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CASE REPORT
Breast

Subcutaneous Tissue Expander Placement with Synthetic Titanium-Coated Mesh in Breast Reconstruction: Long-term Results

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Summary: A subcutaneous, prepectoral, muscle-sparing approach has been recently described for implant-based breast reconstruction. This is a preliminary series of 2-stage breast reconstructions by means of tissue expander placed subcutaneously with the support of a titanium-coated polypropylene mesh. A pilot series of cases was started in 2012. Inclusion criteria were informed consent, age less than 80 years, normal body mass index (range, 18.5–24.9), no T4 and metastatic cancers, no comorbidities, and nonsmoking patients. Expander losses, infections, seromas, skin/nipple necrosis, wound dehiscence, and reinterventions were registered in follow-up visits. Furthermore, patients were followed up in second-stage procedures and for at least 1 year from implant positioning to collect any surgical complication, reinterventions, cosmetic outcome, and oncological data. Between June 2012 and March 2014, 25 cases were enrolled in the study. Expander/implant loss rate was 0%. Skin/nipple necrosis rate was 4%. Infections rate was 12% after first-stage and 4% after second-stage procedure. Seromas rate was 0%. Five (20%) fat graft procedures were performed over the expander before second-stage reconstruction, and no reinterventions were required after second stage. Patients mean score was 99 for cosmetic outcome satisfaction, in a 0–100 scale. Subcutaneous 2-stage reconstruction with synthetic mesh proved safe and feasible. Patients satisfaction is very good after 14 months median follow-up form definitive implant placement. Although the present study involved only a small number of cases, a tissue-expander subcutaneous reconstruction seems to have promising results. Whenever pectoralis major muscle can be spared, a conservative reconstruction might be an option. *(Plast Reconstr Surg Glob Open 2015;3:e577; doi: 10.1097/GOX.0000000000000549; Published online 15 December 2015.)*

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In the United States, 2-stage implant-based breast reconstruction (IBBR) accounts for approximately 70% of reconstructions after mastectomy,[1] and majority of reconstructions are performed by means of acellular dermal matrices (ADMs).[2] Biological matrixes are the most used worldwide,[3] although synthetic meshes are widespread too, as titanium-coated polypropylene mesh (TiLOOOP Bra, pfm medical, Cologne, Germany) in Europe.[4] Such devices, either ADMs or meshes, are traditionally adopted as a muscle extension, creating a "dual plane" coverage of tissue expander (TE)/implant, as described by Spear et al.[5] In 2014, a different approach with subcutaneous implant placement by means of a full synthetic mesh or ADMs coverage was described in direct-to-implant reconstructions.[6–8] Moreover, a recent article shows a significant difference in capsular thickness between TEs placed subcutaneously and those placed in standard submuscular position.[9]

Aim of this report is to analyze surgical safety and long-term outcomes of subcutaneous TE 2-stage reconstruction using a synthetic mesh.

PATIENTS AND METHODS

In 2011, a pilot study was approved by the Hospital Drugs and Devices Service Committee, according with Institutional Ethical Committee rules on nonrandomized clinical studies, for evaluation of performances of a titanium-coated polypropylene synthetic mesh (TiLOOOP Bra) in IBBR.

Patients scheduled at our institution for conservative mastectomies, either nipple-sparing or skin-sparing mastectomy, were thoroughly informed of different reconstruction options, either autologous or prosthetic. If TE approach was chosen, patients were informed of the muscle-sparing subcutaneous option with synthetic mesh coverage only (totally subcutaneous, prepectoral TE adjustment, and wrapped in a mesh bag; Fig. 1). Inclusion criteria were age less than 80 years and normal body mass index (range, 18.5–24.9). Exclusion criteria were previous breast surgery, T4 and metastatic cancers, refusal to sign the consent, comorbidities (diabetes, renal failure, heart failure, cardiovascular diseases, hypertension at oral medications, pulmonary diseases, hepatic diseases, and metabolic diseases), smoking, and previous radiotherapy to chest wall. An informed consent, with description of surgical technique and complications, was signed by every woman. A prospective digital database was created to encompass all baseline characteristics, complications, outpatient visits, reinterventions, second-stage reconstructions, final cosmetic outcome, and oncological follow-up.

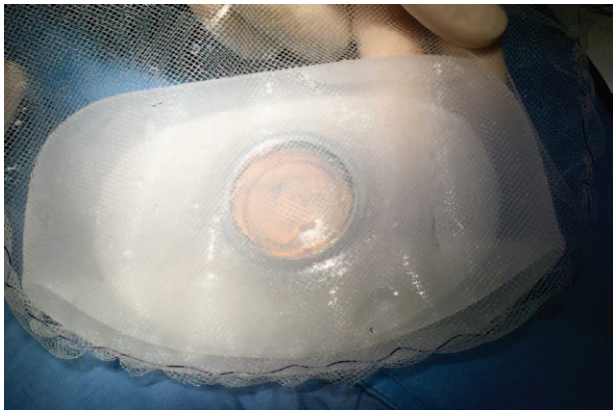


Fig. 1. Ex vivo TE preparation with titanium-coated polypropylene mesh. Complete TE wrapping by means of a titanium-coated polypropylene synthetic mesh bag. A mesh pocket is tailored to embrace TE and is left loosely bigger than TE itself considering the maximum TE diameter at final expansion.

Mesh wrapping around TE was loose, considering final expansion diameter of TE. Outpatient expansions were done every week or every 2 weeks for the first 2 months, with 40–50mL of sterile solution each time. Follow-up visits were performed every 2 months thereafter, even after TE exchange with implant.

Subjective cosmetic evaluation was conducted using the postoperative BREAST-Q module (Memorial Sloan-Kettering Cancer Center and The University of British Columbia © 2006, all rights reserved). According to a study on patient-reported quality of life,[10] the module was divided into multiple independent scales: satisfaction with breasts (16 items), satisfaction with outcome (7 items), psychosocial well being (10 items), physical well being (16 items), and sexual well being (6 items). For each scale, responses were summed and transformed into a score, in a 0–100 scale. Higher scores indicate greater satisfaction or quality of life. Cosmetic evaluation with BREAST-Q was completed within May 2015 for all patients.

RESULTS

Between June 2012 and March 2014, 25 cases were submitted to a subcutaneous TE/first-stage IBBR. After 10 month median interval, second-stage procedures were performed in all cases. Demographics, oncological data, complications after first stage, reinterventions, further complications after second stage, and long-term cosmetic outcome, with 14-month median follow-up from final reconstruction, are shown in Table 1.

DISCUSSION

On the basics of the rationale that both ADMs and synthetic meshes are safe under the mastectomy flaps in the inferolateral pole in a combined submus-

Table 1. Demographics, Oncological Data, Surgical Complications and Long-Term Cosmetic Outcome of Subcutaneous Implant-Based 2-Stage Breast Reconstruction

Demographics and oncological data of included patients	
No. of cases	25
Age: median (range)	60 (40–77)
BMI: median (range)	22 (19–24)
Intervention: no. of cases (%)	
Monolateral	25 (100)
Skin-sparing mastectomy	13 (52)
Nipple-sparing mastectomy	12 (48)
Pathology: no. of cases (%)	
pT0	0 (0)
pTis-pT1	14 (56)
pT2	8 (32)
pT3	3 (12)
pN 0	10 (40)
pN 1	9 (36)
pN 2	5 (20)
pN 3	1 (4)
Neo-adjuvant chemotherapy: no. of cases (%)	8 (32)
Adjuvant chemotherapy: no. of cases (%)	12 (48)
Adjuvant radiation therapy: no. of cases (%)	7 (28)
First-stage, subcutaneous TE placement	
Overall complications: no. of cases (%)	5 (20)
TE loss	0 (0)
Skin-nipple necrosis*	1 (4)
Seroma	0 (0)
Wound dehiscence	0 (0)
Wound-skin infection*	3 (12)
Hematoma*	1 (4)
Atopic reaction versus mesh or prosthesis	0 (0)
Reinterventions†	5 (20)
Second-stage, TE exchange for definitive implant	
No. of cases (%)	25
Interval from first-stage: months, median (range)	10 (6–14)
Overall complications: no. of cases (%)	1 (4)
Implant loss	0 (0)
Skin-nipple necrosis	0 (0)
Seroma	0 (0)
Wound dehiscence	0 (0)
Wound-Skin infection*	1 (4)
Hematoma	0 (0)
Atopic reaction versus prosthesis	0 (0)
Reinterventions	0 (0)
Long-term follow-up after second stage	
Last follow-up in May 2015: months, median (range)	14 (7–23)
Mortality: no. of cases (%)	0 (0)
Local recurrence (chest wall/axilla): no. of cases (%)	1 (4)
Distant metastases	2 (8)
Subjective cosmetic evaluation, BREAST-Q scores‡	
No. of evaluated patients	25
Satisfaction with breasts mean (SD); median (range)	58 (23); 64 (16–95)
Satisfaction with outcome mean (SD); median (range)	99 (9); 100 (63–100)
Psychosocial well being mean (SD); median (range)	77 (26); 87 (18–100)
Physical well being mean (SD); median (range)	94 (12); 96 (54–100)
Sexual well being mean (SD); median (range)	56 (31); 53 (4–100)

*Treated conservatively without implant removal. Wound-skin infection was defined as any swelling and redness of surgical site, which required an antibiotic treatment either per os or intravenously. Infection rate was considered in the follow-up period until TE exchange with implant after first stage and until 1 year after second-stage procedure, according to Centers for Disease Control and Prevention guidelines.[11]
†Reinterventions were because of margin infiltration in 1 case and to fat graft over the expander in 4 cases.
‡For each scale, item responses were summed and transformed into a score, ranging from 0 to 100. Higher scores indicate greater satisfaction or quality of life.
BMI, body mass index.

cular "dual plane" coverage, we assume that it could be safe to cover breast prostheses entirely with such devices. Results in subcutaneous direct-to-implant reconstructions are published in three 2014 studies, with either titanium-coated mesh or ADMs.[6–8] Same approach can be used in 2-stage TE reconstruction as well, particularly because of lesser tension on skin flaps, whenever a 2-stage procedure is chosen either for oncological or for surgical reasons. Subcutaneous reconstructions recreate the anatomical position and ptosis of breast gland. Besides, pectoralis muscle can be spared, avoiding drawbacks such as prosthesis "animation" (See video, Supplemental Digital Content 1, which displays a subcutaneous TE. Monolateral subcutaneous TE (full height, full projection) 3 months after intervention during chemotherapy. This video is available in the "Related Videos" section of the full-text article on http://links.lww.com/PRSGO/A159).

In present series, no TE failure (TE removal), 1 (4%) skin/nipple necrosis, 3 (12%) skin/wound infections, and 1 (4%) hematoma are reported. Complications were all treated conservatively. Five (20%) reinterventions in between first and second stage were all fat graft procedures over the TE, performed in cases submitted to postoperative radiation (always performed before second-stage reconstruction) to ameliorate the subcutaneous softness and thickness.

Only 1 (4%) complication, infection, occurred after second-stage procedures. Final cosmetic outcome, after 14-month median follow-up, was judged with a mean score of 99 in a 0–100 scale by patient-reported evaluations.

Intraoperatively, mesh appears thin, flexible, and completely integrated within TE capsule (Figs. 2,3). The use of ADMs or synthetic meshes provides a scaffold between TE and skin flaps. Such devices are

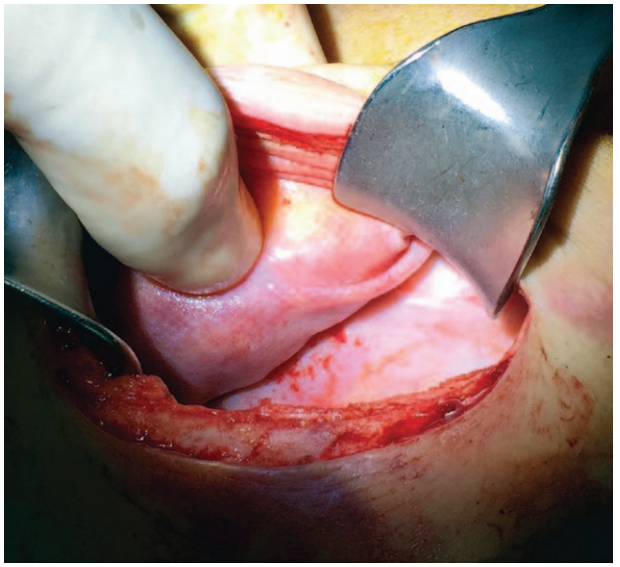


Fig. 2. Titanium-coated synthetic mesh integration within capsule. Appearance of capsule during a second-stage procedure, after TE removal of a reconstructed breast by means of a titanium-coated polypropylene mesh.

effective to fix TEs or implants in the proper position, giving support and preventing displacements. Direct-to-implant studies[6–8] show a seemingly equal safety with either technique. Our results both in a previous study[6] and in this series show a 0% seroma rate, probably because of the loose knitwork of mesh that allows an easy fluid drainage without closed spaces. Seroma still remains the most frequent

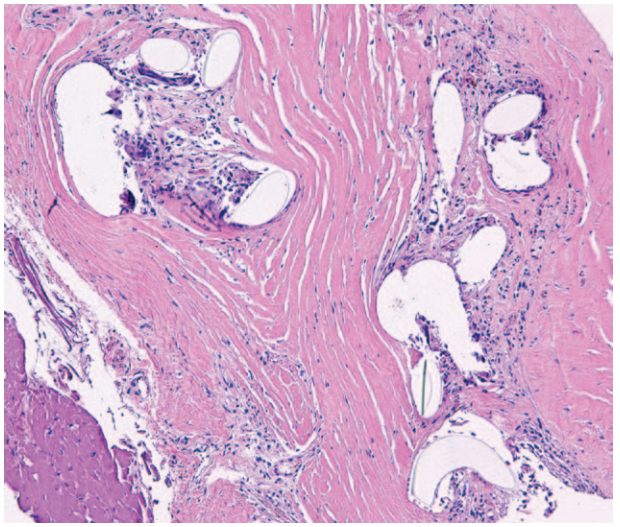
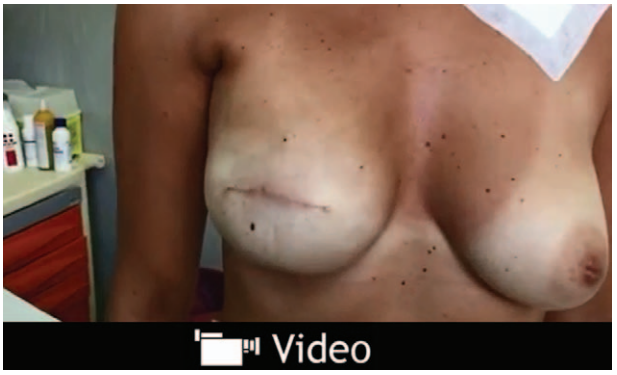


Fig. 3. Microscopic appearance of titanium-coated synthetic mesh integration within capsule. Histology shows cystic spaces containing pale material consistent with the titanium-coated polypropylene mesh. Mild chronic inflammatory response with histiocytes and foreign body giant cells surround the mesh. All elements are completely integrated within fibroblastic tissue.



Video 1. See video, Supplemental Digital Content 1, which displays a subcutaneous TE. Monolateral subcutaneous TE (full height, full projection) 3 months after intervention during chemotherapy. This video is available in the "Related Videos" section of the full-text article on http://links.lww.com/PRSGO/A159.

complication with ADMs.[2] A possible drawback of a subcutaneous TE placement is the thin medial aspect of reconstructed breast, which can cause rippling and make visible the TE or implant later on. This limit can be addressed, whenever significant, with a fat graft procedure.

Obvious limits of this report are small number of cases and absence of a randomized control group.

In conclusion, these results might open a way toward the subcutaneous TE reconstruction as an alternative. As conservative mastectomies have changed the breast surgical oncology scenario, it is time to consider also a "conservative reconstruction" approach sparing muscles.

CONCLUSIONS

After the introduction of subcutaneous direct-to-implant breast reconstructions by means of soft tissue replacement devices, such as ADMs and synthetic meshes, a preliminary experience of subcutaneous TEs placement is reported in this series. Twenty-five patients were submitted to subcutaneous 2-stage reconstruction with TE completely wrapped in a titanium-coated polypropylene mesh and followed up even after second-stage procedure with a 14-month median long-term evaluation using BREAST-Q self reported module.

No TE/implant failures with removal were registered, and complications were minor and treated conservatively. Long-term subjective cosmetic results are excellent. This pilot experience with subcutaneous TE 2-stage reconstruction shows that, granted some selection criteria, this type of "anatomical" reconstruction is feasible, avoiding the drawbacks of muscle "animation" over the implant.

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Ethical Approval: Pilot study approved by Hospital Drugs and Devices Service Committee (CAD 20110517), within Institutional Ethical Committee rules on nonrandomized studies. Written informed consent required, according to ethical standards laid down in 1964 Helsinki Declaration and later amendments.

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