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Mesh versus acellular dermal matrix in immediate implant-based breast reconstruction – A prospective randomized trial

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Abstract

Background: Comparative studies on the use of meshes and acellular dermal matrices (ADM) in implant-based breast reconstruction (IBBR) have not yet been performed.

Methods: This prospective, randomized, controlled, multicenter pilot study was performed at four Austrian breast cancer centers. Fifty patients with oncologic or prophylactic indication for mastectomy and IBBR were randomized to immediate IBBR with either an ADM (Protexa®) or a titanized mesh (TiLOOP® Bra). Complications, failed reconstruction, cosmetic outcome, patients' quality of life and the thickness of the overlying tissue were recorded immediately postoperatively and 3 and 6 months after surgery.

Results: 48 patients participated in the study (Protexa® group: 23; TiLOOP® Bra group: 25 patients). The overall complication rate was 31.25% with similar rates in both groups (Protexa® group: 9 versus TiLOOP® Bra group: 6; $p = 0.188$). There was a higher incidence of severe complications leading to failed reconstructions with implant loss in the Protexa® group than in the TiLOOP® Bra group (7 versus 2; $p < 0.0001$). An inverted T-incision technique led to significantly more complications and reconstructive failure with Protexa® ($p = 0.037$, $p = 0.012$, respectively). There were no significant differences in patients' satisfaction with cosmetic results ($p = 0.632$), but surgeons and external specialists graded significantly better outcomes with TiLOOP® Bra ($p = 0.034$, $p = 0.032$).

Conclusion: This pilot study showed use of TiLOOP® Bra or Protexa® in IBBR is feasible leading to good cosmetic outcomes and high patient satisfaction. To validate the higher failure rates in the Protexa® group, data from a larger trial are required.

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Keywords: Breast; Reconstruction; Mesh; Acellular dermal matrix

Introduction

At the time of breast cancer diagnosis patients have to struggle not only with upcoming systemic therapies and their side effects but also with the fear that there will be a change in their body image after surgery resulting in diminished femininity.

In about one third, mastectomy is indicated and the possibility of immediate or late reconstruction with implants or autologous tissue has to be discussed with the patient at the time of diagnosis and therapy planning. Since skin- and nipple-sparing mastectomies (SSM/

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NSM) have proven to be oncologically safe, the number of immediate implant-based breast reconstructions (IBBR) has increased.[1,2]

Preserving the natural skin envelope and the development of the dual plane technique enabled surgeons to reconstruct the breast immediately with a permanent implant: In patients with ptosis and/or macromastia the implant pocket is defined superiorly by the pectoralis major muscle and inferiorly by the de-epithelialized lower pole mastectomy skin flap using a modified Wise pattern mastectomy reduction mammoplasty incision technique.[3]

In recent years the introduction of acellular dermal matrices (ADM) and synthetic meshes have helped to widen the indication for the dual plane technique to small and non-ptotic breasts by covering the implant's lower pole with the ADM or mesh leading to a so-called internal bra.[4,5]

In recent years many different ADM and mesh products have come onto the market which differ from their origin (human, bovine, porcine), costs and availability around the world.[6,7] The lack of prospective data, reported higher infection and seroma rates in IBBRs with ADMs and the question of cost effectiveness motivated us to conduct a prospective, randomized, controlled, multicenter pilot trial to compare complication rates and cosmetic outcomes between an ADM (Protexa®) and a titanized mesh (TiLOOP® Bra) in immediate IBBR.[8–16]

Materials and methods

Study design

We conducted a prospective, randomized, open, two-arm, multicenter, pilot study in four Austrian breast cancer centers. Cosmetic outcome, complications, patients' quality of life and the correlation of the thickness of tissue covering the implant at the lower pole with the cosmetic outcome and complication rate were defined as study endpoints.

Cosmetic outcome was judged by external specialists and by the surgeon via standardized photographs before and at three visits after surgery (first postoperative visit, and 3 and 6 months after surgery) using a four-point Harris scale (1 = poor, 2 = fair, 3 = good, 4 = excellent).[17]

Patients' quality of life and satisfaction with the cosmetic result were assessed at the same time points using an EORTC QLQ C30 and BR23 questionnaire.

Complications including secondary hemorrhage, wound infection, wound healing problems, hematomas, seromas, skin alterations like erythema or rippling, skin necrosis, and capsular contracture were recorded at these three time points using case report forms.

The thickness of the tissue covering the implant at the lower pole was measured via ultrasound and the correlation with the cosmetic outcome, and the type and rate of complications was analyzed.

Study population

Fifty female patients with breast cancer T1–T3 and patients with an indication for prophylactic mastectomy (such as BRCA 1/2 mutation carriers) over the age of 18 were included in the study between July 2013 and May 2014. Patients with inflammatory breast cancer or prior radiotherapy were excluded.

All cases were previously discussed by the tumor board, including a radiologist's statement concerning the distance of the tumor to the skin and the nipple-areola-complex to ensure SSM or NSM was feasible.

After signing an informed consent form, patients were randomized 1:1 into the TiLOOP® Bra or Protexa® group. Randomization was done using software from the Department of Statistics of the Medical University of Vienna, with online access for the four participating centers.

If the patient was undergoing bilateral mastectomy there was an additional 1:1 randomization to define which breast would be studied.

Materials

TiLOOP® Bra (pfm medical, Cologne, Germany) is made of non-resorbable, titanized, lightweight polypropylene with a monofilament structure.[18]

Protexa® (Tecnoss, Turin, Italy) is a non-cross-linked porcine ADM.[8] According to the manufacturer's instructions Protexa® was placed in sterile saline solution for 15–20 min before use.

For all patients textured anatomical implants were used.

Surgical technique

There was no restriction concerning the type of incision technique used in this study.

In most of the cases, surgeons chose incisions in the inframammary fold, inverted T and periareolar.

After SSM or NSM a subpectoral pocket was created. The inferiomedial pectoralis major muscle was elevated for implant placement. Both the ADM and the mesh were fixed to the inferior border of the released pectoralis major muscle using running resorbable sutures. After placing the implant under the muscle-matrix or -mesh layer, the ADM was fixed with single-button-sutures to define the inframammary fold while the mesh was either fixed in the same way in the inframammary fold or was just put under the textured implant.

For all patients in the ADM group two drains were inserted, one in the subpectoral implant pocket and the other one in the subcutaneous plane, while in patients in the TiLoop® Bra group only one drain was placed in the subpectoral implant pocket. Prophylactic antibiotics were given intra-operatively to all patients.

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Statistics

All parameters were compared between patient groups by χ^2 test, T-test and analysis of variance (one-way ANOVA; Tukey's post hoc test) according to the type of variable (categorical or continuous). In case of skewed data, a non-parametric test (Mann–Whitney test) was applied. A two-sided p-value of <0.05 was considered statistically significant. Statistical calculations were performed using SPSS for Windows, v.22.0 (SPSS Inc., Chicago, IL, USA).

Results

Patient demographics

Fifty patients without prior surgery or radiotherapy were randomized 1:1 into the two groups.

One patient was randomized but withdrew from the study before surgery, another patient was randomized into the Protexa group, but the surgeon decided to use TiLOOP® Bra outside of the study. Of the remaining 48 patients, 25 patients were included in the TiLOOP® Bra group and 23 in the Protexa® group. The mean age of the patients was 48.6 years (TiLoop Bra: 48.07 years (25–72 years); Protexa: 47.12 years (30–64 years)) and the mean BMI was 23.42 kg/m^2 (19–30 kg/m^2) in the TiLoop Bra group and 25.21 kg/m^2 (21–33 kg/m^2) in the Protexa group. We found no significant differences in patient characteristics between the two groups (Table 1).

There were 28 unilateral and 20 bilateral mastectomies with 26 NSM and 22 SSM. An inframammary approach was used in 14 cases, an inverted T-technique in 16 cases, and other incision techniques like periareolar or tennis racket in 18 cases.

The indication for surgery was oncological in 31 patients (21 with invasive breast cancer and 10 with ductal carcinoma in situ), 10 prophylactic mastectomies, and 7 patients with unilateral breast cancer and a prophylactic contralateral mastectomy.

Postoperative radiotherapy was administered to four patients in the Protexa® group and no patients in the TiLOOP® Bra group (p = 0.029). Three of these patients received radiotherapy to the chest wall and one to the local lymphatic system only. Only one of these patients had a failed reconstruction because of an early complication (wound healing problem) before radiotherapy was administered. Neoadjuvant chemotherapy was administered to one patient in the TiLOOP® Bra group and three patients in the Protexa® group. One patient with neoadjuvant chemotherapy from the Protexa® group had a failed reconstruction because of a surgical site infection (p = n.s.).

There was no difference between the two study groups regarding antibiotic use and duration (p = n.s.).

Prophylactic intraoperative antibiotics were given to all patients, with a cephalosporin used in most of the patients (45/48 patients, 93.75%). Seventeen patients received postoperative antibiotics for only the first 24 h after surgery, while five patients were treated with intravenous antibiotics the first 3 days after surgery. Postoperative antibiotic therapy was continued intravenously in 18 cases until drains were removed, and in 8 cases for 5–7 days although drainage was kept for a few days longer. Oral antibiotic therapy was continued in two patients in the TiLOOP® Bra group and six patients in the Protexa® group.

Regarding drainage we found a statistically significant use of more drains in the ADM group (p = 0.001), while we found no significant difference in the number of days drains stayed in situ between the two groups (p = 0.911).

Table 1
Patient characteristics. BMI = body mass index, NSM = nipple sparing mastectomy, SSM = skin sparing mastectomy, IMF = inframammary fold, SNB = sentinel node biopsy, CHT = chemotherapy, RT = radiotherapy, i.v. = intravenous, p.o. = per os; [a] = Median test, [b] = Chi-squared test.

	TiLOOP® Bra (n = 25) (%)	Protexa® (n = 23) (%)	p-Value
Mean age (years)	48.07	47.12	0.15[a]
Mean BMI (kg/m^2)	23.42	25.21	0.66[a]
Indication for surgery			
Malignancy	15 (60.0%)	16 (69.6%)	0.48[b]
Prophylaxis	6 (24%)	4 (17.4%)	
Both	4 (16%)	3 (13.0%)	
Preoperative bra size			
A, B	13 (52%)	9 (39.1%)	0.54[b]
C, D	12 (48%)	14 (60.9%)	
Mean implant size (cc)	320	339	n.s.[b]
NSM	14 (56%)	12 (52.2%)	n.s.[b]
SSM	11 (44%)	11 (47.8%)	n.s.[b]
Incision technique			
IMF	7 (28%)	8 (34.8%)	n.s.[b]
Inverted T	9 (36%)	8 (34.8%)	n.s.[b]
Other	9 (36%)	7 (30.4%)	n.s.[b]
SNB	13 (52%)	12 (52.2%)	0.26[b]
Axillary dissection	5 (20%)	4 (17.4%)	n.s.[b]
Mean drainage duration (days)	10.44	12.04	0.91[a]
Mean duration of antibiotic therapy (days)			
i.v.	5.32	5.35	
p.o.	0.56	2.17	
Overall	5.88	7.5	n.s.[a]
Adjuvant CHT	3 (12%)	5 (21.7%)	n.s.[b]
Neoadjuvant CHT	1 (4%)	3 (13.0%)	n.s.[b]
Postoperative RT	0 (0%)	4 (17.4%)	0.029[b]

Complications and consequences

The overall complication rate was 31.25% with nine complications (39.1%) in the Protexa® group (three seromas, three infections, two wound healing problems, and one red breast syndrome) and six (24.0%) in the TiLOOP® Bra group (one seroma, one infection, two hematomas, and two wound healing problems), but the difference was not statistically significant (p = 0.188). The complication "infection" was defined in clinical signs of infection and

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the use of additional antibiotics. The wound healing problems in both groups were associated with the inverted T-incision technique leading to skin necrosis and/or wound dehiscence at the T-junction.

There was a statistically significant difference in the number of complications leading to failed reconstructions with implant loss, with seven failures in the Protexa® group (30.4%) versus two failures in the TiLOOP® Bra group (7.7%) ($p < 0.0001$; Pearson Chi-square test).

We then analyzed the impact of the following parameters on the complication rate and failed reconstruction rate: incision technique, patient's BMI, age, preoperative bra size, implant size, NSM versus SSM, drainage days, antibiotics, thickness of tissue above the implant measured by ultrasound, indications for mastectomy (oncologic versus prophylactic), pre- and post-operative chemotherapy, and postoperative radiotherapy. The analysis showed a significantly higher rate of complications in those patients undergoing mastectomy for oncological reasons ($p = 0.020$), and in those in whom the inverted T-incision technique was used rather than incision techniques like the IMF or periareolar (10 of 15 complications; $p = 0.034$). However for these 2 parameters there was no significant correlation with the rate of failed reconstruction ($p = 0.75$ and $p = 0.059$, respectively). While the correlation of the inverted T-incision technique with the complication rate and the failure rate was significant in the Protexa® group ($p = 0.037$ and $p = 0.012$, respectively), no significant association was found in the TiLOOP® Bra group ($p = 0.483$ and $p = 0.367$).

Thickness of tissue overlying the lower pole of the implant

There was no statistically significant difference regarding the measurements of the thickness of tissue overlying the lower pole of the implant by ultrasound between the two groups at all three time points. The median measured thickness in the postoperative period was 8.2 mm in the TiLOOP® Bra versus 7.3 mm in the Protexa® group ($p = 0.72$), 8.2 mm versus 6.3 mm 3 months after surgery ($p = 0.13$), and 7.9 mm versus 6.3 mm 6 months after surgery ($p = 0.63$).

QoL questionnaire

There were statistically significant differences between the two treatment groups in the results of the QoL questionnaire at three time points (postoperative within 2 weeks, after 3 months and after 6 months). At the first visit after surgery, a higher proportion of patients in the Protexa® group had more arm pain ($p = 0.039$) and more fatigue ($p = 0.03$). Six months later, a higher proportion of patients in this group showed more affected family life ($p = 0.021$), and less sexual interest ($p = 0.039$) (Table 2).

Table 2
Differences in quality of life parameters. This table shows the significant differences at the first postoperative visit and 6 months after surgery. Each parameter in the questionnaire had to be answered on a scale of 1–4 (1 = not at all to 4 = a lot), for example the impact on family life: none to a lot; Chi-square test.

Quality of life parameter number (%) of patients with:	TiLOOP® Bra N = 25	Protexa® N = 23	p-Value
First visit after surgery			
Arm pain (scale >1)	6 (24%)	11 (47.8%)	0.039
Fatigue (scale 3, 4)	3 (12%)	8 (34.8%)	0.03
6 months after surgery			
Family life (scale >2)	0 (0%)	4 (17.4%)	0.021
Sexual interest (scale 3–4)	12 (48%)	4 (17.4%)	0.039

We investigated parameters influencing the quality of life of our patients and found significant differences between patients with oncologic and prophylactic indications for mastectomy 6 months after surgery. Women who had undergone prophylactic mastectomy showed significantly more overall postoperative pain ($p = 0.033$), fatigue ($p = 0.014$), pain at the operated breasts (0.016) and problems with the skin at the operated breasts ($p = 0.020$). Breast cancer patients had less joy at sexual intercourse than patients after prophylactic mastectomy ($p = 0.017$) (Table 3).

Cosmetic outcome

Patient's satisfaction with the cosmetic outcome was very good and excellent in 87.5% of patients in the TiLOOP® Bra group versus 79.0% in the Protexa® group; the difference was not statistically significant ($p = 0.632$). Examples of the cosmetic outcome validated by medical professionals using the Harris Scale are shown in Fig. 1.

Including all patients, there was a statistically significant better cosmetic outcome in the TiLOOP® Bra group six months after surgery, as validated by the surgeon and 2 independent external specialists who validated standardized photographes and were blinded to the type of ADM/mesh used (Harris Scale 3 and 4: TiLOOP® Bra 95.8% versus Protexa® 72.7%; surgeon: $p = 0.034$ and external specialists: $p = 0.032$, respectively) (Fig. 2).

Table 3
Differences in quality of life depending on the indication of surgery based on the quality of life questionnaire 6 months after surgery. Each parameter in the questionnaire had to be answered on a scale of 4 (1 = not at all to 4 = a lot); Patients with both oncological on one side and prophylactic indication on the contralateral side were excluded from this calculation. Chi-square test.

Quality of life parameter	Malignancy N = 31 (%)	Prophylaxis N = 10 (%)	p-Value
Pain (scale >1)	9 (29%)	4 (40%)	0.033
Fatigue (scale >1)	8 (26%)	7 (70%)	0.014
Breast pain (scale >1)	11 (35%)	8 (80%)	0.016
Breast skin problems (scale >1)	0 (0%)	3 (30%)	0.020
Joy sexual intercourse (scale 1)	9 (29%)	0 (0%)	0.017

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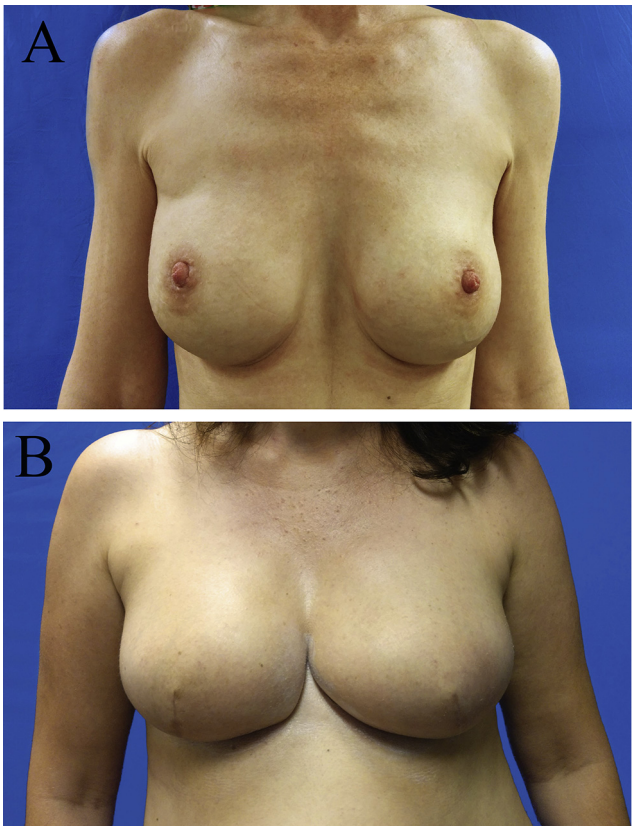

Figure 1. A Patient with bilateral nipple sparing prophylactic mastectomy through an inframammary approach with IBBR using TiLOOP® Bra. Harris Scale: 4. B Patient with skin sparing mastectomy using a modified Wise pattern (inverted T) incision technique and an IBBR with Protexa®. Harris Scale: 4.

When the cases with failed reconstructions were excluded from the analysis, no differences were found between the treatment groups in the cosmetic results validated by medical professionals 6 months after surgery (surgeon: $p = 0.92$, external specialists: $p = 0.3$).

Discussion

Our prospective, randomized pilot study underlines the value of TiLOOP® Bra and Protexa® in immediate direct-to-implant breast reconstruction. Both materials achieved high levels of patient satisfaction with the cosmetic result, with the majority of patients rating the cosmetic outcome as very good or excellent, with similar overall complication rates.

However, patients in the Protexa® group were more likely to have severe complications leading to failed reconstruction with implant loss. When we excluded patients with failed reconstructions, we found similar cosmetic results in the two groups validated by medical professionals.

Generally, our results are difficult to compare with other studies because of the lack of data, and in particular the lack of prospective data, directly comparing these two products using clinical endpoints. Some data show comparable complication rates with or without ADM.[19]

Complication rates range between 17.7 and 29% for titanium-coated meshes and 0–32% for biological matrices, while complications after IBBR without the use of mesh or ADM are reported to be about 15%.[14–17] Pannucci et al. looked at the rate of expander/implant loss of

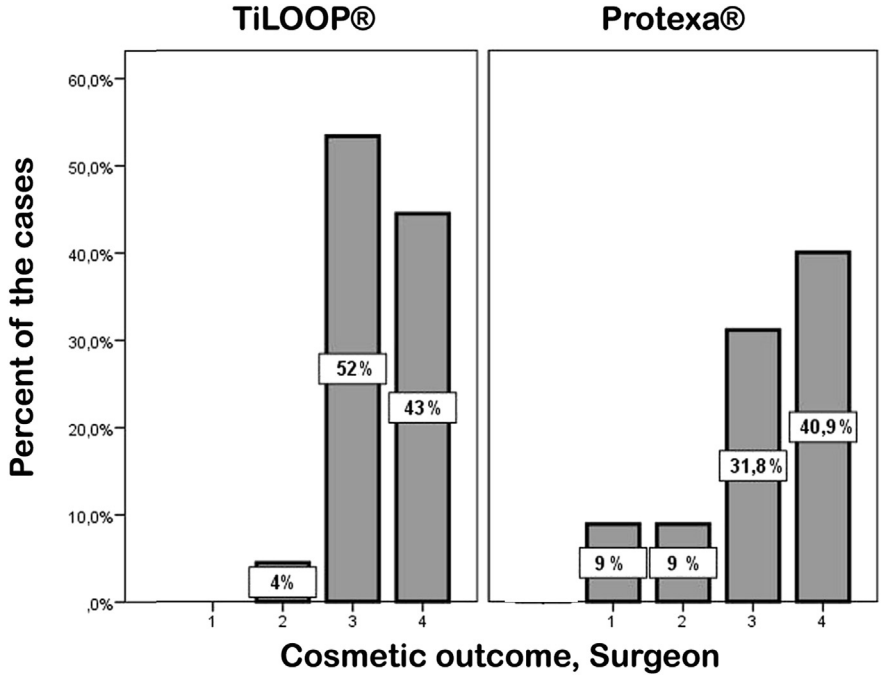

Figure 2. Cosmetic result including patients with failed reconstruction judged by the surgeon six months after surgery. Harris Scale: 1 = poor to 4 = excellent.

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14,249 patients and found that the use of ADM was associated with a 0.7 percent absolute risk increase for expander/implant loss.[20]

In contrast, Potter et al. showed no difference between IBBR with and without Protexa (overall complication rate 26.1%, p = 0.95). They reported six cases of implant loss, of which four were in the Protexa group (p = 0.968) but all were associated with pre-reconstruction radiotherapy. These data are difficult to compare to our data because of the retrospective trial design and the inclusion of irradiated patients. They conclude that robust prospective evaluation is needed to definitely evaluate the role of ADM in IBBR.

The use and the duration of antibiotics is another important point for IBBR. Our study confirms the results of Phillips et al. and Townley et al., who conclude that there is no recommendation for prolonged postoperative antibiotics in IBBR.[21,22]

Even if our study is limited by the small study population, we could show that different antibiotic strategies (type of antibiotics and duration) did not influence the complication rates in both study groups.

In contrast to other studies, we did not find an association between age or BMI with increased complication rates.[23,24]

We hypothesized that the thickness of the tissue overlying the implant at the lower pole influences the cosmetic outcome and the complication rate. We suggested that ADM-assisted reconstructions would show thicker tissue layers than mesh-assisted reconstructions because of the inherent thickness of the material. The results of our study showed no difference in the thickness of tissue and no association with cosmetic outcome or complication rate at all three time points. These findings are limited by the small sample size and by the fact that ultrasound measurement of the thickness of tissue at the lower pole is a non validated tool.

Regarding the surgical technique, our study showed significantly more postoperative complications with the use of inverted T-incision techniques. The higher complication rates associated with this technique of about 30%, especially the risk of skin necrosis at the T-junction, have already been reported.[3]

Interestingly and not reported until now, the inverted T-incision led to higher complication rates and failure rates only in the Protexa® group.

Looking at the quality of life of our patients, we found worse results in the Protexa® group (a higher proportion of patients with more arm pain, p = 0.039; more severe fatigue, p = 0.03; more affected family life, p = 0.021; less sexual interest; p = 0.039).

Currently, the decision which mesh or matrix to use is not based on prospective randomized data. Nevertheless, there are special indications for the use of an ADM like thin skin coverage under 8 mm where the TiLOOP® Bra is not recommended. However, until now published data were not available to confirm this statement.

There are indications where an ADM could be advantageous compared to a titanized mesh such as in revisional breast surgery or after irradiation: retrospective data suggest that there is better blood flow to the irradiated skin and a decreased rate of capsular contracture.[25–29]

However, in terms of risk of reconstructive failure, cosmetic outcome evaluated by medical professionals, and patient's quality of life, our pilot study underlines the value of TiLOOP® Bra in immediate direct-to-implant breast reconstruction in selected patients without additional risk factors.

However, to verify the results of this study, which showed a higher risk of implant loss associated with the use of an ADM (Protexa®), larger prospective randomized trials with different ADMs and mesh products are warranted.

Ethical approval

The ethical board of the Medical University of Vienna as well as the local Institutional ethical boards of the participating breast cancer centers in Linz, Graz, and Villach as well as the Austrian Agency for Health and Food Safety (AGES) approved this study.

Conflict of interest

The authors declare no conflict of interest in this investigator-driven study.

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