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Breast

A Long-term Evaluation of Acellular Dermal Matrix for Immediate Implant-based Breast Reconstruction following Risk-reducing Mastectomy

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Background: Acellular dermal matrices (ADMs) are sometimes used in implant-based breast reconstructions (IBR), but long-term ADM-related evaluations are scarce. In this study, we evaluated early and late complications and patient-related outcomes (PROs) over an 8-year postoperative period in women who had undergone immediate IBR following risk-reducing mastectomy with bovine ADM (SurgiMend).

Methods: This prospective observational single-center analysis involved 34 women at high risk for breast carcinoma. Complications were prospectively recorded during the first year, followed by 4 years of postoperative retrospective chart reviews. Long-term evaluations were done using a questionnaire. Preoperative, 1 year, and 5- to 8-year postoperative PRO assessments were obtained based on results from the BREAST-Q questionnaire.

Results: In 56 breasts, complications after a mean of 12.4 months follow-up included implant loss (7.1%), implant change (1.8%), hematoma (7.1%), breast redness (41.1%), and seroma (8.9%). Most breasts (80.3%) were graded Baker I/II, which indicated a low capsular contracture incidence. After a mean of 6.9 years, the total implant explantation rate was 33.9%, and the revision surgery rate was 21.4%. Two cases of breast cancer were reported during the long-term evaluation. BREAST-Q results indicated significantly decreased satisfaction with outcome ($P = 0.024$). A positive trend regarding psychosocial well-being and declining trend regarding satisfaction with both breast physical- and sexual well-being parameters were reported.

Conclusions: The observed complication rates agree with previous findings concerning ADM-assisted IBR. A high demand for revision surgery exists, and PROs remain relatively stable over time. *(Plast Reconstr Surg Glob Open 2024; 12:e5951; doi: 10.1097/GOX.0000000000005951; Published online 2 July 2024.)*

INTRODUCTION

Approximately 5%–10% cases of breast cancer can be attributed to hereditary factors and inherited mutations, such as germline breast cancer genes 1 and 2 (*BRCA1* and *BRCA2*, respectively).[1] Due to a better understanding of breast cancer genetics, genetic counseling, and genetic testing,[2] more hereditary cancers are expected to be identified in the future.

In women with *BRCA1/2* mutations, bilateral risk-reducing mastectomy (BRRM) can facilitate a reduction in the risk of breast cancer by approximately 90%–95%.[3] BRRM may also be considered an option for women with a family history of breast cancer.[4]

Although undergoing BRRM can reduce concerns about developing or dying from breast cancer,[5] it is important to acknowledge the potential BRRM-related surgical complications and their adverse effects on health-related quality of life (HR-QoL). Immediate breast reconstruction can have a positive effect on HR-QoL and anxiety levels in women undergoing BRRM or mastectomy for breast cancer.[6–8]

Achieving a well-defined lower pole may pose a significant challenge in implant-based breast reconstruction

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(IBR) with subpectoral implant placement and potentially result in less-appealing cosmetic outcomes.[9] Acellular dermal matrices (ADMs) are biological tissues with cellular components that have been removed.[10,11] By serving as a graft between the lower border of the pectoralis major muscle and the inframammary fold, an ADM may facilitate lower pole expansion and improve the breast shape. This technique requires less muscle dissection and permits larger one-stage implant-based procedures compared with those without ADM.[12–14] Better aesthetic outcomes have been reported in comparison with subpectoral implant placement without ADM.[13,15] SurgiMend (TEI Biosciences Inc., Boston, Mass.) is a xenogeneic ADM derived from neonatal or fetal bovine dermal collagen.[16]

Despite numerous publications on ADMs,[12–28] few prospective evaluations and long-term follow-up studies have been published. This study aims to prospectively assess early and late complications and need for revision surgery in women undergoing immediate IBR with ADM (SurgiMend) following bilateral or unilateral risk-reducing mastectomy (RRM). Additionally, the study aimed to examine the long-term effects of this procedure on HR-QoL and patient satisfaction based on the BREAST-Q questionnaire.

Takeaways

Question: What are early and late complications of immediate acellular dermal matrix (ADM)–assisted implant-based breast reconstruction (IBR) following risk-reducing mastectomy? What are long-term, up to 8 years postoperatively, impacts of surgery on patient-reported outcomes (PROs)?

Findings: This study of 30 women undergoing IBR following risk-reducing mastectomy with the use of bovine ADM showed that early complications are common, but with low incidence of capsular contracture. Revision surgery is performed in 21.5% of the patients. PROS are relatively stable over the observed period.

Meaning: Bovine ADM-assisted IBR is a reconstructive option with stable patient-reported outcomes and low capsular contracture, but with a high level of revision surgery over time.

METHODS

Study Design and Patient Selection

This study was a prospective observational single-center analysis that was conducted at Karolinska University Hospital in Stockholm and included women who had undergone immediate IBR following RRM using bovine ADM (SurgiMend) between February 2013 and February 2016.

ADMs were used for all eligible women during the study period, provided no contraindications were identified. The inclusion criteria consisted of women over 18 years old and either a *BRCA1/2* carrier or those with a family history, indicating a high risk for breast carcinoma. All patients were thoroughly informed preoperatively, and their oncological risks had been assessed at a multidisciplinary conference. Women who had undergone previous mastopexy or breast augmentation were not excluded.

Exclusion criteria consisted of hypersensitivity to bovine material, a body mass index (BMI) of more than 30, planned or ongoing pregnancy, or breast feeding. For women with previous unilateral breast cancer who underwent bilateral surgery, only the breast without prior breast cancer was included. Written informed consent was obtained from all participants.

The study was approved by the ethics committee (2012/1261-31/4). An additional approval was obtained in 2021 for the long-term follow-up (2020-06402).

Surgical Technique

Single-dose antibiotics were administrated intravenously before surgery. Incisions were based on breast size and surgeon's preference. After a mastectomy was performed, the pectoralis major muscle was elevated from the chest wall in the inferior and medial part. The ADMs were soaked in saline before insertion and sutured to the inferior lateral border of the pectoralis major muscle and to the inframammary fold. The implants were placed in the subpectoral pocket. Siltex Contour Profile Becker 35 expander implants were used for women with larger size breasts or thin skin flaps, these implants can be used permanently. Drains were placed subpectorally and subcutaneously and removed when output was less than 30-mL to 40-mL fluid over 24 hours. Standard wound dressings were used for the drains, and the patients were instructed to refrain from showering until drains were removed. Prophylactic antibiotics were not continued postoperatively.

Data Collection

Collected clinical data included demographics, BMI, and reconstructive (including type of incision and implant) and oncological characteristics (including history of previous breast cancer and surgery). Complications were registered prospectively during the first postoperative year. Medical charts were retrospectively reviewed for complications and repeat surgery 1–4 years after surgery. Clinical grading of capsular contraction using Baker's classification was done by the plastic surgeons 1 year postoperatively.[29]

The BREAST-Q questionnaire, a validated patient-reported outcome (PRO) instrument was used to assess perception of HR-QoL and patient satisfaction.[30] The questionnaire covers HR-QoL domains (physical well-being of chest and upper body, psychosocial- and sexual well-being) and patient satisfaction domains (satisfaction with breasts, outcome, and care). Patients completed the BREAST-Q Reconstruction module (version 1.0) at three different time-points: (1) baseline evaluation after the preoperative consultation (T1), (2) one year after surgery (T2), and (3) for the long-term evaluation (T3). Questionnaires were sent to the women with a postage-paid return envelope by mail 5–8 years after surgery. At the T3 time point, new consent forms and long-term evaluation

questionnaires were sent along with the BREAST-Q. The form was created by the authors and not validated. This questionnaire included open- and close-ended questions about breast-related problems after the 1-year postoperative consultation and whether any additional procedures had been performed on the breast(s) due to breast reconstruction. If applicable, participants were asked to specify further details.

Raw patient scores in each domain were converted into Rasch-transformed Q scores using the QScore software program (Q Portfolio, New York, N.Y.). These scores range from 0 to 100, with higher scores indicating greater HR-QoL or satisfaction. Each domain can be analyzed independently, thus allowing for separate assessment of pre- and postoperative scores or for comparison to identify changes. There is no overall BREAST-Q score.

Statistical Methods

Resulting values for each BREAST-Q domain and time point were presented with mean and SD. The change over time was analyzed using a repeated measures analysis of variance and comparing the three time-points, T1–T3, at a group level. Twenty-five women (83% of the original cohort) participated in all three measurements and were included in the final statistical analysis. The overall analysis of variance test was presented with a *P* value. A pairwise comparison was conducted between time-points without adjustment for multiple comparisons.

The association between BMI and satisfaction with breast and satisfaction with outcome was estimated using a Spearman rank correlation. R (version 4.1.1) software (2021-08-10) was used for all statistical analyses. Statistical significance was defined as a *P* value less than or equal to 0.05.

RESULTS

Thirty-four women were included in the study. The mean age was 42 years (SD 8.6; range 23–58), and the mean BMI was 23.5 (SD 2.5; range 19–30). Eight breasts had previously undergone augmentation or mastopexy.

Five women underwent unilateral procedures, and 29 women underwent bilateral procedures, resulting in a total of 63 breasts. Seven of the bilaterally operated women had previously undergone unilateral breast conserving surgery. These seven breasts were excluded, leaving 56 breasts for analysis in 34 women.

The breasts were reconstructed using 46 permanent silicone implants and 10 one-stage Siltex Contour Profile Becker 35 expander implants. Details of the surgical parameters are presented in Table 1.

The mean clinical follow-up time was 12.4 months (SD 0.77; range 11.5–14.3). Table 2 outlines early postoperative complications. Breast redness occurred in 23 breasts (41.1%) and the cause, whether infection and/or red breast syndrome (RBS), was not further specified. Among 43 nipple-sparing operations, partial nipple necrosis occurred in eight breasts (19%). Five minor seromas (8.9%) resolved without intervention. Four women had postoperative hematomas (7.1%) that were evacuated.

During the first 3 months following surgery, four implants (7.1%) were lost in four women due to skin flap necroses and exposed ADM. Among these women, three experienced breast redness. Two additional cases of skin flap necrosis were treated conservatively, resulting in six cases of skin flap necrosis (10.7%). One of these implants

Table 1. Surgical Parameters

Parameter	Values
Total no. women	34
Bilateral RRM	29 (85.3)
Unilateral RRM	5 (14.7)
Total no. breasts	63
Breasts excluded	7 (12.5)
Breasts included	56 (87.5)
Incision (*n* = 56)	
Wise pattern	5 (8.9)
Periareolar	14 (25.0)
Transverse mastectomy	8 (14.3)
Submammary fold	25 (44.6)
Lateral lazy-S	4 (7.1)
Nipple-sparing surgery (*n* = 56)	43 (77)
Implant type (*n* = 56)	)
Permanent silicone implant	46 (82.1)
Permanent expander implant	10 (17.9)
Specimen weight, g	
Median (range)	312.5 (146–730)
Implant volume perioperative, mL	
Median (range)	350 (225–535)
End volume of expander, mL	
Median (range)	370 (225–665)

The data are presented as *n* (%) unless specified otherwise.

Table 2. Early and Late Complications and Interventions

During first 3 months	No. Breasts (*n* = 56)
Implant lost or changed	4 (7.1)
Evacuated hematoma	4 (7.1)
Reoperation due to bleeding*	1 (1.8)
Breast redness†	23 (41.1)
Nipple necrosis (n = 43)	8 (19.0)
Necrosis of skin flap and exposed ADM and/or implant	6 (10.7)
Seroma	5 (8.9)
Between 4 months and 1 year postoperatively	
Implant change	1 (1.8)
Implant malposition	3 (5.4)
Capsular contracture (Baker grade)	
I	40 (71.4)
II	5 (8.9)
III	1 (1.8)
IV	0
Not assessed	10 (17.9)
Repeat procedures 1–4 years postoperatively	
Implant change	8 (14.3)
Reconstruction with a deep inferior epigastric perforator flap	1 (1.8)
Autologous fat transplantation	9 (16.1)
Scar correction	1 (1.8)
Patient-reported complications and repeat surgeries 5–8 years postoperatively	(*n* = 49)
Implant change	6 (12.2)
Autologous fat transplantation	1 (2.0)

The data are presented as *n* (%) unless specified otherwise.
*Implant saved.
†Including redness due to RBS and/or infection.

Table 3. Summary of Scores on BREAST-Q Reconstruction Module at Time-point T1 (Baseline), T2 (1 Year Postoperatively), and T3 (5–8 Years Postoperatively)

BREAST-Q Domain	T1 Mean (SD)	T2 Mean (SD)	T3 Mean (SD)	*P**	Mean Change between T1 and T3
No. responding (n)	30	28	26	25†	
Satisfaction with breasts	60.33 (18.10)	61.00 (11.95)	57.92 (18.29)	0.444	–2.41
Psychosocial well-being	69.97 (18.11)	70.29 (23.45)	71.96 (20.69)	0.441	+1.99
Physical well-being of chest and upper body	84.10 (14.38)	81.85 (14.53)	79.73 (14.71)	0.133	–4.37
Sexual well-being	54.52 (19.57)	58.15 (18.36)	52.92 (22.06)	0.409	–1.6
Satisfaction with outcome	NA‡	77.43 (15.24)	67.92 (18.89)	**0.024**	–9.51§

T1: baseline, T2: 1 year postoperative, T3: 5–8 years postoperative.
*Significant values highlighted in bold ($P \leq 0.05$).
†No. women responding to all three questionnaires included in the statistical analysis.
‡Satisfaction with outcome is not scored in the preoperative BREAST-Q questionnaire.
§Mean change between T2 and T3.

was changed after 2 years. Between 4 and 12 months, one implant (1.8%) was changed, and three implants (5.4%) were considered malpositioned.

At the 1-year follow-up, one breast (1.8%) had a Baker III/IV capsular contracture. The majority (80.3%) were classified as Baker I/II. Ten reconstructions (17.9%) were not evaluated for capsular contracture (Table 2).

An additional eight implants (14.3%), including the three malpositioned ones, were changed to improve the aesthetic results, resulting in a total of 13 implants (23.2%) lost or changed within 4 years postoperatively. Other surgical procedures are shown in Table 2.

Twenty-five women (83%) with a total of 41 breasts completed the questionnaire for all three time-points and were included in the final statistical analysis. Table 3 presents the BREAST-Q scores. A significant decrease was observed for the satisfaction with outcome scale ($P = 0.024$). After comparing pre- and postoperative results at the group level, scores in the domains "physical well-being of chest and upper body," "satisfaction with breast" and "sexual well-being" trended downward over time. Conversely, the scale for "psychosocial well-being" gradually increased over time. None of these changes were statistically significant in a pairwise comparison analysis. The individual responses are shown in Figure 1 and illustrate a large spread between individual scores.

A modest correlation was found between the scales for "satisfaction with breast" and "satisfaction with outcome" (Spearman $\rho = 0.37$; $P = 0.054$). No correlation was observed between BMI and satisfaction with breast or satisfaction with outcome.

The long-term evaluation questionnaire was completed by 29 women (85.3%) and included 49 breasts. The mean follow-up time was 6.9 years (SD 0.99; range 5–8). During this period, six further implants (12.2%) were changed, and one patient underwent autologous fat transplantation (2.0%). Overall, 19 implants (33.9%) were lost or changed, and the rate of revision surgery reached 21.4% [12 cases, including autologous fat transplant, changed to a deep inferior epigastric perforator flap or scar correction] over approximately 8 years of follow-up.

Two women (4.1%) were diagnosed with breast cancer during the follow-up. One had a history of breast cancer in the contralateral breast, whereas the other had no history of breast cancer. Both women underwent tumor removal surgery while the implants were left in place.

DISCUSSION

This study shows that bovine ADM-assisted immediate IBR is a reconstructive option that has stable PROs over a period of 8 years, with low rates of capsular contracture but high levels of revision surgery.

Although several published studies examining complications in ADM-assisted breast reconstructions are available,[13,15–21,23–26] minimal research addressing long-term complications, patient satisfaction, and HR-QoL effects has been carried out. We found only one prospective study with a mean follow-up time of 21 months that evaluated patient satisfaction with SurgiMend as an adjunct to IBR for breast cancer treatment or risk reduction.[26] This study reported a low implant loss rate of 1.2% and high patient satisfaction.

Complication rates regarding hematoma, seroma, and skin flap and nipple necroses identified in our study align with findings from other studies.[17,18,31] Some studies, although not prospective, investigated human and porcine-derived ADM up to 8 and 9 years postoperatively and reported relatively stable results with low overall long-term complication rates.[13,32] Our findings are in line with these studies and suggest that most complications occur within the initial months following surgery.

The overall rate of implant exchange or loss was 33.9%, and this high rate was mainly due to unsatisfactory aesthetic outcomes (26.8%). Implant loss related to early complications was 7.1% (four cases). Previous studies reported varying implant loss rates in bovine ADM-assisted breast reconstructions, ranging from 1.2% to 8.3%.[21,26,27,33] It is mandatory to give preoperative information about this risk to patients, and good outcomes require careful patient selection and meticulous surgical techniques.[31]

In a prospective evaluation by Ellsworth et al,[34] reoperation rates up to 38.5% were reported for IBR with ADM and up to 37.1% without ADM over a 5-year period. In a study conducted by Lohmander at al,[20] immediate IBR with ADM did not result in a reduction of repeat surgery when compared with conventional IBR without ADM.

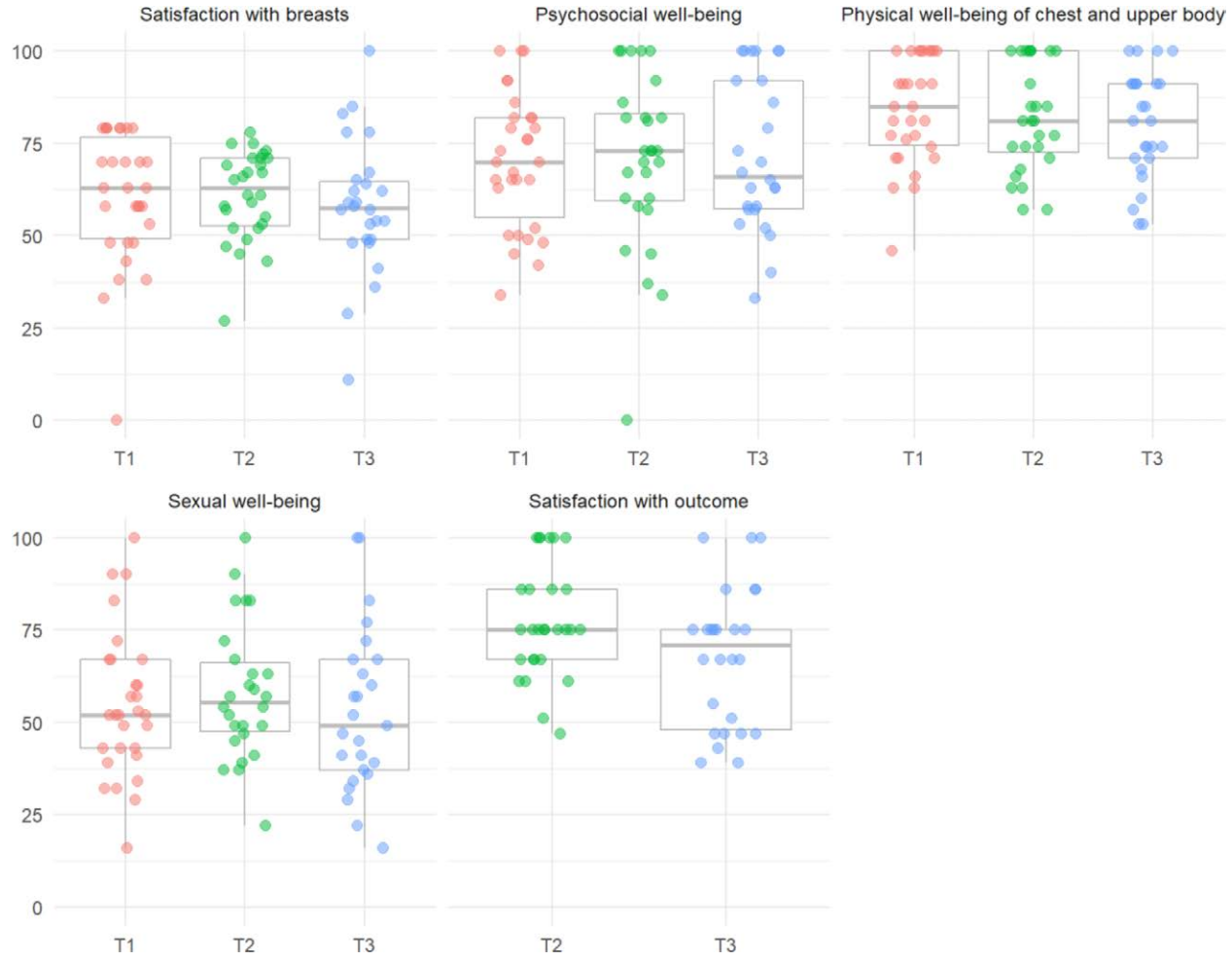

Fig. 1. Distribution of individual values illustrated by BREAST-Q domain and time-point T1 (baseline), T2 (1 year postoperatively), and T3 (5–8 years postoperatively).

These findings indicate a high need for repeat surgery regardless of the use of ADM in implant-based procedures.

Capsular contraction was rare, and most breasts were categorized as Baker grade I/II. Histological analysis of bovine ADM shows a low level of inflammatory reaction,[35] suggesting that ADM causes a reduction in the incidence of capsular contracture in IBR,[13,18,34,36] a finding that aligns with our findings. A meta-analysis of 912 breasts reported zero capsular contracture rate in bovine ADM-supported IBR.[17] In other studies, the incidence of capsular contracture (Baker III/IV) ranged from 3.2% to 13.6%, which is lower compared with reported rates for submuscular IBR without ADM.[13,34] Lisa et al recently reported encouraging results concerning ADM-assisted revision surgery in irradiated breasts to prevent capsular contracture.[37]

RBS is characterized by transient cutaneous erythema over the ADM and is a well-known reaction associated with a reported incidence reaching up to 27%.[38] In our study, "breast redness" (41.1%) included both RBS and suspected or confirmed infections. Distinguishing between these conditions was challenging due to limited availability of fluid for bacterial culturing in most cases. Cultures were obtained whenever possible. Consequently, all women presenting with redness were prescribed oral antibiotics as a precautionary measure to prevent severe infection and implant loss. Antibiotics were ceased once redness subsided, provided signs of infection remained absent. Confirmed infections, with positive bacterial cultures were not noted, which we identify as a limitation of this study. A comparable study by Mazari et al[33] reported a 20% rate of RBS and 25.6% of infection in SurgiMend-assisted breast reconstructions.

Two cases of breast cancer (4.1%) were identified during the long-term evaluation. Women with *BRCA1/2* mutations have a higher risk of ipsilateral recurrence and new primary tumors,[39] and it is well-known that risk-reducing surgery does not completely eliminate the risk of cancer.[3] Controlled trials on recurrence of cancer associated with ADM-assisted reconstructions are needed.[19]

Longitudinal studies using the BREAST-Q questionnaire are few, and most studies using this questionnaire for breast reconstruction with ADM have been cross-sectional and lacked baseline data.[40] To our knowledge, this article describes the first long-term evaluation of HR-QoL following bovine ADM-assisted breast reconstruction with a follow-up period of approximately 8 years.

The BREAST-Q questionnaire was completed by all women pre- and postoperatively, but in women with previous breast conserving surgery, only the healthy breast was included for evaluation of complications. It is important to note that the BREAST-Q results include the overall experience of breast reconstruction, including the experiences of patients with prior breast cancer.

Most variables were relatively stable over time. Even in the domain with the largest mean change and the only one being statistically significant [$P = 0.024$; ie, "satisfaction with outcome" domain (–9.51)], only "a little" change in subjective significance was identified (BREAST-Q User's Guide, version 1.0 suggests that any mean changes of 5–10 be seen as "a little" change).

A decreasing trend in PROs over time was previously reported as a long-term effect of RRM and IBR regardless of reconstruction type.[8,41] Studies comparing PROs of IBR and autologous breast reconstruction show a higher satisfaction with the breasts, overall outcome, and both psychosocial and sexual well-being in patients who undergo autologous reconstruction.[41–43] As all women are not suitable for or do not choose to undergo autologous reconstruction, IBR remains as an option.

Cross-sectional studies evaluating ADM reconstructions with BREAST-Q show satisfactory results,[26,44,45] including higher satisfaction with breasts when comparing ADM reconstruction to submuscular reconstructions without ADM.[13] In other reports, IBR with ADM does not yield better PROs when compared with conventional IBR or two-stage IBR without ADM.[20,22,46] Therefore, selective approaches for the use of ADM should be considered.[46,47]

Dissatisfaction with RRM can be associated with postoperative complications, poor cosmesis and reconstructive problems,[48] and also with inadequate preoperative information,[49] all of which emphasize the need for studies to better inform patients about expected HR-QoL outcomes.

Scores in the domain "psychosocial well-being" showed a slight gradual increase over time. Improved psychosocial well-being was previously reported for both implant and autologous reconstruction.[41] The consistent high score in psychological well-being may be attributed to the reduced concerns about breast cancer.[48]

"Sexual well-being" trended negatively, but no significant change was detected. A negative impact after RRM on sexuality was previously reported. Gahm et al found significantly impaired sensibility, including sexual sensitivity in breasts after RRM.[50,51] Other factors, such as postmastectomy pain syndrome, chest discomfort, and hormonal deficits (in cases of concomitant bilateral prophylactic salpingo-oophorectomy), may also contribute to the negative effect on this domain.

The strengths of this study are the prospective setting, standardized surgical method, presence of preoperative PRO data (baseline), use of the validated BREAST-Q questionnaire, and long follow-up times. To avoid nonresponse bias, only women who completed the BREAST-Q questionnaire at all time-points were included in the statistical analysis.

This study is limited by its small sample size and a single-center design. A randomized study was unattainable due to the limited volume of RRM procedures performed at out hospital. Using a control group consisting of past patients for comparison would not have been appropriate, as surgical techniques have changed over time. This limitation emphasizes the need for larger, multicenter studies to validate and generalize results after RRM and reconstruction.

A nonvalidated questionnaire was used for the long-term evaluation, and no further clinical assessment, including the examination of capsular contracture, was conducted for the patients beyond the first year, representing another limitation.

In conclusion, ADM-assisted immediate IBR is an option for women who are at risk of breast carcinoma. This method presents a stable PRO over time and low capsular contracture but a high level of revision surgery.

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DISCLOSURES

The authors have no financial interest to declare in relation to the content of this article. The acellular dermal matrix used in this study, SurgiMend, was obtained from the manufacturer, TEI Biosciences (Boston, Mass.) as an educational grant. TEI Biosciences had no role in study design, data interpretation, or article preparation.

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