TiLoop® Bra Assisted Breast Reconstruction - Our Experience

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Rezumat

Reconstrucția sânelor cu utilizare de plasă TiLoop® Bra - experiența noastră

Acoperirea suplimentară a polului inferior cu material protetic sau analogi sintetici în timpul reconstrucției imediate a sânelor s-a realizat în ultimii 7 ani în Centrul Național de Oncologie pentru Cercetări Medicale N.N. Petrov, Ministerul Sănătății al Federației Ruse. Inițial, lamboul epidermic a fost singura opțiune pentru acoperirea polului inferior, dar ulterior ADM a fost utilizat ca parte a aprobării clinice. Rata medie a complicațiilor variază între 20-35% din cauza tulburărilor circulatorii (de aport sanguin). Din 2018, o plasă titanizată (TiLoop® Bra) a fost utilizată ca metodă de acoperire suplimentară a polului inferior.

Metode: Din iulie 2018 până în aprilie 2019, au fost efectuate 103 reconstrucții mamare cu utilizarea de plasă TiLoop® BRA. Toate operațiile au fost efectuate pentru tumori maligne ale sânelor, dintre care în 94 de intervenții au fost efectuate pentru carcinom mamar unilateral, iar 9 pentru carcinom mamar bilateral. 74 dintre pacienți au primit terapie neoadjuvantă, 31 au primit terapie adjuvantă, iar 17 pacienți au necesitat radioterapie.

Rezultate: Ratele complicațiilor generale au scăzut semnificativ. S-au înregistrat: pierderea completă a implantului mamar și a endoprotezei (5,88%), contractura capsulară (17,65%), îndepărtarea doar a endoprotezei din cauza sindromului dureros (5,88%), eritem mamar (5,88%).

Cuvinte cheie: reconstrucție mamară, pol inferior, cancer mamar, mastectomie, proteză

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Abstract

Additional covering of the lower pole with allomaterial or its synthetic analogues during immediate breast reconstruction is being performed at the N.N. Petrov National Medical Research Oncology Center, Ministry of Healthcare of Russian Federation for last 7 years. Initially, epidermal flap was the only option for lower pole coverage, later ADM was used as part of clinical approbation. Average complication rate ranges from 20-35% due to blood circulatory (supply) disorders. Since 2018, a titanized mesh (TiLoop® Bra) been used as a additional coverage of the lower pole.

Methods: From July 2018 to April 2019, 103 breast reconstructions were performed using TiLoop-BRA mesh. All operations were performed due to malignant tumors of breast, of which in 94 operations were performed for unilateral breast carcinoma, 9 for bilateral breast carcinoma. 74 patients received neoadjuvant therapy, 31 received adjuvant therapy, 17 patients required radiation therapy.

Results: Overall complications rates significantly decreased. Complete loss of breast implant and mesh endoprosthesis 5.88%, Capsular contracture 17.65 %, Only mesh removal due to painful syndrome 5.88%, * Red breast * syndrome (by analogy with ADM) 5.88%.

Key words: breast reconstruction, lower pole, breast cancer, mastectomy, mesh

Introduction

In Russia in 2018, 70 376 cases of newly diagnosed malignant neoplasms of mammary glands (breast cancer) were registered, of which 26.5% were stage I of the disease, 44.7% - stage II, 20.6% stage III and 7.8% stage IV (1). Thanks to modern diagnostic methods and screening for breast cancer (BC) the specificity of studies in relation to multicentric and multifocal breast cancer has experienced an increase (2).

Indications for complete removal of the breast tissue according to ASBrS Performance and Practice Guidelines for Mastectomy Today are (3):

- 1) breast cancer case, where breast-conserving surgery is inappropriate:
 - large tumor size in relation to volume breast;
 - insufficient tumor response to neoadjuvant chemotherapy or hormone therapy;
 - positive margins of resection after excisional biopsy;
 - the presence of a large number of small scattered microcalcifications (> 10 per 1 cm²);
 - high-risk mutations or a weighty family history of breast cancer;

- local relapse after breast-conserving surgery and radiation therapy;
 - contraindications to radiation therapy.
- 2) prevention in high-risk patients:
 - carriers of genetic mutations or healthy individuals with pronounced family history of breast cancer;
 - history of radiation therapy (as part of treatment of Hodgkin's lymphoma);
 - 3) the patient's preference.

Mastectomy is an effective treatment method that maximizes the relapse-free period in breast cancer, and various reconstruction options provide good aesthetic results.

The key aspects of implant-based breast reconstruction are optimal implant placement and appropriate tissue coverage.

A breast implant is usually placed under the pectoral major muscle. The pectoralis major muscle provides cover for the implant in the superior and medial poles. In the inferior and inferolateral sector, the implant is usually supported by a skin-fat flap. Insufficient or excessive dissection of the muscle pocket can lead to malposition of the breast implant. Mobilization of the fascia of the rectus abdominis muscle, serratus muscle or its fascia can provide additional covering for the

breast implant, but will inevitably lead to additional traumatization.

Additional covering of the breast implant without extensive muscle traumatization can be achieved with the use of acellular dermal matrix (not available in the Russian Federation) or its synthetic analogs such as a titanized mesh.

This allows you to create a single stable pocket between the pectoralis major muscle and the inframammary fold, provide effective support for the lower and lower outer poles and avoid excessive trauma, since in this case there is no need to use the fascia of the rectus abdominis muscle, serratus muscle or its fascia (4-6). Apart from its supportive mechanic properties the mesh affects fibroblast recruitment which provides rapid biontegration and creates even more reliable coverage of the lower and lower outer poles of the breast implant.

All of the above in total gives the reconstructed mammary gland a natural look and reduces the risk of complications (7).

Acellular dermal matrix or its synthetic analogs (synthetic meshes, etc.) help to reduce the risk of complete implant loss in patients at high risk of surgical complications. The group of high risk of surgical complications includes patients with severe concomitant morbid conditions, high body mass index (BMI), etc.

The use of a titanized mesh endoprosthesis is recommended by the AGO expert group (*Fig. 1*).

An important point is the fixation of the titanized mesh endoprosthesis to the

pectoralis major muscle.

The team of authors believes that fixation of the implant with a continuous thread has an advantage over an interrupted suture. With the latter, seals appeared in the projection of the sutures, which visually reduced the aesthetic result (especially with thin skin flaps), and also caused anxiety in patients with suspected recurrence of the disease, which undoubtedly led to a decrease in patient satisfaction with the outcome. In some cases, fixation by nodular suture also leads to the development of filamentous fistulas.

Materials and Methods

103 breast reconstructions using a titanized mesh of large size, extra light 16 g/m² implant were performed from July 2018 to April 2019. In the FSBI "Research Institute of Oncology named after N. N. Petrov" of the Ministry of Health of Russian Federation. All surgeries were performed for breast cancer, of which in 94 cases, surgeries were performed for unilateral breast carcinoma, and 9 for bilateral breast carcinoma. Seventy-four patients received neoadjuvant systemic therapy, 31 received adjuvant systemic therapy, and 17 patients required radiation therapy (*Table 1*).

Product Description

The titanized mesh implants are made of 1a

Muscle Fixation for Immediate Reconstruction after Mastectomy		
	Oxford / AGO LoE / GR	
➤ Autologous tissue (e.g. LDF*)	3b	C [‡]
➤ Acellular dermal matrix (ADM)	2b	B [‡]
➤ No significant increase of long-term complication rate compared to implant without ADM	2b	C
➤ Less capsular contracture compared to two-stage expander/implant without ADM	2b	C
➤ Synthetic mesh	2b	B [‡]

* LDF = Latissimus dorsi flap

Figure 1. AGO guidelines

Table 1.

N	103
Median age , years	42.5 (± 2)
Unilateral mastectomy	94
Bilateral mastectomy	9
Neoadjuvant chemotherapy	74
Adjuvant chemotherapy	31
Adjuvant radiotherapy	17

polypropylene mesh (macroporous, light and monofilament) with a titanized hydrophilic surface. Compared to plain polypropylene, this has a number of advantages:

- better cell viability;
- reducing the risk of inflammation;
- reduction of roughness scars tissue;
- less frequency of mesh sagging.

The polylactide included in the composition has excellent biocompatibility and reduces the frequency of inflammatory reactions due to the titanized coating (4-5). Histological integration of fibroblasts into a titanized mesh endoprosthesis occurs evenly over the entire surface, and by the end of the 3rd month a weak residual inflammatory reaction is determined (7) (*Fig. 2*).

Indications for the use of a titanized mesh 35 g / m²:

- high BMI;
- poor condition of local tissues;
- large breast implant volume in relation to the patient's BMI.

Indications for the use of a titanized mesh 16 g / m²:

- normal BMI;
- good condition of local tissues;
- the balance between the volume of the breast implant and the patient's BMI.

Surgical Technique

The patients underwent skin-sparing or nipple-sparing mastectomy with immediate implant-based reconstruction. The implant was used to cover the lower and the outer-lower pole (1) (*Fig. 3*).

Breast implants were installed as follows: the upper pole of the implants was covered with

Figure 2. Neofascia. Twelve weeks following the installation of a mesh pocket. Neovascularization

the pectoralis major muscle, the lower pole was covered with a titanized mesh (*Fig. 4*).

Fixation of the mesh to the pectoralis major muscle was carried out either with a continuous suture using a multi-filamentous suture material (Vicryl 4.0) or with interrupted sutures (Monocril 3.0) according to the official instructions of PFM Medical, fixation in the caudal, sternal and lateral margins was performed using an interrupted suture with a Vicryl 4.0 thread to achieve hammock effect (8) (*Fig. 5*).

The following algorithm was adopted to reduce the incidence of complications:

Figure 3. Subcutaneous mastectomy with reconstruction using a breast implant and covering of the lower pole with a titanised mesh pocket

Figure 4. Official fixation scheme

- implants irrigation with antibiotic solution (intraoperatively);
- minimal contact of the implant with the air;
- treatment of the surgical wound with the antibiotic solution (cefuroxime 1.5 mg per 250 ml NaCl 0.9%);
- injection of the antibiotic solution into the box with the implant using a thin needle;
- change of gloves of the entire operating team before installing the implant;
- processing of the implant pocket with a solution of betadine with chlorhexidine 0.05% in a 1: 1 ratio;
- cleanliness of the operating field;
- antibacterial prophylaxis in the post-operative period (amoxiclav 625 mg 3 times a day).

The mesh implant was wrapped around the lower pole of the breast implant and placed underneath and behind the latter. If necessary, a new submammary fold was formed.

Complications

In the largest multicenter retrospective study of combined breast reconstruction using a titanized mesh implant, which included 231 patients, no patient-associated characteristics correlated with complete loss of implants after

Figure 5. Fixation of the titanised mesh pocket in the caudal and sternal region

an immediate implant-based reconstruction with the mesh (10).

The risk of complications increased in patients with atypical surgical access. In patients who received radiation therapy, the mesh implant was more palpable than in patients who did not receive radiotherapy.

In general, patients of all groups noted that the mesh implant was almost imperceptible by palpation and did not cause any discomfort. The frequency of complications was as follows: seroma - 4.8% of cases, superficial hematoma of the skin flap - 9.5%, infections - 6.1%, partial necrosis of the skin flap - 3.9%, necrosis of the nipple-areola complex (NAC) - 3, 5%, total skin flap necrosis - 0.4%. Repeated surgical intervention (revision) was required in 13.4% of cases. During the follow-up period of 14 months, capsular contracture was observed in 2.2% of cases (10).

To reduce the incidence of complications, it is necessary to take into account the following features: the thickness of the skin flaps, the risk factors of the proposed surgery, the physique of the patient. To date, there is no effective tool for assessing the quality of the skin flaps, therefore, special attention should be paid to the surgical techniques and the use of modern surgical instruments and devices that reduce the trauma of skin flaps. In patients who have previously received radia-

tion therapy, or in those patients whose subcutaneous fat thickness is insufficient, biological matrices may be the most effective option, since they are thicker than synthetic analogues (11).

Results

In 74 (71.84%) cases, mastectomy was performed via batwing incision. The frequency of complications was as follows: partial NAC necrosis - 22.97% of cases, complete NAC necrosis - 5.41%, infection - 10.81%, red breast syndrome after reconstruction (by analogy with that with the use of acellular dermal matrix) - 9, 46%.

In 5 (4.85%) cases, mastectomy was performed via an inverted T-technique. The frequency of complications: partial NAC necrosis - 22.97%, complete NAC necrosis - 5.41%, infection - 40%, red breast syndrome after reconstruction - 13.51%.

In 24 (23.3%) cases, mastectomy was performed using the inframammary incision. The incidence of complications: infection - 12.5%, red breast syndrome after reconstruction - 8.33%, NAC necrosis - 0.23%.

In patients who underwent simultaneous bilateral breast reconstruction, the incidence of infection was higher than in patients with unilateral reconstruction and amounted to 22.22%, and red breast syndrome after reconstruction was observed in 66.67% of cases.

Neoadjuvant chemotherapy did not statistically affect the incidence of surgical complications (12).

It was found that adjuvant chemotherapy did not affect the final aesthetic result, however, it was capable of increasing the risk of postoperative wound infection. Similar observations were previously described (13).

Among 31 patients who received adjuvant chemotherapy, the frequency of complications was as follows: infection - 12.9% of cases, post-reconstruction red breast syndrome - 48.39%.

Titanized mesh does not affect dose calculations for radiotherapy (14).

In 17 patients who underwent adjuvant radiation therapy, the frequency of complica-

tions was as follows: complete loss of chest and mesh endoprotheses - 5.88%, capsular contracture (Baker III / IV) - 17.65%, reoperation for removal of mesh endoprosthesis only due to pain syndrome - 5.88%, red breast syndrome after reconstruction - 5.88%.

All patients during the follow-up period were interviewed by the department staff using the questionnaire consisting of the following items:

1. Do you have any painful sensations in the area of reconstruction?
 - If yes, please indicate the degree of pain on a scale from 1 to 10.
 - If not, the value is automatically set to zero.
2. In your opinion, was symmetry in underwear achieved?
 - If yes, please rate on a scale of 1-10 points, where 10 points correspond to perfect symmetry.
 - If not, the value is automatically set to zero.
3. Are you satisfied with the result?
 - If yes, please rate it on a scale of 1-10 points.
 - If not, the value is automatically set to zero.
4. Do you feel the mesh implant when during self-examining the reconstructed breast?
 - If yes, please rate the experience on a scale of 1-10.
 - If not, the value is automatically set to zero.

The general results of the questionnaire (all indicators were brought to averaged values) were as follows: for the 1st question the average value was 4 ± 1 point, for the 2nd question - 7 ± 1 point, for the 3rd question - 7 ± 1 point, on the 4th question - 2 ± 1 point.

It is noteworthy that 82% of the respondents emphasized the presence of the lower pole fullness reconstructed breast.

The results of the questionnaire survey among the patients who went through adjuvant radiotherapy (all indicators were brought to average values) were as follows: for the 1st question the average value was 6 ± 1

points, for the 2nd question - 4 ± 1 points, on the 3rd question - 5 ± 1 , on the 4th question - 4 ± 1 point.

Adjuvant chemotherapy did not significantly affect patient survey results.

Oncological Follow-up

Follow-up of the patients was carried out in accordance with the relevant recommendations of the Association of Oncologists of Russia, the Russian Society of Breast Oncology and the individual follow-up plan designed by the treating physician. A titanized mesh implant is not a contraindication to standard treatment protocol and does not affect the quality of instrumental and radiation research methods (15).

Findings

The titanized mesh can be used to improve the results of immediate implant-based reconstruction by enhancing the lower pole fill and providing additional support of the implant. Due to lower prices synthetic meshes seem an attractive alternative to acellular dermal matrices.

Conflict of Interest

The authors declare no conflicts of interests.

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