Evaluation of Asymptomatic Rupture of Breast Implants Filled with Silimed Silicone Gel

Avaliação da ruptura assintomática de implantes mamários preenchidos com gel de silicone Silimed

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Abstract

Introduction Breast augmentation is a cosmetic surgery dating back to 1895, which gained popularity in the 1960s with the introduction of silicone implants. Although it is a common procedure, complications such as implant rupture can occur. "Silent" rupture is particularly concerning, as it presents no symptoms and requires careful monitoring. The United States Food and Drug Administration (FDA) recommends ultrasound (USG) or magnetic resonance imaging (MRI) to identify silent rupture.

Objective To evaluate the rate of asymptomatic rupture in patients with smooth and textured external envelope breast implants from the Silimed (Silimed Indústria de Implantes Ltda.) brand through MRI.

Materials and Methods We selected 97 surgeons from different cities in Brazil who kept records of patients with Silimed. Patients with implants from other manufacturers, pregnant women, and those with contraindications for MRI were excluded. The selected patients underwent clinical exams and MRI scans, with image analysis performed by independent radiologists. Suspected ruptures were confirmed surgically.

Results Of the 161 patients evaluated, only 2 (0.63%) had a suspected implant rupture confirmed surgically, both after 9 years of implantation: one with a smooth implant and the other with a textured implant. Most Silimed implants were considered intact: 99.67% of the textured and 95.24% of the smooth implants.

Conclusion The present study contributes to scientific knowledge about breast implant ruptures and suggests that Silimed implants are safe. The rate of asymptomatic rupture observed in implants with a duration of 5 to 10 years was low.

Keywords
- adverse events
- asymptomatic rupture
- breast implant
- implant rupture
- silicone gel

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Resumo

Introdução O aumento mamário é uma cirurgia estética praticada desde 1895, e que ganhou popularidade na década de 1960 com o surgimento dos implantes de silicone. Embora seja um procedimento comum, podem ocorrer complicações, como a ruptura dos implantes. A ruptura "silenciosa" é especialmente preocupante, pois não apresenta sintomas e requer monitoramento cuidadoso. A United States Food and Drug Administration (FDA) indica os exames de ultrassonografia (USG) ou ressonância magnética (RM) para identificar a ruptura silenciosa.

Objetivo Avaliar a taxa de rupturas assintomáticas em pacientes com implantes mamários de envelope externo lisos e texturizados da marca Silimed (Silimed Indústria de Implantes Ltda.) por meio de RM.

Materiais e Métodos Foram selecionados 97 cirurgiões de diversas cidades brasileiras com prontuários de pacientes que utilizavam implantes Silimed. Foram excluídas pacientes com implantes de outros fabricantes, gestantes, e aquelas com contra-indicações para a RM. As pacientes selecionadas realizaram exames clínicos e RM, e as imagens foram analisadas por radiologistas independentes. Suspeitas de ruptura foram confirmadas cirurgicamente.

Resultados Entre as 161 pacientes avaliadas, 2 (0,63%) apresentaram suspeita de ruptura confirmada cirurgicamente, ambas com 9 anos de implantação: uma com implante liso e outra, com texturizado. A maioria dos implantes foi considerada íntegra: 99,67% dos texturizados e 95,24% dos lisos.

Conclusão Este estudo contribui para o conhecimento científico sobre rupturas de implantes mamários, e sugere que os implantes Silimed são seguros. A taxa de ruptura assintomática em implantes com 5 a 10 anos de implantação foi baixa.

Palavras-chave

- eventos adversos
- gel de silicone
- implantes mamários
- ruptura assintomática
- ruptura do implante

Introduction

The history of breast augmentation dates to 1895, when German surgeon Vincenz Czerny performed the first documented procedure of this type. Czerny used autologous adipose tissue to reconstruct a breast that underwent a benign lipoma removal.[1] This procedure marked the beginning of surgical techniques designed to improve the size and shape of the breasts. Since then, many pioneers have developed new surgical techniques and made significant contributions to breast augmentation.

Thomas Cronin and Frank Gerow were the first to use silicone gel-filled implants in 1962.[2,3] Since then, other surgeons began to publish articles about their techniques, providing significant contributions to improve breast augmentation surgery,[4] such as Dempsey and Latham,[5] Griffiths,[6] Regnault,[7] Hoehler,[8,9] Eiseman,[10] Ho,[11] and Price et al.[12] After all these advances, implant manufacturers have strived to implement improvements in their devices to reduce potential adverse events and increase satisfaction and quality of life for women undergoing breast surgery.[13]

Breast implants have evolved to improve safety and esthetic outcomes.[3,14] The first generation, in the 1960s, contained a viscous gel and presented high rates of capsular contracture; the second generation had thinner membranes, but increased rates of rupture and silicone migration.[15] The third generation introduced reinforced shells and diffusion barriers, while the fourth generation improved gel cohesiveness.[3,14] Finally, the fifth generation brought highly-cohesive gel and anatomical shapes, resulting in greater stability and safety.[15]

According to the International Society of Aesthetic Plastic Surgery (ISAPS) international survey on esthetic/cosmetic procedures performed in 2023,[16] breast augmentation is the second most performed procedure in the world (1,892,777 procedures). However, the use of breast implants can cause some complications, most frequently capsular contracture and implant rupture.[4]

Rupture of the implant membrane may be due to traumatic injury or natural implant wear over time.[17] The rupture can be extra- or intracapsular. An extracapsular rupture features silicone gel extending outside the fibrous capsule, potentially causing localized swelling, breast hardening, silicone gel migration, and breast deformity. In contrast, an intracapsular rupture occurs when the silicone gel leaks from the implant and accumulates within the fibrous capsule that naturally forms around the implant. In this case, symptoms may be mild or non-existent and may include slight hardening of the breast, changes in breast shape or size, and mild pain.[17] These ruptures are more common and difficult to diagnose clinically, as they are usually asymptomatic, being called *silent ruptures*.[18,19]

The correct interpretation of magnetic resonance imaging (MRI) scans is a subject of debate. If not cautious, it can lead

to false-positive or -negative results.[20,21] However, MRI remains the most accurate method to assess the integrity of breast implants.[18–22] It presents a high sensitivity to detect breast implant ruptures, significantly exceeding the sensitivity of mammography.[20,22] The rupture is confirmed during surgery, combined with the imaging report. In 2020, the United States Food and Drug Administration (FDA) published "Breast Implants - Certain Labeling Recommendations to Improve Patient Communication",[23] a document advising patients to undergo a first ultrasound or MRI scan 5 to 6 years after the implantation date, even if there are no symptoms of rupture. Following this first imaging test, the recommendation is to repeat it every 2 to 3 years. However, any abnormal symptoms or inconclusive imaging report before this period warrant an MRI as soon as possible.[23]

The significance and relevance of silent rupture monitoring led to the present descriptive study to evaluate asymptomatic rupture rates in patients with Silimed (Silimed Indústria de Implantes Ltda.) breast implants through MRI and confirmation by surgery.

Materials and Methods

Silimed fully sponsored the current study, and all participants signed an informed consent form. At the time of the study, the author was a professor of the postgraduate course in Plastic Surgery at Pontifícia Universidade Católica do Rio de Janeiro, which was then integrated into the 38th Ward of Santa Casa de Misericórdia do Rio de Janeiro, where Professor Pitanguy's Plastic Surgery Service was located. Silimed sponsored the author to conduct this study as the principal investigator and covered the costs of the MRI scans requested by the doctor. Data collection and analysis followed strict professional ethics standards.

The present study was conducted to fulfil an FDA demand, and it aimed to update the safety data on Silimed silicone gel-filled implants with smooth and textured surfaces in an ambispective manner. In the first part of the retrospective study, 97 surgeons from different Brazilian cities were selected. The inclusion criteria for physicians were surgeons performing breast surgery using Silimed silicone implants from 1990 to 2000 and who had well-organized patient records. Since the current study did not compare different brands, although the physicians had used other implant brands, it only included patients with Silimed implants. The second part of the retrospective study consisted of selecting women who had received Silimed implants by searching the medical records of these surgeons' offices. The prospective part of the study consisted of clinical evaluation, examination, and medical conduct, and it occurred from 2006 to 2010 at Hospital Pró-Cardíaco, in the city of Rio de Janeiro. The Ethics in Research Committee at Centro de Ensino e Pesquisas do Pró-Cardíaco (PROCEP) approved the study (under registration no. 174),. The company sponsoring the study determined the exclusion of patients with metal implants, pregnant women, tattoos, any contraindication for MRI, and patients with implants from other manufacturers. The study also excluded patients with implants for more than 10 years, as this period exceeds the recommendation in the Instructions for Use of the product.

The current study analyzed round and anatomical implants. The former were predominant. It is worth noting that polyurethane foam-coated implants were not evaluated, since, as previously mentioned, the present study was conducted to fulfill a demand by the FDA, which is located in the United States, where these implants are unavailable.

The patients underwent Silimed breast implantation at different times. They underwent clinical examinations and MRI scans. It is worth noting that, although the FDA recommends imaging starting 5 years after implantation, the selection of participants to undergo the test was consecutive, regardless of the implantation period.

All of the clinical exams were performed by the author of the current study. The MRI scans were performed in six medical centers, depending on the location of the home fo the patient. All centers obtained images using a General Electric 1.5-T equipment with dedicated breast coils following the same protocol. Three radiologists received the MRI images, including the study radiologist and two consultants. Image identification consisted of a control number alone. The evaluation occurred individually using standardized forms. To ensure impartiality, the analysis was blinded, with no access to patient information, including previous reports. The suspicion of implant rupture depended on the agreement of at least two specialists. All patients with evidence of rupture on MRI were referred for surgery. The rupture was confirmed during surgery in cases with implant shell breakage, with or without gel leakage. A descriptive statistical analysis was performed with categorical and quantitative variables.

Results

Of the 404 patients recruited, 243 were excluded for having implants different from the devices under study, because they were outside the study period, or for any other reason meeting the exclusion criteria. Thus, 161 patients (322 implants, including 22 smooth and 300 textured) underwent clinical examination and MRI scans. The mean age of the patients was of 44.26 years, while the mean implantation time was of 8.04 years.

The maximum implantation time was pf 10 years. Of the patients examined, 2 (0.63%) had a diagnosis of suspected rupture, 1 with a smooth implant and 1 with a textured implant, both 9 years after implantation. The MRI scans identified that 99.67% and 95.24% of the textured and smooth implants respectively were intact (►**Fig. 1**).

Discussion

In the current study, the rupture rate was of 0.63% (2 implants) in 10 years. Hölmich et al.[24] (2003) used 3 generations of breast implants filled with silicone gel over 2 years. In total, these authors evaluated 317 implants from 271 patients who underwent breast implant surgery from 1973 to 1998. The confirmed rupture rate was of 10% (33 implants), with a 7% rate of potential ruptures (23 cases

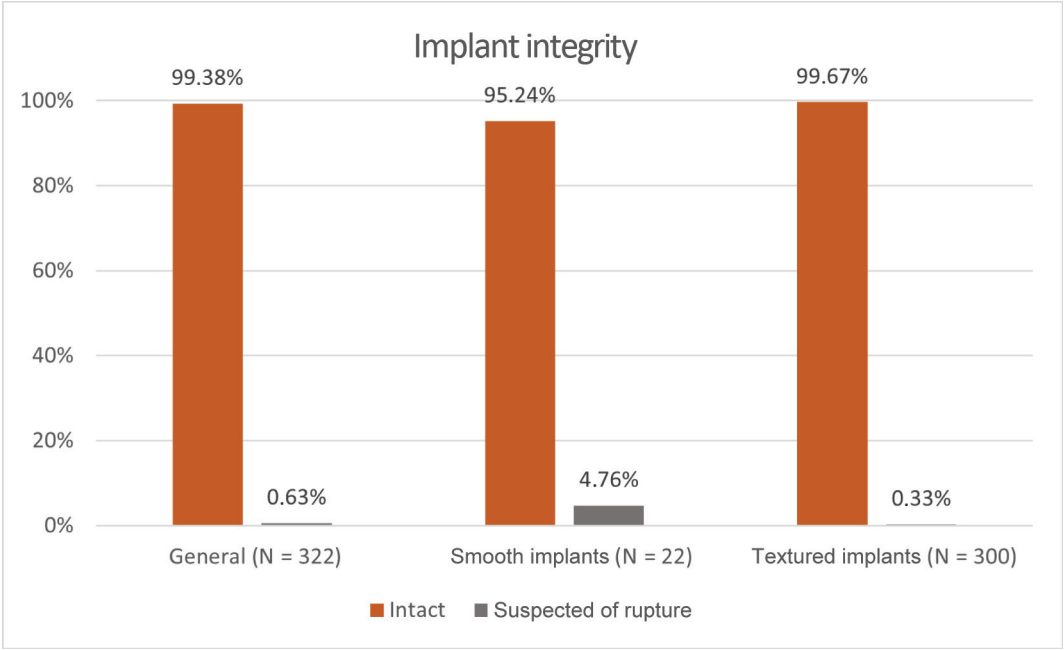

Fig. 1 Silimed implant integrity (percentage).

with no confirmation). Using an estimated rupture curve, they established that a rupture rate of 15% is possible over 3 to 10 years.[24] Pitanguy et al.[25] (2010) conducted a 5-year evaluation at Clínica Ivo Pitanguy from 2004 to 2009. These authors evaluated 59 patients (129 breasts) and, although they did not specify a rupture rate, only 2 surgeries due to rupture were performed during the study.

Scaranelo et al.[26] (2004) evaluated 83 implants with suspected silent rupture from 44 patients. Of these, 30 implants (39%) presented rupture at the time of surgery, and 53 (64%) did not. In addition, 27 implants (32.5%) with no rupture presented gel leakage, and 26 (31.5%) were intact. The mean age of the ruptured implants was of 11.9 years,[26] corroborating the findings that indicate that the longer the implantation time, the greater the chances of rupture. In 2018, Stevens et al.[27] conducted the Sientra Core Study, a 10-year, open-label, prospective, multicenter study designed to evaluate the safety and efficacy of Sientra (Tiger Aesthetics Medical, LLC) breast implants. At that time, the American brand was the authorized representative and distributor of Silimed implants in the United States. The authors[27] performed MRI scans on 571 patients from the third year of implantation onwards and observed a risk of rupture through the Kaplan-Meier estimate of 8.6% (augmentation, revision augmentation, reconstruction, and revision reconstruction groups). It is worth emphasizing the particularities of each published study,[28,29] such as sample size, follow-up time, statistical design, and experimental design, which hinder a direct and objective comparison. Therefore, the differences in the rates should be interpreted with caution, considering variations in the methodological rigor of the published studies that influence the results.

Mammography, ultrasound, and MRI scans are the most frequently-used imaging tests to assess breast implant integrity, often in patients with symptomatic rupture. Although advances in ultrasound techniques are emerging as potential alternatives,[30] MRI remains the most accurate and sensitive test to detect implant integrity.[20,21,31–33]

In the current study, of the two ruptures, one occurred in a smooth implant and the other, in a textured implant. Although the literature associates some adverse events, such as capsular contracture, with a specific surface, there is no consensus regarding ruptures. The rupture rates of textured breast implants vary between studies, with an average rate of 3% to 15.1%, and are influenced by factors such as implant type and duration of use. Haws et al.[34] (2015) reported a low prevalence of rupture in textured implants when compared with smooth implants (of 0.8% and 3.8% respectively).[34] The rupture cases herein reported occurred 9 years after implantation. Although it is impossible to confirm that the rupture happened in the ninth year due to its silent nature, the data corroborates the unanimous findings in the literature[35] that ruptures are associated with longer implantation time.

The high rates of intact breast implants, of 99.67% and 95.24% for textured and smooth implants respectively, indicate a robust performance, in line with the findings that the gel cohesiveness in breast implants is a relevant aspect.[36] These devices consist of high-performance cohesive gel (High-Strength Cohesive-Plus, HSC+, Sientra), with a higher rate of gel integration with the membrane, a maximum index of gel elasticity, and greater shape stability.[37] They are designed and engineered to resist potential damage from surgical techniques and patient singularities. This demonstrates the companies' concern for the constant improvement of the raw materials of the implants, a concern that persists to date. The longevity of these devices makes it increasingly relevant to evaluate products with long implantation periods to demonstrate their safety and performance.

Implant rupture is usually delayed, silent, difficult to diagnose clinically without imaging tests, and it presents

several etiologies.[18,34] Some authors have reported that 8% of women with silicone gel-filled breast implants are asymptomatic and approximately 33% are symptomatic. When symptomatic, these women present pain, capsular contracture, changes in the implant shape, and breast asymmetry.[38] The fact that some women with ruptured implants are asymptomatic and the possibility of a rupture evolving with silicone leakage into the body reinforce the indication for monitoring breast implants through imaging tests. Despite the concern about this complication, data on silent rupture are still unknown, most likely due to the lack of standardized screening and reporting.[39,40]

The results indicate that, although ruptures are rare, the need for regular monitoring remains critical, as asymptomatic cases can still pose health risks.[41] The results of the present study may encourage further research into the long-term performance of different types of implants, particularly in relation to their cohesiveness and age.

Conclusion

Based on the data herein presented, we concluded that the rate of asymptomatic ruptures in patients with Silimed smooth and textured breast implants, assessed through MRI, is low for implantation times from 5 to 10 years. Despite this positive finding, the possibility of silent complications reinforces the significance of clinical surveillance and specific ongoing studies.

Limitations

The impossibility of determining the exact moment of rupture is a limitation to the current study, as this would only be possible through periodic MRI scans during the implant lifespan. Therefore, by stating that there was a suspicion of rupture in 0.63% of the implants inserted 9 years ago, for instance, the hypothesis that the ruptures occurred before 9 years cannot be ruled out. Another limitation is the small sample size and short observation period, which make it difficult to draw conclusions. With 161 patients and 322 implants, the sample may not be representative of the general population of patients with breast implants. In addition, the lack of data on long-term follow-up may limit the complete understanding of implant durability.

Ethics Committee Number
174.

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Clinical Trial
NCT02206282.

Conflict of Interests
The author declares that the present study was fully sponsored by Silimed.

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