



Investigation of ethical and scientific irregularities contained in the article published by the Revista Brasileira de Cirurgia Plástica

Investigação de irregularidades éticas e científicas contidas no artigo veiculado pela Revista Brasileira de Cirurgia Plástica

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With due respect to the authors' professional background, we think that the article distances itself from the ethical and scientific precepts that it should respect.

Initially, it should be noted that the article was not submitted to the Research Ethics Committee, in a notorious affront to Resolution No. 466/12 and Circular Letter No. 166/2018, of the National Health Council.

Furthermore, the report presents inconsistencies that denote the authors' apparent intention to crucify the use of polymethylmethacrylate (PMMA) in cosmetic procedures. In this sense, the statement that PMMA was the causative agent of adverse effects stands out, without there being any evidence for it. The authors did not seek anatomopathological evidence that PMMA was used in the reported procedure. Therefore, it does not seem ethical or scientific to mention PMMA in the article's title without at least evidence of its use in the investigated procedure.

Finally, given the circumstances in which the procedure was performed, the possibility of using an inappropriate product cannot be excluded. Therefore, the mention of PMMA in the title and content of the article, without any evidence that the product was, in fact, the agent causing the adverse effects, does not respect the basic rule of a scientific article, that the conclusion must correspond to the objective of the work.

For these reasons, sure that the article does not conform to the ethical and scientific standards that it must respect, we ask the editor for the appropriate measures.

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Response ●●●●

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Letter in response to the letter to the editor entitled “Investigation of ethical and scientific irregularities contained in the article published by the Revista Brasileira de Cirurgia Plástica.” The authors of the article “Severe complication of the irregular use of PMMA: case report and the current Brazilian situation” are available to clarify any doubts not addressed in the text of the published article; also, they reinforce their commitment to medical ethics and research ethics.

Following the Revista Brasileira de Cirurgia Plástica (RBCP) recommendations and guidelines, we affirm that we fulfill all ethical requirements for the publication of the case report. Such requirements can be accessed through the electronic address: <http://rbcp.org.br/instructions-for-authors>. It is worth mentioning that it is not required by the RBCP to submit articles such as “case report” to the Research Ethics Committee, but rather an Informed Consent Form signed by the patient. It is also noteworthy that when collecting the signature of the said consent form, the patient was of legal age and fully aware and agreed with the case report’s disclosure. The term was correctly presented and following legal criteria.

We refute the intention to crucify the use of PMMA, since we report precisely its use in an irregular and improper way and its consequences. There is no declared position of the authors regarding its use in aesthetic procedures, but verification and publications made by regulatory entities (ANVISA) and medical entities (CRM, CFM, SBCP, and SBD). These can be reviewed in the bibliographic references of the article.

We affirm that six attempts were made to identify exogenous material with an anatomopathological examination in the various tissue samples obtained from each debridement surgery. However, such identification was not possible due to the intense necrosis identified, as it is reported in this transcript of the article: supuration and necrosis of the dermis (Figure 3) and subcutaneous cellular tissue with nodular formations containing pus and exogenous material, as well as signs of bilateral gluteus maximus fasciitis. “

We agree with the statement that the possibility of using an inappropriate product cannot be excluded. This observation is in the discussion of the article: “In the case described, it can be said that both the quality of the product and the technique used are questionable. In this case, the combination of actions not recommended led to the case’s complication and dramatic evolution. “

Finally, we conclude that in the Brazilian context, and with the Federal Council of Medicine (CFM) alert since 2006 about “fanciful and exaggerated disclosure” and mutilating and fatal cases reported in the national media and Brazilian medical articles in recent years, the use of the term “irregular use of PMMA” in the title of the article is appropriate since the patient sought gluteal augmentation through PMMA in a non-specialized center and with an unqualified professional. We affirm that the search for PMMA in non-specialized centers contributes to the significant number of complications due to questionable antisepsis, application of an unskilled technique, and doubtful product quality.

We appreciate the opportunity for such clarifications and make ourselves available for any questions.

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Counterreply ●●●●

Regarding the authors' response, some considerations must be presented.

The article prepared by the authors brings an unfounded reference to PMMA as the causative agent of the adverse effects reported in the case. At the same time, in the response presented to the Letter to the Editor, they state that "6 attempts were made to identify exogenous material with anatomopathological exam in the different samples of tissue obtained in each debridement surgery. However, such identification was not possible due to the intense necrosis identified", that is, it was not verified that the patient used PMMA.

This is an unfounded reference since the authors did not bring evidence that the procedure was performed with PMMA, and, as the authors themselves state, there is no anatomopathological confirmation of the causative agent, only imaging tests, visual inspection, and palpation, which are not suitable for this purpose.

Furthermore, given the narrated circumstances that the procedure was performed in a beauty salon by a non-medical professional, the possibility of using industrial silicone in the procedure cannot be excluded, a hypothesis not addressed by the authors in their article. Then, it is not ethical, nor scientific, quote the PMMA in the title and the article's content, without any evidence that the product was, in fact, the agent that caused the adverse effects.

Evidently, the article's publication resulted in a negative link with PMMA, damaging the entire distribution chain and all the trained professionals -including thousands of plastic surgeons- who make correct use of the product, which is duly registered with ANVISA and other regulatory authorities.

Thus, we understand that the response prepared by the authors must be more emphatic concerning the questions posed, promoting a true retraction to all those who were and continue to be harmed by the publication of an article prepared with flagrant ethical and scientific deviations.

We remain at your disposal.

RBCP Editor's Note ●●●●

Conep's guidelines on the approval of the Research Ethics Committee for "case report" articles appeared before the article was submitted on 10/18/2018, a period close to the moment when the *Revista Brasileira de Cirurgia Plástica* (RBCP) adopted the recommendations of Circular Letter 166/2018 - CONEP / SECNS / MS.

The articles published by the RBCP are, without a doubt, scientific, and their function is to expand, contribute and discuss experiences and discoveries in the field of plastic surgery, without any interest in promoting or criticizing for commercial purposes.

Dov Goldenberg
Editor-in-Chief RBCP