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A Comparative Analysis of Complications and Patient-Reported Outcomes in Implant-Based Breast Reconstruction with Polytetrafluoroethylene (PTFE) versus Allogeneic Dura Mater (DM)

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ABSTRACT

Objective: Mastectomy with immediate reconstruction is a primary surgical treatment for breast cancer. While both synthetic meshes and biological grafts are used in these procedures, their comparative effectiveness requires further investigation. This study evaluates the use of polytetrafluoroethylene (PTFE) mesh versus allogeneic dura mater (DM) in direct-to-implant breast reconstruction for reinforcing the inframammary fold (IMF) and stabilizing the implant.

Materials and Methods: A prospective, randomized, open-label trial enrolled 116 patients (192 breasts) who underwent subcutaneous or skin-sparing mastectomies or subtotal radical resections, all followed by immediate subpectoral implant-based reconstruction. Participants were randomized to receive either a PTFE mesh (60 patients; 96 breasts) or a DM graft (56 patients; 96 breasts) for implant support. Outcomes were assessed through radiological imaging for complications, anthropometric measurements for IMF and implant stability, and the breast evaluation questionnaire version 2.0© (reconstruction module) for quality of life.

Results: The PTFE group demonstrated a lower rate of major complications (3 vs. 7, respectively), while minor complications were comparable (23 vs. 28, respectively). Anthropometric analysis demonstrated that PTFE mesh provided superior stabilization of the IMF and the implant position postoperatively. Quality of life scores were comparable between the two groups.

Conclusion: The use of PTFE mesh in immediate subpectoral breast reconstruction provides reliable anti-gravitational stabilization of the IMF and implant, and is associated with a favorable complication profile and high patient-reported quality of life.

Keywords: Breast reconstruction; dura mater; inframammary fold; polytetrafluoroethylene; quality of life

KEY POINTS

- Implant-based breast reconstruction utilizing either polytetrafluoroethylene (PTFE) mesh or dura mater allografts resulted in similarly favorable complication profiles.
- The synthetic PTFE mesh demonstrated significant advantages in maintaining both implant position and inframammary fold definition.
- Patient-reported outcomes measured by quality of life assessment tools confirmed high satisfaction rates with both reconstruction materials.

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Introduction

Breast cancer constitutes a major global health challenge, exerting a profound medical, social, and psychological burden on populations worldwide (1). Radical mastectomy remains the most frequent operation in the surgical treatment of breast cancer; however, it is usually associated with significant psychological trauma due to loss of the breast (2, 3). Immediate breast reconstruction has thus gained significant importance, as it enables the restoration of natural breast contours concurrently with the oncological operation (4). This approach has proven effective in reducing psychological distress, improving overall quality of life (5-7), and offering economic advantages over delayed reconstruction by minimizing the number of surgical interventions and reducing the time to adjuvant therapy (8). Nevertheless, immediate reconstruction demonstrates oncological safety comparable to that of mastectomy alone, without increasing the risk of local recurrence or distant metastasis (9).

The inframammary fold (IMF) is a critical anatomical structure for achieving a stable aesthetic outcome in implant-based breast reconstruction. Its integrity is often compromised during mastectomy or resection, necessitating specific surgical techniques for restoration. While numerous methods for IMF reconstruction have been described in the literature, none has yet emerged as an optimal solution or a universally accepted "gold standard" (10).

Current literature on implant-based breast reconstruction indicates a shift in focus from biological matrices, such as acellular dermal matrices, to synthetic alternatives (11).

Our study investigates the application of a polytetrafluoroethylene (PTFE) mesh for IMF retention and implant stabilization in direct-to-implant breast reconstruction. The selected material has a well-established safety and efficacy profile in various surgical fields, including hernioplasty (12, 13), neurosurgery (14), cardiovascular surgery (15, 16), and blepharoplasty (17). The control group underwent IMF stabilization using lyophilized autologous dura mater (DM), an established technique with documented clinical applications in ophthalmologic practice (18), maxillofacial practice (19), and neurosurgical practice (20), which has been previously investigated for breast reconstruction (21).

Materials and Methods

Study Population

The study was a prospective, randomized, open-label, controlled, comparative, parallel-group trial designed as a test for equality. The study employed simple (unstratified) randomization, which was a deliberate methodological choice for this pragmatic comparative trial. Patient enrollment and data collection were conducted between December 2022 and May 2025. The primary evaluation endpoints included the analysis of postoperative complications, quality-of-life assessment via the breast evaluation questionnaire (BREAST-Q) version 2.0© reconstruction module, and controlled anthropometric measurements of principal breast landmarks. The study enrolled 116 patients (192 breasts) who underwent subcutaneous or skin-sparing mastectomies or wide local excision (removing up to 90% of the glandular tissue and was performed for multiple benign lesions), followed by immediate implant-based subpectoral breast reconstruction using a reinforcing material. Patients were pre-randomized into two groups: the PTFE group (study group, 60 patients, 96 breasts) and the DM group (control group, 56 patients, 96 breasts). Inclusion criteria for the study were: female sex, Caucasian ethnicity, age ≥18 years, and a subcutaneous adipose tissue thickness of ≤2 cm. Demographic characteristics and pathologies for both groups are presented in Table 1. The data are reported per breast rather than per patient, as the breast was the primary unit of analysis in this study.

The study was approved by the Local Ethics Committee of Federal Scientific and Clinical Center for Specialized Types of Medical Assistance and Medical Technologies of the Federal Medical-Biological Agency (FGBU FNKTS FMBA of Russia) (approval no: 5_2022, date: 07.06.2022) and was registered on ClinicalTrials.gov under the identifier NCT06931548. Informed consent for participation in the study and for pre- and postoperative surveys was obtained in the presence of the investigating physicians prior to surgery and again at 6 months postoperatively.

Polytetrafluoroethylene Mesh

The PTFE mesh (Ecoflon Scientific and Production Complex, Russia) utilized in this study was a non-resorbable, porous, perforated membrane with a thickness of 0.2 mm and perforation diameters of 2.5 mm. The PTFE mesh was supplied in a dome configuration with a diameter of 14 cm and a radius (arc width) of 7 cm. PTFE is approved by the United States Food and Drug Administration (FDA) for applications including cardiovascular grafts and sutures, and its use complies with European regulatory standards. The material pyrogen-free, non-toxic, chemically inert, and biocompatible. The porous architecture of the PTFE mesh is hypothesized to facilitate host tissue integration, while the perforations allow for effective drainage of the breast implant pocket.

Dura Mater Graft

The acellular lyophilized DM allograft (Lyoplast®, Russia) was crescent-shaped, with a thickness of up to 2.5 mm. The DM graft had dimensions of 13–4 cm long and 7–8 cm wide, as provided by the manufacturer. This graft is FDA-approved for

neurosurgical applications and is a biodegradable and bioinert material. It is capable of mimicking native tissue without initiating inflammatory or adhesive processes. Despite the long-standing clinical use of DM, the precise timeline for its complete resorption and biodegradation in soft tissues is not well-defined in the literature. However, a fundamental study from 2014 demonstrated that vascular ingrowth into the DM thickness is evident by day 30, and that by day 70, although the connective tissue framework becomes more fragmented, it does not lose its barrier function (22).

Complications

Postoperative complications were defined as the primary endpoint of this pragmatic trial, as they represent the most objective measure for comparing the materials, thereby minimizing the confounding effects of non-standardized surgical techniques. They were monitored over a 6-month period following surgery and categorized as either having general surgical or aesthetic complications. The general surgical complications included seromas persisting for more than one month, hematomas, marginal necrosis, and infectious complications. Aesthetic complications included prosthesis dislocation and animation deformity.

Additionally, complications were classified as major if they required surgical revision and minor if they resolved with conservative outpatient management (23). Capsular contractures were evaluated separately, as they did not demonstrate clinical significance within the scope of this study.

BREAST-Q

The BREAST-Q version 2.0© (reconstruction module) is a validated, patient-reported outcome instrument designed to assess quality of life. All participants completed the questionnaire preoperatively and at 6 months postoperatively, specifically, the psychosocial well-being, sexual well-being, and satisfaction

Table 1. Patient and breast surgery characteristics

	DTI breast reconstruction with PTFE mesh (n = 96)	DTI breast reconstruction with dura mater graft (n = 96)	p-value
Age, mean ± SD	48±9.18 year	52.5±9.83 year	0.06[a]
BMI, mean ± SD	22.9±2.52 kg/m^2	22.95±2.33 kg/m^2	0.85[a]
Smoking, n (%)	12 (12.5)	9 (20.8)	0.65[b]
Breast cancer, n (%)	68 (70.8)	73 (76)	0.41[b]
pTis (DCIS) N0 M0 (stage 0), n	9	5	0.6[c]
pT1 N0 M0 (stage I), n	28	35	
T0-1 N1 M0/T2 N0 M0 (stage IIA), n	20	20	
T2 N1 M0/T3 N0 M0 (stage IIB), n	11	13	
Fibroadenomas and other nodular mastopathies, n (%)	22 (22.9)	18 (18.8)	0.48[b]
Genetic predisposition, n (%)	6 (6.6)	5 (5.2)	1[c]
Type of breast surgery			
Subcutaneous mastectomy, n (%)	69 (71.9)	74 (77.1)	0.74[c]
Skin-sparing mastectomy, n (%)	5 (5.2)	4 (4.2)	
Wide local excision, n (%)	22 (22.9)	18 (18.8)	
Type of lymphnode surgery			
SLNB, n (%)	51 (53.1)	57 (59.4)	0.71[c]
ALNB, n (%)	17 (17.7)	15 (15.6)	
Neoadjuvant CHT, n (%)	37 (38.5)	28 (29.2)	0.22[b]
Adjuvant CHT, n (%)	41 (42.7)	28 (29.2)	0.07[b]
Radiotherapy, n (%)	17 (17.7)	15 (15.6)	0.7[b]
Implant volume			
200–300 cc, n (%)	25 (26)	25 (26)	0.62[a]
310–400 cc, n (%)	46 (47.9)	51 (53.1)	
410–525 cc, n (%)	25 (26)	20 (20.8)	

DTI: Direct-to-implant; PTFE: Polytetrafluoroethylene; BMI: Body mass index; CHT: Chemotherapy; SLNB: Sentinel lymph node biopsy; ALNB: Axillary lymph node biopsy; ALND: Axillary lymph node dissection; DCIS: Ductal carcinoma *in situ*; [a]: Mann-Whitney U test; [b]: Pearson's chi-square test; [c]: Fisher's exact test; SD: Standard deviation

with breast domains. Data from the physical well-being: chest domain were also collected but excluded from the final analysis because they were deemed non-informative. Patient responses for each domain were converted into scores on a 100-point scale using the official BREAST-Q conversion tables, where higher scores indicate better quality of life.

Anthropometric Measurements

To assess the positions of the IMF and the breast implant, standardized measurements were taken from the nipple to each of the following landmarks: the IMF, the anterior midline, the midclavicular point, and the jugular notch. These measurements were performed intraoperatively at the conclusion of the procedure and at the 6-month postoperative follow-up. The resulting changes in distances were analyzed to evaluate the efficacy of the PTFE and DM stabilization techniques.

Patient-reported quality of life and anthropometric measurements were analyzed as secondary endpoints, acknowledging that these outcomes could be influenced by factors beyond the material type, such as individual patient variables and surgical technique.

Surgical Technique

Preoperative lymphoscintigraphy with technetium-99 identified the sentinel lymph nodes. All procedures were performed under general anesthesia. Surgery commenced with a separate axillary incision for sentinel node biopsy, guided by gamma detection. If the frozen section confirmed metastases, level I–II lymph node dissection was performed.

The type of breast surgical procedure performed (subcutaneous mastectomy, skin-sparing mastectomy, or wide local excision) was selected based on clinical and anatomical factors. Surgical access was via an IMF incision, an inverted-T incision, or an S-shaped incision. Retroareolar tissue was submitted for frozen-section analysis to assess involvement of the nipple-areolar complex.

Following tumor resection, reconstruction began. After hemostasis, a subpectoral pocket was created. A crescent-shaped PTFE mesh was sutured to the inferior border of the pectoralis major and to the projected neo-IMF using continuous Vicryl 3–0 sutures, thereby forming a hammock-like implant pocket. Thus, the upper pole of the implant was covered by the muscle, while the lower pole was supported by the PTFE mesh. A drain was placed prior to layered closure (Figure 1).

Reconstruction using allogeneic DM was performed according to the PTFE technique. Prior to application, the lyophilized DM was rehydrated intraoperatively by immersion in 0.9% normal saline containing a broad-spectrum antibiotic for 3 minutes, in accordance with the manufacturer's instructions. The graft was then fixed identically using a continuous absorbable suture (Figure 2).

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics 23 and Microsoft Excel 2016. We employed descriptive statistics (mean, median, frequency), correlation analysis, and both parametric and non-parametric tests. Group comparisons utilized the Mann-Whitney U test for quantitative variables and the chi-square or Fisher's exact test for categorical data. Results were visualized through contingency tables and diagrams.

Results

A total of 192 cases of immediate implant-based breast reconstruction using additional coverage materials (PTFE or DM) in 116 patients were analyzed. Key patient and surgical data are summarized in Table 1. The groups were comparable in demographic characteristics and treatment methods. The median follow-up period was 14±5 months, with a minimum required follow-up of 6 months.

Among the malignant neoplasms, invasive ductal carcinoma was the most prevalent, identified in 47 cases in the PTFE group and 52 cases in the DM group. Based on molecular genetic typing, the luminal A subtype was the most frequently observed, found in 26 and 41 cases in the PTFE and DM groups, respectively. In 11 cases, prophylactic mastectomies were performed after somatic mutations in the *BRCA1, BRCA2*, or *CHEK2* genes had been identified prior to surgery.

In the PTFE group, postoperative complications were recorded in 26 cases (27.1%): 21 general surgical complications (21.9%) and 7 aesthetic complications (7.3%). Two cases presented with combined general surgical and aesthetic complications.

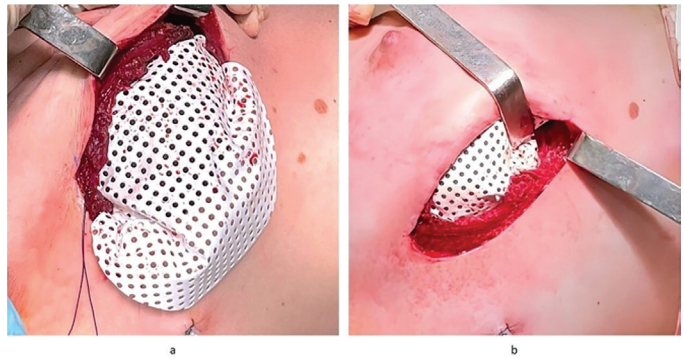

Figure 1. a. Fixation of the perforated porous PTFE mesh to the inferior border of the mobilized pectoralis major muscle, b. fixation of the perforated porous PTFE mesh to the projected neo-inframammary fold

PTFE: Polytetrafluoroethylene

Three cases required surgical revision. Other complications were successfully managed conservatively. The six-month postoperative outcome of breast reconstruction using PTFE is presented in Figure 3.

The DM group experienced complications in 34 cases (35.4%), including 24 general surgical complications (25%) and 15 aesthetic complications (15.6%). Five cases showed combined complications, and seven required reoperation.

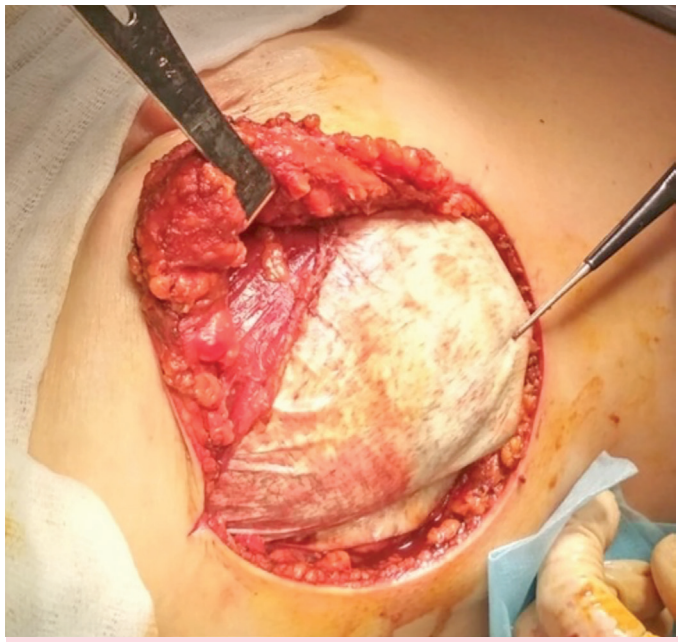

Figure 2. Stage of creating a subpectoral implant pocket using dura mater graft

In seven implant displacement cases, surgical correction was declined. The complete list of complications, with a detailed frequency analysis, is presented in Table 2.

Capsular contractures graded 0–II on the Baker classification were recorded separately because they were clinically insignificant. However, patients who underwent radiotherapy demonstrated significantly greater capsular severity ($p<0.05$).

Despite comparable overall complication rates between the study groups, statistical analysis revealed a significant association ($p<0.05$) between marginal skin necrosis and smoking history. Specifically, 9 out of 11 necrosis cases (81.8%) occurred in smokers.

Anthropometric Measurements

The positions of the IMF and the implant were assessed by measuring distances between anatomical landmarks immediately after surgery and at 6 months postoperatively. Evaluation of these topographic changes identified significant implant displacement (defined as a change >1 cm in any measured distance) in 4.2% (n = 4) of the PTFE group and in 10.4% (n = 10) of the DM group (Table 3).

Postoperative analysis identified several patient factors influencing reconstruction stability. A significant age-dependent effect was observed, with older patients exhibiting a pronounced tendency toward greater displacement of both the implant and the IMF.

A statistically significant correlation was found between larger implant volumes and increased displacement of the prosthesis

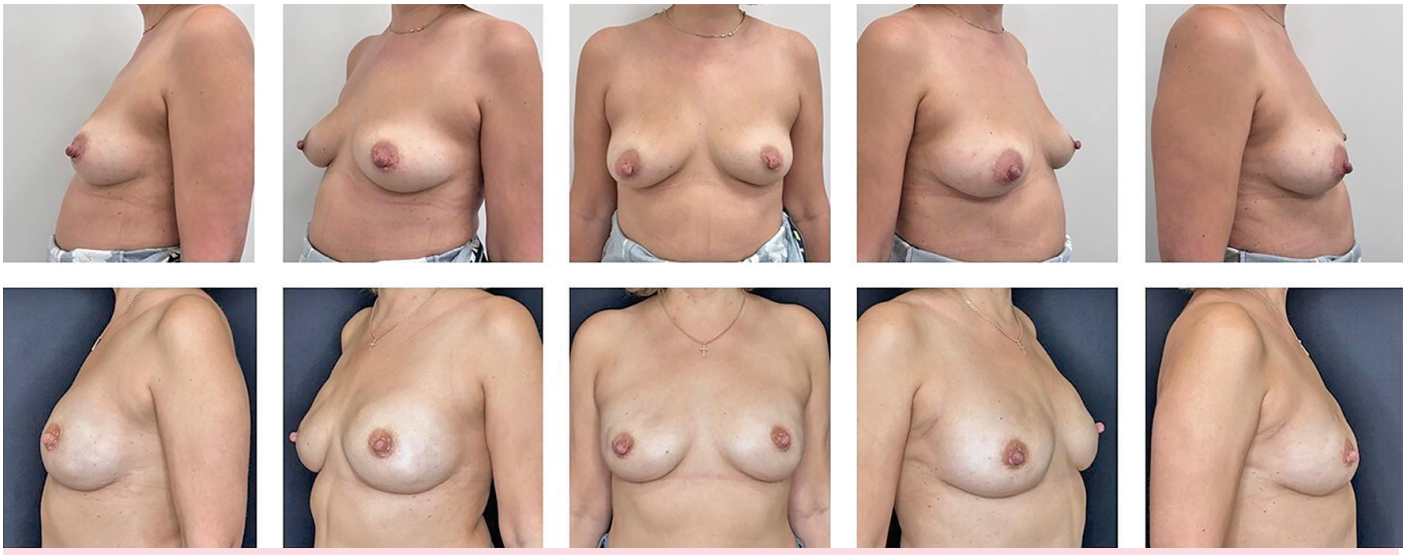

Figure 3. Clinical photographs of a 52-year-old patient with bilateral breast cancer. Above: preoperative appearance. Below: 6-month postoperative outcome following bilateral subcutaneous mastectomy with immediate subpectoral reconstruction using 325 cc implants and polytetrafluoroethylene mesh

and IMF. Furthermore, higher body mass index (BMI) was associated with reduced implant stability, indicating increased implant mobility postoperatively.

BREAST-Q

Patient-reported quality of life was assessed using the BREAST-Q version 2.0© (reconstruction module) preoperatively and at 6 months postoperatively. The two study groups had nearly identical quality of life scores at both time points (Table 4). A trend toward a decline in psychosocial and sexual well-being was observed following reconstruction in both cohorts, although these changes did not reach statistical significance, as noted previously.

Bilateral breast reconstruction was performed on 76 patients (36 in the PTFE group and 40 in the DM group). A comparative analysis of postoperative BREAST-Q scores revealed no statistically significant differences in outcomes between these patients and those who underwent unilateral surgery.

The sexual well-being questionnaire was completed by 41 patients in the PTFE group and 34 in the DM group. In total, 19 (31.7%) and 22 (39.3%) patients in the respective groups declined to complete this module, citing the absence of sexual activity at the time of the study.

Notably, statistical analysis of the "satisfaction with breasts" module revealed similar scores before and after surgery. This finding can be attributed to a subset of patients reporting higher satisfaction with their breasts postoperatively than preoperatively.

A more detailed analysis confirmed a sustained age-related correlation, with older patients exhibiting statistically significantly lower scores in both sexual well-being (assessed pre- and postoperatively) and preoperative satisfaction with breasts.

Discussion and Conclusion

Breast cancer remains a significant medical and social problem requiring comprehensive treatment and rehabilitation. Although breast-conserving techniques are widely used (70–80% of cases), mastectomy remains indicated for 20–30% of patients.

Table 2. Incidence and spectrum of complications across the study groups

	DTI breast reconstruction with PTFE mesh (*n* = 96)	DTI breast reconstruction with dura mater graft (*n* = 96)	*p*-value
Major complications, n breasts (%)*	3 (3.13)	7 (7.29)	0.33[b]
Minor complications, n breasts (%)*	23 (23.96)	28 (29.17)	0.51[a]
General surgical complications, n breasts (%)*	21 (21.9)	24 (25)	0.55[a]
Seroma, n (%)	13 (13.5)	17 (17.7)	0.55[a]
Hematoma, n (%)	3 (3.1)	2 (2.1)	1[b]
Infections, n (%)	1 (1)	3 (3.1)	0.62[b]
Marginal necrosis, n (%)	5 (5.2)	6 (6.3)	1[b]
Aesthetic complications, n breasts (%)*	7 (7.3)	15 (15.6)	19[a]
Prosthesis dislocation, n (%)	4 (4.2)	10 (10.4)	0.16[b]
Animation deformity, n (%)	4 (4.2)	9 (9.4)	0.25[b]
Capsular contractures			
Grade I, n (%)	41 (42.7)	54 (56.3)	0.83[a]
Grade II, n (%)	8 (8.3)	14 (14.6)	0.26[b]

*: Complications were recorded as binary events (present/absent) for each type, regardless of co-occurrence of multiple complication types in a single breast; [a]: Pearson's chi-square test; [b]: Fisher's exact test; DTI: Direct-to-implant; PTFE: Polytetrafluoroethylene

Table 3. Topographic changes in breast landmarks: 6-month postoperative assessment

	DTI breast reconstruction with PTFE mesh (*n* = 96)	DTI breast reconstruction with dura mater graft (*n* = 96)	*p*-value
Nipple to inframammary fold (cm), mean ± SD	0.3±0.1	0.6±0.3	<0.05[a]
Nipple to mid-clavicular point (cm), mean ± SD	0.3±0.1	0.5±0.3	<0.05[a]
Nipple to jugular notch (cm), mean ± SD	0.3±0.2	0.6±0.3	<0.05[a]
Nipple to anterior midline (cm), mean ± SD	0.2±0.2	0.3±0.2	<0.05[a]

[a]: Mann-Whitney U test; DTI: Direct-to-implant; PTFE: Polytetrafluoroethylene; SD: Standard deviation

Table 4. BREAST-Q assessment of quality of life: preoperative and postoperative comparison

	DTI breast reconstruction with PTFE mesh (*n* = 60)	DTI breast reconstruction with dura mater graft (*n* = 56)	*p*-value
Psychosocial well-being preoperative (scores), mean ± SD	80±6.4	80±6.3	0.49[a]
Psychosocial well-being postoperative (scores), mean ± SD	70±5	71±5.8	0.44[a]
Satisfaction with breasts preoperative (scores), mean ± SD	64±9.9	64±11.4	0.13[a]
Satisfaction with breasts postoperative (scores), mean ± SD	64±7	62±6.9	0.1[a]
	DTI breast reconstruction with PTFE mesh (n = 41)	**DTI breast reconstruction with dura mater graft (n = 34)**	***p*-value**
Sexual well-being preoperative (scores), mean ± SD	74±8.6	74±7.5	0.63[a]
Sexual well-being postoperative (scores), mean ± SD	62±5.7	66±6.3	0.84[a]

[a]: Mann-Whitney U test; DTI: Direct-to-implant; PTFE: Polytetrafluoroethylene; SD: Standard deviation; BREAST-Q: Breast evaluation questionnaire

The psychosocial consequences of mastectomy necessitate reconstructive interventions as an essential component of comprehensive treatment (5-7). Implant-based reconstruction is the most common method worldwide (4). This trend is associated with the introduction of subcutaneous and skin-sparing mastectomies into clinical practice.

Recent years have seen active investigation into biological and synthetic meshes in breast reconstruction, aimed at strengthening the IMF and providing additional implant stabilization, although their use remains controversial. The lack of large-scale randomized studies that objectively compare clinical outcomes of reconstructions that use different supplemental covering materials makes it difficult to draw definitive conclusions. Consequently, the choice of a specific technique and type of material is determined primarily by the surgeon's experience and clinical circumstances.

Our study investigated a PTFE-based synthetic mesh for IMF reinforcement and additional implant coverage in immediate subpectoral breast reconstruction. This material is widely used in various surgical fields due to its biocompatibility, chemical inertness, and low friction coefficient (12-17). We also used allogeneic DM as a control in breast reconstruction (21).

This study was not designed to demonstrate the superiority of one technique over the other. In our view, different methodologies, when applied by experienced practitioners, can yield comparable outcomes. Indeed, our findings showed no significant differences between the PTFE and DM groups with respect to postoperative complications or impact on quality of life. The obtained results are consistent with existing literature data (24).

However, attention should be paid to postoperative changes in key anatomical landmarks of the breast. Although the differences did not reach clinical significance, the synthetic PTFE mesh provided a more predictable and stable reconstructive outcome than the biological DM graft.

Data analysis confirmed that older age and higher BMI were associated with an increased likelihood of implant and IMF displacement. This correlation is anatomically plausible: aging leads to decreased skin elasticity due to both reduced synthesis and degradation of collagen and elastin fibers (25), while a higher BMI contributes to chronic mechanical stress on tissues and to the replacement of damaged structural fibers with scar tissue (26).

Study Limitations

While we strived for a comprehensive study design, certain limitations must be acknowledged. Specifically, the 6-month follow-up period, while adequate for assessing primary aesthetic and early complication endpoints, may not fully capture late-onset events. These include seromas (with incidence variably reported, up to 2%) (27) and infections, often associated with secondary bacteremia or invasive procedures unrelated to the initial breast surgery (28). We acknowledge this limitation and will continue prospective monitoring to document any late occurrences.

A key limitation is the non-randomized selection of the surgical incision, which was clinically determined. The approach (inframammary, inverted-T, or S-shaped) depended on tumor location, breast volume, excess skin, and ptosis. While this reflects real-world practice, it introduces a potential confounding factor. In particular, for larger implants (>300 cc), the vertical component of an inverted-T/S incision provides additional lower-pole support, which may independently influence implant stability, complication rates, and the assessment of postoperative quality of life. Although our primary comparison focused on the materials, the effect of the incision itself could not be fully isolated.

The proposed technique of using a synthetic PTFE mesh for supplemental lower-pole coverage in immediate, one-stage, subpectoral implant-based breast reconstruction is an effective approach and is associated with a low complication rate.

Furthermore, the method demonstrates satisfactory support for the IMF and implant position, and produces favorable patient-reported quality-of-life outcomes.

Ethics

Ethics Committee Approval: The study was approved by the Local Ethics Committee of Federal Scientific and Clinical Center for Specialized Types of Medical Assistance and Medical Technologies of the Federal Medical-Biological Agency (FGBU FNKTS FMBA of Russia) (approval no: 5_2022, date: 07.06.2022).

Informed Consent: Informed consent for participation in the study and for pre- and postoperative surveys was obtained in the presence of the investigating physicians prior to surgery and again at 6 months postoperatively.

Footnotes

Authorship Contributions

Surgical and Medical Pracites: A.K., A.M., V.O., M.S.; Concept: A.K., A.M., S.G., I.G.; Design: A.K., S.G., I.G.; Data Collection and/or Processing: A.M., V.O., M.S.; Analysis and/or Interpretation: A.K., A.M., S.G., I.G.; Literature Search: A.M., M.S.; Writing: A.K., A.M., V.O.

Conflict of Interest: The authors have no conflicts of interest to declare.

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