Exploring the value of SERI® Surgical Scaffold

For lasting support and strength from native tissue\textsuperscript{1,2,*}

*At 24 months, newly generated native tissue was stronger than fascia sampled from the rectus abdominis and internal oblique in an ovine subcutaneous thoracic wall implant study designed to measure the strength and thickness of SERI® Surgical Scaffold and newly generated tissue at up to 24 months after implantation of SERI®. Note: Similar results in humans have not been confirmed.

Read other surgeons’ views on SERI® Surgical Scaffold from a recent roundtable discussion.

Roundtable summary presented by Wendy Lewis

Please see Indications and Important Safety Information inside.
Meeting of the minds: how SERI® Surgical Scaffold impacts soft tissue support in breast revision and mastopexy procedures

Five well-known, board-certified plastic surgeons assembled for a roundtable discussion of SERI® Surgical Scaffold on March 6, 2014, in Newport Beach, California.

Each participant’s experience using SERI® Surgical Scaffold for soft tissue support and repair generated valuable discussion about the use of this product technology in mastopexy and breast revision procedures. Before long, fundamental themes about SERI® Surgical Scaffold emerged from the roundtable dialogue, including lasting soft tissue support and strength from native tissue, its ease of use, and its value in soft tissue support and repair applications. Among panel participants and the contributing faculty members, it was clear they felt this innovative technology will make a lasting impact in soft tissue support and repair for breast revision and mastopexy procedures.

Roundtable participants:

M. Mark Mofid, MD, FACS
Dr. Mofid is a voluntary associate clinical professor of plastic surgery at the University of California, San Diego. He is in private practice in La Jolla, California, and publishes and lectures extensively on topics relating to the use of biologics in revisionary and reconstructive breast surgery.

Richard A. Baxter, MD, FACS
Dr. Baxter is a former clinical faculty member of the University of Washington School of Medicine in Seattle and past president of both the Washington Society of Plastic Surgeons and the Northwest Society of Plastic Surgeons. Dr. Baxter serves on the Emerging Trends Committee, the Spokespersons Network for the ASPS, and the Innovative Procedures Committee of the Aesthetic Surgery Research Foundation.

Susan E. Downey, MD, FACS
Dr. Downey has practiced plastic surgery in Los Angeles since 1989. She is currently in private practice and is an associate clinical professor of plastic surgery at the University of Southern California Keck School of Medicine. Dr. Downey is board certified in plastic surgery and is an active member of numerous professional societies including the ASPS, the ASAPS, and the ACS.

Gabriel M. Kind, MD, FACS
Dr. Kind is an associate clinical professor, Department of Surgery, Division of Plastic and Reconstructive Surgery, at the University of California, San Francisco, and a clinical instructor, Department of Surgery (Plastic and Reconstructive Surgery), at Stanford School of Medicine, Stanford University Medical Center. Dr. Kind’s practice focus is breast surgery.

Valerie Lemaine, MD, MPH, FRCS, FACS
Dr. Lemaine is an assistant professor of plastic surgery and vice chair for research at Mayo Clinic in Rochester, Minnesota. She is board certified by the American Board of Plastic Surgery and the Royal College of Surgeons of Canada.

Featuring contributions from RESTORE Program training faculty and key investigators for SERI® Surgical Scaffold studies:

Max R. Lehfeldt, MD
Dr. Lehfeldt is a board-certified plastic surgeon based in Pasadena, California, who specializes in procedures of the face, breast, and body. Dr. Lehfeldt also actively teaches residents at the Huntington Memorial Hospital and the Dermatology Residency of Western University Health Sciences.

Bradley P. Bengtson, MD
Dr. Bengtson is a board-certified plastic surgeon specializing in several aspects of cosmetic surgery including breast revision surgery, breast reduction and lifts, and abdominoplasty. Based in downtown Grand Rapids, Michigan, Dr. Bengtson serves patients from all over the state of Michigan, the United States, Canada, and Europe.

Disclosures: Panel participants received an honorarium from Plastic Surgery Practice in exchange for their time and were compensated for travel expenses.

Learn more and see results from actual case studies at SERI.com

*Methodology: In an ovine subcutaneous thoracic wall implant study designed to measure the strength and thickness of SERI® Surgical Scaffold and newly generated native tissue at up to 24 months after implantation of SERI®. Note: Similar results in humans have not been confirmed.
Indications for Use

SERI® Surgical Scaffold is indicated for use as a transitory scaffold for soft tissue support and repair to 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.

Please see Important Safety Information on the following pages.

Discover the SERI® Surgical Scaffold difference

SERI® Surgical Scaffold offers an exciting product technology only from Allergan. Not derived from human cadaver or animal tissue, it is the first and only Silk-derived Biological Scaffold designed to deliver lasting support and strength from native tissue.1,2 Through bioreplacement, SERI® Surgical Scaffold facilitates the generation of native, well-vascularized tissue that is ≈ twice the starting thickness of the scaffold alone at 24 months.1,2 This newly ingrown tissue is also strong and supportive. At 24 months, newly generated tissue demonstrated nearly twice the average strength of ovine fascia in a full-scale animal model study.1,2 The predictable bioresorption of SERI® Surgical Scaffold means that native tissue provides the majority of load-bearing strength over time.1,2

“The ability to offer soft tissue support while being something that will become bioreabsorbed is a very powerful combination,” said Dr. Kind. “The fact that SERI® Surgical Scaffold is quickly neovascularized may very well turn out to be the biggest advantage in my hands. When using SERI® Surgical Scaffold for soft tissue support and repair in my practice, it is doing what I want it to do.”

Dr. Lemaine stated that, in addition to the bioresorption of SERI® Surgical Scaffold, it offers low elasticity and promotes native tissue ingrowth.1,2 “You get these attributes from a product that’s truly unique because it is the first and only Silk-derived Biological Scaffold,” she said.

CASE REVIEW:

Revisional breast repair to correct multiple deformities using SERI® Surgical Scaffold for soft tissue support

“Revision breast surgery is often challenging because multiple problems can present together. SERI® Surgical Scaffold can be used to address soft tissue issues in a comprehensive manner. By adding soft tissue support to reinforce weakened capsule soft tissues, SERI® Surgical Scaffold off-loads stress on the skin envelope and connective tissues.”

Patient assessment

- A 44-year-old woman had breast augmentation with subpectoral saline implants 7 years previously
- She presented with asymmetry of the inframammary folds (IMFs), hyperanimation and stretch deformity, and lateral fold malposition; the latter was manifested by inadequate upper-pole and medial fullness

Surgical plan

- In order to address the patient’s multiple issues, the plan included:
  - Replacement of the existing implants with high-profile, round, silicone-filled implants
  - Conversion of implant placement from dual-plane subpectoral to split-muscle plane
  - Pocket repair with lateral capsulorrhaphy, using SERI® Surgical Scaffold for interlateral soft tissue reinforcement
  - Circumvertical mastopexy

CASE CONCLUSIONS

- Patients often present for revision breast surgery with a combination of problems
- In this case, SERI® Surgical Scaffold provided soft tissue support that helped to alleviate stress on the skin envelope and connective tissues
- The patient experienced no postoperative complications, and she was very pleased with the aesthetic results

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The appeal of silk-derived SERI® Surgical Scaffold

SERI® Surgical Scaffold is derived from ultra pure silk, a material that is bioreplaced over time with native, well-vascularized tissue for lasting support and strength. According to roundtable participants and contributing faculty members, this unique characteristic has significant appeal among patients.

“When talking to patients about SERI® Surgical Scaffold, we explain that this technology provides soft tissue support using a silk material that has favorable biocompatibility with their own body,” said Dr. Baxter. “It’s easy to talk to patients about. I explain that it’s not the same as the silk suture material they are probably familiar with. It’s a purified form of silk fibrin protein which has minimal inflammatory properties associated with it. This is something that supports tissue generation over time.”

According to Dr. Lehfeldt: “My patients care that SERI® Surgical Scaffold is nontissue based. Patients recognize that silk is a natural material. They are also receptive to the notion that SERI® Surgical Scaffold will be replaced with their own tissue.”

Dr. Bengtson agrees: “The fact that SERI® Surgical Scaffold is a biological scaffold made from silk makes it much easier to convince patients to include it for their surgery.”

Ease of use: a defining benefit of SERI® Surgical Scaffold for soft tissue support

Dr. Kind believes a key SERI® Surgical Scaffold attribute lies in its ease of use. “From our very early experience with SERI® Surgical Scaffold, there were some handling advantages. It’s a very easy material to work with and there are advantages to being able to see through a scaffold, rather than having a sheet of thick material that requires a cutting needle to get through.”

“Yes, that there are not 2 sides is advantageous,” said Dr. Downey. “With SERI® Surgical Scaffold, you don’t have to worry about which way you’re putting it in.”

Dr. Lemaine added, “The characteristics of SERI® Surgical Scaffold are predictable because the actual scaffold attributes are consistent from lot to lot, and that could potentially have an impact on the outcome of your surgery.”

Dr. Lehfeldt agrees with its ease of use. “SERI® Surgical Scaffold is very easy to use right out of the package. It is very easy to manipulate, drape, cut, shape, and its porous design readily facilitates suturing with great visualization. The ability to see the underlying implant intraoperatively is a great attribute and should not be underestimated.”

CASE REVIEW:

Bilateral periareolar mastopexy using SERI® Surgical Scaffold for soft tissue support and repair

“SERI® Surgical Scaffold can greatly assist in reinforcing weak soft tissues of the breast that are prone to recurrent stretch deformity. It provides lasting soft tissue support that takes the burden off of weakened areas while the patient’s own tissue generates, making SERI® Surgical Scaffold useful in many breast procedures including circumareolar mastopexies. I’m very optimistic that we’re going to be looking at some really good results coming up over the next few years.”

Patient assessment

- A 33-year-old woman presented with left-sided stretch deformity/loss of soft tissue support, left implant palpability, bilateral areolar dilatation—left greater than right
- Her original procedure was a bilateral breast augmentation/periareolar mastopexy using Gore-Tex® sutures, purse-string suture technique, and 300-cc moderate-plus gel implants

Surgical plan

- SERI® Surgical Scaffold was used to provide soft tissue support of the lower pole of the left breast from the IMF
- Dr. Mofid planned to perform a bilateral periareolar mastopexy with removal of the Gore-Tex® sutures and soft tissue reinforcement of the nipple-areola complex with SERI® Surgical Scaffold
- Approach: periareolar
- Implant placement: submuscular

CASE CONCLUSIONS

- Using SERI® Surgical Scaffold for soft tissue support of the lower pole of the breast helped, in this case, to correct the lateral and inferior fold malposition as well as the stretch deformity
- The patient no longer had traction rippling, lateral rippling, or traction pleating at the 4-month postoperative visit
- The patient confirmed the implant position is improved and the left implant no longer falls into the lateral chest region
- Inferomedial pectoral “hollow” and areolar dilatation were improved (42 mm bilaterally)
- The patient was very satisfied with the outcome
In addition, handling SERI® Surgical Scaffold as an implant, making sure there is no contact with the skin, changing gloves, and using triple antibiotic irrigation are all critical practices according to Dr. Baxter.

The panelists concurred that there was a minimal learning curve to adapt to using SERI® Surgical Scaffold for soft tissue support and repair in breast revision and mastopexy procedures. Dr. Downey said, “If someone is using ADMs regularly, they will have very little issue in switching over to using SERI® Surgical Scaffold. It is very similar to how I do it with ADMs, using the same suture technique, interrupted, and usually I use the Vicryl® sutures. I think where the learning curve will come in is as we figure out other uses within soft tissue support and repair.”

CASE REVIEW:
Augmentation-mastopexy using SERI® Surgical Scaffold for soft tissue support and repair

Courtesy of Bradley P. Bengtson, MD
Grand Rapids, Michigan

“Mastopexy outcomes may be affected without the use of additional soft tissue support. The larger the breast and the more stretchy the skin, the more stretch deformity of the lower pole of the breast becomes an issue. However, whoever controls the lower pole of the breast, controls the outcome. When these procedures include SERI® Surgical Scaffold for soft tissue support, it is strong enough to provide the soft tissue support for results that last.”

Patient assessment
- A 55-year-old woman presented with Grade III ptosis and loose skin stretch
- She was a healthy nonsmoker with a body mass index within normal range
- She had had 3 pregnancies and had given birth to 3 children
- She had no history of prior breast surgeries

Surgical plan
- The surgical plan was to perform a primary mastopexy with augmentation via an IMF approach
- A 240-cc, round, silicone-filled implant was selected for placement submuscularly in each breast
- The goal of surgery was to reduce the N:IMF from 12 cm to 9.5 cm
- SERI® Surgical Scaffold was used to provide soft tissue support at the lower pole and additional soft tissue support of the breast from the upper pectoralis fascia to the apex of the inferior pedicle
- This support may help reduce the chance of future lower-pole stretch deformity that commonly occurs following these procedures

CASE CONCLUSIONS
- Dr. Bengtson believed the use of SERI® Surgical Scaffold for soft tissue support and repair was beneficial in achieving the desired result for the patient
- There was no palpability of SERI® Surgical Scaffold at 4 months, with minimal palpability at the initial postoperative visit
- There were no postoperative complications
- At 18 months, Dr. Bengtson achieved excellent maintenance of the breast shape and lower pole of the breast, along with the N:IMF distance

*Methodology: In an ovine subcutaneous thoracic wall implant study designed to measure the strength and thickness of SERI® Surgical Scaffold and newly generated native tissue at up to 24 months after implantation of SERI®

Note: Similar results in humans have not been confirmed.

Important Safety Information
Contraindications
- Patients with a known allergy to silk
- Contraindicated for direct contact with bowel or viscera where formation of adhesions may occur

Warnings
- SERI® Surgical Scaffold must be placed in maximum possible contact with healthy well-vascularized tissue to encourage ingrowth and tissue remodeling
- Caution should be used when implanting SERI® Surgical Scaffold in pregnant women. The use of a device that can impede tissue expansion may be hazardous during pregnancy

Please see additional Important Safety Information on the following page.
Making a difference with SERI® Surgical Scaffold

As evidenced by the March 6 peer-to-peer roundtable, SERI® Surgical Scaffold is making a difference in plastic surgery practices because it helps surgeons achieve their desired surgical outcomes in soft tissue support for mastopexy and breast revision procedures.

Dr. Mofid attended an Allergan symposium for SERI® Surgical Scaffold and had planned to use it for soft tissue support and repair after learning about its properties. “A bell went off in my head that I could address soft tissue support needs for circumareolar mastopexy patients with SERI® Surgical Scaffold, so I designed a template and tried it on a cadaver first, and then performed the operation on a patient; it turned out spectacularly well.”

Dr. Mofid continued, “I’ve used SERI® Surgical Scaffold a number of times now for soft tissue support and repair in circumareolar mastopexy. I have also implanted it directly in the breast for revisionary cases and, in my experience, have not seen any major complications thus far, which is promising.”

Dr. Downey has found SERI® Surgical Scaffold to be particularly useful in offering soft tissue support for patients who have had asymmetries or bottoming out, or for recurrent laxity in patients who have experienced significant weight loss. “Massive weight-loss patients tend to have recurrent laxity. SERI® Surgical Scaffold has been very helpful for the tissue laxity that you see in that particular group of patients. As an example, I have a patient who, when she had her lower body lift done, I think they totally disrupted her inframammary folds, so her breasts were heading south very quickly. I used SERI® Surgical Scaffold to support her soft tissue while bringing her breasts back up into the desired position and was very impressed.”

“Dr. Baxter explained a key area where he believes SERI® Surgical Scaffold may impact soft tissue support and repair procedures: “In my opinion, the answer is in a mastopexy breast reduction type of procedure where you implant it in the subcutaneous layer, close to the layer of the fascia. A big issue with mastopexy is maintenance of upper-pole fullness and projection, and the ability to off-load the stress of that from the skin envelope while not disrupting the parenchyma.”

Dr. Bengtson also views SERI® Surgical Scaffold as a great way to offer soft tissue support for mastopexy patients: “Based on my experience, there is nothing quite like SERI® Surgical Scaffold for soft tissue support and repair because of its product characteristics as a biological silk scaffold. It offers a nice strength with pliability, and it is bioresorbed over time to deliver lasting support and strength from the patient’s own supportive tissue framework.”

“I used SERI® Surgical Scaffold to support [my patient’s] soft tissue while bringing her breasts back up into the desired position and was very impressed.”

– Susan E. Downey, MD, FACS

“The ultimate goal in any breast revision surgery is to go into the breast once in hopes of never going back. With the added soft tissue support of SERI® Surgical Scaffold, surgeons may be able to achieve the results the patient desires.”

– Bradley P. Bengtson, MD

Learn more and see results from actual case studies at SERI.com
An innovation in soft tissue support and repair for breast revision and mastopexy procedures

As demonstrated by this roundtable discussion as well as the opinions of Dr. Lehfeldt and Dr. Bengtson, many surgeons are optimistic about the lasting impact SERI® Surgical Scaffold can offer for soft tissue support and repair within breast revision and mastopexy procedures.

Wendy Lewis is president of Wendy Lewis & Co. Ltd., author of 11 books, and a contributing editor to PSP.

“An innovation in soft tissue support and repair for breast revision and mastopexy procedures

The ability of SERI® Surgical Scaffold to support the surrounding soft tissues has helped me to deliver great breast aesthetics for my patients.”

– Max R. Lehfeldt, MD

CASE REVIEW:

Using SERI® Surgical Scaffold for soft tissue support and repair in a case of recurrent capsular contracture

Patient assessment

- The patient had a primary augmentation 20 years ago
- She presented with Baker Grade IV encapsulation with calcified subglandular gel implants bilaterally
- She exhibited chest wall asymmetry

Surgical plan

- Dr. Lehfeldt planned to exchange the patient’s round gel implants with anatomically shaped gel implants, with full projection on the right and moderate projection on the left
- A full capsulectomy would include site exchange from subglandular to submuscular
- SERI® Surgical Scaffold was used for soft tissue support and reinforcement of the dissected pocket

CASE CONCLUSIONS

- No drains were used for this case
- The patient healed well with no wound breakdown or wound-healing complications

Important Safety Information (continued)

Adverse Reactions

Adverse reactions are those typically associated with surgically implantable materials, including infection, inflammation, adhesion formation, fistula formation, and extrusion.

Important: Before using SERI® Surgical Scaffold, read the Instructions for Use which accompany the product for full safety information. This can be found at www.allergan.com or call Allergan Product Support at 1-800-433-8871.

Caution: Rx only.