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Supplement Article

Clinical Use of GalaFLEX in Facial and Breast Cosmetic Plastic Surgery

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Abstract

Resolution of ptosis is a key step to the success of many plastic surgery procedures. Ptosis is a manifestation of tissue stretch. Tissue stretch can occur as a result of the natural aging process or health of the patient, or tissue may stretch under added weight or volume, such as when implants are placed. Surgical rejuvenation of ptotic tissues is very effective and results in marked changes in the patient profile yet the tissue that resulted in the need for the procedure first place has not improved and ptosis can recur. Recent developments in long-term resorbable porous materials have provided surgeons with the opportunity to experiment with tissue reinforcement in plastic surgery procedures. These new materials have a low profile, rapid tissue integration, and a long-term strength retention profile. Long-term resorbable scaffolds such as poly-4-hydroxybutyrate (P4HB) natural scaffold (GalaFLEX scaffold, Galatea Surgical, Inc., Lexington, MA) have shown promise for a host of plastic surgery indications. This article presents clinical experience with GalaFLEX for soft tissue reinforcement in three different clinical applications; including the reinforcement of the superficial muscular aponeurotic system (SMAS) in minimally invasive facelift, reinforcement of the skin envelope in mastopexy, and reinforcement of the breast capsule (pocket) in revisional breast surgery. Soft tissue reinforcement has been shown to provide increased mechanical strength as well as improved maintenance of postoperative results.

Level of Evidence: 5

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The correction of ptosis is one of the hallmarks of plastic surgery.[1,2] Traditional surgical techniques alleviate skin laxity via the careful excision of redundant skin and lift and tighten tissue to provide a rejuvenated profile.[2] Over time, the basic lifting strategy has been modified to include many different methods of dissecting, raising, and securing internal tissue and sometimes muscle to provide tension-free skin closure. For instance, in rhytidectomy, lifts have evolved from skin-only lifts to a minimal tension approach that focuses on dissection and resuspension of the superficial muscular aponeurotic system (SMAS).[3] Stuzin et al were the first to employ soft tissue reinforcement in the SMAS lift; however, only fast resorbing Vicryl (Ethicon, J&J, New Brunswick, NJ) materials were available.[4] Vicryl mesh was rolled with the SMAS to strengthen the suture site.

Modern breast lift and reduction procedures include a multitude of approaches involving a variety of pedicle choices as well as incision patterns.[5-10] Internal manipulation and suturing of the pedicle reduces initial stress and load on the outside skin envelope.[11-14] In most cases, a degree of overtightening of the skin envelope is performed since a degree of recurrent stretch is anticipated. Additional increases in volume–and concomitant increases in weight–can increase this stretch. In cosmetic breast procedures, Goes has been employing scaffolds and meshes to support and lift the breast in mastopexy since at least 1996.[15] After trying multiple configurations of biologically-derived and fully resorbable products, he has noted that these materials do not adequately support the lift in the long term.[16]

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It is standard of care to use porous and/or biologically derived meshes or scaffolds for soft tissue reinforcement in hernia and abdominal wall repair procedures as their use dramatically reduces reherniation rates.[17] Use of these same soft tissue reinforcement products is also becoming more common in plastic and reconstructive surgery procedures where tissue weakness may also affect the overall long-term success of the procedure.[18,19] Single stage breast reconstruction is frequently performed with a scaffold because it provides a stable immediate surgical result.[20-25] We have been exploring the use of GalaFLEX scaffold (Galatea Surgical, Inc., Lexington, MA) in cosmetic procedures.

GalaFLEX is made from poly-4-hydroxybutyrate (P4HB) a long-term resorbable porous scaffold that is known to promote tissue ingrowth and a strong repair in soft tissue applications.[26-30] GalaFLEX scaffold is one of a family of commercially available products made from P4HB fibers, including MonoMax suture (B Braun Aesculap, Tuttlingen, Germany) for abdominal wall closure, Phasix and Phasix ST (C.R. Bard Inc., Murray Hill, NJ) for hernia repair, and BioFiber Scaffold (Tornier/Wright Medical, Edina, MN) for tendon repair. P4HB suture, mesh, and scaffold products have been employed in more than a million patients worldwide.

In our surgeries, this scaffold is a new tool for securing and supporting soft tissues in an elevated position and thus permits a modification of technique away from the use of multiple sutures and excessive plication. It provides additional security that the surgical result will be more stable than it would have been otherwise when supported by suture or skin alone. We have also anecdotally experienced that the appearance of the skin scars are subjectively improved, which may result from the reduction of the tension on the approximated tissue planes. Use of the scaffold to support deeper tissues allows for a diminished load on the skin and incisions.

P4HB SCAFFOLD DESIGN

P4HB is a resorbable thermoplastic polyester that was first commercialized for medical use almost 10 years ago.[31-34] Once implanted in the body, P4HB degrades primarily by bulk hydrolysis to produce 4HB (4-hydroxybutyrate), which can be further catabolized (or degraded) to carbon dioxide and water.[29] Unlike absorbable sutures such as VICRYL RAPIDE (Ethicon, J&J, New Brunswick, NJ) and VICRYL, whose by-products decrease the pH at the wound site, degradation of P4HB is not as acidic, which may reduce the inflammatory response associated with these materials.[35] In addition, P4HB products are highly differentiated from enzymatically degrading biologic scaffolds derived from animal or human tissues. The latter materials require an active cellular process for degradation and remodeling. Inherent in such enzymatically driven degradation processes is a mechanical progression from strong (no degradation) to weak (degrading/remodeling) to strong again (remodeled tissue).[36] This inherent weakness during remodeling leads to stretch under load, and may be the reason that non-crosslinked biologic scaffolds are not employed in hernia repair to any great extent, but are frequently used in direct to implant breast reconstruction.[21,25,37]

In addition, P4HB fibers and scaffolds have a longer, more gradual loss of mechanical strength than PGA (polyglycolic acid) and PDO (polydioxanone) sutures.[38] This is advantageous in applications where a gradual rate of load transfer from scaffold to new tissue is important, and this property is helpful when attempting to prevent recurrence of herniation, ptosis, or tissue stretch. In vivo porcine abdominal wall repair studies have provided evidence that repairs with P4HB demonstrate significant mechanical strength compared to native abdominal wall over a 52-week period despite significant material resorption over time, with no evidence of herniation nor diastasis, and a very low inflammatory response.[28] There is also in vivo evidence that P4HB scaffold repairs exhibit significantly greater strength than Strattice repairs, which lose strength over time.[36] In addition, histology results from explants from breast surgeries at 6 weeks and 7 months after implantation of GalaFLEX indicate robust ingrowth of tissue into the interstices scaffold that is fully vascularized and contains both type I and III collagen.[30]

The expanding line of commercially available P4HB products for hernia repair include a flat woven construct (Phasix) very similar to GalaFLEX, a plug and patch designed for inguinal repair (Phasix Plug & Patch), and a specialized product coated on one side with a hydrogel barrier to minimize adhesion formation when used via the intra-abdominal approach (Phasix ST). These P4HB products are used in Grade III/IV ventral hernia patients with comorbidities such as diabetes, high blood pressure, and obesity.[39,40] Early clinical results from post-market studies in ventral hernia repair indicate very low hernia recurrence and adverse event rates in complicated patients with recurrent hernias.[39,40]

APPLICATIONS IN PLASTIC SURGERY

Facelifting

Rhytidectomy is one of the most common procedures performed in cosmetic surgery.[41] The facelift procedure removes redundant skin, reduces jowls, improves the jawline, and restores the cervicomental angle in the neck.

In the past decade, many surgeons have become proponents of SMAS imbrication and plication to lift and support the deep layers in rhytidectomy.[42] Elevation or plication of the SMAS contribute to the tensile strength and long-

term results achieved in rhytidectomy. If the SMAS is compromised or weak, the improved tissue result may not be retained.

The authors hypothesized that reinforcement of the elevated fixed or plicated SMAS with a scaffold or mesh overlay would help prevent early postoperative loosening and possible rupture of the SMAS imbrication, as well as stabilize the lift. It might also prevent "cheese wiring," the tearing of the sutures through the SMAS that can occur during healing as the skin and subcutaneous tissues swell. This hypothesis was tested through a cadaver study.[43] Reinforcement of cadaver SMAS with P4HB absorbable mesh sutured over the repair was shown to improve tissue breaking strength and suture tearing force.[43] It also reduced the variability in load vs displacement seen among samples tested compared to SMAS sutured with suture alone. These data suggested that P4HB-reinforced SMAS imbrication would support higher loads and provide more consistent, long-lasting SMAS support among patients undergoing rhytidectomy.

The P4HB GalaFLEX scaffold was first used by this author (D.M.T.) in a human facelift procedure in 2011 to strengthen SMAS fixation with suture in rhytidectomy. Initial use was followed up with a multicenter post-market study that looked at patient and surgeon satisfaction as well as indicators of early recovery and procedural durability when the SMAS layer was reinforced with P4HB scaffold in less invasive facelift techniques.[44] The inclusion criteria were age greater than 21-years, non-pregnant female, obtained consent for compliance with study protocol, and no current subject enrollment in other investigational studies. Exclusion criteria were history of connective tissue disease, systemic illness, history of dependence on alcohol or drug use, pregnancy or breast feeding, severe allergies, active infection/abscess, history of tobacco use, or use within the last 12 months. Patients with severe jowling or severe cervical skin redundancy, and/or any history of psychological or medical condition that would constitute unwanted surgical risk were also excluded. Patients were evaluated postoperatively at 1 week, 1 month, 3 months, 6 months, and 12 months. Fourteen women were enrolled into the study.

The objective of the study was twofold: (1) to evaluate early recovery and satisfaction with the early result; and (2) to evaluate the durability of the surgical result and patient satisfaction 1 year after surgery. The patients were required to fill out the Face-Q patient satisfaction questionnaire preoperatively and at all postoperative time points.[45-47] A diary was used to determine measures of early recovery and included pain (VAS scale 0-10), daily record of self-administered pain medication, number of days until the patient felt comfortable going to dinner or a meeting, and how long they used makeup to cover bruising during the two weeks immediately following surgery. Physician assessment of the results included an evaluation of ecchymosis, bruising, swelling, and scaffold or suture palpability at follow-up visits. All surgeons were required to fill out a satisfaction questionnaire at each postoperative visit. Fourteen minimally invasive facelifts were performed in which P4HB scaffold was used to reinforce the SMAS on both sides of the face (28 P4HB scaffold implantations). The product immediately reinforces and strengthens the SMAS plication as well as promoting tissue ingrowth, thereby adhering the dissected tissues planes to one another. Early results indicated that use of GalaFLEX does not increase postoperative pain nor recovery times. Surgeon reported early recovery scores were excellent. A variety of standard healing parameters were assessed by the surgeon and reported out as none (0), scant (1), noticeable (2), very noticeable (3), and severe (4). Ecchymosis and edema had largely resolved by 7 days with average scores of 1.4 and 1, respectively, for all 14 patients. Scaffold visibility was consistently rated as being negligible. At the early 7 and 30-day time points, several patients had scant scaffold palpability that was almost entirely resolved by 90 days; however, the same was true for suture palpability. Skin redness and irritation was minimal and largely resolved by 7 days also. There was no statistically significant difference in patients' satisfaction at 30 days and 1

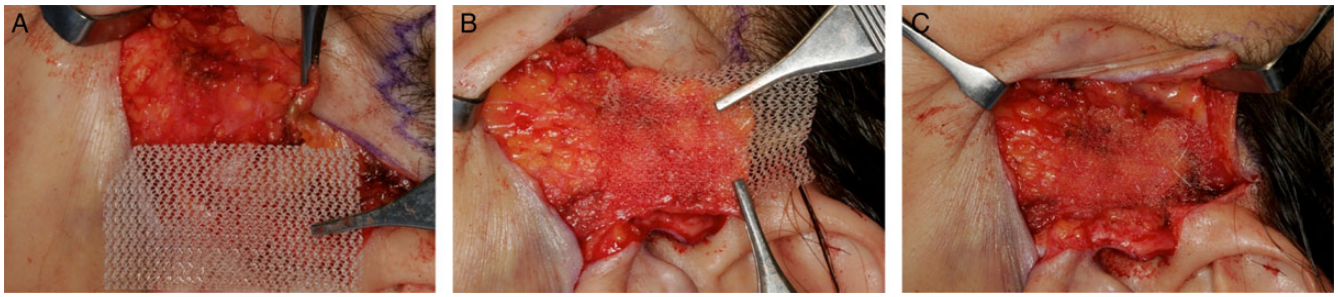

Figure 1. GalaFLEX was employed in a facelift procedure on this 58-year old female to provide stability for the surgical result. (A) SMAS flap elevated and being lifted cranially. (B) GalaFLEX scaffold sutured to SMAS flap. (C) SMAS flap and GalaFLEX scaffold sutured over zygomatic arch.

year, suggesting that the initial surgical result has very good durability for at least 1 year.[48]

A rhytidectomy procedure using a P4HB scaffold involves initial irrigation of the scaffold in antibiotic solution prior to placement. The P4HB scaffold is then cut to size and sutured in place. The SMAS can be managed using either imbrication or plication techniques. In the imbrication technique, a short SMAS flap is elevated then advanced vertically and sutured to the soft tissues over the zygomatic arch, supporting the imbrication with the scaffold (Figure 1A). Eight to ten 5-0 PDSII sutures (J&J, New Brunswick, NJ) are used to suture the scaffold into place taking care to insure the scaffold is flat and no edges of the scaffold are lifting away from the SMAS layer. (Figure 1B) In cases where the SMAS was plicated the scaffold was used to reinforce the plication. Buried, interrupted 3-0 PDSII sutures were used to approximate SMAS-to-SMAS points for the face and platysma-to-SMAS, to create a primary vertical, secondary lateral lift. The scaffold was then cut to overlap the suture line by at least 1 cm and inset with 5-0 Monocryl suture (J&J, New Brunswick, NJ) as described above. In all cases the scaffold was used to support the site where sutures were typically placed. The sutures are placed in each corner and then down the center of the scaffold, ensuring that the corners stay flat to avoid palpability (Figure 1C). Care is taken to assure viable skin coverage over the scaffold and to avoid placing the scaffold directly under the skin closure suture line. The author (DMT) has not had any adverse events in his GalaFLEX procedures in rhytidectomy and browlift.

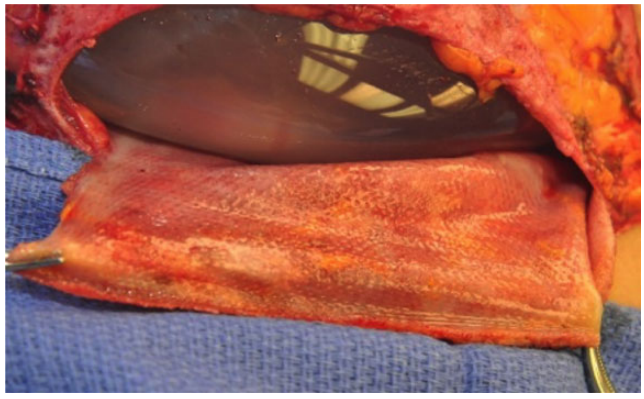

Figure 2. Intraoperative photograph of tissue ingrowth into the P4HB scaffold, as demonstrated on a 33-year old female. The photograph was taken during a revision surgery six weeks after P4HB scaffold implantation. Tissue ingrowth is all the way through the pores of the scaffold.

Breast Lift/Reduction

We (BWV, WPA) routinely use the GalaFLEX scaffold in patients who present with ptotic breasts but seek to achieve a more lifted, youthful appearance without significant changes in volume. This particular monofilament scaffold has a long-term resorption profile that allows for ingrowth of vascularized tissue as evidenced by explants from human breast patients[49] as well as a growing history of human use with a good safety profile. Data on the use of GalaFLEX in cosmetic breast surgery are being collected through a post-market study of 60 mastopexy and reduction patients in which the surgeon has used GalaFLEX.[50]

By comparing the 3-dimensional imaging data of these patients at one and three months after surgery to images taken one year after surgery it is possible to calculate changes in breast stretch. In an early cohort of 11 patients, the average nipple-fold distance changes less than 1 cm (10%) during the first year after surgery and the distance between the sternal notch and the lowest point on the breast also stretches by an average of 5% over that same time period.[51] There was one incidence of delayed wound healing that required local wound care.[51]

In our experience, GalaFLEX scaffold does not irreversibly stretch, and unlike what has been described with ADM in breast reconstruction,[20] a breast that is supported and shaped with GalaFLEX will not "relax" over time. Implantation technique should be adjusted accordingly. As an example, one of our first surgical cases in which GalaFLEX was over-tightened resulted in breast asymmetry

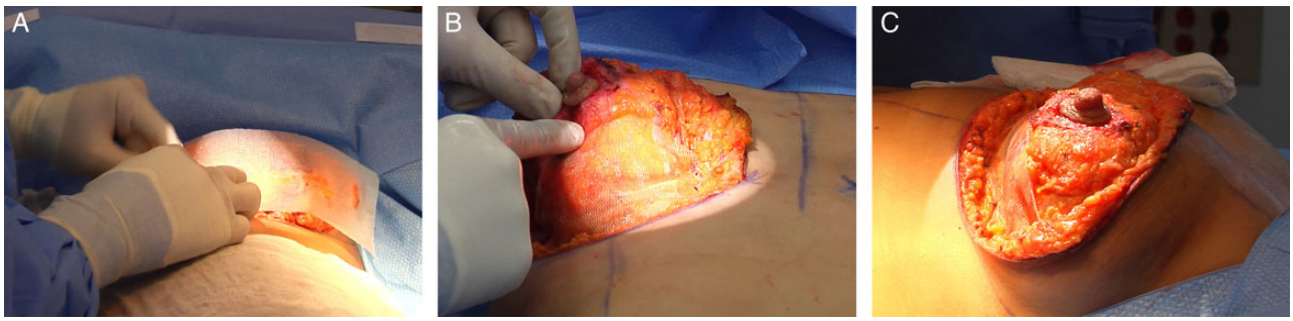

Figure 3. (A) The scaffold is measured and cut to shape if necessary. (B, C) The scaffold is secured medially, centrally and laterally to the chest wall fascia, with a 2-0 MonoMax (Aesculap AG, Tuttlingen, Germany) or PDS suture.

- one breast much higher than the other – that required a surgical correction. By the time the surgical correction was performed at 6 weeks after implantation, the GalaFLEX was well incorporated (Figure 2).

In our experience, placing the GalaFLEX scaffold does not add significant time to the procedure. It is important to use a large enough piece of the scaffold such that the material can be comfortably seated across the lower pole. P4HB scaffolds have been used in a wide variety of mastopexy procedures including central mound, superior and inferior pedicle. Incisions are created and the breast is de-epithelialized, elevating flaps medially and laterally in order to create an area for support of the lower pole of the breast by the scaffold (Figure 3A). Skin flaps are elevated. Before use, the GalaFLEX scaffold is placed in a triple antibiotic or other irrigation solution as is standard practice for most surgical implants.[52]

The scaffold is placed in the inferior pole of the breast in a hammock configuration (Figure 3B). A rectangular 7.5 × 20 cm piece of GalaFLEX scaffold is used in each breast. The scaffold is secured medially, centrally and laterally to the chest wall fascia (Figures 3B-C). Monofilament suture is recommended, and the authors have used 2-0 MonoMax when available in the United States (2-0 MonoMax is not commercially available at this time in the United States, but larger sizes are available; a wide range of sizes are commercially available in Europe) as it is constructed from P4HB, or 2-0 PDS suture; both have a relatively long strength retention profile. There is rapid incorporation of the scaffold into the soft tissues, thus the resorption time of the sutures is less important than with nonporous ADMs. No difference in outcomes between the two sutures has been observed. Additional sutures are placed between these initial sutures as needed. Care is taken not to over tension the mesh—in fact, it is advisable to sit the patient up to assure the mound has the location and appearance that is desired long term, as there will be little change postoperatively. Once the scaffold is sutured in place, skin flaps are re-draped across the lower pole of the breast. It is recommended to position the nipple slightly higher on the chest wall than is done with a standard mastopexy as bottoming out will not occur. Similarly, the vertical limbs of the Wise pattern are made slightly longer since the N-IMF distance will not stretch as much as in a standard mastopexy. Drain use is at the discretion of the surgeon.

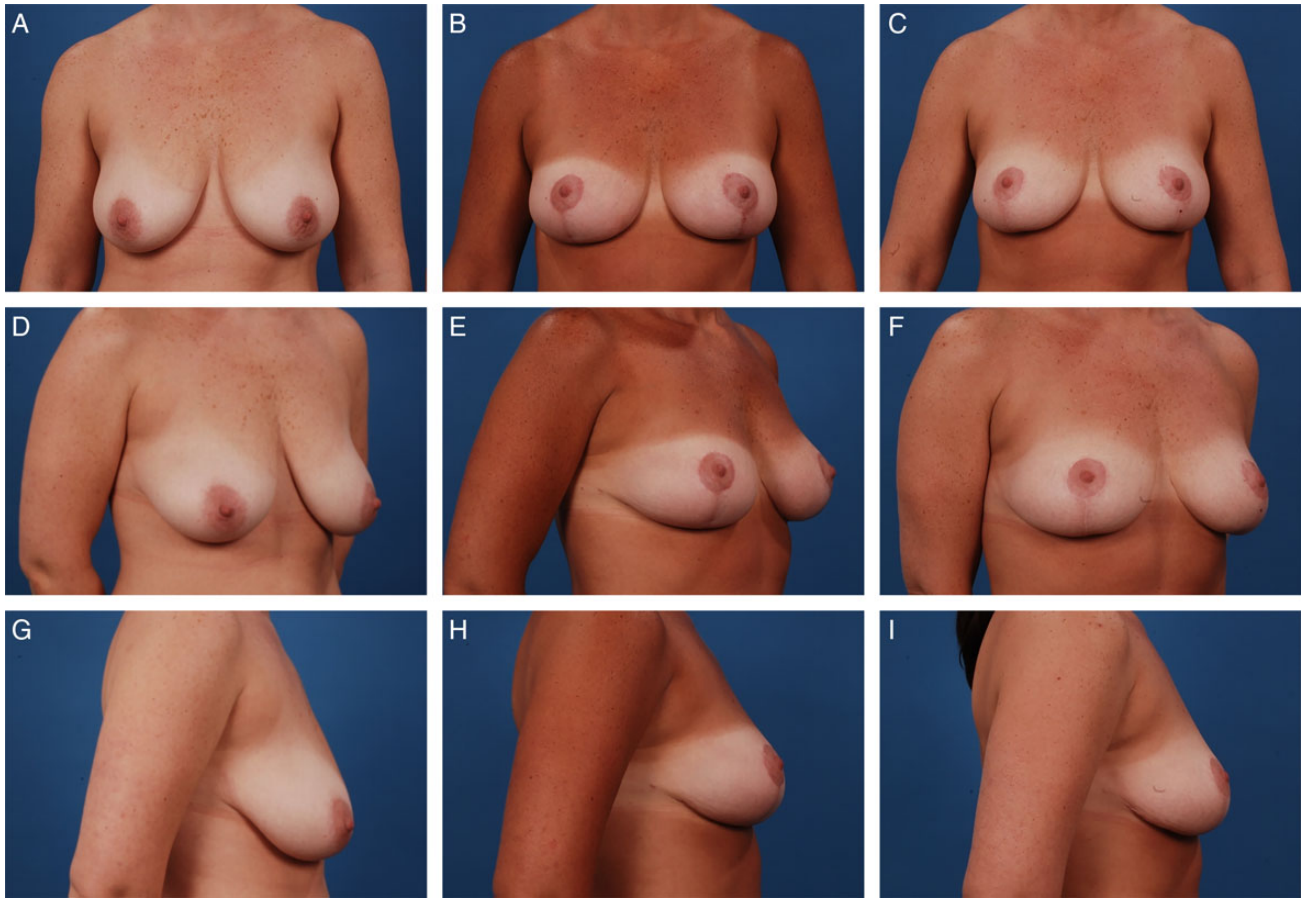

Figure 4. (A, D, G) Preoperative, (B, E, H) 3-month postoperative, and (C, F, I) 1-year postoperative photographs of a 39-year-old female mastopexy patient. GalaFLEX was employed in the lower pole of the breast to provide stability for the surgical result.

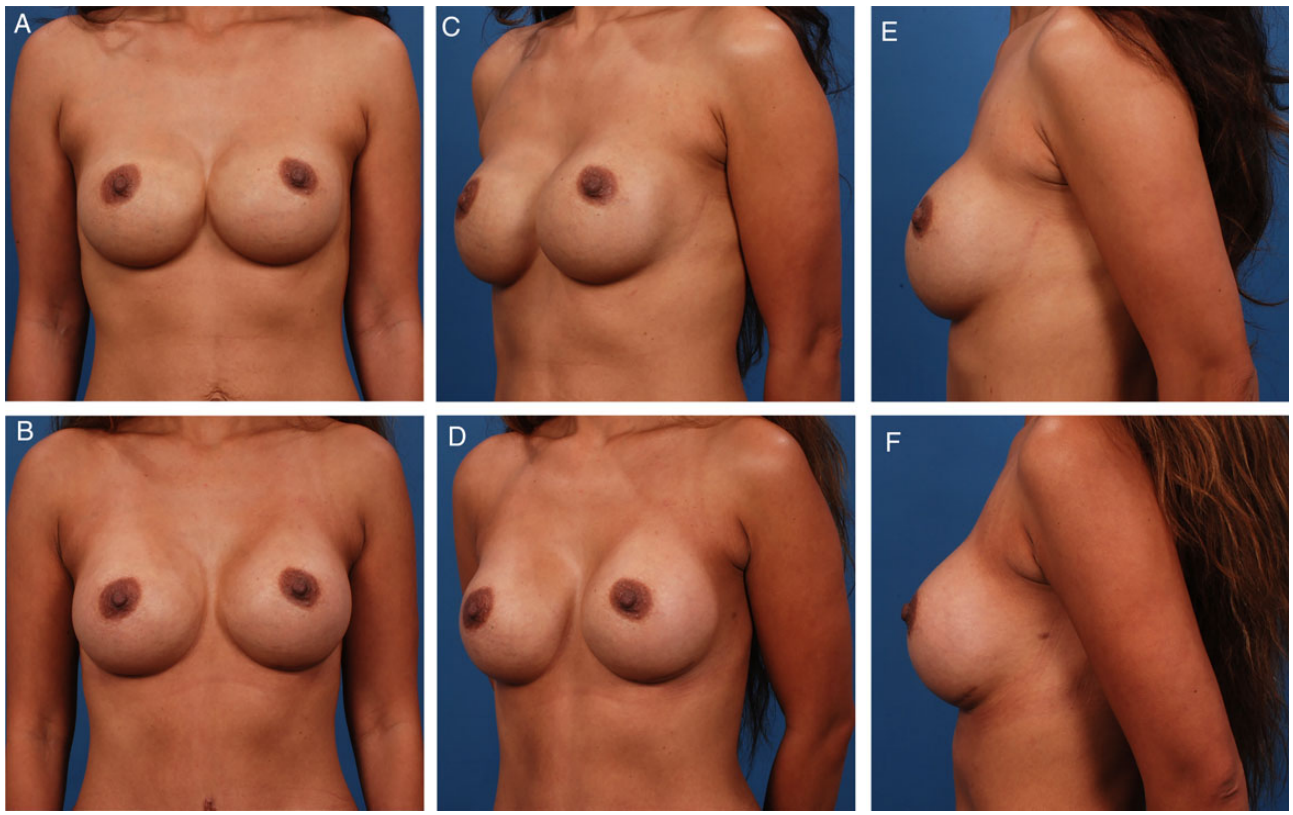

Figure 5. (A, C, E) Preoperative and (B, D, F) 1-year postoperative photographs of a 36-year-old female malposition patient who had undergone two previous surgeries. GalaFLEX was employed to provide stability for the surgical result.

Standard layered closure is completed. An example of a 39-year-old mastopexy patient preoperative, at 3 months, and at 1 year is shown in Figure 4.

Breast Revision Surgery

It is not uncommon for surgeons to perform multiple procedures on a single breast, in part because there are now many complementary technologies for optimizing breast shape and volume. In 2014, ASAPS reported that there were more than 100,000 mastopexies and 71,000 breast revision procedures.[53] Each of these procedures may have also included a cosmetic revision to an augmentation, fat grafting, or correction of pocket stretch. A number of previous augmentation patients are presenting for revision/rejuvenation. Over time, many of these patients have experienced lower pole stretch, and/or implant malposition due to the implant size/weight, pregnancy, or weight gain, necessitating a mastopexy and other procedues to remove excess skin particularly when the implant is being removed. We have found that GalaFLEX can be used in most revision scenarios for which someone might consider an ADM. In particular, cases of pocket stretch or mastopexy augmentation to provide additional support for both the soft tissues and the implant weight. The scaffold is typically palpable under thin flaps for 6 to 9 months. The authors have had no irregularities except in several early cases when the scaffold was anchored to the flaps with suture. This can be corrected with fat grafting, and no visibility was noted.

Collectively, two authors have performed more than 250 cosmetic breast surgeries (at least 500 implantations of P4HB scaffold) in mastopexy or revisionary procedures, with and without breast augmentation with implants or simultaneous exchange of implants with fat grafting. Patient ages have ranged from 17 to 70 years old. Only one P4HB scaffold has been explanted from a patient who developed an infection after a revision procedure with capsulhorraphy. Her implant was removed at the same time, and later both scaffold and implant were re-implanted and the patient healed uneventfully. In addition, one immunocompromised patient due to regular use of Enbrel presented with a late infection at 13 months. She was treated with debridement and antibiotics. We have not experienced any cases of tissue necrosis nor non-integration in any patients.

An example patient would be a 36-year-old female with 2 previous surgeries including a saline augmentation 10 years prior followed by a revision for size exchange to 325

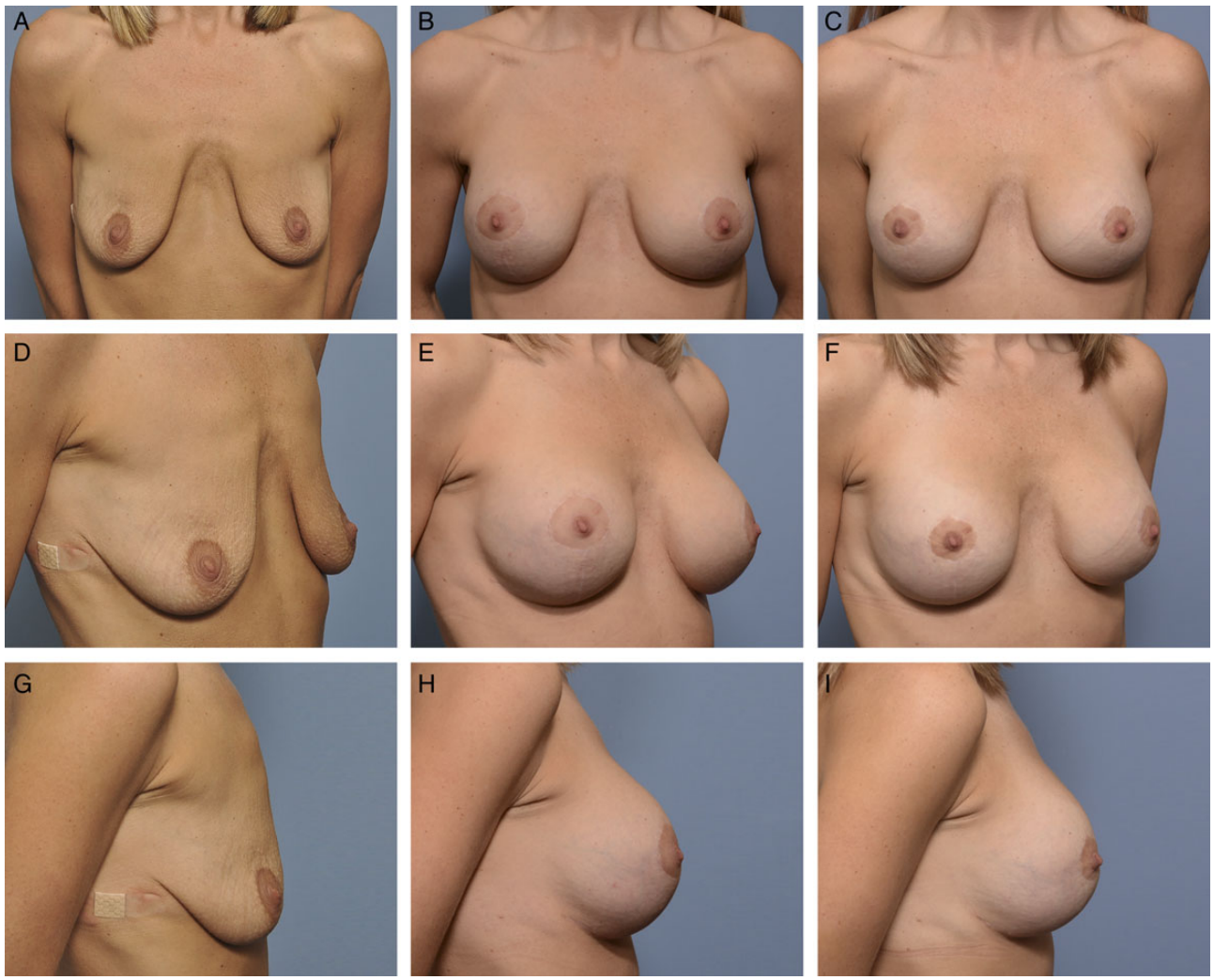

Figure 6. (A, D, G) Preoperative, (B, E, H) 1-year postoperative, and (C, F, I) 2-year postoperative photographs of a 33-year-old female complex revision patient in which GalaFLEX was used to provide stability for the surgical results.

cc smooth saline implants 4 years ago is now presenting with synmastia/ implant malposition. The plan for revision was preoperative saline deflation 4 weeks prior to surgery followed by surgical revision with bilateral neo-subpectoral pocket repair, reinforcement of repair with GalaFLEX scaffold and exchange to Allergan style 15 339 cc implants. Preoperative and 1-year postoperative results are shown in Figure 5.

Although we have less experience with GalaFLEX in the augmentation mastopexy patient, we describe a complicated case here as an illustrative example on how GalaFLEX might be deployed. This patient type is exemplified by a 33-year-old female who presented for breast rejuvenation following two pregnancies. Prior to her pregnancies, she was a C cup. While nursing, she estimated her breast size increased to a DD. Post-pregnancy weight loss resulted in a dramatic decrease in her breast size and a deflated breast with glandular ptosis (Figure 6). A mastopexy/augmentation was performed to rejuvenate her breast profile. GalaFLEX mesh was used to reinforce the lower pole due to the poor quality of her soft tissue envelope and a subpectoral implant used to increase volume (Allergan Style 15 339 cc device). After soaking in antibiotic solution, a 10 × 20 cm piece of GalaFLEX was split diagonally (Figure 7A) and anchored to the chest wall inferiorly, medially and laterally to define the inframammary fold position using 2-0 PDS (Figures 7B-D). An additional two to three 2-0 vicryl sutures were placed to affix the superior edge of mesh to the parenchyma. The scaffold was placed over the breast tissue after inserting the implant. Per surgeon preference, the mesh scaffold could also be sewn in place prior to the insertion of the implant. It can be sutured in place with a sizer in place to diminish any risk of injury to the permanent implant while suturing. Results at one and two years

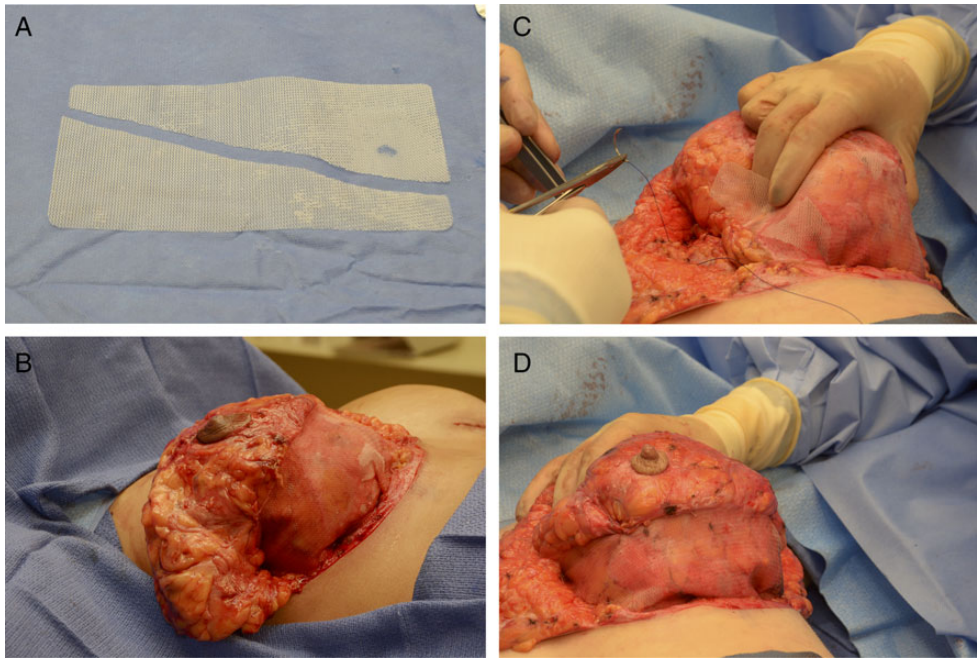

Figure 7. Intraoperative photographs of the surgical placement of GalaFLEX, as demonstrated on a 33-year-old woman. (A) GalaFLEX split diagonally. (B-D) Suturing GalaFLEX in place across the lower pole of the breast to provide stability for the surgical result.

postoperatively demonstrate excellent maintenance of position of the implant and soft tissues, despite the poor quality of the breast envelope and weight of the implant (Figure 6).

DISCUSSION

This article describes the initial development of techniques for implanting the P4HB scaffold and very early evidence indicating a relatively low number of complications associated with our use of GalaFLEX. It is also possible that removing load and tension from the incision line in rhytidectomy and mastopexy may potentially reduce some of the most common adverse events associated with these procedures including wound dehiscence and scar spreading. Data forthcoming from a multicenter study in cosmetic breast surgery with GalaFLEX will provide more detailed information relating to adverse events as well as changes in the breast shape in this patient cohort over time. Ongoing studies in hernia repair will provide additional evidence of the type and rate of adverse events associated with the use of the P4HB scaffolds in soft tissue reinforcement, and open registry studies will be of benefit in capturing a wider patient demographic.

CONCLUSION

In the ongoing effort to correct sagging tissues through cosmetic surgical procedures, there is a consistent need to provide additional support to soft tissues in a variety of areas. Although relatively simple in physical structure, the P4HB scaffold's successful early deployment for reinforcement in plastic and reconstructive surgery is a result of many years of development and optimization of fiber extrusion and product construction as well as innovative technique development on the part of the surgeon. We are very excited to see improved long-term outcomes due to soft tissue reinforcement using P4HB monofilament resorbable surgical scaffold.

Disclosures

Drs Van Natta, Adams, and Toriumi were Principal Investigators for post-market clinical studies using GalaFLEX. Drs Van Natta and Toriumi are or were paid consultants for Galatea Surgical, Inc., a wholly owned subsidiary of Tepha, the company that manufactures GalaFLEX. The authors did not receive compensation for writing the manuscript.

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