Preliminary Report

Poly-4-Hydroxybutyrate (P4HB) Scaffold Internal Support: Preliminary Experience with Direct Implant Opposition During Complex Breast Revisions

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Abstract

Background: The GalaFLEX scaffold is a mesh composed of resorbable poly-4-hydroxybutyrate (P4HB) monofilament fibers that aids in providing immediate internal soft tissue support, similar to that offered by an underwire bra, after breast reduction, lift, or augmentation.

Objectives: Our goal was to explore the possibility of using GalaFLEX as an internal support to prevent future sagging, predominantly in the lower pole of the breast. This preliminary study investigated GalaFLEX as a direct alternative to implants in a variety of complex revisional breast cases. Our intention was to establish a safety and efficacy profile in an effort to promote further investigation.

Methods: A retrospective case series of 5 patients over 2 years were evaluated. Inclusion criteria were capsular contracture with concerns over soft tissue coverage and future ptosis, along with complicated muscle coverage deficits secondary to plane switching.

Results: A retrospective review of photographs taken at the most recent follow-up consistently showed retention of implant position and soft implants. Additionally, patients presented with a mean ± SD Baker Grade Contraction score of 2.8 ± 0.9189 preoperatively compared with a score of 1 ± 0 postoperatively.

Conclusions: This preliminary study shows the initial safety of GalaFLEX but indicates the need for a multicenter, exhaustive study. Its versatility for complex revisional cases combined with acceptable aesthetic outcomes makes GalaFLEX an invaluable tool for plastic surgeons to consider.

Level of Evidence: 4

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The use of the GalaFLEX scaffold in the correction of breast ptosis, as well as an adjunct for superficial musculoaponeurotic system facelifts, has recently been described.[1] First described well over 10 years ago, the poly-4-hydroxybutyrate (P4HB) scaffold has since been utilized most often for loss of domain in the abdomen (MonoMax suture; B Braun Aesculap, Tuttlingen, Germany),[2] hernia repair (Phasix and Phasix ST; CR Bard Inc., Murray Hill, NJ),[3] and tendon repair (BioFiber Scaffold; Tornier/Wright Medical, Edina, MN).[2] Although GalaFLEX has been touted as being fully resorbable with retention of up to 50% to 70% of its strength at 12 weeks, it has been observed as

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Property	GalaFLEX® [2, 7, 15]	Vicryl® Mesh [11]	Seri Scaffold [12]	Tigr™ Matrix [13]	Strattice™ [14, 17]	AlloDerm [14]
Material	P4HB	PLGA	Silk	PGLATMC/ PLATMC	Porcine	Human Dermis
Structure	Monofilament	Multifilament	Multifilament	Multifilament	Extracellular Tissue Matrix	Decellularized Tissue
Absorption Time (Months)	18-24	3	12	24-36	Remodels	Remodels
Primary Absorption Mechanism	Hydrolytic	Hydrolytic	Enzymatic	Hydrolytic	Enzymatic Remodeling	Enzymatic Remodeling
Initial Scaffold Burst Strength (kfg)*	22.5	13.9	15.4	19.0	27.6**	Not Available
Retained Scaffold Strength	50% at 16wks	0% at 4wks	14% at 12wks	50% at 4wks	17% at 12wks	12% at 4wks

Figure 1. Characteristics of GalaFLEX compared with other mesh/biologics available. A comparison of GalaFLEX, Vicryl Mesh, SERI Scaffold, TIGR Matrix, Strattice, and AlloDerm highlights the prolonged retention, and the initial and retained strength of GalaFLEX. Reprinted with permission from Galatea Surgical (Lexington, MA).

long as 18 to 24 months postoperatively following ptosis correction.[2] This fully bioresorbable polymer is eliminated as carbon dioxide and water, with no polymer metabolites remaining after completion of the degradation process (Figure 1).[4] As a Food and Drug Administration–approved mesh, composed of resorbable P4HB monofilament fibers, the unique properties of this class of transgenic *Escherichia coli*-derived natural polymers and have given rise to an innovative method of soft tissue support.

METHODS

GalaFLEX/GalaSHAPE 3D Description

The knitted open-pore design of GalaFLEX is designed to diminish infection risk and promote tissue ingrowth across the monofilament scaffold. The monofilament fibers of which the GalaFLEX is constructed offer 60% less surface area than multifilament fibers, and this has been reported by Williams et al[2] to reduce the number of havens where bacteria can evade antibiotics, resulting in an increase in neovascularization and a reduced inflammatory response (Figure 1). Although these fibers are defined by their high strength, flexibility, prolonged strength retention, and pliability, the GalaFLEX scaffold contains a porous surface that acts as a lattice that facilitates rapid invasion and integration of well-vascularized adjacent tissue.[3] This tissue gains its strength over periods of months. At 7 months, the tissue thickness has increased with minimal inflammatory response. Type 1 collagen is clearly visible within the construct and covers the entirety of the new tissue (Figure 2). Around this same time, at 26 to 32 weeks, the tissue from the scaffold repair site is approximately 1 to 3 mm thick, with most of the repair strength coming from new tissue (Figure 3). It is imperative that the scaffold maintains adequate strength during the tissue-remodeling process.[5] Thus, it is crucial that the loss of strength, while the scaffold reabsorbs, is counterbalanced with a harmonious tissue ingrowth. Over time, the entirety of the scaffold is reabsorbed by the body, and new tissue then yields a strong durable repair.[6] This scaffold strength retention has been designed specifically to yield a final tissue strength during critical wound healing stages that is 3 to 5 times stronger than native tissue (Figure 4).

Revision Cases

In many complicated revisional breast implant cases, the lack of tissue support is a rate-limiting factor to an aesthetically acceptable outcome. Many surgeons have overcome this problem through the use of either acellular dermal matrices (ADMs) or mesh to augment the lower pole.[3] With a suboptimal or even partially destroyed pectoralis major muscle, the need for lower pole support becomes inherent for both implant position and total coverage to combat capsular contracture. Although ADMs can complement sound surgical technique, we have documented here our use of GalaFLEX as an “internal bra” to support

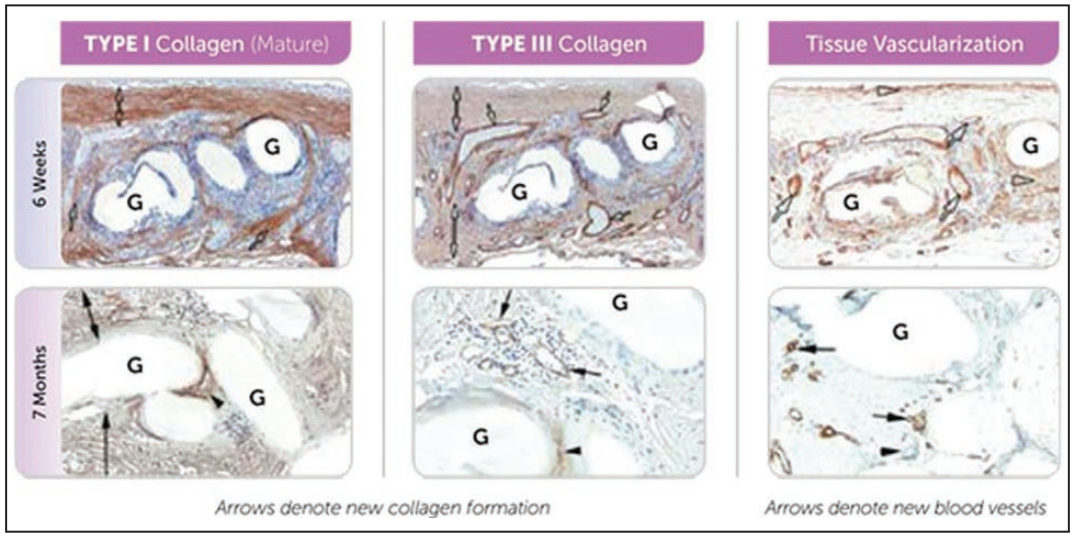

Figure 2. GalaFLEX collagen I/III deposition and tissue revascularization. Top figures: Representative histological cross-sections of the GalaFLEX scaffold demonstrating tissue ingrowth, vascularization, and the formation of mature connective tissue at 6 weeks postimplantation. Microscopic analysis of human tissue containing the GalaFLEX scaffold (denoted as "G") explanted from a healthy mastopexy site at 6 weeks. Top left: Collagen type I stain showing deposition of mature type I collagen throughout the GalaFLEX scaffold. The double-headed arrows show type I collagen formed along the GalaFLEX scaffold, and the arrows show type I collagen formed in the pores of the scaffold. Top middle: Collagen type III stain showing deposition of mature type III collagen throughout the GalaFLEX scaffold. The double-headed arrows show type III collagen formed along the GalaFLEX scaffold, and the arrows show type III collagen formed in the pores of the scaffold. Top right: CD31 stain showing neovascularization of new tissue formed around the GalaFLEX scaffold. Arrows indicate the positions of endothelial cells lining the vascular channels through the tissue. Arrowheads show the location of cells producing a mild inflammatory response to the scaffold as it degrades. Reprinted with permission from Galatea Surgical (Lexington, MA). Bottom figures: Representative histological cross-sections of the GalaFLEX scaffold at 7 months postimplantation demonstrating increased thickness of the connective tissue and maturation of the tissue. Microscopic analysis of human tissue containing the GalaFLEX scaffold (denoted as "G") explanted from a mastopexy site at 7 months. Bottom left: Collagen type I stain showing deposition of abundant mature type I collagen throughout the connective tissue and infiltrated in the pores of the GalaFLEX scaffold. The double-headed arrows show intervening type I collagen between the GalaFLEX scaffold fibers, and the arrowhead shows type I collagen around and in direct contact with the GalaFLEX scaffold. Bottom middle: Collagen type III stain showing deposition of abundant mature type III collagen throughout the connective tissue and infiltrated in the pores of the GalaFLEX scaffold. Bottom right: α smooth muscle actin (SMA) immunohistochemical stain showing neovascularization with differentiated blood vessels in a connective tissue matrix. The arrows show SMA-positive cells forming the wall of well-differentiated blood vessels in the connective tissue matrix, and the arrowhead shows glandular ducts (SMA-negative).

the implant, an approach that has never been described previously, due to cost restrictions, concern over seromas, lack of integration, and the need for nonhuman or porcine derivatives. The safety, success, and longevity of GalaFLEX in cases of mastopexy and reduction mammaplasty has been supported by both a multicenter study by Adams et al[1] as well as the senior author's (DCM) own experience with 60 patients.

This internal support will help prevent future sagging, predominantly in the lower pole of the breast. The distance between the sternal notch and the lowest point on the breast has been shown to remain comparably stable when a scaffold is used. Before GalaFLEX was available, the drop of the vertical limb was more prevalent, causing a sagging effect. Adams et al[1] suggested that the retention of position with GalaFLEX provided longevity of the corrected position with a 5% change over a 12-month period. With the introduction of GalaFLEX, the breast is able to hold its shape longer, therefore reducing the risk of subsequent surgeries being required.

Patient Selection

A case series of 5 patients were evaluated from May 2016 to May 2018. Although this study was not approved by an institutional review board, written consent after thorough discussion along the guidelines of the Declaration of Helsinki was obtained from each of the patients. The inclusion criteria were capsular contracture with concerns for soft tissue coverage and future ptosis, along with complicated muscle coverage deficits due to subglandular to submuscular plane switching. Patients were excluded if there were incomplete records or if the implant was not in direct opposition to the GalaFLEX.

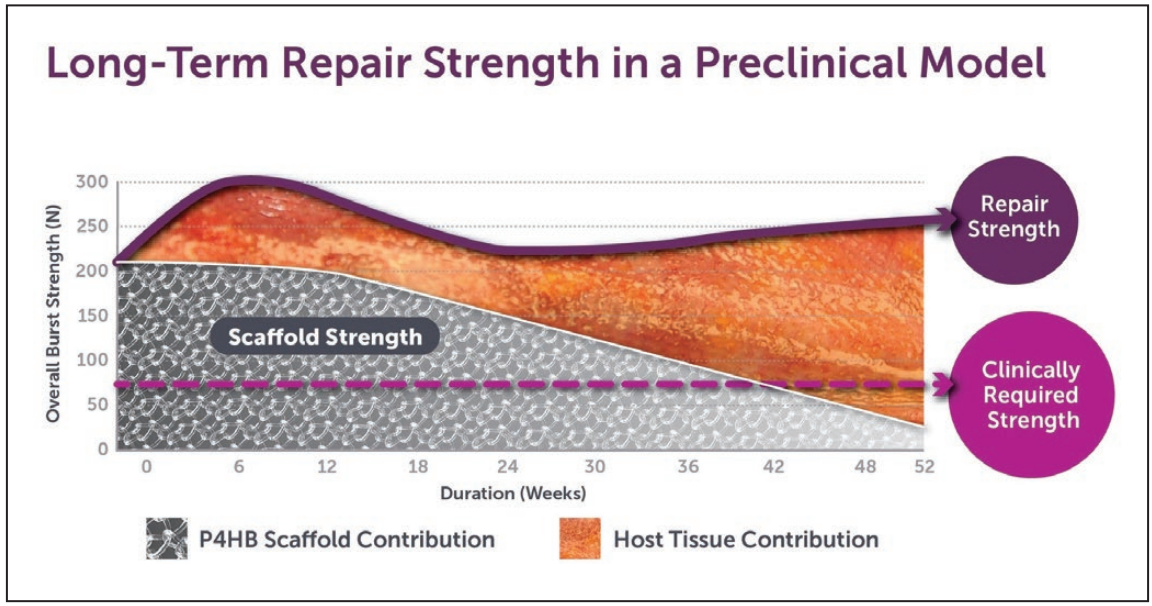

Figure 3. Long-term repair strength in a preclinical model: remodeling of P4HB mesh to provide a strong repair in a porcine hernia repair model (derived from data in references 3, 5, 12, and 13). Reprinted with permission from Galatea Surgical (Lexington, MA).

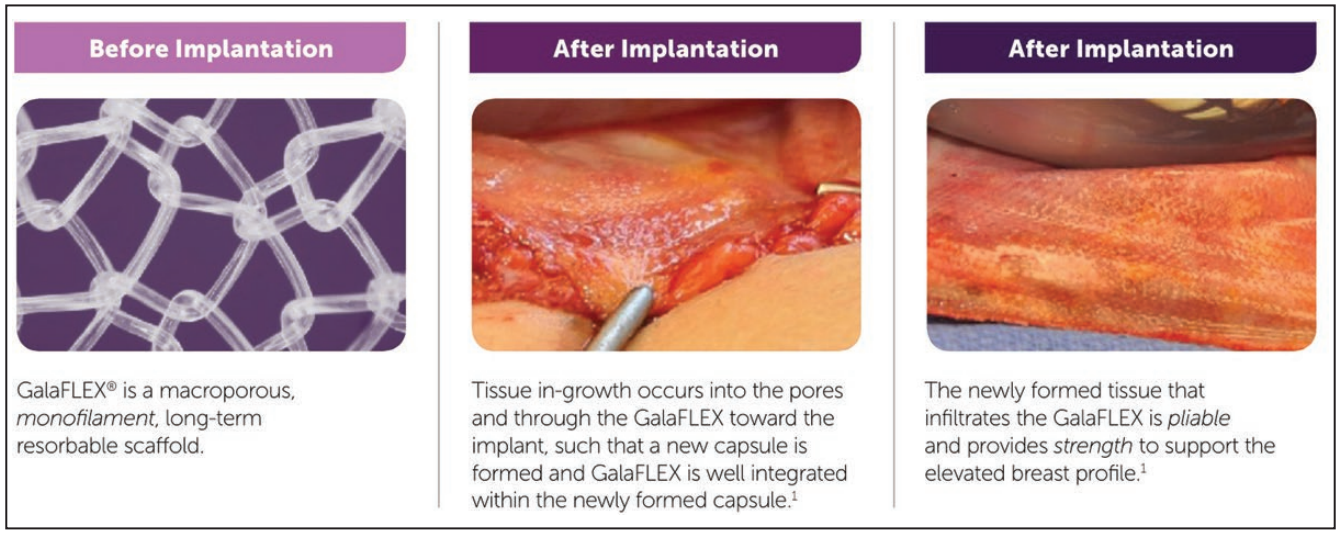

Figure 4. Scaffold strength retention: remodeling of P4HB mesh to provide a strong repair in a porcine hernia repair model (derived from data in references 3, 5, 12, and 13). Reprinted with permission from Galatea Surgical (Lexington, MA).

GalaFLEX Inset Technique

One piece of GalaFLEX sheet 15.3 cm × 20.3 cm in size was utilized to bridge the deficit between the pectoralis major muscle and the inframammary fold in the intended implant location, or to bridge the edges of a pectoralis major muscle defect. We hypothesized that this approach would reduce tension on the closure by providing support to the implant, as well as disperse concentric scarring from any residual capsule. The GalaFLEX sheet was folded in half, and 2 semicircles for each breast (7.5 cm × 20.3 cm) were cut out and dipped into Betadine. These semicircles were then inset into place by suturing to the inferior aspect of the pectoralis major muscle utilizing a running 0 Vicryl suture after confirmation that there was a strong purchase of tissue close to the rib. Each piece was additionally secured to each breast at the 10 o'clock and 2 o'clock positions (Figure 5).

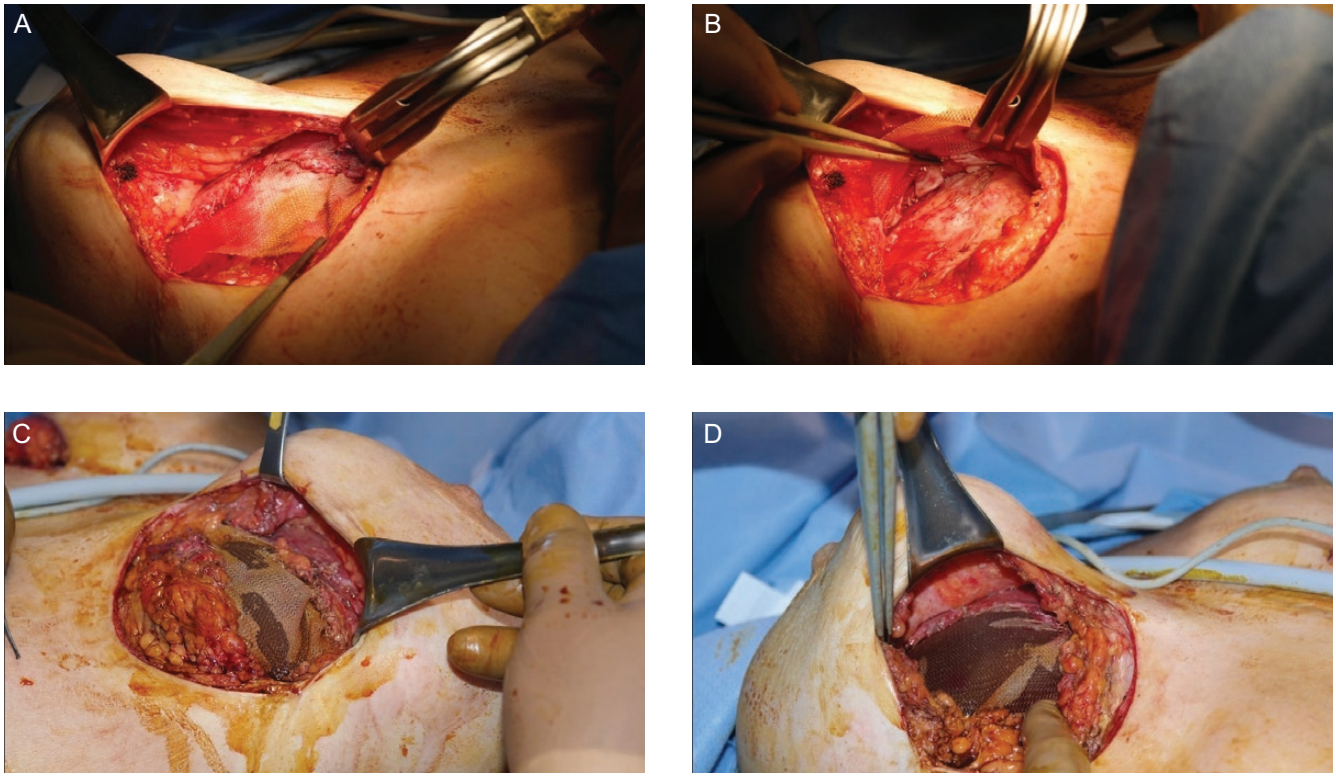

Figure 5. A 42-year-old woman with Baker IV capsular contracture with GalaFLEX 7.5 cm × 20.3 cm placement after site change from subglandular to subpectoral plane and near-total capsulectomy, removal of Mentor High Profile implants (375 cc on the right and 400 cc on the left), and placement of Sientra Low Profile 400-cc silicone implants through an inframammary incision. (A) GalaFLEX sown to muscle edge. (B) Inspection of subpectoral pocket with muscle and GalaFLEX anteriorly. (C) Placement of GalaFLEX on implant. (D) Complete coverage of the implant with GalaFLEX

In situations requiring an implant, prior to implant placement, gloves where changed to a powderless type suitable for a "no-touch" technique. The implant was first soaked in Betadine solution and then placed into the pocket. The pocket was irrigated with a solution of 10 mL of saline and 10 mL of Betadine prior to placing the implant. The implant was then placed into position, and manually manipulated to layer it out and remove any folds.

The GalaFLEX was stretched over the lower pole, and, utilizing 0 Vicryl, we attached the scaffold to a flap of glandular fascial tissue that we had created at the inframammary fold on each side to provide coverage of the mesh under the incision (Figure 6). A 3-0 Maxon was utilized to close the deep dermis, and the skin was closed with a 3-0 Prolene subcuticular suture.

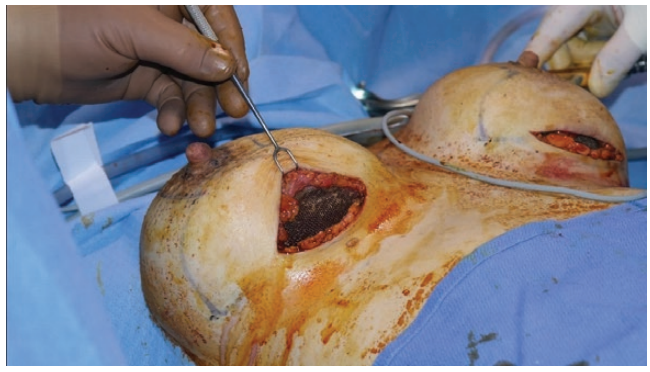

Figure 6. A 33-year-old woman with Baker IV capsular contracture on the left and Baker III capsular contracture on the right, with GalaFLEX 7.5 cm × 20.3 cm placement after removal of Mentor 325-cc saline implants, total capsulectomy, and placement of 560-cc Allergan Style SRM smooth-walled silicone implants in a subglandular plane through an inframammary incision, and standard mastopexy.

RESULTS

The mean patient age was 46.2 ± 12.44 years (range, 33–66 years) with a mean BMI of 22.4 ± 2.83 kg/m^2 (range, 19.2–25.8 kg/m^2) (all data are given as mean ± SD). Further demographic analysis showed that the group was entirely white, and had a follow-up that ranged from 4.36

to 22.57 months (mean follow-up, 15.34 ± 6.70 months). All patients had implants previously and presented with a mean Baker Grade Contraction score of 2.8 ± 0.9189 preoperatively, compared with a score of 1 ± 0 postoperatively. The presenting complaints for all of the patients were related to capsular contracture, although 1 patient had an additional concern of rippling of her right implant. The mean volume of the implants removed was 452.3 ± 100.123 cc (range, 325–600 cc), and the mean volume of the implants placed was 540 ± 157.043 cc (range, 400–800 cc) (Table 1).

GalaFLEX has been utilized in conjunction with mastopexy for soft tissue or glandular breast support.[1] However, the mesh has yet to be reported as being placed directly next to the implant. In this case series, the retrospective review of photographs taken at the most recent follow-up consistently showed retention of implant position and soft implants.

Surgical incisions were essentially uniform: all but 1 were inframammary incisions; the exception was a periareolar incision. In 4 patients, pocket development involved subpectoral positioning of the implants while the remaining patients had subglandular implant placements. It should be noted that 1 patient had a site change operation, converting a previous subglandular implant position to a subpectoral position, utilizing the GalaFLEX as an extension of the pectoralis muscle. Capsule work was unique to each patient, including simple capsulotomies, bilateral open pants-over-vest capsulorrhaphy, anterior capsulectomy, near-total capsulectomy, and total capsulectomies (Table 2).

Of the 5 implants utilized, 4 were 2-dimensional (2D) 15.3 cm × 20.3 cm GalaFLEX mesh and the remaining implant was a 7.5 cm × 21 cm GalaSHAPE 3D. Of the 4 GalaFLEX 2D meshes utilized, 3 were symmetrically bisected into 7.5 cm × 20.3 cm tabbed constructs for each breast, whereas the other was asymmetrically divided to accommodate soft tissue demands, with the right side 8 cm × 15 cm and the left 12 cm × 15 cm (Table 2).

Implants were explanted from 4 patients and replaced with new implants, whereas the remaining patient's implants were washed in Betadine and replanted. Of the 4 implants removed, none were ruptured. The implants from these 4 patients included Mentor 325 cc saline, Mentor High Profile 375 cc and 400 cc, 600 cc Bioplasty Misti textured, and Allergan Textured Saline 450 cc style 168 MP (Table 2).

The implants placed were exclusively smooth walled with a size range of 400 to 800 cc, yielding a mean volume of 540 ± 157.04 cc. All but 1 implant was silicone filled. The silicone implant models used were Allergan Natrelle INSPIRA SRM (Allergan plc, Dublin, Ireland), Sientra Low Profile (Sientra, Inc., Santa Barbara, CA), Mentor Moderate Classic Style 7000 (Mentor, Santa Barbara, CA), and Allergan Natrelle INSPIRA Style SRM (Allergan plc, Dublin, Ireland); the saline implant was an IDEAL model (Ideal Implant Incorporated, Irving, TX) (Table 2).

Table 1. Demographics

Demographics	Mean ± SD
Age, years	46.2 ± 12.438
BMI, kg/m^2	22.4 ± 2.826
Follow-up, days	460.2 ± 200.921
Implants removed, cc	452.3 ± 100.123
Implants placed, cc	540 ± 157.043

Capsular contracture ranging from nonpathologic (Grades I–II) to pathologic (Grades III–IV) was noted preoperatively in all of the patients, and was a mean of 2.8 ± 0.9189 preoperatively. Postoperatively, the mean capsular contracture was 1 ± 0 (Table 3).

Common reoperation complications, such as areola widening, stitch abscess, hematoma, loss of the nipple-areola complex and hypopigmentation, implant malposition, and repeat capsular contracture, were not found. Over a mean of 15.34 months (1.26 years), all patients reported verbal satisfaction with the final results compared with their preoperative status. Patient satisfaction was not captured with a Breast-Q survey on the grounds of cost, but instead a qualitative assessment at each postoperative visit was performed to evaluate satisfaction or any complaints.

Representative patient results can be viewed in Figures 7-8 and Supplemental Figures 1-2.

DISCUSSION

The struggle against ptosis has been previously waged with surgical adjuncts such as ADMs. However, due to their cost and lack of integration, another option has long been sought. Although ADMs have been viewed as revolutionary in terms of breast reconstruction for many of the reasons described above, the desire for the "next generation" in soft tissue support is always present. GalaFLEX has in this respect provided versatility, bridging the need for breast reconstruction with advanced cosmetic solutions to critical soft tissue needs. Although the direct implant opposition of GalaFLEX has never previously been described, our experience of its varied uses showcases the safety profile and clinical utility of this system.

GalaFLEX offers benefits due to its cost and its nonpermanence. ADMs, although mainstream in breast reconstruction, result in significant costs that are not often viable in a cosmetic setting. The costs of ADMs have hindered both reparative and cosmetic efforts in patients with various tissue support needs. GalaFLEX provides all of the

Table 2. Patient-Specific Indications and Results

Patient number	Age, years	BMI, kg/m^2	Follow-up	Baker Grade contraction	Incision	Pocket	Capsule work	Implant removed	Implant placed	Smooth or textured	Implant size, cc	Saline/ silicone	GalaFLEX type	GalaFLEX size, cm
1	33	21.4	677	L: IV R: III	Inframammary	Subglandular	Total capsulectomy	Mentor 325 cc Saline	Allergan Natrelle Inspira Style SRM	Smooth	560	Silicone	GalaFLEX 2D	7.5 × 20.3
2	42	24.9	533	L/R: IV	Inframammary	Subpectoral	Near Total Capsulectomy	Mentor High Profile R 375/L 400	Sientra Low Profile	Smooth	400	Silicone	GalaFLEX 2D	7.5 × 20.3
3	41	25.8	131	L/R: II	Inframammary	Subpectoral	Capsulotomy	600 cc Bioplasty Misti Textured	Mentor Moderate Classic Style 7000	Smooth	800	Silicone	GalaSHAPE 3D	7.5 × 21
4	66	19.2	483	L/R: II	Inframammary	Subpectoral	Bilateral Open Pants-Over-Vest Capsulorrhaphy	None	Allergan Natrelle Inspira Style SRM	Smooth	445	Silicone	GalaFLEX 2D	7.5 × 20.3
5	49	20.7	477	R: II, Rippling L: III	Periareolar	Subpectoral	Anterior Capsulectomy	Allergan Textured Saline 450 cc Style 168 MP, 507R and 501 on L	IDEAL	Smooth	495	Saline	GalaFLEX 2D	R: 8 × 15; L: 12 × 15

Table 3. Baker Grade Contracture

Patient	Preoperative	Postoperative
1	L: IV R: III	L/R: I
2	L/R: IV	L/R: I
3	L/R: II	L/R: I
4	L/R: II	L/R: I
5	R: II L: III	L/R: I
Mean ± SD	2.8 ± 0.9189	1 ± 0

reliability of biologic meshes with increased retention of position at about half the cost.

The soft tissue support that GalaFLEX provides differs greatly from that of its ADM counterparts.[7] The mesh rigidity and architecture retain shape for longer than ADMs, as illustrated by the lack of the classic stretch deformity observed in ADM-assisted constructs. The senior author (DCM) noted the need to alter the placement of the GalaFLEX to a relatively more caudad position at the exact desired location as opposed to the normally cephalad placement of the ADM that can result in caudal displacement over time. Although the retention of position at follow-up was impressive, longer-term follow-up is clearly needed to gauge any ptotic recurrence.

GalaFLEX provides many of the benefits of ADMs while avoiding their complications. Maxwell et al[8] documented the successful treatment of capsular contracture with ADMs in revisional aesthetic breast surgery. Although our follow-up has been brief with a small sample size, we have achieved a similar decrease in capsular contracture rates. With GalaFLEX, there was a statistically significant (*t* test) decrease in the Baker Grade Contraction score from 2.8 ± 0.9189 preoperatively to an average of 1 ± 0 postoperatively ($P < 0.05$) (Table 3). We speculate that this similarity stems from the similar performance between GalaFLEX and ADMs in implant isolation from glandular tissue and inflammatory process interruption by regenerative tissue. The use of GalaFLEX does not circumvent sound surgical technique to thwart capsular contracture, such as sterility, pocket manipulation, and implant coverage, but rather can function as a welcome alternative to ADMs without the complications.[9] Although capsular contracture with GalaFLEX usage has never previously been studied, and admittedly long-term studies are still to be performed, short-term follow-up supports these claims.

The variety of capsule work was tailored to each patient. Every effort was made to perform a total capsulectomy

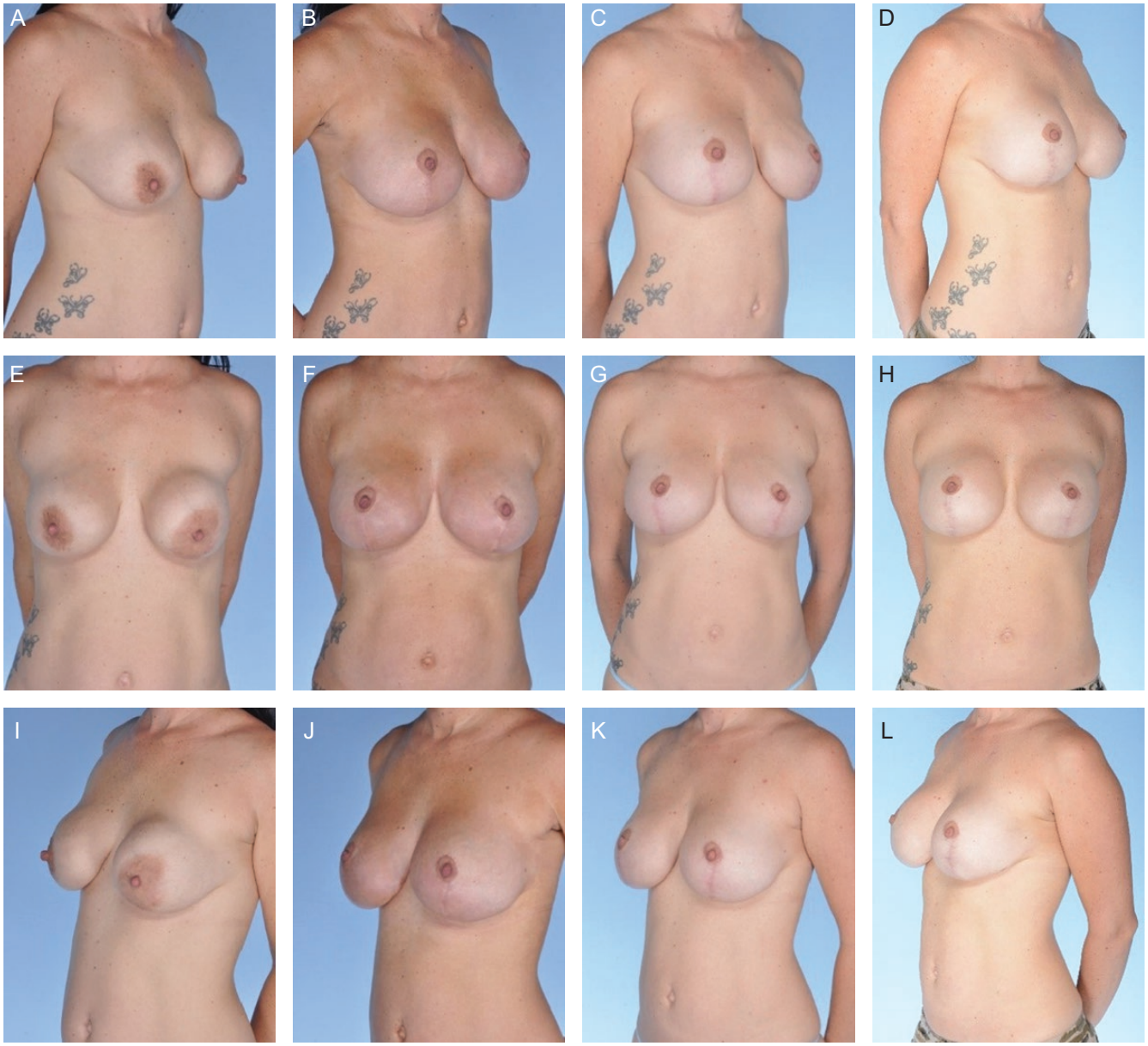

Figure 7. A 33-year-old woman (A, E, I) preoperative, (B, F, J) 3 months, (C, G, K) 6 months, and (D, H, L) 22 months postoperative with removal of implant, bilateral total capsulectomy, standard mastopexy, and Allergan Style SRM smooth-walled silicone 560-cc replacement. She presented with thin tissue (< 1 cm on a pinch test). She had Mentor 325-cc silicone implants placed 12 years ago. She subsequently presented with Grade IV capsular contracture on the left and Grade III capsular contractures on the right. GalaFLEX placed directly on the implant after a total capsulectomy provided a rescue from her thin soft tissue problem along with much-needed support of the 560-cc Allergan Natrelle Inspira SRM that was placed. Relieving the tension both on the inframammary incision as well as providing support in a subglandular plane, where it is more challenging, offered a soft durable repair of a contracture-related breast deformity.

unless there were concerns for patient safety. Patients without total or near-total capsulectomies are admittedly at higher risk of recurrence of capsular contracture. The highest risk is likely to be to patient 4, who underwent a capsulorrhaphy with removal and replacement of the same implant. Due to her concerns over implant positioning and the lack of lower pole support rather than the nature of her capsule, the decision to replace the same implant without a capsulectomy was made. This allowed us to circumvent the complications of a capsulectomy in an already inflammatory pocket. She has had a soft breast with no recurrence of capsular contracture thus far, but we will continue to follow each patient to document any recurrence.

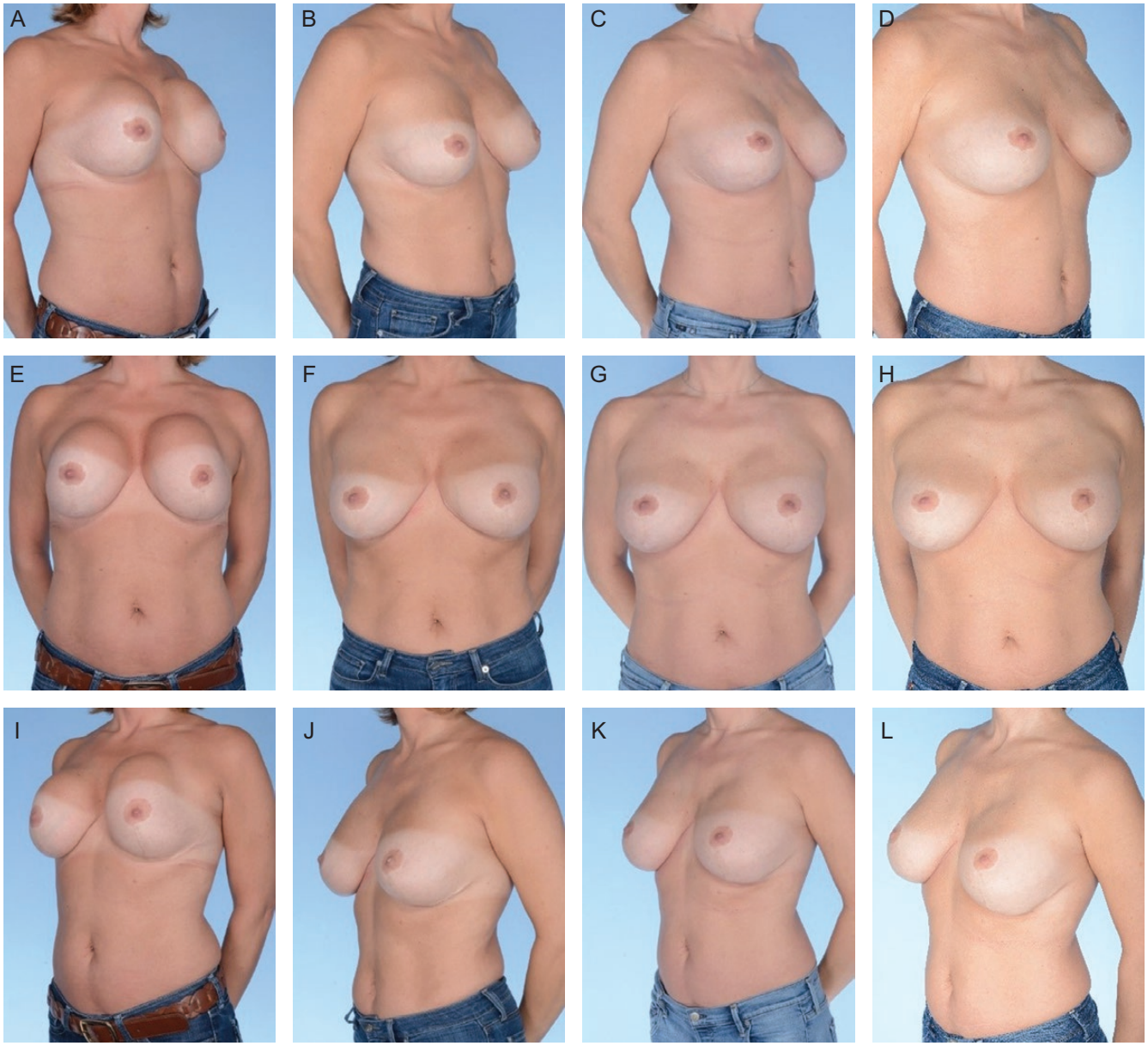

Figure 8. A 42-year-old woman (A, E, I) preoperative, (B, F, J) 1 month, (C, G, K) 4 months, and (D, H, L) 17 months postoperative site change from subglandular to subpectoral, capsulectomy with a 400-cc Sientra silicone LP implant replacement. She had a mastopexy 16 years prior followed by a breast augmentation 3 years prior. She presented with Baker Grade IV capsular contracture bilaterally. Intraoperatively, significant pectoralis retraction obviated a need to bridge the gap to the inframammary crease. Here GalaFLEX was placed directly on her implants after a near-total capsulectomy and used after a site change from subglandular to subpectoral to augment tensionless closure techniques and to break up concentric scarring from her capsular contracture.

The increase in tissue strength during wound healing reaches its maximum around the time that GalaFLEX dissolves, thus providing much needed support during a time when wound strength is low but exponentially rising.[10] In a very similar fashion to the role of ADMs in breast reconstruction, the GalaFLEX provides immediate internal soft tissue support, similar to that offered by an underwire bra. Typically, at approximately 18 to 24 months,[11] the mesh is fully absorbed by the body, leaving tissue that is reported to be 3 to 5 times stronger than normal tissue.[12] The residual tissue after GalaFLEX disintegration offers increased tensile strength and hence longevity of the conglomerate implant/glandular position. The GalaFLEX scaffold mesh also appears to provide evidence that soft tissue reinforcement can prevent pseudoptosis.[13]

The limited long-term review makes the current evaluation preliminary in nature. Although our average follow-up was 460.2 days, patient 3 was lost to follow-up, preventing us from achieving at least a 1-year follow-up for all 5 patients. Clearly, longer-term follow-up is essential to corroborate the findings so far.[14] A multicenter trial involving randomization of GalaFLEX and ADM usage is our next step.[15] The full extent of GalaFLEX usage has also not been discussed.[16] For example, GalaFLEX could provide complete coverage of the implant in a similar fashion to which ADMs are used for pre-pectoral breast reconstruction. While this would entail the use of multiple meshes sown together, it was deemed unnecessary for our patients.

Drains have been utilized extensively as part of seroma/hematoma management, mostly in reconstructive cases. However, complex cosmetic reconstruction is very different from breast cancer reconstruction with drains serving a range of purposes in cancer patients undergoing reconstructive procedures. Even though we have not utilized drains in the current study, the decision to do so should be left to the judgment of the surgeon. In the cosmetic patient, drains would mainly serve as a function of any foreign material in situ. The lack of seroma in this small cohort is suggestive of the decreased fluid retention rate in GalaFLEX thus the assumption that drains would be unnecessary.

The palpability of the mesh was assessed throughout the follow-up. Adams et al[1,17] reported palpability for up to 6 to 9 months, but in our repeated follow-ups, palpability was diminished but still present up to 1 year and 10 months after insertion. This appears to contradict the company's literature, which suggests complete resorption at 12 to 18 months.[11] The palpability did not, however, seem to bother the patients; they did not complain about it or deem it significant once it was brought to their attention. It is nevertheless clear that in order to assess the integration, further studies, and perhaps imaging, need to be undertaken.[18]

The placement of the P4HB mesh in relation to the capsule can generally be broken down into 2 categories. In 3 patients, the capsule work entailed, at the very least, a removal of the anterior capsule, which allowed for the GalaFLEX to be sandwiched between the native soft tissue anteriorly and the implant posteriorly. In 2 cases in which capsulorrhaphy/capsulotomy was performed, the P4HB mesh was placed similarly but with enough capsule removed through radial and longitudinal strip capsulectomies to allow for significant opposition between native tissue and the GalaFLEX to allow for revascularization (Figure 2).

This preliminary experience with utilizing GalaFLEX in direct opposition to the implant was meant to show the safety and versatility of this material in this context. It is clear that the next step should be a multicenter randomized trial involving multiple surgeons that compares GalaFLEX with various ADMs[19,20] and with mastopexy alone. We realize that the various implants, surgical approaches, and follow-ups comprise a heterogeneous group, but these anecdotal experiences are meant to initiate a discussion about the possibility of using GalaFLEX as a reinforcing layer for secondary complex breast augmentations.

CONCLUSIONS

The previously unreported technique of direct-on-implant GalaFLEX placement has been suggested as providing simple, reproducible, and consistent adjunctive support. This preliminary study demonstrates the initial safety of GalaFLEX but highlights the need for further studies comparing it with ADMs. The versatility of GalaFLEX for complex revisional cases combined with acceptable aesthetic outcomes makes this an invaluable tool for plastic surgeons to consider.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

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