CASE STUDY

William P. Adams, Jr., MD
Park Cities Medical Plaza Building,
Private Plastic Surgery Practice,
Dallas, TX
Associate Clinical Professor of
Plastic Surgery at UT Southwestern
Medical Center, Dallas, TX

Breast Plastics

Mastopexy with GalaFLEX® Scaffold

Overview

Mastopexy corrects ptosis and rejuvenates the breast profile by lifting the parenchyma and tightening the surrounding skin envelope. Irrespective of mastopexy technique, we still struggle to obtain a beautiful, stable, long-term shape that justifies the scarring.[6] Techniques such as superior pedicle with auto-augmentation may sometimes help provide some upper pole volume. However, recurrent ptosis still may occur as the skin envelope stretches in response to the weight of the breast.[7] Sampaio-Goes pioneered efforts to counteract recurrent ptosis and maintain shape using nonresorbable, partially resorbable, and fully resorbable meshes, as well as biologic materials in peri-areolar double skin mammaplasties.[8-10] Although in concept soft tissue reinforcement in mastopexy should support the overlying skin envelope and prevent recurrent ptosis, in practice several limitations exist. Permanent meshes can contract and cause long-term issues with palpability and visualization. Previous absorbable meshes (e.g. Vicryl and Dexon) provide only short-term support. Biologics may not integrate well and are generally cost-prohibitive. This case study describes the use of GalaFLEX, a long-term, high strength, biologically derived, porous scaffold to support the results of a central mound mastopexy.

Key Points

GalaFLEX Scaffold:

- Provides long term support
- Offsets tension and load placed on skin envelope
- Resorbs naturally through hydrolysis

GalaFLEX® SCAFFOLD
*A **Bioresorbable** Surgical Scaffold*

Biologically Derived:
Produced by a **safe, biologic fermentation** process standard in pharmaceutical production[1]

Monofilament:
Monofilament designs have been reported to **reduce risk of infection** as compared to multifilament scaffold[1,2,3,4,5]

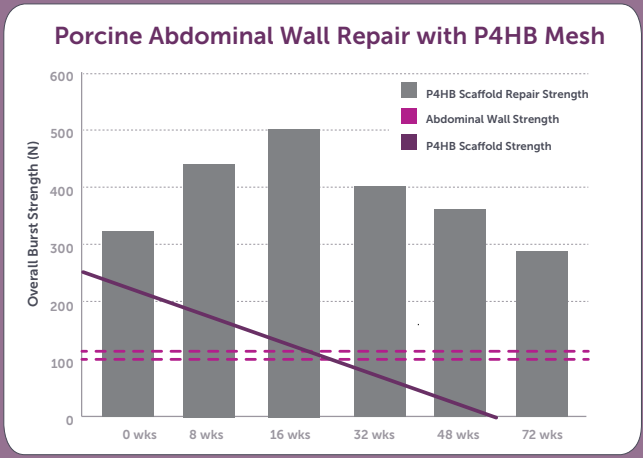
Strong:
Provides a lattice for new tissue ingrowth resulting in tissue **3-5x stronger** than native tissue[3]

Bioresorbable:
Naturally broken down to CO_2 and H_2O, with full bioresorption by **18-24 months**[1]

GALATEA SURGICAL

Background

GalaFLEX® scaffold is an FDA cleared product indicated for soft tissue reinforcement in plastic and reconstructive surgery. It is a surgical scaffold made from poly-4-hydroxybutyrate (P4HB). P4HB products have been in human use since 2007 and have been used in a variety of plastic surgery procedures including hernia repair, facelift, browlift, and various breast procedures. In-vivo porcine abdominal wall repair studies have shown that ingrown tissue into P4HB matrices becomes stronger over the course of a year as the scaffold gradually loses strength and resorbs in 18-24 months.[2] Repairs using a GalaFLEX scaffold are 3-5 times stronger than native tissue.[3]



As GalaFLEX gradually resorbs, neovascular tissue proliferates through the porous scaffold. The repair site is significantly stronger than native tissue at every measured time point.[2]

CASE SERIES OVERVIEW:

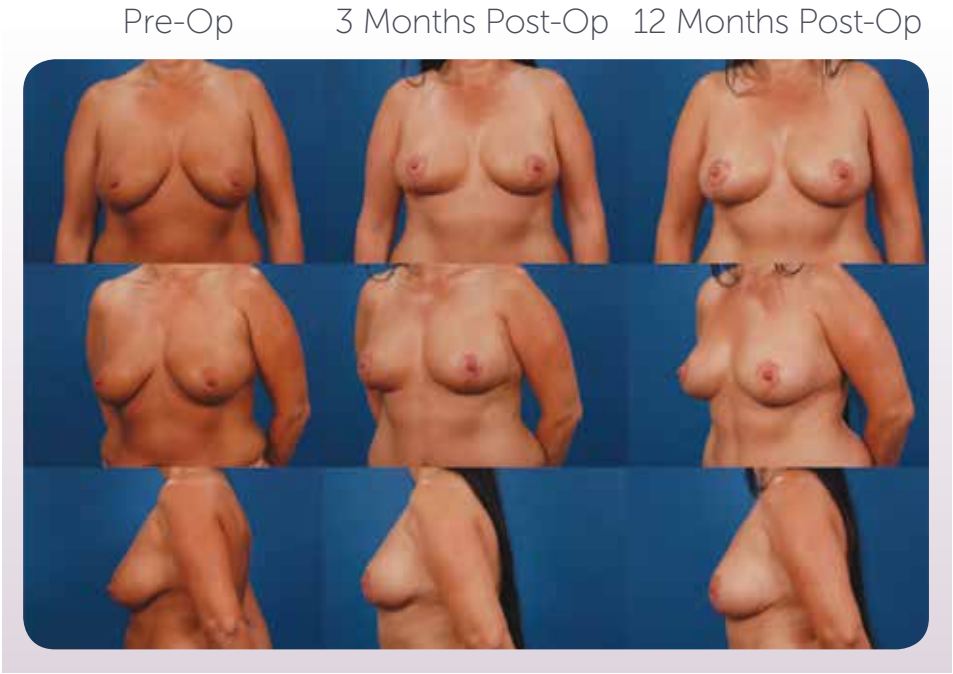
Mastopexy with GalaFLEX® Scaffold

In this case series, we review the surgical rejuvenation strategy for three healthy females presenting with a relatively large amount of breast parenchymal tissue such that augmentation was unnecessary. The surgical plan was a central mound mastopexy with soft tissue reinforcement using GalaFLEX across the lower pole to support a long term, stable result. Physical measurements and 3D longitudinal assessments (3D Vectra, Caneld Scientific) were recorded pre-operatively and at 1 week, 1 month, 3 months, 6 months and 12 months post-operatively.

Results

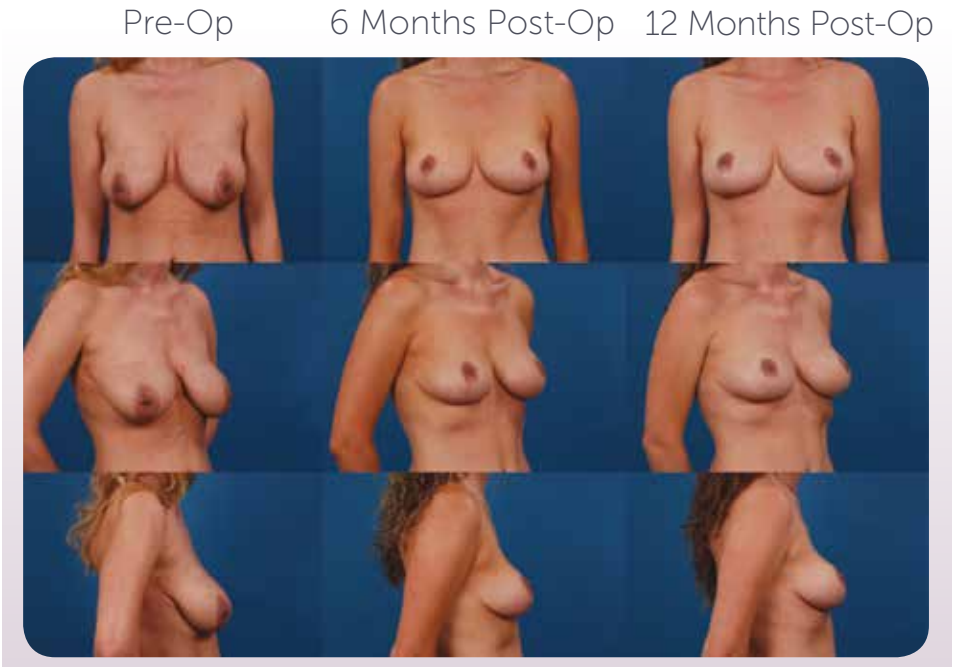
Patient One

The first patient in this series is a 43 year old female presenting with grade 2 ptosis. This patient was seeking a correction of her nipple position and breast shape. Pre-operatively the nipple to infra-mammary fold, upon maximal stretch, was 11.5cm on the right and 11cm on the left with a breast width of 15cm on each side. Post-operative composite images at 3 and 12 months show good maintenance of breast shape and fullness. Post-operative N:IMF at 12 months was 8cm on both sides.



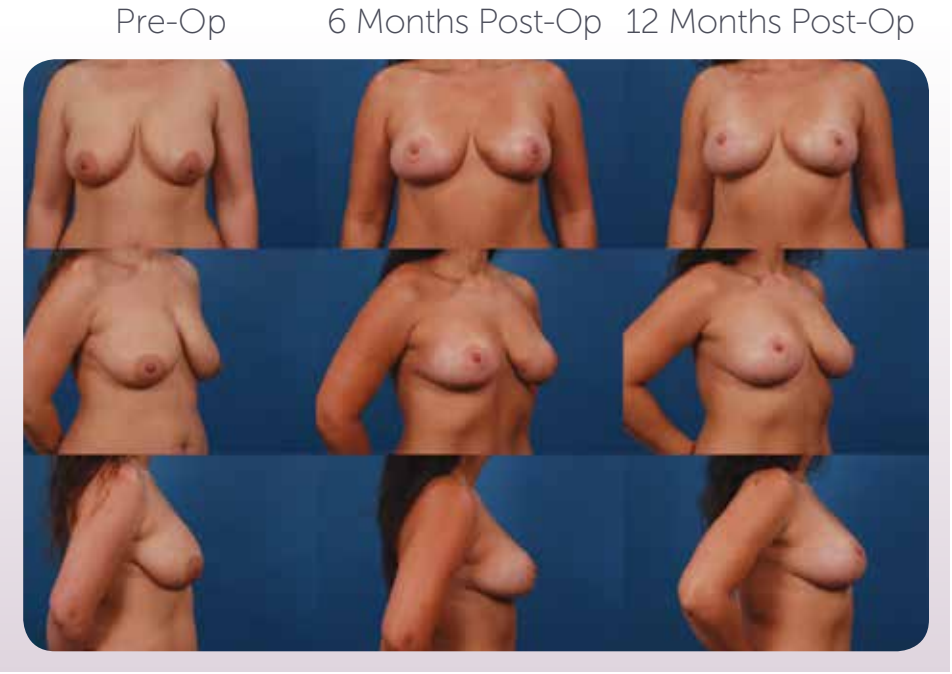
Patient Two

The second patient in this series is a 31 year old female presenting with grade 2 ptosis. This patient was seeking a correction of her nipple size and position as well as her breast shape. Pre-operatively the nipple to infra-mammary fold, upon maximal stretch, was 13cm on the right and 13.5cm on the left with a breast width of 14cm on each side. Post-operative composite images at 6 and 12 months show good maintenance of breast shape and fullness. Post-operative N:IMF at 12 months was 9cm each.



Patient Three

The third patient in this series is a 33 year old female presenting with grade 2 ptosis. This patient was seeking a breast lift after having 2 children. Pre-operatively the nipple to infra-mammary fold, upon maximal stretch, was 13.5cm on the right and 13cm on the left with a breast width of 15cm on each side. Post-operative composite images at 3 and 12 months show good maintenance of breast shape and fullness. Post-operative N:IMF at 12 months was 11cm on the right and 11.5cm on the left.



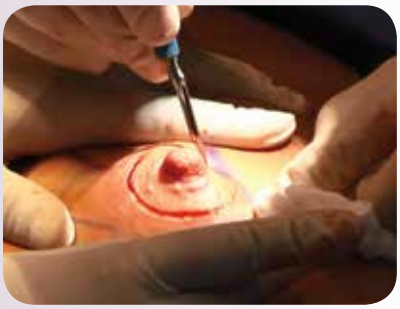
Discussion

GalaFLEX is a biologically derived scaffold that is knitted from completely resorbable monofilament fibers. Repair strength after resorption is 3-5 times stronger than native tissue.[3] These product attributes mitigate many of concerns normally associated with synthetic, permanent, and multifilament implants. Intraoperatively, GalaFLEX aids in the positioning and shaping of the breast by reinforcing the tissue. Throughout the post-operative period, GalaFLEX offsets the tension normally placed on the skin envelope and provides a strong structure for healthy tissue to grow through. Once the scaffold is completely resorbed, the ingrown tissue may contribute to the longevity of aesthetic results. Preliminary calculations of N:IMF change between 3 and 12 months indicate that the average change for patients in this study is less than 10%. Analysis of the 3-dimensional images of these and other patients will provide additional information about maintenance of breast shape as well as upper and lower pole volumes when GalaFLEX is used for soft tissue reinforcement.

KEY TECHNICAL POINTS

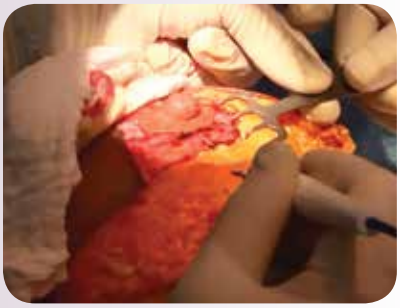
1. Discuss the GalaFLEX procedure with your patients, outlining the risks and benefits.
2. Cut the GalaFLEX to a size that fits the patient.
3. Use long term resorbable sutures to secure the GalaFLEX, such as MonoMax (B. Braun).
4. Ensure that GalaFLEX is secured under adequate tension, allow for one finger width between the breast and GalaFLEX.

Technique



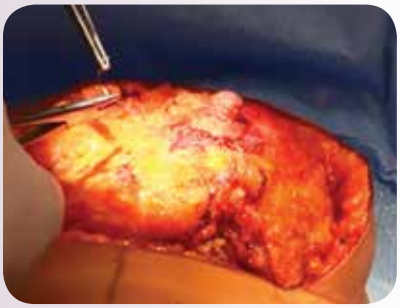
Incision and De-Epithelialization

Standard central mound mastopexy incision and de-epithelialization is performed, enabling support of the lower pole of the breast by GalaFLEX.



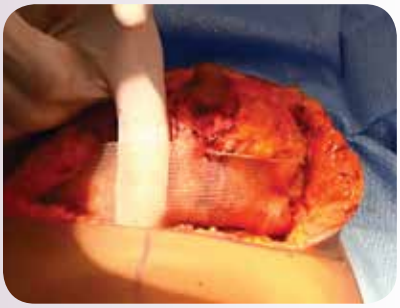
Flap Development

This skin flap development is accomplished using traction-counter traction and electrocautery. Sharp skin hooks ease dissection. Superior development is taken up to the pectoral fascia. The entire central mound of the breast is exposed for easier tissue manipulation and placement of GalaFLEX.



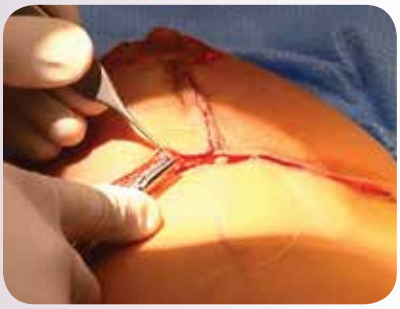
Central Mound Resection or Plication

Once the flap dissection is complete the entire central mound is exposed which facilitates modification of the central mound including resection, plication or other manipulations as desired.



GalaFLEX Scaffold Insertion

Before use, GalaFLEX is placed in an antibiotic irrigation solution. The GalaFLEX scaffold is placed in the inferior pole of the breast as a lower pole hammock and is secured under tension. A rectangular 4x8 inch piece of GalaFLEX is used in each breast. The scaffold is secured medially, then laterally to the pectoralis fascia, with a 2-0 MonoMax suture (B. Braun). Tension may be checked by placing an index finger between the scaffold and the breast.



Nipple Maturation & Closure

Skin flaps are re-draped across the lower pole of the breast and the nipple is matured using breast width - nipple to fold relationships. In general, a drain was not used with no issues identified. Standard layered closure is completed.

References

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Indications for Use

Galatea scaffolds are indicated for use as a bioresorbable scaffold for soft tissue support and to repair, elevate and reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction. Galatea scaffolds are also indicated for the repair of fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Important Safety Considerations

Possible complications include infection, seroma, pain, scaffold migration, wound dehiscence, hemorrhage, adhesions, hematoma, inflammation, extrusion and recurrence of the soft tissue defect. The safety and use of a Galatea scaffold for patients with hypersensitivities to the antibiotics kanamycin sulfate and tetracycline hydrochloride is unknown. Galatea scaffolds have not been studied for use in breast reconstructive surgeries. The safety and effectiveness of a Galatea scaffold in neural tissue and in cardiovascular tissue has not been established. Because a Galatea scaffold is fully bioresorbable, it should not be used in repairs where permanent support from the mesh is required.

Consult the Galatea scaffold Instructions for Use for complete prescribing information, including its indications for use, warnings and precautions.

Examples of clinical outcomes in this case study are not intended to convey or warranty the outcomes or benefits from soft tissue support using GalaFLEX.

Galatea Surgical, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421

Phone: (781) 357-1750
Fax: (781) 357-1701
Email: Contact@GalateaSurgical.com
www.galateasurgical.com