Hybrid Implant: Initial Study with 279 Units of an Innovative Breast Implant

Implante híbrido: Estudo inicial com 279 unidades de um implante mamário inovador

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Abstract

Introduction Breast augmentation remains one of the most performed surgical procedures in the world, with wide use of implants for aesthetic and reconstructive purposes. However, current implants still present limitations, including the risk of displacement and restricted mobility.

Objective To evaluate the safety and efficacy of a new hybrid breast implant, developed by the author, that combines two coating surfaces (cohesive silicone gel with a microtextured or smooth base and polyurethane).

Materials and Methods The implant is patented and, after authorization from the Brazilian National Health Regulatory Agency (ANVISA, from the Portuguese Agência Nacional de Vigilância Sanitária), we conducted a pilot single-group interventional clinical trial from April 2020 to June 2022 at a private institution. In total, 135 women received 279 units of the implant and underwent follow-up for 2 years.

Results The results showed a favorable safety profile, with low rates of postoperative complications. The most common occurrences were mastalgia (4.3%) and skin rash (2.1%). There were no reports of complications such as capsular contracture, implant rupture, or gel migration throughout the follow-up period. Moreover, the satisfaction rate was high among patients and the surgeon. The cases of dissatisfaction referred to the volume of the implant, leading some patients to opt for an exchange for larger sizes.

Conclusion These findings show that the hybrid implant is an innovative and safe alternative in breast surgery, providing a more efficient technique and potentially reducing long-term complications.

Keywords

- breast
- breast implants
- clinical trial, phase III
- mammaplasty
- prostheses and implants

Resumo

Introdução A mamoplastia de aumento é um dos procedimentos cirúrgicos mais realizados no mundo, com uso amplo de implantes mamários para fins estéticos e reconstrutivos. No entanto, os implantes disponíveis ainda apresentam limitações, como risco de deslocamento ou restrição de mobilidade.

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Objetivo Avaliar a segurança e eficácia de um novo implante mamário híbrido, desenvolvido pelo autor, que combina duas superfícies de revestimento (gel de silicone coesivo com base microtexturizada ou lisa e poliuretano).

Materiais e Métodos O implante é patenteado e, mediante autorização da Agência Nacional de Vigilância Sanitária (ANVISA), foi conduzido um ensaio clínico piloto, intervencionista, de grupo único entre abril de 2020 e junho de 2022, em uma instituição privada, com a inserção de 279 unidades do implante em 135 mulheres, acompanhadas por 2 anos.

Resultados Os resultados demonstraram um perfil de segurança favorável, com baixas taxas de complicações pós-cirúrgicas. As ocorrências mais comuns foram mastalgia (4,3%) e erupção cutânea (2,1%). Não houve relatos de qualquer complicação até o final do seguimento, como contratura capsular, ruptura do implante ou migração do gel. Além disso, a taxa de satisfação foi alta tanto entre os pacientes quanto entre o cirurgião. Os casos de insatisfação estavam relacionados ao volume do implante, levando algumas pacientes a optarem por uma troca por tamanhos maiores.

Conclusão Com esses achados, o implante híbrido se mostrou uma alternativa inovadora e segura na cirurgia mamária, oferecendo uma técnica mais eficiente e potencialmente reduzindo complicações a longo prazo.

Palavras-chave
- ensaio clínico fase III
- implantes de mama
- mama
- mamoplastia
- próteses e implantes

Introduction

Breast augmentation remains one of the most frequently performed surgical procedures worldwide. According to the International Society of Aesthetic Plastic Surgery (ISAPS), in 2022, this procedure was among the 5 most popular and the most common among women, with 2.1 million surgeries performed globally. In Brazil, it was the 2nd most frequent surgical procedure, totaling 243,923 interventions in the same year.[1]

Breast implants have a wide use in modifying or restoring the breast contour, shape, and volume, playing an essential role in both cosmetic and reconstructive surgery. Since the development of the first implants in the 1960s, there have been significant advances in the composition and design of these devices. Currently, implant classification relies on three main characteristics: filler type, shell surface, and three-dimensional shape.[2]

The most common fillers include saline solution and silicone gel. This gel can have different levels of cohesion to provide distinct viscosity and firmness. The shell, usually composed of silicone, is manufactured with multiple overlapping layers to increase tear resistance and minimize silicone gel diffusion. The International Organization for Standardization (ISO) 14607/2024 determines that the external surface of implants can be smooth, microtextured, macrotextured, or coated with polyurethane.[3] According to recent scientific evidence, the implant surface has a direct influence on its safety and effectiveness. Smooth implants are more prone to capsular contracture than textured ones. Meanwhile, polyurethane-coated implants demonstrate a lower incidence of this complication, one of the main long-term adverse events in breast surgery.[2]

Despite advances, the implants currently available have limitations. Smooth or microtextured implants may present poor tissue adhesion, which increases the risk of displacement and compromises the aesthetic outcome. In contrast, fully polyurethane-coated implants reduce migration but have a contraindication for placement in the retromuscular position due to their higher adhesion, which can restrict regional mobility.[4,5]

Given these limitations, the author developed a new hybrid or mixed breast implant model that combines different coating surfaces in strategic locations. The device consists of a smooth or microtextured base and a partial polyurethane coating. The microtextured or smooth base, which contacts the posterior structures, minimizes excessive adhesion. The polyurethane coating on the upper surface of the implant, covering approximately 1/4 to 1/3 of its height, provides greater fixation and stability, reducing the risk of migration. Furthermore, the differential distribution of silicone gel cohesiveness results in a balance of support and softness, optimizing aesthetic outcomes and patient comfort. The introduction of a prosthesis with hybrid characteristics could represent a significant advance in breast surgery, offering greater versatility and more predictable outcomes for patients and surgeons.

Objective

The present study evaluated the safety and efficacy of a new hybrid breast implant developed by the author. This new device combines two coating surfaces (microtextured or smooth and polyurethane).

Materials and Methods

The present pilot, interventional, single-group, prospective, longitudinal clinical trial occurred from April 2020 to June 2022 at a private institution. The clinical trial complied

with all recommendations of Resolution no. 9/2015 of the Collegiate Director Board (RDC 09/2015) of the Brazilian National Health Regulatory Agency (ANVISA, from the Portuguese Agência Nacional de Vigilância Sanitária).[6]

The subject of the current study is a new breast implant product with a hybrid texture, due to the combination of two coating surfaces (microtextured or smooth base and polyurethane), known as a hybrid implant. The hybrid implant consists of a shell or membrane of a medical-grade silicone elastomer (polydimethylsiloxane) and a special single-lumen barrier layer. The coating on the outer surface of the membrane consists of two well-established materials, that is, microtexture (in the lower third) and polyurethane (in the upper 2/3) (►**Fig. 1**). This coating differentiates the new device from other breast implants currently on the market. ►**Fig. 2** shows the intraoperative exposure of the hybrid implant positioned in the breast pocket, highlighting the two distinct surfaces. ►**Fig. 3** illustrates the anatomically positioned hybrid implant, with its upper portion partially covered by the pectoralis major muscle. The volumes manufactured and used in the present study were 315 mL and 360 mL. The 315-mL implant has a base diameter of 10.8 cm and a projection of 5.7 cm, while the 360-mL implant has a base diameter of 11.3 cm and a projection of 5.9 cm, thus characterizing an extra-high round implant.

The German company POLYTECH Health & Aesthetics GmbH manufactured the pilot batch of the product. According to ANVISA's Rule 8, RDC no. 751/2022, the risk classification of the implant is Class IV. All raw materials from the hybrid implant are medical-grade and biocompatible. The membrane and filling materials present memory properties, meaning they return to their original shape after exposure to stress. Implantation can occur in the retromuscular, retroglandular, and retrofascial positions. The hybrid implant underwent standard quality tests, including mechanical testing, design verification, material analysis, and certification, and passed all of them. The implant sterilization used a validated dry-heat process.

Fig. 1 Graphical representation of the hybrid implant, highlighting the division between the polyurethane (upper) and microtextured/smooth (lower) surfaces.

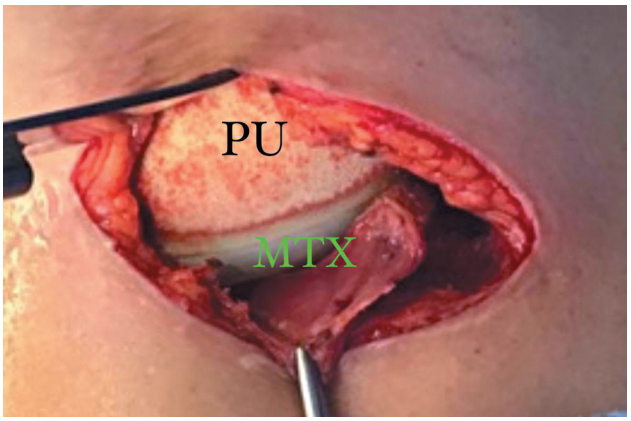

Fig. 2 Intraoperative exposure of the hybrid implant positioned in the breast pocket, highlighting the two distinct surfaces. The coating of the upper part consists of polyurethane (PU), facing the upper pole of the breast, and the microtextured/smooth base (MTX) is in contact with the pectoral muscles.

POLYTECH donated the hybrid implants, which were used only after receiving an import authorization in a previously approved special communication. Research participants were recruited based on the inclusion criteria and subsequently underwent surgical implantation.

Inclusion criteria were women aged 19 to 65 years, with indications for breast augmentation surgery due to hypomastia, breast asymmetry, mastectomy sequelae, pectus excavatum, Poland syndrome, burn sequelae, or amastia, without other comorbidities, and with preoperative exams within normal ranges. The basis for indicating hybrid implant placement was the patient's desire and chest measurements. Exclusion criteria included smokers, alcoholics, subjects with any allergy to the device components, patients undergoing treatment for chronic diseases, subjects who underwent severe weight loss, and pregnant/lactating women.

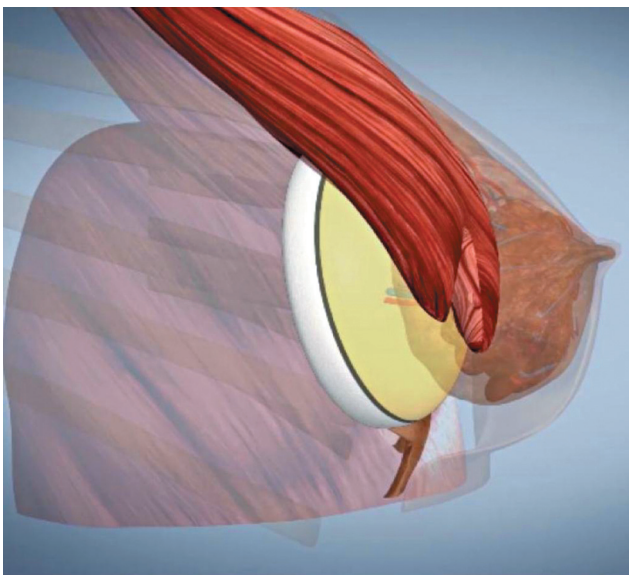

Fig. 3 Anatomically positioned hybrid implant, with its upper portion partially covered by the pectoralis major muscle.

Procedures occurred under local anesthesia and sedation. For implant placement, the incision was inframammary, with approximately 4 cm in length. Mastopexy used an inverted T approach. The implant placement plane varied according to clinical indication, and it was retromuscular (or submuscular) or anteromuscular (or subglandular). Skin closure occurred in three planes using absorbable Monocryl (Ethicon Inc.) suture. There was no need for drainage.

The average observation period was six months after breast implant surgery, with analysis of the new implant's behavior. Following these six months, the assessment of the hybrid implant's behavior included the incidence of complications, patient and surgeon satisfaction, ease of implantation, and preoperative and postoperative photographs. The monitoring of study participants and the implant's behavior occurred for a total period of 24 months.

To evaluate the performance of the new implant, the analysis variables were classified according to the time at which they were evaluated.. Variables assessed immediately after surgery and within 45 days were classified as immediate outcomes and included the presence of hematoma, infection, seroma, scar dehiscence, breast tenderness, rash, and implant migration. Variables assessed after the first 45 days were classified as late outcomes and included implant rupture, capsular contracture, and gel migration. The immediate and late outcome variable analysis determined the incidence of events during the evaluation period about the total number of implants in the study (n = 279).

The present study measured surgeon and patient satisfaction-related variables about the total number of study participants (n = 135). The satisfaction variables included patient satisfaction, dissatisfaction with implant volume, ease of implant insertion, and surgeon satisfaction.

Data analysis was descriptive. For continuous variables, we calculated minimum, maximum, mean, median, standard deviation, and number of observations. For categorical variables, we determined absolute and relative frequencies. We calculated the exact limits of the 95%CIs to analyze immediate and late events, as well as satisfaction levels.

The Research Ethics Committee (CEP/CONEP) approved this clinical trial under number CAAE 71569416.0.0000.5440. The study adhered to the principles outlined in the Declaration of Helsinki regarding ethical standards.[7] The study followed regulatory procedures with ANVISA according to Process no. 25351.205766/2019-48 and obtained a license regarding the Special Communication in the Clinical Investigation Dossier of a Medical Device (DICD) no. 8002/2019 on November 26, 2019.

Results

The study used 279 hybrid implant units in 135 women. The mean age of participants was 33 years with a standard deviation of 10 years. The most common surgical indication was hypomastia (56.3%), which occurred mainly in women under 35 years of age. All participants denied any history of anesthesia-related issues or medical conditions and had no comorbidities.

Of the 135 patients, 92 underwent primary surgeries and 43 secondary surgeries. Among the 92 primary cases, 72 received the implant alone, with no breast skin or parenchyma resection, one patient had Poland syndrome, and 20 subjects underwent tissue resection with pexy. Of the 43 secondary surgeries, 31 patients underwent breast skin and parenchyma resection, and 12 replaced the implant alone.

Of the 135 surgical cases, 85 had implants inserted in the retromuscular space and 50 in the retroglandular space. All 85 retromuscular implants required myotomy. Eighty-two patients required a vertical approach in the pectoralis major muscle, and, in five subjects, myotomy was transverse, characterizing a dual-plane, split-free myotomy. Three patients underwent an implant exchange due to dissatisfaction with the volume, with the replacement of 315-mL by 360-mL protheses.

The most frequent immediate postoperative complications (within the first 45 days) were mastalgia (n = 12; 4.3%) and skin rash (n = 6; 2.1%) (►**Table 1**). There were no reports of complications, such as capsular contracture, implant rupture, or gel migration, up to the end of the two-year follow-up.

All satisfaction rates, both for participants and the surgeon, were above 97% (►**Table 2**). Three participants (2%) reported dissatisfaction with the implant volume and replaced their devices with larger ones 6 months after the initial placement.

Table 1 Frequency of immediate complications associated with the hybrid implant

Immediate complications	N = 279	%	LL (95%CI)	UL (95%CI)
Mastalgia	12	4.3	2.2	7.4
Skin rash	6	2.1	0.8	4.6
Implant migration	5	1.8	0.6	4.1
Seroma	5	1.8	0.6	4.1
Hematoma	2	0.7	0.1	2.6
Infection	2	0.7	0.1	2.6
Scar dehiscence	2	0.7	0.1	2.6

Abbreviations: LL, lower limit; UL, upper limit.

Table 2 Satisfaction index of research participants and the surgeon regarding the hybrid implant

Satisfaction	N = 135	%	LL (95%CI)	UL (95%CI)
Patient with surgery	135	100	97.3	100
Patient with volume	132	98	0.5	6.4
Surgeon with procedure	134	99	95.9	100
Implantation ease	135	100	97.3	100

Abbreviations: LL, lower limit; UL, upper limit.

►**Figs. 4**, **5** illustrate the aspects obtained with the hybrid implant in two participants.

Discussion

The hybrid implant demonstrated safety and efficacy, considering the observed frequency of both immediate and late complications, as well as during the two-year follow-up period. Capsular contracture, one of the main adverse events in long-term breast surgery, was not observed in the patients in this study after two years of follow-up.[8]

Liu et al. (2015)[4] conducted a systematic review with meta-analysis to evaluate the incidence of capsular contracture in breast augmentation and breast reconstruction with smooth or textured implants. Their meta-analysis included 20 studies, with a total of 4,486 patients and 8,867 implants. These authors demonstrated that smooth-surface implants had a significantly higher risk of capsular contracture than textured implants, with a relative risk (RR) of 3.10 (95%CI: 2.23–4.33). Moreover, a subgroup analysis indicated that capsular contracture was more frequent with smooth implants (RR = 2.30; 95%CI: 1.17–4.50). The authors concluded that textured implants could reduce the incidence of capsular contracture, regardless of follow-up time and type of surgical procedure. These findings suggested that the implant surface plays a critical role in tissue response.

In a systematic review, Duxbury et al. (2016)[5] compared the long-term safety and postoperative morbidity of polyurethane-coated silicone breast implants with textured silicone implants. In primary reconstructions, the incidence of capsular contracture with textured implants ranged from 10 to 15% over 6 years, increasing to 24.6% after 10 years. In

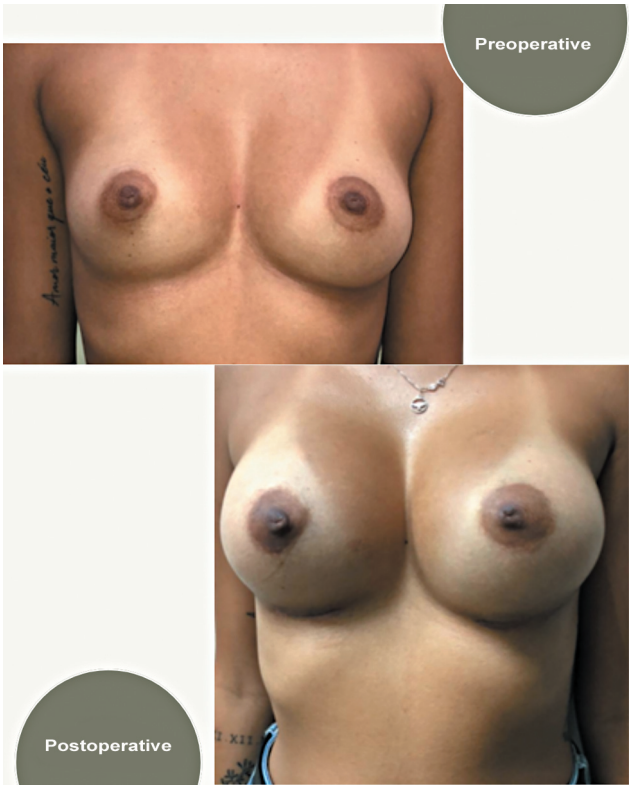

Fig. 4 Preoperative image and 12-month outcome of the 360-mL hybrid implant.

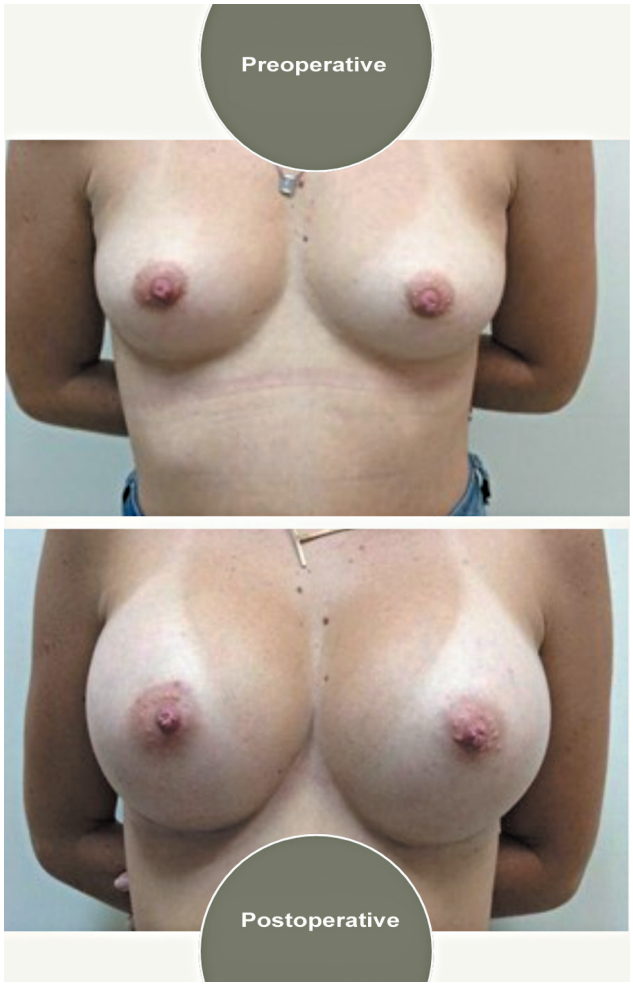

Fig. 5 Preoperative image and 12-month outcome of the 360-mL hybrid implant.

studies with polyurethane-coated implants, the rates were significantly lower, recording 1.8% over four years and 3.4% over eight years. Twelve studies analyzed the incidence of seroma, including four that used polyurethane implants. Regarding hematoma, the rates ranged from 1.1 to 2.7% with textured implants and 1.2% with polyurethane-coated implants. The risk of malposition was slightly lower with polyurethane implants (1.8%) compared to textured implants (from 2.1-4%). The rate of complications such as rash, inflammation, and irritation in patients with textured implants ranged from 0.9 to 2.1% over 6 years. However, these complications were more frequent with polyurethane implants, with rates from 4.2 to 5.4% in primary reconstructions and 4.3 to 4.7% in studies including different types of surgeries.

Commercially available breast implants, regardless of surface roughness or implantation technique, generate friction and rubbing against adjacent tissues. This continuous friction can trigger a persistent inflammatory response, acting as a trigger for chronic inflammatory reactions. The lack of proper resolution of this inflammation can lead to the development of breast implant-associated inflammatory diseases.[9,10]

The new hybrid implant, coated with a combination of microtexture or a smooth polyurethane surface, is an innovative approach to minimizing this friction. Its structure was designed to interact synergistically with the muscular forces in the region, adhering anteriorly and gliding posteriorly, which reduces friction with the surrounding tissues. This mechanism favors better tissue integration and may contribute to decreasing the exacerbated inflammatory response. Munhoz et al. (2019)[11] reported that excessive friction between the implant and adjacent tissues can contribute to chronic inflammation, capsule formation, and the release of silicone particles. These undesirable events can compromise long-term outcomes. These authors also emphasized that polyurethane surfaces provide greater cell adhesion and control of the inflammatory response. Surfaces with a lower specific area and medium roughness help reduce bacterial colonization and promote more controlled tissue integration.

The interposition of a polyurethane surface on the slopes resulting from the muscle incision was designed to prevent previously observed undesirable outcomes attributed to the reapproximation of the incised muscle edges in contact with a lightly textured surface.[12] However, this limitation was not observed with the hybrid surface implant. The development of a hybrid implant, with an anterior polyurethane surface and a posterior microtextured surface, aimed to prevent excessive adhesions to the structures underlying the implant. No tissue injuries were seen in this context, and the introduction of a polyurethane implant into the retromuscular space demonstrated physiological safety, providing greater stability in myotomies.

Conventional implants, which have a single surface, lack this adaptability. In polyurethane-coated implants, for instance, total fixation can lead to movements incompatible with the natural dynamics of the tissues. In contrast, with textured or smooth implants, mobility within the surgical space can generate excessive friction. The hybrid implant positioned in the retromuscular plane uses its microtextured base to optimize sliding within this space, respecting the natural function of this region. When placed anterior to the muscle, its adhesion to the mammary gland allows the pectoralis major muscle and its anterior fascia to maintain their normal mobility without interference.[13]

The study results indicate that the use of the hybrid implant is associated with a higher level of satisfaction among both patients and the surgeon. The ease of implant insertion was also satisfactory, contributing to a more efficient surgical technique and representing an innovative and safe alternative in breast surgery.

The term *hybrid* was chosen to name and describe the breast implant developed because it combines two coating surfaces. However, this term has also been applied to the surgical technique, as demonstrated in a prospective study by Sforza e Spear (2021)[14] evaluating the efficacy of so-called hybrid breast augmentation, which combines silicone breast implants with autologous fat grafting. Despite the different definitions of *hybrid* (one, focused on implant design, the other, on surgical strategy), both approaches share similar goals of improving aesthetics, increasing safety, and reducing complications, such as capsular contracture. These advances reflect a promising trend in the evolution of breast augmentation.

The present study evaluated the clinical and aesthetic viability of the new hybrid implant. Based on the results, we propose a randomized clinical trial as a future perspective, after due registration with ANVISA and marketing authorization, to compare this implant with additional commercially available devices. The limitations of the current study include the lack of histopathological evaluation, which could be incorporated into subsequent studies, and the follow-up time, which limited the observation of long-term effects. These limitations are expected in pilot studies assessing safety and initial clinical response but reinforce the need for further investigation.

Conclusion

We conclude that the hybrid implant is a safe and effective option for breast augmentation, with no significant postoperative complications observed during the two-year follow-up period. Notably, there were no cases of capsular contracture during this period, reinforcing its potential to minimize this common complication. In addition to the clinical benefits, the implant also demonstrated high satisfaction rates among both patients and the surgeon, demonstrating its effectiveness from both a functional and aesthetic perspective. These results indicate that the hybrid implant represents a promising alternative for optimizing surgical outcomes in breast augmentation.

Clinical Trials
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Ethics Committee number
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Conflict of interests
The author has no conflict of interests to declare.

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