Mastopexy with GalaFLEX: A Case Series

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.¹ 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.² Sam-paio-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 mammoplasties.³⁵ 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 communication describes the use of GalaFLEX, a long-term, high strength, naturally-derived porous scaffold to support the result of a central mound mastopexy.

GalaFLEX Key Points:
- Provides long term support
- Offsets tension and load placed on skin envelope
- Assists with longevity of aesthetic results
- Completely resorbable
GalaFLEX® mesh is an FDA cleared product for indications including soft tissue reinforcement in plastic and reconstructive surgery. It is a surgical scaffold made from poly-4-hydroxybutyrate (P4HB), a normal component of human connective tissue. 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 12-18 months.⁶ Repairs using GalaFLEX are 3-5 times stronger than native tissue.⁷

### Porcine Abdominal Wall Repair with P4HB Mesh

*Mesh repair and P4HB mesh burst strength measured in Newtons*

![Graph showing mesh repair and P4HB mesh burst strength over time](image)

GalaFLEX gradually resorbs, collagen proliferates through the mesh's porous scaffold. The repair site is significantly stronger than native abdominal wall tissue at every measured time point.⁶

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, Canfield Scientific) were recorded pre-operatively and at 1 week, 1 month, 3 months, 6 months and 12 months post-operatively.
In the image, the process of breast augmentation using GalaFLEX is illustrated.

**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 as an internal bra cup.

**Flap Development**
Thin 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 the 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 Mesh Insertion**
Before use, GalaFLEX is placed in an anti-biotic irrigation solution. The GalaFLEX mesh is placed in the inferior pole of the breast as a lower pole hammock and is secured under tension. A rectangular 3x8 inch piece of GalaFLEX is used in each breast. The mesh 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 mesh 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 early cases a drain was used, in later cases a drain was not used with no issues identified. Standard layered closure is completed.
**Patient One**
The first patient in this series is a 43 year old female presenting with grade 11 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 11.5 cm on the right and 11 cm on the left with a breast width of 15 cm on each side. Post-operative composite images at 3 and 12 months show good maintenance of breast shape and fullness. Post-operative N:1MF at 12 months was 8 cm on both sides.

**Patient Two**
The second patient in this series is a 31 year old female presenting with grade 11 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 13 cm on the right and 13.5 cm on the left with a breast width of 14 cm on each side. Post-operative composite images at 6 and 12 months show good maintenance of breast shape and fullness. Post-operative N:1MF at 12 months was 9.5 cm on both sides.
GalaFLEX is a naturally derived scaffold that is knitted from completely resorbable monofilament fibers. Repair strength after resorption is 3–5 times stronger than native tissue. These product attributes mitigate many of concerns normally associated with 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 health 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 1 and 12 months indicate that the average change for these 3 patients is 6%. This change falls within the margin of error for the assessment method. 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. Soak GalaFLEX in antibiotic solution prior to use. 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.

**Patient Three**

The third patient in this series is a 50 year old female with a history of massive weight loss (100 lbs) presenting with grade III ptosis. This patient was seeking a correction of her breast shape. Pre-operatively the nipple to infra-mammary fold, upon maximal stretch, was 12cm on the right and 14cm on the left with a breast width of 15.5cm 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.
REFERENCES


RX Only. Before using GalaFLEX® mesh read the instructions for use which accompany the product for indications and a more comprehensive list of contraindications, warnings and precautions.