INTRODUCTION

Implant-based breast reconstruction after mastectomy may include the use of a device to provide support and stability. Soft-tissue support devices, egg, acellular dermal matrix (ADM) products are commonly used during reconstruction and can produce more complete coverage, higher fill volumes, and rapid expansion of tissue expanders. In retrospective analyses, soft-tissue support devices were associated with complications such as seroma, infections, and reconstruction failure at higher rates versus traditional submuscular implant coverage. Prospective controlled studies on the use of soft-tissue support devices would establish overall outcomes and the risk of such complications.

Background: Soft-tissue support devices are used during breast reconstruction. This study investigated long-term clinical data following SERI Surgical Scaffold (SERI) implantation, a bioresorbable, silk-derived scaffold for soft-tissue support.

Methods: This was a prospective, multicenter study in 103 subjects who received SERI during stage 1 of 2-stage breast reconstruction with subpectoral tissue expander placement (Natrelle Style 133V; Allergan plc, Dublin, Ireland) followed by subpectoral breast implant placement. Investigator satisfaction (11-point scale: 0, very dissatisfied and 10, very satisfied) at 6 months was the primary endpoint. Ease of use, satisfaction, scaffold palpability/visibility, breast anatomy measurements via 3D images, SERI integration, histology, and safety were also assessed through 2 years after stage 1 surgery.

Results: Analyses were performed on the per-protocol population (103 subjects; 161 breasts) with no protocol deviations that could affect outcomes. Ease of use and subject and investigator satisfaction with SERI were high throughout 2 years. Breast anatomy measurements with 3D images demonstrated long-term soft-tissue stability of the lower breast mound. Key complication rates per breast were tissue/skin necrosis and wrinkling/rippling (8.1% each) and seroma, wound dehiscence, and breast redness (5.0% each). Over 2 years, 4 breasts in 4 subjects underwent reoperation with explantation of any device; 2 breasts required SERI explantation. SERI was retained in 98.8% of breasts (159/161) at 2 years.

Conclusions: SERI was associated with high and consistent levels of investigator and subject satisfaction and demonstrated soft-tissue stability in the lower breast through 2 years. SERI provides a safe, long-term benefit for soft-tissue support in 2-stage breast reconstruction. (Plast Reconstr Surg Glob Open 2017;5:e1327; doi: 10.1097/GOX.0000000000001327; Published online 16 May 2017.)
SERI Surgical Scaffold (SERI; Allergan plc; Dublin, Ireland) is a biodegradable, silk-derived scaffold for soft-tissue support. Its biomechanical properties (i.e., load, stress, and stiffness) are similar to those of host tissue; SERI has demonstrated good biocompatibility and a mild, self-limited foreign-body response.5,6

In an ovine model of 2-stage, implant-based breast reconstruction, histologic analysis showed bioresorption of SERI by 1 year. Most of the load-bearing responsibility and strength of SERI were transferred to newly generated tissue by this time.7

The current prospective study obtained long-term clinical data following the implantation of SERI during stage 1 surgery in 2-stage breast reconstruction. Interim data for 71 subjects who completed 1 year of postsurgical assessments were previously reported.8 Here, we report the final data for all subjects through 2 years.

METHODS

This study was conducted in accordance with Good Clinical Practice guidelines. Institutional review boards at each site approved the protocol; all subjects provided written informed consent. Study design and eligibility criteria were previously reported. Briefly, this prospective, multicenter, single-arm study enrolled women who received SERI during stage 1 of 2-stage breast reconstruction. Subjects included women undergoing breast reconstruction with subpectoral placement of a tissue expander (Natrelle Style 133V; Allergan plc, Dublin, Ireland) followed by exchange with a breast implant. Exclusion criteria included ongoing or planned breast radiation treatment. Any patient with a disease that might affect wound healing was excluded. These included patients with uncontrolled diabetes or an autoimmune disease, immunodeficiency, or immunosuppressive drugs unrelated to breast cancer. Patients who smoked within the year before SERI implantation were also excluded. An abscess or infection at the time of surgery, or any condition that might interfere with a subject’s participation in the study or confound study results also led to exclusion. Data were collected at the first postoperative visit, tissue expansion visits, stage 2 surgery (to replace tissue expanders with permanent implants), and follow-up visits at 6, 12, and 18 months and at 2 years after stage 1 surgery.

Study Outcome Measures

The primary outcome measure was investigator satisfaction with SERI at 6 months after stage 1 surgery, as measured on an 11-point scale (0, very dissatisfied; 10, very satisfied). Secondary outcome measures included investigator assessment of ease of use with SERI at the time of stage 1 surgery, measured on a 5-point scale, (1, very difficult to use; 5, very easy to use). Ease of use was assessed for each of the following scaffold criteria: preparation before implantation, cutting and shaping before implantation, positioning/drapability during implantation, cutting and shaping after implantation, and suturing during implantation (including tension and stretch).

Additional measurements included subject satisfaction based on a 5-point scale (1, very dissatisfied; 5, very satisfied) for the question: “Overall, how satisfied are you with your breast(s)?”

Palpability of SERI was assessed by pressing firmly on the lower pole of the breast in upright subjects, scored using a 4-point scale (0, not palpable at all; 5, easily palpable). Visibility of SERI was evaluated as a yes/no determination while subjects were upright. Palpability and visibility were assessed at first visit after stage 1 surgery, immediately before stage 2 surgery, and at 6, 12, and 18 months and 2 years after stage 1 surgery.

Breast anatomy measurements were calculated from 3D photographs (Canfield Scientific, Inc; Fairfield, N.J.). Breast width, distance from sternal notch to apex, sternal notch to inframammary fold, and apex to inframammary fold were measured by Canfield technicians using the 3D images.

SERI integration was assessed by investigators as: (1) scaffold capsule adherence to the tissue expander surface using a 4-point scale [0, no adherence; 3, complete adherence (80–100% of surface area)], (2) integration of the scaffold to the surrounding tissue using a 4-point scale [0, no integration; 3, complete integration (80–100% of surface area)], and (3) vascularization of the area using a 3-point scale [0, no vascularization; 2, tissue is vascularized].

One small incisional biopsy was taken from approximately halfway between the scaffold/pectoralis margin and the inframammary fold within the lateral half of the load-bearing region from each breast during stage 2 surgery. All collected histologic samples were evaluated by a single pathologist.

Predefined adverse events (AEs) of interest, based on prior experience with common complications occurring with breast reconstruction surgery, were prospectively recorded.

Statistical Analyses

This article presents data from the per-protocol (PP) population, which included subjects with no protocol deviations that could affect the primary measure throughout the study, such as postoperative radiation therapy after stage 1 surgery. The PP population was analyzed as the primary study group.

Disclosure: Supported by Allergan plc, Dublin, Ireland. Drs. Karp, Choi, Lehfeldt, and Fine have served as clinical investigators for Allergan plc. Dr. Kulber has served as a clinical investigator for Allergan plc and has served on the Musculoskeletal Tissue Foundation Scientific Advisory Board. Dr. Downey has served as a consultant for Allergan plc, Mentor, Ethicon, and Pacira. Dr. Duda has served as a clinical investigator for Allergan plc, Mentor, and LifeCell. Dr. Kind has served as a clinical investigator for Allergan plc and has served on speaker bureaus for LifeCell and Novadaq. Dr. Jewell has served as a consultant for Allergan plc, Keller Medical, Solta, and New Beauty Magazine; has received research funding through grants or contracts from Allergan plc, Mentor, Pfizer-Excaliard, and Solta; and holds patents or has patents pending with AerTech and Pfizer-Excaliard. Ms. Murphy is an employee of Allergan plc and owns stock in the company. The article processing charge was paid for by Peloton.
Descriptive statistics, including mean, median, range, and confidence intervals (CIs), as appropriate, were reported. For the primary analysis, the frequency distribution of satisfaction scores was categorized into discrete ranges, and deviation from normality of the distribution was analyzed using the Kolmogorov–Smirnov test. Subgroup analyses explored the relationship of specific variables to investigator satisfaction with SERI and subject satisfaction with breasts. Race, baseline age, unilateral versus bilateral implantation, and presence or absence of radiation treatment were assessed with descriptive measures.

**RESULTS**

Of the 160 subjects enrolled, 21 (13.1%) were discontinued for not receiving an implant (Fig. 1). The full-analysis population included 139 subjects (214 breasts) implanted with SERI. Thirty-six of 139 subjects were excluded from the PP population, 28 of whom received unplanned radiation therapy after implantation. The other 8 subjects were excluded for various reasons, including not receiving a breast implant, having another support device implanted, being involved in another clinical trial, and not meeting eligibility criteria. All satisfaction, effectiveness, and safety analyses were performed on the PP population, which included 103 subjects (161 breasts).

**Demographic and Baseline Characteristics**

Subjects were primarily white, with a mean age of 50.7 years and mean body mass index of 24.8 (Table 1). At stage 1 surgery, 58 subjects (56.3%) underwent bilateral mastectomy and 45 (43.7%) underwent unilateral mastectomy, all with SERI implantation. Nine subjects underwent bilateral mastectomy for breast cancer, 9 underwent bilateral prophylactic mastectomy, and 40 underwent unilateral mastectomy for breast cancer with prophylactic mastectomy on the contralateral breast. Thirty-eight subjects had unilateral mastectomy for breast cancer, and 7 subjects had unilateral prophylactic mastectomy. Mean (SD) procedure time for stage 1 surgery was 86.0 (41.0) minutes. Intraoperative tissue expander initial fill volume was at least 200 cc in 68.3% of breasts and tissue expander final fill volume was 300–499 cc in 47.2% of breasts (Table 2). Mean initial and final fill volumes were 247.6 cc and 493.7 cc, respectively; mean number of fill visits was 4.3. More than half of all breasts (61.2%) required 4–6 volume fill visits. The median time from stage 1 surgery to full expansion was 79 days. From a starting size of 250 cm², 76.4% of SERI were trimmed to <200 cm² when placed. Final mean SERI size was 145.0 cm².

**Investigator Assessment of SERI**

SERI was associated with a high degree of investigator satisfaction at 6 months. In the PP population, the mean (95% CI) satisfaction score was 9.6 (9.44–9.67); all ratings were 7 or greater; 88.5% were 9 or 10. Mean investigator satisfaction for the PP population was 9.3 at stage 2 surgery and remained at least 9.3 through 2 years (Fig. 2). At each visit, more than 80% of ratings were 9 or 10.

At each study visit from postoperatively at stage 1 surgery through 2 years, palpability of edges wrinkles and/or pores/interstices were rated as “not palpable” in 85.4–98.8% of SERI scaffolds. Investigators rated nearly all (range, 96.1–100%) SERI as not having any visible edges, wrinkles, and pores/interstices at each visit from postoperatively at stage 1 surgery through 2 years. During stage

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Fig. 1. Subject disposition. *One additional subject with a protocol deviation had an incomplete implantation and was not included in the full-analysis population. †One subject completed the study (as indicated on the study exit CRF), so she is not considered to be discontinued, but only 128 subjects completed the month 24 visit.
1 surgery, investigators rated SERI as easy or very easy to use for more than 98% of subjects with respect to each of the following: scaffold preparation before implantation, scaffold cutting and shaping before implantation, scaffold position/drapability during implantation, scaffold cutting and shaping after implantation, and scaffold suturing during implantation.

Subject Satisfaction

Subject satisfaction increased significantly from a mean (95% CI) of 3.6 (3.41–3.73) at screening to 4.3 (4.20–4.48) at stage 2 surgery and 4.8 (4.67–4.86) at 2 years. Mean subject satisfaction scores were higher than baseline at each visit after stage 1 surgery. At all visits after screening, most ratings were 5. At visits from 6 months to 2 years after stage 2 surgery, 92.4–97.4% of subjects reported scores of satisfied or very satisfied. Radiation therapy, race, unilateral versus bilateral implantation, and age did not affect investigator satisfaction with SERI or subject satisfaction with breasts.

Breast Anatomy Measurements

3D image measurements showed that soft-tissue stability of the lower breast was maintained through 2 years (Fig. 3). After reconstruction, breasts had shorter mean distances from the sternal notch to apex and sternal notch to inframammary fold versus baseline and larger mean distance from the apex to the inframammary fold. Mean breast widths were similar before and after reconstruction. Across all anatomical measurements, little change was seen from 6 months through 2 years, which represents the stability of the lower pole (Fig. 4). In particular, the distance from the sternal notch to the inframammary fold (the best measure of lower breast mound stability) was a mean (95% CI) of 24.0 cm (23.7–24.2) at month 6, 24.5 cm (24.3–24.7) at month 12, 24.6 cm (24.4–24.8) at month 18, and 24.5 cm (24.2–24.7) at 2 years. No evidence of later-term stretch was observed, and the reconstructed breast envelope showed stability.

Table 1. Demographic Characteristics

| Characteristics                        | PP Population (N = 103) |
|----------------------------------------|-------------------------|
| Age (y), mean (SD)                     | 50.7 (9.7)              |
| White, n (%)                           | 83 (80.6)               |
| BMI (kg/m²), mean (SD)                 | 24.8 (3.94)             |
| Married, n (%)                         | 71 (68.9)               |
| Primary occupation, n (%)              |                         |
| Professional, technical, managerial    | 57 (55.3)               |
| Homemaker                              | 15 (14.6)               |
| Clerical/sales                         | 5 (4.9)                 |
| Service                                | 8 (7.8)                 |
| Other                                  | 18 (17.5)               |
| Education, n (%)                       |                         |
| College graduate or higher             | 64 (62.1)               |
| Some college or vocational school grad | 26 (25.2)               |
| High school diploma/GED                | 12 (11.7)               |

GED, general educational development.

Table 2. Surgery Characteristics

| Parameters                          | PP Population (N = 103 Subjects; 161 Breasts) |
|-------------------------------------|-----------------------------------------------|
| Stage 1 surgery                     |                                              |
| SERI trimmed to <200 cm² (%)*       | 76.4                                          |
| Final SERI size (cm²), mean (SD)    | 145.0 (68.6)                                 |
| SERI sutured to muscle in edge-to-edge manner (%) | 65.8                                          |
| Initial fill volume 2-200 cc (%)    | 68.3                                          |
| Initial fill volume (cc), mean (SD) | 247.6 (129.5)                                |
| Final fill volume 300–499 cc (%)    | 47.2                                          |
| Final fill volume (cc), mean (SD)   | 499.7 (147.9)                                |
| Procedure time (min), mean (SD)     | 86.0 (41.0)                                   |
| Drains                              |                                              |
| One per breast (%)                  | 56.5                                          |
| Two per breast (%)                  | 43.5                                          |
| Tissue expansion                    |                                              |
| Number of fill visits, mean (SD)    | 4.3 (2.04)                                    |
| Subjects requiring 1–3 volume fill visits (%) | 38.8                                          |
| Subjects requiring 4–6 volume fill visits (%) | 61.2                                          |
| Time to full tissue expansion (d), median (range) | 79 (19–376)                                  |
| Stage 2 surgery, no. subjects (no. breasts) | 100 (157)                                    |
| Unilateral, n (%)                   | 43 (43.0)                                     |
| Bilateral, n (%)                    | 57 (57.0)                                     |
| Procedure time (min), mean (SD)     | 83.0 (63.6)                                   |

*Starting size of SERI was 250 cm².

Fig. 2. Investigator satisfaction with SERI.
Scaffold Integration and Histology

At stage 2 surgery, 85.2% of capsules were at least minimally adhered to the tissue expander surface, indicating that SERI did not interfere with normal healing. During stage 2 surgery, investigators observed local tissue growth through the SERI device and integration with the tissue expander. Almost all scaffolds (98.7%) were completely integrated with the surrounding tissue and had vascularized capsules (96.8%).

Of the 153 histology samples from 198 breasts during stage 2 surgery, 95.4% were classified as normal. In the normal samples, the pathologist found that most tissue reactions were appropriate or expected with regard to an implanted device. When observed, tissue inflammation tended to be minimal or mild. Most normal samples showed evidence of SERI bioresorption to some extent. When observed, capsule tissue was generally thin, and many had well-organized structure. Lymphocytes were present in most samples, although the density varied. Abnormal histologic samples presented with characteristics such as lack of bioresorption and none to minimal integration.

Safety

There were 84 predefined AEs of interest (52.2% of breasts). Most (84.5%) were mild in severity, and only 2.4% were severe. Those reported in more than 2% of breasts are shown in Table 3. Based on predefined AEs, tissue or skin necrosis occurred in 13 breasts (8.1%), wrinkling/rippling in 13 (8.1%), seroma in 8 (5.0%), wound dehiscence in 8 (5.0%), and capsular contracture in 4 (2.5%). Mild cellulitis on the breast occurred in 2 breasts (unilateral on the right side in 2 subjects). One unilateral device-related, periprosthetic infection of moderate severity was treated with debridement and a course of oral antibiotic medication. The other, a severe periprosthetic infection, was treated with fluid drainage/aspiration and a course of oral antibiotic medication. Both cases of mastitis resulted in SERI explantation as described below. No deaths or unanticipated adverse device effects were reported throughout the study.

Two subjects (2 of 161 breasts) underwent unilateral reoperation with SERI explantation. One subject had SERI and breast implant removed due to periprosthetic infection 1 month after stage 1 surgery; the other had SERI and tissue expander removed due to a breast infection and wound dehiscence 7 months after stage 1 surgery. Therefore, 98.8% of breasts retained SERI at 2 years. Overall, 4 breasts (2.5%) in 4 subjects had explantation of at least 1 device (i.e., SERI, tissue expander, or implant).

Two patients (2/103) (1.9%) had reoperations for pocket looseness. In both cases, the pockets were plicated to adjust the position of the implant. The SERI was not removed. There were no reoperations for pocket tightness.

DISCUSSION

In this study, use of SERI scaffold for soft-tissue support and repair in stage 1 of 2-stage breast reconstruction was associated with high and consistent levels of investigator and subject satisfaction, breast soft-tissue stability, particularly of the lower breast mound, and low rates of AEs and explantations over 2 years. As evidenced by breast anatomy measurements, the lower pole remained highly stable over time. Our findings confirm the pre- and intraoperative ease of use and high satisfaction for up to 1 year reported by surgeons who have used SERI in procedures for soft-tissue support and repair. Additionally, our findings of high subject satisfaction with breast reconstruction at all time points support those of a systematic review of 28 studies showing that, overall, subjects were satisfied.
Fig. 4. Representative photos over 2 years. A, A 42-year-old subject; diagnosis, prophylactic mastectomy; tissue expander, Natrelle 133SV-12; final fill volume, 400 cc; implant, Natrelle 20 (Allergan plc; Dublin, Ireland) smooth/round (450 cc). B, A 42-year-old subject; diagnosis, breast cancer; tissue expander, Natrelle 133MV-15; final fill volume, 610 cc; implant, Natrelle 20 smooth/round (550 cc). C, A 50-year-old subject; diagnosis, prophylactic mastectomy; tissue expander, Natrelle 133MV-13; final fill volume, 620 cc; implant, Natrelle 20 smooth/round (550 cc).
with breast reconstruction, regardless of the technique used, and that age and procedure timing did not affect general satisfaction. That study identified factors that influence subject satisfaction, including breast symmetry, size, shape, and scars.  

Investigators found SERI to be easy to use before and during implantation. Most SERI scaffolds were not palpable or visible at any point throughout the study; they had integrated with the surrounding tissue and become vascularized by the time of stage 2 surgery.

Compared with submuscular implantation without surgical support, use of SERI may provide some advantages in aspects of the surgical procedure for breast reconstruction, such as larger initial fill volumes and fewer fills required to complete the tissue expander fill. 2,10–12 Prior studies reported average initial fill volumes of approximately 130 cc for submuscular implantation without surgical support, 2,10 whereas, in the current study, two-thirds of subjects had fill volumes greater than 200 cc. Similarly, previous studies report a mean of 4.3–6 tissue expander fills needed to achieve final fill volume2,10–12 in this study, approximately 40% of subjects required only 1–3 fills for final fill volume.

Histologic findings were consistent with an expected mild inflammatory response to a foreign body. Histologically normal samples were associated with resorption of the scaffold and replacement with well-vascularized tissue.

A number of AEs, such as capsular contracture, seroma, hematoma, and tissue or skin necrosis, have been commonly reported following breast reconstruction with surgical support devices. 2,10 A meta-analysis comparing rates of complications in 153 breasts that had ADM-based reconstruction with 2,910 breasts having traditional musculofascial surgical techniques found a 3-fold increase in rate of seroma and a greater than 2-fold increase in the rate of explantation with ADM-based reconstruction. 14 In the current study, these and other AEs were prospectively collected as predefined AEs of interest. Most of the predefined AEs were not observed in this study. Of those that were observed, most occurred in fewer than 5% of subjects. These rates are within the range of previous reports for similar procedures. Meta-analyses of studies on ADM-based breast reconstruction have reported pooled complication rates up to 10.9% for skin necrosis, 6.9% for seroma, 5.7% for infection, 1.3% for hematoma, and 0.6% for capsular contracture. 2,4,6 A recent 15-year, single-center retrospective review of cases found similar incidences of complications such as seroma (3.5%), hematoma (3.6%), and surgical-site infection (12.7%). 2,15 A recognized limitation of these previous studies is the retrospective nature of most data on complication rate analyses. Although these comparisons are useful to provide context for the results of our study, no studies have directly compared SERI and ADMs.

A prospective study of breast reconstruction surgery in 128 subjects using 2 different ADMs assessed surgical outcomes for 2 years after surgery. 16 The complication rates for AEs commonly observed with surgical support devices were skin necrosis (19.6%), infection (15.1%), seroma (4.5%), hematoma (1%), and poor integration (13.9%). In the current study, complication rates for SERI were lower or in line with rates shown for the ADMs. In the current study, skin necrosis occurred in 8.4%, breast infection in 2.3%, seroma in 7.5%, hematoma in 4.2%, and minimal or no integration in 3.9% of breasts.

Over the 2-year follow-up in this study, rates of surgical complications of reoperations with concurrent explantation of SERI were generally low. Of the 161 breasts, 2 (1.2%) required SERI explantation; thus, SERI was retained in 98.8% of breasts at 2 years. This is lower than reported in the literature and is probably related to the fact that patients with increased likelihood of wound healing problems (such as uncontrolled diabetes, smokers, and immunosuppressed patients) were excluded from the per-protocol group that are the subjects of this study. The low rate of surgical reoperation for ptosis (n = 1) and pocket looseness (n = 2) along with results from 3D anatomical measurements support the effectiveness of SERI in maintaining soft-tissue stability in the lower breast. Investigators and subject satisfaction were consistently high in both year 1 and 2, and scaffold palpability and visibility were low at all time points. Overall, the safety profile, as shown by explantation and the incidence and severity of AEs, demonstrated a low incidence of complications over 2 years of postsurgical follow-up.

In-depth data on investigator and subject satisfaction are limited by use of a 1-question survey to assess subject satisfaction compared with more complex and validated instruments. The single-arm design of this study did not allow for direct comparisons. The subjective nature of AE characterization and lack of consensus terminology limit, to some degree, comparison with other findings.

CONCLUSIONS

SERI provided durable, long-term soft-tissue support in this 2-stage breast reconstruction study. Through 2 post-

Table 3. Predefined AEs (by Breast) Occurring at >2% Frequency (PP Population)

| Event*                 | PP Population (N = 161 Breasts) |
|------------------------|----------------------------------|
| Tissue or skin necrosis| 13 (8.1)                         |
| Wrinkling/rippling      | 13 (8.1)                         |
| Breast redness         | 8 (5.0)                          |
| Seroma                 | 8 (5.0)                          |
| Wound dehiscence       | 8 (5.0)                          |
| Hematoma               | 7 (4.5)                          |
| Skin rash              | 6 (3.7)                          |
| Delayed wound healing  | 5 (2.8)                          |
| Asymmetry              | 5 (2.5)                          |

All data represent the number (%) of breasts in which the AE occurred in the safety population (n = 1). Percentages were calculated using the total number of implants (N = 161) as the denominator.

*Predefined AEs with incidence less than 2% were cellulitis, device-related infection, and breast infection. No events were reported for autoimmune disease, breast cancer, bruising (breast), capsule calcification, connective tissue disease, deep wound infection, breast implant deflation, device infection, device migration, elevated Creatine protein, erosion (skin), expander/implant palpability/visibility, fever, fluid accumulation, hypertrophic scarring, immune/allergic response, implant extrusion, implant malposition, infection, inflammation, irritation (breast), keloid scarring, local tissue reaction, loss of skin sensation, lymphadenopathy, lymphedema, pulmonary embolism, red breast syndrome, skin hypersensitivity, skin paresthesia, superficial wound infection, suture infection, swelling, tethering, tissue expander deflation, and vessel damage/bleeding.
operative years, SERI was associated with consistently high satisfaction, breast mound stability, and low complication rates. Breast anatomy measurements with 3D images demonstrated long-term soft-tissue stability of the lower breast mound.

SERI is an effective and safe option, with consistent performance over time and with long-term benefit for soft-tissue support and repair in 2-stage breast reconstruction.

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