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IDEAS AND INNOVATIONS

Breast

Innovative Application of GalaFLEX Poly-4-Hydroxybutyrate Scaffold in Breast Reduction/Mastopexy with Inferiorly Based Dermo-adipose Flap

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Summary: Breast reduction is one of the most required plastic surgery procedures worldwide, improving significantly the quality of life for patients with macromastia and gigantomachia. Despite various proposed approaches aiming to yield more stable results postreduction, no single technique has demonstrated unequivocal superiority. Recurrence ptosis at 6–12 months postoperative remains a challenging concern. To improve this issue, the authors propose a novel application of the poly-4-hydroxybutyrate (P4HB) scaffold on the anterior surface of the Ribeiro dermo-adipose flap. The primary aim was to establish a durable and resilient biological connection between the mammary gland and the flap, thereby promoting long-lasting outcomes in breast reduction procedures. The P4HB scaffold is a monofilament, single-layer, biologically derived, fully resorbable, rapidly integrating within breast tissue; this biological process stimulates the formation of freshly vascularized connective tissue up to a thickness of 2–3 mm. Within 18–24 months, the scaffold undergoes gradual resorption through hydrolysis-based mechanism, providing enhanced strength and resistance to the native tissue, as shown in animal model. A key innovation proposed by the authors involves the division of a 15×20 cm rectangular sheet of the P4HB scaffold along its diagonal, resulting in two right triangles. This modification ensures increased height of the device if compared with the traditional splitting technique of the scaffold. The strategic establishment of a biological bridge between the mammary gland and flap through the implementation of the P4HB scaffold could potentially enhance the longevity and aesthetics of breast reduction outcomes. *(Plast Reconstr Surg Glob Open 2024; 12:e5676; doi: 10.1097/GOX.0000000000005676; Published online 13 March 2024.)*

IDEA

Based on the authors' extensive experience, the dermo-adipose inferior-pedicled flap exhibits an intriguing "antislip" function, effectively countering lower pole expansion over time. Alternative "internal bra" techniques have been shown to contribute significantly to improved soft tissue support, thereby reducing the recurrence of breast ptosis.[1] Notably, the poly-4-hydroxybutyrate (P4HB) scaffold represents a fully resorbable, biocompatible, monofilament, and biologically derived structure, capable of integration with newly generated native connective tissue within its macropores. After a period of 18–24 months, the scaffold is completely resorbed through hydrolysis, leading to reduced inflammation.[2]

Even if the P4HB scaffold is still not FDA approved for breast surgery in the United States, promising data from multicenter clinical studies in other countries (CE approval) have already been reported for its use in augmentation mastopexy, breast reduction, and breast revision surgery, demonstrating its ability to deliver enduring aesthetic results.[3–6]

To ensure optimal results, the authors recommend a single, large rectangular sheet of P4HB scaffold (15×20 cm) for both breasts. Even if the monofilament design of this scaffold is intended to minimize the risk of infection, with a low infection rate compared with other

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Received for publication November 19, 2023; accepted January 25, 2024.

DOI: 10.1097/GOX.0000000000005676

Disclosure statements are at the end of this article, following the correspondence information.

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biological meshes,[7] the authors advocate for positioning the scaffold at least 1 cm above the lower breast incision, avoiding leaving the device directly under the horizontal scar (Fig. 1). After the inferiorly based dermoadipose flap harvesting, the anchoring of the Ribeiro flap to the pectoralis major fascia is performed with a 2/0 long-lasting absorbable monofilament suture. Before scaffold placement, it is essential to follow strict procedures, including the use of sterile gloves, changing surgical instruments, and disinfecting the breast, similar to routine of breast implant surgery. In contrast to the traditional method of splitting the P4HB scaffold sheet into two rectangles, the authors propose dividing a 15 × 20 cm mesh into two right triangles. This approach allows for a more comprehensive coverage of the dermo-adipose flap along its entire height. [**See Video 1 (online),** which shows preoperative markings of the resection pattern, the inferiorly based dermo-adipose flap, and the scaffold positioning.] [**See Video 2 (online),** which shows inferiorly based dermoadipose flap harvesting and intraoperative placement of the scaffold.]

Consequently, two equal right triangular sheets are obtained, with a bisector length greater than half the original side of the rectangle (10 cm). Placing the apex of the resulting triangle upward to align it with the Ribeiro flap height (up to 12 cm) with the major side resting on the base of the flap, as illustrated in Figure 1, we figure out almost a full coverage of the flap.

The scaffold should be positioned to cover as much of the flap surface as possible. The extremities of the scaffold are sutured to the pectoralis major fascia using resorbable 2/0 monofilament thread; furthermore, additional sutures to the dermal layer of the flap may facilitate early mesh adherence.

No glandular-scaffold stitches are required due to the rapid integration capacity of P4HB within the breast tissue, effectively bridging the gap between the gland and the flap.

DISCUSSION

In our practice, the dermo-adipose inferior-pedicled flap is usually harvest with a base-pedicle between 10 and 12 cm and maximum height of 10 cm preserving some LICA/AICA perforator to figure out the tissue's survival. By splitting a 15 × 20 cm rectangular P4HB scaffold sheet into two right triangles, we can effectively cover flaps with an extended height of 12 cm, increasing the coverage provided by two 10-cm high rectangles. In our technique, the scaffold is positioned 1.5 cm above the lower breast incision to prevent potential scaffold infection in case of wound dehiscence, especially at the T junction. Moreover, when combining this distance with the height of the triangle, we achieve adequate coverage for flaps with heights up to 13.5 cm. [**See Video 3 (online),** which shows the intraoperative authors' method of splitting the GalaFLEX scaffold]. The triangle's base is 25 cm; this offers an optimal coverage for the width of the flap.

The P4HB scaffold's ability to promote collagen deposition and vascular network formation enhances neofibrous tissue genesis. Previous studies have demonstrated rapid tissue regeneration, resulting in the formation of newly layered tissue that is approximately three to four times stronger than native tissue.[8]

Takeaways

Question: Recurrence of breast ptosis after reduction mammaplasty surgery is a real concern for every surgeon. How we can enhance the outcome's longevity?

Findings: To improve this issue, the authors propose a novel application of the poly-4-hydroxybutyrate scaffold on the anterior surface of the Ribeiro dermo-adipose flap with a modification that ensures increased height of the device if compared with the traditional splitting technique of the scaffold.

Meaning: This novel application of the poly-4-hydroxybutyrate scaffold holds significant potential to enhance the longevity and aesthetics of breast reduction outcomes.

Three additional scaffold triangles, highlighted in red as shown in Figure 1, will protrude by the flap, enhancing the flap's fixation to the pectoralis fascia.

This bio-connection between the gland and the flap could amplify the flap's antislip capacity, potentially serving as a crucial factor for achieving more long-lasting results and reducing ptosis recurrence, even in cases of severe ptosis, as we can see in Supplemental Digital Contents 1 and 2. (**See figure, Supplemental Digital Content 1,** which shows a preoperative photograph taken in frontal projection. Preoperative photograph of a 57-year-old patient who underwent through inverted-T breast reduction with inferiorly based dermoadipose flap using the GalaFLEX Poly-4-Hydroxybutyrate scaffold according the author's technique. **http://links.lww.com/PRSGO/D117**.) (**See figure, Supplemental Digital Content 2,** which shows a 3 years postoperative photograph taken in frontal projection. This is a 3-year postoperative photograph of the same 57-year-old patient who underwent thorough inverted-T breast reduction with inferiorly based dermoadipose flap using the GalaFLEX poly-4-hydroxybutyrate scaffold according the author's technique. **http://links.lww.com/PRSGO/D118**.)

More recently, we carried out a pilot case-control study including only breast reduction patients, one group with placing the P4HB scaffold and the other group without (control group), with the same surgical technique. More specifically, we treated 15 consecutive patients affected by grade III ptosis who were undergoing breast reduction with inferior-based dermoadipose flaps, five of them using the P4HB scaffold and the other 10 without scaffold. The very preliminary report shows a slightly reduced stretch of the inferior pole (measured as nipple-inframammary fold distance elongation variation) in the scaffold group compared with control group (5.6% versus 12% after 12 months from surgery), in accordance with previous studies. No complications occurred in our case series. Infection, seroma, and delayed healing are reported in the literature as rare complications in larger number case studies.[4,6]

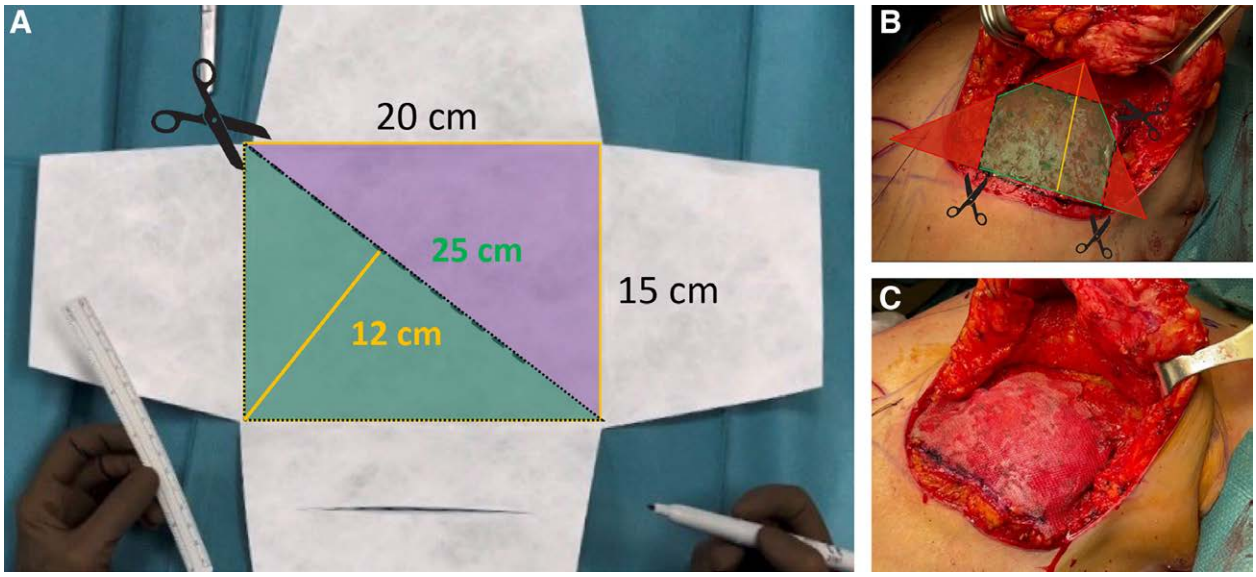

Fig. 1. Graphic representation of the authors' method of splitting the GalaFLEX scaffold and intraoperative placement of the scaffold. A, Splitting a 15 × 20 cm scaffold sheet diagonally permits obtaining two triangles with 25 cm base and 12 cm height (bisector of the triangle), for the coverage of both dermo-adipose flaps. B, Intraoperative placement of the cut scaffold. C, Trimming of exceeding extremities to fully cover the flap.

The article describes a new technique to use P4HB scaffold in inverted-T breast reduction/mastopexy, with the aim to improve this procedure in terms of cost-effectiveness ratio, as well as being beneficial to plastic surgeons' clinical practice.

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DISCLOSURES

Barbara Cagli is an advisory board member of Galaflex by BD, which provided GalaFLEX P4HB 15 × 20 cm scaffolds. All the scaffolds were used by the first operator (B.C.) and were not given free of charge. The other authors have no financial interests to declare in relation to the content of this article.

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