

Clinical Application of a Silk Fibroin Protein Biologic Scaffold for Abdominal Wall Fascial Reinforcement

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Background: Preclinical studies have demonstrated that macroporous silk fibroin protein scaffolds are capable of promoting physiologically durable supportive tissue, which favors application of these engineered tissues for clinical implantation. The safety and effectiveness of a long-lasting, transitory, 510(k)-cleared purified silk fibroin biologic scaffold (SBS) are investigated for soft-tissue support and repair of the abdominal wall.

Methods: We conducted a multicenter retrospective review of all consecutive patients who underwent abdominal wall soft-tissue reinforcement with an SBS device between 2011 and 2013. Indications, comorbid conditions, surgical technique, complications, and outcomes were evaluated.

Results: We reviewed the records of 172 consecutive patients who received an SBS for soft-tissue support. Of those, 77 patients underwent abdominal wall fascial repair, with a mean follow-up of 18.4 ± 7.5 months. Procedures using an SBS included reinforcement of an abdominal-based flap donor site (31.2%), ventral hernia repair (53.2%), and abdominoplasty (15.6%). The overall complication rate was 6.5%, consisting of 2 wound dehiscences, 1 with device exposure, 1 seroma, 1 infection with explantation, and a perioperative bulge requiring reoperation. There were no reports of hernia.

Conclusions: Postoperative complication rates after 18 months were low, and most surgical complications were managed nonoperatively on an outpatient basis without mesh removal. To our knowledge, this is the only series to report on a long-lasting, transitory SBS for abdominal wall repair and reinforcement. Procedure-specific outcome studies are warranted to delineate optimal patient selection and define potential device characteristic advantages. (*Plast Reconstr Surg Glob Open* 2014;2:e246; doi: 10.1097/GOX.0000000000000217; Published online 4 November 2014.)

Violation of abdominal wall fascial integrity can be associated with significant morbidity, including abdominal hernia and contour de-

formity.¹ For ventral hernia repair, the rates of bulge formation and hernia reoperation vary greatly within the literature, between 6% and 50% depending

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on the complexity of the defect, repair technique, and patient factors including tissue integrity and comorbid conditions.² In prospective randomized controlled trials, incisional hernia repair reinforced with prosthetic mesh is associated with better outcomes than incisional hernia repair without prosthetic mesh reinforcement.^{3,4} Recently, tissue-based bioprosthetic mesh has gained popularity for its use in complex abdominal wall reconstructions (AWRs) owing to lower rates of mesh infection, fistula formation, and mesh explantation than the rates reported for AWRs with synthetic mesh.⁵⁻⁷ However, tissue-derived mesh has several shortcomings such as storage and handling requirements, elasticity, animal origin, product variability, cost, and device failure.⁸⁻¹⁰

Breast reconstruction using free or pedicled transverse rectus abdominis muscle (TRAM) flaps or deep inferior epigastric artery perforator (DIEP) flaps inherently violates the rectus fascia and can similarly result in abdominal wall herniation or bulge formation in approximately 2% to 9%^{11,12} and 4% to 33%¹³ of patients, respectively. Reported risk factors include obesity, bilateral reconstructions, and increasing the amount of fascia sacrificed such as with harvest of both the medial and lateral row perforators.¹⁴⁻¹⁶ The placement of synthetic or biologic mesh for the reinforcement of fascial closures has been reported to reduce the risk of bulge and hernia formation by 70% compared with primary fascial closure alone.¹⁷

Although the benefits of mesh for hernia repair and AWR are well established, the combination of synthetic or bioprosthetic mesh and fascial plication for cosmetic abdominoplasty has been described only in limited case reports.¹⁸⁻²⁰ In patients with significant musculofascial laxity or atrophic fascia with or without a history of significant weight loss, suture plication alone may produce additional fascial stretching and tearing. Radiologic evaluation of anterior rectus sheath plication with suture alone has demonstrated a durability of about 6 months.²¹⁻²³ Debate persists over the optimal patient selection for abdominoplasty with mesh reinforcement, and the long-term benefits must be weighed against device complication profiles.

Silk from the silkworm, *Bombyx mori*, has been widely used as a permanent surgical suture material

for centuries. Sericin (a glue-like glycoprotein) may be removed from raw silk, leaving a purified core of silk fibroin protein that has demonstrated characteristics of durability and biocompatibility in vitro and in vivo.²⁴⁻²⁶ Preclinical studies of silk fibroin protein biologic scaffolds (SBSs) have reported favorable qualities, such as strength repair as regenerative scaffold, and native tissue remodeling to form bone, ligament, vascular grafts, trachea, and ventral hernia models.²⁷⁻³¹ SBS has a mild, self-limiting foreign-body response, which results in degradation of fibroin and deposition of host tissue matrix and cells leading to an increase in biomechanical properties similar to those of host tissue.³²⁻³⁴ A silk fibroin biologic-derived scaffold composed of the purified protein fibroin (SERI surgical scaffold, Allergan, Irvine, Calif.) was approved in the United States in 2009 for use as a transitory scaffold for soft-tissue support and repair.^{35,36}

Yet to be defined is the ideal biocompatible mesh that can support abdominal fascia until native collagen tissue is deposited with mesh replacement to form a stable abdominal wall. In the present study, we evaluated the safety and effectiveness of a long-lasting, transitory, 510(k)-cleared SBS for soft-tissue support and repair of the abdomen.

METHODS

We conducted a multicenter retrospective review of all consecutive patients who underwent abdominal wall soft-tissue reinforcement with an SBS between 2011 and 2013. We compared the surgical outcomes of SBS for the repair of ventral hernias; reinforcement of TRAM, DIEP, and vertical rectus abdominis muscle (VRAM) flap donor sites; and cosmetic abdominoplasties. Indications, comorbid conditions, surgical technique, complications, and outcomes were evaluated, and procedure-specific complication rates were determined via subcohort analyses. The results of postoperative device evaluation with computed tomography (CT) and ultrasound were reviewed when available. Each SBS device was tailored to the size of the individual patient's defect from an original 10×25 sheet. All SBS devices were rinsed and surgical sites were irrigated with triple antibiotic solution³⁷ (50,000 U of bacitracin, 1 g of cefazolin, and 80 mg of gentamicin in 500 ml of normal saline), and skin was reprepared with povidone iodine solution before device placement. Routine follow-up included physical examination in an outpatient clinic weekly for 1 month after discharge, then every 3 months for 1 year, and then annually thereafter.

For ventral hernia defects, complete midline musculofascial closure was achieved with no bridging of any defects. The size of fascial defects was

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estimated from preoperative CT when available or from clinical examination of defects under physiologic tension. At the discretion of the surgeon, larger ventral hernias were repaired using the Rives-Stoppa retrorectus technique, whereby the mesh was placed between the posterior rectus sheath and the rectus abdominis muscle to avoid direct bowel contact with the device.³⁸ Briefly, SBS mesh was used to reinforce the midline fascial closure with 3–5 cm of musculo-fascial underlay by securing the mesh to the lateral rectus border and semilunar line using interrupted #1 polypropylene full-thickness, horizontal mattress sutures placed 1–2 cm apart in a retrorectus position. The decision to perform perforator-sparing component separation^{39,40} was based on surgical judgment to achieve fascial closure. Smaller ventral hernias (<25 cm²) were repaired via midline fascial closure and placement of an SBS onlay reinforcement of the anterior rectus fascia.

TRAM, DIEP, and VRAM flap abdominal donor sites were repaired with either anterior rectus fascia onlay or interposition SBS placement. Briefly, SBS mesh was used to reinforce fascial closure as an interposition with 2–3 cm of fascial overlap by securing the mesh to the medial and lateral rectus fascia border and semilunar line using interrupted #1 polypropylene full-thickness, horizontal mattress sutures placed 1–2 cm apart followed by complete fascial closure over the device. Anterior rectus fascial closure with onlay placement of SBS was performed with 6–8 cm of overlap using interrupted #1 polypropylene full-thickness, horizontal mattress sutures placed 1–2 cm apart. Cosmetic abdominoplasty procedures were performed in standard fashion with rectus muscle approximation and midline fascial plication, with SBS onlay reinforcement oriented long-axis vertically using interrupted #1 polypropylene fascial sutures placed 1–2 cm apart.

Descriptive statistical analyses were performed using SAS 9.2 software (SAS Institute, Cary, N.C.) and R statistical software (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

We reviewed the medical records of 172 patients who received an SBS for soft-tissue support. Of those, 77 patients (71 women, 6 men) underwent abdominal wall fascial repair or reinforcement, with a mean follow-up of 18.4 ± 7.5 months. The demographics of the overall study population and subcohorts are summarized in Table 1. There were no active smokers represented in the study cohort. Procedures necessitating an SBS included reinforcement of an abdominal-based flap donor site (31.2%), ventral hernia

Table 1. Demographics and Outcomes by Surgical Technique

Variable	%
Overall patients	N = 77
Mean age (y)	52.2 (range, 25–80)
Surgical complications	5 (6.5)
Device exposure	2 (2.6)
Device explantation	1 (1.3)
Mean follow-up (mo)	18.4 ± 7.5
Anatomic placement	
Retrorectus (Rives-Stoppa)	26 (33.8)
Interposition	14 (18.2)
Onlay	37 (48.1)
Ventral hernia repair	N = 41 (53.2)
Age (y)	52 (range, 31–80)
BMI	30.8 ± 6.3
Previous hernia repair	8 (19.5)
Preexisting comorbidity	7 (17.1)
Fascial defect size (cm ²)	83 (range, 9–86)
Component separation	18 (43.9)
Complications	3 (7.3)
Hernia	0
Infection	1 (2.4)
Seroma	0
Wound dehiscence	2 (4.9)
TRAM/DIEP/VRAM donor site	N = 24 (31.2)
Age (y)	54 (range, 31–64)
BMI	30.2
Complication	1 (4.2)
Bulge	1 (4.2)
Infection	0
Seroma	0
Wound dehiscence	0
Abdominoplasty reinforcement	N = 12 (15.6)
Age (y)	43 (range, 25–54)
BMI	27.1
Previous abdominoplasty	2 (16.7)
Complication	1 (8.3)
Bulge	0
Infection	0
Seroma	1 (8.3)
Wound dehiscence	0

All data are number of patients (%) unless otherwise specified. BMI, body mass index.

repair (53.2%), and abdominoplasty (15.6%). The location of SBS device placement was classified as onlay (48.1%), interposition (18.2%), or retrorectus (33.8%). Average drain duration was 10.7 days ± 2.9 days.

Ventral Hernia

Ventral hernia repairs were performed in 41 patients (35 women, 6 men) (Fig. 1). The patients' mean age was 52 years (range, 31–80), and their mean body mass index was 30.8 ± 6.3 kg/m². Concurrent ostomy placement was reported in 4.9% of patients, and 19.5% had undergone previous ventral hernia repairs. On the basis of Ventral Hernia Working Group recommendations, 80.5% were classified as grade 2, and the remaining 19.5% were classified as grade 3.¹ Bilateral component separation was performed in 43.9% of ventral hernias at the discretion of the surgeon. The type of

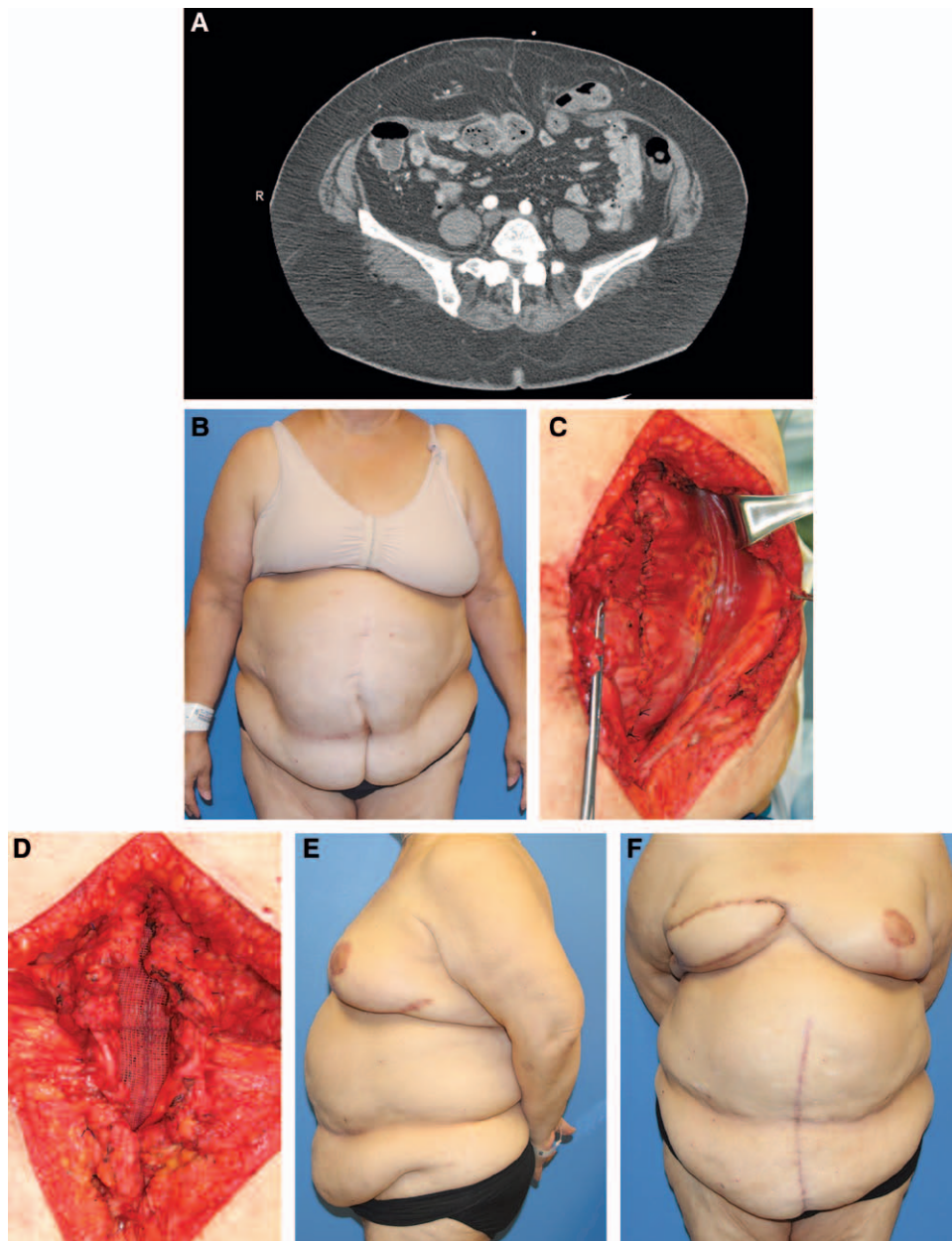


Fig. 1. Ventral hernia with retrorectus mesh reinforcement: Patient was a 58-year-old morbidly obese (body mass index, 42.3) woman with diabetes, history of exploratory laparotomy complicated by peritonitis and abdominal abscesses, and 2 previous ventral hernia repairs now with a 9 cm in width ventral hernia. A and B, Bilateral component separation was performed, followed by creation of the retrorectus plane and closure of the posterior rectus sheath. C, A 10 × 25 cm silk fibroin scaffold was placed for fascial reinforcement (D) followed by complete fascial closure. Postoperative course was uncomplicated as seen at 1 year. E and F, A right latissimus dorsi flap and left mastopexy were performed in the interim for breast cancer.

repair was reported as either retrorectus (63.4%) or onlay (36.6%) for placement of SBS reinforcement. The mean area of mesh used was 244.5 cm² (range, 200–250 cm²). Sixteen patients (39%) underwent postoperative oncologic surveillance with abdominal CT, magnetic resonance imaging, and/or ultrasound. For CT and magnetic resonance

imaging evaluations, the SBS device was radiolucent at all time points evaluated. The SBS device was visible on abdominal ultrasound evaluation up to 6 months postoperatively. Patients received 1–4 drains that were placed subcutaneously and completely removed at a mean of 12.7 days [standard deviation (SD) ± 3.2 days].

Abdominal Flap Donor-site Reinforcement

Abdominal flap donor-site reinforcement was performed in 24 women with complete fascial closure of the defects (Fig. 2). The patients' mean age was 54 years (range, 31–64), and their mean body mass index was $30.1 \pm 3.6 \text{ kg/m}^2$. Soft-tissue flaps raised from the abdomen were classified as DIEP (37.5%), muscle-sparing (MS)-2 TRAM (45.8%), MS-1 TRAM (8.3%), or VRAM (8.3%).⁴¹ The type of repair was reported as either interposition (57.1%) or onlay (42.8%) for placement of SBS reinforcement of fascial repair. The mean area of mesh used was 65.8 cm^2 (range, 45–70 cm^2) for interposition placement and 232.8 cm^2 (range, 180–250 cm^2) for onlay placement. For abdominal donor sites, all patients received 2 drains that were placed subcutaneously and completely removed at a mean of 10.2 days (SD ± 3.2 days).

Abdominoplasty

Abdominoplasty with fascial plication and SBS mesh onlay reinforcement was performed in 12 women (Fig. 3). The patients' mean age was 43 years (range, 25–54), and their mean body mass index was $27.1 \pm 3.2 \text{ kg/m}^2$. The mean area of mesh used was 234 cm^2 (range, 180–250 cm^2). All patients received one drain that was placed subcutaneously and removed at a mean of 5.2 days (SD ± 1.8 days).

Complications

The overall complication rate was 6.5%, which included 2 wound dehiscences (2.6%). Three unplanned reoperations (3.9%) were performed for wound dehiscence, one with device exposure, an infection necessitating explantation (2.4%), and a perioperative bulge (2.4%). Both cases of wound dehiscence occurred in the ventral hernia cohort. The first patient developed a 4-cm skin dehiscence at an inverted T-junction that was treated clinically with dressing changes and healed within 2 weeks. The second wound dehiscence was 6 cm long and also occurred at an inverted T-junction and had an SBS device exposure. The patient was treated with dressing changes and then underwent revisionary surgery with soft-tissue debridement and closure. The SBS device was left in place with no further complications. In a morbidly obese patient, an acute bulge formed during intense coughing on postoperative day 9 following an MS-2 TRAM flap for breast reconstruction. The patient's abdomen was immediately reexplored, and both the fascial closure and SBS device suture line were found to have dehisced. The abdominal site was repaired with reinsert of the SBS device with no further postoperative complications. An infection necessitat-

ing explantation was reported in an obese patient undergoing ventral hernia. There were no reports of hernia. Soft-tissue incorporation and vascularization of an SBS device was observed during an elective scar revision of an abdominal donor site at 1 year following an SBS onlay reinforcement of a TRAM flap (Fig. 4).

DISCUSSION

This is the first case series to establish the safety, complication rates, and clinical outcomes at 18 months of a purified silk-derived fibroin protein scaffold for repair and reinforcement of the abdominal wall. For the described indications, the purpose of using an SBS device was to function as a long-lasting fascial support until new healthy collagen tissue, produced by the patient, could replace the mesh, resulting in abdominal wall stability. Silk fibroin protein combines versatility for scaffolding, with mechanical strength, and stabilization.⁴² Although this is an initial experience in select patients, the perioperative and early postoperative complication rates were low, and most surgical complications were managed non-operatively on an outpatient basis without requiring mesh removal.

This case series presents an SBS as an alternative option to supporting musculofascial repair that involves engineering the microstructure, architecture, and mechanical properties of a biomimetic and biologically derived polymeric scaffold.^{23,24} Within abdominal wall repair, the mechanical properties of a biomaterial and its integration into the adjacent tissue are critical parameters for successful reconstruction and reduction of fascial repair failure and hernia recurrence. The mechanical properties of the biomaterial are important because the material has to be able to sustain initial mechanical load of a repaired site before cells can degrade the material and lay down new matrix/tissue to increase the overall mechanical strength of a defect site.^{22,27} There is a fine balance that exists between the rate of degradation of material and rate of deposition of new tissue that is dependent on the composition, structure, and initial mechanical properties of the material. The rate of degradation should not be faster than the rate of deposition of new tissue because in this scenario the material will fail to keep the integrity of the repaired site.³⁰

The design and development of biodegradable matrices that will replace native tissue without necrosis or scar formation is a challenging area of research. The composition, architecture, and mechanical properties of a scaffold or matrix are important criteria for soft-tissue support formation

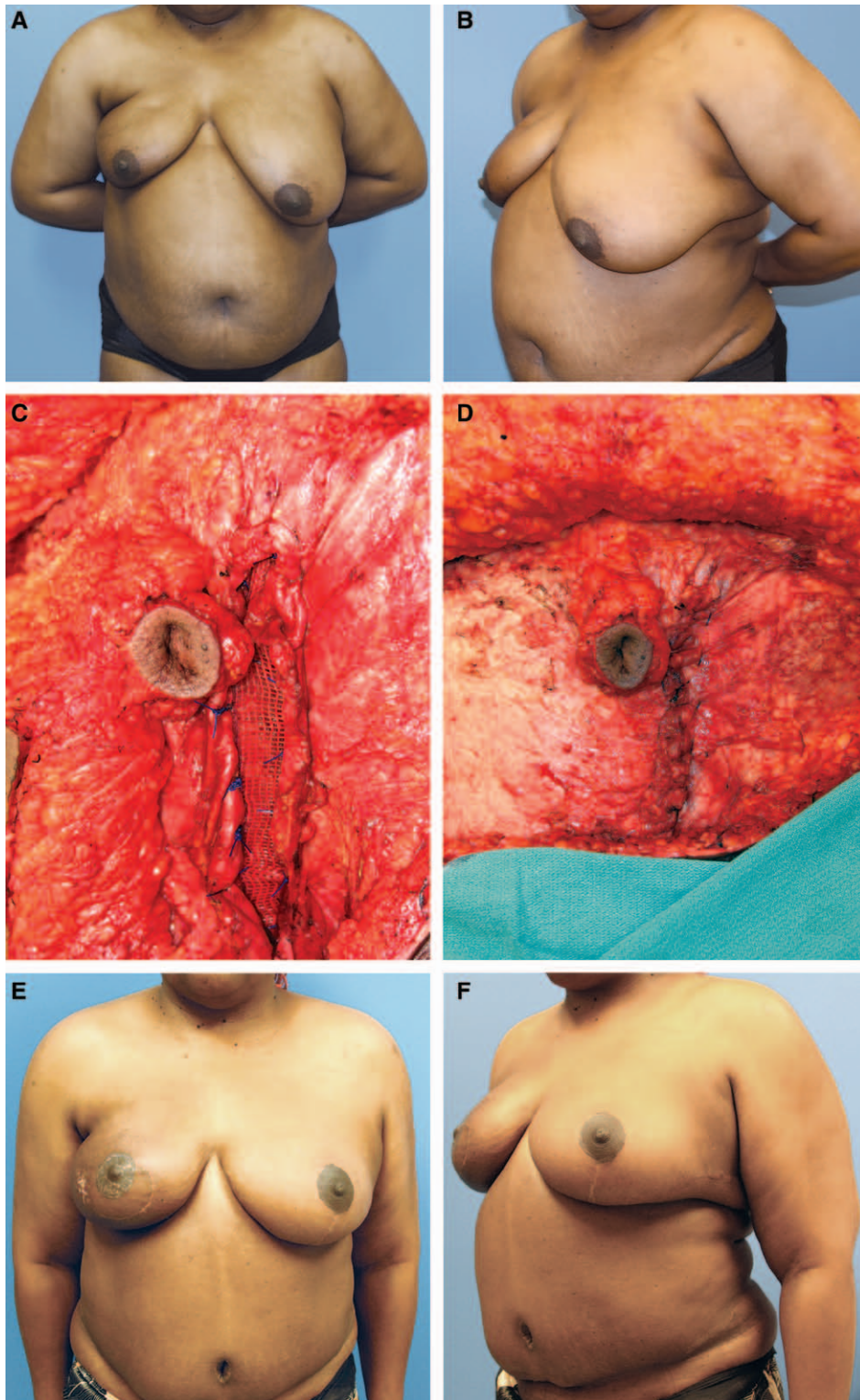


Fig. 2. TRAM flap donor site with mesh interposition reinforcement: Patient was a 64-year-old morbidly obese (BMI, 38) woman (A and B) who presented with recurrent right breast cancer with previous breast-conserving therapy and external-beam radiotherapy to the right chest wall. A right mastectomy was performed with immediate MS-2 free TRAM flap reconstruction and contralateral breast reduction. C, An 8×10 cm silk fibroin scaffold was used as an interposition mesh (C) to reinforce complete fascial closure of the abdominal donor site (D). Postoperative course was uncomplicated as seen at 1 year (E and F).

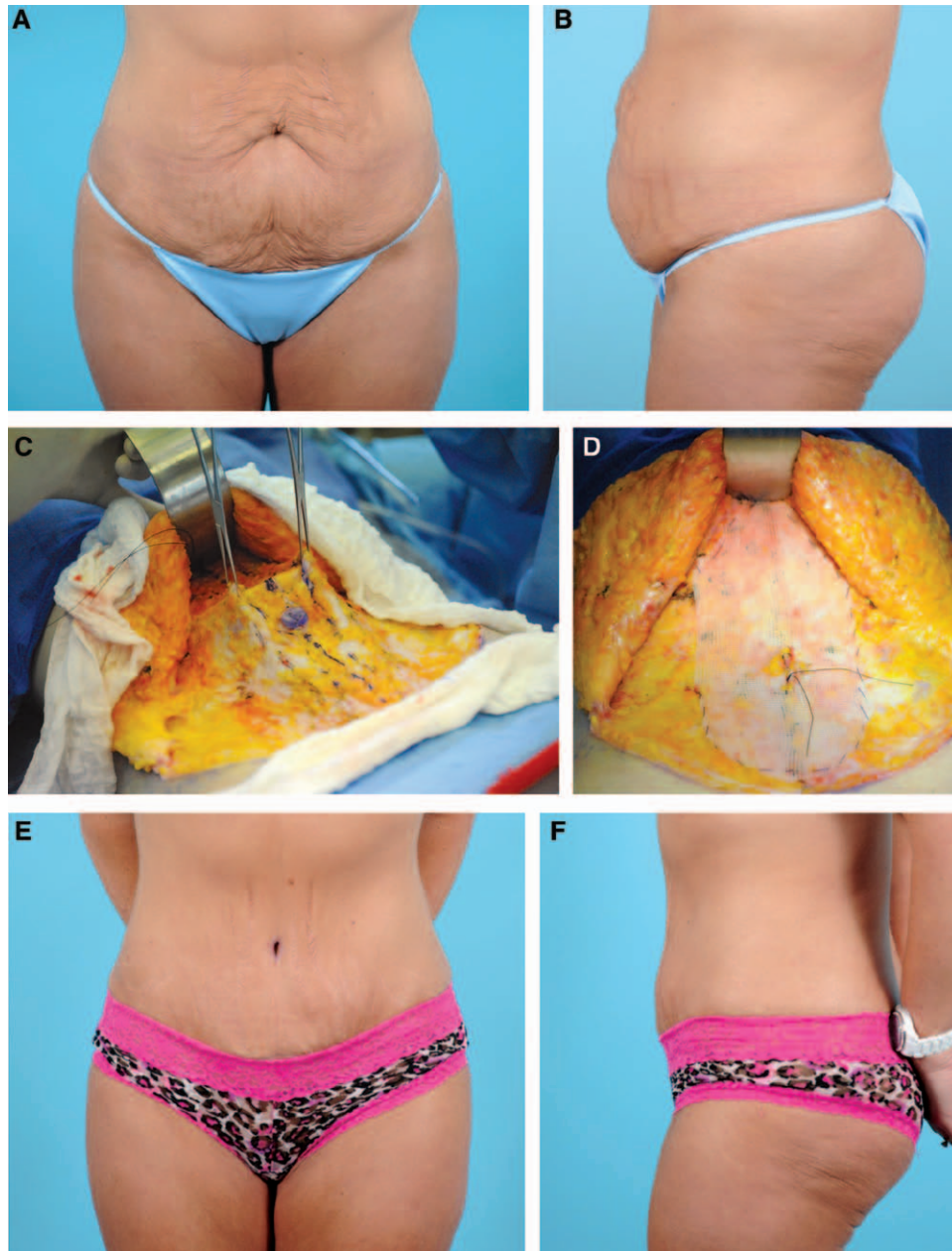


Fig. 3. Abdominoplasty with mesh onlay reinforcement: Patient was a 33-year-old multiparous woman (A and B) status post 60-pound weight loss who presented with significant musculofascial laxity after 60-pound weight loss. C, Following a standard abdominoplasty approach, a vertically oriented silk fibroin scaffold as an onlay reinforcement of the midline fascial plication (D). Postoperatively at 6 months (E and F).

due to its load-bearing requirement. The structural and biological characteristics also control the initial inflammatory response, cell conductivity or infiltration, generation of the neo-extracellular matrix, biodegradation of the biomaterial scaffold, mechanical properties of the remodeled or regenerated tissue, vascularization, and differentiation of cells.^{28,29} The critical balance that needs to be maintained in the wound healing of load-bearing

tissues, such as fascia, is that the degradation rate of the implanted biomaterial should equal the deposition of new matrix so that mechanical strength is not compromised.^{31,32} Novel silk fibroin-based scaffolds and meshes have been created to provide a unique architectural support without compromising the mechanical integrity of the repair site initially or during the process of remodeling. The silk fibroin protein polymer is derived from the silk

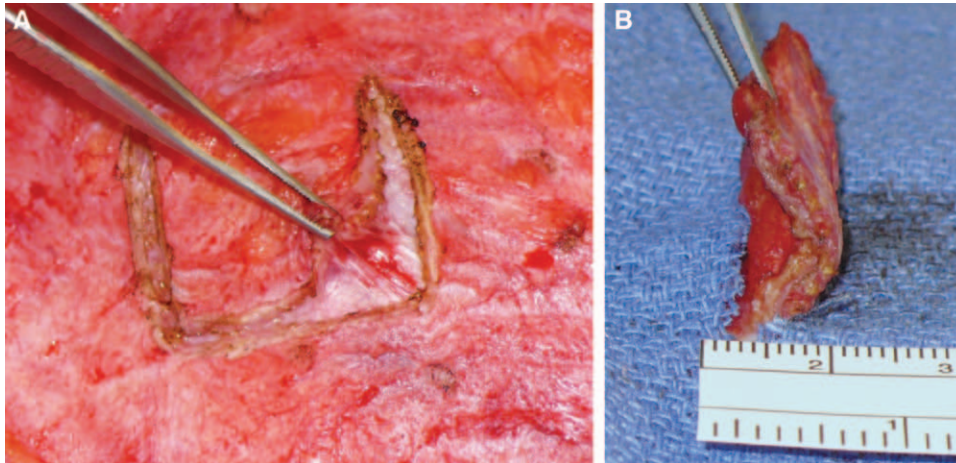


Fig. 4. SBS tissue incorporation: Evaluation of SBS and soft tissue incorporation observed during an elective scar revision of an abdominal donor site 1 year following an SBS onlay reinforcement of a TRAM flap (A). Note that the thickness of tissue was approximately 2–3 mm (B).

fiber, which has a high level of single axis orientation and high tensile strength with flexibility.^{22,24} This polymer mimics structural and functional properties of collagen and is used by the silkworm for guidance and load-bearing applications, and the same properties of silk fibroin have been exploited here for musculofascial repair.^{30,32}

Proper surgical technique and patient selection are essential to the successful and durable treatment of the abdominal wall. Because of robust tissue ingrowth of the SBS device, complex ventral hernias were repaired using a Rives-Stoppa retrorectus technique. In a meta-analysis of ventral herniorrhaphy with mesh, Albino et al⁴³ reported that recurrence rates were highest for onlay (17%) and interposition techniques (17%) compared with underlay (7%) and retrorectus techniques (5%) and that seroma rates were lowest following retrorectus repair (4%). In our experience and that of other centers, certain types of meshes can cause high rates of dense abdominal adhesions and can fistulize into bowel; therefore, intraperitoneal placement of an SBS device should be avoided.^{44–46} Placement of an SBS device into a grossly contaminated field was not evaluated as part of this series and is relatively contraindicated owing to wound-related morbidity. The overall bulge and hernia rates in the current study were particularly low at 1.3% and 0%, respectively. Despite the relatively short follow-up times, these rates compare favorably to those in other nationally published series, which range from 7% to 80%.^{5,47} Technical aspects of abdominal wall repair, such as complete fascial closure, perforator-preserving dissection, and obliteration of dead space, contributed to good outcomes and may have superseded the effects of the SBS device.⁴⁸

Many techniques have been described for mesh reinforcement of fascial plications for aesthetic operations of the abdominal wall.^{18–22} In this study, vertical placement of the mesh was chosen for reinforcement of the fascial plication from the costal margin to the pubis. Patients with significant myofascial laxity such as that resulting from massive weight loss, failed previous plications, or significant diastases were preferentially selected to most benefit from fascial reinforcement with SBS for the purpose of creating a more durable repair. Long-term objective proof of superiority of SBS reinforcement for cosmesis and durability when compared to standard suture plication will be required to justify the change in technique within a traditionally cost-sensitive aesthetic market.

The present study had several limitations. Although the study population is the only series of abdominal wall reinforcement with SBS, procedure-specific subgroup analyses were not possible to determine statistically significant differences between comparable synthetic or bioprosthetic devices. Prospective comparative studies are required to differentiate the indications that most benefit from the use of an SBS. In addition, a mean follow-up time of only 18 months is not likely sufficient to capture long-term rates of bulge formation and hernia recurrence, which evolve over years. A paucity of randomized control studies exist owing to problems in defining standardized patient inclusion criteria. In this study and many others on abdominal wall reinforcement, the patient population is too small to have adequate statistical power to determine superiority over alternative techniques. Level I and II data will be the ultimate key to choosing the right patient for the right type of mesh in the right position for different clinical scenarios.

CONCLUSIONS

Abdominal wall defects can be successfully repaired and reinforced with an SBS with low postoperative complication rates. This is the only series to date reporting on the surgical results of a long-lasting, transitory biologic-derived scaffold for abdominal wall repair. This case series consists of a heterogeneous patient population, and further procedure-specific outcome studies with longer follow-up are warranted to delineate optimal patient selection and define potential device characteristic advantages.

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