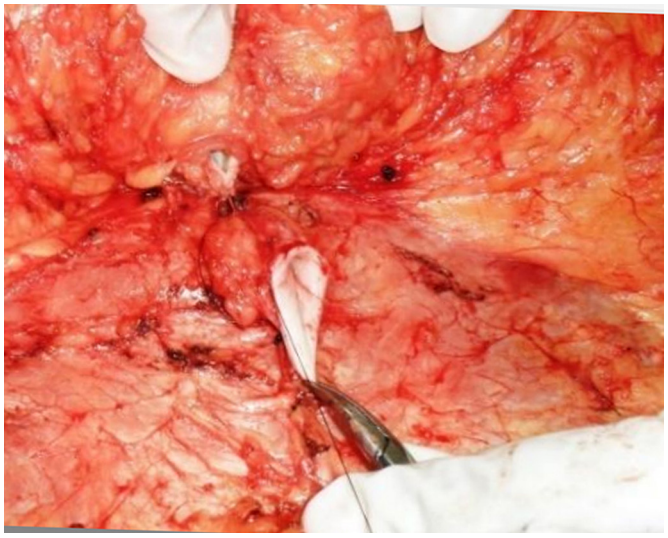

Figure 6. Mounting the upper abdominal flap to the cephalic base of the umbilical stump.

The abdominal flap was then pulled up to the suprapubic line for definitive fixation. Silicone umbilical belts were used in all patients.

RESULTS

The 97 patients were followed for up to 12 months after classic abdominal dermolipectomy with omphaloplasty based on an isosceles triangle with double fixation. A questionnaire was used for self-evaluation (Table 1) at 1 year postoperatively. Patients were asked about the degree of satisfaction with the umbilical abdominoplasty scar and whether they would recommend the surgery to a friend; they were also encouraged to write any comments related to the surgery.

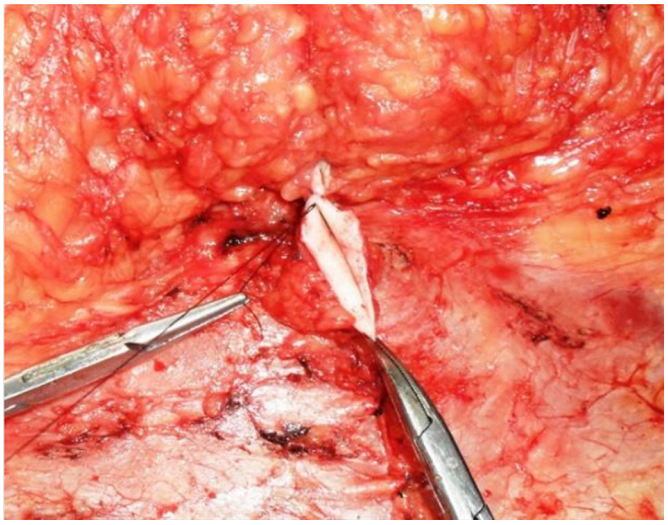

Figure 7. Transcutaneous U sutures joining the central portion of the umbilical base in the subdermal region of the upper portion of the umbilical incision.

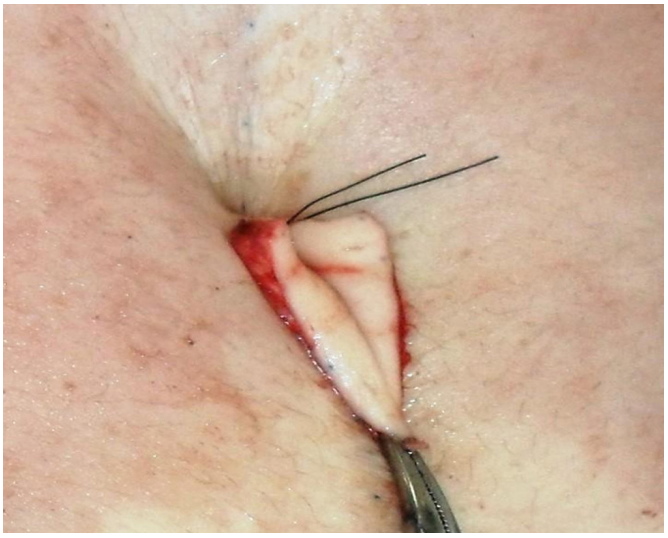

Figure 8. Transfer of the umbilicus through the abdominal flap incision.

In all, 85.5% of the patients were very satisfied with the final outcome of the procedure, 8.2% were satisfied, and 6.1% were slightly satisfied. With respect to the umbilical scar, 82.5% were very satisfied, 10.3% were satisfied, and 7.2% were slightly satisfied.

Only 11 patients commented on the size of the abdominoplasty scar and 18 complained of severe postoperative pain.

The surgeon assessed these 97 abdominoplasty patients at 90, 180, and 360 days postoperatively. At 1 year, the patients were evaluated for umbilical position on the abdomen, type of scar (atrophic, hypertrophic, and contracted), and scar depth; the overall results

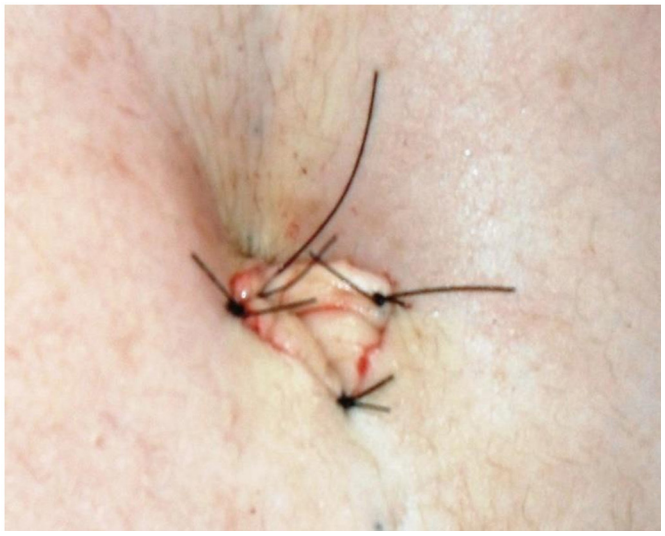

Figure 9. Fixation of the angles of the umbilical triangle to the angles of the skin incision.

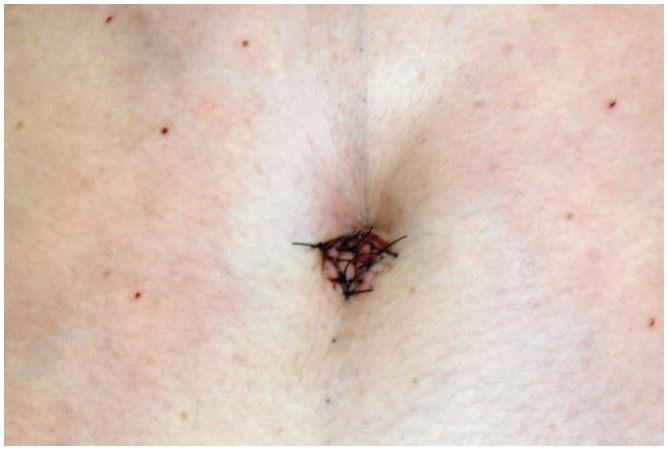

Figure 10. Fixation of the umbilical scar on a new bed using interrupted U sutures.

were satisfactory, with a low rate of complications (Figures 12, 13, 14, 15).

The complications are listed in Table 2.

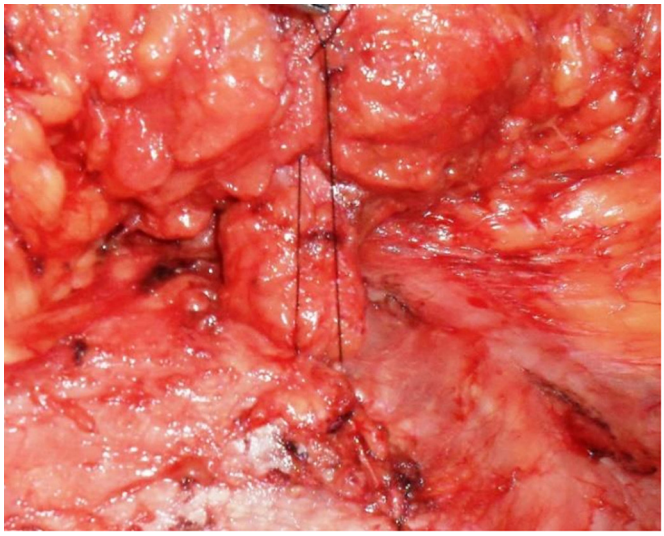

Figure 11. Fixation of the infraumbilical portion of the abdominal flap to the aponeurosis of the rectus abdominis in the caudal portion of the umbilical stump.

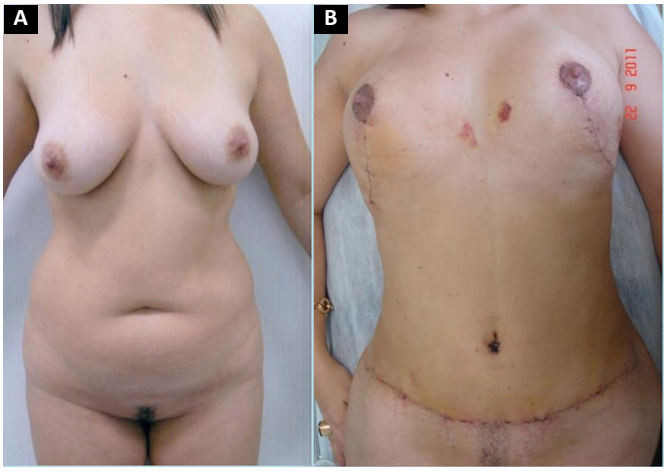

Figure 12. A: Preoperative appearance; **B:** Immediate postoperative appearance.

DISCUSSION

The degree of satisfaction with abdominoplasty is usually high because of visible postoperative

Table 1. Patient self-assessment of satisfaction.

	Very Satisfied	%	Satisfied	%	Slightly Satisfied	%	Yes	%	No	%
How do you rate the abdominal scar?	83	85.5	08	8.2	06	6.1				
How do you rate the umbilical scar?	80	82.5	10	10.3	07	7.2				
Would you recommend the surgery to a friend?							92	94.8	05	5.1
List any relevant observations										

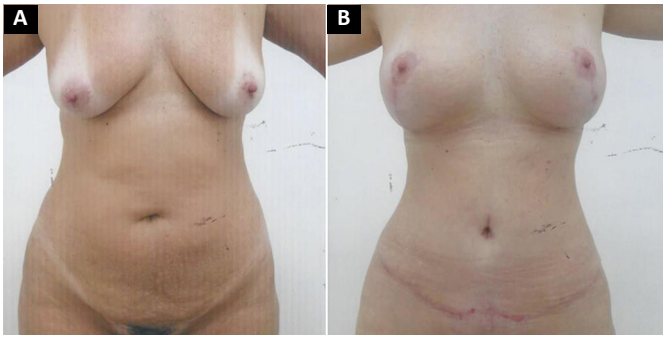

Figure 13. A: preoperative appearance; **B:** Postoperative appearance at 3 months.

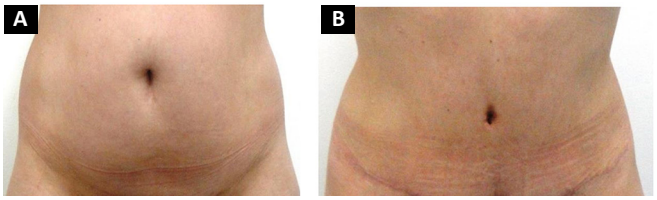

Figure 14. A: preoperative appearance; **B:** Postoperative appearance at 6 months.

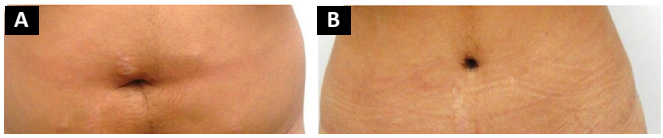

Figure 15. A: preoperative appearance; **B:** Postoperative appearance at 12 months.

Table 2. Scar complications.

Contraction	Number	Percentage
Hypertrophy	03	3.09%
Atrophy	02	2.06%
Necrosis	02	2.06%
Necrose	00	0%

improvement, compared to the appearance of an abdomen affected by multiparity and fluctuations in body weight.

A poor-quality umbilicus compromises satisfaction with abdominoplasty, and the choice of an appropriate technique is a challenge for the plastic surgeon.

The technique described herein, with abdominal flap fixation to the aponeurosis of the rectus abdominis, superior and inferior to the umbilicus, avoids traction on the umbilical scar, favors the healing process, and promotes a natural appearance, approximating that of an ideal umbilical scar.

The 7 patients who reported poor satisfaction with the umbilical scar underwent a second surgical procedure for correction. This group included 2 patients with an enlarged scar, 2 with a hypertrophic scar, and 3 with scar contraction. Another patient with contraction had an unsatisfactory outcome, but the evaluation was made by the surgeon alone. All other patients reported being satisfied or very satisfied with the umbilical scar.

The 5 patients who would not recommend the surgery to a friend thought that the scar would be smaller, despite being given preoperative information. These 5 were among the 8 who reported only slight satisfaction with the abdominal scar.

Only 11 patients reported expecting a different appearance. Another 18 reported postoperative pain.

CONCLUSION

Omphaloplasty based on an isosceles triangle with double fixation was easy to perform and resulted in a more natural appearance, with overall patient satisfaction.

COLLABORATIONS

RC Analysis and/or interpretation of data; statistical analyses; final approval of the manuscript; conception and design of the study; completion of surgeries and/or experiments; writing the manuscript or critical review of its contents.

BVBLC Analysis and/or interpretation of data; statistical analyses; writing the manuscript or critical review of its contents.

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Original Article

Quality of life and aesthetic results after mastectomy and mammary reconstruction

Qualidade de vida e resultado estético após mastectomia e reconstrução mamária

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ABSTRACT

Introduction: Due to the increased incidence of breast cancer, the demand for breast reconstruction has been increasing, along with concerns regarding the satisfaction and quality of life of the patients. Mastectomy can be a traumatic experience, especially when it is perceived as a mutilation, which can impact self-esteem and emotional stability. The BREAST-Q® questionnaire was internationally validated and formulated for the pre- and postoperative assessment of quality of life related to breast reconstruction. This study aimed to evaluate quality of life and aesthetic result satisfaction in patients who underwent breast reconstruction with implants by comparing the period after breast reconstruction with the period before. **Method:** A retrospective longitudinal observational study was carried out by reviewing the charts of patients who underwent breast reconstruction using silicone or tissue expander implants from January 2014 to December 2016, in association with a cross-sectional study of the Breast-Q® questionnaire and an evaluation of aesthetic results based on photographic analysis before and after surgery. **Results:** We selected 74 patients who underwent breast reconstruction with implants (79.7% with silicone prostheses and 20.3% with expanders); 95.94% of the reconstructions were immediate, and no particular laterality predominated. We obtained statistical significance in the domains of both breast satisfaction and physical well-being. Most cases were considered satisfactory by the external evaluator. **Conclusion:** The patients' quality of life in the period after breast reconstruction with breast implants was superior to that in the period prior to the procedure.

Keywords: Breast neoplasms; Prostheses and implants; Quality of life; Surgery, Plastic; Mastectomy.

Institution: Hospital Daher Lago Sul, Brasília, DF, Brazil.

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Conflicts of interest: none.

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■ **RESUMO**

Introdução: Em decorrência do aumento na incidência de câncer de mama, a procura pela reconstrução mamária vem crescendo, juntamente com a preocupação em relação à satisfação e à qualidade de vida das pacientes. Mastectomia pode ser vivenciada de modo traumático, sendo considerada mutilação, afetando autoestima e estabilidade emocional. O questionário BREAST-Q® foi validado internacionalmente e formulado para avaliação pré e pós-operatória da qualidade de vida relacionada à reconstrução mamária. O objetivo do estudo é avaliar a qualidade de vida e satisfação com o resultado estético das pacientes submetidas à reconstrução mamária com implantes, comparando o período anterior com o período posterior à reconstrução mamária. **Método:** Realizado estudo observacional longitudinal retrospectivo por meio da revisão de prontuários de pacientes submetidas à reconstrução mamária com uso de implantes de silicone ou de expansor de tecido no período de janeiro de 2014 a dezembro de 2016, associado a estudo transversal por meio da aplicação do questionário Breast-Q® e avaliação do resultado estético após análise fotográfica pré e pós-operatória. **Resultados:** Foram selecionadas 74 pacientes que foram submetidas à reconstrução mamária com implantes (79,7% com prótese de silicone e 20,3% com expansor); 95,94% das reconstruções foram imediatas e não houve predomínio quanto à lateralidade. Obtivemos significância estatística tanto no domínio satisfação com a mama quanto no domínio bem-estar físico. A maioria dos casos foram considerados satisfatórios pelo avaliador externo. **Conclusão:** A qualidade de vida das pacientes no período posterior à reconstrução mamária com implantes mamários é superior em relação ao período anterior ao procedimento cirúrgico.

Descritores: Neoplasias da mama; Implante de prótese; Qualidade de vida; Cirurgia plástica; Mastectomia.

INTRODUCTION

According to the National Cancer Institute, breast cancer is the second most common type of cancer among women in Brazil and worldwide, after non-melanoma skin cancer. Approximately 25% of all new cancer cases registered every year are breast cancers, and around 57,960 new cases of breast cancer registered in Brazil were expected in 2016. In 2013, 14,388 Brazilians, including 14,206 women, died from the disease[1].

Owing to the increased incidence of breast cancer, the demand for breast reconstruction is also growing, along with concerns regarding the satisfaction and quality of life of patients.

Mastectomy, even when accompanied by immediate breast reconstruction, can be a traumatic experience for women and may be perceived as a mutilation, significantly impacting their self-esteem and emotional stability. In addition, after the surgery, patients may present with symptoms such as pain or discomfort in the breast area, changes in tactile sensation, and impaired upper limb functionality after dissection of the axillary lymph nodes, among others, all of which affect their quality of life[2].

Given this scenario, breast reconstruction can be an important means of regaining a positive body image, re-establishing social engagement, and improving quality of life[3].

The techniques used in breast reconstruction include the use of silicone prosthesis and tissue expanders and may be carried out immediately after mastectomy or may be delayed.

The silicone gel breast prosthesis was developed in 1961 by Cronin, Gerow, and Dow Corning Corp. and introduced in 1963, significantly advancing the field of breast reconstruction. In France, Arion introduced the first tissue expander in 1965, but it was not until 1982

that Radovan described its use in breast reconstruction. In 1984, Becker developed a definitive tissue expander. Techniques that have developed in tandem with the use of these alloplastic materials have improved patients' quality of life, reducing the impact of perceived mutilation and surgical time, with the advantages of a shorter hospital stay, absence of donor area, and reduced risk of complications[4,5].

The most effective way to evaluate quality of life is by means of validated questionnaires that focus on the treatment in question[6,7]. The BREAST-Q® questionnaire has been validated and specifically developed to assess pre- and postoperative quality of life related to breast reconstruction[7,8].

OBJECTIVE

The main objective of this study was to evaluate patients' quality of life and satisfaction with the aesthetic result following breast reconstruction with implants via comparison between the pre-reconstruction and post-reconstruction periods.

MATERIALS AND METHODS

This was a retrospective longitudinal observational study conducted by reviewing the medical records of patients who underwent breast reconstruction using silicone implants or tissue expanders from January 2014 to December 2016, in association with a cross-sectional study of the application of the BREAST-Q® questionnaire and evaluation of aesthetic results based on an analysis of pre-and postoperative photographs.

The research project followed the legal procedures determined by resolution 196/96 of the National Health Council regarding research involving human beings and was conducted in accordance with the principles of the Declaration of Helsinki.

All surgeries were performed by the same plastic surgeon in 5 hospitals located in the city of Brasilia (DF).

The variables evaluated were age, body mass index (BMI), comorbidities, type of breast reconstruction performed, the result of the histopathological study of lesion biopsy, laterality, time of breast reconstruction (immediate or delayed), symmetrization, preservation of the nipple-areola complex (NAC) upon mastectomy, postoperative complications, chemotherapy (CT), and radiotherapy (RT), as well as whether all stages of breast reconstruction were completed.

The inclusion criteria set for the study were:

1. Patients undergoing total mastectomy due to breast cancer or for prophylactic reasons;
2. Patients undergoing breast reconstruction by techniques involving a breast prosthesis or tissue expander;
3. Patients who agreed to the free and informed consent terms, authorizing the use of their records and their photographs for scientific purposes.

The exclusion criteria were:

1. Patients who underwent other breast reconstruction techniques;
2. Patients who did not answer the pre- and postoperative BREAST-Q questionnaire;
3. Patients who refused to participate in the study.

Questionnaire for assessing quality of life – BREAST-Q®

Quality of life of patients was evaluated by the BREAST-Q®, a questionnaire validated internationally for the development of scales to assess quality of life related to breast reconstruction from the patient's perspective[6,7]. It was developed based on the guidelines of the FDA (U.S. Food and Drug Administration/Guidance and Compliance Regulatory Information). The questionnaire is composed of 4 independent modules (reductive mammoplasty, breast augmentation, breast reconstruction, and mastectomy). Each of the modules includes a core of independent scales that assess 6 domains (satisfaction with breasts, satisfaction with outcome, psychosocial well-being, sexual well-being, physical well-being, and satisfaction with care).

The patients' responses to the items in each domain are transformed by the Q-Score® scoring software to yield a total score (for each scale) ranging from 0 to 100. For all BREAST- Q® scales, a higher score indicates greater satisfaction or a better quality of life[7,8].

The questionnaire was translated into Portuguese without any change in the meaning of any sentence. Two versions of the questionnaire were used, one specific to the preoperative period and one for the postoperative period. For the preoperative questionnaire, 4 domains were used (satisfaction with breasts, psychosocial well-being, physical well-being, and sexual well-being). For the postoperative questionnaire, 5 domains were used (satisfaction with breasts, satisfaction with outcome, psychosocial well-being, sexual well-being, and physical well-being), plus one subdomain (satisfaction with nipple).

Satisfaction and aesthetic result

A medical assessment of the aesthetic result was performed after analyzing pre- and postoperative photographs obtained from the medical records. The

surgeon's satisfaction with the results achieved was classified as unsatisfactory in cases rated as poor or regular or satisfactory in cases rated as good or very good. Patient satisfaction was assessed by the BREAST-Q® questionnaire.

Surgical technique

The same surgical technique was applied to both procedures: reconstruction using either a prosthesis or an extender. The choice between the two techniques was always made at the time of surgery when the pliancy of the muscle was tested through the placement of molds. In cases where it was not possible to achieve a proper size with direct implantation of the prosthesis, a tissue expander was used.

Initially, the patient was subjected to mastectomy under general anesthesia by a mastology team and the weight of the part removed was assessed. Thereafter, the plastic surgery team took charge, preparing a submuscular pocket after infiltration with 0.9% saline solution and epinephrine (1:300,000), using the greater pectoral muscle, rectus abdominis, and the fascia of the anterior serratus (when possible) or the muscle itself. Rigorous hemostasis was performed followed by testing with molds and implant placement, either a prosthesis or expander. Finally, the surgical pocket was closed, a Portovac drain was placed, and the skin flaps were adjusted followed by sutures.

Statistical analysis

The statistical analysis was performed using SPSS 22.0 (IBM-SPSS Inc., Armonk, New York) software. Categorical variables were analyzed with the chi-square test and Fisher's exact test. The results were considered statistically significant when $p \leq 0.05$.

RESULTS

A total of 74 patients who underwent breast reconstruction with implants were selected: 59 (79.72%) with a silicone prosthesis and 15 (20.27%) with an expander (Table 1). The age of the patients ranged from 24 to 81 years, with an average of 55 years and a median of 54 years. The BMI ranged from 17.95 to 36.98, with an average of 24.50.

Among the 74 breast reconstructions, 71 (95.94%) were performed at the same time as mastectomy and classified as immediate breast reconstruction. Only 3 (4.05%) reconstructions were late reconstructions. In terms of laterality, 50% were unilateral and 50% were bilateral (Table 1).

In 30 (40.54%) of the breast reconstructions performed, the NAC was spared. In addition, 48 (64.86%) patients underwent a second operation for breast symmetrization (Table 1).

Table 1. Breast Reconstruction Data.

Demographic data – breast reconstruction		
Silicone prosthesis		59 (79.72%)
Expander		15 (20.27%)
Immediate		71 (95.94%)
Late		03 (4.05%)
Unilateral		37 (50%)
Bilateral		37 (50%)
Nac preservation		30 (40.54%)
Symmetrization		48 (64.86%)
CT		45 (60.81%)
	ADJ	24 (53.33%)
	NEO	21 (46.67%)
RT		24 (32.43%)
		Total = 74 (100%)

Of the 74 patients undergoing breast reconstruction, 45 (60.81%) received complementary CT after mastectomy, 24 (53.33%) underwent adjuvant CT (ADJ), and 21 (46.67%) underwent neoadjuvant CT (NEO). Twenty-nine (39.18%) patients did not undergo any type of CT. RT was required in 24 (32.43%) patients (Table 1).

In terms of comorbidities, 17 (22.97%) of the patients who underwent breast reconstruction had none. In contrast, 16 (21.62%) patients were hypertensive, 15 (20.27%) presented with dyslipidemia, 13 (17.57%) had hypothyroidism, 8 (10.81%) reported being treated for depression, 6 (8.11%) had diabetes type II, 3 (4.05%) had arrhythmia and/or other cardiac disorders, 1 (1.35%) had multiple myeloma, 1 (1.35%) had thrombophilia, and 1 (1.35%) was a carrier of a genetic mutation for thrombosis. In addition, 5 (6.76%) patients were smokers and 15 (20.27%) reported being ex-smokers. Many patients had more than one comorbidity.

With regard to surgical complications after breast reconstruction surgery, 33 (44.59%) patients did not experience any type of complication. However, there were 14 (18.92%) cases of seroma, 7 (9.46%) cases of slight necrosis in the NAC region, 6 (8.11%) cases of slight dehiscence in the T region, 5 (6.76%) cases of hematoma, 3 (4.05%) cases of breast asymmetry, and 3 (4.05%) cases of capsular contracture. Three other complications were observed, including infection (2 cases) and late venous thrombosis. Some patients had more than one complication (Table 2).

Of the 74 patients selected, 52 (70.27%) answered the pre-reconstruction questionnaire, while 48 (64.86%)

Table 2. Postoperative Complications.

Post-operative complications	
Seroma	14 (18.92%)
Slight nac necrosis	07 (9.46%)
Dehiscence	06 (8.11%)
Hematomas	05 (6.76%)
Asymmetry	03 (4.05%)
Capsular contracture	03 (4.05%)
Others	03 (4.05%)
	Total = 74 (100%)

answered the post-reconstruction questionnaire. The responses of 4 patients who did not answer the post-reconstruction questionnaire were excluded from the study. In addition, the responses of 3 more patients were excluded because they were incomplete, yielding a total of 45 (60.81%) patients with responses. Statistical analysis of the pre- and post-reconstruction responses was performed.

In terms of the breast satisfaction domain, statistical significance in the comparison of the pre- and post-reconstruction responses was found for the following two questions: "How you look in the mirror clothed?" and "Being able to wear clothing that is more fitted?", with $p = 0.00121$ and $p = 0.0249$, respectively (Figures 1 and 2).

Tables 3, 4, and 5 show the number of answers, in percentages, for each question in the pre- and post-

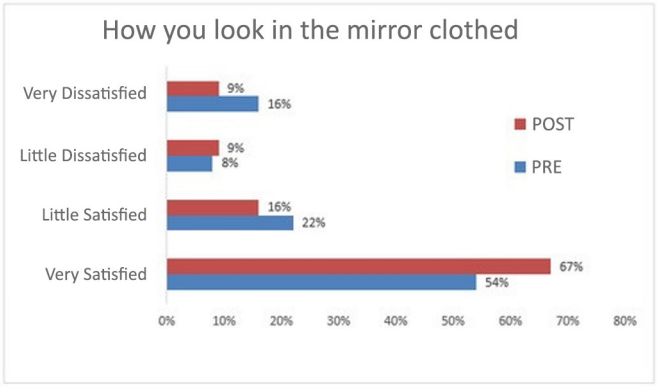

Figure 1. How you look in the mirror clothed .

reconstruction questionnaires. In addition, they display the p values obtained by statistical analysis. Table 3 refers to the psychosocial well-being domain, Table 4 refers to the physical well-being domain, and Table 5 refers to the sexual well-being domain. Statistical significance was shown for 4 questions in the physical well-being domain, as shown in Table 4, but not for the psychosocial well-being and sexual well-being domains.

Table 6 presents the descriptive statistics of

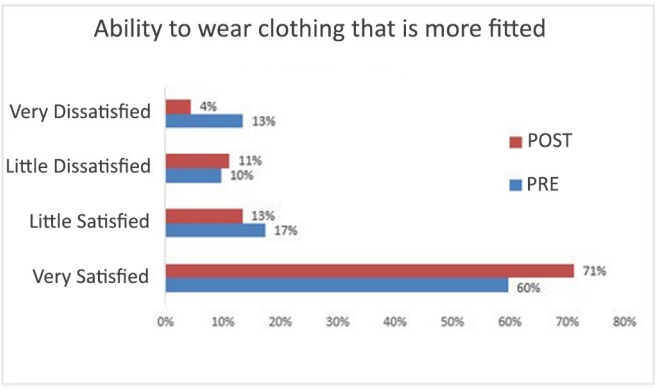

Figure 2. Ability to wear clothing that is more fitted.

the results obtained from the Q-Score®, as well as the statistical analysis comparing the responses of patients for the pre-reconstruction period with those for the post-reconstruction period.

Among 74 patients, breast reconstruction with symmetrization and reconstruction of the NAC was achieved in 40 (54.05%) patients, whose cases were analyzed by an experienced plastic surgeon without correlation with the proposed work. The majority of cases were rated as excellent by the external evaluator, and only 1 case was rated as poor. In total, 37 (92.5%) cases were considered satisfactory and 3 (7.5%) unsatisfactory. (Figure 3)

DISCUSSION

Breast cancer is the most prevalent cancer in women and often leads to a significant decrease in the ability to have a normal life[1]. The beneficial effects of breast reconstruction on quality of life and psychosocial well-being are well documented. In a variety of studies, women who underwent reconstruction after mastectomy showed improvements in self-image, sexuality, and decreased rates of depression[9-12].

Plastic surgery is a specialty in which results are evaluated mainly by patient satisfaction[13]. Therefore, studies with the main objective of evaluating quality of life and aesthetic outcome satisfaction in patients undergoing breast reconstruction are critical.

Innumerable breast reconstruction techniques are available, and the selection of which technique will be used in each patient is influenced by several factors, including BMI, comorbidities, presence of donor areas for autologous reconstruction, patient preference, expectation as to the results, lifestyle factors, staging, need for radiotherapy, type of mastectomy, laterality (unilateral or bilateral), and others[14].

Breast reconstructions with prostheses and/or tissue expanders are widely performed throughout the world and continue to be an excellent alternative

Table 3. Psychosocial Well-Being (Pre- and Post-Reconstruction).

Psychosocial well-being		Pre (%)	Post (%)	*P* value
Confident in social settings				
	All of the time	56	54.55	
	Most of the time	30	29.55	
	Some of the time	6	9.09	0.9286
	A little of the time	6	4.55	
	None of the time	2	2.27	
Able to do things that you want to do				
	All of the time	41.18	44.44	
	Most of the time	39.22	42.22	
	Some of the time	9.80	8.89	0.6620
	A little of the time	5.88	2.22	
	None of the time	3.92	2.22	
Emotionally healthy				
	All of the time	31.37	46.67	
	Most of the time	50.98	35.56	
	Some of the time	7.84	8.89	0.1755
	A little of the time	5.88	6.67	
	None of the time	3.92	2.22	
Of equal worth to other women				
	All of the time	49.02	50	
	Most of the time	29.41	31.82	
	Some of the time	15.69	11.36	0.1442
	A little of the time	0	4.45	
	None of the time	5.88	2.27	
Self-assured				
	All of the time	37.25	38.64	
	Most of the time	41.18	45.45	
	Some of the time	13.73	9.09	0.4324
	A little of the time	1.96	4.55	
	None of the time	5.88	2.27	
Feminine in clothing				
	All of the time	49.02	47.73	
	Most of the time	29.41	36.36	
	Some of the time	13.73	6.82	0.1178
	A little of the time	1.96	6.82	
	None of the time	5.88	2.27	
Accepting own body				
	All of the time	37.25	40.91	
	Most of the time	41.18	40.91	
	Some of the time	11.76	9.09	0.6593
	A little of the time	1.96	4.55	
	None of the time	7.84	4.55	

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Table 3. Psychosocial well-being (pre- and post-reconstruction).

Normal				
	All of the time	39.22	46.67	
	Most of the time	43.14	35.56	
	Some of the time	7.84	11.11	0.5750
	A little of the time	1.96	2.22	
	None of the time	7.84	4.44	
Equal to other women				
	All of the time	39.22	47.73	
	Most of the time	39.22	29.55	
	Some of the time	11.76	13.64	0.3179
	A little of the time	3.92	6.82	
	None of the time	5.88	2.27	
Attractive				
	All of the time	25.49	38.64	
	Most of the time	37.25	27.27	
	Some of the time	15.69	22.73	0.0662
	A little of the time	13.73	6.82	
	None of the time	7.84	4.55	

Table 4. Physical well-being (pre- and post-reconstruction).

Physical well-being		Pre (%)	Post (%)	*P* value
Neck pain				
	All of the time	2.08	0.00	
	Most of the time	6.25	4.55	
	Some of the time	14.58	27.27	0.1347
	A little of the time	10.42	11.36	
	None of the time	66.67	56.82	
Back pain				
	All of the time	2.08	2.27	
	Most of the time	12.50	9.09	
	Some of the time	20.83	27.27	0.3240
	A little of the time	16.67	25	
	None of the time	47.92	36.36	
Shoulder pain				
	All of the time	2.08	0.00	
	Most of the time	10.42	6.82	
	Some of the time	14.68	22.73	0.2905
	A little of the time	14.58	11.36	
	None of the time	58.33	59.09	

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Table 4. Physical well-being (pre- and post-reconstruction).

Pain in arms				
	All of the time	4.17	0.00	
	Most of the time	4.17	2.27	
	Some of the time	16.67	20.45	0.0396*
	A little of the time	37.50	25	
	None of the time	37.50	52.27*	
Pain in ribs				
	All of the time	2.08	0.00	
	Most of the time	14.58*	2.27	
	Some of the time	20.83*	11.36	0.0007*
	A little of the time	18.75	18.18	
	None of the time	43.75	68.18*	
Muscle pain				
	All of the time	6.38	2.27	
	Most of the time	4.26	6.82	
	Some of the time	19.15	15.91	0.5263
	A little of the time	17.02	15.91	
	None of the time	53.19	59.09	
Difficulty lifting or moving your arms				
	All of the time	6.38	2.27	
	Most of the time	4.26	6.82	
	Some of the time	8.51	4.55	0.1253
	A little of the time	31.91	22.73	
	None of the time	48.94	63.64	
Difficulty sleeping due to discomfort in the breast area				
	All of the time	10.64*	2.27	
	Most of the time	6.38	15.91*	
	Some of the time	21.28	22.73	0.0257*
	A little of the time	25.53	18.18	
	None of the time	36.17	40.91	
Chest pain				
	All of the time	6.38	6.82	
	Most of the time	6.38	4.55	
	Some of the time	12.77	11.36	0.9500
	A little of the time	23.40	27.27	
	None of the time	51.06	50	
Tightness in breast area				
	All of the time	6.38	7.32	
	Most of the time	6.38	7.32	
	Some of the time	17.02	14.63	0.7006
	A little of the time	21.28	29.27	
	None of the time	48.94	41.46	

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Table 4. Physical well-being (pre- and post-reconstruction).

Pulling in breast area				
	All of the time	6.38	6.82	
	Most of the time	4.26	4.55	
	Some of the time	4.26	11.36	0.2634
	A little of the time	19.15	11.36	
	None of the time	65.96	65.91	
Pain when breast are touched				
	All of the time	8.70	4.55	
	Most of the time	13.04	13.64	
	Some of the time	19.57	27.27	0.1271
	A little of the time	39.96	25	
	None of the time	21.74	29.55	
Sensitivity in breast area				
	All of the time	4.26*	0.00	
	Most of the time	0.00	6.82*	
	Some of the time	23.40	22.73	0.0121*
	A little of the time	23.40	15.91	
	None of the time	48.94	54.55	
Sharp pain in breast area				
	All of the time	0.00	0.00	
	Most of the time	2.13	2.27	
	Some of the time	4.26	6.82	0.3886
	A little of the time	2.13	4.55	
	None of the time	91.49	86.36	
Unbearable pain in breast area				
	All of the time	2.13	2.27	
	Most of the time	0.00	4.55	
	Some of the time	10.64	11.36	0.1931
	A little of the time	34.04	25	
	None of the time	53.19	56.82	
Throbbing in breast area				
	Tempo todo	2.13	0.00	
	Maioria das vezes	4.26	0.00	
	Algumas vezes	6.38	9.09	0.1274
	Poucas vezes	21.28	25	
	Nunca	65.96	65.91	

for patients with contraindications for autologous reconstruction, those who cannot be subjected to extensive surgery, and those not wanting a prolonged postoperative recovery or a scar in the donor area[15].

A total of 74 women between 24 and 81 years of age were selected for the present study. According to the National Cancer Institute (INCA), breast tumors in women aged less than 35 years are relatively rare, and the incidence rises progressively from that age onward, especially after 50 years of age[16]. In our study, with the exception of one 24-year-old patient, all the patients were aged over 35 years.

The mean BMI presented in this study was 24.5 kg/m^2, which is higher than that in previously published data that indicated an average BMI of 22.0 kg/m^2 in breast reconstruction patients[17].

Table 5. Sexual well-being (pre- and post-reconstruction).

Sexual well-being		Pre (%)	Post (%)	*P* value
Sexually attractive in your clothes				
	All of the time	21.28	24.44	0.1683
	Most of the time	40.43	35.56	
	Some of the time	10.64	15.56	
	A little of the time	17.02	6.67	
	None of the time	4.26	6.67	
	Not applicable	6.38	11.11	
Comfortable/at ease during sexual activity				
	All of the time	25.73	20	0.9291
	Most of the time	25.73	28.89	
	Some of the time	12.77	15.56	
	A little of the time	10.64	8.89	
	None of the time	4.26	4.44	
	Not applicable	21.28	22.22	
Confident sexually				
	All of the time	23.40	20	0.9907
	Most of the time	29.79	28.89	
	Some of the time	14.89	15.56	
	A little of the time	8.51	8.89	
	None of the time	4.26	4.44	
	Not applicable	19.15	22.22	
Satisfied with your sex life				
	All of the time	23.40	20.45	0.1864
	Most of the time	25.53	31.82	
	Some of the time	21.28	13.64	
	A little of the time	2.13	9.09	
	None of the time	4.26	2.27	
	Not applicable	23.40	22.73	
Confident sexually when unclothed				
	All of the time	23.40	20.45	0.7145
	Most of the time	23.40	31.82	
	Some of the time	10.64	9.09	
	A little of the time	14.89	13.64	
	None of the time	4.26	6.82	
	Not applicable	23.40	18.18	
Attractive sexually when unclothed				
	All of the time	17.02	20	0.9097
	Most of the time	29.79	31.11	
	Some of the time	14.89	11.11	
	A little of the time	17.02	13.33	
	None of the time	6.38	6.67	
	Not applicable	14.89	17.78	

Table 6. Q Score® Pre and Post-Reconstruction.

Groups		Variation	Average	Standard Deviation	*P*
Satisfaction with breasts	Pre	0-100	73.946	27.0606	0.932
	Post	0-100	74.432	24.0865	
Psychosocial well-being	Pre	0-100	69.4	22.4794	0.005
	Post	0-100	82.568	19.531	
Physical well-being	Pre	0-100	67.325	16.7491	0.215
	Post	0-100	71.659	15.0255	
Sexual well-being	Pre	0-100	61.056	22.0233	0.482
	Post	0-100	64.795	23.7023	

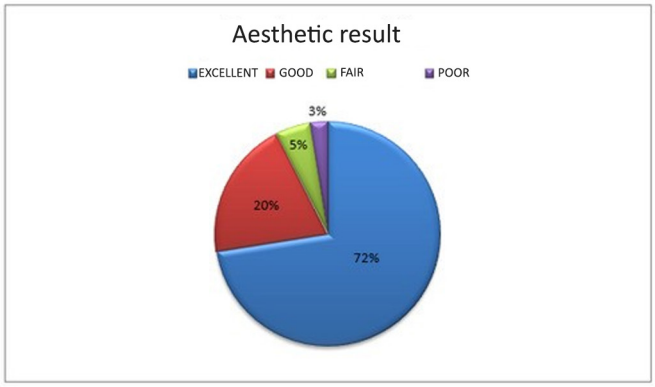

Figure 3. Aesthetic result.

In our study, the complication rate was 55.4%, with the majority being slight seroma formation (18.92%) and slight necrosis in the NAC region (9.46%). The overall incidence of any type of complication in this study was comparable with published studies that reported a complication rate ranging from 4% to 58%[18-22].

Although the use of implants facilitates faster and simpler breast reconstructions, it tends to be associated with specific complications, such as capsular contracture. The percentage of verified capsular contracture in this study was 4.05%, which is lower than the 10% to 56% rate reported in other studies[18-22].

Bilateral reconstructions have been gaining ground in recent years, either for therapeutic reasons due to the characteristics of the tumor, for indications of prophylactic mastectomy due to genetic alterations that lead to a significant increase in the risk of cancer, or even by the decision of the patient to undergo prophylactic contralateral mastectomy.

According to some studies, there is a positive influence of bilateral breast reconstruction on breast satisfaction owing to the symmetry that is more easily achieved and the fact that concern about the risk of cancer in the contralateral breast can be reduced[10]. In our study, half of the cases underwent bilateral reconstruction and the other half underwent unilateral. Most of the cases considered optimal included bilateral reconstructions. However, in the 3 cases with asymmetry as a complication in our study, the breast reconstruction was bilateral.

The majority of patients underwent immediate reconstruction (95.94%). According to previous reports, the majority of women opt for this form of breast reconstruction in an attempt to lessen the negative feelings triggered by the disease and its treatment, as well as to improve self-esteem, resolve the lack of a breast, and facilitate greater freedom in clothing options. After mastectomy, the absence of the breast alters a woman's body image, potentially generating a sensation of mutilation and the loss of femininity and sensuality[23]. There are published reports demonstrating better social interaction, higher levels of professional satisfaction and fulfillment, and a lower frequency of depression at one year after surgery among women who underwent mastectomy associated with immediate reconstruction[24,25].

The treatment of breast cancer is guided by the characteristics of the tumor, and radiotherapy and chemotherapy are complementary to mastectomy. While radiotherapy decreases the incidence of local recurrence and improves the survival of patients, it can affect breast symmetry, impair aesthetics, and decrease quality of life. In previous studies on patients who underwent breast reconstruction with implants and radiotherapy, radiotherapy was found to negatively impact their quality of life and breast satisfaction[26,27]. Of the 74 patients undergoing breast reconstruction in our study, 45 (60.81%) underwent chemotherapy (CT) and 24 (32.43%) underwent radiotherapy. Of the 29 cases considered optimal by the external evaluator, 9 (31.033%) underwent radiotherapy. Of the 8 cases considered good, 3 (37.5%) received radiotherapy. Moreover, of the 3 cases considered fair and poor, 2 (66.67%) received radiotherapy.

Factors related to quality of life and aesthetic outcomes of breast reconstructions performed with

implants were evaluated by means of the BREAST-Q® questionnaire, which was developed and validated as a specific measure of quality of life.

In 2016, Kuroda et al[28]. used the BREAST-Q® to evaluate aesthetic results and quality of life outcomes in Brazilian patients who underwent immediate breast reconstruction using implants and demonstrated that breast reconstruction leads to satisfactory quality of life outcomes.

In the present study, we observed that breast reconstruction, despite the complications inherent to the procedure, facilitates enhanced quality of life and patient satisfaction. In the domains of satisfaction with breasts, psychosocial well-being, physical well-being, and sexual well-being, the scores were higher scores in the postoperative questionnaire than in the preoperative questionnaire quantified by Q-Score®. In particular, a significant result in the domain of "psychosocial well-being" was found ($p = 0.005$).

In a 2014 retrospective study, Ng et al[29]. evaluated 143 mastectomized patients (79 with reconstruction and 64 without) using the BREAST-Q® questionnaire. The reconstruction group showed higher BREAST-Q® scores in the domains of "satisfaction with breasts", "psychosocial well-being", and "sexual well-being" and also showed improved self-esteem, increased clothing options, and a greater sense of overcoming the cancer.

In 2013, Zhong et al. evaluated 29 mastectomized patients before and after breast reconstruction with the BREAST-Q® questionnaire and observed improvements in satisfaction with breasts and psychosocial and sexual well-being.

In terms of the statistical analysis comparing the responses of the two groups for each question, statistical significance was found for the following 6 questions: "How you look in the mirror clothed?" ($p = 0.00121$); "Being able to wear clothing that is more fitted?" ($p = 0.0249$); "How often do you feel pain in the arms?" ($p = 0.0396$); "How often do you feel pain in the ribs?" ($p = 0.0007$); "How often do you have difficulty sleeping due to discomfort in the breast area?" ($p = 0.0257$); and "How often do you feel sharp pain in the breasts?" ($p = 0.0121$).

It is interesting to highlight the positive responses to the questions in the physical well-being domain, as more physical symptom complaints were expected after the surgical procedure. In 2013, Eltahir et al[30]. assessed the quality of life of women following breast reconstruction in comparison with those of patients who underwent mastectomy, using the BREAST-Q® questionnaire, and observed that women showed less pain and fewer limitations after reconstruction ($p = 0.007$).

CONCLUSION

The quality of life of patients in the period after breast reconstruction with silicone prostheses or tissue expanders was higher than that in the pre-reconstruction period.

Despite the feeling of mutilation and trauma incurred by the mastectomy procedure, breast reconstruction, when carefully executed by a well-trained and specialized team, can yield excellent aesthetic results.

COLLABORATIONS

MCC	Analysis and/or data interpretation, final manuscript approval, realization of operations and/or trials.
ACC	Conception and design study, writing - review & editing.
CADCF	Analysis and/or data interpretation, final manuscript approval, realization of operations and/or trials.
GCS	Conception and design study, writing - review & editing.
LDPB	Conception and design study, writing - review & editing.
RCSD	Conception and design study, writing - review & editing.
FTV	Formal analysis.
JCD	Final manuscript approval.

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Original Article

Impact of aesthetic mammoplasty on the self-esteem of women from a northeastern capital

Impacto da mamoplastia estética na autoestima de mulheres de uma capital nordestina

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■ **ABSTRACT**

Introduction: The main reason that leads someone to undergo aesthetic surgery is the need to obtain approval and affection from other people, which, consequently, enhances self-esteem. This study compared the level of self-esteem between the different types of mammoplasty and measured the degree of interference in the self-esteem of women undergoing aesthetic mammoplasty and the level of satisfaction after surgery. **Methods:** A prospective, longitudinal, analytical, qualitative-quantitative study was held with 40 patients undergoing primary aesthetic mammoplasty. The Rosenberg Self-Esteem Scale was used together with questionnaires on psychosocial aspects in the pre- and post-operative period of two months. Associations were evaluated by Fisher's exact test. Differences in means were evaluated by a univariate analysis of variance (independent samples), and bivariate analysis (matched sample). The level of significance was 5%, and the software used was R Core Team 2017. **Results:** Breast reduction, breast implantation, mastopexy, and association between mastopexy and breast implantation accounted for 45%, 30%, 12.5%, and 12.5% of cases, respectively. The majority expressed being dissatisfied with their body before surgery and indicated the breasts as the major reason. The desire to raise self-esteem was the main motivation among the group. A high level of post-surgical satisfaction was observed among the participants, with surgery interfering in the professional, personal, and sexual aspects. **Conclusion:** There was an average increase in the self-esteem of the participants who underwent mammoplasty, and the three types of surgery yielded similar results regarding the variation of self-esteem.

Keywords: Patient satisfaction; Self concept; Reconstructive surgical procedures; Mammaplasty; Quality of life.

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■ **RESUMO**

Introdução: O principal motivo que leva alguém a submeter-se à cirurgia estética é a necessidade de obter aprovação e afeto de outras pessoas, o que, consequentemente, melhora sua autoestima. Este estudo comparou o nível de autoestima entre os diferentes tipos de mamoplastia e mensurou o grau de interferência na autoestima das mulheres submetidas à mamoplastia estética e o nível de satisfação pós-cirúrgico. **Métodos:** Estudo prospectivo, longitudinal, analítico, quali-quantitativo com 40 pacientes submetidas à mamoplastia estética primária. Foi utilizada a Escala de Autoestima de Rosenberg e questionamentos sobre aspectos psicossociais no pré e pós-operatório de dois meses. As associações foram avaliadas pelo teste Exato de Fisher. As diferenças de média foram avaliadas por meio da Análise Variância univariada (amostra independente) e bivariada (amostra pareada). O nível de significância foi de 5% e o software utilizado foi o R Core Team 2017. **Resultados:** Redução da mama, implante mamário, mastopexia e associação entre mastopexia com implante mamário totalizaram 45%, 30%, 12,5% e 12,5%, respectivamente. A maioria mostrou-se insatisfeita com o corpo no pré-cirúrgico e apontou a mama como maior incômodo. O desejo de elevar a autoestima mostrou-se como a principal motivação entre o grupo. Por fim, foi alto o nível de satisfação pós-cirúrgico entre as pacientes, tendo a cirurgia interferido em aspectos profissionais, pessoais e sexuais. **Conclusão:** Houve aumento médio na autoestima das pacientes submetidas à mamoplastia e os três tipos de cirurgia produziram iguais resultados quanto à variação de autoestima.

Descritores: Satisfação do paciente; Autoimagem; Procedimentos cirúrgicos reconstrutivos; Mamoplastia; Qualidade de vida.

INTRODUCTION

There is an endless quest for perfect bodies in contemporary society. Personal satisfaction and physical well-being are an essential part of quality of life[1]. In contrast to the excessive effort to obtain the ideal body, the emergence of plastic surgeries presented another possibility: achieving a perfect body rapidly[2,3].

The search for standards of beauty is linked to dubious diets and uncontrolled surgical procedures. The excessive desire for a harmonious appearance can hide psychosomatic phenomena, such as bulimia and anorexia, and other psychopathological traits, such as Body Dysmorphic Disorder (BDD)[4].

According to researchers int his field, aesthetic surgery interferes directly and positively in the self-esteem of patients who do not have severe BDD, as well as improves their lives in the psychosocial aspect[5]. Given that the abovementioned are psychological disorders, they must be perceived as a kind of affliction, and plastic surgery, therefore, must be perceived as an appropriate therapeutic treatment in some cases[6].

Brazil is the second country in the world that performs the most plastic surgeries; some of the most common procedures are liposuction, dermolipectomy, mastopexy, prosthesis, and breast reduction[7].

Women tend to evaluate more positively the gains of the surgery than men because they internalize more media messages about beauty and, therefore, undergo more procedures, among them, aesthetic mammoplasty.

The main reason for aesthetic mammoplasty is to address disproportional breasts or severe ptosis, perceived as defective. Augmentation mammoplasty alternates between the first and second most commonly performed plastic surgery in Brazil and the world, as the breast is a symbol of femininity, maternity, and sexuality, and therefore, its augmentation carries high expectations and often promotes improvement in quality of life[8,9].

A lack of knowledge and opportunity for a new study was perceived, given that there are few studies measuring the degree of interference in the self-esteem of women specifically seeking cosmetic mammoplasty.

Few studies have compared the level of self-esteem between the different types of mammoplasty.

OBJECTIVE

This study aimed to measure the impact of aesthetic mammoplasty on the self-esteem of women, to shed light on the level of expectation and motivation in the pre- and post-operative period, as well as satisfaction in the post-operative period.

METHODS

Population and sample

This longitudinal prospective study evaluated a population of 40 women. The inclusion criteria for this study were women who underwent primary aesthetic mammoplasty at two private plastic surgery clinics in a capital city in Northeastern Brazil.

Data collection

The initial data collection was performed from December 2016 to January 2017. To answer the pre-surgical procedure questionnaire, the participants were approached in the waiting rooms of surgeons' offices in the last pre-operative consultation. The participants received information about the research objectives and then signed the informed consent form.

Two months after surgery, there was a follow-up and a new application of the questionnaire, in which specific questions on the level of satisfaction in the post-operative period, interference with activities, and desire to perform another surgery were added. In both moments, they were at total liberty to question and clear their doubts. This study was approved by the ethics and research committee of Tiradentes University, Aracaju, Sergipe, with CAAE number: 629097 16.1.0000.5371.

Study site

Data collection was conducted in two private plastic surgery clinics located in Aracaju, state of Sergipe, namely, the Clínica Integrada Homo and Clínica Concept. Subsequently, the data analysis and drafting of the manuscript was performed at the Tiradentes University, also in Aracaju, state of Sergipe.

Questionnaire

Self-esteem was assessed using the Rosenberg Self-Esteem Scale. The scale is internationally validated and widely used for assessing self-esteem. It is a self-administered questionnaire consisting of ten close-ended sentences, with five referring to positive self-image and five to negative self-image, using a four-point Likert scale. The options indicate the degree of disagreement or agreement with the proposed sentence: 0 = strongly disagree, 1 = disagree, 2 = agree, 3 = strongly agree.

The interpretation of the sum of all items of the scale (crude score) should be made with a table of standards appropriate to sex and age. The crude score corresponding to the 15th percentile should be equivalent to a standard deviation (SD) below the mean. The 85th percentile should correspond to an SD above the mean. Scores that fall below the average indicate low self-esteem, and those above the average correspond to high self-esteem.

Data analysis

The collected data were described by means of simple frequencies and percentages when categorical variables, or mean and standard deviation when continuous, discrete, or ordinal. The associations were evaluated with Fisher's exact test. The differences in means were evaluated by the univariate analysis of variance (independent samples) and bivariate analysis (matched sample). The level of significance was 5%. R Core Team 2017 was used to run the analyses.

RESULTS

Demographic characteristics

The study sample consisted of 40 female participants with a mean age of 32.825± 10.8531.

With regard to professional work, 84.8% reported being active in the labor market. As to the level of schooling, 46.1% had completed higher education and 35.9% high school; 7.7% completed and 10.3% did not complete primary schooling.

Motivations, proposals, and influences for completion of surgery

The primary motivation for the completion of the surgical procedure, considering all types of mammoplasty in the current study, was the desire to raise self-esteem. This motivation was found in 37.5% of the participants. When asked about who suggested surgery, 85% reported that the decision was their own initiative. In 22.5% of cases, it was by suggestion of friends and 10% of relatives.

Among the 40 participants, 57.5% reported that the main influence was the need for personal acceptance.

Need for a social explanation on the surgical procedure performed

Regarding the option to inform people on the surgical intervention, only 7.5% would not provide any information.

Post-surgical satisfaction

With regard to post-surgical satisfaction regarding the breasts, 25.6% reported moderate satisfaction and 74.4% reported high satisfaction. Among the 40 participants, one preferred to refrain from responding. Figure 1 shows the relationship between satisfaction and the types of mammoplasty.

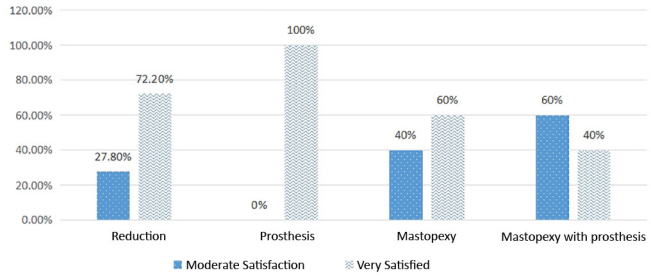

Figure 1. Post-surgical satisfaction.

Pre-surgical score of the Rosenberg Self-Esteem Scale

In the pre-surgical period, the participants had a crude score of 32.1 ± 5.3. The mean of the pre-surgical percentile was 50 ± 26.5.

Only 10% had low self-esteem (percentile < 15) in the pre-surgical period.

Post-surgical score of the Rosenberg Self-Esteem Scale

In the post-surgery period, the participants had a gross score of 34.9 ± 4.6. The mean post-surgical percentile was 63.3 ± 26.6.

Of the participants who had low self-esteem (percentile < 15) in the pre-surgical period, 50% passed to average or high self-esteem, and one of them passed from the 5th in the pre-surgical period to 95th percentile in the post-surgical period.

Variation in pre- and post-surgical scores on the Rosenberg Self-Esteem Scale

There was a general increase of 13.3% (variation shown in Figure 2), considered average in accordance with Cohen's Test, in the self-esteem of participants undergoing aesthetic mammoplasty ($p = 0.009$). Considering the type of mammoplasty performed, the variation can be seen in Figure 3.

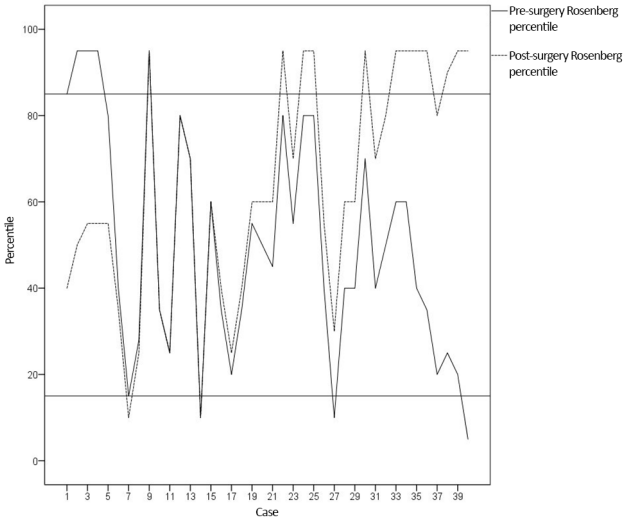

Figure 2. Variation of the percentile in the Rosenberg Self-Esteem Scale.

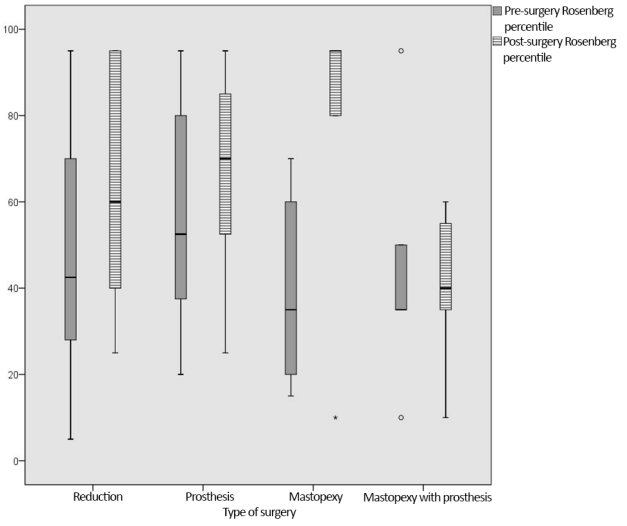

Figure 3. Variation of pre- and post-surgical percentile on the Rosenberg Self-Esteem Scale according to type of mammoplasty performed.

Interference of mammoplasty in personal, professional, and/or social life

In 25.6% of participants, the result of plastic surgery did not interfere in their personal, professional and/or social life. For 74.4%, surgery interfered positively and in different ways. There was an increase of 51.3% in self-esteem, improvement in appearance in 12.8% and greater social acceptance in 10.3% of participants. One of the participants preferred to abstain from responding.

The surgery interfered in a positive manner on the aspects addressed in 44.4% of the participants who underwent mastopexy, in contrast to 83.33% of those

who did not have the procedure ($p = 0.032$).

Interference in the sexual life

In relation to the interference caused by the surgery in sexual life, 60% reported a positive influence; 20% reported a moderate level and 40%, high. Meanwhile, 5% reported a negative interference: 2.5% reported a low negative impact and 2.5%, moderate. There was no interference in the sexual life for 30% of the participants, and 5% reported that they had no sex life.

DISCUSSION

The mean age of the individuals included in our study was 32.825 ± 10.8531 years (minimum age 18 years and maximum of 58), characterizing a similar sample of women who undergo these procedures based on data reported in the 2005 Census of the Brazilian Society of Plastic Surgery (2016).

We observed a general increase in the Rosenberg Self-esteem Scale of 13.3 percentile in the self-esteem of participants attributed to aesthetic mammoplasty ($p = 0.009$), which is an average increase according to the Cohen's test. This result is consistent with the fact that plastic surgery is considered an adequate therapy for the improvement of self-esteem[6]. Moreover, it corroborates a previous study that demonstrated how intervention in body image results in improvements in the quality of life and biopsychosocial aspects of patients, with a statistical correlation ($p < 0.005$) between general health: 90 patients at the Ivo Pitanguy Institute reported increased self-esteem in the post-operative period and positive influence on their relationships[8].

Several authors have also reported how body satisfaction reflects on the quality of life and emotional and social performance of the individual in society. The quest for beauty through plastic surgery is associated with an aim of change in acceptance and social position[10-12].

Although the average pre-surgical percentile in this study was 50 ± 26.5, i.e., the majority of women already had average self-esteem, there was a gain in the post-surgical percentile, with an average of 63.3 ± 26.6. Only 10% had low self-esteem (percentile < 15) before surgery. These participants could represent the population of women with BDD who request plastic surgery. As they do not believe they suffer from a mental disorder, these women, before looking for a psychologist or psychiatrist, seek out plastic surgeons. In the post-operative period, 50% left the low self-esteem zone and 50% remained.

In a literature review of prospective studies on patients with BDD seeking plastic surgery, Brito et al.[5] concluded that patients with mild BDD could also benefit from the results of cosmetic surgery.

A study of 115 women divided into groups based on the number of surgeries performed and response to the Body Shape Questionnaire and Sociocultural Attitudes Questionnaire Regarding Appearance reported that 30.43% of the women who had already performed more than one surgical procedure indicated being dissatisfied with their body image; the study concluded that this result may be a reflection of the presence of traces of BDD verified in the study participants, as in the post-surgical period of women with severe BDD, the real or imaginary defects remained[4]. If the surgeons are not aware of the symptoms of the disease, they can re-operate these patients, but may always obtain a negative outcome in relation to the post-operative satisfaction of these patients.

The two participants in the present study that continued to report low self-esteem in the post-surgical period indicated moderate satisfaction with the results. In addition to the possibility of undiagnosed BDD, it is reasonable to think that the experience and external factors experienced by the participant may have altered this personal recognition after surgery. One possibility would be that the participants did not understand the items requested by the data collection instrument, although this seems less likely because these two participants completed higher education.

The literature describes the importance of investigating motivations and influences on the indication of aesthetic surgery[13]. Individuals who seek aesthetic surgery for purely temporal and external reasons may not be able to assess and understand the long-term risks and benefits of the surgery. Surgeons need to discuss and understand the feelings and expectations of patients related to surgery and make them understand that it is impossible to control the feedback they receive on their altered appearance.

According to the present study, the majority of the participants sought mammoplasty for internal reasons, as the main motivation for performing the surgical procedure was the desire to raise their self-esteem (37.5%). The majority (85%) stated that the choice of surgery was their own initiative, and 57.5% reported that the main influence was the need for acceptance. Comparing the motivations with the post-surgical satisfaction, the data found are consistent with the literature: of the participants who responded on post-surgical satisfaction, all were satisfied with the results (25.6% reported moderate satisfaction and 74.4%, high satisfaction).

However, a relevant result in this sample was that 92.5% responded that they would have social

satisfaction with the procedure performed, which proves the necessity to obtain approval and more affection from other people. In addition, for 32.5% of the cases, the decision of undergoing the surgical procedure was upon the suggestion of friends or family.

Foustanos et al.[14] obtained similar results, and their findings were confirmed by this study. A project, by means of a questionnaire on self-image, self-confidence, and work environment applied to 100 women who underwent aesthetic plastic surgery, also reported that appearance influences professional development and that social praise affects confidence at work[14]. In the present study, 84.8% of the participants reported having a profession. Therefore, enhancing physical appearance was reflected as gaining vigor, youth, and self-confidence necessary for professional self-assertion.

This study also showed that the three types of surgery (breast reduction, breast implantation, and mastopexy) produced the same outcome in self-esteem variation. Reductive surgery, in addition to the aesthetic issue, brings relief to the physical discomfort caused by large breast volumes. Based on this principle, we can imagine that reductive surgery would bring a higher gain in the variation of self-esteem. However, this hypothesis was not tenable, considering that surgeries of only an aesthetic nature are as impactful in improving the quality of life and biopsychosocial aspects of participants as reparative surgeries.

In relation to post-surgical satisfaction, 60% of the participants who underwent mastopexy were satisfied, and 40% reported positive and high interference in their sexual life.

Of the participants who underwent mastopexy, 70% had already had children. The literature describes the breast as a symbol of femininity and female sexuality[9]. Thus, it has erogenous power and represents a bodily identity. If the woman suffers significant physical alterations in the breast, including those resulting from breastfeeding, then there will be impairment of the psychological functions. Accordingly, the main motivation of 50% of the participants who opted for mastopexy was the increase of self-esteem.

In our sample, surgeries interfered positively on personal, professional, and/or social life in 44.4% of the participants who underwent mastopexy. This result was expected, as those who undergo mastopexy are usually younger, sexually and professionally active women who have had their breasts modified by changes in skin elasticity owing to pregnancy, breastfeeding, weight fluctuations, and other factors. However, this positive influence was also present in 83.33% of those who did not undergo this specific procedure ($p = 0.032$).

The positive influence is reflected in several procedures, among them, breast enlargement with silicone prosthesis that revealed that 100% of the participants showed a high post-surgical satisfaction.

On May 17, 2017, the Ibero-Latin American Federation of Plastic Surgery signed a declaration of commitment to implement higher safety in the specialty, and with the purpose of defining actions to reduce the number of deaths and sequels caused by surgery, thus preserving patients' health. This action is critical to providing a better guarantee of satisfactory aesthetic results and to preserving patients' lives, in consideration of the world indices in this regard: Brazil and Mexico make up this group, two countries that most perform plastic surgeries in the world[15].

All of the participants who participated in this study reported being well-informed about the procedure that they had planned to undergo, the possible therapeutic options according to their needs, and the possible risks and disadvantages of the procedure to be performed. Of the participants in the study, 97.5% reported understanding that aesthetic plastic surgery has no guarantees of specific results, and 55.5% displayed optimism or tranquility facing this situation. These data refer to the participants' confidence in the surgical team. These findings are relevant and show a greater concern for clarifications to attain higher safety and promote confidence.

CONCLUSION

The study measured the impact of aesthetic mammoplasty on the self-esteem of women. We found an average increase in the self-esteem of the participants who underwent aesthetic mammoplasty, which could indicate that plastic surgery may be considered an appropriate therapy for improving self-esteem.

The types of surgery produced the same outcome regarding the variation of self-esteem. The solely aesthetic-oriented surgeries were as impactful in improving the quality of life and biopsychosocial aspects of the participants as reparative surgeries.

The post-operative satisfaction of a patient depends on the association between a desire for surgically changing one's body image with consistent and well-structured motivations and a greater concern of surgeons for the legal aspects in relation to providing good guidance on therapeutic options, with clear explanations regarding the potential risks and benefits of the surgical procedure to be performed.

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COLLABORATIONS

GRS Analysis and/or data interpretation, conception and design study, conceptualization, data curation, final manuscript approval, investigation, project administration, realization of operations and/or trials, validation, writing - review & editing.

DCA Analysis and/or data interpretation, data curation, realization of operations and/or trials.

CV Analysis and/or data interpretation, realization of operations and/or trials.

RAC Analysis and/or data interpretation, realization of operations and/or trials.

GGL Visualization, writing - original draft preparation, writing - review & editing.

LS Visualization, writing - original draft preparation, writing - review & editing.

RAC Visualization, writing - original draft preparation, writing - review & editing.

DP Final manuscript approval, project administration, supervision, writing - review & editing.

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Original Article

Esthetic refinements to the appearance of the vulva in sex reassignment surgery

Refinamentos estéticos na aparência da vulva na cirurgia de adequação genital

MATHEUS ZAMIGNAN MANICA [1]*

■ **ABSTRACT**

Introduction: Sex reassignment surgery is a reliable and safe option, which has drastically reduced dysphoria and improved the quality of life of transgender individuals. The most studied and used technique is penile inversion with modifications, which results in appropriate esthetic appearance and functionality, but the surgical technique has not been standardized. Partial satisfaction rates up to 38% and dissatisfaction rates of 15% may cause up to 66% of cases to undergo additional procedures. The objective is to suggest esthetic refinements to the appearance of the vulva and compare some of the techniques described, seeking to increase the postoperative esthetic and functional satisfaction. **Methods:** A retrospective study with 7 patients undergoing sex reassignment surgery between August 2017 and February 2018 was conducted. The clitoris is constructed with the glans in the form of a trident, using the corona to build the corpus cavernosa of the clitoris and increase the area of erogenous sensation. A section of the prepuce is used to increase the coverage of the clitoris and cover the inner surface of the labia minora, which are defined with the use of sutures. **Results:** Adequate sensitivity and satisfaction with the result and capacity of orgasm in all patients were observed. There was no stenosis, fistula, or necrosis of the clitoris with this technique. Only 1 case needed an additional procedure for better esthetic definition. **Conclusion:** The technique presented leads to high patient satisfaction and erogenous sensitivity, with some advantages compared to other techniques. However, prospective studies with larger numbers of patients are needed to define a more effective surgical technique.

Keywords: Vulva; Transsexualism; Transgender Individuals; Sex Reassignment Surgery; Sex Reassignment Procedures.

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■ **RESUMO**

Introdução: A cirurgia de adequação genital tem se mostrado uma opção segura e confiável, com redução drástica na disforia e melhora da qualidade de vida das pessoas transgênero. A técnica mais estudada e utilizada é a inversão peniana com suas modificações, com aparência estética e funcionalidade adequadas, porém sem padronização da técnica cirúrgica. Índices de até 38% de satisfação parcial e 15% de insatisfação podem levar até 66% dos casos a realizar procedimentos adicionais. O objetivo é sugerir refinamentos estéticos na aparência da vulva e comparar com algumas das técnicas descritas, buscando aumentar a satisfação estética e funcional pós-operatória. **Métodos:** Estudo retrospectivo com 7 pacientes submetidas à cirurgia de readequação sexual entre agosto de 2017 e fevereiro de 2018. O clitóris é feito com a glande em formato de tridente, utilizando a coroa para construir os corpos cavernosos do clitóris e aumentar a área de sensação erógena. Faixa de prepúcio é usada para aumentar a cobertura do clitóris e cobrir a face interna dos pequenos lábios, que são definidos com o uso de suturas. Resultados: Sensibilidade adequada e satisfação com o resultado e capacidade de orgasmo em todas as pacientes observadas. Não houve estenose, fístula ou necrose do clitóris com essa técnica. Somente 1 caso precisou de procedimento adicional para melhor definição estética. **Conclusão:** A técnica apresentada tem alta satisfação das pacientes e sensibilidade erógena, com algumas vantagens em relação a outras técnicas. Porém, estudos prospectivos com número maior de pacientes são necessários para definir a técnica cirúrgica mais efetiva.

Descritores: Vulva; Transexualismo; Pessoas Transgênero; Cirurgia de Readequação Sexual; Procedimentos de Readequação Sexual.

INTRODUCTION

Transsexuality is a dynamic and biopsychosocial condition in which a person has the subjective feeling of belonging to a different gender than the anatomical gender (corresponding phenotype and genotype)[1]. These individuals have significantly lower quality of life indices compared to the general population, which is probably related to problems of personal self-esteem and a social character[2].

The World Professional Association for Transgender Health (*WPATH)* standardized principles based on evidence for the care of transgender individuals, both for the diagnosis and treatment, taking into account that gender correction surgeries are needed to alleviate gender dysphoria in these individuals[3].

Accordingly, genital surgery is a safe and reliable option, which drastically reduces dysphoria and improves the quality of life[4,5] in relation to psychological aspects and social relations, with an improved ability to develop relationships, greater professional acceptance, and greater feeling of integration into society[6].

Transgender women who undergo genital surgery seek reconstruction of the external genitalia with appropriate esthetic appearance and functionality. Different techniques can accomplish this, including penile inversion techniques, scrotal flaps, scrotal grafts, non-scrotal grafts/flaps, and techniques that use the large intestine or peritoneum[4].

The most studied and currently used technique is penile inversion[4,7,8], which is recommended initially before recommending intra-abdominal techniques[8]. This technique involves dissection of the penile skin, formation of a neovaginal cavity between the rectum and bladder, and inversion of the skin in this cavity, and may use a full-thickness graft of the scrotal skin for the vaginal covering. Despite the differences in surgical details, the criteria for patient selection, and the evaluation of results[8,9], this technique presents good results[10], with an overall satisfaction index of 88%[4].

From the functional point of view, satisfaction with the result is seen in more than 86% of the patients[4,11,12], with more than 70% reaching an orgasm[1,4,8,10,13].

Even so, additional procedures are often necessary to achieve the best possible result[14,15]. Additional corrections of the labia after surgery are needed in 43% of cases[10] and other procedures in general in up to 66% of patients[6], given that 28% to 38% of patients reported being only partially satisfied[7] and 9% to 15% reported being dissatisfied with the results obtained[1,7,9,11].

These indices can be even higher due to low rates of responses to quality of life questionnaires in several studies[1]. The esthetic and functional outcome of surgery seems to be the most important factor in the satisfaction or the repentance of the patients after the surgery[5], determining the need for additional procedures.

However, the surgical technique or preoperative care[16] have not been standardized, due to the lack of long-term follow-up of patients and few publications reporting refinements and technical advances[17].

OBJECTIVE

This study proposes to suggest esthetic refinements to the appearance of the vulva, describing some parallels and limitations of some of the reported techniques, seeking to increase the postoperative esthetic and functional satisfaction. The author describes a series of 7 cases and the results of these technical modifications.

METHODS

A retrospective study with 7 patients operated with the technique described in this article, between August 2017 and February 2018, was held. The patients fulfilled the requirements of the Federal Council of Medicine for surgery in Brazil (older than 21 years of age, at least 2 years since gender transition, and follow-up with a multidisciplinary team consisting of a psychologist, psychiatrist, endocrinologist, social worker, and surgeon). Informed consent was obtained from all patients.

Preoperative care

On the day before surgery, the patients are advised to have a residue-free diet during the day (without red meat, vegetables, fruits, carbonated drinks, or alcohol) and liquid diet at dinner. The intestinal preparation is done with two tablets of bisacodyl at lunch and two tablets at the end of the afternoon. At night, patients ingest 120 mL of lactulone diluted in 500 mL of filtered orange or lemon juice, which is ingested within 30 minutes, followed by oral hydration up to 8 hours before the scheduled time of surgery to prevent dehydration.

Surgical technique

With the patient in the lithotomy position, a perineal and scrotal skin graft is withdrawn, preserving a 2 cm extension triangular perineal flap, at the level of the central tendon of the perineum (Figures 1A and 1B). Orchiectomy is performed with ligation of the inguinal cord at the level of the superficial inguinal ring. The urethra is separated from the corpus cavernosum using a catheter to guide its dissection and the bulbospongiosus muscle and excess corpus spongiosum are removed.

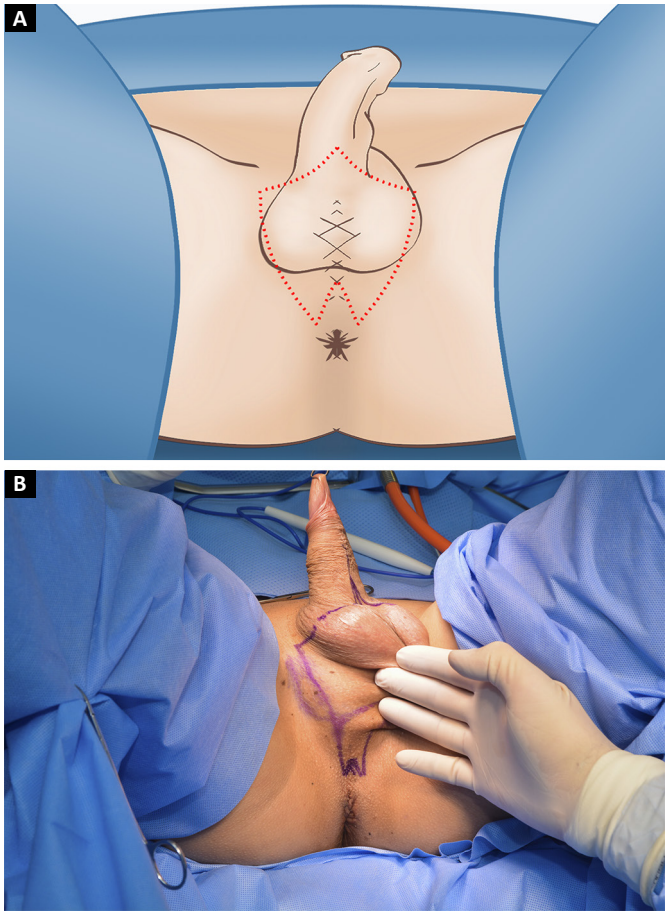

Figure 1. A: Schematic showing the marking of the skin graft and the perineal flap; **B:** Marking of the skin graft and the perineal flap.

The glans is incised to prepare the clitoris in the form of a trident (Figure 2), including 1.5 cm of its dorsal portion in a rounded shape, extending laterally to the corona and the cervix of the glans up to the prepuce, preserving a range of proximal preputial skin of 1.5 cm. The tube of penile skin is separated from the penile shaft, preserving its pedicle.

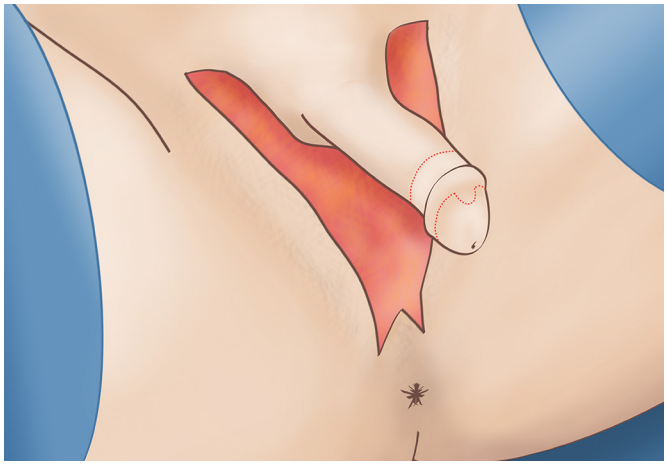

Figure 2. Illustration showing the flap marking to prepare the clitoris.

The tunica albuginea is incised laterally and included together with the neurovascular pedicle, being separated from the corpora cavernosa, which are ligated at its base and removed. The suture of the trident lateral regions near the central flap in its most proximal portion is performed with vicryl 3.0, which simulates the corpora cavernosa of the clitoris and defines the clitoral glans in the central region. The entire flap is folded over and fixed in the pubic symphysis. The urethra is spatulated, with its distal portion resected in a triangular shape, which is attached anteriorly to the clitoris with vicryl 3.0, between the distal portions of the lateral flaps of the trident (Figure 3).

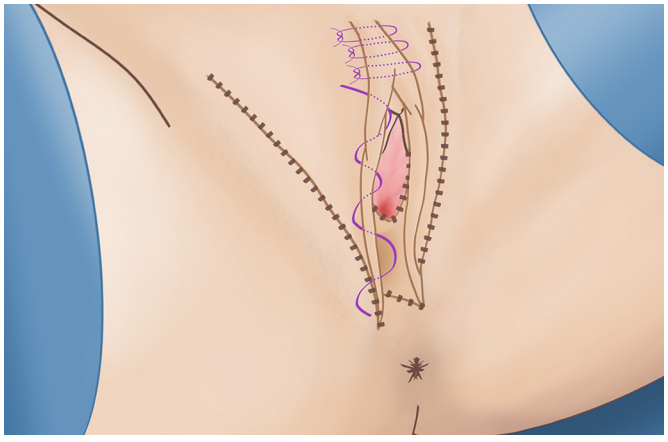

Figure 3. Schematic showing all flaps in position. The sutures to prepare the prepuce and the anterior commissure and definition of the labia minora are also shown.

The construction of the vaginal canal is performed using a combination of blunt dissection with electrocautery, through the central tendon of the perineum and the Denonvilliers' fascia. The rectal wall is protected posteriorly by one of the hands of the surgeon, while the other hand performs the dissection and the assistant uses an enlightened valve to move anteriorly the urethra and the penile tissue. The vaginal cavity is dissected by about 15 cm deep.

The removed scrotal skin is prepared as a total skin graft and sutured in a pouch to the penile flap. The hair follicles are individually cauterized and, after hemostatic review, the penile flap is invaginated and inserted into the cavity. The posterior skin of this flap is opened to accommodate the perineal flap. Suction drainage is used to prevent fluid accumulation between the flap/graft and the canal, which is held in place by a vaginal tamponade of gauze soaked in metronidazole and bacitracin cream.

The exteriorization of the clitoris and the labia minora is performed by incising the penile flap at the midline at the height of the clitoris until immediately below the urethral ostium. The lower region of the urethral stump and the preputial skin of the clitoris are sutured to the penile skin with vicryl 3.0. In order to define the anterior commissure of the lábia and the clitoral prepuce, 3 transdermal running sutures are made cranially to the clitoris with vicryl 3.0, with an inlet and an outlet opening 1 cm from the midline (Figure 3). A Greek bar suture is performed to define the labia minora from the height of the clitoris to the vaginal ostium with vicryl 3.0 (Figure 3). The excess scrotal skin is resected and the skin closed in 3 planes (Figures 4A and 4B), followed by compressive dressing.

Postoperative care

The patient is kept at absolute rest for 24 hours. The dressing is removed on the second day and walking is encouraged. On the third day, the drain is removed and the patient is discharged from the hospital with a urinary probe and a vaginal plug. The patient returns between the 7th and 10th day, when the vesical catheter and the vaginal tampon are removed and postoperative dilatations are initiated.

RESULTS

The mean age of the 7 patients was 28.3 ± 6.8 years. The only relevant medical history was hypothyroidism (n = 1) and HIV infection[1], both of which were adequately clinically controlled. None of the patients were smokers. Surgical history included augmentation mammoplasty (n = 4) and facial feminization (3), with 1 patient without any previous surgeries. All patients had undergone previous hormonal treatment. The mean depth reached in the dissection of the vaginal canal was 15.14 ± 0.73 cm. The hospital stay was 3 days in all cases.

Among the complications, 1 case needed additional surgery for correction due to the loss of

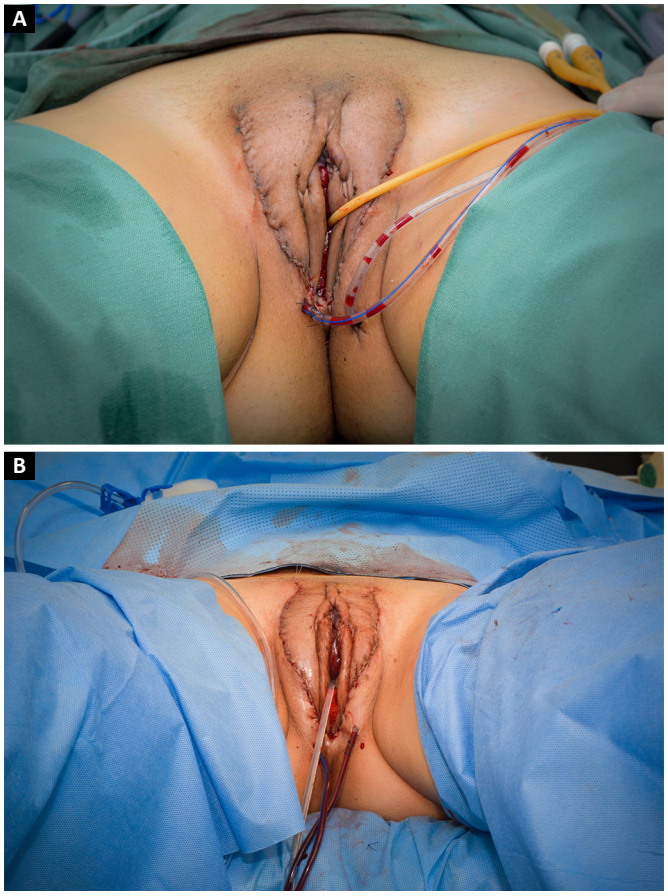

Figure 4. A: Immediate postoperative aspect; **B:** Immediate postoperative aspect.

definition of the anterior commissure and higher clitoral exposure than desired (Figure 5). The more serious complications were postoperative bleeding (n=1), which required blood transfusion and cauterization of the bleeding vessel, and a rectal lesion (1), which was intraoperatively repaired. There was no fistula or stenosis in this group of patients, nor was there a partial or total necrosis of the clitoris.

No patient presented with complaints related to vulvar sensitivity and all reported being satisfied with the surgery and being able to reach orgasm after 3 months of the procedure.

DISCUSSION

Georges Burou and Harold Gillies are known for their description of the penile inversion technique in transgender women in 1950s[7,18], with the inclusion of a scrotal flap by Howard Jones[18]. The classic procedure of choice for clitoral reconstruction is to use the glans (total or partially) as a neurovascular pedicle flap in island, described by Hinderer[19] and modified by Brown[20]. The inclusion of the tunica albuginea[21] is technically simple and decreases the risk of nerve injury.

Figure 5. Eight months postoperative aspect showing loss of the anterior commissure and exposure of the neoclitoris.

The basic steps of the penile inversion technique involve: orchiectomy, penile disassembly, creation of the vaginal cavity between the rectum and bladder, reconstruction of the clitoris and orthotopic female urethral meatus, and creation of the labia majora[16]. Adequate urogenital function and an attractive esthetic result should be sought from the genitals, which are key factors for a high rate of satisfaction of patients submitted to surgery[14].

This includes adequate urethral positioning to foster a straight jet of urine, with an appropriately wide and deep vagina for sexual intercourse and with adequate sensitivity to experience orgasm, and the use of the whole tissue available for this is recommended[14]. Modern techniques with the preservation of tissues showed best indices of sexual function compared to the simple penile inversion in standardized questionnaires[22], which reinforces this recommendation. Thus, in patients with a small penis and without the use of additional coverage of the vaginal cavity, the esthetic result will depend on the chosen neovaginal depth, which is resolved with the use of skin grafts[7].

The main objectives of an optimal clitoridoplasty are as follows: reproducible, reliable, and safe single stage technique; appropriate clitoris size under normal functional conditions; reconstruction of the anatomical structure with erectile tissue preserving its erogenous innervation; presence of mucous or epithelial tissue in the vestibular region and around the clitoris; absence of painful or withdrawn scars; and presence of frenulum and preputial covering[23].

The sensitivity of the clitoris is important as a pre-requisite likely to achieve the sexual orgasm[13]. When the dorsal region of the glans is used for the clitoris, a greater stimulus intensity is required for light touch and pressure stimuli than in cisgender women with comparable vibration sensitivity[12].

Similar results were obtained in another study[13], which emphasized the common occurrence of hypersensitivity of the clitoris and the need for a clitoral hood to protect it from the hyperstimulation caused by clothes and movement. The technique of the author addresses both of these needs, increasing the area of erogenous sensation to include the region of the corona of the glans and prepuce to the dorsal flap, and at the same time the clitoris also being surrounded by the foreskin and cranially approximated skin.

The anatomical basis for the creation of the dorsal neurovascular flap using the author's technique has already been described. Small branches parallel to the dorsal nerve of the penis run along the dorsolateral surface of the penis and penetrate posteriorly in the whole area of the penile corona[24]. Immediately below the lateroventral corona of the penis, the dorsal nerve is divided in four branches: a proximal branch heading dorsally in the direction of the coronal tissue, a branch diverging (laterally to medially) to the central parenchyma of the glans, and two other branches diverging laterally and ventrally toward the ventral region[23].

To increase the sensitivity of the clitoris, it is suggested that the Buck fascia be incised laterally, starting at the base of the penis and the elevation of the neurovascular pedicle be made deeply to the tunica albuginea of the corpus cavernosum[24]. This preserves more nerve fibers, which run dorsolateral 1.5 to 2 cm from the midline in the erect penis[23].

Techniques using the region of the corona of the glans to increase the surface area and the erogenous sensory potential of the clitoris have already been described. Clitoridoplasty using the ventral region of the glans[25] would lead to a more complete erogenous sensation compared to that using the dorsal region by following the anatomical direction of the nerves in the glans, including the two lateroventral branches of the dorsal nerve[23].

Another technique described uses a bifid and symmetrical flap of the corona of the glans in the shape of a lotus flower[23], preserving the preputial skin in the flap and positioning the urethra in a manner similar to that described here. The author's criticism of this technique is the excessive anteroposterior elongation of the clitoris, which does not present the ideal clitoral shape from the esthetic point of view and which decreases the vestibular area above the urethral meatus. In addition, this technique involves the removal of oval-shaped skin (5.0 x 4.0 cm) from the dorsal region of the penile flap to externalize the clitoris and urethra, which decreases the amount of tissue available to define the labia minora and may increase clitoral exposure.

A very similar technique to that of the author is used for years in Thailand[26], with the preparation of a flap in M preserving preputial skin, which is folded over itself to make the labia minora. An appraisal of the author to this technique is that the small labia minora are made only to the height of the urethral meatus, which would be the maximum length of the lateral M flaps and the adjacent prepuce, and not to the lateroposterior region of the vaginal introitus as is expected in the vulvar anatomy.

Accordingly, the definition of the labia minora subsequently depends exclusively on the excess skin of the penile flap. The author also prefers the rounded shape of the central region of the trident, as bringing it from the lateral flaps forms a discreet anterior projection, building the clitoris more reliably (a technique demonstrated by Marci Bowers to the author, in the 1st half of 2014). In the author's view, the approach to expose in block the clitoris/urethra decreases the risk of urethral stenosis and preserves a greater quantity of skin for preparation of the labia minora.

Preputial skin can be used to define the labia minora, as described in the previous paragraph, but the most common approach is to use the lateral and proximal part of the penile flap. Some authors perform this procedure in a second stage, some months after the vaginoplasty[14]. Thus, zetaplasty can be used in the pubic region for the advancement of the labia minora[18] or for clitoral coverage and labial convergence[13,27]. The use of sutures to define the labia minora has been described[28].

As held by the author, the preputial skin is sutured to the longitudinal opening of the penile flap, forming the inner wall of the labia minora. The Greek bar suture from the clitoris to the posterior region of the vaginal meatus helps better define the labia minora (a technique demonstrated by Marci Bowers to the author, in the 1st half of 2014). Similarly, the approximation of the cranial skin toward the clitoris in the direction of the midline defines the anterior commissure and the clitoral prepuce, protecting it from tactile hyperstimulation.

Some of the techniques use a long scrotal flap to prepare the posterior vaginal wall[7,23,26,27,29]. The author has experience with this type of longer flaps and believes (as the authors of these techniques) that the posterior commissure suture line should be interposed with a flap to avoid stenosis, but currently prefers a short flap to avoid growth of hair in the vagina.

There is a progressive improvement in the timing of the perception of the esthetic result by patients and medical staff due to the improvement in postoperative edema and the healing of surgical wounds[29], which was also verified by the author (Figures 6 and 7).

The satisfaction with surgery reported by patients was excellent and higher than that reported

Figure 6. Two months postoperative aspect (patient in the lithotomy position).

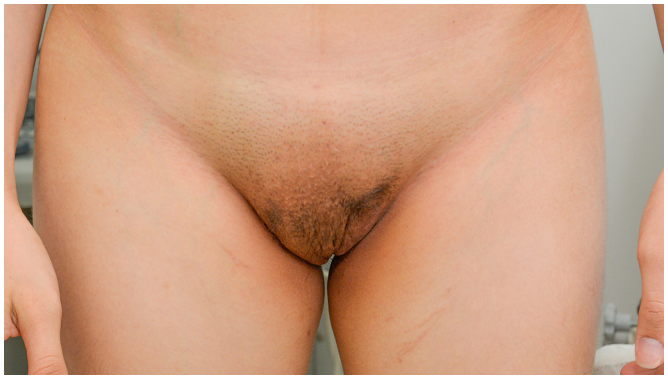

Figure 7. Two months postoperative aspect (patient standing).

earlier[1,4,10,11], although the small number of patients makes it impossible to perform a statistical comparison and some studies do not specify the technique used. The same is the case with the sensitivity and the ability of patients to achieve orgasms.

Some reports indicate that more than half of the patients operated on show a greater intensity of orgasms compared to the preoperative period[1]. Other factors may be associated with sexual satisfaction and may contribute to the overall well-being, such as stability and satisfaction with relationships, acceptance of body image, mood disorders, and physical health[6,7].

CONCLUSION

The esthetic refinements defended in this article by the author and proposed by the surgeons who preceded him seek the closest possible results of sex reassignment surgery to the female anatomy and proper vaginal function, presenting high levels of satisfaction and sensitivity. This area is constantly evolving, but obviously has its limitations. Patients must always be aware that additional procedures are often necessary to achieve the best possible result[15], and their expectations, often unrealistic and unattainable, must be adjusted.

Due to the significant dissemination of information on and awareness of transgenderism, studies on sex reassignment surgeries are advancing at a higher pace[14], but more prospective studies are needed, as well as standardization of surgical procedures and long-term follow-up with larger numbers of patients to identify the most effective techniques for better aesthetic and functional results and greater satisfaction of patients, among the various technical variations and preferences of the surgeons.

COLLABORATIONS

MZM Analysis and/or interpretation of data; statistical analyses; conception and design of the study; conception and design of the study; writing the manuscript or critical review of its contents.

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Original Article

Carpal tunnel syndrome associated with amyloidosis

Síndrome do túnel do carpo associada à amiloidose

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■ **ABSTRACT**

Introduction: Amyloidosis features protein deposition in the organs and tissues and has been associated with carpal tunnel syndrome (CTS) when it occurs in the wrist. The objective is to describe a case series of patients undergoing surgery for CTS associated with amyloidosis. **Methods:** The study included 12 patients who underwent surgery to treat CTS in whom amyloidosis was proven by biopsy; the follow-up period was 5 years. The patients were evaluated by clinical tests, electroneuromyography, radiological images, and biopsy. **Results:** All patients presented with musculoskeletal complaints, severe symptoms of median nerve compression, and changes on neurophysiological tests. Surgery, synovectomy, and biopsy were performed. In the postoperative period, five patients (41%) developed chronic pain and reflex sympathetic dystrophy. **Conclusion:** A higher frequency of postoperative pain was observed in the patients, demonstrating the need for caution in the approach and treatment of this association.

Keywords: Amyloidosis; Carpal tunnel syndrome; Reconstructive surgical procedures; Orthopedic procedures; Delivery of health care.

■ **RESUMO**

Introdução: A amiloidose é caracterizada pela deposição de proteínas nos órgãos e tecidos, e tem sido associada à síndrome do túnel do carpo (STC) quando ocorre no punho. O objetivo é descrever uma série de casos de pacientes submetidos à cirurgia para STC associado à amiloidose. **Métodos:** O estudo incluiu 12 pacientes que se submeteram à cirurgia para tratar a STC cuja biópsia identificou amiloidose; o seguimento foi de cinco anos. Os pacientes foram avaliados por testes clínicos, eletroneuromiografia, imagens radiológicas e biópsia. **Resultados:** Todos os pacientes apresentaram queixas musculoesqueléticas, sintomas severos de compressão do nervo mediano, alterações nos testes neurofisiológicos. Realizou-se a cirurgia, sinovectomia e biópsia. No pós-operatório, cinco pacientes (41%) desenvolveram dor crônica e distrofia simpático-reflexa. **Conclusão:** Observou-se maior frequência de dor pós-operatória na amostra, o que revela a necessidade de atenção na abordagem e tratamento dessa associação.

Descritores: Amiloidose; Síndrome do túnel carpal; Procedimentos cirúrgicos reconstrutivos; Procedimentos ortopédicos; Assistência à saúde.

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INTRODUCTION

Amyloidosis is the deposition of abnormal proteins and accumulation of insoluble amyloid fibrils in the tissues and organs[1-3]. This process occurs through the aggregation of proteins, production of ordered polymers, and formation of protofilaments and fibrils. Recent theories have suggested that the lesions result from multiple mechanisms, not only fibrin deposition but also the precursor structures (transthyretin, apolipoproteins, insulin, prion proteins, lysozyme, cystatin C) that interact with the affected cells[2,3].

A disease-related mutation in the TTR gene has been described. Associations with pathological inflammatory states and neoplastic and hereditary factors have been identified. Some of these associations do not seem to have clinical impacts. However, the criteria for amyloidosis include age > 50 years, chronic infection or inflammatory disease, family history of amyloidosis, multiple myeloma, renal disease, and dialysis.

Nevertheless, depending on fibril deposition amount and location, the disease may be more aggressive, affecting any organ, including the kidneys, heart, and nerves[1-3]. Different types of amyloidosis have been classified and described, including primary, secondary, familial, microglobulin beta 2, and localized.

The association between amyloidosis and carpal tunnel syndrome (CTS) has a prevalence of 2–8%[4-6]. This association is usually followed by hemodialysis or familial amyloidosis. The clinical diagnosis of CTS includes paresthesia, pain, weakness in the hands, and thenar atrophy. Nerve conduction studies by electroneuromyography are useful for detecting the peripheral nerve involvement present in cases of neuropathic amyloidosis[7-9].

The gold standard diagnostic method for amyloidosis is a biopsy of the affected tissue after staining with hematoxylin-eosin and Congo red. Although median nerve compression can be caused by extrinsic and intrinsic factors, amyloid deposition alone can cause nerve compression, being an already established association; however, the clinical evolution of the operated cases merits study[4,6].

METHODS

A total of 807 patients underwent CTS surgery at our institution over a 5-year interval; of them, 436 underwent biopsy and synovectomy. This procedure was performed in accordance with the transoperative findings of synovial thickening. The removed synovial tissue was sent for histopathological study, which revealed that 12 (3%) patients tested positive for amyloidosis.

This was a retrospective study that included analysis of these patients' medical records with respect to their clinical findings, history, comorbidities, diagnostic tests performed, and postoperative follow-up. The study was submitted and approved by the CEP/APS Ethics Committee (CAEE no. 53326916.2.0000.0022).

Pre-operative evaluation

The patients were clinically evaluated for symptoms of paresthesia, numbness, tingling, and pain. The physical assessment included Tinel's test, Phalen's test, the Semmes–Weinstein monofilament test, the short thumb abductor and opponens pollicis rating scale (0–5, such as the British Medical Research Council Scale), and dynamometer force measurements.

Complementary examinations, such as electroneuromyography of the limbs, radiography of the wrist, and magnetic resonance imaging, were also performed. The severity criteria for CTS were classified according to the neurophysiological rating scale described by Bland (Table 1)[10]. The diagnosis of reflex sympathetic dystrophy was made in accordance with International Association for the Study of Pain guidelines[8]. The surgeries were performed in the Departments of Plastic Surgery and Orthopedics of our institution, and the surgeons performed the pre- and post-operative ratings.

Surgical procedure

All procedures were performed under general anesthesia or a regional brachial plexus block. Tourniquets were used in the arm after exsanguination of the limb with a systolic pressure of 100–120. The classic open volar incision was used to release the carpal tunnel and the fascia of the forearm. The median nerve and flexor tendon sheath were inspected (Figure 1). During surgery, the flexor tendon sheath and transverse carpal ligament were biopsied when thickening and macroscopic changes were evident (Figure 1).

The histopathological studies included staining with hematoxylin-eosin and Congo red, and the assessment of amyloid deposits was performed using polarized light (Figure 2). Chart 1 summarizes the disease severity.

RESULTS

Charts 2 and 3 describe the clinical and demographic distribution of the 12 patients (nine females, three males). Eleven patients were >50 years of age. The time between the onset of the initial

Chart 1. Grading of electroneuromyography findings according to the Bland classification.

Degree	
0	Normal
I	Very mild; demonstrable only with more sensitive tests
II	Mild; sensory nerve conduction slow velocity, normal motor latency
III	Moderate; sensory potential preserved with motor slowing, motor latency of the abductor pollicis brevis (APB) < 6.5 ms
IV	Severe; sensory potential absent, but motor response preserved, distal motor latency to APB < 6.5 ms
V	Very severe; terminal latency to APB > 6.5 ms
V	Extremely severe; sensory and motor potentials unrecordable (surface motor potential from APB < 0.2 mV amplitude)

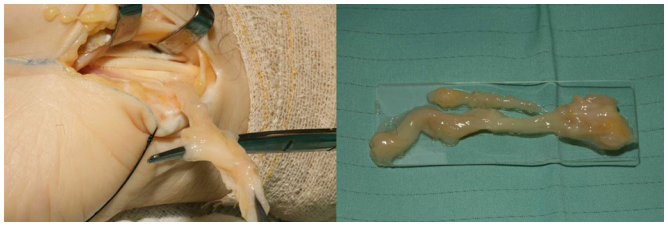

Figure 1. Intraoperative retinaculotomy of the flexors and partial synovectomy showing a segment of the synovium referred for biopsy.

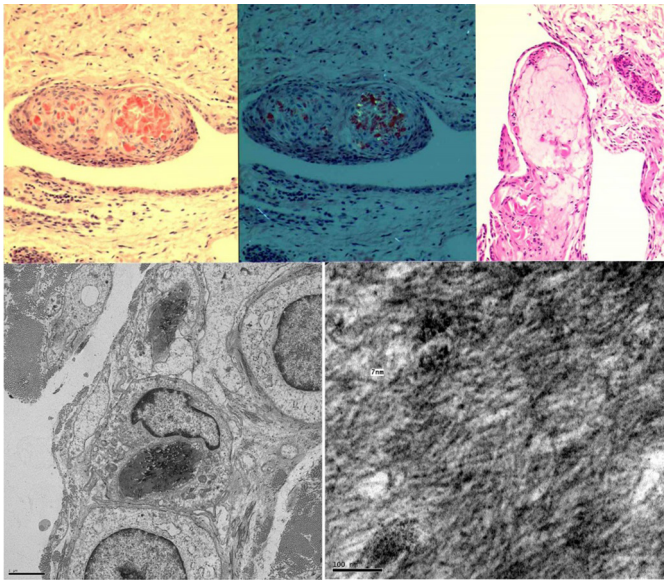

Figure 2. Hematoxylin-eosin staining; and Congo red staining, which emits apple green birefringent fluorescence under polarized light and electron microscopy evaluation.

symptoms and surgery ranged from 6 months to 17 years; 11 patients had the disease for more than 1 year; and the follow-up period was 1–9 years.

All patients had associated musculoskeletal complaints, such as polyarticular pain, stenosing tenosynovitis, and shoulder bursitis. One case of associated polyneuropathy with no family history was found. Some erythrocyte sedimentation rates were slightly elevated (26–27 mm in the first hour). Only one patient presented radiographic changes in the wrist that were associated with a history of trauma.

Six patients had degenerative changes in the joints (cervical, shoulder, or knee). No patient had a history of cancer or hemodialysis. However, two patients had a family history of intestinal and brain cancer. One man reported acute myocardial infarction. One woman presented with CTS and the deposition of adipose tissue and previous trauma of the wrist associated with radiocarpal joint degeneration.

In this series of 12 patients, five (41.6%) had complex regional pain and symptom recurrence after the carpal tunnel release. Three patients had difficulty controlling reflex sympathetic dystrophy with the recommended treatment. All cases presented CTS associated with flexor tenosynovitis and a localized form of amyloidosis.

The prevalence of chronic pain as a complication after the surgical procedure was 45.5%; consequently, analgesics including paracetamol, gabapentin, amitriptyline, codeine, and corticosteroids were administered. Among the five patients who presented with this undesirable surgical complication, three were diagnosed with reflex sympathetic dystrophy, one with neuropathic pain, and one with effort-related pain.

Synovectomy was performed in all cases of this series, although epineurolysis was not necessary and not performed in any case because no neural invasion by the amyloidotic tissues was observed. Instead, the flexor sheath was invaded by these tissues. As there was no cleavage plan to remove all tissues, a partial synovectomy was used to reduce local volume and enable the histopathological examination.

DISCUSSION

The association between amyloidosis and peripheral neuropathy was reported for the first time by De Navasquez in 1938 and Kyle et al.[6]. Several proteins and its precursors have been implicated in amyloidosis (transthyretin, apolipoprotein AI, apolipoprotein AII, cystatin C, gelsolin, fibrinogen alpha chain, lysozyme, and β2 microglobulin (Aβ2-M)[2,11-16]. In addition, more

Chart 2. Clinical, intraoperative, and histopathological examination criteria.

Grading of symptoms	
Grade I	Intermittent symptoms of pain and paresthesia, nocturnal paresthesia in the distribution of the median nerve, motor and sensory exam normal.
Grade II	Constant symptoms with a reduction of the fine pincer grasp and sensory alterations in the Semmes-Weinstein Monofilament test with weakness of the thenar muscles.
Grade III	Extensive sensory loss and atrophy of the thenar muscles.
Perioperative findings	
I - Normal	Thickening and flattening of the nerve with normal vascularization and structures of the epineurium, without fibrosis.
II - Moderate	Moderate decrease in vascularization, mild to moderate fibrosis in some part of the nerve, mild to moderate synovial thickening.
III - Severe	Loss of vascularization, diffuse fibrosis around the nerve, large synovial thickening, and appearance of pseudoneuroma.
Histopathological findings	Fibrosis, thickening of the collagen bundles, hyaline degeneration, proliferation of the synovia, edema and vascular lesions, amyloid deposits.

Chart 3. Demographic and clinical aspects of patients studied.

Age	Sex	Musculoskeletal change	Clinical score	EMG score	Surgical score	Time between symptom onset and treatment	Follow-up	Postoperative evolution
38	F	Wrist, elbow, and shoulder	III	6	III	17 years	9 years	Dystrophy
74	F	Elbow and shoulder	II	6	II	2 years	3 years	Dystrophy
72	F	Knee	II	5	III	2 years	6 years	Normal
62	F	Cervical spine	III	5	III	1 year	3 years	Improvement
71	M	Shoulder	III	5	II	6 months	4 years	Improvement
56	F	Tenosynovitis	III	5	III	2 years	1 year	Dystrophy
48	M	Tenosynovitis	III	5	I	1 year	3 years	Chronic pain and atrophy
50	F	Cervical spine	I	5	II	2 years	5 years	Normal
64	M	Column and polyarthralgia	II	5	III	1 year	1 year	Normal
53	F	Cervical and dorsal	III	5	III	3 years	6 years	Improvement
73	F	Tenosynovitis	III	5	III	5 years	1 year	Improvement
72	F	Shoulder, knee, and cervical	III	5	III	5 years	5 years	Neuropathic pain, polyneuropathy

* Improvement was defined as a reduction in pain symptoms and recovery of feeling evidenced by Phalen's, Tinel's, and sensory and motor test results and electroneuromyography findings < grade IV.

than 80 transthyretin mutations have been described, and evidence indicates that the fibrinogen and other protein aggregations perform an important role in the pathogenesis of CTS[17].

The main clinical manifestations and syndromes associated with neuropathy are related to light-chain or primary amyloidosis and familial forms of the autosomal dominant disease[2,13]. The diagnosis of amyloidosis is usually made at approximately 60 years of age with a male predominance of 2:1[2,4,5]. The most common presentation is peripheral neuropathy, although CTS can occur without alterations in the skin, proteinuria, or skeletal manifestations (degenerative arthropathy, chronic arthralgia, or arthritis)[16-20].

CTS may be associated with different types of amyloidosis, especially their primary forms, in patients on chronic hemodialysis14,18,21. In this disease, the first stages of nerve compression involve progressive

ischemia and a local inflammatory process. During the gradual compressive process, demyelination occurs and nerve conduction velocity decreases in the area of compression.

Our study found that all patients had axon loss, demyelination, low focal conduction, and signs of denervation, which are classified as grade V electroneuromyography findings. For these patients, a differential diagnosis, including radiculopathy, motor neuron disease, polyneuropathy, ulnar neuropathy, and other deposition diseases such as gout and rheumatoid arthritis, is important.

Virchow introduced the first histochemical diagnostic test for amyloidosis, later perfected by Benhold (1922) with Congo red staining that emits a light apple green fluorescence under polarized light[4,5]. This test is considered the gold standard for the diagnosis of amyloidosis[6]. Based on the literature, this test was used to confirm the disease in our series of cases, and an additional electronic microscopy assessment was performed.

On electronic microscopy, major and minor fibrillar components were identified that presented a pentamer aspect, known as P component[8]. We believe that complementary clinical and electrophysiological tests are important for the early diagnosis of CTS, the identification of amyloidosis, and an early therapeutic plan. We recognize the challenges of grading the symptoms, signs, and surgical findings since their accuracy depends on clinician experience and knowledge of the natural characteristics of the disease.

During the clinical follow-up, the cohort showed a high prevalence of chronic pain compared with patients with idiopathic CTS[9]. Based on the experience of the authors, chronic pain was controlled more effectively by combining analgesics and non-steroidal and steroidal anti-inflammatory agents. Some surgeons have postulated that chronic postoperative pain can be related with the anesthetic technique or tourniquet used.

Nevertheless, another study performed at our institution did not demonstrate this association[22]. We believe that the systemic disease (amyloidosis) can influence peripheral nerve recovery after surgical trauma and may even increase the cases of chronic pain. The risk factors for the association between amyloidosis and CTS may not have been well evaluated in this study due to the small sample size and the limitations of retrospective cases series.

Patients with a long history of compressive symptoms of the median nerve, associated with severe changes on an EMG examination, complaints, musculoskeletal disorders, and a history of myocardial infarction, hemodialysis, and family history of neuropathy, are indications for intraoperative biopsy during the surgical nerve decompression and amyloidosis assessment.

The authors believe that the poor result may have occurred for various reasons such as the fact that the patients had a severe form of CTS before surgery, as indicated by clinical scores, EMG, and surgery; and associated articular diseases. Although one of the limitations of the present study our inability to assess risk factors between amyloidosis and CTS since the 12 evaluated patients had equally poor postoperative courses, it could also have been seen for a variety of other reasons, or simply been a group of most severely affected patients regardless of whether they had amyloid deposits.

However, our findings call attention to this group of patients with poor preoperative presentation possibly associated with amyloidosis and worse postoperative prognosis. This study's findings emphasize the importance of this association and the need for more research to increase our understanding of the risk factors and consequences of the association between peripheral nerve disease and amyloidosis.

CONCLUSION

This infrequent association affected the results of this case study, with a higher prevalence of postoperative pain. The strategies adopted for treating patients with CTS associated with amyloidosis in our institution include the assessment of amyloidosis when treating patients with other musculoskeletal complaints, especially those older than 60 years of age who present with symptoms of CTS, thenar atrophy, and electroneuromyography grade V findings. We suggest treating these patients with early nerve decompression, synovectomy, assessing amyloid deposits, and effectively controlling postoperative pain.

COLLABORATIONS

KTB	Conception and design study, data curation, project administration.
GCSA	Analysis and/or data interpretation, final manuscript approval, writing - original draft preparation.
UPS	Investigation, methodology, supervision.
GBM	Methodology, project administration, writing - review & editing.

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Original Article

Nile tilapia skin xenograft versus silver-based hydrofiber dressing in the treatment of second-degree burns in adults

Xenoenxerto (pele da Tilápia-do-Nilo) e hidrofibra com prata no tratamento das queimaduras de II grau em adultos

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■ **ABSTRACT**

Introduction: Recent studies have suggested the use of biological dressings made of aquatic animals as biomaterials in regenerative medicine since they demonstrate good adherence to the wound bed. The objective of this study was to evaluate the efficacy of Nile tilapia skin (Oreochromis niloticus) as an occlusive biological dressing in the management and treatment of second-degree burns in adults. **Methods:** This clinical study included 30 patients randomly treated with Nile tilapia skin (n = 15) or Aquacel Ag® silver-based hydrofiber dressing (n = 15). **Results:** The Nile tilapia skin yielded a similar mean treatment time (9.6 ± 2.4 days) to that of the comparative material (10.7 ± 4.5 days). There was no statistically significant intergroup difference ($p > 0.68$) in pain during dressing changes. No disadvantage in pain was noted, as 66.7% of patients treated with Nile Tilapia skin reported a decrease in pain events. Moreover, 60% of the patients treated with the Nile Tilapia skin did not require dressing replacement at any time during treatment. For the Aquacel AG® dressing, 53.3% of the patients required more than one dressing replacement. **Conclusions:** Our findings suggest that the Nile tilapia skin is as effective as an occlusive biological dressing. The average treatment time (complete wound healing) and pain reports during dressing changes were similar between groups. Furthermore, pain after and number of dressing exchanges (when performed) were not worse.

Keywords: Burns; Occlusive dressings; Healing; Biological dressings; Cichlids.

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■ **RESUMO**

Introdução: Estudos recentes apontam a utilização do curativo biológico com base em animais aquáticos como biomaterial na medicina regenerativa, apresentando boa aderência ao leito das feridas. O objetivo foi avaliar a eficácia da utilização da pele da Tilápia-do-Nilo (Oreochromis niloticus) como curativo biológico oclusivo, no manejo/tratamento de queimaduras de 2º grau em adultos. **Métodos:** Estudo clínico com 30 pacientes aleatoriamente tratados com pele da Tilápia-do-Nilo (n = 15) e hidrofibra com prata Aquacel Ag® (n =1 5). **Resultados:** Em relação à duração, o tratamento com a pele da Tilápia-do-Nilo obteve uma média de dias de tratamento (9,6 ± 2,4) similar ao material comparativo (10,7 ± 4,5). Quanto ao relato de dor durante a troca de curativos, não houve diferença estatisticamente significante ($p > 0,68$) entre os grupos. Após a troca do curativo, não houve inferioridade no registro do valor na escala analógica de dor, em que 66,7% dos tratados com pele da Tilápia-do-Nilo relataram diminuição dos eventos álgicos. Constatou-se ainda que 60% dos pacientes tratados com a pele da Tilápia-do-Nilo não tiveram seus curativos substituídos em qualquer momento do tratamento. Para o curativo Aquacel AG®, 53,3% dos pacientes tiveram mais de uma substituição de curativos. **Conclusões:** Com base na pesquisa, pode-se concluir que a pele da Tilápia-do-Nilo é eficaz como curativo biológico oclusivo. Houve similaridade entre os grupos para a média de dias de tratamento (completa cicatrização da ferida) e para o relato de dor durante a realização do curativo. Também, a não inferioridade relacionada a dor após os curativos e suas trocas (quando existentes) e na quantidade de substituições destes.

Descritores: Queimaduras; Curativos oclusivos; Cicatrização; Curativos biológicos; Ciclídeos.

INTRODUCTION

Approximately 1 million people in Brazil suffer burns every year, particularly second-degree superficial and/or deep burns[1,2]. The ideal dressing for such burns is easy to obtain, has good flexibility and adhesion to the wound bed, resists stretching, is easily handled, can suppress pain, if of low cost, is simple to store and, above all, prevents hydroelectrolytic losses and bacterial contamination, promotes epithelization, and encourages the adequate formation of granulation tissue in cases of grafting[3].

Temporary skin substitutes and synthetic/biosynthetic dressing have been considered useful in the treatment of superficial burns because they reduce the frequency of dressing changes[4]. However, these materials are expensive and ineffective for deep burns[5]. Thus, alternative biological materials have been sought for this purpose. Tissues of animal origin, such as porcine skin and porcine intestinal submucosa, are among the materials used[6]. Recent studies have suggested the use of Nile tilapia skin (*Oreochromis niloticus*) as a biomaterial in regenerative medicine since it presented good adhesion to the wound bed in rats[3] and satisfactory results of histological, histochemical, and tissue traction tests with human skin[6].

Tilapia skin displays good tensile and compression resistance[7], indicating that it may be usable as a biological dressing for burns. The presence of peptides with possible antimicrobial functions within this tissue reinforces this possibility [8-10].

OBJECTIVE

This study aimed to evaluate the efficacy of the use of Nile tilapia skin as an occlusive biological dressing compared to silver-based hydrofiber dressing (Aquacel AG®) in the management and treatment of superficial and deep second-degree burns in adults.

METHODS

This analytical interventional open clinical study with a convenience sample was performed at Hospital São Marcos, Recife/PE. The study was approved by the Research Ethics Committee of the Federal University of Pernambuco (no. 2.735.537). A clinical evaluation verified the general health conditions and the inclusion criteria: Presence of superficial and/or deep second-degree burns affecting up to 10% of the burned body surface; maximum 72 hours since the burn occurred; age 20–60 years; and the absence of previous treatment for the current burns or significant comorbidities.

A total of 30 patients were selected. After receiving the initial explanation and providing written informed consent, they were randomly distributed into two groups: occlusive biological dressing with Nile tilapia skin (n = 15) or conventional treatment with the Aquacel AG® silver-based hydrofiber dressing (n = 15). The therapeutic process is described in Chart 1.

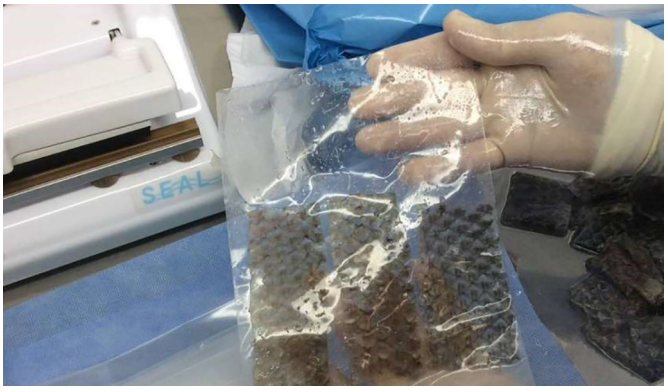
Nile tilapia skins are decontaminated (2% chlorhexidine and glycerol at high concentrations) and sterilized with gamma irradiation (Cobalt 60) to ensure the safety of their use in humans in addition to sampling microbiological testing for Gram-positive and -negative bacteria and fungi (Figure 1).

The procedures for both groups are described in Chart 2.

The outcomes for this study were:

1. Number of days required to achieve complete wound healing. The wound was considered healed when 95% or more of the initial burn area was re-epithelialized.
2. Pain assessment using a visual analog scale (VAS). ZERO corresponded to no pain, while TEN indicated the worst pain felt during cleaning and after application of the dressing. At each patient visit, the dressing's condition was evaluated and the pain score was recorded.
3. Number of times a replacement Nile tilapia skin or Aquacel AG® dressing was required.

The results were analyzed using descriptive statistics of absolute and relative frequencies and mean and standard deviation. The treatments were evaluated



Source: https://gr21.com.br/pele-de-Tilapia-a-nova-promessa-no-tratamento-de-queimaduras/

Figure 1. Nile tilapia skin sterilized and packaged for human use.

Chart 1. Therapeutic process applied to patients.

Visit 1 (screening):
• Collection of written informed consent
• Clinical evaluation - physical examination, vital signs, anthropometric data;
• Evaluation of the eligibility criteria (inclusion and exclusion criteria);
• Allocation to the test or control group (according to randomization);
• Photographs of the wound;
• Preparation of the dressing;
Guidelines on the procedures of the protocol and application of the visual analog scale (VAS) for pain
Treatment visits:
• Clinical evaluation;
• Dressing evaluation - verification if dressing replacement is necessary in the test and control groups;
• Photographs of the wound;
• Application of the VAS
Follow-up Visit - 7 (± 3) days after withdrawal of the dressing:
• Clinical evaluation;
• Photographs of the wound;
• Study discharge

TCLE: Termo de Consentimento Livre e Esclarecido.

Chart 2. Treatment procedures in the test and control groups.

	Procedures
First dressing	• Removal of blisters or loose skin • Washing the lesion with running water and 2% chlorhexidine • Application of dressing • Test group: Occlusive biological dressing with Nile Tilapia skin (n = 15) • Control group: Conventional treatment with silver hydrogel (Aquacel AG®) (n = 15) • Coverage with cotton gauze, crepe bandages, and elastic tubular netting.
Return	• Removal of the dressing and gauze layer • Evaluation of the dressing for adherence to the wound bed • Replacement only when not adhered

using Fisher's exact test with a significance of $p < 0.05$ using SPSS version 20.0 software.

RESULTS

Of our cohort, 53.3% were treated with Nile tilapia skin, while 46.6% were treated with Aquacel AG®.

Table 1 shows that the mean treatment times in days were similar between the Nile tilapia skin and the Aquacel AG® (9.6 ± 2.4 and 10.7 ± 4.5 days, respectively).

Table 2 shows that the patients in both groups reported a VAS score greater than 5 during the exchange of dressings ($p > 0.05$; Fisher's exact test).

After the dressing was changed, a new VAS pain score was collected. Table 3 shows that 86.7% of patients treated with Nile tilapia skin showed a reduced VAS score, and an analysis using Fisher's exact test showed that it was not inferior to the Aquacel AG®.

Table 4 presents values regarding the number of skin substitutions or dressings required for complete re-epithelialization represented by patient discharge. Note that 60% of the patients who were treated with the Nile tilapia skin did not require skin replacement at any time during treatment, whereas 53.3% of patients treated with Aquacel AG® required more than one dressing replacement ($p = 0.71$), which indicates that the Nile tilapia skin was not inferior to the Aquacel AG®.

Figures 2 and 3 show the clinical results of two patients in the study from the first visit until medical discharge (complete re-epithelization).

DISCUSSION

Studies have shown that hot liquids are the most common thermal agents that cause burn injuries[1,2,11,12]. In this study, 45% of the cases were due to overheated liquids.

The treatment and care of burns aim to provide a suitable environment for re-epithelialization and control the proliferation of microorganisms, which may delay the healing process[13]. Thus, biological dressings must display properties that prevent microbial growth, promote epithelization, and encourage the formation of granulation tissue[6,14].

Records of the use of silver-based dressings date back to the 18th century[15]. Various properties of this material have been studied, including accelerating healing time, antimicrobial activity, and rapid re-epithelization. Despite its large-scale use, some disadvantages, including cytotoxicity, have inspired the study of other materials[12,15,16].

Although we are far from an ideal temporary skin substitute, biological dressings have shown better functional and aesthetic results[6,14]. In this context, Nile tilapia skin is a promising product. Tilapia represents 45.4% of the total fish production in Brazil, but its skin is a waste byproduct of which only 1% is used in handicrafts. Tilapia skin must still be subjected to scientific analyses of its activity in humans. Several studies have compared human skin with Tilapia skin[6,7,14,17-20], and favorable results were described regarding their histological and histochemical aspects and tensiometric properties[18,20].

In this study, Nile tilapia skin was used in the treatment of 15 patients, 53.3% affected by second-degree superficial burns and 46.7% by second-degree deep burns.

Table 1. Descriptive statistics of the number of days (complete epithelization of the wound) according treatment type applied to second-degree burns in adults, Hospital São Marcos, Recife/PE – 2018.

	Categories	Treatment type		*P* value
		Nile tilapia skin	Aquacel AG®	
Number of days (discharge)	Minimum	5	4	0.36
	Maximum	14	19	
	Average	9.6	10.7	
	Standard deviation	2.4	4.5	

Table 2. Statistical value of the pain VAS score during dressing exchange according to treatment type applied to second-degree burns in adults, Hospital São Marcos, Recife/PE - 2018.

			Treatment type		Total	*P* value
			Nile tilapia skin	Aquacel AG®		
Pain (during dressing exchange)	≤ 5 points	n	5	3	8	0.68
		%	33.3%	20.0%	26.7%	
	> 5 points	n	10	12	22	
		%	66.7%	80.0%	73.3%	
Total		n	15	15	30	
		%	100.0%	100.0%	100.0%	

Table 3. Statistical value of the pain VAS score after the application of dressings according to treatment type for second-degree burns in adults, Hospital São Marcos, Recife/PE - 2018.

			Treatment type		Total	*P* value
			Nile tilapia skin	Aquacel AG®		
Pain (after dressing application)	≤ 5 points	n	13	7	20	≤0.050
		%	86.7%	46.7%	66.7%	
	> 5 points	n	2	8	10	
		%	13.3%	53.3%	33.3%	
Total		n	15	15	30	
		%	100.0%	100.0%	100.0%	

Table 4. Comparison of treatments according to number of dressing exchanges in the treatment of second-degree burns in adults, Hospital São Marcos, Recife/PE - 2018.

			Treatment type		Total	*P* value
			Nile tilapia skin	Aquacel AG®		
Number of exchanges	0	n	9	7	16	0.71
		%	60%	46.7%	53.33%	
	≥ 1	n	6	8	14	
		%	40%	53.3%	46.67%	
Total		n	15	15	30	
		%	100%	100.0%	100%	

To use animal skin as an occlusive dressing, a rigorous disinfection and sterilization protocol must be followed. Recent research indicates that chemical sterilization and radiosterilization are effective for the preparation of Nile tilapia skin[18]. The skins were provided by the Center for Research and Development of Medicines of the Federal University of Ceará, which is responsible for the sterilization processing.

Tilapia skin molds and adheres to the wound, creating a kind of tampon that prevents contamination and fluid loss.

The results of this study showed that the mean treatment time with Nile tilapia skin (9.6 ± 2.3 days) was similar to that with Aquacel AG® (10.7 ± 4.5 days).

Pain during and after the dressing change was assessed using a VAS. Patients in both groups reported a VAS score > 5 at the time of the initial cleaning and dressing application process. At the end of the dressing application, 86.7% of the patients in the Nile tilapia skin group reported feeling less pain, proven by VAS scores ≤ 5, compared to 46.7% of patients in the Aquacel AG® group ($p = 0.05$).

Skins and dressings are changed according to the amount of exudate. However, the higher the number of exchanges, the higher the risk of infection, the higher the cost of treatment, and the greater the possibility that the patient will feel pain. Given these aspects, it should be emphasized that fewer patients treated with Nile tilapia skin required dressing exchanges. In nine patients (60%) treated with Nile tilapia skin, there was no need for replacement of any dressing, while 53.3% of patients treated with Aquacel AG® required at least

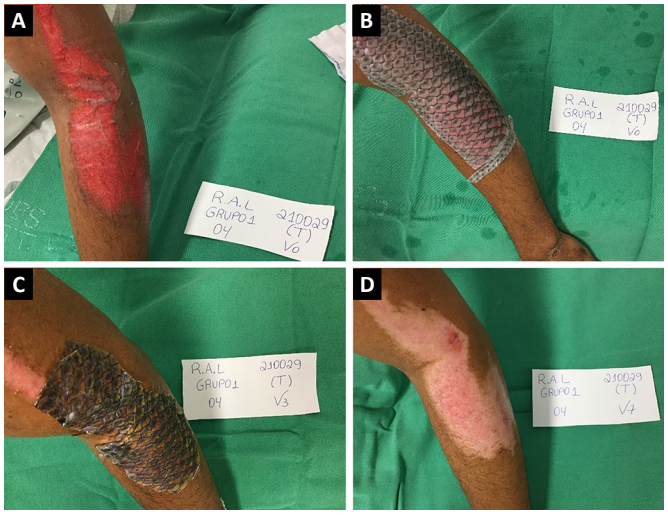


Figure 2. Clinical case of a patient treated with occlusive biological dressing (Nile tilapia skin). **A:** Wound assessment and cleaning and visual analog scale (VAS) pain assessment; **B:** Dressing with the Nile tilapia skin at the first clinical appointment and VAS pain assessment; **C:** Evaluation of the bandage after 7 days; **D:** Complete epithelization of the wound after 16 days.

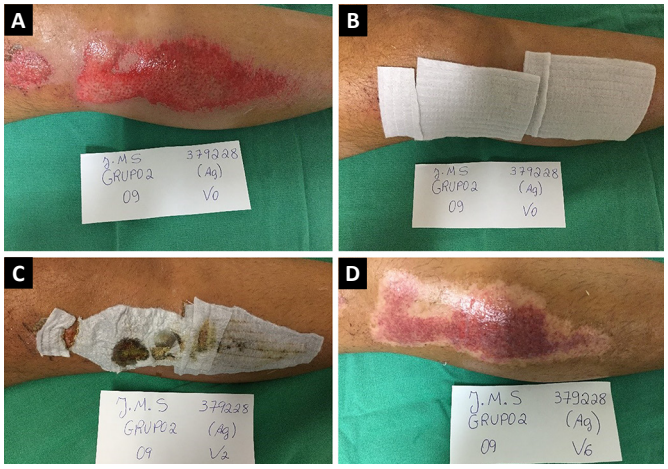


Figure 3. Clinical case of a patient treated with a silver-based hydrofiber dressing (Aquacel AG®). **A:** Wound assessment and cleaning and visual analog scale (VAS) pain assessment; **B:** Dressing with Aquacel AG® at the first clinical appointment and VAS pain assessment; **C:** Evaluation of the dressing after 7 days; **D:** Complete epithelization of the wound after 18 days.

one exchange. Thus, considering the p *value* = 0.71 ($p \geq 0.05$), skin healing with Nile tilapia skin was not inferior to that with Aquacel AG®.

The findings of this study suggest that Nile tilapia skin is as effective as Aquacel AG® in the management and treatment of second-degree burns in adults.

CONCLUSIONS

Based on the results of this study, Nile tilapia skin is an effective occlusive biological dressing in the management and treatment of second-degree burns in adults. The average treatment time of the patients treated with Nile tilapia skin (9.6 ± 2.4 days) was similar to that of patients treated with Aquacel AG® (10.7 ± 4.5 days). Furthermore, no significant intergroup difference was noted in pain level after dressing or the need for replacement during treatment.

COLLABORATIONS

MJBM Analysis and/or data interpretation, conceptualization, data curation, funding acquisition, investigation, methodology, realization of operations and/or trials, writing - original draft preparation, writing - review & editing.

CTB Conceptualization, final manuscript approval, formal analysis, supervision, writing - review & editing.

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Original Article

Quality of randomized clinical trials published by plastic surgeons: a long-term follow-up study

Qualidade dos ensaios clínicos aleatórios publicados por cirurgiões plásticos: seguimento de longo prazo

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■ **ABSTRACT**

Introduction: In two previous studies, the quality of randomized clinical trials (RCTs) with the participation of at least one plastic surgeon was assessed in two periods: from 1966 to 2003 and from 2004 to 2008. The objective is to evaluate the evolution of the quality of RCTs published by plastic surgeons in the subsequent five-year period, from 2009 to 2013. **Methods:** RCTs published from 2009 to 2013, in English, with the participation of at least one plastic surgeon, were identified by an electronic search and classified according to allocation concealment by two independent evaluators. The quality of the studies with adequate allocation concealment was evaluated by two evaluators using the Delphi List and the Jadad Scale. **Results:** Of the 6,997 identified studies, 261 were classified according to allocation concealment. Of these, 43 (16.47%) had adequate allocation concealment. According to an assessment conducted using the Delphi List, there was an improvement in the items "most important characteristics of the prognosis" ($p < 0.001$), "use of an independent evaluator" ($p = 0.0029$), and "measures of variability and estimation of points for the primary variable" ($p = 0.0057$) compared to the 1966-2003 assessment ; there was no difference in the assessment of the same items from 2004-2008. Regarding the Jadad Scale, there was an increase in the scores from 2009 to 2013 compared to the 1996-2003 period ($p < 0.0004$); however, there was no significant difference in the 2004-2008 period. **Conclusion:** There was no difference in the quality of the RCTs published by plastic surgeons in the 2009-2013 period compared to the previous five-year period (2004 to 2008). However, both periods indicated higher quality compared to the 1966-2003 period.

Keywords: Randomized controlled trials as a subject; Evidence-based medicine; Statistical analysis; Random distribution; Plastic surgery.

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■ **RESUMO**

Introdução: Em dois estudos prévios, avaliou-se a qualidade dos ensaios clínicos aleatórios (ECAs) com a participação de pelo menos um cirurgião plástico, em dois períodos: 1966 a 2003 e 2004 a 2008. O objetivo é avaliar a evolução da qualidade das publicações de ECAs por cirurgiões plásticos no período subsequente de cinco anos, de 2009 a 2013. **Métodos:** ECAs publicados de 2009 a 2013, em língua inglesa, com a participação de pelo menos um cirurgião plástico, foram identificados por busca eletrônica e classificados quanto ao sigilo de alocação, por dois avaliadores independentes. Os estudos com sigilo de alocação adequado tiveram a qualidade avaliada por dois avaliadores, utilizando-se a Lista de Delphi e a Escala de Qualidade de Jadad. **Resultados:** Dos 6.997 estudos identificados, 261 foram classificados quanto ao sigilo de alocação. Destes, 43 (16,47%) tinham sigilo de alocação adequado. Segundo a avaliação pela Lista de Delphi, houve melhora, em relação a 1966-2003, nos itens "características mais importantes do prognóstico" ($p < 0,001$), "uso de avaliador independente" ($p = 0,0029$) e "medidas de variabilidade e estimativa de pontos para a variável primária" ($p = 0,0057$); não houve diferença em relação a 2004-2008. Quanto à Escala de Qualidade de Jadad, houve um aumento dos escores em relação a 1996-2003 ($p < 0,0004$), mas também sem diferença significante em relação ao período 2004-2008. **Conclusão:** Não houve diferença na qualidade das publicações de ECAs por cirurgiões plásticos no período de 2009 a 2013, em relação aos cinco anos anteriores (2004 a 2008). Entretanto, ambos os períodos apresentaram maior qualidade quando comparados ao período de 1966 a 2003.

Descritores: Ensaios clínicos controlados aleatórios como assunto; Medicina baseada em evidências; Análise estatística; Distribuição aleatória; Cirurgia plástica.

INTRODUCTION

A randomized clinical trial (RCT) is a prospective study design that compares the effect of interventions on humans in one or more groups against a control group. RCTs are the best source of evidence for health interventions. Evidence-based medicine (EBM) is defined as the use of the best existing scientific evidence, provided by appropriately designed and conducted RCTs results, combined with individual clinical expertise and patient preferences and values, for deciding on individual patient care[1-4].

EBM became popular in the 1980s and impacted all fields of medicine, including Plastic Surgery[5]. The application of EBM principles can not only determine the best treatment for the patient but can also reduce the costs of healthcare systems[2]. However, particularly in the surgical areas, there are challenges to overcome, including the belief that the application of EBM could reduce the autonomy of surgeons, and that the best scientific evidence does not always exceed the best practices. This concern is even greater in Plastic Surgery, in which the results are measured not only by the occurrence of complications and need for reintervention, but mainly by patient satisfaction with aesthetic results[6].

Nevertheless, the EBM practice in Plastic Surgery is no longer a trend, it is a reality[6]. Information obtained from research with methodological rigor has become the key point of EBM and translation of knowledge[7]. Therefore, the results of well-conducted RCTs can have a significant impact on medical care by contributing to the establishment of solid scientific evidence that will serve as basis for clinical care protocols and interventions[8].

Research in Plastic Surgery will have a much greater influence on clinical practice if studies with greater impact are published[9,10]. Thus, the identification and systematic evaluation of the RCTs conducted by plastic surgeons, and their impact on the specialty, allow the implementation of evidence-based practice, with direct benefits for patients[11,12].

Several studies have indicated that plastic surgeons recognize the need to improve the level of evidence of research in Plastic Surgery, and this recognition reflects in the continuous increase in publications of clinical trials by this specialty[2,8,12-17].

A previous study identified RCTs with properly described allocation concealment, published by plastic surgeons between 1966 and 2003, and evaluated their quality[18]. Subsequently, in another study, the evolution was assessed over a subsequent five-year period (2004 to 2008), and a quantitative and qualitative increase in the RCTs published by plastic surgeons were observed[8]. This study aimed to test whether there was a quantitative and qualitative improvement in the RCTs in Plastic Surgery in another five-year period (2009 to 2013) compared to previously studied periods.

OBJECTIVE

To evaluate the evolution of randomized clinical trials in Plastic Surgery with adequately described allocation concealment, published between 2009 and 2013, compared to previously studied periods (1966-2003 and 2004-2008).

METHODS

The project was approved by the Research Ethics Committee of the Federal University of São Paulo – Paulista School of Medicine (UNIFESP - EPM), under the number 842.388, CAAE 37661814.8.0000.5505. The cases were selected by convenience, consisting of all the recovered RCTs that met the study eligibility criteria, published over a five-year period (January 2009 to December 2013)

Electronic searches were performed to identify the largest number of RCTs that were published by plastic surgeons in English. Specific search strategies were developed for each studied database, CCTR (Cochrane Central Register of Controlled Trials), LILACS (Latin American and Caribbean Health Science Literature), EMBASE (Excerpta Medica Database), and MEDLINE (MEDLARS- Medical Literature Retrieval System - online).

The abstracts of all retrieved articles were read by an evaluator and those that met the eligibility criteria (possible RCTs in which at least one plastic surgeon participated and published in English between 2009 and 2013) were selected for the reading of their full texts. Studies that were not conducted by plastic surgeons or without the participation of at least one plastic surgeon, and those published in a language other than English, were excluded. At this stage, whenever there was any doubt, the study was selected for reading in its entirety.

The full texts of the articles which had their abstracts selected were read by an evaluator to confirm the eligibility criteria. Subsequently, two independent evaluators classified the selected articles according to their allocation concealment[19], and the disagreements were resolved in a consensus meeting. The RCTs published by plastic surgeons, with adequately described allocation concealment, were selected and constituted the sample of this study.

The selected RCTs were then evaluated for their quality. The evaluation was conducted independently by two evaluators, followed by a consensus meeting. Two validated instruments were used for quality assessment: the Delphi List[20] and the Jadad Scale[21].

The Delphi List is a list of generic criteria for quality evaluation of clinical trials that should be used in combination with other instruments. It does not use scores and all items have two answer choices: "yes" or "no" (Chart 1)[20].

The Jadad Scale is based on scores: one point is given for each "yes" answer, and a zero point for each "no" answer. Points counted for the first two items (randomization and double blinding) depend not only on how they are described, but also on the use of appropriate methods for this purpose. If the methods are described and appropriate, an additional point is given for each item. If the methods used to generate the randomization sequence or create the blinding conditions are described but inappropriate, the item will receive a zero point. Therefore, the scale encompasses scores from 0 to 5. The study will be considered of poor quality if it receives two or fewer points (Chart 2)[21].

The results were compared to those obtained in the two previous studies that used the same method to evaluate the quality of the RCTs published by plastic surgeons in the 1966-2003 and 2004-2008 periods[8,18].

Statistical analysis

Kappa and McNemar tests were used to analyze the concordances and disagreements between the evaluators. The Chi-square test was applied to compare the categorical variables evaluated in the three periods (1966-2003, 2004-2008, and 2009-2013). Kruskal-Wallis analysis of variance was used to compare the Jadad scores in the three periods. The Kolmogorov-Smirnov test was applied to compare, two by two, the Jadad scores in the studied periods[22].

Statistical analysis was performed using the BioEstat 5.3 program (Instituto Mamirauá, Pará and Amazonas, Brazil). In all tests, the level of significance used was 0.05 or 5%.

Chart 1. Delphi List Items[20]

1.a.	Were the patients randomly allocated to the treatment groups?
1.b.	If individuals were randomly allocated to the treatment groups, was concealment allocation maintained?
2.	Were the groups comparable in terms of the most important characteristics of the prognosis?
3.	Were the inclusion and exclusion criteria specified?
4.	Did an independent evaluator evaluate the results?
5.	Did the caregiver wear a mask?
6.	Did the patient wear a mask?
7.	Were the measures of variability and the estimation of the points presented for the primary variable?
8.	Did the study include an analysis by intention to treat (all allocated patients)?

Chart 2. Jadad Scale Items[21]

1.a.	Was the study described as randomized (use of words such as “random” and “randomized")?
1.b.	Was the method appropriate?
2.a.	Was the study described as double-blind?
2.b.	Was the method appropriate?
3.	Were the losses and exclusions described?

RESULTS

The electronic search identified 6,997 articles in the analyzed databases. One evaluator selected 616 articles, excluding 6,381 that were clearly not RCTs, were repeated in different databases, or did not include the participation of at least one plastic surgeon.

After reading the full texts of the 616 publications, the evaluator excluded 336 articles for the following reasons: one article was published in a language other than English (Russian); 219 did not include the participation of at least one plastic surgeon; 116 were not RCTs. Of the 280 remaining articles, 19 were repeated within the same database. Thus, the final selection comprised 261 studies.

Two evaluators independently classified the 261 selected studies according to their allocation concealment[19]. The kappa coefficient of agreement (kw) between the two evaluators was 0.94 ($p = 0.000$). After a consensus meeting, 43 RCTs published in English, with the participation of at least one plastic surgeon, and with adequately described allocation concealment were selected.

The comparison of the Delphi list items between the 2009-2013 period and previous study periods (1966-2003 and 2004-2008) is shown in Table 1. A significant improvement in scores was observed when comparing the items “Groups were comparable in terms of the most important characteristics of the prognosis” ($p < 0.001$), “Inclusion and exclusion criteria were specified” ($p = 0.0029$), and “Measures of variability and estimation of points were presented for the primary variable” ($p = 0.0057$) in the 1966-2003 and 2004-2008 periods.

The kappa coefficient of agreement (kw) between the two evaluators in the evaluation of the 43 RCTs for Jadad scores[21] was 0.67 ($p = 0.0000$). Table 2 shows the distribution of the RCTs according to Jadad scores.

DISCUSSION

The present study evaluated the evolution of the quality of RCTs published by plastic surgeons since 1966. The long follow-up period of 47 years, using the same method, facilitated a clear analysis of the evolution of studies over this period.

Considering the growing demand for specialized treatments and the limitation of health resources, there has been a growing interest in the practice of so-called “evidence-based medicine,”[12,14,23,24] and the qualitative and quantitative increase of publications of RCTs by plastic surgeons evaluated in the 47 years confirms this interest.

Conducting RCTs in surgical areas is accompanied by many difficulties and challenges, which includes ethical issues that make it impossible to use placebo procedures or even all procedures, compared to a surgical intervention; the impossibility of blinding the surgeon; learning curves; technical differences between surgeons, among others[25,26]. Thus, the production of RCTs in this field has been slower compared to other medical specialties[24,27-31].

Despite the difficulties in conducting a randomized clinical trial in plastic surgery, evidence-based medicine is the key to the progress of this specialty[15]. Thus, the clinical trials that are effectively conducted should follow strict quality standards and methodological

Table 1. Quality assessment using the Delphi List after consensus meeting and comparison with the 1966-2003 and 2004-2008 periods.

	1966-2003		2004-2008		2009-2013		Chi-square test
	Yes n (%)	No n (%)	Yes n (%)	No n (%)	Yes n (%)	No n (%)	
1.a. Were the patients randomly allocated to the treatment groups?	34 (100.0)	0	28 (100.0)	0	43 (100.0)	0	-
1.b. If individuals were randomly allocated to the treatment groups, was concealment allocation maintained?	34 (100.0)	0	28 (100.0)	0	43 (100.0)	0	-
2. Were the groups comparable in terms of the most important characteristics of the prognosis?	14 -41.2	20 -58	27 -96.4	1 -3.6	30 -69.8	13 -30.2	$\chi^2 = 21.6$ $p < 0.0001$
Were the inclusion and exclusion criteria specified?	17 (50.0)	17 (50.0)	19 (67.9)	9 (32.1)	37 (86.0)	6 (14.0)	$\chi^2 = 11.7$ $p = 0.0029$
Did an independent evaluator evaluate the results?	17 -50	17 -50	18 -64.3	10 -35.7	21 -48.9	22 -51.1	$\chi^2 = 1.85$ $p = 0.3964$
5) Did the caregiver wear a mask?	11 -32.4	23 -67.6	9 -32.1	19 -67.9	16 -37.2	27 -62.8	$\chi^2 = 0.28$ $p = 0.8709$
6. Did the patient wear a mask?	20 -58.8	14 -41.2	14 -50	14 -50	24 -55.8	19 -44.2	$\chi^2 = 0.49$ $p = 0.7814$
Were the measures of variability and the estimation of the points presented for the primary variable?	15 -44.1	19 -55.9	19 -67.9	9 -32.1	34 -79	9 -21	$\chi^2 = 10.32$ $p = 0.0057$
8 Did the study include an analysis by intention to treat (all allocated patients)?	13 -38.2	21 -61.8	9 -32.1	19 -67.9	18 -41.8	25 -58.2	$\chi^2 = 0.68$ $p = 0.7120$

Table 2. Quality Scale scores after consensus meeting.

SCORES	STUDIES					
	1966-2003		2004-2008		2009-2013	
	n	%	n	%	n	%
0	4	11.8	0	0	0	0
1	1	2.9	0	0	0	0
2	15	44.1	4	14.2	4	9.3
3	7	20.6	11	39.3	17	39.5
4	4	11.8	2	7.1	6	13.9
5	3	8.8	11	39.3	16	37.2
Total	34	100	28	100	43	100

Kruskal-Wallis analysis of variance:

$p = 0.0001$

1966-2003 < 2004-2008 and 2009-2013

Kolmogorov-Smirnov test:

Maximum differences between the cumulative proportions:

1966 - 2003 vs. 2004 - 2008: $\chi^2 = 12.18$; $p = 0.0023$

1966 - 2003 vs. 2009 - 2013: $\chi^2 = 18.63$; $p < 0.0001$

2004 - 2008 vs. 2009 - 2013: $\chi^2 = 0.16$; $p = 0.9192$

rigor, so that they may have more impact on clinical practice[11,12,32].

In order to improve the quality of RCTs, a group of researchers and editors elaborated the CONSORT (Consolidated Standards of Reporting Trials) Statement, initially published in 1996 and updated in 2001[31,32]. From the review on the use of the CONSORT Statement, published in 2010, which comprises a checklist and a flow diagram, it became popular and was adopted by most medical journals as the standard for describing RCTs[33].

The use of the CONSORT Statement has contributed to an increase in the quality level of the published RCTs. An important limitation of the present study was the lack of use of the CONSORT checklist to assess the quality of published RCTs. However, it should be noted that the checklist, in its current form, was not available when the two previous studies were designed and conducted, and this study aimed to strictly use the same method as the two previous studies, thus, allowing a long-term evolution assessment.

A progressive increase in the number of RCTs published by plastic surgeons was observed over time. No RCT appropriately describing allocation concealment was published by plastic surgeons from 1966 to 1983. The first RCT with these characteristics was published in 1984, comparing the occurrence of capsular contracture after the use of saline implants or silicone gel for breast reconstruction[34]. From then on, a progressive increase was observed, following the popularization of EBM from the 1980 decade[6], but with a substantial increase only from the 2000s onwards.

In the present study, a higher concentration of publications was observed in Europe and North America, following a trend described in the other two periods for comparison (1966-2003 and 2004-2008). Momeni et al. [11], when evaluating RCTs in three major plastic surgery journals from 1990 to 2005, also observed a higher number of publications in Europe and North America.

The Delphi List[20], used in this study, evaluates three dimensions of the quality of an RCT: internal validity (degree of validity of the study for the assessed sample), external validity (degree of validity of the study in extrapolating its results to the population), and statistical analysis. The comparison of the Delphi List items between the present study (2009-2013) and the first studied period (1966-2003) [20] indicates a greater number of responses, with statistical significance, for the items: "The groups were comparable in terms of the most important characteristics of the prognosis," "The inclusion and exclusion criteria were specified," and "Measures of variability and estimation of points were presented for the primary variable." This shows an increase in the quality of RCTs published in the current period regarding these items. However, there was no change in the quality of the studies when the 2009-2013 period was compared to the previous five-year period (2004 to 2008).

The Jadad Scale is a short, simple, reliable, valid, and widely used instrument[21,35]. Originally designed to assess pain in RCTs, it can be applied in other fields of medicine, since the items are not specific[21]. Olivo et al.[35], in a systematic review, analyzed the scales used to assess the methodological quality of RCTs in the health domain. They found that most of the scales did not have strict control over their development, nor were they tested for validity and applicability. They also observed that the Jadad Scale[21] has been one of the most cited and used in the academic community of the health domain, besides having the best evidence for validity and applicability.

The evaluation of the Jadad scores[21] indicated that there was a statistically significant increase in quality when comparing the 1966-2003 period to the 2004-2008 and 2009-2013 periods. However, there was no improvement in quality when comparing the 2009-2013 period to the previous five-year period (2004 to 2008), indicating a stabilization in the quality of RCTs.

Yu et al.[36] conducted a cross-sectional study aimed at assessing the quality of RCTs publications on surgery that were published in the 2003-2013 period. They used the conformity of the items to the CONSORT 2010[32,36] checklist as quality criteria. They observed that the studies published in 2013 obtained higher scores than those published in 2003, and this was statistically significant, suggesting an improvement in the quality of publications. They concluded that there has been an increase in the quality of RCTs publications on surgery in the last decade. However, this quality remains at suboptimal levels, especially regarding surgical interventions[36].

In this study, it was observed that the studies indicated a stabilization in quality compared to the last analyzed period (2009 to 2013) and the period before that (2004 to 2008) regarding the methodological criteria assessed using the Delphi List[20] and the Jadad Scale[21]. This could indicate that plastic surgeons, after a significant improvement, may have reached a basic level of quality in terms of criteria used for the publication of RCTs. However, several other items would need to be incorporated in order to increase their quality. This need reflects in the constant improvement of the CONSORT 2010[37] checklist, and in the requirement, by an increasing number of journals, of compliance with the checklist items for an RCT to be accepted for publication.

Plastic Surgery is characterized by a long history of innovation, which continues to this day, and has many contributions to share with other medical, clinical, or surgical specialties[31]. Existing barriers should not be considered as obstacles to scientific growth of the specialty, but as challenges to be overcome.

CONCLUSION

There was no difference in the quality of randomized clinical trials (RCTs) with appropriately described concealment allocation, published by plastic surgeons from 2009 to 2013 compared to the previous five-year period (2004 to 2008). However, both periods had better quality RCTs than the 1966-2003 period.

COLLABORATIONS

TBM Analysis and/or data interpretation, conception and design study, data curation, final manuscript approval, formal analysis, methodology, project administration, resources, writing - original draft preparation.

DFV Analysis and / or interpretation of data, statistical analysis, study design and design, project administration, methodology, writing - review and editing, supervision.

MSN Final approval of the manuscript.

LMF Final approval of the manuscript.

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Original Article

Epidemiological profile of patients with cleft lip and palate in a reference service in the Federal District

Perfil epidemiológico de pacientes portadores de fissuras labiopalatinas em serviço de referência no Distrito Federal

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ABSTRACT

Introduction: Cleft lip and palate, the most common congenital malformations of the head and neck, result from fusion failure of embryonic facial processes during the first 12 weeks of pregnancy. Their phenotypic presentation varies and involves different levels of complexity. The objective is to determine the epidemiological profile of patients with cleft lip and palate treated at the Hospital Regional da Asa Norte regarding sex, cleft type, laterality, age, presence of associated syndromes, and corrective surgical procedures. **Methods:** This was a retrospective descriptive study of 322 medical records of patients treated by the HRAN team from August 2013 to July 2017. The data collected were entered into an Excel spreadsheet and submitted to statistical analysis. The study received ethical approval. **Results:** Of the 322 patients enrolled in the service, 169 were male (52.48%). The most frequent type of cleft was the trans-foramen (65.25%). With regard to laterality, a higher prevalence of cleft was observed on the left (20.50%). Only 19% of the patients had associated malformations. Cheiloplasty was the most frequent surgical correction performed by service (54%). The age of the patients was 1–53 years (median, 1.87 years). **Conclusion:** The study contributes information important to society, government, and treatment professionals. In line with the literature, the more prevalent cleft was unilateral left trans-foramen and the most frequent surgery was cheiloplasty.

Keywords: Cleft palate; Cleft lip; Descriptive epidemiology; Reconstructive surgical procedures; Congenital abnormalities.

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■ **RESUMO**

Introdução: As fissuras labiopalatinas são as malformações congênitas mais comuns dentre as que ocorrem na cabeça e pescoço, e se devem à falha de fusão dos processos faciais embrionários durante as primeiras 12 semanas de gestação. Sua apresentação fenotípica é variada e com diferentes níveis de complexidade. O objetivo é determinar o perfil epidemiológico dos pacientes portadores de fissuras labiopalatinas atendidos no Hospital Regional da Asa Norte (HRAN) quanto a sexo, tipo de fissura, lateralidade, idade, presença de síndromes associadas e procedimentos cirúrgicos corretivos. **Métodos:** Trata-se de um estudo descritivo retrospectivo no qual foram analisados 322 prontuários de pacientes atendidos pela equipe do HRAN no período de agosto de 2013 a julho de 2017. Os dados colhidos foram lançados em planilha Excel e submetidos à análise estatística. O trabalho foi aprovado pelo Comitê de Ética e Pesquisa. **Resultados:** Dos 322 pacientes atendidos no serviço, 169 eram do sexo masculino (52,48%). O tipo de fissura mais frequente foi a transforâmica (65,25%). Com relação à lateralidade, observou-se maior predomínio da fissura à esquerda (20,50%). Apenas 19% dos pacientes possuem malformações associadas. A queiloplastia foi a correção cirúrgica mais realizada pelo serviço (54%). A idade dos pacientes variou de 1 ano até 53 anos, com mediana de 1,87 anos. **Conclusão:** O estudo contribuiu com informações importantes para a sociedade, governo e profissionais envolvidos no tratamento. Em consonância com a literatura, observou-se que a fissura mais prevalente foi a transforâmica unilateral esquerda e a cirurgia mais realizada foi a queiloplastia.

Descritores: Fissura palatina; Fenda labial; Epidemiologia descritiva; Procedimentos cirúrgicos reconstrutivos; Anormalidades congênitas.

INTRODUCTION

Cleft lip and palate, the most common congenital malformations that affect the head and neck, occur due to lip and palate fusion failure in intrauterine life[1-3]. They can be divided into isolated cleft lip, cleft palate, and cleft palate[3-6]. The prevalence of this disease is uncertain, but it affects approximately 1 in every 700 live births depending on factors such as ethnicity, geographical origin, and socioeconomic level[4]. It may occur in isolation or associated with syndromes. It is estimated that 50–70% of clefts occur in isolation or in a non-syndromic form[1,4].

The frequency of cleft lip and palate differs between the sexes. While cleft lip with or without cleft palate affects more males, the presentation is inverted with isolated cleft palate, which affects more females at a ratio of 2:1. As for laterality, unilateral cleft lip is more prevalent on the left side than the right, also by a ratio of 2:1[2,4,7-9].

The etiology is diverse and uncertain due to embryological error, being influenced by genetic, environmental, and socioeconomic factors[1,4]. Studies indicate that smoking, drugs, parents' age, social class, consanguinity, and ethnicity are involved in the onset of this malformation, relating in different ways to the occurrence of fissures[1,4,5,10,11]. Gestational history, drug use, and family history are essential to possible associated genetic factors. Folic acid is a protective factor[7].

Based on embryological origin, Spina proposed a classification of clefts considering their position in relation to the incisive foramen. In group I, complete pre-incisive foramen cleft, which affects the lip, dental alveolus, and nasal floor, and incomplete, which affects only the lip. Group II includes trans-incisive foramen clefts. Group III refers to clefts that only affect the palate, which can be complete or incomplete. Cleft lip and palate can be unilateral or bilateral[5,7].

The diagnosis of oral clefts can be done during prenatal monitoring with ultrasound. Hard palate clefts are difficult to visualize and can only be diagnosed after the 28th week. Thus, in general, only cleft lip is

diagnosed in the early prenatal period during the first trimester[7,12,13]. Surgical correction of oral clefts can occur according to the cleft type presented and the treatment protocol established by each service[7,14,15].

OBJECTIVE

Few studies have assessed the epidemiological profile of patients with oral clefts, especially in Brazilian territories. Given the need to better understand this profile, the present study aims to describe the frequency of cleft types and the prevalence of surgical procedures in patients with cleft lip and palate who attended and underwent surgery at the Multidisciplinary Service of Care for Patients with Cleft Lip and Palate of the Hospital Regional da Asa Norte (HRAN), Brasília, Federal District (DF).

METHODS

This retrospective descriptive study was performed at the Multidisciplinary Service of Care for Patients with Cleft Lip and Palate of the HRAN located in the city of Brasília, DF. This is a medium-sized hospital and a reference center for the care of patients with cleft lip and palate in the Midwest region. The present study was approved by the Ethics and Research Committee of the Health Sciences Teaching and Research Foundation (FEPECS) (protocol 53767715.4.0000.5553) and conducted in accordance with Resolution No. 196/96, which oversees research involving human beings.

The study population comprised all patients undergoing surgical procedures of the Multidisciplinary Service of Care for Patients with Cleft Lip and Palate between August 2013 and July 2017. Patients for whom information was missing from their medical records were excluded from the study.

The researchers collected data from the medical records of patients diagnosed with cleft lip and palate in an Excel spreadsheet. The variables analyzed included date of surgery, patient sex, patient age at surgery, surgery performed, diagnosis according to Spina classification, laterality of clefts, and family history of clefts and associated anomalies. Subsequently, a statistical analysis was performed with the proportions tests and Chi-square test using R software for Windows.

RESULTS

Between August 2013 and June 2017, 586 patients were surgically treated in this service, but only 322 met the study's inclusion criteria. Of the 322 patients enrolled in the service, 169 were male (52.48%). Patient age ranged from less than 1 year to 53 years, with a median of 1.87 years.

Patient origin was variable. The reference service assists the Federal District and surrounding areas. However, some patients are from the North and Northeast regions of Brazil.

Patient Diagnosis

For both sexes, the left and bilateral foramen clefts were the most prevalent (20.50% and 18.94%, respectively). The proportions test yielded a p value of 0.6098. As observed in Table 1, in males, the most common clefts were bilateral trans-foramen (21.30%), left trans-foramen (18.93%), and right trans-foramen clefts (15.38%). The proportions test yielded a p value of 0.2974. In females, the more frequent clefts were left trans-foramen (22.22%), bilateral trans-foramen (16.34%), and incomplete post-foramen clefts (16.34%) ($p = 0.2354$).

Cleft Laterality

Initially, the frequency of laterality (uni- and bilateral) of the most common clefts, pre-foramen and trans-foramen clefts of patients, in general and by sex (Table 2) were analyzed. In the study population, a left unilateral cleft was the most common in both sexes. Thereafter, the prevalence of pre- and trans-foramen clefts was analyzed by sex and in general (Table 3) since they were the most common in both sexes. As the proportion test revealed a p value less than 0.001, the trans-foramen clefts are more prevalent.

Statistical tests were performed to analyze whether the clefts (pre- and trans-foramen) were related to sex among patients treated in this service. Tests were also performed to identify if the cleft laterality (uni- or bilateral) had a predilection to either sex. According to the Chi-squared test (Table 4), in the population studied, both the diagnosis of laterality and the clefts themselves are independent of patient sex.

Kinship

The heredity of the clefts by sex from 2015 to 2017 was subjectively analyzed. Most of the patients had no relatives with this diagnosis. Among males, 77.78% had no relatives with oral cleft, whereas in females, 83.05% had no affected relatives.

Associated Malformations

When analyzing the presence of malformations associated with oral cleft of patients by sex, one can observe that 90.46% of the cleft patients do not have this diagnosis. In males, only 9.36% of the patients

Table 1. Patient diagnosis by sex.

Diagnosis (cleft)	Male	Percentage	Female	Percentage	Total	Percentage
Incomplete left pre-foramen	14	8.28%	11	7.19%	25	7.76%
Incomplete right pre-foramen	6	3.55%	9	5.88%	15	4.66%
Bilateral incomplete pre-foramen	3	1.78%	0	0.00%	3	0.93%
Complete left pre-foramen	9	5.33%	7	4.58%	16	4.97%
Complete right pre-foramen	14	8.28%	11	7.19%	25	7.76%
Bilateral complete pre-foramen	3	1.78%	3	1.96%	6	1.86%
Left trans-foramen	32	18.93%	34	22.22%	66	20.50%
Right trans-foramen	26	15.38%	16	10.46%	42	13.04%
Bilateral trans-foramen	36	21.30%	25	16.34%	61	18.94%
Complete post-foramen	11	6.51%	12	7.84%	23	7.14%
Incomplete post-foramen	15	8.88%	25	16.34%	40	12.42%
Total	169	100.00%	153	100.00%	322	100.00%

Table 2. Cleft laterality by sex.

Laterality	Male	Percentage	Female	Percentage	Total	Percentage
Right unilateral	46	32.17%	36	31.03%	82	31.66%
Left unilateral	55	38.46%	52	44.83%	107	41.31%
Bilateral	42	29.37%	28	24.14%	70	27.03%
Total	143	100.00%	116	100.00%	259	100.00%

Table 3. Cleft type by sex.

Diagnosis (cleft)	Male	Percentage	Female	Percentage	Total	Percentage
Pre-foramen	49	34.27%	41	35.34%	90	34.75%
Trans-foramen	94	65.73%	75	64.66%	169	65.25%
Total	143	100.00%	116	100.00%	259	100.00%

presented with this diagnosis compared to 9.74% of females.

Among the 9.56% syndromic cleft patients, 5 had cardiac malformations; 1 had thoracic malformation; 1 had cranial malformation; 2 had intellectual disability; and 6 had two or more associated malformations, the most prevalent being cardiac, ocular, limbs, and urinary system.

Type of surgery

As shown in Figure 1, at HRAN Cleft Center, the most frequent surgery is cheiloplasty, followed by palatoplasty.

Age

Figure 2 shows the relationship between patient age at surgery, type of surgery performed (palatoplasty, cheiloplasty, or rhinoplasty), and sex. For palatoplasty, the median age for both sexes was 3 years (mean age of females, 9 years; mean age of males, 6 years). For cheiloplasty, the mean age was 4 years for males and 8 years for females. The median age was before the first year of life and 1.42 years, respectively, in males and females. For rhinoplasty, the mean age was 20.54 years (median, 17 years) for males and mean was 19.2 years (median, 22.71 years) for females.

DISCUSSION

A referral center requires the services of several professionals to offer a complete and qualified treatment for cleft patients. However, Paranaíba et al.[15] reported that 75% of the treatment units in Brazil have only the following specialists in their services: plastic surgeon, dental surgeon, and speech therapist. At the HRAS, the following professionals are recommended in the interdisciplinary team: plastic surgeon, otorhinolaryngologist, craniofacial surgeon, dentist, odontopediatrician, orthodontist, nutritionist, speech therapist, psychologist, pediatrician, nurse, social worker, and geneticist.

Table 4. Statistical analysis of laterality and sex versus diagnosis and sex.

Test	Sex	N (%)	Chi-square test	Ratio (F/M)
Laterality	Female	116 (44.8%)	$x^2 = 1.301$	1 : 1.23
	Male	143 (55.2%)	$p = 0.52$	
Pre-foramen x trans-foramen	Female	116 (44.8%)	$x^2 = 0.03$	1 : 1.23
	Male	143 (55.2%)	$p = 0.85$	

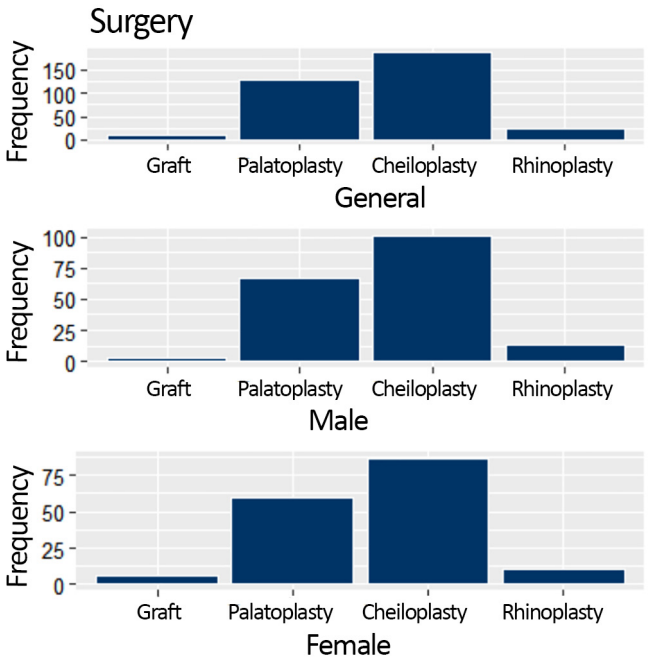

Figure 1. Surgery type overall and by sex.

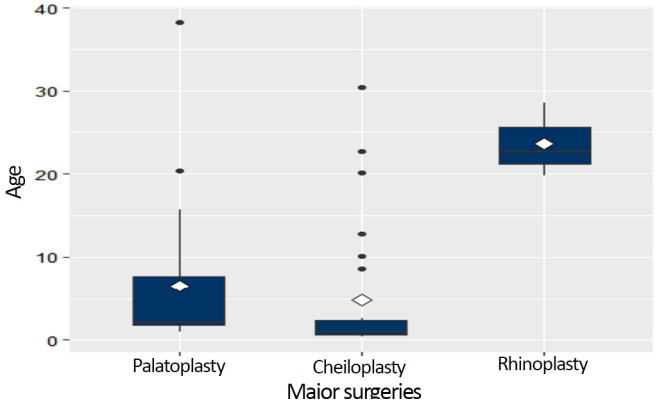

Figure 2. Boxplot of age by surgery type.

The exact prevalence of cleft lip and palate in Brazil is not known. Studies performed in other centers reported a prevalence of malformation at 0.49 in Rio Grande do Norte; 0.88 in Porto Alegre, RS; and 1.54 in Bauru, SP, for every 1000 live births[3,6,16]. As cleft lip and palate became a notifiable disease in the DF in September 2017 (Law 5.958/2017), it was not possible to determine its prevalence in the analyzed period (August 2013 to June 2017) in the literature or by using data from the government. Thus, there is a possibility of underreporting, which would have hindered the determination of its prevalence in the local population.

Regarding sex, published reports indicate an increased frequency of oral clefts in males[2,8,9,16-22]. Although 169 of the 322 children studied (52.48%) were boys, it was not possible to affirm this in the population studied, as there was no statistical relevance.

Of the total of 322 records of oral clefts of patients of HRAN, there is a greater proportion of labial clefts and trans-foramen clefts (80.4%) when compared to isolated cleft palate (19.6%). This finding is in agreement with the literature, in which there are reports of predominance of cleft lip and palate ranging between 69.1% and 81%, taking pre-foramen clefts and trans-foramen clefts as a joint entity [10,19].

As for the diagnosis by the Spina classification, the most prevalent types of clefts were left trans-foramen (20.50%) and bilateral cleft (18.94%), followed by right trans-foramen clefts (13.04%) and incomplete post-foramen clefts (12. 42%). As the p value was greater than 0.05 (p-value of 0.6098), it is not possible to state the prevalence of any type of cleft in this study. However, the literature reports a predominance of left trans-foramen clefts followed by incomplete post-foramen clefts[18]. Studies that do not discriminate laterality also reported higher frequencies of trans-foramen clefts (24.89 - 37.1%) and post- foramen clefts (26.9 - 31.7%) [17,20].

Regarding the distribution of cleft type by sex, left trans-foramen clefts were more common in females (22.22%), while bilateral trans-foramen clefts were more common in males (21.30%). However, the p value for both sexes was greater than 0.05, so it is not possible to determine the prevalence of cleft type in this sample, although studies in Eslováquia, Rio Grande do Sul (BR), Minas Gerais (BR), and Pernambuco (BR) reported the prevalence of cleft lip with or without involvement of the palate was higher in boys and the incidence of isolated cleft palate was higher in females[4,7-9,18-22]. Regarding laterality, there was a greater prevalence of unilateral left clefts (41.31%), which were 1.3-fold more common than right unilateral clefts (31.66%). Similarly, in the medical literature, left clefts are more commonly described[2,8,9,13,16-18,20-22].

Although the etiology is multifactorial,

inheritability is reported in the scientific community as the most important factor of oral cleft involvement. The risk of a child being born with a cleft is increased by 40-fold when the parents have this malformation[2,5]. In this study, 19.85% of patients had a family history of oral clefts, a value close to that observed in the literature (23%)[5].

According to the literature, trans-foramen clefts are the most prevalent and there is a higher incidence in males (1.5:1.0)[23]. In line with the literature, in the present study, trans-foramen clefts were also the most common (65.25%). However, there was no statistically significant influence of sex in the diagnosis of trans-foramen cleft in the sample studied.

In Brazil, few studies have analyzed the frequency and type of congenital malformations associated with patients with cleft lip and palate[5]. A study conducted in 2014 in the state of Paraíba and one in 2005 in São Paulo reported that 7% and 9.18% of the clefts were syndromic, respectively[5,24]. Of the patients treated at the HRAN, only 9.54% have associated malformations. This underscores the importance of patients with cleft lip and palate being examined in detail to detect other associated malformations[5].

According to the literature, malformations of the lower and upper limbs are the most common (33%), followed by malformations of the cardiovascular system (24%)[7]. Among the cleft patients treated at the HRAN, cardiac malformations were the most prevalent (25.8%).

The treatment of oral clefts is surgical and each reference center has its own treatment protocol. In accordance with the protocol established by the Cleft Service of the HRAN, cheiloplasty is the first procedure performed in patients with cleft lip and palate; just the lip is corrected in infants under 3 months of life once they reach the minimum organic condition required to undergo general anesthesia[7,14].

The fact that 80% of the patients treated at the HRAN had pre-foramen and trans-foramen clefts explains why cheiloplasty is the most common surgical procedure performed by the service. The results of this study show that the mean age of males is 4 years while that of females is 8 years, while the median is before the first year of life and 1.42 years in males and females. Nevertheless, some patients underwent cheiloplasty belatedly, thus changing the mean. This could occur because the HRAN cleft service treats patients regardless of age at presentation; or difficulty accessing the health service; or after a late diagnosis. Consequently, treatment is not always performed at the age recommended by the protocol. However, it is interesting to note that, as the results reveal, most of the patients treated at this service receive surgical treatment in the first year of life.

According to the HRAN protocol, palatoplasty is performed in patients with cleft lip and palate at the age of at least 18 months and when their weight is appropriate. In this study, 36.08% of patients underwent this surgical procedure. The median age in both sexes was 3 years, while the mean age of females was 9 years and that of males was 6 years. Thus, as with cheiloplasty, this surgery is also performed in older ages in this service, likely for similar reasons.

Rhinoplasty is also part of the treatment protocol in cases of nasal deformity. Thus, it is less common and performed only after correction of the cleft lip and palate or when the patient is at least 16 years old[14]. At the HRAN, in agreement with the literature, only 6.82% of patients underwent this surgical procedure. The mean age was 20.54 years and the median age was 17 years, in line with published recommendations.

According to Paranaíba et al.[15], the techniques of Veau and Van Langenbeck are the most commonly used in palatoplasties in international reports. In cheiloplasties, a review of Brazilian surgical protocols showed a preference for the Millard technique for unilateral cheiloplasty and of the Spina and Millard techniques for bilateral cases. In the cleft department of HRAN, the majority of surgeries are performed using the Fisher or Millard techniques for cheiloplasties and the Van Langenbeck and Sommerlad techniques for palatoplasty.

CONCLUSION

The epidemiological profile of patients with cleft lip and palate treated at the HRAS indicates that the majority of patients are male with non-syndromic diagnoses and no family history of this diagnosis. It was not possible to determine a prevalence between the sexes. Trans-foramen clefts were most common, mainly left sided. The most frequent surgery was cheiloplasty, since pre-foramen and trans-foramen clefts were the most common. However, the exact prevalence of this malformation in the DF could not be found in the period analyzed using the local literature and governmental data.

COLLABORATIONS

EVR	Analysis and/or data interpretation, data curation, formal analysis, writing - original draft preparation.
TOP	Analysis and/or data interpretation, formal analysis.
GNM	Formal analysis.
LRR	Conception and design study.
LGM	Conception and design study, supervision.

MDS Supervision.

DRP Final manuscript approval, writing - review & editing.

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Original Article

Epidemiological analysis and evolution of patients undergoing reconstructive plastic surgery in a trauma referral hospital

Análise epidemiológico-evolutiva de pacientes submetidos a cirurgia plástica reparadora em um hospital de referência em trauma

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■ **ABSTRACT**

Introduction: Trauma injuries are sudden aggravations to health that may lead to temporary disabilities and interfere with the victim's quality of life. The reconstructive plastic surgery (RPS) unit of the Urgency and Emergency Metropolitan Hospital (Hospital Metropolitano de Urgência e Emergência - HMUE) is a referral unit for the treatment of trauma patients in the state of Pará, Brazil. **Methods:** This was an observational, analytical, and cross-sectional prospective study. The study population was composed of 78 patients treated from December 2015 to December 2016. **Results:** The study population was predominantly male, autonomous, and aged between 21 and 30 years. Traffic accidents were the most frequent cause of trauma. The most affected area was the lower limbs, and the most common type of surgery performed was grafting. Viability was in the range of 90-100% in both patients undergoing graft and flap surgery. No significant association was found between the age range of patients and the degree of viability. However, there was a relationship between the number of days from the accident until the medical intervention and the degree of graft viability. **Conclusion:** Patients admitted to the hospital on the same day of the accident were six times more likely to present graft viability above 80%, and therefore, to have a favorable outcome.

Keywords: Reconstructive surgical procedures; Epidemiology; Wounds and injuries; Clinical Evolution.

Institution: Hospital Metropolitano de Urgência e Emergência, Ananindeua, PA, Brazil.

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■ **RESUMO**

Introdução: Lesões decorrentes de trauma são agravos súbitos à saúde que podem levar a deficiências temporárias e interferir na qualidade de vida das vítimas. O serviço de Cirurgia Plástica Reparadora (CPR) do Hospital Metropolitano de Urgência e Emergência (HMUE) atua como a unidade de referência no tratamento de feridas dos pacientes vítimas de trauma no Estado do Pará. **Métodos:** Estudo observacional analítico, do tipo transversal prospectivo. A população foi composta por 78 pacientes atendidos no período de dezembro de 2015 até dezembro de 2016. **Resultados:** A população predominante foi de pacientes do sexo masculino, autônomos, entre 21 a 30 anos. Os acidentes automobilísticos foram os mais prevalentes. A área corporal mais afetada foi a dos membros inferiores e o tipo de cirurgia mais realizada foi enxerto. Tanto entre os pacientes submetidos à cirurgia de enxerto quanto os de retalho, predominou a viabilidade no intervalo de 90-100%. Não foi verificada associação significativa da faixa etária dos pacientes sob o grau de viabilidade. Houve relação entre o número de dias do acidente até a intervenção com o grau de viabilidade do enxerto. **Conclusão:** Os pacientes internados no hospital no mesmo dia do acidente têm seis vezes mais chance de apresentar viabilidade do enxerto acima de 80% e, portanto, desfecho favorável.

Descritores: Procedimentos cirúrgicos reconstrutivos; Epidemiologia; Ferimentos e lesões; Evolução clínica.

INTRODUCTION

The reconstructive plastic surgery (RPS) unit of the Urgency and Emergency Metropolitan Hospital (HMUE) in Ananindeua acts as a referral unit for the treatment of trauma patients in the state of Pará, Brazil. It also provides referral support for other specialties of the hospital, and therefore, receives a large volume of patients[1].

Trauma injuries are sudden health problems that can lead to death. Trauma injuries may be a result of urban violence or traffic accidents, termed as external causes in the International Classification of Diseases[2].

Trauma injuries are one of the leading causes of preventable death. Therefore, knowing the epidemiological and evolutionary profile of patients involved in these type of accidents allows the use of more effective strategies for the prevention and reduction of temporary or permanent disabilities that interfere negatively with the victims' quality of life[3,4].

OBJECTIVE

To outline the epidemiological and evolutionary profile of patients seen at the HMUE.

METHODS

This was an analytical, observational, and cross-sectional prospective study conducted at the RPS unit of the HMUE. The population was comprised of 78 patients treated by the HMUE reconstructive plastic surgery team from December 2015 to December 2016.

Patients of both genders and all age groups who were victims of trauma and treated in the RPS unit of the HMUE from December 2015 to December 2016 and who agreed to participate in the study and signed an informed consent form (ICF) were included in the study. Patients who were treated outside of this interval, patients younger than 18 years who did not have authorization from a legal guardian, unconscious patients, or patients who refused to sign the ICF or who failed to meet the analyzed criteria were excluded from the study.

Data was collected on two separate occasions. First, an interview was conducted with patients before reconstructive surgery. Patients answered an epidemiological questionnaire and information related to the trauma was collected. Then, information was collected after the invention regarding the treatment performed and its evolution, in accordance with medical supervision and medical records.

Pearson's non-parametric chi-square test for trend/adhesion and for association between nominal variables, symbolized by χ^2, was adopted. A *p*-value of <0.05 was considered statistically significant. In order to verify the significant or non-viable prevalence of the surgery according to factors such as age, hospital distance (km), days between the accident and hospitalization, and hospitalization days prior to surgery, the odds ratio (OR) was calculated with a significance level of 0.05.

The collected data were tabulated, processed, and analyzed by means of descriptive and inferential statistics. The programs Microsoft Excel and Statistical Package for Social Sciences (SPSS) (version 22.0), both for Windows 7, were used for the statistical analysis of data.

The project was approved by the ethics committee of the State University of Pará (Universidade do Estado do Pará), Biological and Health Sciences Center, Campus II (Opinion No. 1.004.945).

RESULTS

Most study patients were in the age range of 21 to 30 years (32.05%), followed by the age range of 11 to 20 years (21.79%) and 31 to 40 years (20.51%). The male sex was predominant among patients, as was origin from the municipality of Belém (32.05%) and autonomy (34.62%), with a significant trend ($p < 0.005$).

With regard to the mechanism of trauma, 78% of accidents were blunt traumas, 18% were penetrating traumas, and 4% were unreported. Among the patients who were classified as having penetrating traumas, 64% were the result of firearms and 36% were the result of bladed weapons. Car accident (collision between vehicles) was the main type of accident among patients, with the lower limbs being most affected (in 67.95% of cases), followed by the upper limbs (16.67% of cases).

With respect to hospital distance, the majority of patients (47.44%) travelled between 1-30 km from the site of the accident to the HMUE. Approximately 66.67% patients were hospitalized on the same day of the accident. Most patients (38%) waited between 30-59 hospital days before the operation.

Table 1 shows that 82.05% of patients underwent some type of skin graft surgery. Table 2 shows that both patients who underwent graft surgery (82.05%) and those who underwent flap surgery (14.10%) had viability in the range of 90-100%.

Table 3 shows that with graft surgery, 84.38% of patients had a good outcome, followed by 15.63% of patients who had a fair outcome. With flap surgery, 54.55% of patients had a good outcome, followed by 27.27% with a fair outcome, and 18.18% with a poor outcome. Among patients who had graft and flap surgery, 66.67% had a good outcome and 33.33% had a poor outcome. It should be noted that among both patients who underwent graft and flap surgeries, a good outcome was predominant.

There was a correlation between the date of

Table 1. Type of surgery performed for 78 patients by the RPS unit at the HMUE- Ananindeua, PA, 2016.

Variable	N	%	*p* - value
Type of surgery			
Graft	64	82.05	
Flap	11	14.10	<0.0001**
Graft and flap	3	3.85	

Source: Data from this study (2016)[1]; Pearson's Chi-square test (p-value <0.05); **Highly significant difference; *Significant difference; NS Non-significant; RPS: reconstructive plastic surgery; HMUE: Hospital Metropolitano de Urgência e Emergência.

Table 2. Distribuição segundo o percentual de Viabilidade e Tipo de Cirurgia de n=78 pacientes atendidos pela CPR no HMUE. Ananindeua – PA, 2016.

Viability (%)	Type of surgery						Total
	Graft		Flap		Graft/flap		
	Qty	%	Qty	%	Qty	%	
0-19	0	0	1	1.28	1	1.28	2
20-29	0	0	1	1.28	0	0	1
70-79	1	1.28	0	0	0	0	1
80-89	9	11.54	3	3.85	0	0	12
90-100	54	69.23	6	7.69	2	2.56	62
Total	64	82.05	11	14.1	3	3.85	78

Source: Data from this study (2016); RPS: reconstructive plastic surgery; HMUE: Hospital Metropolitano de Urgência e Emergência.

hospitalization after the accident and graft viability. Among patients who were hospitalized on the same day of the accident, 63.16% presented graft viability above 80%, whereas only 5.26% presented graft viability less than 80%. In patients who were admitted a day or more after the accident, the percentage of patients with less than 80% viability was two-fold higher (10.53%). That is, among patients who waited more than one day to be admitted, the percentage of graft variability was lower. In Table 4, the OR indicates that patients hospitalized on the same day as the accident were six-fold more likely to present graft viability above 80% ($p < 0.05$).

No significant correlation was found ($p > 0.05$) between the number of days which passed between hospitalization and surgery and the degree of graft viability. In order words, the viability rate was independent of the number of days patients waited after admission before undergoing reconstructive surgery.

DISCUSSION

Our study had a predominance of male patients (87.18%). Similar studies[5,6] also found a predominance of males. Males are more involved in traumatic events. Social and cultural factors related to gender expose the male sex to higher trauma risks, such as excessive speed when driving cars, hazardous maneuvers in traffic, violent behavior, and a greater consumption of alcohol, making them more vulnerable to external causes[7].

With regard to age, other studies also demonstrated that the age range between 21 and 30 years was the most frequent[8].

With respect to the origin of patients, the municipality of Belém was the most common origin (32.05%) with a significant trend ($p < 0.05$), followed by the municipality of Ananindeua (5.13%), where the HMUE is located. Belém has more traumatic events than Ananindeua because it is a capital city and has a larger population. Another reason is the geographic relationship between these two cities: they are close, almost a conurbation, thus facilitating the regulation and transport of patients to the HMUE.

Approximately 47.44% of enrolled patients were smokers. Patients with diabetes and alcoholic intake had a low frequency (1.28%). However, this value was probably underestimated since data was collected by an interview and many may have felt afraid to speak truthfully about alcoholic beverage intake.

In this study the mechanism of trauma was classified as blunt or penetrating, with 78% being classified as blunt traumas (events such as car accidents, falls, accidents at work, etc.) and 18% being classified as penetrating traumas (events involving perforation by bladed weapons or firearms). Approximately 4% of traumas were unreported. A similar result was found in a 2016 study[9], in which 78.24% of injuries were blunt traumas, 21.39% were penetrating, and 0.37% were not included in these classifications. In 2014, another study reported that 86.4% of traumas were blunt, whereas 13.6% were penetrating[10].

In this study, car accident (38.46%) was the main type of accident and showed a significant trend ($p < 0.05$), which is consistent with a study conducted in 2014 in which car accidents ranked as the main cause of attendance (44.85%)[11].

Traffic accidents are complex events because

Table 3. Distribution of the type of surgery performed on 78 patients treated by the RPS at the HMUE, Ananindeua, PA, 2016.

Result (%)	Type of surgery						Total
	Graft		Flap		Graft/flap		
	Qty	%	Qty	%	Qty	%	
Poor (loss > 80% or dehiscence)	0	0	2	18.18	1	33.33	3 (84%)
Fair (loss between 30-79%)	10	15.63	3	27.27	0	0	13(16.66%)
Good (<20% of loss)	54	84.38	6	54.55	2	66.67	62(79.5%)
Total	64		11		3		78

Source: Data from this study (2016). RPS: reconstructive plastic surgery; HMUE: Hospital Metropolitano de Urgência e Emergência.

Table 4. Distribution of patients according to the number of days between the accident and hospitalization and surgical viability - HMUE, Ananindeua, PA, 2016.

Days between accident and hospitalization (n=76)	Viability				Odds Ratio	*p* - value
	0% to 80%		Above 80%			
	n	%	n	%		
On the same day	4	5.26	48	63.16	6.00	0.0120*
1 or more days	8	10.53	16	21.05		

Fonte: Data from this study (2016) [(1)]; Odds Ratio (*p*-value < 0.05)

they may be related to human failure, vehicle failure, and even the environment. Some of these factors are the result of driver carelessness, such as hazardous maneuvers, alcohol intake and drug abuse, excessive speeding, and fatigue, as well as climatic conditions, inadequate roads and signage, and lack of vehicle maintenance[12].

In this study 71.70% of patients were in accidents involving motorcycles, and the majority (96.77%) were victims of collision accidents with other vehicles. Of the fall accidents, 45.45% involved motorcycles, whereas 27.27% of run-over accidents involved motorcycles.

Majority of the patients (47.44%) travelled between 1-30 km from the site of the accident to the hospital, a statistically significant result. This result is possibly justified by the predominant origin of patients from Belém, which is a town near Ananindeua where the HMUE is located.

Regarding the number of days between the accident and hospitalization, 66.67% patients were hospitalized on the same day as the accident. This trend is significant ($p < 0.05$), probably because most of the injured were from Belém, a city close to the HMUE.

With respect to the number of days between the date of admission and the date of reconstructive surgery at the HMUE, 38.46% of patients underwent surgery 30-59 days after hospital admittance. The second highest proportion of patients (33.33%) underwent surgery less than 30 days after admission. These trends were significant ($p < 0.05$).

The patients referred to the RPS unit were first admitted to the emergency room, where they usually underwent general and/or orthopedic surgery, before being referred to the plastic surgery unit, which explains this timeframe for the reconstructive intervention. Another reason for this interval may be due to the delay in requesting other specialties so that the plastic surgery team could evaluate the patient or the wait to improve wound conditions before performing surgery.

The most common surgical procedure performed in this study was skin grafting (82.05%), with a significant trend ($p < 0.05$). Flap surgery was performed in 14.10% patients, and 3.85% patients underwent graft and flap surgery. A similar 2017 study[8] also identified skin grafting as the most common reconstructive procedure (62.1% of cases). Fasciocutaneous flap was the second most frequent procedure, performed in 21.9% of cases, followed by muscle flap in 12.6%, and microsurgical flap in 3.4%. However, only patients with lower limb trauma were analyzed. In this study, we did not differentiate the type of flap, which may be interesting to do in future studies.

The results showed that the most affected body area was the lower limbs in 67.95% cases, with a significant tendency ($p < 0.05$), followed by the upper limbs (16.67%), head (5.13%), and trunk (2.56%), whereas 7.69% cases were unreported. In the epidemiological analysis of trauma victims in a similar study[13], the most affected body regions were the lower limbs (27.4% cases), followed by the upper limbs (22.1% cases).

Complex limb wounds are increasingly common, mainly due to the growing number of motorcycle accidents[14]. The leg region has a thin subcutaneous layer and few muscle bellies, permitting the exposure of the tibia and tendons in trauma with the loss of soft tissue, which is often associated with fractures[15].

In patients who underwent skin graft surgery (82.05%) and in patients who underwent flap surgery (14.10%), the predominant viability was between 90-100%. This result demonstrates that the HMUE reconstructive surgery team followed preoperative, intraoperative, and postoperative recommendations, as a viability of 90-100% in surgical skin grafts and flaps reflects a successful management of patient extrinsic factors.

There was no significant prevalence ($p > 0.05$) of the age group with viability, meaning the viability of the surgery was independent of the patient's age. Pearson's correlation test was also performed, which confirmed that there was no significant correlation between age and degree of viability. The degree of correlation between the two variables was negative and weak ($r = -0.155$), which was in contrast to existing literature. Elderly patients are more susceptible to surgical wound rupture and healing delay than younger patients. With aging, collagen undergoes qualitative and quantitative changes. The collagen content in the dermis diminishes with age, and the aged collagen fibers present distorted architecture and organization[16].

There was a significant correlation ($p < 0.05$) between the number of days before hospitalization after the accident and the degree of viability. The OR indicates that patients hospitalized on the same day as the accident were six-fold more likely to present viability above 80% ($p < 0.05$). Early admission influences the early care of trauma and helps prevent wound infection, an important factor in the delay of surgical treatment. Therefore, the earlier the patient is hospitalized, the faster care is received, preventing the injury from developing into infection and necrosis.

In this study, 47.43% of patients were smokers, whereas 52.56% were non-smokers. When the influence of smoking on the viability of surgery was analyzed, viability was above 80% in both smokers (44.87%) and non-smokers (50%). These results are in contrast to a study conducted in 2012[17], which found that the risk of developing wound healing complications was twice as high in smokers than in non-smokers.

There was no significant correlation ($p > 0.05$)

between the number of days that the patient had to wait to perform reconstructive surgery after admission and the degree of viability. In other words, the viability of the surgery did not depend on the number of days that the patient waited to perform plastic surgery after admission, thus proving that preoperative, intraoperative, and postoperative care was more important than the speed in performing the procedure.

Closure reconstruction should be performed only when the wound bed is suitable to receive coverage[18]. Local and systemic wound factors and patient condition should be assessed, since they are crucial for treatment success[19].

CONCLUSION

In conclusion, the profile of the average patient admitted to the reconstructive plastic surgery unit for trauma was young, male, of an economically active age, autonomous, a smoker, and from the city of Belém. Blunt trauma was the predominant cause of injury. The main traumatic events were traffic accidents and aggressions, with lower limbs being the most affected area of the body. The most commonly performed type of surgery was graft surgery. The percentage of surgical viability was independent of the age and distance travelled by the patient from the accident site to the hospital. Patients hospitalized on the same day as the accident were six times more likely to have surgical viability above 80%.

COLLABORATIONS

FSV	Final manuscript approval; supervision.
FAS	Analysis and/or data interpretation; conception and design study; data curation; investigation; project administration; writing - original draft preparation.
ANNF	Analysis and/or data interpretation; resources; writing - original draft preparation; writing - review & editing.
JPSN	Analysis and/or data interpretation; conception and design study; data curation; investigation; project administration; resources; writing - review & editing.
LSM	Conception and design study; formal analysis; investigation; methodology; project administration; resources; validation.

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Review Article

Body dysmorphic disorder from the perspective of the plastic surgeon

Transtorno dismórfico corporal sob a perspectiva do cirurgião plástico

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■ **ABSTRACT**

Body dysmorphic disorder (BDD) is found with a certain frequency in aesthetic-related care. However, it is underdiagnosed due to the difficulty in differentiating a personal dissatisfaction with body image of a pathological complaint. For BDD patients, the discomfort generated by their "defect" is often disproportionate to that observed on physical examination. In addition, in an attempt to correct their "defect", the patients undergoes various surgical procedures, which are often considered insufficient by the patients to solve their problem. Hence, this study aimed to expand the already existing discussions in the specialized literature. Since there are only a few studies on the topic, we plan to discuss this condition so as to contribute towards identification of the characteristics of this disorder, thus, avoiding unnecessary surgical procedures and guiding the specialist's actions in case of a legal dispute.

Keywords: Reconstructive surgical procedures; Psychiatry; Body image; Body dysmorphic disorders; Aesthetics.

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■ **RESUMO**

O transtorno dismórfico corporal é encontrado com uma certa frequência nos atendimentos relacionados à estética. Entretanto, permanece subdiagnosticado devido à dificuldade de diferenciar uma insatisfação pessoal natural com a imagem corporal de uma queixa patológica. Para os pacientes com TDC, o incômodo gerado pelo seu "defeito" costuma ser desproporcional ao que observamos no exame físico. Além disso, na tentativa de corrigir aquilo que não lhe agrada, ele se submete a diversos procedimentos cirúrgicos que, em grande parte das vezes, considerará insuficiente para a resolução do seu problema. Nesse sentido, buscamos, com este trabalho, ampliar as discussões já existentes na literatura especializada. Assim, assumindo a escassa bibliografia, tencionamos, além de construir discussões acerca dessa afecção, o que pode contribuir para a identificação dos traços desse transtorno, evitando, por conseguinte, a realização de procedimentos cirúrgicos desnecessários e nortear as ações do especialista no que diz respeito à possibilidade de uma disputa judicial.

Descritores: Procedimentos cirúrgicos reconstrutivos; Psiquiatria; Imagem corporal; Transtornos dismórficos corporais; Estética.

INTRODUCTION

The search for beauty or attractive appearance to others seems to be the object of fascination for humanity. Although it involves stereotypes that vary according to cultural standards, the notion of beauty, a dynamic concept of quest for perfection, may at some point, approach what has been termed psychic disorder, as already described by studies conducted in the area of psychiatry.

When we made a historical incursion, we realized that while endemic diseases and pests decimated a large number of people, obesity prevailed, as a synonym for health and well-being. Currently, we are observing a movement contrary to this perception, whose presuppositions show the supremacy of slenderness, i.e., being slim is considered beautiful. In this new context, delimiting the thin line between personal desire for aesthetic improvement and body dysmorphia can be a difficult task[1].

In the literature, dysmorphophobia was first described by Morsellini in 1886[2]. However, in Pitanguy et al.[3] referred to this term in 1976 in Brazilian literature. Dysmorphophobia is also known as the eponym of the Quasimodo Complex[4] and more recently as body dysmorphic disorder (BDD); dysmorphophobia was established as a disease in Volume III of the *Diagnostic and Statistical Manual of Mental Disorders* of 1987 (DSM-III-R) and is reported as *"Body Dysmorphic Disorder"* in the current DSM V, published in 2013[5].

In clinical practice, we observed that the patients affected by BDD present extreme dissatisfaction with their appearance, which translates into intense suffering. We also found reports of functional impairments in social and work life, high levels of stress and comorbidities. These factors contribute to the constant search for aesthetic procedures, culminating in mostly poor results[4,6,7].

We understand that when performing physical examination, specialists often notice minimal or nonexistent changes. From this viewpoint, it is up to the surgeon to identify the patient's type of disorder and to refer him, if necessary, to the psychiatrist. We emphasize, however, that in most cases this type of psychopathology may go unnoticed, and the professional should, therefore, try to protect himself against possible legal disputes[8]. This is the reason of this study.

Thus, on the basis of extensive research and clinical experience, we will try to develop the ideas presented here, with the intention of collaborating with the mosaic of studies carried out in the plastic surgery research field.

OBJECTIVE

In this study, we intend to demonstrate the relevance of BDD relevance in patients seeking plastic surgery services and to focus the attention of the physician on this condition, that is often forgotten.

We also seek to reiterate the importance of correct screening so that the team can refer patients for the appropriate treatment, thus, avoiding unnecessary aesthetic procedures. We also propose, in the case of BDD diagnostic uncertainty, to suggest possible ways for the surgeon to protect himself against the possibility of future legal problems.

METHODS

We conducted qualitative and quantitative research, wherein we searched for articles, dissertations, book chapters and theses that focus on BDD, dysmorphophobia and Quasimodo syndrome. To broaden our theoretical scope, in what concerns specifically databases, we emphasize PubMed, SciELO, Lilacs and Bireme.

DISCUSSION

Starting from the current expansion of aesthetic surgical procedures, which exceeded 10 million in 2005, according to Crerand et al.[9], and reached 629 thousand in Brazil alone in 2009[10], the exaggerated worship of physical form is evident. Among the factors that motivate the requirement for such aesthetic surgical procedures is the common notion that a sculptural body is necessary to achieve professional and personal success. Similarly, an increasingly precocious aesthetic concern among young people, the endless quest for perfection (facilitated by the vast tools of Plastic Surgery), constant discussions about diet, exercise, and fashion, which corroborate certain patterns of beauty, can feed among other factors, the experience lived in BDD. Such lifestyle conditions provide an environment conducive to the development of this condition, thus, making it more evident.

Bellino et al.[11] reported that 0.7% of the general population experiences the disease, while Macley reported an incidence of 1% to 2%[12]. Aouizerate et al. reported that 9.1% of the population may seek cosmetic surgery[13]. Although there are several social factors involved, the etiology is not fully understood to date. It is believed that the etiology may be associated with the patients' own psychological status regarding their image, as built from childhood and influenced by the external environment during development[14,15]. In addition, the patients who present an exaggerated self-criticism of their aesthetic appearance may be more likely to progress to this pathological condition[16].

More recent studies suggest the involvement of neurobiological abnormalities. For example, it is possible to detect neurotransmitter changes using functional magnetic resonance. Moreover, the studies also reported abnormal activations of specialized areas, as assessed by analytical and detailed visual processing, in these patients; these abnormal activations were more intense in patients with severe symptoms[7].

It is also observed that the patient may identify with the image of a certain person or character, leading him to seek ways that make him appear similar to the figure with whom he identifies himself. This identification may be related to what is considered an ideal of beauty and is often embodied in famous personalities, family members, or even inanimate figures, such as dolls[17].

BDD often develops in adolescence; the condition evolves gradually, with the initial concerns that were considered "normal" degenerating to pathological, over time (months to years). However, in some cases, BDD is suddenly triggered by important emotional events. At this point, the degree of *insight* involved, i.e., the self-perception of disease is variable. Hence, the patient's level of perception of his illness is minimal compared to the discomfort generated by the defect. Therefore, in objective terms, the sites involved in the complaints are similar to those of non-pathological conditions. However, we note that the level of suffering generated is intensified, which can lead to extreme stress, obsession, and emotional torture.

In this pathological context, the presence of another comorbidity, such as social phobia, becomes less important than it was in the past when very little was known about the disease[18].

Specialized studies indicate that a significant proportion of 12–15% of the patients have a correlation with obsessive compulsive disorder (OCD)[6], characterized by the presence of compulsive and repetitive behavioral stereotypes, such as the act of looking at oneself too long in the mirror or applying makeup excessively, a factor that can lead to confusion in the distinction between BDD and OCD. Moreover, depression, anxiety, abusive use of psychoactive substances, and even suicidal idealization are emphasized in 22 to 28% of the cases[19].

We have commonly observed that obsessive-compulsive disorder and other psychiatric conditions are associated with eating disorders, such as anorexia and bulimia, which are also associated with dysmorphophobia[17]. The degree of severity may range from almost normal to mild to severe impairment of functionality in patients who only leave the house at night to avoid public encounters.

In severe cases described in the available literature, there are events of violence against the physician, including murders, fruits of achieved "failure"[6,8,13]. Therefore, we should be aware of BDD in patients seeking aesthetic care who report of various

procedures performed, which were unsatisfactory or unnecessary.

Consequently, even in those who have had little or no previous surgery, it is up to the specialist to carry out careful anamnesis, with the purpose of eliciting a diagnosis due to unfounded complaints of minimal or unnoticeable defects, refined physical examination, and administration of a questionnaire[20] investigating the degree of discomfort generated by the "deformity". If necessary, the doctor may contact surgeons who have treated the patient previously or even seek medical history[8].

We propose that treatment should be conducted mainly by the psychiatrist and the psychologist and should involve cognitive-behavioral measures and lifestyle changes, inclining towards a more active lifestyle. We also understand that medication can be used, such as selective serotonin reuptake inhibitors and tricyclic antidepressants, which can produce satisfactory results. After this follow-up, the patient may return to the plastic surgery outpatient clinic for reassessment[21].

Based on our discussion thus far, we understand that from a legal viewpoint, the plastic surgeon must protect himself against possible judicial litigation. Hence, preoperative documentation is of great value in the case of BDD. We also emphasized the use of a questionnaire, such as COPS[22].

The surgeons may also protect themselves by ensuring that the patients signs a Free and Informed Consent Term (FICT), through which the patient can authorize that his current physician can contact other experts already consulted, thus, valuable information may be obtained from the patient's records that may reveal presence of the disorder. Finally, we believe that the patient should agree that the final surgery outcome may not be exactly as he expects, since the surgical process is subject to biological variations and intercurrences inherent to the surgeon[8].

Considering the possibility of a legal dispute, we must mention that we were unable to find guidelines that a plastic surgeon must follow in this respect in the available literature. However, considering the cases already described, we understand that these can serve as a reference for the specialist in such situations.

In judicial dispute cases, we also noted that a patient's lawyer could question the validity of the signed FICT in the court, based on the presence of BDD, which in the light of law, would compromise the judgment of his client. Nevertheless, we believe that such an argument could be invalidated, since there is no established diagnosis of BDD in the patient's medical history. Thus, although signing this document is a legal practice to ensure that the patient is aware of all the risks involved in a surgical procedure, we defend that it is the physician's duty to inform the patient of the possible material risks and complications and of clarifying that the final surgical result is influenced by interference from factors not related to medical conduct, thus, avoiding questioning of the document's validity and possible allegations of negligence[8].

CONCLUSION

Considering the BDD prevalence and its relevance among patients seeking aesthetic surgeries, we emphasize the diagnostic possibility of BDD in patients with unfounded and distorted complaints. Due to the challenging nature of the disease, the surgeon must be careful in his approach, including proper anamnesis and careful observation. We believe that demonstrating receptivity and understanding is fundamental, rather than merely referring the patient to the psychiatrist.

We reiterate that surgery in these cases will often lead to unsatisfactory results for both the patient and the surgeon and may even lead to judicial outcomes.

Regarding the appropriate treatment, we suggest selective serotonin reuptake inhibitors and cognitive behavioral therapy, according to the condition's severity.

With respect to other considerations, we suggest that more studies are needed with the aim of facilitating diagnosis and standardization of conducts. In addition, we believe that it is necessary to estimate the real prevalence of psychopathology in the population, which could imply decreased requirement for unnecessary surgical procedures and fewer lawsuits.

Finally, from the legal viewpoint, the physician must guard against possible legal problems involving the surgical outcomes and the dissatisfaction of a BDD patient. To do so, the physician must use all various resources available, considering that there are no laws or well-defined guidelines for a legal dispute between BDD patient and his doctor.

COLLABORATIONS

MTD	Analysis and/or data interpretation, conceptualization, final manuscript approval, writing - original draft preparation, writing - review & editing.
MPDC	Analysis and/or data interpretation, final manuscript approval, project administration, writing - original draft preparation, writing - review & editing.
LDC	Writing - original draft preparation, writing - review & editing.

GVD Writing - original draft preparation, writing - review & editing.

AAS Writing - original draft preparation, writing - review & editing.

LVD Writing - original draft preparation, writing - review & editing.

LDC Writing - original draft preparation, writing - review & editing.

YMO Writing - original draft preparation, writing - review & editing.

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Review Article

Prevalence of lymphedema after mastectomy in women living with breast cancer: a systematic review of the influence of immediate reconstruction

Prevalência de linfedema após mastectomia em portadoras de câncer de mama: uma revisão sistemática acerca da influência da reconstrução imediata

RAFAEL VILELA EIRAS RIBEIRO [1,2]*

■ **ABSTRACT**

This study aimed to analyze, through systematic review of literature, the influence of immediate reconstruction on the prevalence of lymphedema after mastectomy, in women living with breast cancer. The analysis considered the most relevant studies originally published, in any language, up to August 2018, indexed on the databases of the US National Library of Medicine, Cochrane Central Register of Controlled Trials, Web of Science, and Scientific Electronic Library Online. The sample comprised 10 publications that met the established criteria for inclusion and exclusion , including 2,425 patients who were subjected to mastectomy alone, and 2,772 patients who were subjected to mastectomy associated with immediate reconstruction of the breast . The prevalence of lymphedema was 20.95% in patients who had been subjected to mastectomy alone (n = 508), and 5.23% among those patients who were subjected to mastectomy associated with immediate reconstruction of the breast (n = 145), the difference being statistically significant ($p < 0.001$). We concluded that mastectomy, when associated with immediate breast reconstruction, has a positive influence on the prognosis of patients living with breast cancer, thereby providing a much lower rate of lymphedema when compared with mastectomy alone.

Keywords: Mastectomy; Breast cancer–related lymphedema; Mammoplasty; Breast neoplasms; Excision of lymph nodes.

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■ **RESUMO**

Este estudo objetivou analisar, por meio de uma revisão sistemática da literatura, a influência da reconstrução imediata na prevalência de linfedema após mastectomia em pacientes portadoras de câncer de mama. Foram analisados os mais relevantes estudos publicados originalmente em qualquer idioma até agosto de 2018, indexados às bases de dados US National Library of Medicine, Cochrane Central Register of Controlled Trials, Web of Science e Scientific Electronic Library Online. A amostra foi composta por 10 publicações que se adequaram aos critérios de inclusão e exclusão estabelecidos, incluindo 2.425 pacientes submetidas a apenas mastectomia e 2.772 pacientes submetidas à mastectomia associada à reconstrução imediata da mama. A prevalência de linfedema foi 20,95% nas pacientes submetidas a apenas mastectomia (n = 508) e de 5,23% nas pacientes submetidas à mastectomia associada à reconstrução imediata (n = 145), havendo diferença estatisticamente significativa ($p < 0,001$). Concluiu-se que a mastectomia associada à reconstrução imediata influencia positivamente o prognóstico das pacientes portadoras de câncer de mama, proporcionando um índice significativamente menor de linfedema, quando comparada à realização de apenas mastectomia.

Descritores: Mastectomia; Linfedema relacionado a câncer de mama; Mamoplastia; Neoplasias da mama; Excisão de linfonodo.

INTRODUCTION

In Brazil, it is estimated that breast cancer shall be the most common cancer among women in 2018 and 2019, accounting for 29.5% of all new cases of cancer in the country[1]. The treatment of patients with breast cancer, and therefore this cancer's aggressiveness, is set by the characteristics of the illness at the time of diagnosis. The main interventions that can be carried out, whether singly or in combination, are surgery (conservative surgery or mastectomy), radiotherapy, chemotherapy, and hormone therapy[2].

Among the complications that occur after surgery for breast cancer, the most common one is lymphedema, a chronic condition that is brought about by the presence of a protein-rich fluid in the interstitial space[3-6]. The onset of lymphedema can happen immediately after surgery, in rare cases, or occur years after treatment[6-10].

The etiology and risk factors for lymphedema seem to result from several different factors, which are not totally known. In general, it is well known that the main risk factors are: lymphadenectomy and/or axillary radiotherapy; obesity; and invasive procedures on limbs on the same side as the breast cancer[11,12].

Whenever mastectomy is recommended, breast reconstruction is also considered and can be performed either immediately or after the initial procedure (late breast reconstruction)[13]. However, considering the fall in morbidity provided by breast reconstruction carried out immediately after mastectomy, thereby reducing the surgical procedure and increasing patient satisfaction, it is important to identify the rate at which lymphedema occurs when this type of surgical procedure is performed.

OBJECTIVE

This study aimed to analyze, through systematic review of literature, the influence of immediate breast reconstruction on the prevalence of lymphedema after mastectomy, among patients with breast cancer.

METHODS

To comply with the proposed objective, we used a method based on the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA)[14] guideline for systematic reviews. We analyzed the most relevant studies that were originally brought out in any language, up to August 2018, but which were in some way indexed by the databases: US National Library

of Medicine (PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science and Scientific Electronic Library Online (SciELO), where the searches were carried out.

Seeking to choose high-quality studies of scientific evidence, we sought meta-analyses and randomized controlled clinical trials (RCCTs) on human subjects, without any restrictions as to the year of publication.

The following key words have been used, in different combinations: "lymphedema", "lymphoedema", "postmastectomy", "mastectomy", "breast cancer surgery", "prevalence", and "incidence".

Criteria for inclusion and exclusion were applied, as set out in Chart 1.

The selection of the publications was first made based on an analysis of the title and of the abstract of the studies obtained resulting from the searches (Stage 1), then moving on to the elimination of duplicate results obtained in the different databases as researched (Stage 2). Afterwards, the complete versions of the publications were read, with the application of the criteria of inclusion and exclusion (Stage 3), seeking to select the publications to be included in the sample.

We must point out that the sample for this study has included all the studies that have enabled the collection of data on the prevalence of lymphedema in female patients with breast cancer, specifically after mastectomy, or in cases of mastectomy associated with immediate breast reconstruction, or comparative studies considering these two surgical approaches. The exclusion criteria were the same as those used by Menezes at al[15], that addressed late breast reconstructions, as also any studies in which lymphedema occurred only in a cumulative way, not allowing the collection of data regarding the total number of patients who developed this disease[9,16].

In the publications included in the study sample, data were collected regarding the type and the number of surgical operations, the mean age of the patients, the method used for diagnosis, the period of monitoring, criteria for the identification of lymphedema, and the number of patients who exhibited this disorder. This data were then subjected to a meta-analysis for the establishment of the results of this study.

The statistical analysis of data, comparing the prevalence of lymphedema between mastectomized patients who had and had not been subjected to immediate breast reconstruction, was made using the software SPSS for Windows 15 (IBM SPSS Software,

Chart 1. Criteria for inclusion and exclusion of publications.

Criteria for Inclusion		
Delineation	•	RCCT
•	Meta-analysis	
•	Series of cases	
Sample	•	Humans
Intervention	•	Mastectomy only
•	Mastectomy associated with immediate reconstruction	
•	Comparison between the approaches as mentioned	
Period of publication	•	Unspecified
Language	•	Undefined
Criteria for Exclusion		
Delineation	•	Poorly explained and/or incomprehensible methodology
•	Case report	
•	Review of the literature	
Intervention	•	Mastectomy associated with late breast reconstruction
•	Non-surgical or unspecified treatment	
Method of publication	•	Abstract only

New York, USA), with use of the exact Fisher test with a significance level of $p < 0.05$.

RESULTS

The searches carried out in different databases resulted in a sample of 248 different publications, which was reduced to 71 after the first stage of analysis (title and abstract), then further reduced to 33 after the second stage of analysis (removal of duplicates), and finally the group was further reduced, with only 10 publications remaining after the third and final stage of analysis (analysis of the full content of the articles); these met the criteria established for inclusion and exclusion.

Out of the 10 studies included in the sample of this meta-analysis, five addressed the prevalence of lymphedema in patients subjected to mastectomy alone[10,17-20]; two discussed the prevalence of lymphedema in patients subjected to mastectomy associated with immediate breast reconstruction[6,21], while the final three studies compared both approaches[22-24].

In all, the publications included in this sample included 2,425 patients who were submitted only to mastectomy, and 2,772 patients who had been subjected to mastectomy associated with immediate breast reconstruction; the mean ages of these two groups were 51.05 and 47.75 years respectively. The patients who were subjected only to mastectomy had a body mass index (BMI) of 25.97, while those patients who had mastectomy with immediate breast reconstruction had a mean BMI of 23.86 (Tables 1 and 2).

As we can see in Tables 3 and 4, lymphedema had a prevalence of 20.95% among patients who had mastectomy only (508/2,425), while in the case of those patients who had mastectomies associated with immediate breast reconstruction, the prevalence was 5.23% (145/2,772). The exact Fisher test showed a statistically significant difference ($p < 0.001$).

DISCUSSION

Interest in the prognosis for patients undergoing treatment for breast cancer has increased considerably over the last few decades, both as a result of the increase in the number of new cases as also due to a search for better therapeutic options[2,6,8-10]. One of the factors that has triggered new studies is the occurrence of lymphedema in patients who have been subjected to mastectomy[4-6,11,21,22], a topic that is still a cause for considerable controversy in the literature, especially with regard to factors related to etiology.

Here, we must point out that some factors of methodology could justify the controversy between the results obtained in different studies, such as the methods and the diagnostic criteria regarding lymphedema, as used by different authors. Most of the studies included in the sample used in this research used the method based on measurement of the circumference of the arm as a way to diagnose lymphedema[10,17-19,22]. There was a study that used a perometer together with arm measurement[18] or on an exclusive basis[24]; studies that used subjective evaluation by a specialist doctor (not using specific instruments, but just mentioning the appearance of clinical signs and symptoms)[6,23]; a study that made use of self-examination[20]; and another study that did not even mention the method used[21].

As a criterion for diagnosis of lymphedema, most studies used an arm circumference of over 2 cm as the only criterion[10,17,19,22] or together with an increase of at least 10% in arm volume[18]. There was also one study that used the presence of hydropsy and a difference of at least 1.27 cm between arm circumferences[20]; four studies did not describe the diagnostic criterion in their methodologies[6,21,23,24].

It is well known that lymphedema can appear

Table 1. General characteristics of the patients subjected to mastectomy only.

Study	Surgical operations (n)	Mean age (years)	Mean BMI (kg/m^2)	*Follow-up*
Freitas Júnior et al.[17]	109	42.0	-	48 months
Petrek et al.[20]	263	52.3	-	20 years
Nesvold et al.[18]	263	55.0	26	Mean: 48 months
Park et al.[19]	450	50.0	-	24 months
Avraham et al.[22]	130	61	26	-
Card et al.[23]	549	-	28.6	Mean: 59 months
Lee et al.[24]	595	46.0	23.3	Mean: 53 months
Pandey & Shrestha[10]	66	-	-	12 months
TOTAL	2,425	-	-	-
MEAN	-	51.05	25.975	-

n: Number of cases; BMI: Body Mass Index; kg = kilos; m^2 =square meter; -: not specified in publication.

Table 2. General characteristics of the patients subjected to mastectomy and immediate breast reconstruction.

Study	Surgical operations (n)	Mean age (years)	Mean BMI (kg/m²)	*Mean Follow-up*
Avraham et al.[22]	186	45	24	-
Card et al.[23]	541	-	25.7	59 months
Crosby et al.[21]	1,499	50	25.7	56 months
Lee et al.[24]	117	45.0	21.9	53 months
Lee et al.[6]	429	43.0	22.0	45.3 months
TOTAL	2,772	-	-	-
MEAN	-	45.75	23.86	53.3 months

n: Number of cases; BMI: Body Mass Index; kg = kilos; m² =square meter; -: not specified in publication.

Table 3. Prevalence of lymphedema after mastectomy alone.

Study	Surgical operations (n)				Lymphedema				
	Total	SM	SM+ALND	MRM	SM (n)	SM+ALND (n)	MRM (n)	Total n	Total %
Freitas Júnior et al.[17]	109	-	-	-	-	-	-	15	13.76
Petrek et al.[20]	263	-	-	-	-	-	-	128	48.67
Nesvold et al.[18]	263	77	-	186	6	-	37	43	16.35
Park et al.[19]	450	54	145	251	3	32	77	112	24.89
Avraham et al.[22]	130	59	71	-	8	28	-	36	27.69
Card et al.[23]	549	474	100	-	-	-	-	57	10.38
Lee et al.[24]	595	-	-	595	-	-	110	110	18.49
Pandey & Shrestha[10]	66	12	-	54	2	-	5	7	10.61
TOTAL	2,425	676	316	1,086	19	60	229	508	20.95

n: number of cases; -: data not supplied by the study; %: percentage; SM: simple mastectomy; SM+ALND: simple mastectomy associated with axillary lymph node dissection; MRM: modified radical mastectomy.

Table 4. Prevalence of lymphedema after mastectomy associated with immediate breast reconstruction.

Study	Surgical operations (n)				Lymphedema				
	Total	SM	SM+ALND	MRM	SM (n)	SM+ALND (n)	MRM (n)	Total n	Total %
Avraham et al.[22]	186	93	93	-	6	23	-	29	15.59
Card et al.[23]	541	474	100	-	-	-	-	21	3.88
Crosby et al.[21]	1,499	1,067	432	-	7	43	-	50	3.34
Lee et al.[24]	117	-	-	117	-	-	11	11	9.40
Lee et al.[6]	429	280	149	-	-	-	-	34	7.93
TOTAL	2,772	1,914	774	114	13	66	11	145	5.23

n: number of cases; -: data not supplied by the study; %: percentage; SM: simple mastectomy; SM+ALND: simple mastectomy associated with axillary lymph node dissection; MRM: modified radical mastectomy.

immediately after mastectomy or even years after surgery[6-10], and two of the studies here that were analyzed show that most patients showed some signs of lymphedema in the first year after surgery.[17,18].

Age is a controversial causative factor. While two studies included in this study did not find any statistically significant differences with regard to this variable[19,21], another three studies did indeed show a rise in the occurrence of lymphedema related to increased age of the patients who had mastectomies at the time of surgery[6,17,24].

Moreover, some authors have associated the development of lymphedema in post-mastectomy patients with overweight and obesity[11,12]. In general, the studies included here confirm this association. Apart from the studies where overweight and obesity are statistically shown to be causative factors[17,19], in the studies where obesity showed no statistical association

with lymphedema, there was a significant association of overweight as a causative factor[20,22].

Furthermore, some studies have also confirmed that higher BMI levels (BMI > 25) were significantly associated with the occurrence of lymphedema[6,21]. According to Freitas Júnior et al.[17], a possible cause for this positive association between higher BMI and the onset of lymphedema lies in the greater difficulty for the lymph to return in patients with a greater amount of fatty tissue.

We also point out that, in this study, the BMI of the patients who had mastectomy alone was higher (25.97 kg/m^2) than that of patients who had mastectomies associated with immediate breast reconstruction (23.86 kg/m^2). This shows that studies should standardize selection or division of the patients into groups according to their BMI to make it more feasible to confirm this factor as an element of proneness to the occurrence of lymphedema after mastectomy.

Some authors mention that dissection of the axillary lymph node is also a risk factor for the development of lymphedema after a mastectomy[11,12]. This was confirmed by this systematic review, as studies show that lymphadenectomy significantly increases the occurrence of lymphedema[6,19], both when a simple mastectomy is performed along with dissection of the axillary lymph nodes, as also when the technique of modified radical mastectomy is used[19].

It is well known that immediate breast reconstruction is a technique that confers many benefits to the patients, especially those whose breast cancers are in the early stages. These benefits include: prevention of disfiguration of the chest wall; reduction in costs; increased self-esteem; and general improvement in quality of life[6,23,25]. This technique has been prioritized in literature because it confers these benefits without affecting the biological behavior of the breast cancer or promoting any relapse or having any interference on auxiliary chemotherapy[23,26].

In this study, we observed that apart from the benefits mentioned in the literature with regard to immediate breast reconstruction, this technique also has a potential to reduce the development of lymphedema among patients with mastectomies. Confirming the findings of some previous studies[22-24], the results of this study show that the immediate breast reconstruction technique brought a significant reduction (p <0.001) in cases with lymphedema that was present in 5,23% of the patients subjected to mastectomy with immediate reconstruction, compared to the 20.95% observed among patients who received no breast reconstruction.

It is important to emphasize that literature states that radiotherapy can be an important causative factor for the development of lymphedemas among patients who have had mastectomies for treatment of breast cancer[11,12]. However, out of the ten studies included in the sample used in this study, most of them[10,17,18,20-23] did not address the radiotherapeutic protocols to which the patients were subjected. This made it infeasible to establish a correlation between this factor and the development of lymphedema in both the treatment approaches addressed here.

In the three studies that considered this approach[6,19,24], there was an influence of radiotherapy on the development of lymphedema, which increased according to the use of radiotherapy or the increase of the quantity used. In this regard, we mention the importance of standardization and division of groups of patients in further studies addressing this subject.

We also stress the importance of carrying out further studies on the occurrence of lymphedema in mastectomized patients, with methodologies duly standardized between them, and with greater monitoring time, especially when comparing mastectomy alone and the association of mastectomies with immediate or late breast reconstruction, which is still a gap in the literature. This would favor the acceptance and acknowledgment of surgical techniques that offer a better prognosis to patients with breast cancer.

CONCLUSION

Based on our systematic review, we concluded that mastectomy associated with immediate breast reconstruction positively influenced the prognosis of patients with breast cancer, resulting in a significantly lower rate of occurrence of lymphedema, when compared to cases where mastectomy alone was performed. Provided there are no contraindications, we can use immediate breast reconstruction after mastectomies on patients undergoing treatment against breast cancer, in a safe and efficient way, with a view to reducing the risk of developing lymphedema.

COLLABORATIONS

RVER Analysis and/or data interpretation, conception and design study, data curation, final manuscript approval, investigation, methodology, project administration, realization of operations and/or trials, writing - original draft preparation, writing - review & editing.

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Review Article

New technologies and innovations in breast surgery

Novas tecnologias e inovações em cirurgia mamária

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■ **ABSTRACT**

Introduction: Breast surgery with silicone implants is gaining popularity and has become the most performed plastic surgery worldwide. However, there is increasing concern about the safety of silicone breast implants due to associated complications. **Objective:** To review existing technologies, technological trends, and existing methods to minimize complications related to silicone breast implants. **Methods:** We conducted a literature review of articles describing new technologies and trends to reduce complications related to silicone breast implants, along with information on patents and manufacturers of silicone breast implants. **Results:** We initially identified 78 articles, out of which 40 were shortlisted for publication . All articles had a common aim of obtaining better results and reducing complications related to silicone implants, either in aesthetic or reconstructive surgeries. **Conclusion:** The search for a breast implant that reduces possible and frequent complications, especially biofilm formation, infectious processes, and abnormal immune response, was the focus of most articles studied. Acellular dermal matrix and fat grafting have been reported in the literature as promising alternatives.

Keywords: Mammoplasty; Breast implants; Silicone elastomers; Reconstructive surgical procedures/trends.

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■ **RESUMO**

Introdução: A cirurgia de mama, especialmente as associadas aos implantes de silicone, teve uma crescente popularização, tornando-se a cirurgia plástica mais realizada no mundo. Junto com esta proliferação, observa-se um aumento da preocupação com a segurança dos implantes mamários de silicone, pelas intercorrências relacionadas. **Objetivo:** Revisar métodos existentes para minimizar as complicações relacionadas com implante mamário de silicone, bem como as tecnologias existentes e tendências tecnológicas para implantes mamários de silicone. **Métodos:** Foi realizada revisão de artigos científicos relacionados com novas tecnologias e tendências para redução das complicações relacionadas com implantes mamários de silicone, bem como as patentes e fabricantes de implante de silicone mamário. **Resultados:** Identificamos inicialmente 78 referências, sendo reduzido para 40 para publicação, todos com linhas de pesquisas que buscam melhores resultados e redução das complicações relacionadas com implantes de silicone, seja esta cirurgia com objetivo estético ou reconstrutivo. **Conclusão:** A busca por um implante mamário que reduza as possíveis e frequentes complicações, principalmente a formação do biofilme, processos infecciosos e resposta imune, é o foco da maioria das pesquisas encontradas. Com o mesmo objetivo, porém surgindo mais recentemente como alternativas, existem as pesquisas para o uso de matriz dérmica acelular e a lipoenxertia, com boas expectativas.

Descritores: Mamoplastia; Implantes de mama; Elastômeros de silicone; Procedimentos cirúrgicos reconstrutivos/tendências.

INTRODUCTION

Thousands of women opt for breast surgery, since well-endowed breasts are an indicator of feminine beauty in various cultures and there is great social appeal and media stimulation advocating these procedures[1]; this has recently led to a revolution in the silicone industry, with a significant increase in the number of manufacturers offering various models, different profiles, gel densities, and various characteristics of envelopes for pleasant and safe results.

Breast surgery with silicone implants has off late been experiencing growing popularity as the most commonly performed aesthetic surgical procedure worldwide[2]. With aesthetic silicon breast implant surgeries being performed worldwide only in 2016, according to statistics from the International Society of Aesthetic Plastic Surgeons, Brazil was responsible for 13.64% (206,250) of these.

In fact, the number of breast reconstruction surgeries is growing, with silicone implants being used more predominantly than regional tissue flaps due to the ability of silicone to mimic natural breasts[3]. Representatively, only in the United States, 300,000 new cases of breast cancer are diagnosed every year. Of these, 118,000 patients choose to undergo breast reconstruction, out of which 69% opt for silicone implants while the remaining 31% use flaps[4].

Alongside the increasing popularity of silicone breast implants, there is an increased concern about their safety[5], manufacturing defects[6], and the most common complications related to the presence of synthetic material in the breast region, such as capsular contracture, infections, biofilm formation[7], bleeding, rupture[8], and rarer conditions such as siliconomas[9], and more recently, breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)[10-13], which have been reported in several articles[1].

These complications may lead to unexpected additional treatments and reinterventions in 25 to 36% patients[14]. In another study[1], rates of reoperation were compared between two brands of manufacturers 6 years after the procedure. Reintervention rates of 28% and 19.4% were observed in aesthetic surgeries performed with Allergan® implants and Mentor® implants, respectively. In the same study, reintervention rates of 51% and 33.9% were observed in repair

surgeries performed with Allergan® implants and Mentor® implants, respectively, with a significant increase in costs incurred during the treatment of these complications[14], in addition to compromised patient-physician relationship and uncertainty about the safety and reliability of silicone implant surgeries.

On literature review, we identified research articles aiming at obtaining better results and especially, minimizing complications related to silicone implants, in both aesthetic and reconstructive surgeries.

OBJECTIVE

This study aims to review the existing technologies and technological trends related to silicone breast implants and methods to minimize related complications.

METHODS

We carried out a literature review of articles published in the last 10 years related to patents, manufacturers, and new technologies and trends to reduce complications related to silicone breast implants.

RESULTS

Initially, 78 articles were found, out of which 40 were shortlisted for publication. All articles had a common aim of obtaining better results and reducing complications related to silicone implants, in both aesthetic or reconstructive surgeries.

The published studies, new implant models, and issued patents focus on research of factors that diminish the immune response, improve the coating surface, and nanotechnology, in addition to exploring the feasibility of implants with acellular dermal matrix and fat grafting. Research has also been carried out to find ways to improve the implant content.

Factors associated with complications of breast implants were studied and may be related to the implant itself, surgical management, manufacturing artifacts, and the response of the body to silicone[8].

DISCUSSION

For ease of understanding, we have divided the discussion into four topics:

1. Surface of silicone implants
2. Latest technology in silicone implants
3. Association of silicone implants with acellular dermal matrix
4. Association of silicone implants with fat grafting

Surface of silicone implants

Most studies found in the literature were focused on the improvement of the surface of breast silicone implants.

It is important to understand that the surface properties of the implant impact the inflammatory cellular response, because the surface is the interface between the implant and organic tissues, and the primary site where the antigen-antibody reaction occurs. Development of implants is fundamental in providing satisfactory solutions to minimize long-term clinical complications[15].

Therefore, there has been a lot of research for its improvement, especially to avoid infection and capsular contracture.

Topical antibiotics. The use of topical antibiotics has been mentioned in several studies, demonstrating that when instilled or implanted into the external surface of silicone implants, antimicrobials decrease the formation of biofilm, capsular contracture, seroma, and infection[16].

Importantly, recent clinical studies[17-19] reported that infections due to breast silicone prostheses can be treated at a single time using both aesthetic and repair surgery, with subsequent resolution of the infection.

Povidone-iodine solution. At the end of 2017, the Food and Drug Administration (FDA) approved the use of Betadine (povidone-iodine) to prevent the formation of biofilm and infection, as it has a broad spectrum against Gram+ bacteria, which are related to capsular contracture, and Gram-, more related to BIA-ALCL. Previously, since 2000, the FDA believed that povidone-iodine could degrade the silicone implant capsule, and this change represents a major advance in the prevention of complications.[20]

Recently, a controlled experimental study has demonstrated decontamination of infected breast silicone implants after brushing povidone-iodine for 1 minute and removing excess saline solution[21]. This leads to a heightened expectation of the treatment of infection in one surgical stage, as described in other studies[17-19].

Surface texture. It is generally known that capsular contracture is more frequent in implants with a smooth surface and less frequent in microtextured and macrotextured surfaces. Some recent studies[22-24] sought to minimize this complication but could not completely avoid it.

More recently[23,24], there is evidence of increased bacterial contamination in silicone implants with macrotextured surfaces due to more space being available for bacterial growth.

Moreover, scientific evidence[10-13] shows that BIA-ALCL is more likely to occur in macrotextured silicone implants.

Alternative surfaces of silicone breast implant

Novel surfaces aimed at preventing complications related to the textured surface of conventional implants are being developed.

A study reported the development, manufacture, and evaluation of an implant surface obtained from human tissue aimed at biomimicking, with increased compatibility and decreased capsular contracture[25]. This *in vitro* experimental study used a treated and prepared fat surface of 3 patients fixed with gold and palladium and demonstrated a decreased inflammatory response that was evaluated by cytokine and C-reactive protein levels.

Another study described a modification of the surface with implantation of carbon ions[26] tested in 3 different doses in order to increase biocompatibility. This implantation reduced surface roughness, bacterial adhesion, and capsule formation in an *in vitro* and *in vivo* experimental study in 16 rats. The results were more evident with higher doses of carbon ions.

A patent issued in 2017 (registration No. US2017/0049549 A1 by Bayat and contributors - University of Manchester, UK) describes a new biomimetic textured surface topography, with roughness control on macro, micro, and nanoscales simulating the topography (basement membrane and papillary dermis) of human skin. No experimental or clinical trials analyzed this patent.

Another patent (registration No. US0209618 A1 by Mark Anton, 2017) describes a second outer layer of polytetrafluoroethylene (PTFE) to decrease capsular contracture, acting as a reservoir. It utilizes PTFE, rifampicin, verapamil, α-tocopherol (Vitamin E), and methylprednisolone to reduce the risk of infection and biofilm formation, thus forming a third layer with slow or late release, promoting cellular adhesion. It would be used to confer a more natural appearance, similar to natural skin and lighter, because PTFE has a lower density than silicone. It makes use of nanotechnology that repels water (hydrophobia) helping in biocompatibility, with less possibility of capsular contracture. We found no clinical trials analyzing this patent as well.

Nanotechnology in breast silicone implants

Nano and surface microtopography aim at influencing cell polarization, alignment, migration, coupling, adhesion, proliferation, and morphological nature at the nano and micro levels, thus leading to cells reacting more naturally to surrounding structures[27].

Recent studies suggest that the inflammatory response in these new models is lower, with better scattered and spindle-shaped fibroblasts and milder surface reactions by macrophages, thus indicating a more favorable foreign body reaction[1,27].

In the technological line, some studies describe a breast silicone implant coated with halofuginone nanofibers[28], inhibitors of collagen synthesis type I that interferes with the synthesis of transforming growth factor β (TGF-β) which, in an experimental study using the submuscular plane of 28 rats, showed no systemic reaction; a decrease in histiocytes, CD68 marker (type I collagen), TGF-β, fibroblasts, type I and III collagens; and capsular thickening.

More recently, a clinical study[29] analyzed 5813 breast implants, with a maximum of 3 years of follow-up, using implants with nano and microtextures, built with uniform topography using three-dimensional silicone printing to create optimized biocompatible external surfaces. The manufacturing was described as particle-free and did not use extrusion of foreign material to create the surface geometry, thus allowing a surface of uniform and controlled thickness. Complications such as seroma, infection, hematoma, dehiscence, rupture, and malposition of the implant occurred in 0.36% of the implants with nanotexture surface and in 1.06% of the surface implants with microtexture surface. However, capsular contracture and the eventual incidence of BIA-ALCL could not be evaluated conclusively in a short time period.

Latest technology silicone implants

We identified 4 silicone breast implants utilizing innovative and recent technology:

Ideal Implant®. It is a structured breast implant approved by the FDA and Health Canada in November 2014 which combines the benefits of saline and gel implants with intercommunicate lumens filled with saline solution, with frontal and posterior valves for filling. It was subjected to screening in 502 patients, 399 undergoing primary augmentation and 103 undergoing implant replacement and used in 35 different cities by 45 certified plastic surgeons with 6-year follow-up in 438 cases (87.3%). The satisfaction reported by the patients was 89.7% in primary cases and 91.6% in cases of implant replacement, and the satisfaction reported by surgeons was 92.6% in primary cases and 94% in cases of implant replacement. Contractures of Baker grades III and IV were observed in 5.7% of primary cases and 11.5% of cases of implant replacement. Rupture/deflation were observed in 1.8% of primary cases and 4.7% of cases of implant replacement.

Microchip or Microtransponder. Two articles[18,29] described a 9×2.1-mm sized radiofrequency microchip or microtransponder positioned inside the silicone gel near the center of its base, for identification and postoperative tracking by Radio-Frequency Identification (RFID), with a specific device of the

manufacturer Motiva®. RFID is a technological trend in other specialties such as veterinary. In the field of breast implants, it provides technical information about the implant. It is expected that in the future, RFID can store data from breast exams, hospital data from surgery, and global online updates.

The presence of RFID raised questions about its safety in imaging diagnostic methods, especially magnetic resonance imaging (MRI), with possible interference in the diagnosis of breast neoplasms, because it has a ferrite/copper antenna and iron is a material with great interference with artifacts on MRI. Initial evaluations show that RFID is compatible with clinical MRI, with a magnetic field of 1.5 or 3.0 Tesla, causing temperature increase (3 °C) after 15 minutes of continuous pulse (regular exams rarely exceed 3 minutes), and not showing any RFID displacement or torsion.

Initial evaluations show that an artifact is seen on MRI, being greater in the inner posterior face of the implant with extension to the chest wall, without significantly affecting the breast tissue and subcutaneous tissue. Further studies need to be conducted to evaluate this interference, especially if the RFID migrates to the interior of the implant over the years, and in cases of implant rotation with the base positioned next to the breast tissues.

B-Lite®. It refers to a light silicone breast implant which relies on the reduction of mechanical tension on the tissues to reduce pain in the postoperative period. It consists of silicone gel with borosilicate crystal microspheres, chemically attached to the silicone gel, fixed by a curing process and treated to increase the hydrophobic property and ensure that it remains fixed to the silicone gel without mixing and avoiding overflow of these microspheres, which leads to a reduction in the weight of the implant by up to 30%[31]. In this study, conducted in 100 cases, the B-Lite® implant was used in half of the patients and conventional Eurosilicone® and Allergan CUI® gel implants were used in the other half, with access through the breast crease and the subglandular plane in more than 90% of the cases. A statistically significant reduction in pain and shorter recovery time was demonstrated by the Fischer's test and Cox regression model[32].

Diagon/Gel 4Two® implant. The Polytech® Diagon/Gel 4Two® implant consists of an implant with polyurethane coating (macrotexture) and two types of gel inside, a less dense posterior one and a higher density anterior one to better position the areola and support the residual breast tissue[33].

A preliminary study with 894 cases followed for 5.5 years, showed low rates of complications with no statistical significance, with 2 cases of late seroma, 4 cases of hematomas, no case of capsular contracture, and having a patient satisfaction rate of 90%. Since it is a new type of implant, further statistically significant studies need to be conducted to better evaluate complications, if any.

Association of silicone implants with acellular dermal matrix

More recently, acellular dermal matrix (ADM) has appeared as an alternative especially for breast reconstructive surgery with silicone implants to improve the positioning of the implants and tissue expansion dynamics, providing greater intraoperative filling and lower frequency of expansion sessions, leading to superior aesthetic results. The refinement of the technique and accumulated experience have decreased the morbidity initially related to ADM[34].

It has now emerged as a potential tool for surgical prevention of capsular contracture. ADMs are immunologically inert, minimizing capsular formation in experimental models, which results in decreased inflammatory process, proliferation of myofibroblastic cells, and capsular thickness. This reduction is observed even in irradiated tissues.

Some surgeons modified ADMs by performing fenestrations to improve support, and the results were similar. It has already been used for both prevention and treatment of capsular contractures[35].

Currently, there are several types of ADMs, and they have been used for breast reconstruction with the following silicone implants: AlloDerm (LifeCel Corp. Branchburg, NJ), DermaMatrix (Synthes Inc. West Chester, PA), FlexHD (Ethicon Inc. Somerville, NJ), Strattice (Lifecell Corp), and SurgiMend (TEI Biosciences Inc. Waltham Mass.). They differ in terms of the origin of the tissues, processing, storage, sterility, and need for surgical preparation.

A recent meta-analysis[34] compared results of several ADMs obtained from human cadavers and used in breast reconstruction. Seventeen retrospective articles and one randomized article were evaluated. The study evaluated complications (infection, seroma, flap necrosis, reconstruction failure, and general complications) in the Flex HD, Dermamatrix, and Alloderm ADMs. The authors concluded that complications were similar in the 3 ADMs evaluated. However, the results were poorly consolidated due to the scattered data from the various articles evaluated.

A study published in 2013[36] evaluated the costs of breast reconstruction with and without ADM and showed that the use of ADM significantly decreased postoperative follow-ups. However, the high cost of

ADMs did not exceed the cost obtained with a lower number of follow-ups.

The use of the fibrin silk mesh to coat the implant has been described as an alternative to coating with acellular tissue[9]. It is made with silk, associated with polyethylene oxide, and is manufactured with a technique using polymers and metal nanofibers.

Association of silicone implant with fat grafting (*lipofilling*)

Autologous fat grafts have gained increasing attention and wide acceptance due to improved results in breast reconstruction. They have limitations on isolated use due to soft consistency. Thus, a combination of the classic silicone implant technique with simultaneous handling of subcutaneous tissue with fat grafting is the most versatile and powerful modality for obtaining synergistic results[37].

Many clinical studies have shown a reduction in complications including capsular contracture[38,39] with the use of fat grafts,. An experimental study conducted in 20 sows showed improvement in capsular contractures with autologous fat grafts, probably due to neovascularization of the tissues around the silicone implant[40]. Its use in cosmetic breast surgery is still controversial[35].

CONCLUSION

The search for a breast implant that reduces the common complications, especially the formation of biofilm, infectious processes, and immune response, is the focus of most of the studies found. Acellular dermal matrix and fat grafting have been reported in the literature as promising alternatives to that effect.

We conclude that there is a trend towards continuous improvement in breast augmentation surgery, with aesthetic or restorative purposes, with fewer complications and better results expected in the future.

COLLABORATIONS

RSG Data curation, investigation, project administration, writing - original draft preparation.

EBG Supervision, writing - review & editing.

HFCG Supervision, writing - review & editing.

LMF Supervision, visualization.

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Review Article

Impact of fractional CO_2 laser treatment on hypertrophic scars and keloids: a systematic review

Impacto do tratamento com laser fracionado de CO_2 em cicatrizes hipertróficas e queloides: uma revisão sistemática

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■ **ABSTRACT**

Introduction: Hypertrophic scars and keloids cause aesthetic and functional damages, and are difficult to treat. This review aimed to identify prospective studies on fractional CO_2 laser to present the clinical and histological changes and the methodology used for the evaluation of scars before and after intervention. **Methods:** We conducted an electronic review (LILACS, Medline, and SciELO) of studies published between January 2004 and December 2017, using the search terms "keloid/queloide," "hypertrophic scar/cicatriz hipertrófica," and "CO_2 laser ," according to the PRISMA Statement. Studies that compared scars before and after isolated treatment with fractional CO_2 laser were selected. Two independent reviewers analyzed the data. **Results:** One hundred two articles were analyzed, of which 7 met the inclusion criteria. Of the 7 articles, all analyzed hypertrophic scars, 2 analyzed keloids in addition to hypertrophic scars, and 3 analyzed histological changes. Most studies showed a statistically significant difference in clinical scores between before and after treatment of hypertrophic scars, with improvement in symptoms, flexibility, and scar height. Between the 2 studies that analyzed keloids, 1 reported a clinical difference after treatment. The histological changes showed significant differences in the orientation and density of the collagen fibers, and in the thickness of the epidermis. **Conclusion:** The use of fractional CO_2 laser should be considered as a promising treatment option for pathological scars, as it improves clinical signs and symptoms such as color, thickness, and pruritus.

Keywords: Gas laser; Hypertrophic scar; Keloid; Carbon dioxide; Pathology.

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■ **RESUMO**

Introdução: Cicatrizes hipertróficas e queloides causam dano estético e funcional e são de difícil tratamento. O objetivo desta revisão foi identificar estudos prospectivos do tratamento com o laser fracionado de CO_2, mostrando as alterações clínicas e histológicas e a metodologia utilizada para a avaliação das cicatrizes antes e após intervenção. **Métodos:** Foi realizada uma revisão eletrônica (LILACS, Medline e SciELO) de estudos publicados entre janeiro de 2004 e dezembro de 2017, com os termos "keloid/queloide", "hypertrophic scar/cicatriz hipertrófica" e "laser CO_2", de acordo com o PRISMA Statement, sendo selecionados os estudos que comparassem as cicatrizes antes e depois de tratamento isolado com laser fracionado de CO_2. Os dados foram analisados por dois revisores independentes. **Resultados:** Foram analisados 102 artigos, sendo que 7 cumpriam os critérios estabelecidos. Destes, os 7 analisaram cicatrizes hipertróficas, 2 deles também analisaram queloides, e 3 estudaram alterações histológicas. Houve diferença estatística entre os escores clínicos medidos antes e após tratamento de cicatrizes hipertróficas na maioria dos estudos, com melhora nos sintomas, na flexibilidade e altura da cicatriz. Entre os 2 estudos que analisaram os queloides, 1 deles demonstrou diferença clínica após tratamento. Nas alterações histológicas, houve diferença na orientação e densidade das fibras de colágeno e na espessura da epiderme. **Conclusão:** O laser fracionado de CO_2 deve ser considerado como opção promissora no tratamento de cicatrizes patológicas, visto que melhora os sinais e sintomas clínicos como cor, espessura e prurido.

Descritores: Lasers de gás; Cicatriz hipertrófica; Queloide; Dióxido de carbono; Patologia.

INTRODUCTION

Scars cause significant aesthetic and psychosocial impacts on patients in the practice of plastic surgery. Hypertrophic scars and keloids are lesions that commonly appear after skin injury, causing aesthetic and functional damages, which are sometimes difficult to treat. Clinical evaluation of a scar is necessary to determine the correct treatment and effectiveness of the therapy. Multiple objective and subjective tools were created to characterize scars, which suggests that none of these tools is complete enough to evaluate the clinical and psychosocial aspects of pathological scars[1].

Keloids are violaceous scars of hard consistency that exceed the limits of the initial wound and are more frequently found in individuals with genetic predisposition, mainly those of black and oriental ethnicities, with an incidence of 4.5–16%, as compared with an incidence of < 1% in Caucasians. The sites of greatest involvement are the chest, back, and joints, with no sex-specific pattern.

They are also influenced by sex hormones, which explains their higher incidence between ages 10 and 30 years, and during pregnancy. Histological examination revealed an increase in glycosaminoglycans and type I and III collagens, with disorganized and irregularly dispersed fibers.

Hypertrophic scars are high, tense, reddish, do not exceed the limits of the original lesion, and tend to regress over time. On histological examination, they show an increase in type III collagen, with organized fibers and fibers parallel to the epidermis. Both can cause pain and itching, and have abundant dermal collagen due to an imbalance between its synthesis and degradation. However, its pathophysiology has not yet been fully elucidated[2].

Failures in the regulatory mechanisms of healing, which have not yet been well established, such as the decrease in apoptosis of fibroblasts and the role of growth factors, particularly transforming growth factor B1 (TGF-B1), have been studied in the development of this disorder. Matrix metalloproteinase 9 (MMP9), a family of enzymes responsible for connective tissue degradation, is known to be less evident in keloids and hypertrophic scars than in healthy skin

in immunohistochemical tests, and measurement of MMP9 level is important for the histological evaluation of the effectiveness of the treatment performed[3-5].

Several treatments are available for these two conditions, among which the combination of intralesional corticosteroid injections, silicone bandages, and local pressure is referred to as standard treatment by the International Advisory Panel on Scar Management consensus (IAPSM), despite its limitation. Second-line therapy for refractory cases, in turn, includes ablative or non-ablative laser therapy and surgical excision associated with the use of silicone gel. Fractional laser treatments induce a healing response, increasing type III collagen levels and remodeling the tissue[6].

Tissue resurfacing using fractional photothermolysis was introduced in 2004. The fractional technique produces columns of thermal and ablative damage, known as microthermal treatment zones (MTZ), interspersed with areas of untreated skin, a process that accelerates tissue recovery. In 2007, a new method to produce MTZ using ablative carbon dioxide (CO_2) was described. This method proved effective in reaching all layers of the skin (stratum corneum, epidermis, and dermis) through ablation and coagulation, with maximum control of tissue damage without reducing the efficacy and with the remodeling of collagen lasting for at least 3 months after treatment, which was confirmed by immunohistochemistry[7,8].

Intracellular and extracellular water absorbs the energy of the CO_2 laser at a wavelength of 10,600 nm, causing rapid heating and vaporization of the tissue to a depth of 20 to 60 μm. The heating of the dermis causes contraction and remodeling of the collagen with a thermal necrosis zone ranging from 20 to 50 μm. Reepithelialization occurs after 5 to 10 days, and erythema time depends on the energy used[9].

The standard treatment for hypertrophic scars and keloids, which are frequently encountered conditions in the routine practice of plastic surgery and dermatology, do not always help achieve satisfactory results, and clinical improvement is difficult to evaluate. The use of lasers was introduced as a secondary alternative for the treatment of these conditions, and the mechanism of the clinical and histological changes of the treated tissues is still under study, with no consensus so far. As few studies in the literature confirm these data and the overall improvement of a scar is difficult to objectively evaluate, the methodologies used to confirm the results obtained after the treatment of pathological scars with CO_2 laser must be reviewed.

OBJECTIVE

This systematic literature review aimed to identify prospective experimental before-and-after studies on the treatment of hypertrophic scars and keloids that used fractional CO_2 laser and identified clinical and histological changes and described the methodology used for evaluating scars before and after intervention.

METHODS

An extensive electronic review was conducted in the Latin American and Caribbean Literature in Health Sciences (LILACS), Health Information from the National Library of Medicine (Medline), Web of Science, and Scientific Electronic Library Online (SciELO) electronic library databases. We searched the databases using a combination of the following terms: "keloid/quelóide," "hypertrophic scar/cicatriz hipertrófica," and "CO_2 laser," according to the PRISMA Statement[10].

Two independent researchers tracked the titles and abstracts of the articles identified. Afterward, the full texts of the potentially relevant articles were reviewed. The inclusion criteria were controlled or non-controlled experimental studies, studies published between 2004 and 2017, and studies that included patients with hypertrophic scars or keloids in which isolated treatment with fractional CO_2 laser was used, with a clearly described methodology.

Studies in languages other than English, Spanish, and Portuguese, and outcomes other than clinical or histological evaluation of scars before and after treatment were excluded.

The articles were subdivided into groups according to the condition treated (keloid and/or hypertrophic scar) and the outcome (clinical and/or histological). The results are presented in tables according to the outcomes.

The results of each group (mean and standard deviation, and percentage indexes) were analyzed, and the control, pretreatment, clinical outcomes (according to the scar evaluation scale used), and histological outcome, when applicable, were compared.

RESULTS

Initially, 102 articles were identified in the electronic databases by evaluating their titles and abstracts. The full texts of 28 publications were evaluated, and 7 studies were selected for inclusion according to the established criteria.

The studies were subdivided according to the outcome studied. Of the studies, 7 investigated the clinical changes in the treatment of hypertrophic scars, of which 2 investigated keloids and 3 (already

selected in previous selections) reviewed histological and immunohistochemical parameters.

Clinical outcomes in hypertrophic scars

Table 1 shows the main results of studies on changes in hypertrophic scars evaluated using clinical measurement scales. Considering that statistically significant results have a p value of <0.05, a statistically significant difference was observed between the clinical scores measured before and after treatment by El-Zawahry et al.[7], Azzam et al.[3], Makboul et al.[5], Lei et al.[13], and Hultman et al.[14]. Choi et al.[12] reported significant improvements in flexibility and scar height.

Clinical outcomes in keloids

Only two studies that compared pretreatment and posttreatment keloids were found considering the criteria established for this review. Azzam et al.[3] reported a significant difference in the clinical scale scores that they used, with improvement in the treated

Table 1. Outcome parameters of fractional CO_2 laser treatment of hypertrophic scar.

First author/year	N	Comparison Groups	Platform parameters	Outcome measures	Clinical outcomes	Significance between the groups
El- Zawahry, 2015[7]	11	Before sessions of fractional CO_2 laser X After treatment	3 sessions, DEKA, 30w, 800-μm spacing, 800-μs dwelling time, stack 1	VSS[a] POSAS[b]	Hypertrophic scars showed improvement in texture and significant decreases in Vancouver score and POSAS.	*$p = 0.011$ (VSS)* *$p = 0.017$ (POSAS observer score)* $p = 0.180$ (POSAS patient score
Azzam, 2015[3]	7	Half of the scar treated with fractional CO_2 laser X Half of the scar left untreated	*4 sessions with 6-week intervals; DEKA; 25w; stack 3; 600-μs dwelling time; 700–800 spacing- hypertrophic keloid: 30w; stack 4; 1000 μs; 800 spacing*	VSS	The VSS score was significantly lower in the treated scar halves than in the untreated scar halves.	$p = 0.042$ (after 3 months) $p = 0.027$ (after 6 months)
Makboul, 2014[5]	40	Before sessions of fractional CO_2 laser X After treatment	4 sessions with 1-month intervals; ATL 250 CO_2 medical laser system; 25 w; time on = 1 ms; pixels per inch = 6	VSS	A statistically significant difference in the VSS score was found between before and after the fractional CO_2 laser treatment.	$p > 0.001$ (VSS)
Drooge, 2015[11]	12	Half of the scar treated with fractional CO_2 laser X Half of the scar left untreated	3 sessions with 8-week intervals; UltraPulse Encore - Lumenis Inc, Santa Clara, CA - spot diameter 120 μm, 600 Hz, 30–40 mJ	POSAS GPA[c]	GPA showed no statistically significant difference between the treated and untreated sides of the scar. Statistical analysis revealed no significant difference in POSAS score between the two sides of the scar.	$p = 0.70$ (GPA at 6 months) $p = 0.09$ (POSAS)
Choi, 2013[12]	10	Before sessions of fractional CO_2 laser X After treatment	1–9 sessions with 4- to 8- interval; Lutronic Corp, Korea; 40–60 mJ; 150 spots/cm^2	VSS 5-point rating scale	Flexibility and scar height significantly improved, while the improvements in vascularization and pigmentation were negligible.	49.8% (change in VSS) 51% (flexibility) 75% (height)
Lei, 2017[13]	15 8	Before the fractional CO_2 laser sessions X After treatment	3 sessions with 3-month intervals; UltraPulse Encore Lumenis, Yokneam, Israel; 150–175 mJ, 40 Hz; distance between spots 3–5 mm	VSS UNC[d] patient satisfaction survey	VSS and UNC scores showed statistically significant differences from before to after fractional CO_2 laser treatment.	$p < 0.0001$ (VSS) $p < 0.0001$ (UNC)
Hultman, 2014[14]	14 7	Before sessions of fractional CO_2 laser X After treatment	2–6 sessions with 4- to 6-week intervals; Lumenis UltraPulse, Santa Clara, CA	VSS UNC4P[e]	Fractional CO_2 laser treatment resulted in significant improvements in the scars.	$p < 0.001$ (VSS) $p < 0.001$ (UNC4P)

[a]VSS: Vancouver scar scale[10]; [b]POSAS: Patient and observer scar assessment scale[15]; [c]GPA: Global patient assessment; [d]UNC: University of North Carolina scar scale; [e]UNC4P: University of North Carolina 4P scar scale.

scar halves ($p = 0.006$). El-Zawahry et al.[7], in turn, reported no improvement in scars, which can be seen in Table 2.

Histopathological outcomes

El-Zawahry et al.[7] and Azzam et al.[3] reported significant differences in the orientation and density ($p = 0.001$ and $p < 0.05$, respectively) of collagen fibers before and after treatment. The latter also reported an increase in the immunohistochemical expression level of MMP9 ($p < 0.05$). Makboul et al.[5] reported greater thickness of the epidermis after treatment ($p < 0.001$) and decreased immunohistochemical expression of TGF-B1 ($p < 0.008$). The main histopathological results are shown in Table 3.

DISCUSSION

The treatment of pathological scars is considered to be unpredictable, although it is standardized worldwide. The mechanism of keloid formation and hypertrophic scars, which may help guide treatment, is still under study. The functions of growth factors (TGF-B1) and degradation proteins (MMP9) are still

Table 2. Outcome parameters of fractional CO_2 laser treatment of scars and keloids.

First author/year	N	Comparison groups	Outcome measures	Clinical outcomes	Significância entre os grupos[c]
El- Zawahry, 2015[7]	3	Before sessions of fractional CO_2 laser X After treatment	VSS score[a] POSAS score[b]	Keloid scars showed no improvement in texture or Vancouver or POSAS score.	$p = 0.102$ (VSS) $p = 0.180$ (POSAS observer score) $p = 0.018$ (POSAS patient score)
Azzam, 2015[3]	12	Half of the scar treated with fractional CO_2 laser X Half of the scar left untreated	VSS score	The VSS score was significantly lower in the treated halves than in the untreated halves.	$p = 0.006$ (after 3 months) $p = 0.018$ (after 3 months)

[a]VSS: Vancouver scar scale[10]; [b]POSAS: Patient and observer assessment scale[15]; [c]Values representing differences in pretreatment and posttreatment scores (mean and standard deviation).

Table 3. Parameters of histopathological outcomes

First author/year	N	Comparison groups	Outcome measures	Histological outcomes	Significance between the groups[d]
El-Zawahry, 2105[7]	10	Scar[a] treated with CO_2 X Scar left untreated	- Uniformity, density, and orientation of collagen fibers in the ablation area[b]	- After 3 months: less dense and more aligned collagen fibers in hypertrophic scars (n = 8)	$p = 0.001$
				- Decreased thickness of hypertrophic scars*	$p = 0.012$
				- After 3 months: less dense and more aligned collagen fibers in keloids (n = 2)	$p = 0.046$
				- No difference in average keloid thickness	$p = 0.18$
Azzam, 20153	30	Scar[c] treated with CO_2 X Scar left untreated	- Uniformity, density, and orientation of collagen fibers in the ablation area[b]	- After 3 months: less dense and more aligned collagen fibers	$p < 0.05$
			- Immunohistochemical evaluation of MMP9[c]	- Larger expression Immunohistochemistry of MMP9 after treatment	$p < 0.05$
Makboul, 2014[5]	8	Scar treated with CO_2 X Scar left untreated	- Thickness of the epidermis - Presence of TGF-B1	- Increased thickness after treatment (3 months)	$p < 0.001$
				- Lower immunohistochemical expression (6 months)	$p < 0.008$

[a]A 2.5-mm punch biopsy (tests: hematoxylin and eosin, Masson trichome for collagen, and Elastica van Gieson for elastic fibers); [b]superficial papillary and reticular dermis; [c]a 4-mm punch biopsy (tests: hematoxylin and eosin, Masson trichome for collagen, immunohistochemistry for anti-matrix metalloproteinase [MMP9]); dmean and standard deviation; *no significant difference between decreased thickness and clinical scores.

uncertain. Options such as the CO_2 laser are important adjuvants in treatment[1].

Azzam et al.[3] reported clinical improvements in Vancouver scar scale (VSS) scores and histological findings 3 months after treatment with an ablative CO_2 laser. They observed more flexible scars and better organized and thinner collagen bundles, with significant increases in MMP9 level after 1 month.

A study that evaluated the effect of fractional ablative CO_2 in burn scars reported decreased densities of collagen bundles and changes in the orientation of these fibers through histopathological examination, which clinically contributed to changes in scar texture[6].

Another prospective and descriptive study conducted with a sample of 40 scars in a population of 30 patients reported that the use of a combination of Nd:YAG of 1064 nm and fractional CO_2 laser at 20 W was significantly effective in improving the vascularization and flexibility of the treated skin, besides reducing itching, only in hypertrophic scars. Moreover, one of the most important effects of the laser on the scar is the generation of heat, which culminates in an inflammatory process that increases vascular permeability, the production of metalloproteinases, and the decomposition of collagen fibers[9].

Scar clinical evaluation scales were developed to better understand treatment results, although histopathological analysis of collagen changes and immunohistochemical markers is important for providing scientific evidence[15,16].

Although the mechanism of photothermolysis in the treatment of scars is uncertain, the columns produced by thermal injury, characterized by localized epidermal necrosis and denaturation of collagen, initiate a sequence of events that results in a balance between collagenesis and collagenolysis[17].

This review selected studies that compared hypertrophic scars and keloids of any nature between before and after treatment with fractional CO_2 laser, either from a clinical or histological point of view. Some studies reported a significant improvement in the characteristics and symptoms of scars[3,5,6,12-14]. Evidence of modification of histopathological characteristics related to collagen, growth factors, and immunohistochemical markers was also reported[3,5,6].

The authors argue that fractional CO_2 laser should be considered as a promising treatment option for pathological scars. Despite the scarcity of studies with good methodology, this treatment option has been shown to clinically and histologically alter scar tissues, thereby modifying collagen fibers and improving clinical signs and symptoms such as pruritus, color, and thickness.

COLLABORATIONS

LEAS Analysis and/or data interpretation, conception and design study, conceptualization, data curation, investigation, methodology, project administration, supervision, visualization, writing - original draft preparation, writing - review & editing.

AH Analysis and/or data interpretation, conception and design study, conceptualization, final manuscript approval, project administration, supervision.

MF Conceptualization, final manuscript approval, project administration, supervision, writing - review & editing.

IC Analysis and/or data interpretation, data curation, realization of operations and/or trials, writing - original draft preparation.

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Case Report

Surgical resection of symptomatic calcinosis in a patient with systemic sclerosis

Ressecção cirúrgica de calcinose sintomática em paciente com esclerose sistêmica

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■ **ABSTRACT**

Introduction: Systemic sclerosis is a rare, autoimmune, progressive disease that affects connective tissues and internal organs by inflammation, which can cause calcinosis cutis. It can progress to painful and disabling conditions, and can become infected, especially when skin ulceration is present. **Objective:** To present a case of calcinosis in the inguinal region and its surgical recovery. **Case Report:** A female patient with calcinosis in the bilateral inguinal region presenting with moderate/severe pain had a failed clinical treatment. We performed surgical resection of the calcinosis cutis, which had formed clusters of fibrosis with adhesion to the fascia of the external oblique muscle. We used simple nylon 2.0 sutures along the subdermal plane to perform primary closure and continuous nylon 3.0 sutures along the intradermal plane for aesthetic closure and minimal inflammatory reaction. Her postoperative recovery was positive. **Conclusion:** The best treatment for calcinosis cutis is still unclear. Treating complications becomes essential for reducing patients' morbidity and increasing their quality of life.

Keywords: Sclerosis; Calcinosis; Reconstructive surgical procedures; Operative surgical procedures; Rheumatology.

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■ **RESUMO**

Introdução: A esclerose sistêmica é uma doença rara, autoimune, com evolução progressiva, que afeta os tecidos conectivos e órgãos internos por inflamação, podendo causar calcinose de subcutâneo. Podem evoluir para quadros dolorosos e incapacitantes, podendo tornar-se infectados, principalmente quando ulceram pela pele. **Objetivo:** Apresentar caso de calcinose em região inguinal e sua evolução cirúrgica. **Relato de Caso:** Paciente feminina portadora de calcinoses em região inguinal bilateral, apresentando algia moderada/grave com falha de tratamento clínico. Realizada ressecção cirúrgica das calcinoses, que formavam cordões de fibrose com aderência na fáscia do músculo oblíquo externo. Realizado fechamento primário com nylon 2.0 pontos simples subdérmicos e ponto intradérmico continuo nylon 3.0 para fechamento estético e menor reação inflamatória. Boa evolução pós-operatório. **Conclusão:** O melhor tratamento da calcinoses ainda não é claro. O tratamento das complicações se torna essencial para reduzir a morbidade e aumentar a qualidade de vida do paciente.

Descritores: Esclerose; Calcinose; Procedimentos cirúrgicos reconstrutivos; Procedimentos cirúrgicos operatórios; Reumatologia.

INTRODUCTION

Systemic sclerosis is a rare, autoimmune, progressive disease that affects connective tissues and internal organs by inflammation, fibrosis, or vasculopathies[1]. It is more common in women (4:1), and its onset occurs between the ages of 30 and 50 years[1]. Calcinosis cutis is frequently found in systemic sclerosis, but its spectrum of presentations is reported anecdotally[2].

When present, calcinosis can progress to painful, disabling conditions and may become infected, especially with skin ulcerations, requiring a surgical treatment approach[3]. As of now, calcinosis related to systemic sclerosis has received little attention in studies, including its pathogenesis and related diseases[3]. While surgical treatments for calcinosis cutis in hands and fingers have been reported, we found few studies about calcinosis cutis in other areas, such as the present case of calcinosis cutis in the inguinal region[4].

CASE REPORT

A 53-year-old female patient was referred to and treated in the rheumatology department of the University Hospital of the Federal University of Santa Catarina (HU/UFSC) in Florianópolis, Santa Catarina. She was diagnosed as having systemic sclerosis 20 years before and presented with calcinosis in the bilateral inguinal region, which was suggestive of dystrophic calcinosis.

A surgical procedure to remove the calcium lesions was requested because of continuous moderate/severe pain without precipitating and relieving factors, and the risks of ulceration and infection from the progressive characteristic of the localized disease.

Clinical treatment with medication was given but failed to stop the progression of the calcinosis or attain remission. The patient took azathioprine and prednisone to stabilize the underlying disease and denied prior surgeries. In the physical examination, she presented with a hardened cluster of lesions adhered to the subcutaneous tissue in the inguinal region and bilateral flanks that were compatible with calcinosis and felt discomfort with light, passive movements. She showed no signs of localized infection or ulceration. The lesions covered an area of 20 × 5 cm (Figure 1). Ultrasonography of the inguinal region showed hyperechoic linear and irregular masses projecting from the subcutaneous tissue in the inferior area of the lateral abdominal wall, the largest ones being 36 mm in length, which were compatible with calcification.

Concerning the progressive state of the localized disease, the unsuccessful attempt at clinical drug treatment, and the patient's considerable pain, surgical resection was indicated.

We marked the inguinal region, contemplating the entire affected area through palpation in the physical and imaging examination (a cutaneous site marking of approximately 15 × 4 cm). Local anesthesia was administered with 50 mL of solution containing 20 mL of 2% lidocaine, 1/120,000 adrenaline, and 100 mL

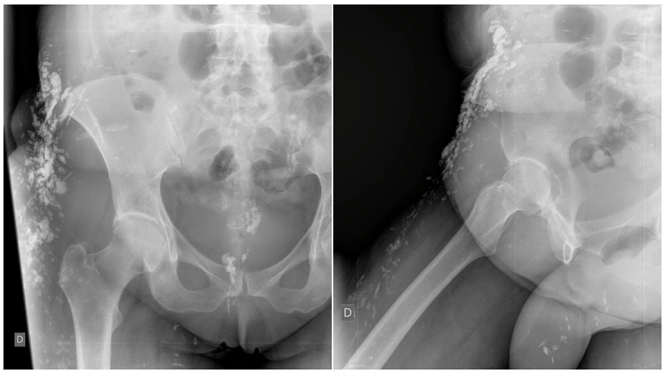

Figure 1. Anteroposterior and oblique radiograph of the inguinal region presenting with calcinosis cutis in the direct inguinal region, flanks, and perianal region.

of saline. We performed cutaneous and subcutaneous resections to remove the calcinosis, which had formed clusters of calcium lesions, some of which had adhered to the fascia of the external oblique muscle, without resection of the fascia or external oblique muscle.

We removed a single block containing cutaneous and subcutaneous tissues affected by the calcinosis. After hemostasis, we used simple nylon 2.0 sutures in the subdermal plane for primary closure and continuous 3.0 nylon sutures in the intradermal plane for aesthetic closure and minor inflammatory reaction (Figure 2).

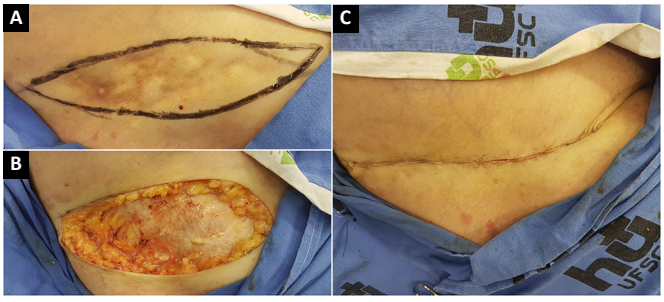

Figure 2. Counterclockwise. **A:** Preoperative marking (15 × 4 cm) of the inguinal region. **B:** Resection of the calcinosis in a single cutaneous and subcutaneous block, maintaining the fascia of the oblique external muscle. **C:** Closure by planes with intradermal sutures.

The site was dressed with neomycin and mild cutaneous compression, and the dressing was to be changed daily after a bath. The patient adhered to the postoperative follow-up care, and the intradermal sutures were removed on the 12th day. At this time, the patient no longer presented with localized daily pain caused by calcinosis; thereby, a subjective analysis of the patient's pain (preoperative and postoperative) was conducted.

In the second postoperative month, the patient's condition progressed with the extrusion of a subdermal suture without the need for secondary surgery and without a surgical wound, other intercurrences, or complications.

The photographs show a favorable aesthetic result on the 90th postoperative day (Figure 3). The histological evaluation demonstrated no degree of malignancy in the calcifications (Figure 4). The patient is currently under follow-up care by the plastic surgery department of HU/UFSC and did not present with new calcifications in the surgical area or atrophic scars during recovery.

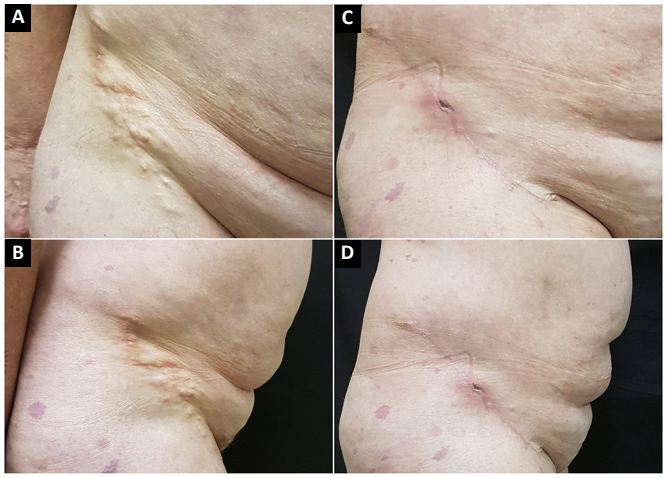

Figure 3. A and **B:** Preoperative images of the inguinal region (anterior profile). **C** and **D:** Postoperative images after 3 months of recovery, showing topical and trophic healing. The extrusion site of the subdermal suture in the healing process by secondary intention is shown.

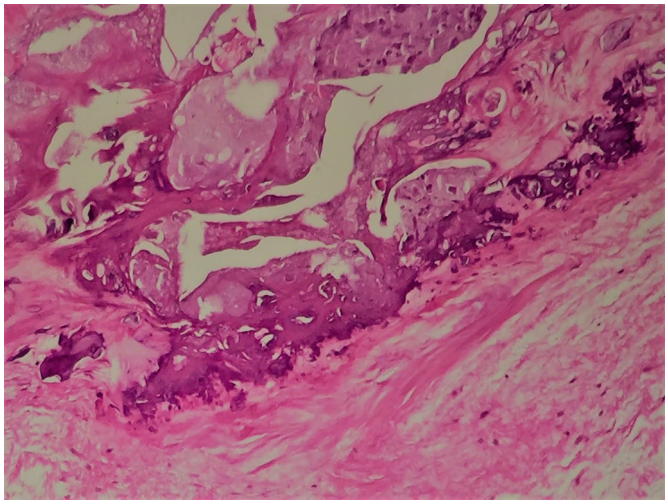

Figure 4. Calcification in the hypodermis (hematoxylin-eosin staining, original magnification ×100).

DISCUSSION

Systemic sclerosis is a disabling disease that involves the interdisciplinary participation of physicians, as it indiscriminately affects all body systems. The rheumatologist is in charge of clinical follow-up, as it is a connective tissue disorder. However, the collaboration of other specialties sometimes becomes unquestionable[5].

Calcification of soft tissue is generally categorized into four types, namely dystrophic calcification, metastatic calcification, idiopathic calcification, and calciphylaxis. In dystrophic calcification, serum calcium and phosphate levels are normal. This is commonly related to connective tissue diseases such as dermatomyositis and scleroderma[5].

Calcinosis caused by systemic sclerosis is a condition in which the last treatment option is surgical resection because of the uncertainty of recovery from surgical trauma before the underlying disease. Drug treatment, which has not been standardized, seeks to contain the progression of calcinosis in terms of size and cutaneous ulceration. Drug intervention has provided mixed results in its effectiveness, and its results vary according to studies.

Calcium channel blockers have demonstrated the greatest efficacy among other drug interventions. They promote a decrease in the influx of calcium into the cell, thereby decreasing the formation of intracellular crystals. While colchicine does not affect the calcium lesions themselves, it reduces secondary inflammation[6-9].

As in this case, some patients present moderate to severe pain due to the clusters of sensitive cutaneous innervations, which accelerate the search for their surgical treatments. Nonetheless, little information is available in the surgical literature on calcinosis in patients with connective tissue disease, particularly in the inguinal region, which is an unusual topography of the disease, as it normally occurs in the extremities and joints[6,7].

Although risks of pain recurrence and additional calcification due to surgical trauma are present, treatment of calcinosis before it progresses to localized ulceration and infection is favorable[7].

This case report serves as a reference for future research. The best treatment for calcinosis cutis is still unclear, as no fully effective treatment is available. We attempted clinical drug treatment to stop or slow disease progression. Surgical treatment is the last option because of uncertainties about recovery from surgical trauma[2].

Consequently, treating complications becomes essential to reducing the patients' morbidity and increasing their quality of life. In cases with an imprecise postoperative recovery, the physician-patient relationship should guide procedures to prevent future discontent of treatment outcomes.

COLLABORATIONS

CPG Conception and design study, methodology, project administration, writing - original draft preparation.

NBR Data curation, writing - original draft preparation.

CMM Data curation, writing - original draft preparation.

FCNG Data curation.

JBE Conceptualization, supervision, writing - review & editing.

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Case Report

Extended and pedicled pectoralis major flap for right orbitofrontal-parietal reconstruction following invasive squamous cell carcinoma resection

Retalho de peitoral maior estendido e pediculado para reconstrução de região orbito-fronto-parietal direita após exérese de carcinoma espinocelular invasivo

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■ **ABSTRACT**

Introduction: The myocutaneous flap is often used in reconstruction of head and neck defects. However, it is restricted to the middle third of the face. Perforating artery dissection techniques allow further lengthening of the pedicle, thus achieving coverage of the orbitofrontal-parietal region. **Case report:** A 63-year-old male with a poorly-differentiated invasive squamous cell carcinoma presented with a final defect of 12.0 × 18.0 cm in the right orbitofrontal-parietal region, with dura mater, frontal sinus, and right upper orbit exposure after resection. We designed a pectoralis major flap, with a cutaneous island equaling the defect in dimensions, in the right parasternal region, from the fourth intercostal space to the subcostal region (extended). The pedicle was sectioned after 4 weeks. The coverage was effective, with no major complications, and a satisfactory aesthetic result. **Conclusion:** This flap can be an excellent option for reconstruction of the upper third of the head when there are limitations to microsurgery.

Keywords: Cutaneous neoplasia; Squamous cell neoplasia; Surgical flaps; Myocutaneous flap; Pectoral muscles.

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■ **RESUMO**

Introdução: O retalho miocutâneo de peitoral maior é um dos mais usados na reconstrução de defeitos da cabeça e pescoço, porém com restrição ao terço médio da face. Com técnicas de dissecção de perfurantes, consegue-se alongar mais o pedículo, obtendo coberturas da região orbito-fronto-parietal. **Relato de Caso:** Paciente masculino de 63 anos apresentando carcinoma espinocelular invasivo pouco diferenciado, que após sua ressecção cirúrgica apresentou defeito final de 12,0 x 18,0cm na região órbito-fronto-parietal direita com exposição de dura-máter, seio frontal e órbita superior direita. Foi desenhado retalho de peitoral maior com ilha cutânea de dimensões iguais ao defeito na região paraesternal direita, desde o quarto espaço intercostal até a região subcostal (estendido). O pedículo foi seccionado após 4 semanas. A cobertura foi efetiva, sem complicações maiores e resultado estético satisfatório. **Conclusão:** Este retalho mostrou ser uma excelente opção para reconstrução do terço superior da cabeça quando existam limitações para a realização de microcirurgia.

Descritores: Neoplasias cutâneas; Neoplasias de células escamosas; Retalhos cirúrgicos; Retalho miocutâneo; Músculos peitorais.

INTRODUCTION

The pectoralis major myocutaneous flap is often used in reconstruction after head and neck tumor resection. Ariyan et al. first described this technique in 1979[1].

Few reports have described the use of this flap in reconstruction above the orbits, due to the risk of necrosis and the difficulty of flap mobilization, rotation, and extension.

Defects in the scalp and upper third of the face remain a challenge for surgeons. Advances in surgery have included use of perforating arteries and improved techniques of dissection of the pectoral pedicle. These have allowed release and lengthening of the pectoralis major muscle, augmentation of its arc of rotation, and gain in the extension of the flap (cutaneous island) to obtain more distal coverage in the head and upper third of the face.

OBJECTIVE

This study reported the use of an extended pedicled muscle flap to cover defects in the right orbitofrontal-parietal region after resection of invasive squamous cell carcinoma.

CASE REPORT

A 63-year-old male with an ulcerated, grade III, poorly-differentiated squamous cell carcinoma presented 6 months after initial resection and grafting with a recurrent tumor in the right parietal region. The patient had a 5.0-cm right parietal ulcerated lesion with an adjacent osteolytic component, another frontal lesion measuring 3.0 cm, and another 4.0-cm lesion in the right lower frontal region with signs of adjacent bone involvement. Invasion of the paranasal sinus and right superomedial orbit had occurred (Figure 1).

The case was evaluated by the oncological surgery and neurosurgery teams of the Guilherme Álvaro Hospital, Santos, SP, for tumor resection with curative intention, in collaboration with the plastic

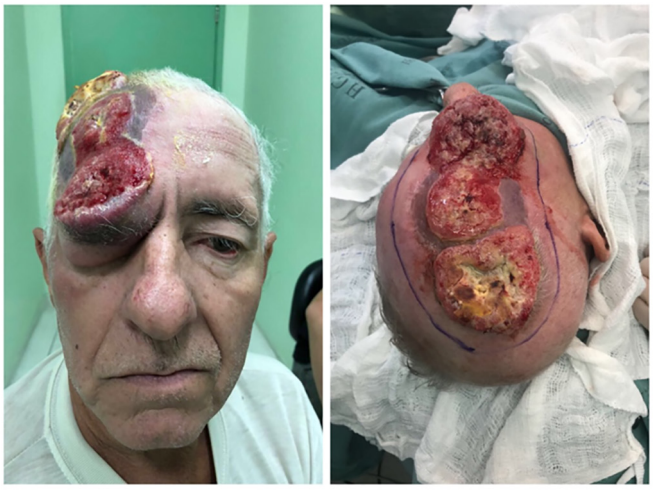

Figure 1. Invasive squamous cell carcinoma, lateral view.

surgery team for immediate reconstruction. The lesion was resected with lateral margins of 15 mm, with resection of the affected bone in the parietal and upper frontal regions and anterior and posterior walls of the right frontal sinus, leaving the dura mater exposed.

The superomedial bony portion of the right orbit was resected, revealing communication with the right frontal sinus and right nasal cavity; the globe, ocular muscles, and 1.0 cm of the upper eyelid were preserved. The final defect measured 12.0 × 18.0 cm in the right orbitofrontal-parietal region, with dura mater, frontal sinus, and right upper orbit exposure (Figure 2).

Figure 2. Partial resection of the frontoparietal bone and superomedial orbit, with dura mater exposure.

For reconstruction, we marked a pectoralis major flap measuring 12.0 × 18.0 cm in the right parasternal area, from the fourth intercostal space to the subcostal region (extended), to enable coverage of the defect without lateral traction on the head (Figure 3).

We detached the pectoralis muscle, while preserving the thoracoacromial pedicle, leaving only a long muscular band in the axis of the vascular pedicle, and performed total section of the muscle at the base of the flap; a cutaneous band on the pedicle was left for protection and maintenance of the perforating cutaneous thoracoacromial pedicle.

We performed total section of the superior pectoral nerve, partial section of the deltoid muscle insertion in the clavicle to reduce rotation tension in the external pedicle, and released the vascular pedicle to the thoracoacromial trunk at the origin of the axillary artery. The closure of the donor area was performed with tension-free advancement flaps (Figure 4).

To obliterate the frontal-orbital-nasal communication, a contralateral frontal muscle flap was created and sutured in place.

Figure 3. Pectoralis flap and perforating area (in blue) markings.

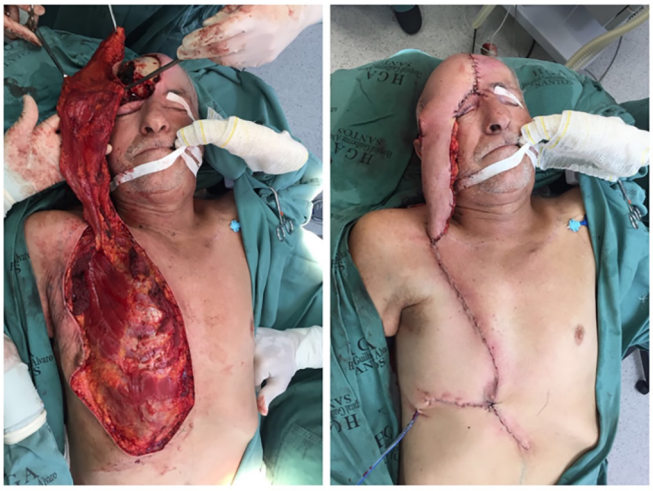

Figure 4. Flap dissection and suturing of donor area.

During recovery, the patient developed a 3.0-cm necrotic area at the distal edge of the flap; this was resected together with the pedicle 4 weeks later. Wet dressings were applied to the area of resected necrosis until granulation tissue was observed, with subsequent grafting. The coverage was effective, with no major complications or hematomas, and a satisfactory aesthetic result was achieved despite the extensive oncologic surgery. The patient remains under follow-up, and is receiving radiotherapy because of high risk of recurrence and infiltration of the dura mater and frontal sinus mucosa (Figure 5).

DISCUSSION

The pectoralis major flap is commonly used for head and neck reconstruction, but its applicability in the supraorbital area has a risk of failure and necrosis due to tension. Its use depends largely on patient anatomy. The cutaneous island on the pectoralis muscle typically measures 6.0 × 12.0 cm. The skin flap should not be extended more than 20% beyond the edge of

Figure 5. Postoperative appearance 10 days after pedicle resection and 40 days after oncological surgery

the muscle[2]. This type IV flap with a thoracoacromial dominant pedicle is easy to monitor and dissect.

Most reports on this flap discuss a musculocutaneous or muscular type, with a mostly minor complication rate of 33% and a 2% risk of necrosis[3].

Cadaver studies by Rikimaru et al.[4,5] identified the main cutaneous perforating arteries of the second and third intercostal area using microvascular angiography. Based on these studies, Nishi et al.[6] described flaps using pectoral and deltopectoral perforating arteries.

Zhang et al.[7] described a pectoral region flap in an anatomical study of the perforating branches of the thoracoacromial artery, and reported the existence of 1 or 2 main perforators within 4.0 cm of the point of union of the acromioxiphoid and midclavicular lines. These perforators allowed a pedicle flap using thoracoacromial artery perforators to be performed. This flap can be performed with microsurgical technique for superior defects[8-10].

With this anatomical knowledge of the perforators of the thoracoacromial vascular pedicle, a large cutaneous island can be maintained, and the muscle can be partially or totally resected. The flap rotation arc may improve with muscle detachment, careful dissection of the pedicle, and section of deltoid muscle bands, and infraclavicular tunneling has been described. Surgery is ideally performed in a single session, but an external pedicle is needed to obtain coverage distant from the donor bed, as in the present case. The literature to date has not reported a pedicled pectoralis major flap that has been extended this far while remaining viable.

The extended pedicle flap was an excellent surgical option for reconstruction of the upper third of the head following extensive tumor resection, in an area with limitations to microsurgery; with anatomical knowledge and careful dissection, we obtained a satisfactory result.

COLLABORATIONS

AOE	Conception and design study, data curation, methodology, realization of operations and/or trials, writing - original draft preparation.
DCL	Methodology, realization of operations and/or trials, writing - review & editing.
AFC	Data Curation, realization of operations and/or trials, writing - review & editing.
CFG	Data curation, realization of operations and/or trials, writing - review & editing.
LG	Realization of operations and/or trials, writing - review & editing.
RGN	Writing - original draft preparation, writing - review & editing.
ORS	Final manuscript approval, methodology, writing - review & editing.

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Case Report

Giant malignant fibrous histiocytoma of the face: case report of microsurgical repair using a transverse rectus abdominis myocutaneous flap

Fibrohistiocitoma maligno gigante de face: tratamento reparador microcirúrgico utilizando retalho miocutâneo transverso do reto do abdome - Relato de caso

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■ **ABSTRACT**

Introduction: The resection of invasive tumors of the head and neck can result in extensive and complex defects requiring immediate repair. One repair option is the transfer of a transverse rectus abdominis myocutaneous (TRAM) flap pedicled on deep inferior epigastric vessels using vascular microsurgery. This study aimed to register a procedure used in the microsurgical treatment of giant malignant fibrous histiocytoma of the face using a TRAM flap. **Case Report:** A male patient sought medical care for a giant tumoral lesion in the right hemiface. Computed tomography of the skull revealed a voluminous expansive process of vegetating aspect with poorly defined borders. The excision of the tumor affected the right masseter and temporalis muscles, parotid gland, and right orbital and malar bones. Subsequently, microsurgical withdrawal of the TRAM flap was performed with the deep inferior epigastric artery through a surgical incision in the hypogastric area. Dissection of the facial artery and vein under microscopy and venous and arterial anastomoses followed. The flap was intact with good perfusion and no signs of infection. **Conclusions:** Microsurgical facial reconstruction allows head and neck surgeons to resect large tumors.

Keywords: Myocutaneous flap; Reconstructive surgical procedures; Neoplasms; Rectus abdominis; Face.

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■ **RESUMO**

Introdução: A ressecção de tumores invasivos de cabeça e pescoço pode resultar em defeitos extensos e complexos exigindo reparação imediata. Uma das opções de reparação é a transferência, utilizando técnica de microcirurgia vascular, do retalho musculocutâneo do reto abdominal pediculado nos vasos epigástricos inferiores profundos (TRAM). O presente estudo tem como objetivo registrar um procedimento utilizado no tratamento reparador microcirúrgico de fibrohistiocitoma maligno gigante de face com retalho TRAM. **Relato de Caso:** Paciente procurou atendimento médico devido a lesão tumoral gigante em hemiface direita. Foi realizada a tomografia computadorizada do crânio revelando volumoso processo expansivo de aspecto vegetante com limites mal definidos. Após os procedimentos básicos no pré-operatório, realizou-se a exérese do tumor que acometia músculos masseter e temporal direito, glândula parótida, assoalho orbitário à direita e osso malar. Posteriormente, retirou-se o retalho microcirúrgico do músculo reto do abdome em conjunto com a artéria epigástrica inferior profunda através de incisão cirúrgica da área hipogástrica. Em seguida, dissecção da artéria e veia facial utilizando microscópio e anastomoses venosa e arterial. Quanto à evolução retalho apresentou-se íntegro, com boa perfusão, sem sinais de infecção. **Conclusões:** A reconstrução facial microcirúrgica oferece liberdade ao cirurgião de cabeça e pescoço para realizar grandes ressecções tumorais.

Descritores: Retalho miocutâneo; Procedimentos cirúrgicos reconstrutivos; Neoplasias; Reto do abdome; Face.

INTRODUCTION

Malignant fibrous histiocytoma is a malignant mesenchymal neoplasm (sarcoma) of soft tissues in which histiocytes act as facultative fibroblasts or some elements of the primitive mesenchyme give rise to fibroblasts and histiocytes[1-4]; malignant fibrous histiocytoma can occur anywhere in the body. Due to tumor aggression, complete and early resection of the lesion with free margins accompanied by regional lymph node excision is the therapeutic approach indicated in all cases of malignant fibrous histiocytoma[2,5].

The resection of large invasive tumors of the head and neck can result in extensive and complex defects, leading to the exposure of vital structures as well as direct communication between the oronasopharynx and the brain, thus requiring immediate repair. These patients may have significant limitations, with high morbidity rates and decreased quality of life[6,7].

Accordingly, several microsurgical flaps have been used to repair defects of the head and neck region[1]. Several studies have asserted the superiority of free musculocutaneous flaps over fasciocutaneous flaps, the most common being the rectus abdominis flap, although the anterolateral free thigh flap is also widely used[6,8-11].

The advantages of using the rectus abdominis flap include its low incidence of complications, the ease of its elevation, and the presence of a long, large-caliber, and constant vascular pedicle represented by the deep inferior epigastric artery[8,11].

Thus, the objective of this case report is to present the microsurgical repair of a patient with a malignant giant fibrous histiocytoma of the face using a transverse rectus abdominis myocutaneous (TRAM) flap.

CASE REPORT

This study was performed in accordance with the precepts of the Declaration of Helsinki and the Nuremberg Code respecting the Research Regulations Involving Human Beings (Resolution CNS 196/96) of the National Health Council. This retrospective study used data obtained through semi-structured interviews, direct observations, and documentary assessments that included the patient's medical records; these steps were performed after approval of the draft project by

the Research and Extension Nucleus of Medicine and Ethics Commission of the State University of Pará and authorized by the Clinical Director of the Ophir Loyola Hospital and the patient through an informed consent form.

History

A 56-year-old man sought medical care for a giant tumor lesion in the right hemiface. He reported that it first developed in 1995 as an erythematous papule in the right malar region and progressively grew to an ulcerative-vegetative lesion on the face. The patient sought medical assistance with the initial diagnosis of American cutaneous leishmaniasis and treatment with *N*-methyl glucamine; without improvement, a biopsy revealed squamous cell carcinoma, for which he was referred to our service for radiotherapy (RT).

Two years after the initial treatment, a new lesion emerged in the right hemiface accompanied by local burning pain for which new RT sessions were instituted.

Five years later, in 2002, a fast-growing ulcerative mass appeared on the scar lesion produced by RT and was accompanied by local moderate-intensity pain and the secretion of a foul-smelling purulent bloody fluid.

On performing a physical examination, it was found that the patient was emaciated with a hyperemic ulcerative-vegetative lesion with a giant necrotic and infected center in the right hemiface that extended to the ipsilateral orbit measuring 11 × 10 cm and with inflammatory signs (Figure 1). The patient's right hand was missing as a result of a work accident. Examinations of the thorax and abdomen were unaltered, and a hemogram revealed hypochromic and microcytic anemia and leukocytosis.

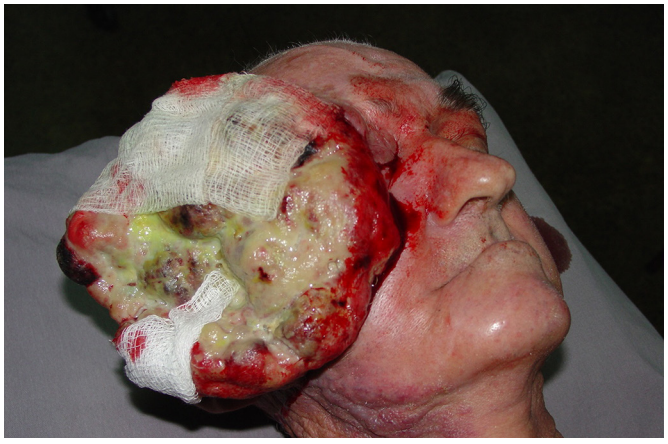

Figure 1. Ulcerative-vegetative tumor with a necrotic and infected center in the right hemiface.

Computed tomography of the skull revealed a large expansive process with a vegetating aspect and poorly defined borders compromising soft parts; signs of bone destruction of the walls of the zygomatic arch; impairment of the right temporal muscle; and an intimate relationship with the right eyelid region and the anterior edge of the eyeball.

In 2003, the tumor was resected, followed by microsurgical reconstruction with a TRAM flap.

Surgical technique

The procedure began with a perilesional incision and careful dissection of the tumor lesion, followed by excision of the tumor that involved the masseter and right temporal muscles, parotid gland, orbital floor dissection to the right, and malar bone and submandibular lymph node dissection to the right.

Subsequently, a surgical incision was made in the hypogastric area, including the entire infraumbilical area, which was 21 × 37 cm in its major dimensions, and the hypogastric segment was detached accompanied by dissection of the deep inferior epigastric artery (IEA) and ligation of the vein and the IEA with removal of the microsurgical flap.

Dissection of the facial artery and vein was done using a 40× magnification microscope, and venous and arterial end-to-end anastomoses of the facial vein and artery with IEA vessels using 10-0 mononylon wire were performed. Patency and flow success were verified using appropriate microsurgical instruments, followed by fixation of the TRAM flap in the resected area using Vicryl 2-0 wire (Figure 2).

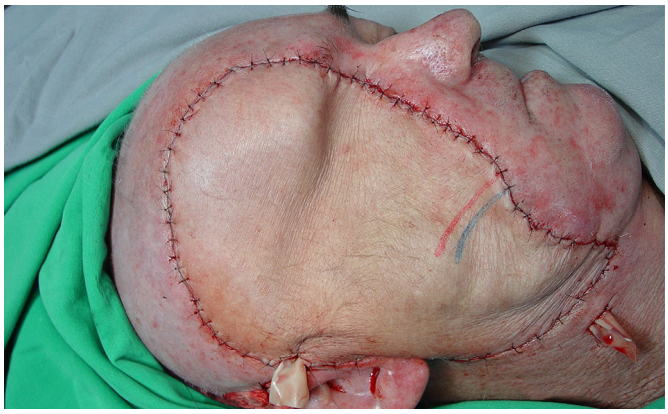

Figure 2. Photograph taken in the immediate .postoperative period.

RESULTS

After the surgical procedure, the patient was transferred to the Intensive Therapy Center, where

he remained for 2 days and was medicated with dobutamine and dopamine for hypotension. The flap was viable with good perfusion and no signs of ischemia; antibiotic therapy was continued.

On the fifth postoperative day, a purulent secretion was noted in the drain. A new antibiotic regimen was initiated; after some adjustments due to diarrheal episodes, it was maintained until discharge 16 days after surgery when the patient was in a good general condition with an intact TRAM flap.

A histopathological examination of the collected material showed poorly differentiated epidermoid carcinoma, Broders grade III. An immunohistochemical evaluation with HMB-45, S-100, vimentin, PCNA, AE1, and AE2 antigens and cytokeratin showed that the lesion was of mesenchymal origin and was compatible with malignant fibrous histiocytoma with high proliferative activity.

Eight months after surgery, the patient returned to the outpatient clinic with an intact flap with good perfusion and no signs of infection or increased volume. The suture line was in a good scarring condition. He reported a difference in the skin coloration of his face and the flap. Deviation of the labial commissure to the left was evident, as was weakness in the abdominal wall in the flap donor area.

DISCUSSION

Here we opted to use a TRAM flap to correct facial defects after tumor excision for its functional and esthetic advantages[9], absence of previous abdominal surgeries in the patient, technical ease of the flap dissection by a qualified professional, previous tumor resection not requiring a change in decubitus, and the flap's versatility.

Studies have indicated that necrosis of the transferred flap is the most common complication of this microsurgical repair technique[6,12]; previous RT is a risk factor due to its effects on recipient vessels. This causes greater difficulty with vessel dissection and the preparation for vascular anastomosis[6,13].

However, in this study, no necrosis of the TRAM flap was observed despite a history of RT. Another complication is incisional hernia in the donor area, which can easily be circumvented with the use of an absorbable suture without reinforcement and synthetic material mesh[6,8,10] in the follow-up period (12 months). In this case, fragility of the abdominal wall (donor area) was observed after flap withdrawal as described elsewhere in the literature.

The difference in color between the skin of the face and the flap as reported in the literature was quite visible in this patient in the initial phase, but it decreased gradually over time[6].

Regarding the clinical manifestation of malignant fibrous histiocytoma, this case was uncommon since such tumors in the head and neck region are rare, the condition is more common in children, and the tumor is usually 1-2 cm in diameter according to the literature surveyed[1-4]. This case involved an 11-cm tumor in a sexagenarian.

CONCLUSIONS

Microsurgical facial reconstruction, especially using a TRAM flap, enables the head and neck surgeon to perform large tumor resections and preserve the quality of life of cancer patients.

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COLLABORATIONS

RAAA Analysis and/or data interpretation, final manuscript approval, supervision, writing - review & editing.

BRAP Contribution: supervision, writing - review & editing.

RCCA Analysis and/or data interpretation, conception and design study, data curation, writing - original draft preparation, writing - review & editing.

BFAP Conception and design study, data curation.

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Case Report

Elastic suture: a treatment option for extensive skin loss

Sutura elástica: uma opção no tratamento de extensas perdas cutâneas

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■ **ABSTRACT**

Extensive skin loss presents major challenges for plastic surgeons, making it necessary to develop different techniques to close extensive wounds. In this context, the elastic suture technique was performed in two patients at the Independência Hospital of the Divina Providência Group in Porto Alegre. This alternative technique was fast and effective and had a low cost. The technique is divided into two stages: the elastic suture itself, which consists of the approximation of the wound edges with the aid of an elastic band; and closure of the skin already approximated in the previous stage. The elastic suture is a highly safe and simple closure technique with the ability to approximate the edges of extensive wounds, avoiding the use of more complex techniques in some cases.

Keywords: Suture techniques; Bottom edge; Wounds and injuries; Rubber; Healing

■ **RESUMO**

Em meio a tantos desafios aos quais os cirurgiões plásticos são impostos quando se trata de grandes perdas cutâneas, faz-se necessário o desenvolvimento de diferentes métodos de fechamento de grandes feridas. Assim sendo, foi realizada a técnica da sutura elástica em dois pacientes do Hospital Independência do grupo Divina Providência em Porto Alegre, uma alternativa que se demonstrou rápida, eficaz e de baixo custo. A técnica é dividida em duas etapas, a primeira com a sutura elástica propriamente dita - na qual consiste na maior aproximação dos bordos com auxílio de um elástico -, e a segunda com o fechamento da pele já aproximada pela fase anterior. Assim sendo, com o uso da técnica nesses dois pacientes, foi possível concluir que a sutura elástica é uma técnica de fechamento simples, com grande segurança e funcionalidade para aproximação de bordos de grandes feridas, evitando, em alguns casos, o uso de técnicas mais complexas.

Descritores: Técnicas de sutura; Extremidade inferior; Ferimentos e lesões; Borracha; Cicatrização.

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INTRODUCTION

Extensive skin loss in the lower limbs presents great treatment challenges. These lesions are caused by extensive trauma, exposed fractures, vasculopathies, and neoplasms and are characterized by difficulty approximating wound edges, which can lead to aesthetic and functional damage[1].

The treatment options range from primary closure to reconstruction using distant flaps. Some plastic surgeons specialize in this area and perform different techniques to close the lesions depending on their extension. In this context, the elastic suture was included in the therapeutic strategy for lower-limb reconstruction, a technique divided into two surgical times: the aid of an elastic sutured into the skin that approximates the wound edges; and the removal of this elastic and the wound edges sufficiently approximated so only a simple suture closes the wound. This mechanism uses the biomechanical properties of the skin with the aid of only a sterile elastic band. The elastic suturing was performed in two patients at the Independência Hospital of Porto Alegre, RS.

The present study aimed to describe the elastic suture technique and confirmed its safe applicability in cases of skin loss in the lower limb based on the description of two surgical cases and a literature review.

METHODS

The present study consists of two case reports of patients treated at the Independência Hospital of the Divina Providência Group in Porto Alegre, RS, in 2017. Based on the surgical method used, a literature review was conducted using the Google Scholar, PubMed, and Lilacs databases. The abstracts that were relevant for the topics were initially identified and selected; subsequently, the open access articles that clearly addressed the elastic suture treatment were reviewed.

Two patients were selected for the two stages of the procedure. The first stage includes the elastic suture and consists of debridement of the wound edges and suturing of the sterile elastic into the most superficial layer of the skin. The elastic was fixed to the skin with a mononylon thread, and was interlaced and sutured back into the skin. This process was repeated until the wound edges were approximated in all affected areas. One week after this first stage, the elastic was removed and the wound was fully closed with mononylon 3.0 thread.

CASE REPORTS

1-G.L.S.N., 24-year-old man. The patient suffered a motorcycle accident in October 2014 and required surgical treatment for a right tibial shaft fracture. The postoperative course was successful and he was discharged. In July 2017, the patient returned to the hospital complaining of progressive exposure of the synthetic material with signs of a site infection. Thus, the plaque was removed in July 2017. However, the patient had an extensive surgical wound that required debridement and assessment by the plastic surgeon. The lesion size in the anterior region of the right leg was 15 × 4.3 cm (Figure 1). The patient then underwent elastic suturing to cover the lesion. The first stage of the procedure was performed in August 2017; in the second stage 1 week later, the wound already measured 15 × 1.1 cm, which made the primary suturing possible, and the patient was discharged 4 days after the second surgery. The patient's condition progressed well, the surgical wound healed completely, and he was discharged from the plastic surgery team's outpatient clinic in February 2018.

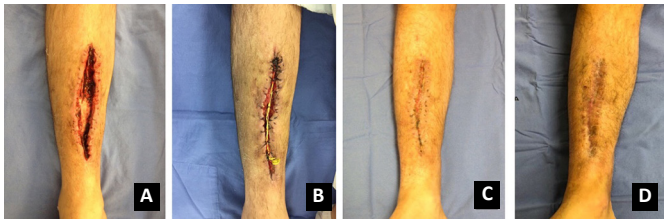

Figure 1. A: Skin lesion – preoperative view; **B:** Elastic suture – immediate postoperative view; **C:** First week postoperative view; D: 2-month postoperative view.

2-N.D.S., 45-year-old woman. The patient was suicidal in October 2017 accidentally injured her left leg with a shotgun blast. Consequently, she had an exposed fracture in the left tibia and fibula with a lesion in the anterior region of the leg measuring 17 × 4.5 cm (Figure 2). An orthopedic procedure to treat the fractures of both bones of the leg using an external fixator was conducted and an assessment by the plastic surgeon was requested. Elastic suturing was indicated and performed in December 2017 in two stages, and the wound's width had decreased to 1.2 cm 1 week later. The patient progressed adequately after plastic surgery and continues to be followed up at the hospital outpatient clinic.

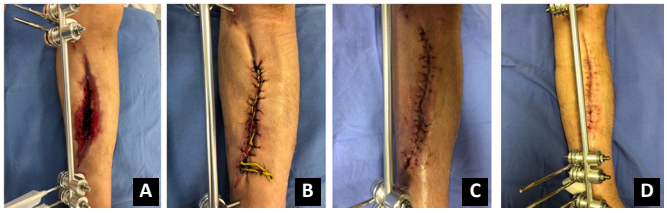

Figure 2. A: Skin lesion – preoperative view; **B:** Elastic suture - immediate postoperative view; **C:** First week postoperative view; **D:** 1-month postoperative view.

DISCUSSION

After the technique was performed, the lesion healed as well as with the use of grafts and flaps since collagen is the main structure of the healing process, as it is constantly produced and degraded by fibroblasts and exerts tensile strength and supports the tissue. Throughout the basic stages, the produced collagen is replaced by the formation of cross-links between the fibers[2]. Therefore, the elastic suture works at this healing stage, facilitating and accelerating this wound tensile process.

In addition, during the first 24–36 hours, epithelial cells are produced and migrate to the central area of the lesion and induce another force that favors closure of the wound edges. However, the elastic suture is more effective during the maturation stage of the wound healing process since the wound is then under constant contraction due to the movement of all the surrounding thick skin, reducing the area of the disordered scar tissue[2].

The tensile suture technique helps prevent the excessive productions of collagen and epithelial tissue, which cause scarring defects due to the differentiation of fibroblasts to myofibroblasts. Moreover, use of the elastic suture in elderly patients can overcome the lack of tissue flexibility, while the progressive decrease in collagen production can be beneficial in the wound healing maturation stage in diabetic patients since most wound healing stages are impaired by high blood glucose levels[3].

The biomechanical principle of tissue tensile strength is the main mechanism explored in the elastic suture technique. The distribution of the tensile strength of the skin increases metabolic activity, which promotes vessel development and collagen fiber proliferation for tissue healing. Moreover, the viscoelastic properties of the skin allow gradual extension by a continuous traction–creep phenomenon[3]. Since primary closure of lesions is the first treatment choice whenever possible, the healing process associated with elastic suturing leads to this primary closure at the end of the procedure.

The comparison of two techniques of elastic suturing demonstrated that fixation of the elastic subcutaneously and in the superficial fascia spared the tissue from necrosis. Raskin's technique in 1993[4] proposed fixation of the interlaced elastic directly on the wound edges, whereas the technique of Leite *et al.* in 1996[5] proposed fixation of the elastic subcutaneously and in the superficial fascia[3,6]. We used Raskin's technique in both cases of the present study.

CONCLUSION

The outcomes of our two patients were very positive and corroborated findings already described in the literature. This technique was effective, low cost, fast, and safe and resulted in good wound healing. In addition, it did not leave a second scar in the donor area as occurs with graft use.

COLLABORATIONS

DSF Final manuscript approval, project administration, realization of operations and/or trials, supervision, writing - original draft preparation, writing - review & editing.

ALP Analysis and/or data interpretation, conception and design study, data curation, final manuscript approval, realization of operations and/or trials, writing - original draft preparation, writing - review & editing.

YPS Analysis and/or data interpretation, conception and design study, data curation, final manuscript approval, formal analysis, methodology, writing - review & editing.

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Case Report

Use of the "spaghetti" technique for surgical treatment of lentigo maligna

Uso da técnica em "spaghetti" para tratamento cirúrgico do lentigo maligno

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■ **ABSTRACT**

Lentigo maligna (LM) is a melanoma in situ that commonly presents as a macula with progressive and irregularly pigmented growth, especially in the face of elderly people with sun-damaged skin. This melanoma in situ has a risk (30-50%) of progression to lentigo maligna melanoma. Complete surgical excision of the lesion requires margins of at least 10 mm, even for lesions in situ. However, when the growth of LM occurs in areas of aesthetic or functional implications (face, neck, and soles), the excision is often reduced to preserve important anatomic structures and for cosmetic purposes. Moreover, the peripheral margins may be clinically ill-defined and not always pigmented, and thus, such cases are associated with underestimated extension and risk of insufficient resection. The "spaghetti" technique, described by Gaudy Marqueste, is a strategic surgical approach based on sampling of a range of "spaghetti-like" strips to determine the margins of the lesion prior to removal of the tumor. After the pathological confirmation of neoplasia-free margins, the main central lesion is resected, allowing reconstruction of the defect in the same procedure, as an alternative to Mohs micrographic surgery.

Keywords: Lentigo; Melanoma; Excision Margins; Reconstructive surgical procedures; Nose.

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■ **RESUMO**

O lentigo maligno (LM) é uma forma de melanoma *in situ* que mais comumente se apresenta como uma mácula de crescimento lentamente progressivo, pigmentada, na face de idosos com pele danificada pelo sol. Esse melanoma *in situ* tem um risco (30% a 50%) de progressão para lentigo maligno melanoma. A excisão cirúrgica completa da lesão requer margens de pelo menos 10mm, mesmo para lesões *in situ*. Porém, quando o crescimento de LM ocorre em áreas de implicações estéticas ou funcionais (face, pescoço, solas), a excisão é frequentemente reduzida para preservar estruturas anatômicas importantes e por razões cosméticas. Além disso, as margens periféricas podem ser clinicamente mal definidas e nem sempre pigmentadas, com extensão subestimada e risco de ressecção insuficiente. A "técnica de espaguete", descrita por Gaudy Marqueste, é uma cirurgia estratégica baseada na amostragem de uma faixa de tecido "*spaghetti-like*" para determinar as margens da lesão antes da remoção do tumor. Após a confirmação anatomopatológica de margens livres de neoplasia, a lesão principal central é ressecada, permitindo a reconstrução do defeito no mesmo procedimento, sendo uma alternativa à cirurgia micrográfica de Mohs.

Descritores: Lentigo; Melanoma; Margens de excisão; Procedimentos cirúrgicos reconstrutivos; Nariz.

INTRODUCTION

Lentigo maligna (LM) is a melanoma *in situ* that commonly presents as a macula with progressive and irregularly pigmented growth, especially in the face of elderly people with sun-damaged skin[1]. The risk of progression to lentigo maligna melanoma varies from 30-50% in this type of lesion[2].

Treatment options for LM include surgical excision with oncologic margins or non-surgical treatments such as cryotherapy, curettage, electrocautery, laser, radiotherapy, fluorouracil, and imiquimod. However, these non-surgical methods have high recurrence rates (20-100%)[3].

Complete surgical excision of the melanoma *in situ* requires circumferential margins of at least 5 mm[4]. In cases of LM in areas with substantial aesthetic or functional implications (face, neck, and soles of the feet), surgical margins are usually reduced to preserve important anatomic structures. In addition, clinical margins of the LM may be poorly defined and not always pigmented, and thus, such cases are associated with underestimated extension, which increases the risk of inadequate resection,[5] and the appropriate treatment is challenging.

The "spaghetti technique", described by Gaudy Marqueste, is a surgical technique based on the sampling of a narrow band of tissue just beyond the lesion to determine the surgical margins before resection of the tumor lesion. This tissue band is referred for conventional histopathological examination and, if the margins are free of tumor tissue, the central lesion is then resected, minimizing tissue loss; thus, being an alternative to Mohs micrographic surgery[5].

CASE REPORT

The medical records of patient M.B.M.C., a 54-year-old man with skin phototype III on the Fitzpatrick scale, who presented with a pigmented lesion with irregular edges and coloration and progressive growth located on the nasal tip of approximately 1.5 cm in diameter, were reviewed (Figure 1).

The patient underwent incisional biopsy of the lesion in April 2018 with a diagnosis of melanoma *in situ* type lentigo maligna.

The "spaghetti technique" was then used to determine the surgical margins before complete resection of the lesion (Figure 2). Tumor limits were defined with the aid of confocal dermoscopy and subsequently a band of skin beyond the tumor with a margin of 1 mm was resected (Figures 3 and 4).

The surgical piece was marked with a nylon 5.0 suture at the 12 o'clock position to guide the histopathological examination, which subdivided it into 4 quadrants (12 - 3 hours, 3 - 6 hours, 6 - 9 hours, and 9 - 12 hours).

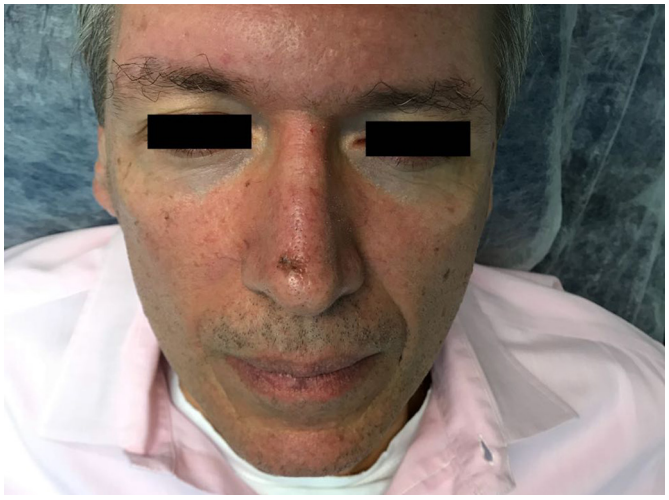

Figure 1. Lentigo maligna on the nasal tip.

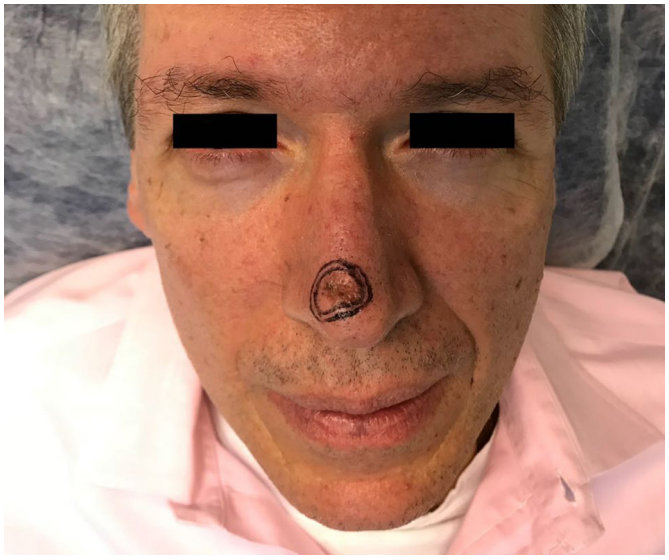

Figure 2. Pre-operative marking of the margins of the lesion.

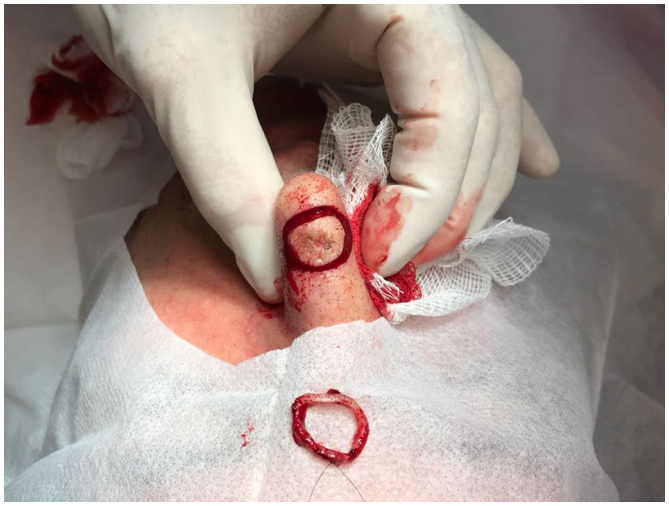

Figure 3. First surgical stage with resection of the skin "spaghetti" strip, circumferential to the tumor.

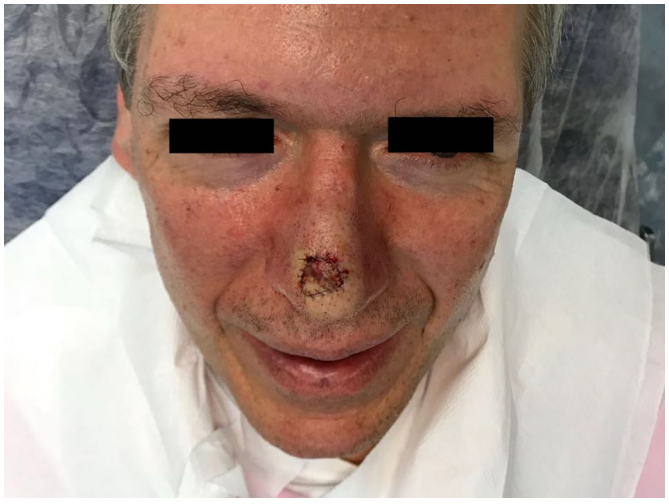

Figure 4. Skin suture after resection of the circumferential margin

The result of the examination revealed neoplastic involvement in the margins of the 3 to 6 o'clock quadrant. The margins were enlarged, and the material was forwarded again for analysis (Figure 5).

The resection of the central lesion was performed after 15 days of expansion of margins that proved to be free of neoplastic involvement by histopathological examination. During the resection, the scar tissue peripheral to the central lesion was encompassed and local reconstruction was performed with a Rintala flap during the same surgery (Figures 6 to 8).

The patient recovered well, without any signs of recurrence during a six-month follow-up period.

DISCUSSION

The "spaghetti technique" is an easy and safe method to control surgical margins in the case of lentigo maligna, especially when the lesion is in an area where there is a greater risk of impairment of vital structures.

One of the precautions that must be taken during the resection of the tumor lesion is englobing the scar area from previous surgeries to prevent local recurrence.

The skin suturing after resection of the circumferential margin in the «spaghetti» technique should be done in a careful manner with minimal passage of the needle to the healthy tissue.

Other techniques, such as the "square" technique and the "perimeter" technique, have used the concept of pathological control of margins before total resection of LM. In these techniques, a geometric resection shape (square, triangle, or pentagon) is determined to facilitate the analysis of margins while maintaining the central lesion intact. The objective is to verify the periphery of this geometric figure before resection[6,7].

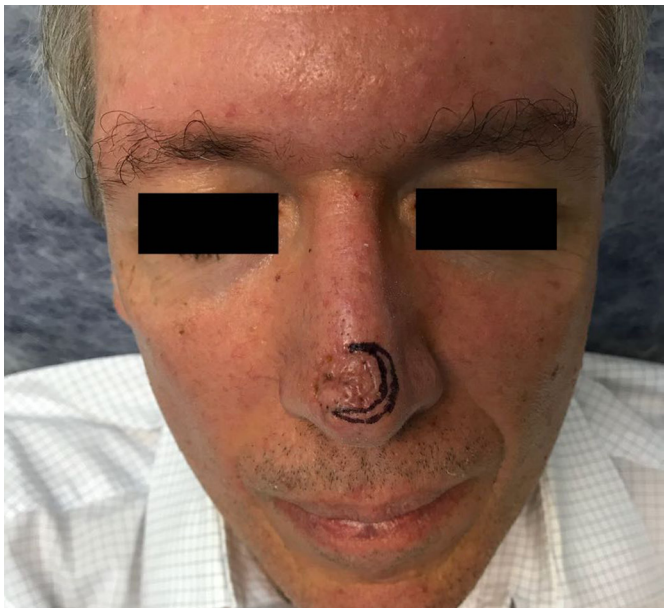

Figure 5. Widening of margins of the 3 to 6 o’clock quadrant.

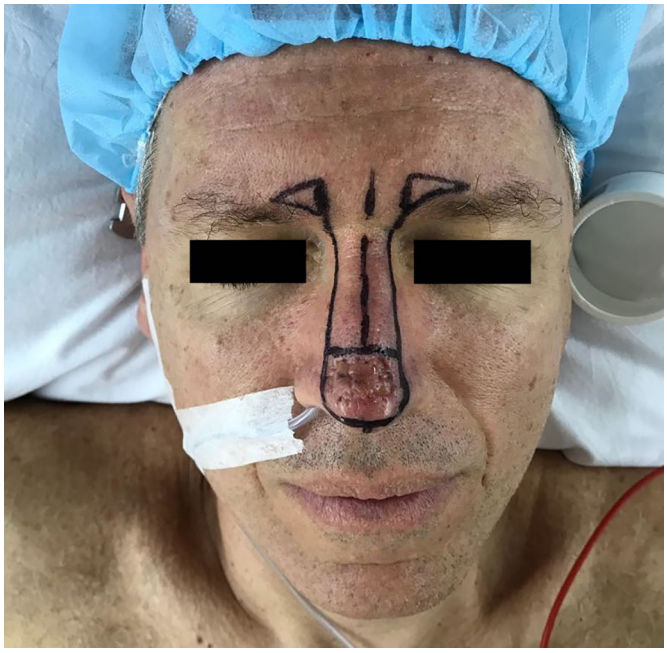

Figure 6. Pre-operative marking of the resection of the central lesion with immediate reconstruction with the Rintala flap.

The advantage of the «spaghetti» technique is the higher preservation of adjacent tissues when compared to that with the other techniques mentioned.

Mohs micrographic surgery is also an option in these cases, but a trained team must perform the operation. In addition, by using paraffin blocks, the “spaghetti” technique is more reliable than those techniques using freezing[5].

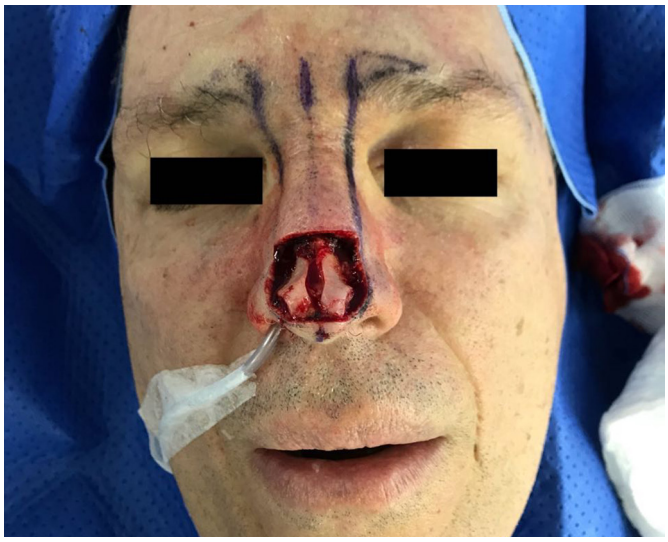

Figure 7. Second surgical stage with resection of the central lesion and reconstruction in the same procedure.

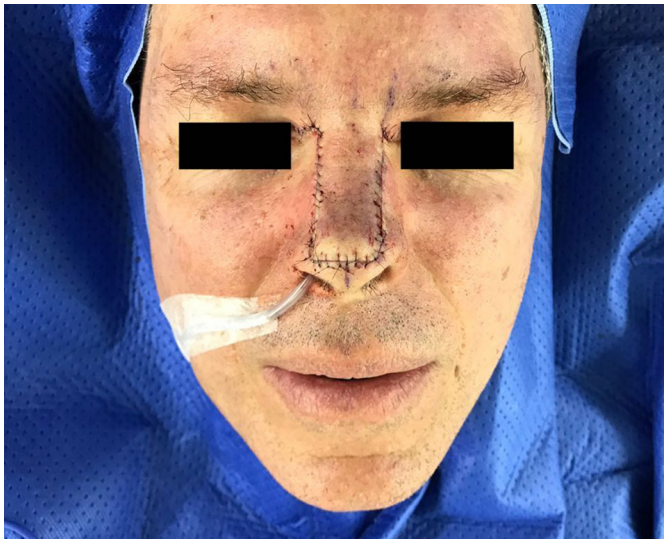

Figure 8. Final appearance in the immediate postoperative period.

The disadvantages of the technique consist of the requirement of at least two surgical operations, which may increase the risk of complications of the surgical wound. Conversely, it may be more comfortable for the patient, since it prevents the permanence of open wounds and allows the removal of the tumor with immediate reconstruction. Confocal dermoscopy is a tool that can be used to assist the delimitation of the tumor margins, but may not be accessible.

In this case, the “spaghetti” technique proved to be a good option in the treatment of the LM as a simple and reproducible method, ensuring the control of margins and lower morbidity for the patient.

COLLABORATIONS

GSS	Analysis and/or data interpretation, conception and design study, data curation, writing - original draft preparation, writing - review & editing.
FBH	Writing - review & editing.
CHSTS	Writing - review & editing.
LADS	Writing - review & editing.
FHSP	Supervision, writing - review & editing.
IDAOSF	Supervision, writing - review & editing.
CSS	Supervision, writing - review & editing.
ERB	Conception and design study, final manuscript approval, supervision, writing - review & editing.

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Special Article

Severe complication due to inappropriate use of polymethylmethacrylate: a case report and current status in Brazil

Complicação grave do uso irregular do PMMA: relato de caso e a situação brasileira atual

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■ **ABSTRACT**

Introduction: Use of permanent fillers can lead to significant complications. In Brazil, polymethylmethacrylate (PMMA) is a product approved by the Agência Nacional de Vigilância Sanitária (ANVISA), but its use exceeds its indications, leading to serious complications. Recommendations for restricted use have been in place for more than a decade, but cases with serious consequences due to inappropriate use are still seen. **Objective:** To report a serious complication due to inappropriate use of PMMA and discuss the current status of PMMA use in Brazil based on recommendations of medical societies and regulatory agencies. **Methods:** This report describes a case of extensive necrosis of the gluteal region after injection of PMMA by a non-qualified practitioner; the report also reviews the literature on the current status of PMMA use in Brazil. **Discussion:** Despite the efforts of medical societies, acute and chronic complications are still reported in the Brazilian literature. In 2016, more than 17,000 PMMA-related complications were reported; nevertheless, reliable epidemiological data remain unavailable because the number of treatments, the quality of the product, and the training of practitioners remain unregulated. **Conclusion:** A significant number of repair procedures are performed in Brazil to correct complications resulting from the use of PMMA. The severity of the reported case highlights the need to combat bad practice by untrained professionals, as well as the need for greater control of PMMA marketing by regulatory agencies.

Keywords: Polymethylmethacrylate; Skin fillers; Brazil; National Health Surveillance Agency; Health advice; Reconstructive surgical procedures/adverse effects.

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■ **RESUMO**

Introdução: Os preenchedores permanentes, apesar de resultados duradouros, são verdadeiros problemas quando causam complicações. No Brasil, o PMMA é um produto aprovado pela Anvisa, mas seu uso extrapola suas indicações, levando a complicações graves. Há mais de uma década, existem recomendações sobre sua restrição, mas casos com consequências graves do seu uso irresponsável são atuais. **Objetivo:** Relatar complicação grave do uso irregular do PMMA e discutir a realidade brasileira atual baseado em determinações das entidades médicas, assim como dos órgãos reguladores. **Métodos:** É relatado um caso de necrose extensa da região glútea após a injeção de PMMA por profissional não qualificado e discutida a situação brasileira atual do produto com base nas entidades médicas e revisão da literatura do Brasil. **Discussão:** Apesar do esforço das entidades médicas, são inúmeros os casos de complicações agudas e crônicas relatados na literatura brasileira. No ano de 2016, foram registradas mais de 17 mil complicações relacionadas ao PMMA, mesmo assim, é difícil estabelecer dados epidemiológicos confiáveis, pois não há controle do número de aplicações, da qualidade do produto utilizado e da capacitação dos profissionais que o utilizam. **Conclusão:** No Brasil, há um número expressivo de procedimentos reparadores para correção de complicações decorrentes do uso do PMMA. A gravidade do caso relatado traz à tona a necessidade de combate à má prática por profissionais não capacitados, assim como um controle mais rigoroso da comercialização do produto por entidades reguladoras.

Descritores: Polimetil metacrilato; Preenchedores dérmicos; Brasil; Agência Nacional de Vigilância Sanitária; Conselhos de saúde; Procedimentos cirúrgicos reconstrutivos/efeitos adversos.

INTRODUCTION

Fillers used in aesthetic medicine can be divided into 2 major groups: absorbable fillers and permanent fillers[1]. Some of the advantages of absorbable fillers include the reversibility of undesired results, whether by action of an "antidote" or through resorption by the body itself. With permanent fillers, however, complications become a real problem due to persistence of the product and perpetuation of unwanted results[2].

These complications are inherent to all types of fillers and may be classified as acute or chronic. Acute complications include vascular embolism, necrosis, allergic reactions, and infections. Chronic complications include granuloma formation, deformities, and inflammatory reactions[2].

The acute complications deserve attention because they depend directly on practitioner qualifications and training. For the most part, this type of complication is more related to treatment technique and not necessarily to the product used[3].

The most commonly used permanent filler is polymethylmethacrylate (PMMA). PMMA is available as polymeric microspheres ranging in size from 30 to 103 μm. These spheres are suspended in a vehicle of bovine collagen, carboxymethylcellulose, or sodium hyaluronate, which are resorbed after a few days[2].

In 2006, the U.S. Food and Drug Administration approved ArteFill® for use by physicians alone, and limited its application to perioral volume augmentation, e.g., nasolabial filling, excluding that of the lips[4]. In Brazil, the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, ANVISA) recommends use by trained medical professionals, and does not contraindicate use for body filling or provide guidelines for aesthetic use[5].

As PMMA is inexpensive and easily obtained, numerous cases of complications have occurred, arising from use by untrained professionals in substandard aesthetic centers. This case report describes complications due to use of PMMA filler in a

clandestine clinic in the city of São Paulo, and discusses the current status of PMMA use in Brazil.

CASE REPORT

A 21-year-old female presented with a history of injection of 900 ml of PMMA in the buttocks 12 days prior. The procedure was performed in a beauty salon by a nonmedical professional. She had pain and ulcerated wounds with purulent secretions at the injection site (Figure 1), and had already received ciprofloxacin and clindamycin for 7 days without improvement, as well as day hospital treatment with ceftriaxone and prednisone.

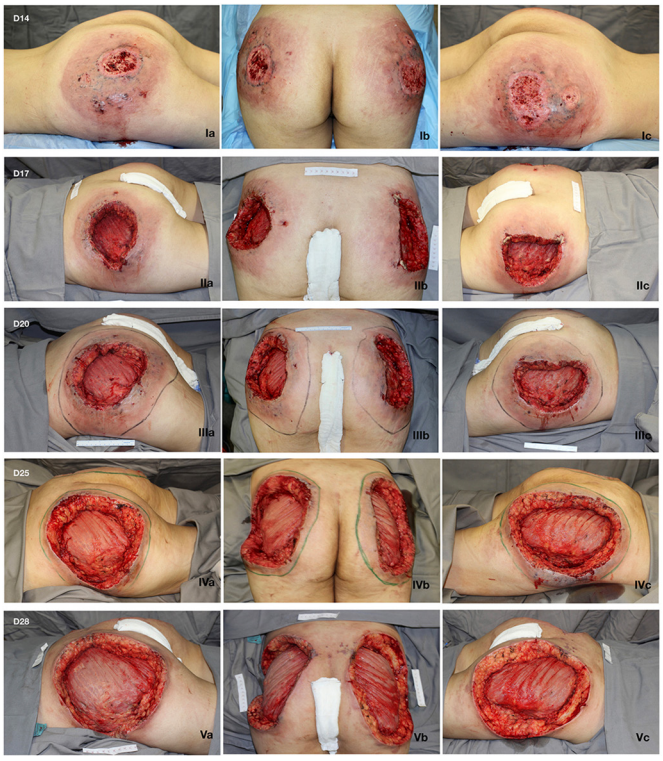

Figure 1. Surgical wound appearance after serial debridement. a: left lateral, b: posterior, c: right lateral; **I:** at 14 days; **II:** after first debridement; **III:** after second debridement, circumferential increase in surgical wound hyperemia and coalescence of wounds in the sacral region; **IV:** after third debridement, circumferential increase in surgical wound hyperemia; **V:** after fourth debridement, appearance of necrosis in the sacral region.

On admission, the patient was afebrile and hemodynamically stable. Laboratory tests showed leukocytosis and elevated C-reactive protein, and computed tomography showed densification and thickening of the skin and subcutaneous tissue of the gluteal regions, in addition to multiple nodular formations consistent with exogenous material/granulomas (Figure 2), but no evidence of collections.

She initially received empirical broad-spectrum antibiotic therapy, but the wound deteriorated.

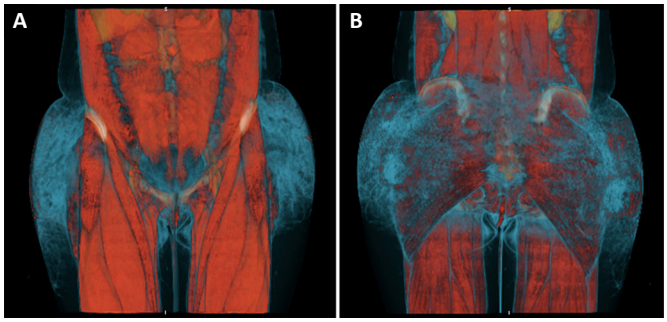

Figure 2. 3D tomographic reconstruction on admission. Blue represents infiltration of subcutaneous tissue in the bilateral gluteal regions at PMMA application sites. **A:** anterior view; **B:** posterior view. In retrospective analysis, image of infiltrated area coincided with that of debridement area.

Serial debridement was performed (Figure 1), and continuous negative pressure therapy was applied at 125 mmHg, with sequential exchanges every 3 to 5 days. Suppuration and necrosis of the dermis (Figure 3) and subcutaneous tissue were observed, with nodular formations containing pus and exogenous material in addition to signs of bilateral gluteus maximus fasciitis. Fragments of soft tissue were sent for culture, but no microorganism was identified.

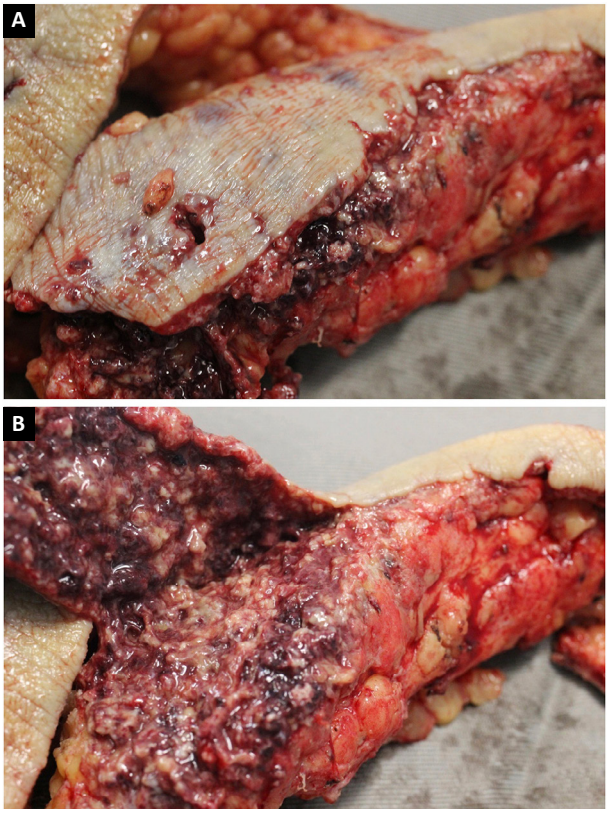

Figure 3. Skin necrosis in a surgical specimen. A: purplish spots on the surface; **B:** epidermis folded back to show dermis and subcutaneous tissue with extensive necrosis.

Due to the severity of the inflammatory/infectious process, she remained in the intensive care unit for 14 days, and developed acute renal failure. She showed progressive improvement after the 3rd debridement.

Given the size of the wound after sequential debridement and the extensive loss of nutrients, hemoglobin, and microelements, bilateral homologous skin grafting was performed over the gluteus maximus (Figure 4), with addition of negative pressure therapy (Figure 5).

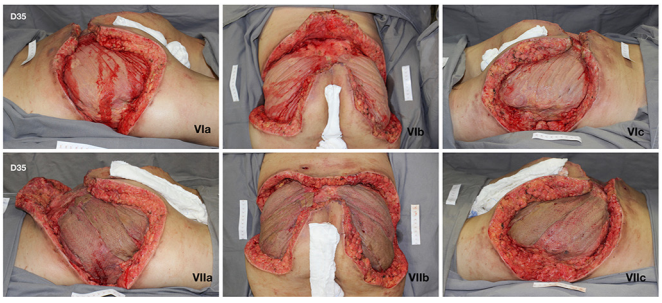

Figure 4. Wound appearance after serial debridement and homologous skin grafting. **a:** left lateral, **b:** posterior, c: right lateral; **VI:** after sixth debridement, showing extension to the sacral region; **VII:** 1:1.5 mesh graft over the gluteus maximus bilaterally.

After 3 weeks of treatment with biological dressings (homologous grafts) and improvement of nutritional parameters, autologous skin grafting was performed (Figure 6) with 1:1.5 mesh. The graft showed good integration (Figure 7) without functional deficits, and the patient was discharged after 68 days of hospitalization.

PMMA in Brazil

The use of PMMA as a filler has been approved under federal law since 2004 for treatment of HIV-associated lipodystrophy[6]. However, indiscriminate use for aesthetic purposes without scientific evidence merited a public alert by the Federal Medical Council (Conselho Federal de Medicina, CFM) in 2006, as non-qualified practitioners promoted a technique known as "bioplasty".[7]

In 2007, ANVISA prohibited the preparation of PMMA products by compounding pharmacies in order to regulate quality and purity[8].

In 2008, complications related to PMMA use in a series of 32 cases led to classification into 5 types: necrosis, granuloma, chronic inflammatory reaction, lip complications, and infection. Necrosis is always an acute complication, whereas inflammatory complications can occur many years after injection. The rarity of the complications was highlighted, but it was difficult to estimate the incidence and prevalence in the entire population. In addition, concern was raised about serious complications, which, in addition to being permanent, are often untreatable[2].

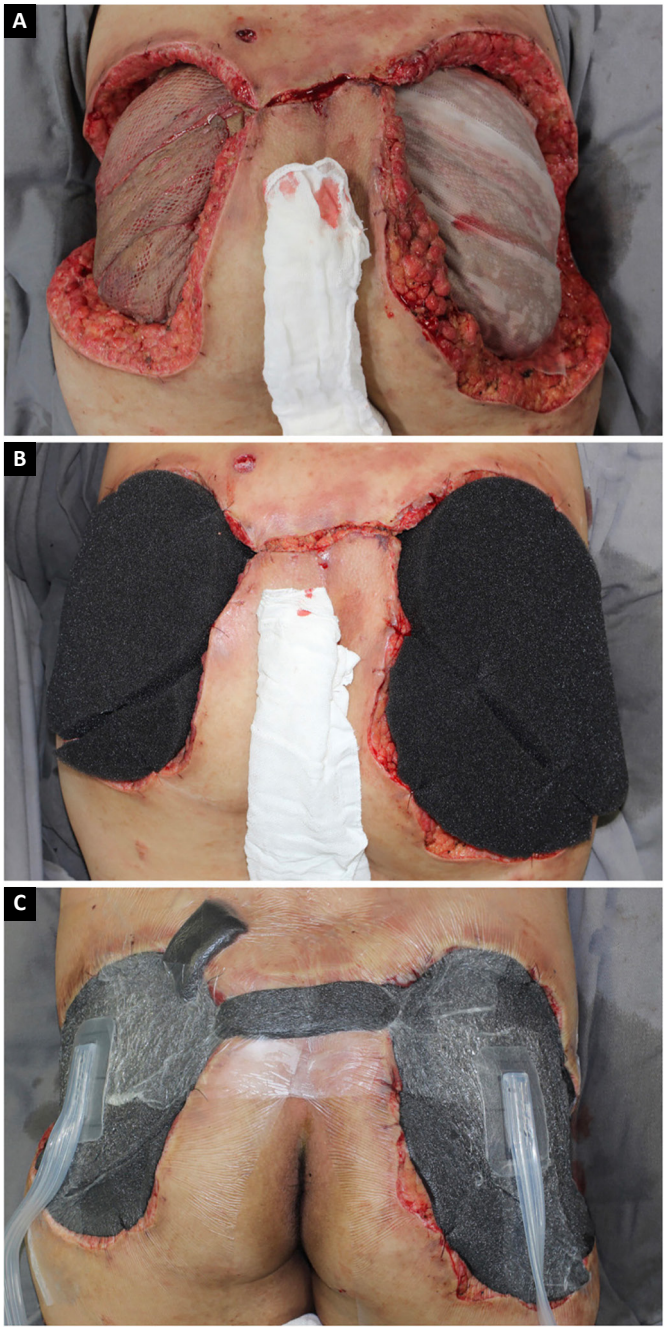

Figure 5. Negative pressure therapy at homologous graft sites. **A:** left gluteal wound with 1:1.5 mesh graft and right gluteal wound with non-adherent gauze on the graft; **B:** negative pressure dressing sponge in place; **C:** continuous vacuum at 125 mmHg.

In 2009, another series of 18 cases with various complications related to PMMA use highlighted the indiscriminate use of this substance owing to its low cost and the lack of regulation of its sale to nonspecialist physicians and nonphysicians[9]. In 2012,

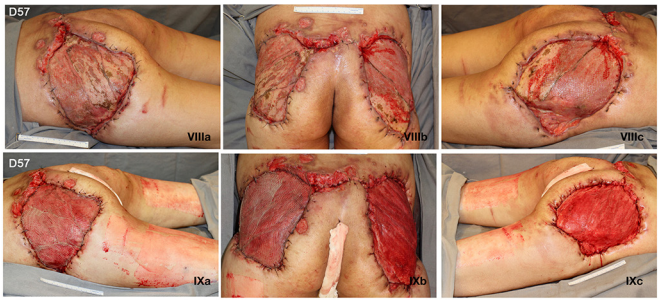

Figure 6. Wound appearance after 3 weeks with homologous grafting and subsequent immediate autologous grafting. **a:** left lateral; **b:** posterior; **c:** right lateral; **VIII:** after ninth debridement and 3 weeks of homologous grafting over the gluteus maximus; **IXa:** 1:1.5 mesh graft over gluteus maximus after debridement of hypertrophic granulation and epidermal remnants of previous homologous graft; **IXc:** appearance of wound bed after debridement of previous homologous graft.

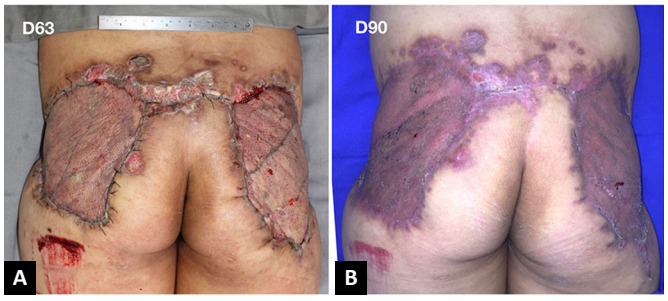

Figure 7. A: Sixth postoperative day. Appearance of partial, autologous 1:1.5 skin mesh graft. **B:** 1-month postoperatively, showing integration of graft and wound.

a histopathological study of 63 cases of complications attributed to PMMA identified 5 cases with acute complications, all of which developed necrosis after injection[10].

In 2010, the Regional Medical Council of Paraná (Conselho Regional de Medicina do Paraná, CRM-PR) issued an opinion that the unrestricted use of PMMA in gluteal augmentation, or use in large quantities, was unsafe and unpredictable, and could lead to chronic reactions and unmanageable complications[11]. In 2012, ANVISA issued a safety alert highlighting the possible chronic complications of PMMA, as well as the need for professional training in its use[12,13].

In 2013, the CFM issued a new opinion reinforcing the 2010 opinion of the CRM-PR and reaffirming the limited indications for PMMA injection, noting that use in large quantities could lead to unpredictable results[14]. In this opinion, both the Brazilian Society of Plastic Surgery (Sociedade Brasileira de Cirurgia Plástica, SBCP) and the Technical Chamber of Plastic Surgery of the CFM recommended that PMMA only be used by physicians, as well as in small doses and with restrictions.

The 2016 census by the SBCP-SP (regional São Paulo branch) reported that a total of 4,432 procedures were performed to treat complications of PMMA injection, equivalent to 0.7% of the total number of reparative procedures in that year[15]. In the same year, more than 17,000 complications associated with use of PMMA were recorded in Brazil. Meanwhile, the use of nonsurgical procedures (primarily for filling) increased by 390% in a 2-year period[16].

DISCUSSION

Based on the data for the last decade, concerns about these procedures are inevitable. Despite the significant and immediate results in aesthetic filling, the unregulated popularization of PMMA use, in addition to its use in large volumes with inadequate technique, have shown that PMMA can be harmful when misused for this purpose.

In Brazil, the regulation and supervision of aesthetic medical centers by responsible agencies remain inadequate. In addition, despite the efforts of medical societies, misinformation is widely disseminated, made worse by increasing exposure on social media. This misinformation exposes patients to unsafe procedures.

With reports of significant adverse outcomes in the Brazilian media in recent years, including mutilating and fatal cases, medical societies have spoken out against the use of PMMA for aesthetic purposes. In 2018, both the SBCP and the Brazilian Society of Dermatology (Sociedade Brasileira de Dermatologia, SBD) issued a warning on the use of PMMA, with a contraindication for use in large amounts, reinforcing the unpredictability of results and requesting the recategorization and restriction of its use by ANVISA[17].

Reports of adverse outcomes related to PMMA are rare in the medical literature, with complication rates ranging from 0.01% to 3%[2,18]. Although small, these numbers deserve attention, since underreporting of complications is known to occur, both because they may be delayed and also due to omission of reporting in the medical record[3]. Furthermore, it may be unclear whether complications are caused by PMMA itself or poor technique. Complications caused by permanent fillers deserve special attention, because they create chronic problems and are difficult to treat. Despite the availability of protocols, there is no consensus on standardization of treatment[19].

Complications, such as necrosis, are even rarer (0.003%)[18]. Technical failure is attributed to the application of needles in flat surfaces and not necessarily to PMMA. In one author's account of personal experience with more than 5,000 cases published in 2012[20], a complication rate of 0.01% was reported, with no necrosis observed. This was ascribed

to adherence to 3 principles: deep plane application, use of a microcannula, and use of pure and certified PMMA.

In the case described herein, both the quality of the product and the technique used were questionable. The combination led to severe complications.

Acute local inflammation within the first hours after treatment was an important warning sign that required close monitoring. With progression to necrosis, aggressive surgical debridement combined with negative pressure therapy were imperative for treatment of inflammation and preparation of the wound bed[21]. Debridement surgery is challenging, because healthy tissue is invaded by necrotic tissue, creating a false impression of satisfactory treatment. Coverage of the wound after proper cleaning is also challenging, however, and sequelae and deformities may not be be fully corrected by plastic surgery.

The use of diagnostic tomography in the present case was a predictor of the extent of necrosis, since it revealed densification of affected tissue, even in areas that still appeared clinically healthy. The findings coincided with the debrided areas. There are no comparable studies in the literature.

CONCLUSION

Despite low published complication rates in Brazil, an excessive number of repair procedures are needed to correct complications from use of PMMA. The severity of the reported case highlights the need to combat bad practice by untrained practitioners, as well as the need for greater regulation of the commercialization of PMMA. Complications can lead to death and permanent deformity, and treatment is challenging.

COLLABORATIONS

KTK	Analysis and/or data interpretation, conception and design study, data curation, final manuscript approval, investigation, methodology, project administration, realization of operations and/or trials, writing - original draft preparation, writing - review & editing.
MM	Realization of operations and/or trials.
DAM	Realization of operations and/or trials, supervision, writing - review & editing.
AAMJ	Supervision.
RG	Supervision, visualization.

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Special Article

Plastic surgery for the treatment of contagious diseases: lobomycosis

Cirurgia plástica e o tratamento de doenças infectocontagiosas: lobomicose

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■ **ABSTRACT**

Introduction: Lacaziosis is a rare disease that mainly affects workers in tropical areas, with approximately 500 cases reported worldwide. Lacaziosis is a parasitic disease caused by the saprophytic fungus Lacazia loboi; there is no specific treatment for this disease. Surgery is the most effective treatment for the deformities caused by the disease. However, it is a temporary treatment, since disease recurrence is frequently observed. Lacazia loboi affects two species of dolphin, Tursiops truncates and Sotalia guianensis. The available literature discusses the surgical treatment in a superficial way , because there are no specific studies describing the surgical treatment for this disease. **Methods:** Here, we describe our 8 years of experience with lacaziosis at the Hospital de Base de Porto Velho - Rondônia; a total of 22 patients underwent surgical treatment and were followed-up. **Results:** The majority of the patients (91%) had already submitted to at least one surgical treatment together with antifungal treatment. The patients presented with lesions with disease progression ranging from 5 months to 6 years prior to surgical treatment. Only two patients were treatment-naive. **Conclusion:** Our patients were followed-up; however, only 11 of the 22 patients returned for follow-up. Recurrences were observed in 9 of the 11 patients, with a latency period of 5 months.

Descriptors: Lobomycosis; Reconstructive surgical procedures; Communicable diseases; Advanced treatment; Recurrence; Lacazia.

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■ **RESUMO**

Introdução: Lacaziose é uma doença rara que afeta principalmente trabalhadores de áreas tropicais, sendo descritos aproximadamente 500 casos no mundo. A lacaziose é um doença parasitária causada pelo fungo saprófita *Lacazia loboi*, para o qual não existe um tratamento específico. A cirurgia é o tratamento mais eficiente para as deformidades causadas pela doença. Entretanto, é um tratamento temporário, uma vez que as recidivas são frequentes. *Lacazia loboi* acomete duas espécies de golfinhos, o *Tursiops truncates* e o *Sotalia guianensis*. A literatura aborda o tratamento cirúrgico de maneira superficial, pois não existem trabalhos específicos descrevendo o tratamento cirúrgico para essa doença. **Métodos:** Descrevemos aqui nossos 8 anos de experiência no Hospital de Base de Porto Velho-Rondônia com 22 casos submetidos a tratamento cirúrgico e acompanhados. **Resultados:** A maioria dos pacientes (91%) já se submeteram a pelo menos um tratamento cirúrgico associado ao tratamento antifúngico. Os pacientes apresentavam lesões com tempo de evolução entre 5 meses e 6 anos previamente ao tratamento cirúrgico. Apenas dois casos eram virgens de tratamento. **Conclusão:** Nossos pacientes foram acompanhados, mas apenas 11 dos 22 pacientes retornaram para acompanhamento. Recorrências foram observadas em 9 dos 11 pacientes, com um período de latência de 5 meses.

Descritores: Lobomicose; Procedimentos cirúrgicos reconstrutivos; Doenças transmissíveis; Tratamento avançado; Recidiva; Lacazia.

INTRODUCTION

The first report of Lobo's disease, called lobomycosis or currently known as lacaziosis, was first described in 1930 by a Brazilian dermatologist, Jorge Lobo.

The majority of the cases described in humans, approximately 500 cases worldwide, is restricted to jungle regions, with hot and humid climate, abundant water courses, and high rainfall, such as the Brazilian Amazon region.

Approximately 300 cases were registered in Brazil; lacaziosis cases have also been reported in Peru, Colombia, Venezuela, French Guiana, Guyana, Bolivia, Ecuador and Suriname, with approximately 200 registered cases registered[1]; rare cases have also been described in other parts of the world, such as North America[2,3], Central America and some European [4,5] and African countries[6].

The etiologic agent is the saprophytic fungus, *Lacazia loboi*, which is present in water, soil and vegetation. The mode of transmission is not known, and infection may be transmitted by inoculation of the fungus by solutions of continuity of skin; this is often caused by trauma with plant fragments and insect stings[7,8].

History and pathogenesis

The parasite, *Lacazia loboi*, over time, has been designated in different ways, with the current nomenclature being adopted in 1999 by Taborda et al.[7]. The term *lacazia* comes from the name of the Brazilian mycologist, Carlos da Silva Lacaz, who greatly contributed to a better understanding of this disease, and the term *loboi* was adopted to honor the first physician to describe the disease, Jorge Lobo.

In 2007, Hibbett et al.[8] classified the fungus as belonging to the phylum Ascomycota, subphylum Pezizomycotina, class Eurotiomycetes, subclass Eurotiomycetidae, order Onygenales, and family Onygenceae.

Its phylogenetic classification was based on the identification of the fungus using the 18s ribosomal subunit DNA and a 600-bp fragment of the CHS2 gene (chitin synthetase 2) from yeast cells [9,10].

In addition to humans, two species of dolphin, *Tursiops truncates*[11] *and Sotalia guianensis*[12.13], are affected by this parasite. No cases of lacaziosis in harbor porpoises or dolphins in the area of the Amazon basin have been described.

The individuals most affected are laborers in the aforementioned areas, with most of them being rubber

tappers, lumberjacks, farmers, fishermen, and miners of precious stones[7,8]; these individuals are usually males aged around 50 years[14].

Little is known about the mode of transmission of the disease; the only known way is the inoculation of the parasite from cells infected with the fungus. Inter-human transmissions have never been described. There is only one report of transmission to humans in the literature, wherein the infection was transmitted by a piercing and blunt accident with material infected with the parasite[15,16]; however, transmission may occur when there is contamination in areas of the skin with loss of continuity (wounds) and lobomycosis lesions[11].

Once in contact with the dermis, the fungus is phagocytosed and slow proliferation of the parasite is then initiated. Dissemination may occur through local lymphatic continuity via the regional and hematogenic ganglia[7,16,17]. There is no information regarding the incubation period or latency of this disease; however, elimination or treatment of this infection is difficult due to the high resistance of the parasite, with disease recurrence being very frequent. There are reports of individuals infected by dolphins, with the latency periods varying from 3 months to 4 years[18-20].

There is only one case report of lacaziosis[11]. The immunological response of the skin to the parasite is still not clearly understood. From a histological viewpoint, the lesions are characterized by little organized granulomas composed of histiocytes (CD68), Langerhans cells, and multinucleated giant cells. Immunohistochemical studies revealed the presence of a small number of the following mononuclear cells: T lymphocytes (CD3+), helper T lymphocytes (CD4+), cytotoxic T lymphocytes (CD8+), B lymphocytes (CD20+), plasmocytes (CD79+), and NK cells (CD57+)[19]. Vilani-Moreno et al.[21] suggested that fungi are phagocytosed by histiocytes, which give rise to the giant Langerhans cells; thus, the typical granulomas observed in this disease are formed.

Langerhans cells are responsible for the presentation of antigens in numerous infections. To better understand the disease, Quaresma et al.[18] performed an immunohistochemical study of Langerhans cells and verified that although there are no morphological changes with respect to normal cells, there is an escape mechanism for the presentation of these antigens by Langerhans cells[21].

The is no association between lobomycosis and specific antigens of the class II HLA system; however, the decrease in the frequency of HLA-DR7 antigen in the patient group compared to the control group indicates a protective relationship of HLA-DR7 with lobomycosis.

Clinical Presentation

The lesions of lobomycosis usually appear in exposed areas and in response to trauma; the lesions are frequently observed in the ears, upper and lower limbs, face, chest, and cervical region, and especially in areas with low temperature.

The clinical diagnosis of lobomycosis is usually delayed, since the patients seek medical service due to a nodular lesion in the subcutaneous tissue that is slightly pruriginous and painless and grows slowly and steadily over the years.

Brito & Quaresma[6] classified the lesions of lobomycosis as monomorphic and polymorphic (macules, papules, nodules, gums, nodular plaques, verruciform lesions, scarring, and aphthous lesions), with a predominance of nodular lesions.

More recently Opromolla et al.[20], ranked them as: i) isolated form (Figure 1); (ii) disseminated form (Figure 2); and (iii) multifocal form (Figure 3), that is, multiple localized lesions in just one limb or limb segment. There are other descriptions based on the morphological appearance of the lesions, such as descriptions provided by Lacaz[14], Dias et al.[22], and Ramos and Silva[23], which are as follows: infiltrative, keloidal, plaque, verruciform, and ulcerated (Figures 4-6, respectively). Another lacaziosis classification system was suggested by Lacaz[24] et al., who described it as isolated form, disseminated form, and multifocal (Figures 4, 5, and 6, respectively). The existing classifications often differ only in the description of the lesions (author's note).

Diagnosis

The diagnosis can be established by mycological examination, histopathological assessment, and immunohistochemical staining. To date, the culture of this parasite has not been obtained[13]. In our service, the mycological examination is conducted initially through puncture of the nodules, aspiration of the contents, and direct observation of the parasite on a slide. The anatomopathological examination is performed with hematoxylin-eosin staining, as proposed by Vilela et al.[10]. Fungi can also be visualized by fresh Grocott-Gomori staining or with calcofluor and Periodic acid–Schiff (PAS) staining[7].

Staining with ethidium bromide revealed that the majority of the fungi is non-viable, since ethidium bromide is a marker of nucleic acids, and the parasites found do not have nucleic acids in the cell membrane[21]. The cells are yeast-like, and spherical, with a diameter ranging from 6 μm to 12 μm; the cells have birefringent cell membranes and may be isolated

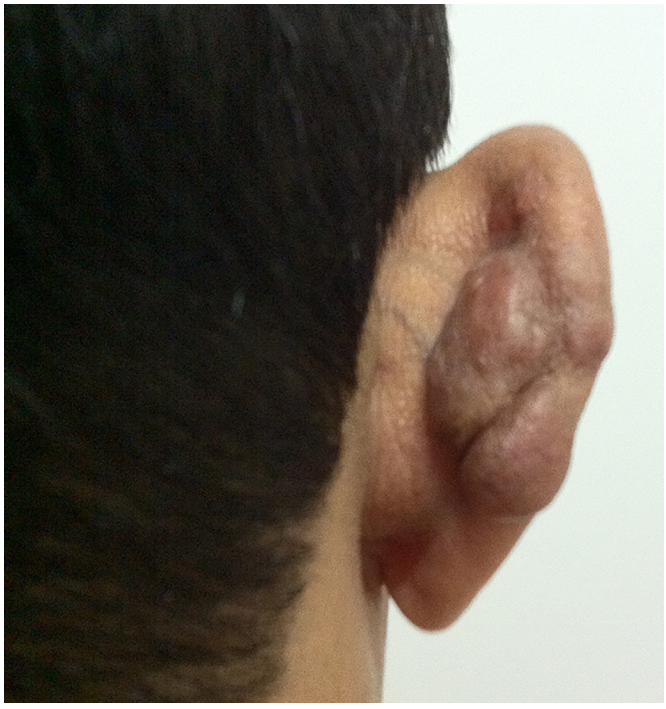

Figure 1. Infiltrative form: A patient with a lesion in the left ear that progressed during a disease course of 23 years. Note a satellite lesion below the ear.

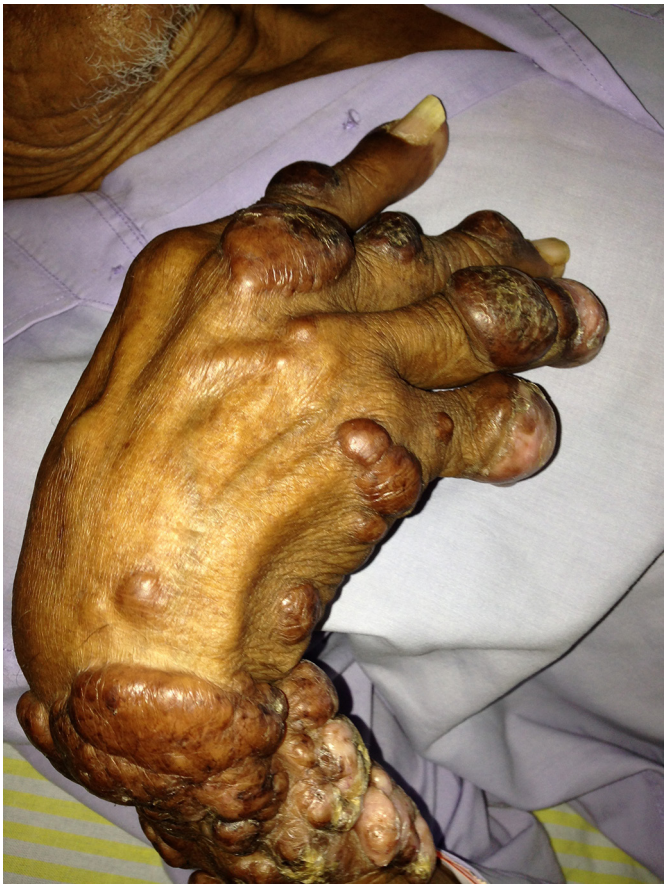

Figure 2. Keloid form: A patient with a lobomycosis lesion in the right breast that progressed during a disease course of 20 years.

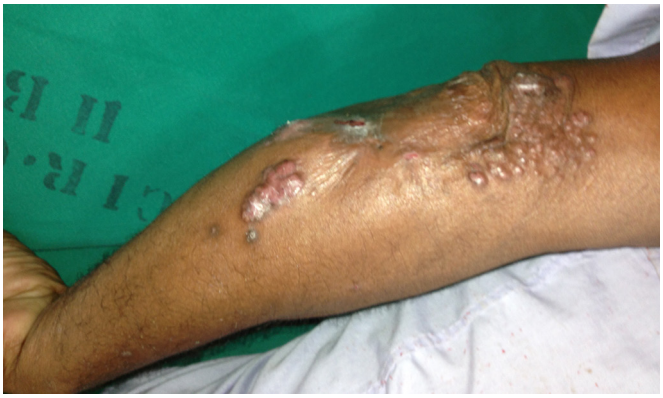

Figure 3. Plaque form.

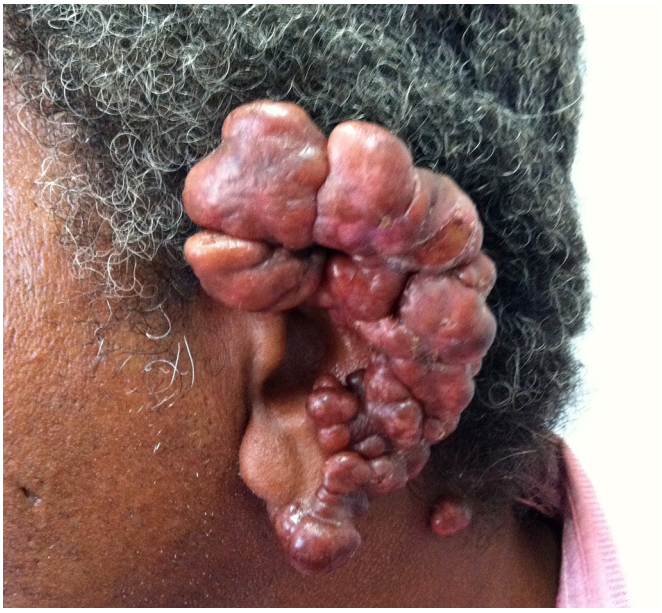

Figure 4. Isolated form: A single lesion in the right ear that progressed during a disease course of 2.8 years..

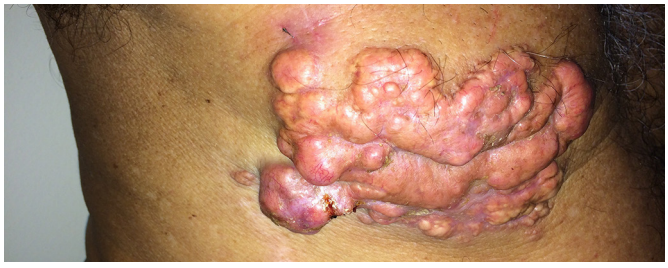

Figure 5. Disseminated form: A patient with lesions affecting the whole lower limb.

or may show gemmulation, usually presenting with a rosary distribution.

The epidermis can be normal, atrophic, and hyperplasic or ulcerated with fungi that are located in the hyperplastic bottom[25]. The evaluation of the dermis infiltrates of lymphocytes, histiocytes, epithelioid cells, giant cells, plasma cells, and eosinophils, revealed

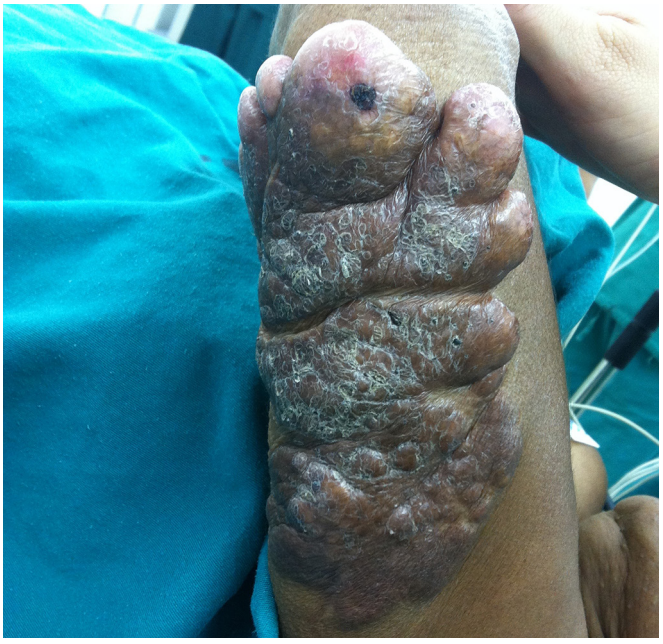

Figure 6. Multifocal form: Multiple foci of lesions in the forearm, elbow, and arm.

vasodilation and vascular neoformation. The histiocytes present sporadically with fungi in their interior, suggesting that they are phagocytosing the fungi; these cells eventually give rise to the multinucleated giant Langerhans cells[26].

Differential Diagnosis

There are several conditions that may interfere with the diagnosis of lobomycosis or lacaziosis. These include the more frequently observed keloid scar[27] (Figure 7), other fungal infections, such as cromomycosis (Figure 8), sporotrichosis, phaeohyphomycosis, and histoplasmosis, tuberculoid leprosy (Figure 9), verruciform elephantiasis resulting from paracoccidioidosis (Figure 10), and diffuse anemia leishmaniasis (Figure 11).

A well-performed clinical history is of paramount importance for the differential diagnosis, especially in case of diseases associated with fungal infections, since the clinical evolution of this type of disease is usually slow, and confusion may arise due to the association with other events experienced by the patient throughout life.

Treatment

To date, there is no effective treatment for lacaziosis. Several studies have reported on the surgical treatment and disease relapse, but little is known regarding the best technique that can be used with

Figure 7. Keloid scar at 1 year postoperatively after a cesarean section.

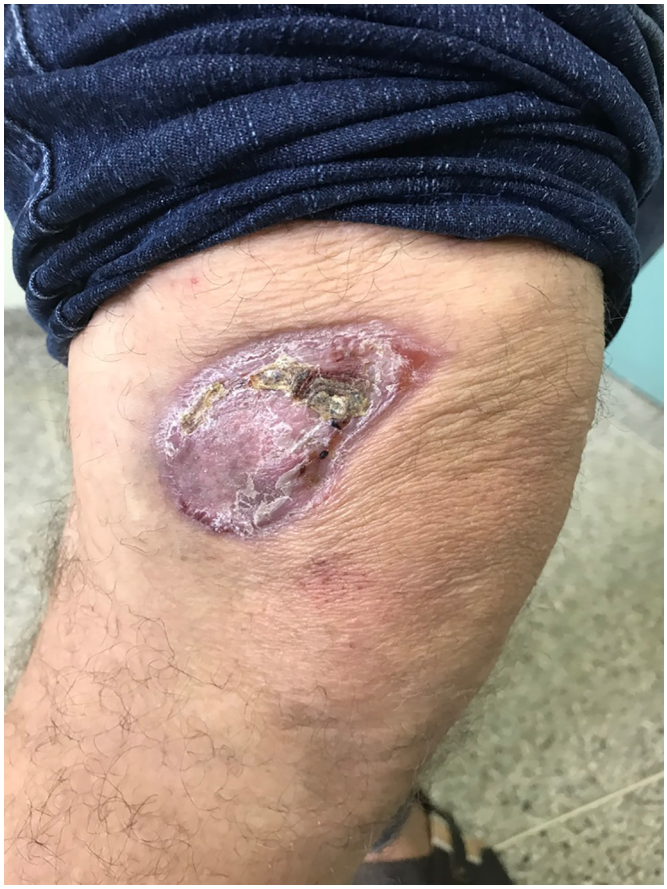

Figure 8. Chromoblastomycosis: A lesion of chromoblastomycosis that progressed during a disease course of 25 years. More characteristic form of the lesion.

respect to the lesion margins, involvement of other tissues, and the time to disease recurrence.

Currently the choice of treatment is defined according to the clinical presentation of the disease. For the unifocal and localized forms, surgical treatment is performed, followed by treatment with various

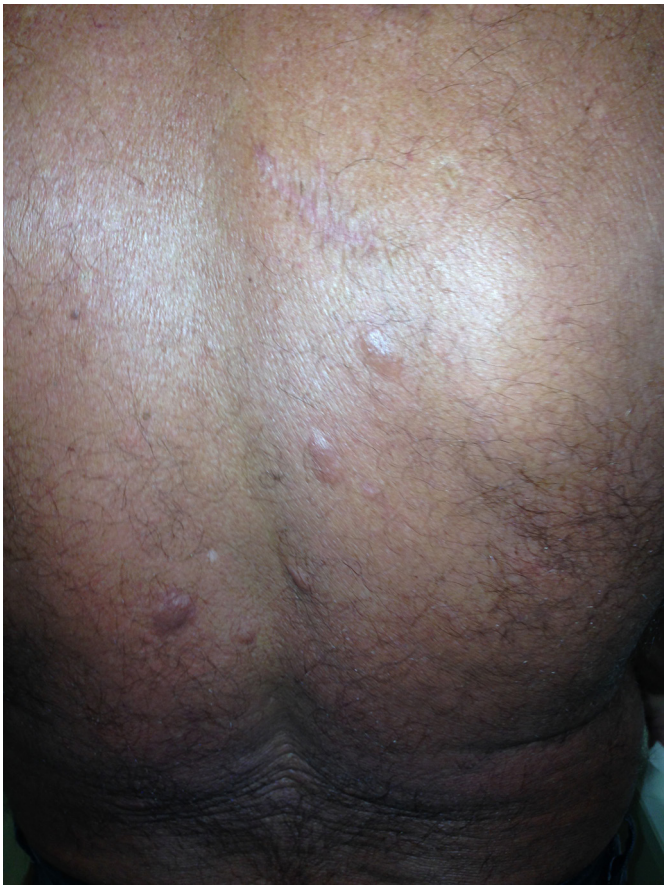

Figure 9. Virchow leprosy: keloid nodular lesions observed in the dorsal region.

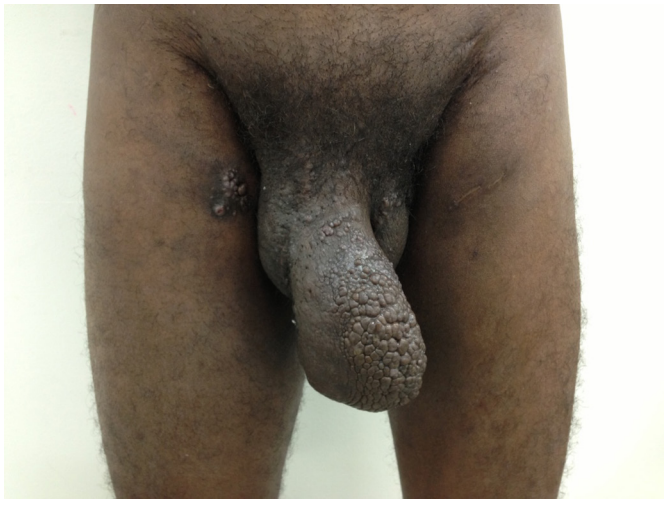

Figure 10. Elephantiasis nostras verruciformis due to paracoccidioidosi s: mycosis complicated by repetitive cellulitis in the inguinal region.

combinations of medications, such as clofazimine (50 mg/day), dapsone (100 mg/day), or itraconazole[15], which begins immediately after surgery and is continued for at least one year, with the aim to decrease the chances of relapse and eventually achieve a cure.

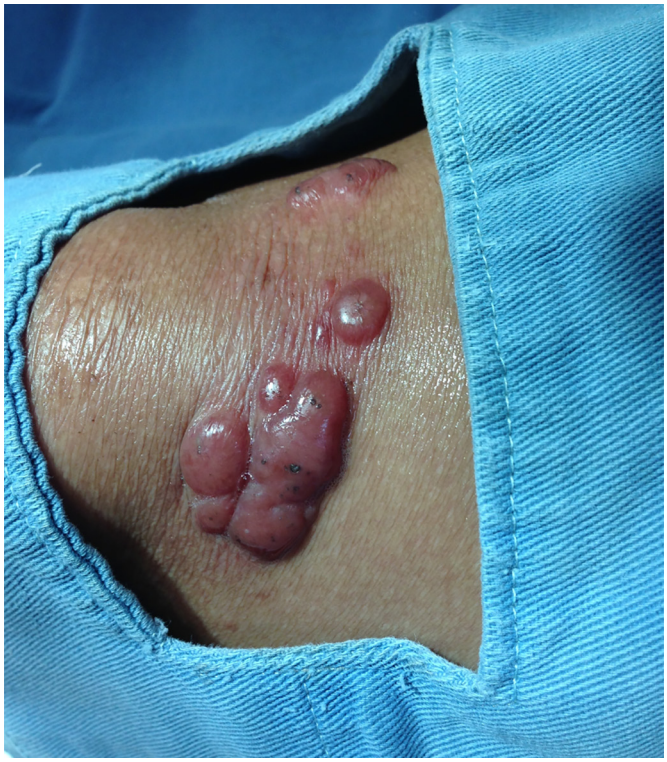

Figure 11. Anergic diffuse leishmaniasis.

According to Miranda et al.[27,28], administration of clofazimine in the postoperative period at doses of 300 mg/day in the first month, 200 mg/day in the second month, and 100 mg/day until completing 24 months of treatment best impedes disease relapse. Some reports suggested that the disease was cured with the use of posaconazole[29] and of other drug combinations[7].

The best results in the medium term are obtained with surgical treatment, since it devolves a little of the quality of life of patients who present with deforming injuries and invoke revulsion[30].

Surgical treatment

Several reports describe the surgical treatment of lacaziosis; however, there are only a few studies on the techniques used during the surgical treatment of these lesions. Here, we will discuss the surgical aspects of the lesions of the patients submitted to surgical treatment at the Hospital de Base de Porto Velho and Hospital Santa Marcelina from June 2006 to July 2014.

Informed Consent

All patients submitted to surgical treatment signed the informed consent form authorizing the surgery, and anatomopathological assessment and allowed the dissemination of data regarding the treatment used and the photographs taken during

the course of treatment. This study is registered with the institutional Ethics Committee under number 48872115.9.0000.0013.

METHODS

From 2006 to 2014, a total of 22 patients, 19 male and 3 female, underwent surgical treatment. The patients were aged 35–68 years. None of the patients had relatives with the disease or similar lesions, confirming the findings reported by Dias et al. in 1970[22].

A 97-year-old patient diagnosed with the disease 63 years ago was referred to our clinic for the removal of lesions on the trunk (Figure 12), hands, and penis (Figure 13); he had previously undergone resection of some lesions and was not aware of the precise number of previous surgeries. He also underwent drug treatments, without mentioning which.

He did not allow surgeons to remove the lesions that bothered him. This patient had disseminated lobomycosis, with numerous lesions on the thorax, hands, arms, legs, and an injury to the body of the penis.

This patient returned 5 years later, with the same complaints and presented with slight clinical evolution of the nodulations. He did not allow surgical treatment again; however, the case drew our attention due to the slow evolution of the pre-existing lesions.

Among the 22 patients who submitted to surgical treatment, the duration of the disease ranged from 7 years to 45 years.

The clinical presentation in these patients was as follows: the lesion was located at only 1 site in 9 patients; 10 patients, including 6 male patients, presented with lesions in only 1 ear and 1 patient presented with a lesion in the middle third of the right thigh; 3 female patients presented with a lesion in the right arm, while another presented with a scar on the left lumbar region, and 1 patient presented with a popliteal cavity lesion; localized form with local dissemination and/or symmetrical (same injured anatomical structure) distribution was observed in 11 patients, with lesions being located in both ears in 3 patients and on the limbs in 7 patients with focal lesions on the hand, dorsum of the hand, forearm, with multiple nodules of lacaziosis, suggesting the occurrence of local dissemination, while 1 patient presented with a lesion in the foot with nodules in the dorsal region of the same foot; and 2 patients presented with the systemic form of lacaziosis, i.e., numerous disseminated lesions, one of whom refused surgical treatment.

All patients visited our facility with complaints of pruritic nodular lesions, and 20 of 22 patients had already undergone at least one surgery, with time of disease recurrence ranging between 5 months and 6

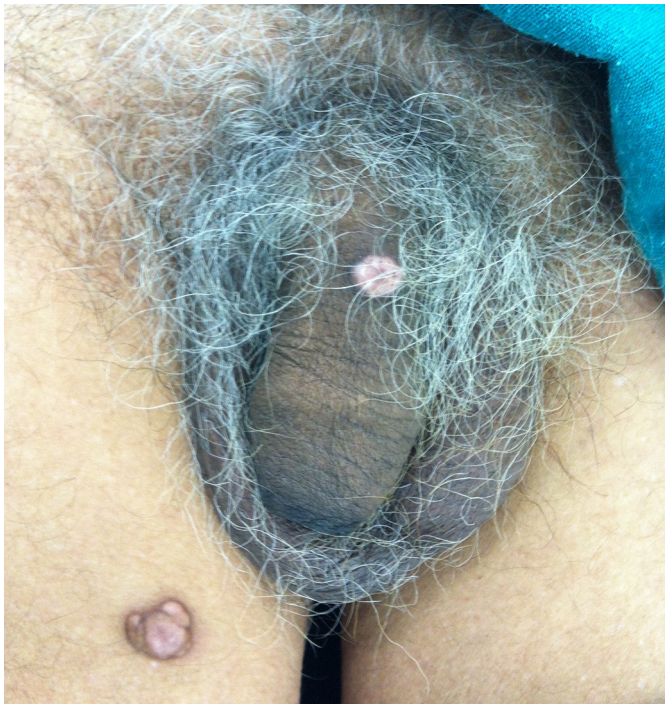

Figure 12. Disseminated lobomycosis in a 97-year-old patient.

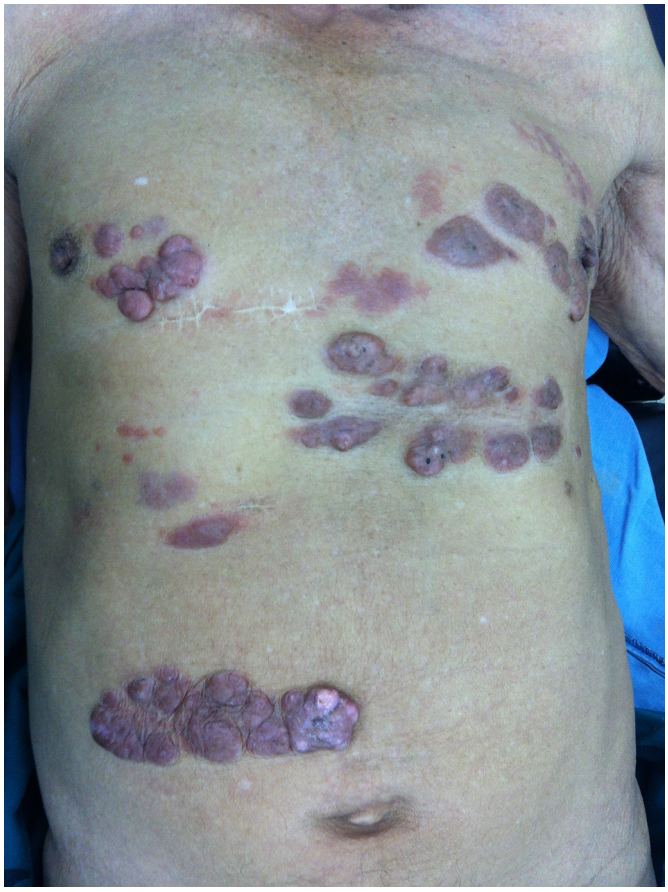

Figure 13. Disseminated lobomycosis in a 97-year-old patient.

years. Two patients has not undergone any surgical and clinical treatment previously and presented with slow growing pruritic nodular lesions; they had developed the lesions following insect stings approximately 1.5 years ago.

Twenty-one patients were rural workers, and only 1 lived in the countryside, but it was of the home.

Surgery

All patients underwent clinical and laboratory assessment, prior to the surgery; the following tests were performed: blood workup, estimation of urea, creatinine, and blood glucose levels, coagulation tests, and electrocardiography. Patients who were administered local or regional anesthesia were evaluated by the anesthesia team.

Lesions in the ears

In patients with ear lesions, we were able to confirm that injuries do not invade the cartilage, affecting only the skin and subcutaneous tissue during the surgical treatment (Figures 14 and 15); this has already been reported in the available literature.

The cartilage in all cases had a normal macroscopic aspect. Among patients who had undergone surgical treatment of lesion in this regions, many presented with partial resection of the ear lesions, including the cartilage, being the withdrawal of existing lesions and the reconstruction of the pinna performed at the same surgical time, when possible.

In patients with lesions in the forearm, the nodular lesions on the arm and hand were resected; these lesions were circumscribed lesions and did not invade the adjacent tissues, blood vessels, muscles, and tendons (Figure 16 and 17).

DISCUSSION

The patients who submitted to surgical treatment received no adjuvant treatment. Twenty of the 22 patients were already administered medication for lobomycosis, without any significant improvement. They refused medication due to the difficulty presented in receiving the medication, which is a prolonged treatment. In our 8-year experience of operating on and monitoring these patients, we noticed that disease relapse will occur, but there is no specific time for disease relapse. Among the 11 patients who returned to our facility for follow-up, 9 presented with disease relapse; the time of relapse ranged from 5 months to 6 years. The remaining patients, or are recent cases, or did not return for follow-up.

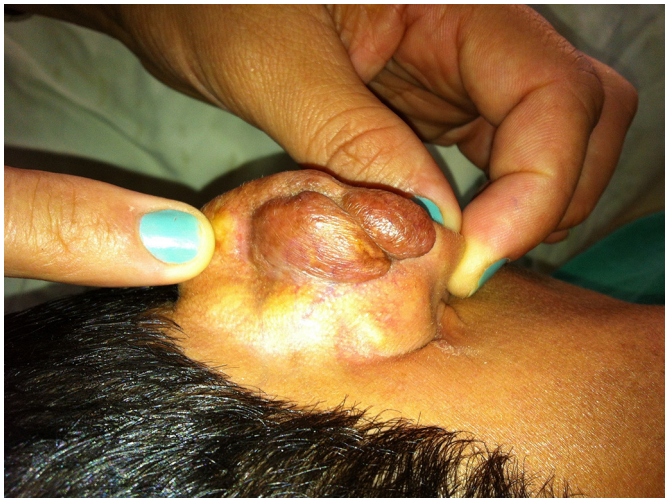

Figure 14. Lesion of the right ear (preoperative).

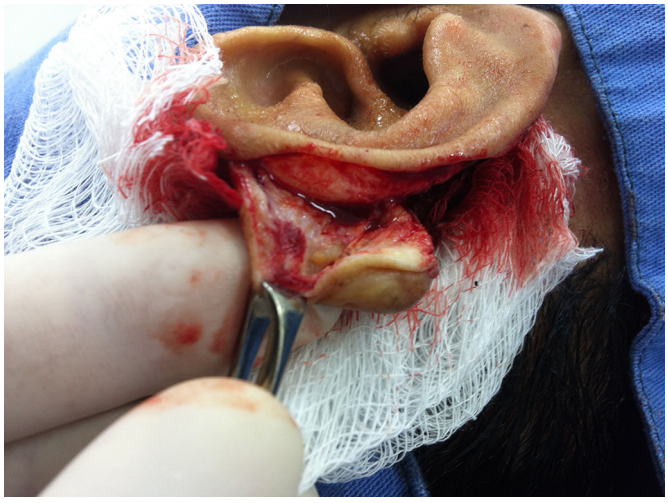

Figure 15. Dissection of the lesion showing intact auricular cartilage.

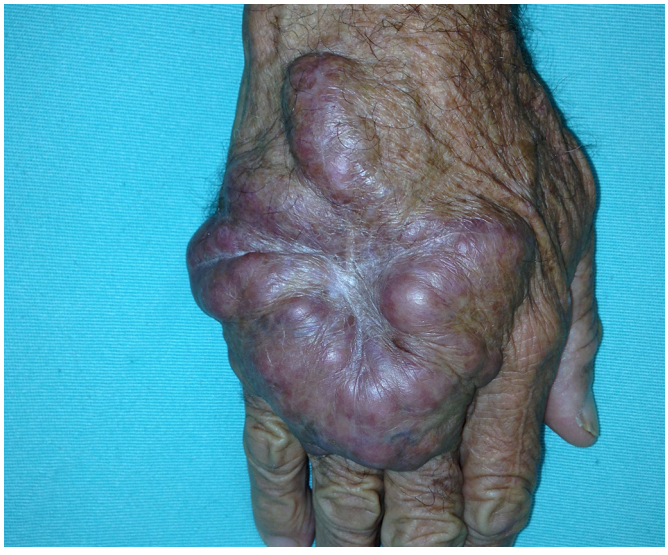

Figure 16. A lesion in the dorsal region of the right hand.

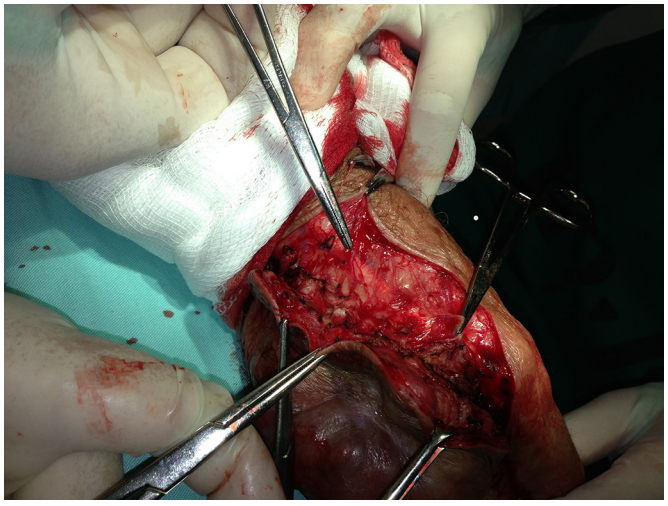

Figure 17. Dissection of a nodular lesion of lobomycosis circumscribed to the dorsal region of the hand with no invasion of the tendons and /or other tissues.

In many case, disease recurrence, such as small nodules and/or nodules along the affected limb, was noted on the grafted areas. Surgical margins were 0.5 cm of the lesion edge and the deep margin; the deeper tissues were not affected.

Lobomycosis is a deforming disease that deprives patients of social conviviality, and surgery is the only effective treatment for the removal of the lesions, although it is a temporary option. Patients are informed about relapses, and surgery is always the chosen option to relieve them of the discomfort caused by the presence of the lesions.

CONCLUSION

We confirm that surgery is one of the effective treatments for lacaziosis. All the characteristics described in the literature were confirmed, namely, the lesions did not affect the other tissues, such as blood vessels, tendons, and cartilage.

We could not confirm whether the dissemination route of the disease was lymphatic, hematogenic, or contiguity. We suggest that the disease recurrence occurred in the grafted areas because greater deep margin resection could not be performed without damaging the adjacent tissues.

Little is known about lacaziosis and its pathogenesis; it is a rare disease without an effective clinical treatment. Plastic surgery units should be responsible for the surgical treatment of this disease, which, when indicated, preserves noble structures, such as auricular cartilage, and restores the patients' self-esteem and dignity, albeit temporarily.

COLLABORATIONS

RLK Analysis and/or data interpretation, conception and design study, final manuscript approval, investigation, methodology, realization of operations and/or trials, supervision, visualization, writing - original draft preparation, writing - review & editing.

CFJ Analysis and/or data interpretation, conception and design study, data curation, investigation, methodology, visualization, writing - review & editing.

AEKC Data curation, investigation, realization of operations and/or trials, writing - review & editing.

LFF Analysis and/or data interpretation, data curation, realization of operations and/or trials, writing - review & editing.

ASP Analysis and/or data interpretation, data curation, investigation, validation.

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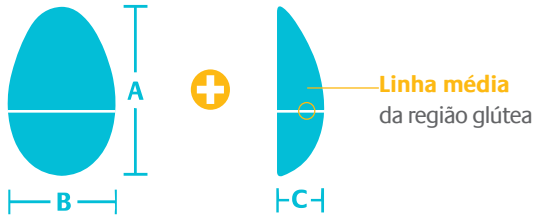
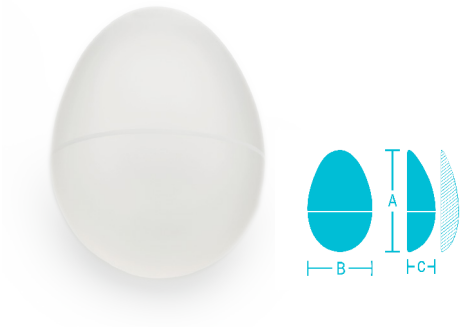


Com a colaboração de diversos cirurgiões plásticos, a Silimed desenvolveu um modelo exclusivo, o glúteo Quartzo, um implante referência no que há de melhor em relação a implantes glúteos, possibilitando um resultado estético muito natural.



Glúteo Quartzo

Apresenta base oval com projeção alta. A escolha do modelo depende da avaliação clínica do cirurgião associada ao desejo do paciente. A superfície lisa opaca é obtida através de tecnologia diferenciada.

Glúteo Redondo

Apresenta base redonda, superfície lisa brilhante e são preenchidos com gel de silicone coesivo de alto desempenho, proporcionando consistência ideal para a região.

Os implantes foram desenvolvidos tanto para o público feminino quanto o masculino, alcançam uma maior projeção glútea, resultando assim em um alto grau de satisfação e melhora na qualidade de vida ao paciente.

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