Implant-Based Breast Reconstruction Using a Titanium-Coated Polypropylene Mesh (TiLOOP Bra): A Multicenter Study of 231 Cases

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Background: An alternative to implant-based breast reconstruction using acellular dermal matrix is the use of a titanium-coated polypropylene mesh. The mesh was approved for implant-based breast reconstruction in Europe in 2008, but only limited clinical data are available.
Methods: Two hundred seven patients (231 breasts) with skin-sparing/nipple-sparing or modified radical mastectomy and immediate or delayed implant-based breast reconstruction using titanium-coated polypropylene mesh were evaluated retrospectively. The primary endpoints were identification of patient-related and surgical factors that were predictive for an adverse outcome and the development of recommendations for patients eligible for implant-based breast reconstruction using the mesh. Complications were divided into major (need for additional surgery), minor (conservative treatment), and implant loss. Univariate and multivariate logistic regression analyses were performed to determine the influence of the patient- and procedure-related characteristics on postoperative complications and implant loss.
Results: No risk factors were observed for patient-associated complications. Major complications occurred in 13.4 percent, minor complications in 15.6 percent, and implant loss in 8.7 percent of patients. Univariate analysis revealed procedure-related risk factors for postoperative complications with a bilateral procedure ($p = 0.013$) or skin expansion before implant surgery ($p = 0.043$). Multivariate analysis confirmed these risk factors and revealed an increased risk for implant loss in patients with skin necrosis ($p < 0.001$) and capsule fibrosis ($p < 0.001$).
Conclusions: This titanium-coated polypropylene mesh shows acceptable complication rates and can be a helpful device in implant-based breast reconstruction. The mesh should only be used in primary cases and, when adhering to the proposed indications, is a safe and convenient option in implant-based breast reconstruction. (*Plast. Reconstr. Surg.* 132: 8e, 2013.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Risk, III.

Skin- and nipple-sparing mastectomies are oncologically safe procedures that have been frequently used over the past decade.[1] Although autologous breast reconstruction is the standard reconstructive procedure, with excellent cosmetic results, an increase in implant-based breast reconstruction has been observed.[2,3] However, some patients are not suited for or do not wish to undergo autologous breast reconstruction. The reasons include an increased indication

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for mastectomy, mainly prophylactic mastectomies resulting from *BRCA1/2* gene mutations and prophylactic contralateral mastectomies. The additional development and use of new materials, such as acellular dermal matrix, that are being increasingly discussed in the literature might have contributed to this increase. Donor-site morbidity can be spared, and the surgical extent and patient impairment are being reduced.[4–6] The additional advantages of these supportive interpositional materials are based on the reduced surgical time compared with autologous tissue reconstruction. Alternative procedures, such as the dual-plane technique, in which no additional matrices are used, also produce excellent results. The limitations are associated with higher risks for implant migration, malpositioning of the inframammary fold, and poor implant coverage at the lower lateral and inferior poles.[4,7] Acellular dermal matrix has been described to overcome these difficulties and has been frequently used since its introduction.[5,6,8–17] The use of different available matrices in implant-based breast reconstruction results in implant stability at the inferolateral pole; improved definition of the inframammary fold with a better lower pole projection; and reduced implant migration without recruiting the anterior rectus fascia, pectoralis major, and/or serratus anterior muscles to cover the implant.[18–20]

A possible alternative to acellular dermal matrix is the application of a titanium-coated polypropylene mesh, which was approved for breast reconstruction in Europe in 2008. The surgical approach is identical to that used in acellular dermal matrix reconstruction and has been described previously.[21] However, the indications for applying acellular dermal matrix or titanium-coated polypropylene mesh differ considerably based on the surgeon's experience, the patient's skin condition, and the approval status of the device. Despite limited clinical data regarding its safety and outcomes, this mesh is widely used in Europe and has been recommended by the German Arbeitsgemeinschaft Gynäkologische Onkologie–Breast Study Group (Oxford LoE 2b).[22] In this retrospective multicenter study, we investigated the largest cohort of patients undergoing implant-based breast reconstruction using titanium-coated polypropylene mesh.

PATIENTS AND METHODS

Between April of 2008 and October of 2011, we performed a retrospective, multicenter, observational study of 207 patients who underwent skin- or nipple-sparing mastectomies or modified radical mastectomy with immediate or delayed breast reconstruction using titanium-coated polypropylene mesh (TiLOOP Bra; pfm medical, Cologne, Germany). Informed consent from the patients was not required, as the data were evaluated retrospectively and anonymously. The study was conducted in conformity with the Declaration of Helsinki.[23] The first author (M.D.), together with the corresponding surgeon of each center, reviewed all patient charts and data to eliminate a possible bias.

Study Aims

The primary study endpoints were the identification of patient and surgical factors predictive of an adverse outcome and the development of recommendations for patients eligible for implant-based breast reconstruction using titanium-coated polypropylene mesh. The secondary study outcomes were the prevalence rates of complications and implant failure.

Patient Selection

The patient selection criteria for titanium-coated polypropylene mesh breast reconstruction were similar to those used for breast reconstruction with acellular dermal matrix.[24] The primary candidates for implant-based breast reconstruction using the mesh were patients eligible for skin- and nipple-sparing mastectomy. The preoperative assessment included information about the pros and cons of different reconstructive procedures in conformity with the patient expectations. The patient demographics, including age, body mass index, and comorbidities, were registered. The surgical procedures were divided into no previous surgery, major previous surgery, and minor previous surgery.

Major operations included skin-sparing mastectomy, nipple-sparing mastectomy, and modified radical mastectomy (with and without previous expansion). Minor previous operations were defined as breast-conserving therapy with or without axillary or sentinel lymph node biopsy. The history of radiotherapy and chemotherapy was recorded. Both events were classified as either before or after implant-based breast reconstruction.

All patients required a follow-up of at least 4 weeks, as demanded for the standard definition of surgical-site infections by the Centers for Disease Control and Prevention and the National Nosocomial Infection Surveillance System.[25]

The mean follow-up was defined as the interval between surgery and the most recent follow-up evaluation.

Surgical Technique Using Titanium-Coated Polypropylene Mesh

To ensure a high level of surgical expertise, all patients were operated on (mastectomy and reconstruction) by a gynecologic breast surgeon certified by the Working Group for Plastic, Aesthetic and Reconstructive Surgery in Gynecology.[26] The patients were generally evaluated for autologous or alloplastic surgery, considering factors such as patient preference, body habitus, comorbidities, and prior abdominal surgery. The surgical technique using titanium-coated polypropylene mesh has been described previously.[24] In short, patients with a mid-sized breast appeared most suited for implant-based breast reconstruction. The mastectomy incision was chosen according to the tumor location and breast size and shape. Whenever possible, the incision was placed in the inframammary fold or as a tennis racket incision. Care was taken to create viable mastectomy flaps while also removing all visible breast tissue in the retroareolar region. The mesh was sutured to the lower muscle border with either running or interrupted resorbable sutures. No antibiotic rinse was used over the titanium ligation. The implant was placed in the definite submuscular position, and the mesh was spread over the implant and fixed to the inframammary fold either by single sutures or by wrapping around the implant (Fig. 1). Drains were placed in the epipectoral and subpectoral spaces and removed when the fluid amount was less than 20 to 30 cc per day. Antibiotics were given as a single intravenous perioperative prophylactic injection and continued as long as the drains remained in place.

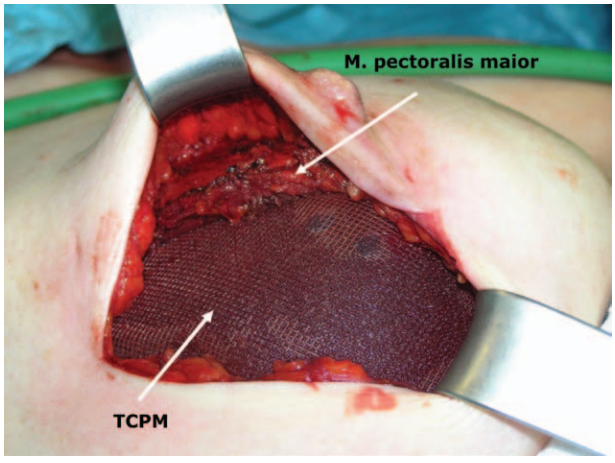

Fig. 1. Intraoperative view of titanium-coated polypropylene mesh (*TCPM*).

Complications

Complications were divided into major and minor complications as described by Lin et al.[27] Major complications were defined as those events related to the reconstruction with titanium-coated polypropylene mesh that required additional surgical intervention: infections, wound dehiscence, skin necrosis, seromas, and hematomas. Infections were considered surgical complications when the previously adequate course of intravenous antibiotics was unsuccessful and surgical revision was needed.

Minor complications were those events that could be treated conservatively without surgical intervention. These included local infections with successful antibiotic treatment and superficial hematomas and seromas that could be treated with puncture and compression. Implant failure was defined as any type of device failure needing revision surgery.

Statistical Analysis

Statistical analyses were performed using IBM SPSS for Windows Version 19.0 (IBM Corp., Armonk, N.Y.) to evaluate the extent to which procedure- and patient-related characteristics were predictive of postoperative complications in general. A similar analysis was performed to distinguish between risk factors for major and minor complications. In addition, an analogous analysis examined how these characteristics correlated with implant loss, as reported by Kobraei et al.[28]

First, univariate analyses were performed to reveal the unadjusted significant associations between prognostic variables. The univariate analysis of the patient-related characteristics included smoking history, hypertension, diabetes mellitus, age, body mass index, and radiotherapy and chemotherapy histories. The procedure-related characteristics included previous expander or implant surgery, other previous breast operations, lymph node status, axillary treatment, surgery performed in combination with titanium-coated polypropylene mesh, implant shape, primary or secondary breast reconstruction, unilateral versus bilateral, and reconstructive versus prophylactic procedure. Thereafter, variables yielding values of $p \leq 0.05$ in the univariate analyses were entered into the multivariate model to highlight some adjusted associations between the outcome and covariates. All patient- and procedure-related characteristics were applied as binary explanatory variables. The

continuous variables of age and body mass index were converted into binary explanatory variables to facilitate a clinically relevant assessment of their impacts on the outcome. Others have described this approach, and mean values of 50 years and 27 kg/m^2 were defined, as reported previously.[29,30]

Odds ratios were determined to estimate the relative risks of postoperative complications and implant loss, with an odds ratio greater than 1.0 indicating an increased risk for a reduced outcome when the characteristic is present. A value of $p < 0.05$ was considered to be significant, and a 95 percent confidence interval was generated for the true value of each odds ratio.

RESULTS

A total of 207 patients (231 breasts) underwent implant-based breast reconstruction using titanium-coated polypropylene mesh. Patients had a mean (±SD) age of 47 ± 11.6 years (range, 24 to 74 years) and a mean body mass index of 23 ± 3.5 kg/m^2 (range, 16 to 39 kg/m^2). Diabetes and smoking were recorded for seven and 34 patients, respectively. Of the 231 mastectomies, 173 were of curative intent and 58 were prophylactic because of *BRCA1/2* gene mutations or patient desire (Table 1). A bilateral procedure was performed in 24 patients. The remaining 183 patients had unilateral procedures. Major and minor operations were performed in eight and 26 patients, respectively, before implant-based breast reconstruction with the mesh. The patient recruitment per institute ranged from 14 to 81 patients. A case series of patients is shown in Figures 2 and 3.

General complications occurred in 67 breasts (29 percent), major complications occurred in 31 breasts (13.4 percent), and minor complications occurred in 36 breasts (15.6 percent). In 18 patients (7.8 percent), the mesh had to be removed. Implant loss occurred in 20 breasts (8.7 percent). Capsule fibrosis was increased in patients with major complications (p = 0.018). Further surgical complications grouped according to minor and major complications are listed in Table 2. Mesh extrusion was observed in none of the patients who had revision surgery before possible implant extrusion (e.g., in patients with skin necrosis).

Table 1. Indications for Operations Using Titanium-Coated Polypropylene Mesh

Indication	No. of Patients*	No. of Breasts
Curative mastectomy	153	173
Prophylactic mastectomy	34	58
Total	187	231

* In four patients, unilateral curative mastectomy was combined with contralateral prophylactic mastectomy, resulting in a total of 187 patients rather than 183.

The mean follow-up was 14 months (range, 1 to 41 months). In 202 breasts, immediate implant-based breast reconstruction was performed. Major complications occurred in 25 breasts (12.4 percent) and minor complications occurred in 34 breasts (16.8 percent). Secondary implant-based breast reconstruction was performed in the remaining 29 breasts. Major complications occurred in six breasts (20.7 percent) and minor complications occurred in two breasts (6.9 percent).

Influence of Patient- and Procedure-Related Characteristics on Postoperative Complications

None of the patient-related characteristics was a significant risk factor for major or minor complications (Table 3). The univariate analysis of the procedure-related characteristics for major and minor complications revealed an increased risk for complications when skin expansion was performed before mesh use compared with an immediate implant procedure (p = 0.043; odds ratio, 8.400; 95 percent CI, 0.951 to 74.185) and in patients with a bilateral procedure (p = 0.013; odds ratio, 0.248; 95 percent CI, 0.088 to 0.704) (Table 4). The multivariate analysis confirmed these risk factors.

Influence of Patient- and Procedure-Related Characteristics as Risk Factors for Implant Loss

No patient-related characteristics were correlated with implant loss in patients undergoing implant-based breast reconstruction with mesh (Table 5). In the univariate model, only reconstruction after modified radical mastectomy with the mesh was significantly associated with implant loss (p = 0.043; odds ratio, 5.500; 95 percent CI, 1.248 to 24.240) (Table 6).

Infection-Related Characteristics as Risk Factors for Implant Loss

Postoperative capsule fibrosis (p = 0.001; odds ratio, 26.125; 95 percent CI, 4.442 to 153.665) and skin necrosis (p = 0.004; odds ratio, 10.300; 95 percent CI, 2.515 to 42.178) were both univariate risk factors for implant loss (Table 7) and were independently confirmed in the multivariate analysis.

DISCUSSION

Implant reconstruction after skin- or nipple-sparing mastectomy is associated with satisfying results and is the most common procedure for filling the mastectomy defect.[3,31] Predominantly

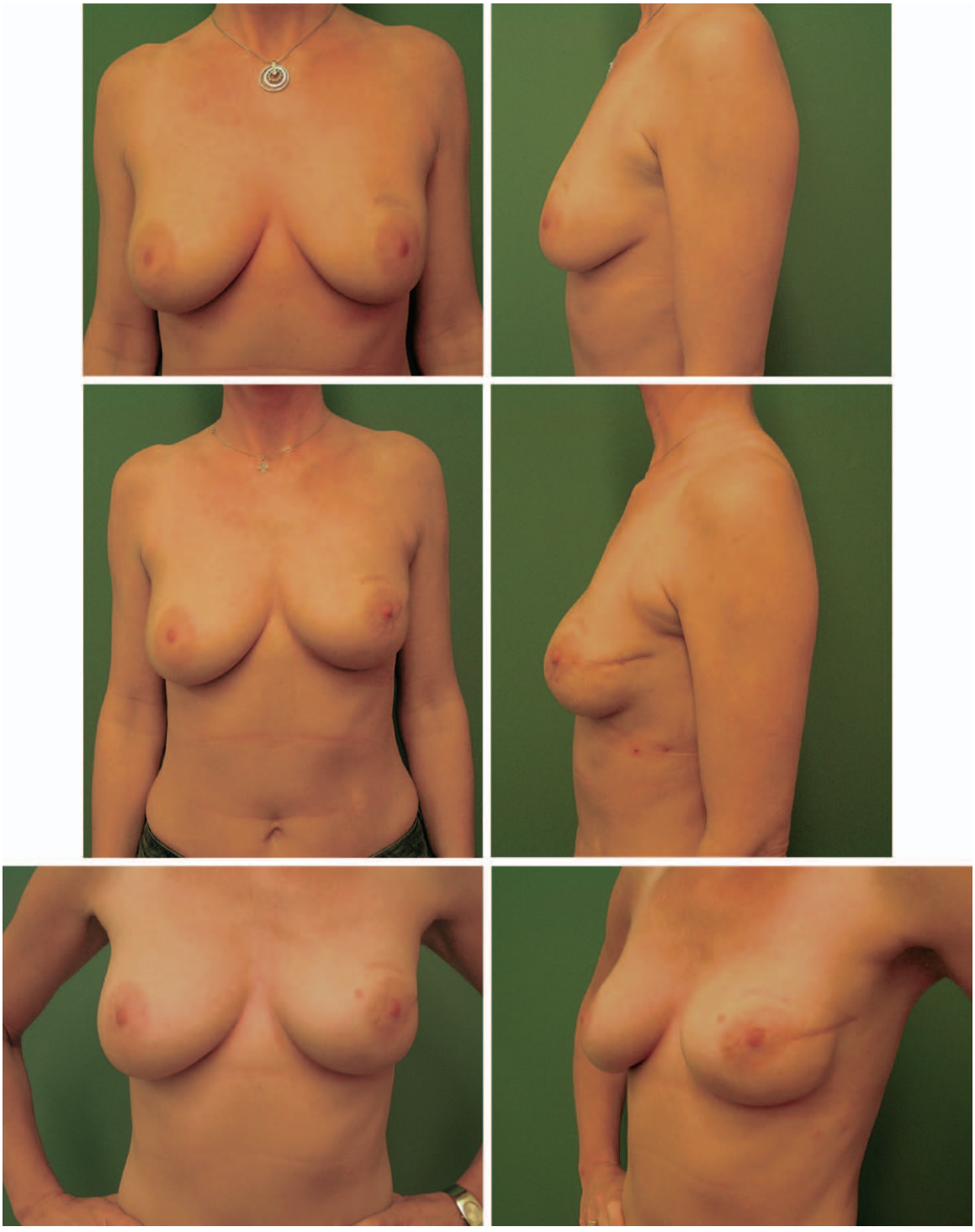

Fig. 2. (*Above*, *left*) Before subcutaneous nipple-sparing mastectomy with implant-based breast reconstruction and titanium-coated polypropylene mesh, left breast (patient with ductal carcinoma in situ who was not eligible for breast-conserving therapy). (*Above*, *right*) Lateral view before surgery. Left breast 2 months after surgery, frontal (*center, left*) and lateral (*center, right*) views. Left breast 6 months after surgery, frontal (*below*, *left*) and oblique (b*elow*, *right*) views.

biological meshes, supporting implant-based breast reconstruction, have been introduced in recent years, and data on acellular dermal matrix in implant-based breast reconstruction have become increasingly available. Implant-based breast reconstruction using titanium-coated polypropylene mesh is a novel approach widely used in Europe, despite the lack of clinical studies.

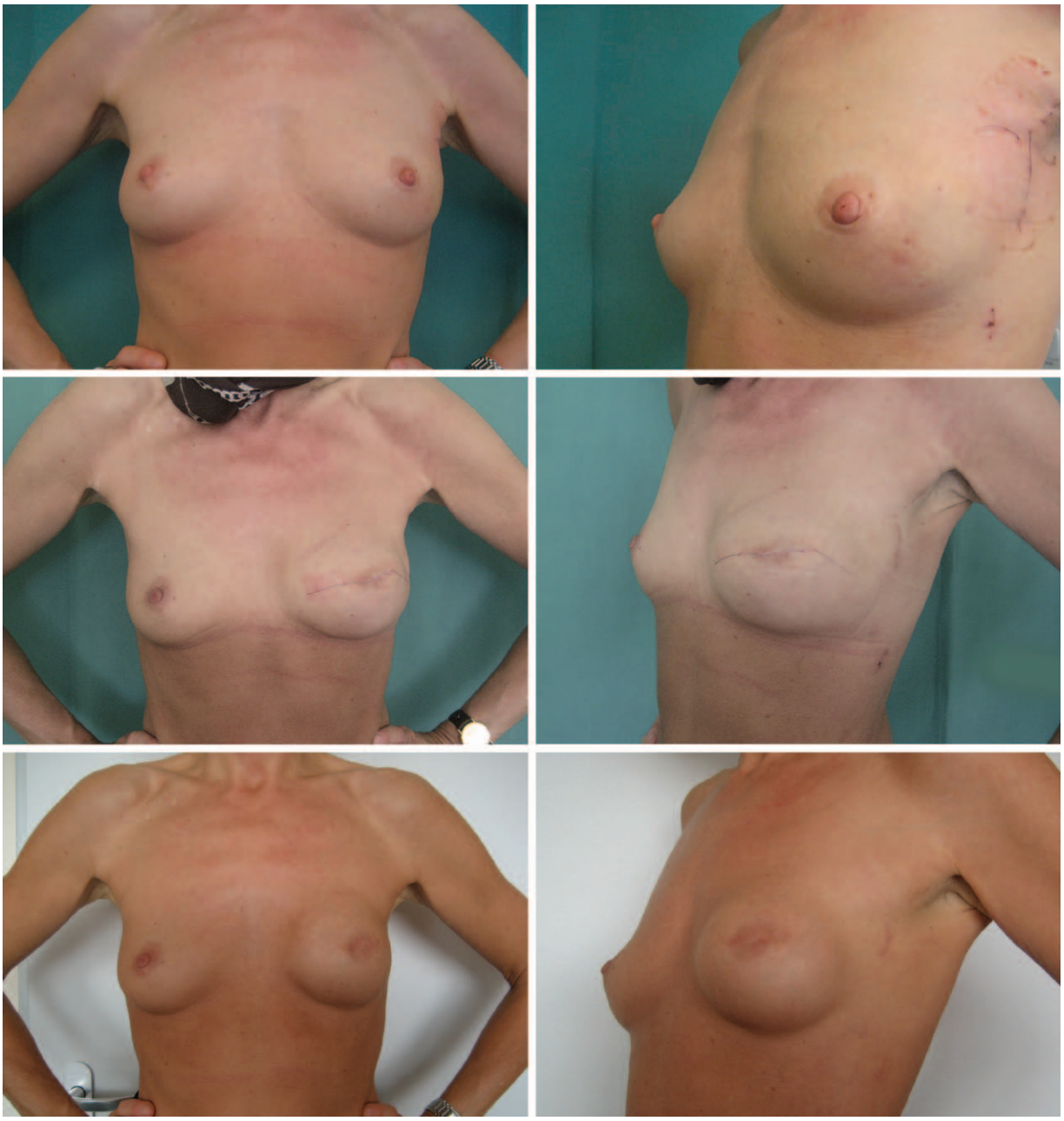

Fig. 3. (*Above*, *left*) Invasive breast cancer (left breast) with accompanying ductal carcinoma in situ after breast-conserving attempt (before skin-sparing mastectomy). (*Above*, *right*) Before skin-sparing mastectomy, oblique view. Immediately after skin-sparing mastectomy and implant-based breast reconstruction with titanium-coated polypropylene mesh, frontal (*center, left*) and oblique (*center*, *right*) views. Left breast 6 months postoperatively, frontal (*below, left*) and oblique (*below*, *right*) views.

The identification of patient- and surgery-related risk factors is important when reporting on a new technique. The complications should be comparable with those of established procedures, such as no additional matrix or the "standard of care," which is acellular dermal matrix in this case. Moreover, comparing individual studies in general has a methodologic bias, which is partially responsible for the conflicting and large range of reported complications. Our attempt was to reduce this bias by defining complications and risk factors as described in previous outcome studies.[27–30] Prospective randomized clinical studies comparing implant-based breast reconstruction with acellular dermal matrix, titanium-coated polypropylene mesh, or none of them does not appear

Table 2. Overall Complications with Titanium-Coated Polypropylene Mesh and Subgroup Analysis of Surgical Complications Grouped According to Minor and Major Complications

Characteristic	Minor Complication	Major Complication	*p**	Overall (%)
Total	36	31		231
Postoperative seroma	7	4	0.351	11 (4.8)
Superficial hematoma	17	5	0.007	22 (9.5)
Skin infection	10	4	0.116	14 (6.1)
Skin necrosis	3	6	0.169	9 (3.9)
Necrosis of the nipple	6	2	0.183	8 (3.5)
TCPM explantation	0	18	<0.001	18 (7.8)
Mastectomy flap necrosis	0	1	—	1 (0.4)
Capsule fibrosis	0	5	0.018	5 (2.2)

TCPM, titanium-coated polypropylene mesh.
*Fisher's exact test.

Table 3. Univariate Analysis of Patient-Related Characteristics as Risk Factors for Major and Minor Postoperative Complications*

Characteristic	Odds Ratio	95% CI	*p*
Smoking	1.920	0.488–7.549	0.495
Hypertension	1.808	0.510–6.409	0.542
Diabetes mellitus	0.455	0.349–0.592	0.463
Age > 50 yr	2.813	1.002–7.895	0.073
BMI > 27 kg/m^2	0.444	0.104–1.890	0.320
Radiotherapy†	0.428	0.077–2.379	0.437
Chemotherapy	0.724	0.258–2.030	0.608
Neoadjuvant/history of chemotherapy	1.742	0.371–8.177	0.704
Adjuvant	0.418	0.114–1.532	0.227

BMI, body mass index.
*Multivariate analysis was not performed, as none of the patient-related characteristics proved to be statistically significant for either major or minor complications.
†The influence of preoperative and postoperative radiotherapy was not evaluated because only two patients received radiotherapy after implant-based breast reconstruction with titanium-coated polypropylene mesh; four patients received radiotherapy before surgery.

Table 4. Univariate Analysis of Procedure-Related Characteristics as Risk Factors for Major and Minor Postoperative Complications*

Characteristic	Odds Ratio	95% CI	*p*
Previous expander or implant	8.400	0.951–74.185	0.043
Previous breast surgery†	1.731	0.656–4.566	0.330
Minor surgery before TCPM surgery‡	1.126	0.718–1.765	0.791
Major surgery before TCPM surgery§	2.424	0.708–8.305	0.115
Histological positive vs. negative LN	0.506	0.117–2.196	0.490
Axillary surgery‖ during TCPM use	0.737	0.281–1.931	0.627
Surgical type with TCPM			
SSM/NSM	0.261	0.063–1.092	0.096
NSSM	2.152	0.333–13.918	0.642
Implant exchange	0.411	0.300–0.562	0.181
MRM	4.304	0.421–44.017	0.307
Implant vs. expander use with TCPM	0.664	0.145–3.037	0.716
Implant shape (anatomical vs. round)	0.516	0.407–0.654	0.243
Primary vs. secondary reconstruction	4.080	0.759–21.925	0.131
Unilateral vs. bilateral procedure	0.248	0.088–0.704	0.013
Reconstructive vs. prophylactic surgery	0.337	0.095–1.195	0.141

TCPM, titanium-coated polypropylene mesh; LN, lymph nodes; SSM, skin-sparing mastectomy; NSM, nipple-sparing mastectomy; NSSM, no skin-sparing mastectomy; MRM, modified radical mastectomy.
*Multivariate analysis was not performed, as none of the procedure-related characteristics proved to be statistically significant for implant loss.
†Surgical intervention with concern for axillary lymph nodes excluded.
‡Minor surgery was defined as breast-conserving therapy with or without axillary or sentinel lymph node biopsy.
§Major surgery was defined as skin- and nipple-sparing mastectomy and modified radical mastectomy (with and without previous expansion).
‖Axillary surgery was defined as sentinel lymph node biopsy or complete axillary lymph node extirpation.

Table 5. Univariate Analysis of Patient-Related Characteristics as Risk Factors for Implant Loss*

Characteristic	Odds Ratio	95% CI	*p*
Smoking	1.475	0.461–4.714	0.513
Diabetes mellitus	1.772	0.203–15.498	0.479
Age > 50 yr	2.937	1.160–7.440	0.024
BMI > 27 kg/m^2	1.108	0.305–4.017	0.745
Radiotherapy†	0.294	0.038–2.277	0.323
Chemotherapy	1.287	0.503–3.291	0.627
Neoadjuvant/history of chemotherapy	2.206	0.651–7.481	0.251
Adjuvant	0.908	0.280–2.945	1.000

BMI, body mass index.
*Multivariate analysis was not performed, as none of the patient-related characteristics proved to be statistically significant for implant loss.
†The influence of preoperative and postoperative radiotherapy was not evaluated because only two patients received radiotherapy after implant-based breast reconstruction with titanium-coated polypropylene mesh; four patients received radiotherapy before surgery.

Table 6. Univariate Analysis of Procedure-Related Characteristics as Risk Factors for Implant Loss*

Characteristic	Odds Ratio	95% CI	*p*
Previous expander or implant	1.935	0.656–5.708	0.211
Previous breast surgery†	1.166	0.464–2.929	0.817
Minor surgery before TCPM surgery‡	0.916	0.312–2.683	1.000
Major surgery before TCPM surgery§	1.734	0.543–5.539	0.364
Histologic positive vs. negative LN	0.771	0.211–2.817	1.000
Axillary surgery‖ during TCPM use	1.166	0.464–2.929	0.817
Surgical type			
SSM/NSM with TCPM	1.196	0.413–3.463	0.779
NSSM with TCPM	0.524	0.066–4.170	1.000
Implant exchange and TCPM	0.579	0.072–4.630	1.000
MRM and TCPM	5.500	1.248–24.240	0.043
Implant vs. expander use with TCPM	2.148	0.656–6.998	0.255
Implant shape (anatomical vs. round)	0.908	0.870–0.947	0.617
Primary vs. secondary reconstruction	2.597	0.867–7.785	0.147
Unilateral vs. bilateral procedure	0.323	0.105–1.000	0.056
Reconstructive vs. prophylactic surgery	0.308	0.069–1.368	0.174

TCPM, titanium-coated polypropylene mesh; LN, lymph nodes; SSM, skin-sparing mastectomy; NSM, nipple-sparing mastectomy; NSSM, no skin-sparing mastectomy; MRM, modified radical mastectomy.
*Multivariate analysis was not performed, as none of the procedure-related characteristics proved to be statistically significant for implant loss.
†Surgical intervention with concern for axillary lymph nodes excluded.
‡Minor surgery was defined as breast-conserving therapy with or without axillary or sentinel lymph node biopsy.
§Major surgery was defined as skin- and nipple-sparing mastectomy and modified radical mastectomy (with and without previous expansion).
‖Axillary surgery was defined as sentinel lymph node biopsy or complete axillary lymph node extirpation.

Table 7. Univariate Analysis of Infection-Related Characteristics as Risk Factors for Implant Loss

Characteristic	Odds Ratio	95% CI	*p*
Mastectomy flap necrosis	0.083	0.054–0.127	0.087
Capsule fibrosis	26.125	4.442–153.665	0.001
Postoperative seroma	2.494	0.500–12.429	0.244
Necrosis of the nipple	1.336	0.158–11.254	0.564
Skin necrosis	10.300	2.515–42.178	0.004
Skin infection	3.209	0.816–12.618	0.109
Superficial hematoma	1.061	0.229–4.909	1.000
Postoperative hematoma needing revision	4.578	0.829–25.288	0.115

feasible because their application depends on the implant-covering skin situation. In Germany, acellular dermal matrix is considered expensive and is not covered by health insurance. Therefore, the indication for acellular dermal matrix is seen very rarely, whereas titanium-coated polypropylene mesh is widely used. In the case of sufficient subcutaneous tissue, no additional matrix is used, whereas with moderate to insufficient subcutaneous tissue, the mesh is an option. In the absence of subcutaneous tissue, biological matrixes are preferred.

Smoking, diabetes, and age were not patient-related risk factors in our study, which was most likely attributable to the generally healthy study population. Radiotherapy, an established risk factor for postoperative complications in implant-based breast reconstruction, was also not identified as a risk factor, most likely because of the low number of patients receiving radiotherapy (two

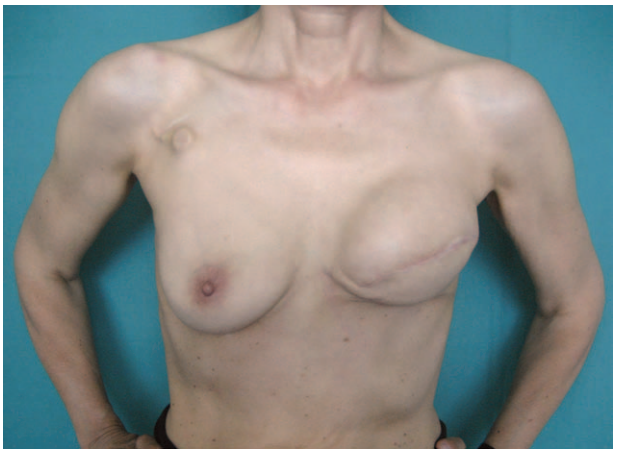

Fig. 4. Patient after modified radical mastectomy who desired secondary breast reconstruction. With a body mass index of 19 kg/m^2, she was not a candidate for autologous reconstruction. The surgical procedure was complex, with an elevation of the inframammary fold and mobilization of a thoracoepigastric flap. The implant had to be removed 3 months later.

patients after implant-based breast reconstruction with titanium-coated polypropylene mesh and four patients before surgery). Based on our experiences and on other reports, implant-based breast reconstruction with or without the mesh should not be performed in patients scheduled for postmastectomy irradiation.[21]

In retrospect, not all women in our collective were eligible for implant-based breast reconstruction using titanium-coated polypropylene mesh (Fig. 4). We observed an increased number of complications after expander or implant surgery before mesh implantation. The mesh, therefore, might not be a good tool for breast reconstruction in secondary cases. Modified radical mastectomy preceding mesh reconstruction was also associated with an increased risk for implant loss. The limited data from our study are in line with our clinical experiences, in which titanium-coated polypropylene mesh should not be used in these patients.

From a clinical point of view, the titanium-coated polypropylene mesh was more palpable in patients with radiotherapy in their medical history compared with patients without radiotherapy. In very thin mastectomy flaps, the mesh was barely, if at all, palpable. When asked, patients did not mention any discomfort.

What Scientific Information Is Available, and Why Should This Titanium-Coated Polypropylene Mesh Be Used?

Titanium-coated polypropylene mesh is a lightweight, nonabsorbable mesh and consists of a monofilament structure that is available in three different bra-like sizes. Cellular reactions, such as proliferation and apoptosis, were observed at the lowest level when using this lightweight mesh compared with non–titanium-coated meshes.[32] Compared with common non–titanium-coated meshes, this lightweight mesh had a much better biocompatibility.[33] Only a mild infiltration of inflammatory cells and sufficient neovascularization of the granulated tissue around the mesh pores were observed, indicating an exceptional compatibility with human tissue. Previous investigations on titanized meshes support these findings.[33] Histologic examination after immediate two-stage breast reconstruction showed a well-incorporated mesh into the surrounding tissue.[34]

After skin-sparing mastectomy or nipple-sparing mastectomy, the implant pocket is usually larger compared with patients after two-stage expander reconstruction. Based on our clinical observations, titanium-coated polypropylene mesh helps control the mastectomy space and implant. It is a supportive tool for facilitating implant-based breast reconstruction by fixating the pectoralis major muscle and preventing the pectoralis major from migrating superiorly. In addition, the mesh helps stabilize the implant pocket caudolaterally, allowing the reconstructed breast to appear slightly ptotic. The mesh comes in an inframammary fold–like shape, which helps define the inframammary fold and can prevent the implant from bottoming out. Further benefits are a reduced morbidity from full muscle coverage and control of the natural landmarks. In clinical practice, the breast maintained its softness after surgery, with the mesh being barely palpable. It also represents potential support in young athletic women with a lack of autologous tissue for breast reconstruction. However, by preserving autologous tissue in the first-line treatment, that tissue remains available for the treatment of implant failure or breast cancer recurrence.

Titanium-coated polypropylene mesh combines the benefit of cost with the technical material advantages over much heavier, nontitanized meshes and provides new perspectives for breast surgeons.[24] At €400 in Europe, the mesh is less expensive than acellular dermal matrix (approximately €3000), but it has not yet been approved by the U.S. Food and Drug Administration. Further potential cost savings are associated with the decreased surgical time and shorter hospitalization compared with autologous breast reconstruction.

To reduce complications, surgical experience is important in the preoperative assessment

(medical and surgical histories, skin condition, patient desire). A successful outcome depends on the surgeon's clinical judgment to achieve a viable skin flap, which depends on the patient's body habitus, risk factors, and anticipated surgical procedure. In patients undergoing implant-based breast reconstruction, the remaining subcutaneous tissue after skin- or nipple-sparing mastectomy is important in assessing the intraoperative use of titanium-coated polypropylene mesh. Unfortunately, we were not able to extract this information from the surgical reports. The available soft tissue after skin- or nipple-sparing mastectomy depends on the patient's appearance and previous treatments. In thin patients, the remaining subcutaneous tissue is generally less than that in obese patients. Our own data did not confirm different complication rates compared with body mass index. One reason for this observation could be the low body mass index rate in our patients as a result of patient selection.

Although our study lacks a control group, the complication rates were comparable to those in patients with implant-based breast reconstruction alone.[35–37] The study by Cordeiro et al., one of the largest, reported an overall incidence of early complications of 15.5 percent in implant-based breast reconstruction alone.[38]

An unanswered question remains the effect on breast cancer surveillance after implant-based breast reconstruction with titanium-coated polypropylene mesh. However, the authors know of no interferences using palpation, breast ultrasound, or mammography.[39] During the ultrasound follow-ups, no difficulties regarding cancer surveillance were observed in our collective (Fig. 5).

Our study is limited because of its focus on risk factors and complications in patients undergoing implant-based breast reconstruction using titanium-coated polypropylene mesh only. No attempt was made to determine the degree to which postoperative complications or implant loss influenced patient satisfaction or the long-term success of the reconstructive procedure. The soft-tissue proportion could not be evaluated from the retrospective data. Statements on soft-tissue relationships were all based on clinical impressions. In future studies, the soft-tissue thickness should be measured intraoperatively. Furthermore, this retrospective study lacks a control group, and a comparative study would have been preferred. A prospective observational trial using the mesh in implant-based breast reconstruction will be initiated in Germany beginning in January of 2013.

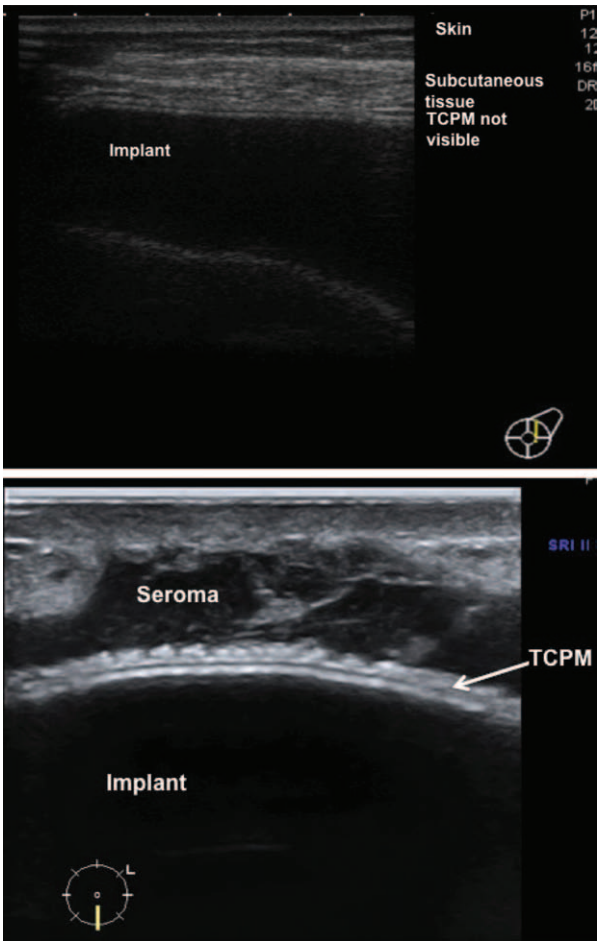

Fig. 5. (*Above*) Ultrasound image of a patient 6 months after immediate implant-based breast reconstruction using titanium-coated polypropylene mesh (*TCPM*). The subcutaneous tissue can be well investigated, with the mesh being not visible to the investigator. (*Below*) Ultrasound image of a different patient who developed a postoperative seroma after immediate implant-based breast reconstruction using the mesh. The mesh can be distinguished in the ultrasound image without interfering with the examination.

The strength of this study is its multicenter approach. All patients were operated on by a certified breast surgeon, reflecting an authentic incidence of complications and eliminating a bias by single-surgeon reports. Based on our findings and clinical experience, titanium-coated polypropylene mesh for implant-based breast reconstruction can be used for the following: in single-stage breast reconstruction, in prophylactic mastectomies, and in immediate two-stage breast reconstruction using a tissue expander and a secondary replacement by a permanent silicone implant. The use of any mesh (biological or synthetic) should be assessed preoperatively, and the patient must be informed of the intraoperative decision for or against its use.

CONCLUSIONS

On the basis of our results, titanium-coated polypropylene mesh can be used to facilitate immediate implant-based breast reconstruction in selected patients but is not suitable for secondary cases. No patient-related risk factors could be identified in the course of implant-based breast reconstruction using this mesh. Further outcome reports are necessary to evaluate its status in implant-based breast reconstruction. Our data indicate that titanium-coated polypropylene mesh is a safe and convenient option in primary cases. Careful preoperative patient selection, in compliance with our findings, is vital in preventing postoperative complications.

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