

# Experience with the use of titanized polypropylene mesh (TiLOOP® Bra) in oncoplastic breast surgery

Paepke S, Niemeyer M, Krol J, Müller D, Machens HG, Kiechle M

1 Interdisciplinary Breast Center and Gynecological Clinic, Technical University of Munich (TU München)

2 Clinic for Plastic and Reconstructive Surgery, Technical University of Munich (TU München)

Address for correspondence

Dr. St. Paepke  
Ltd. OA Senologie  
IBZ der TU München  
Ismaninger Str. 22 81675 München  
stefan.paepke@lrz.tum.de

## Summary

The indication for mastectomy is given in around 30% of all cases of primary breast cancer; this rate has remained unchanged. Immediate reconstruction following mastectomy shows both benefits for the psychological stabilization of the patient and demonstrable benefits with regard to breast-cancer-specific survival, and is therefore absolutely to be favored from the perspective of medical practice. A skin-sparing mastectomy or a nipple-areola-complex-preserving subcutaneous mastectomy can be applied with an identical standard of oncological safety, and with improved cosmetic results.

The problem of plastic reconstructive surgery therefore shifts to primary reconstruction with new requirements associated with volume replacement where the skin cover of the breast is preserved. Immediate reconstruction can be achieved using the body's own tissues or in combination with prosthetic inserts.

In contrast to sliding flap procedures, surgical techniques involving expanders or implants offer the benefit of substantially reducing patient stress, e.g. through reduced duration of surgery, a significantly shortened postoperative hospital stay, reduced cost of surgery, and the ability to modify and switch to flap procedures in the event of complications. The existing disadvantages of the sub-muscular prosthesis insert can be rectified through the use of supportive, covering, extraneous materials. This is deemed viable, and forms a new addition to the 2010 AGO guidelines (guidelines of the German Working Group for Gynaecological Oncology).

In our view, the application of titanized mesh combines the advantages of cost over artificial dermis with the technical material advantages over a heavier, non-titanized mesh – viewed critically in postoperative care – of an extra-light, stretch-angle-conditioned and titanized mesh structure. Through the use of titanized alloplasts, improved cosmetic results on the one hand, and a reduction in capsular fibrosis on the other are to be expected, the latter of which, as a long-term complication, also remains problematic where radiotherapy treatment is indicated.

The 2010 AGO recommendations evaluate the application of tissue-supporting extraneous materials with “+/-”; the clear surgical benefits are pitted against an absence of well-founded research results.

A report on the institute's own experience with titanized polypropylene mesh (TiLOOP® Bra) is compiled in the following summary.

## Introduction

An almost unchanged proportion of locally advanced breast cancers, an increasing proportion of multicentric carcinomas as a result of improved imaging sensitivity, and an increase in primary or secondary prophylactic intervention all result in a consistent rate of ablative breast operations with a trend towards an increasing proportion of plastic reconstructive procedures.

In addition to modified radical mastectomy with removal of all mammary gland tissue and nipple-areola complex, the spectrum of ablative procedures also increasingly comprises skin-sparing mastectomy and NAC-preserving ablative intervention. In recent times in particular, international data sources have included a vast number of publications that outline surgical variations of procedures and long-term results. The increasing volumes of data substantiate both the safety of the procedures detailed with regard to postoperative complications and the degree of long-term safety with regard to the local recurrence rate. This necessitates a change of requirements with regard to primary plastic reconstructive procedures such as (to a certain degree) more complex flap procedures (TRAM, muscle-sparing TRAM, DIEP, S-Gap, etc.), and equally the use of expander and implant-supported surgical techniques.

Data relating to mesh-supported techniques were first made the subject of professional discussion in this respect around three years ago (Brunnert K, Jahrestagung der Deutschen Gesellschaft für Senologie [Annual Conference of the German Association for Senology] 2007).

In contrast to sliding flap procedures, surgical techniques involving expanders or implants offer the benefit of substantially reducing the impact on the patient, thanks to the reduced duration of surgery and shortened postoperative hospital stay, reducing the cost of surgery, and the ability to resort to flap procedures in the event of complications.

The sub-pectoral prosthesis insert, however, has certain disadvantages:

- Thin or insufficient covering of the prosthesis (locus minoris resistentiae ventrally and caudally)
- Risk of tissue straining as a result of early and/or excessive tension after filling
- Damage to skin cover (e.g. plication) as a result of overly hesitant expansion
- Herniation of expander caudally or through break in cover surface
- As a result of the above, risk of complications or subsequent surgeries.

The disadvantages listed above can be rectified or reversed through the insertion of supporting, covering extraneous materials.

Extraneous materials available (not exhaustive):

- Meshes
- Titanized meshes
- Artificial dermis

## TiLOOP® Bra material properties

The TiLOOP® Bra titanized polypropylene mesh, comprising a monofilament fiber and laser-cut edges, constitutes an extra-light mesh configuration with high stretch capacity and minimized shrinkage tendency with tissue-like flexibility and high biocompatibility. It is approved as a soft-tissue-strengthening implant with a shape and size optimized for reconstructive breast surgery.

The pore diameter is  $\geq 1$  mm, and the prosthetic knitted fabric has an elasticity of  $\geq 16$  N/cm with a weight of just  $16 \text{ g/m}^2$ .

The TiLOOP® Bra is available in three different designs for supporting small breasts ( $< 200$  g), medium-sized breasts ( $< 350$  g), and larger breasts ( $< 500$  g).

**Table: TiLOOP® Bra material parameters**

<b>Weight:</b>	Extra light $16 \text{ g/m}^2$	Light $35 \text{ g/m}^2$	Strong $65 \text{ g/m}^2$
<b>Thickness:</b> (DIN EN ISO 5084)	0.20 mm	0.30 mm	0.45 mm
<b>Pore size:</b>	$> 1$ mm	$> 1$ mm	$> 1$ mm
<b>Fiber diameter:</b>	30 dtex ( $65 \mu\text{m}$ )	58 dtex ( $90 \mu\text{m}$ )	103 dtex ( $120 \mu\text{m}$ )
<b>2D porosity:</b>	73%	61%	53%
<b>3D porosity:</b>	91%	87%	82%
<b>Physiological Elasticity at 16 N:</b>	23%	20%	8%
<b>Breaking strength:</b> (Grab test):	37 N	61 N	142 N
<b>Dimensions:</b>	Small	Medium	Large
a	195 mm	215 mm	235 mm
b	95 mm	115 mm	135 mm
c	120 mm	140 mm	160 mm

In our view, the application of titanized mesh combines the advantages of cost over artificial dermis with the technical material advantages over much heavier, non-titanized meshes of an extra-light, stretch-angle-conditioned, and titanized mesh structure.

Improved cosmetic results are achievable through the application of titanized alloplasts, owing to the optimized shaping of the implant or expander bed.

Based on histopathological, immunohistochemical, and molecular biological studies, titanized alloplasts exhibit a reduced inflammatory reaction. In contrast to conventional materials, reduced shrinkage tendency together with the least chronic inflammatory activity are also demonstrated. It is therefore to be expected that the rate of capsular fibrosis occurring as a long-term complication can be diminished.

Clinical results with regard to the application of titanized alloplasts in surgery further demonstrate a reduction in chronic problems (3.5%) compared with uncoated materials, as well as an improved quality of life for the surgery patient.

## Own experience

The materials-related technical data and benefits reported have paved the way for the application of titanized polypropylene mesh in plastic reconstructive primary reconstruction using sub-pectoral expanders or implant inserts following nipple-areola-complex-preserving mastectomy. As of 2008, this has been performed on an occasional, and, with appropriate experience, consistent basis. We have since overseen 52 operations of this nature, involving 46 patients.

The indication for surgery is made and the surgical procedure planned during the interdisciplinary case review in the Breast Center. Consulting hours arranged to run in parallel in the senology and plastic surgery areas facilitate optimal preparation of case presentations and comprehensive patient consultation.

### Previous indication spectrum in the IBZ, TU München (Interdisciplinary Breast Center, Technical University of Munich)

1. Primary reconstructions
  - 1.1. Subcutaneous NAC-preserving operations with retention of skin cover, necessitating immediate volume filling.
  - 1.2. Primary prophylactic subcutaneous mastectomy with retention of skin and NAC with sub-muscular expander/implant reconstruction with BRCA 1 or 2 mutation, or significant family history and patient request
  - 1.3. Secondary prophylactic contralateral subcutaneous mastectomy with retention of skin and NAC with submuscular expander/implant reconstruction
  - 1.4. Skin-sparing mastectomy with submuscular expander/implant reconstruction with corresponding indication with locally advanced diagnostic findings, extensive DCIS, or relapse of breast cancer
2. Secondary reconstruction
  - 2.1. Following preceding mastectomy as subpectoral expander insertion and subsequent change to implant
3. Corrective surgery
  - 3.1. Following sub-pectoral corrective surgery and augmentation in the case of Poland Syndrome conducted extra muros with caudalization of implant, repositioning and stabilization of caudal covering using TiLOOP® Bra (small) titanized polypropylene mesh
  - 3.2. Following subcutaneous NAC-preserving mastectomy and necessary secondary radical mastectomy, stabilization of muscular cover

## Surgical procedure

The surgical procedure depicted in this document is based largely on individual experience and specialist discussions held in the course of surgery-oriented workshops with intensive exchanges of experience.

As with any non-standardized field of surgery, surgical avenues must not be restricted, particularly since the procedural logic is inherently bound up with the nature of the problem.

If the insertion of a titanized mesh is deemed necessary, in our experience the following points should be taken into account:

- Consideration of expansion requirements
- Evaluation of the required elongation of the expander and thus loose insertion of the mesh without draping

### **Implantation steps:**

1. The Musculus pectoralis major is separated from the chest wall and exposed from the caudal end to the edge of the sternum.
2. The TiLOOP<sup>®</sup> Bra mesh implant is attached to the caudal and lateral end of the Musculus pectoralis using a continuous suture. Upon attachment of the TiLOOP<sup>®</sup> Bra mesh implant to the edge of the muscle, allowance must be made for the flexible and elastic alignment of the mesh material fabric to ensure that postoperative elongation of the caudolateral section of the reconstructed breast remains possible.
3. The lower section of the TiLOOP<sup>®</sup> Bra mesh implant is fixed to the inframammary fold using monofilament suture material with individual stitches.

It is urgently recommended that the patient wears a support bra and “Stuttgart Belt” following surgery in order to support and improve postoperative elongation in the caudolateral breast pole area.

## Complications

In two patients, it was necessary to perform corrective surgery when minimal suture dehiscence occurred, with the mesh becoming visible. Surgery involved sliding skin-flap grafting for a more secure cover. There were no further complications for either patient.

Three complete removals of the expander/implant reconstruction had to be performed owing to infection or impaired wound healing. (Two of these cases were reported because corrective operations had been performed extra muros.)

In one patient, approx. four months after prophylactic subcutaneous mastectomy with NAC retention and with sub-pectoral Becker expander insertion and caudal mesh strengthening of the muscular covering (BRCA 2 mutation carrier), massive seroma development occurred, to which two punctures (sterile puncture specimen) brought no improvement; in view of a secondary wound infection, the reconstruction was completely reversed, and a large section of the skin cover and the Becker expander were removed. After healing, secondary reconstruction was carried out using DIEP.

## Postoperative care and imaging

From an oncological point of view, a thorough follow-up as part of postoperative care must be guaranteed; this means that the materials used must not impose restrictions on imaging capabilities for detecting potential recurrences.

In our experience, the application of the TiLOOP<sup>®</sup> Bra imposes no restrictions on imaging procedures. In interval checks following mesh insertion in the period of expander filling and following implant insertion and partial mesh support, the TiLOOP<sup>®</sup> Bra extra light approved for breast surgery can be seen in a high-resolution ultrasound (Esaote; 18 MHz linear) over several weeks as a series of tiny hypoechoic areas (max. 0.2 mm), like a string of beads, with corresponding acoustic phenomena dorsally of the mesh. In the peripheral zones, too, which are of principal relevance in postoperative care, limitations to assessability cannot be established.

## Closing remarks

In specific cases, the use of the TiLOOP<sup>®</sup> Bra extra light titanized polypropylene mesh offers clear benefits in oncoplastic breast surgery.

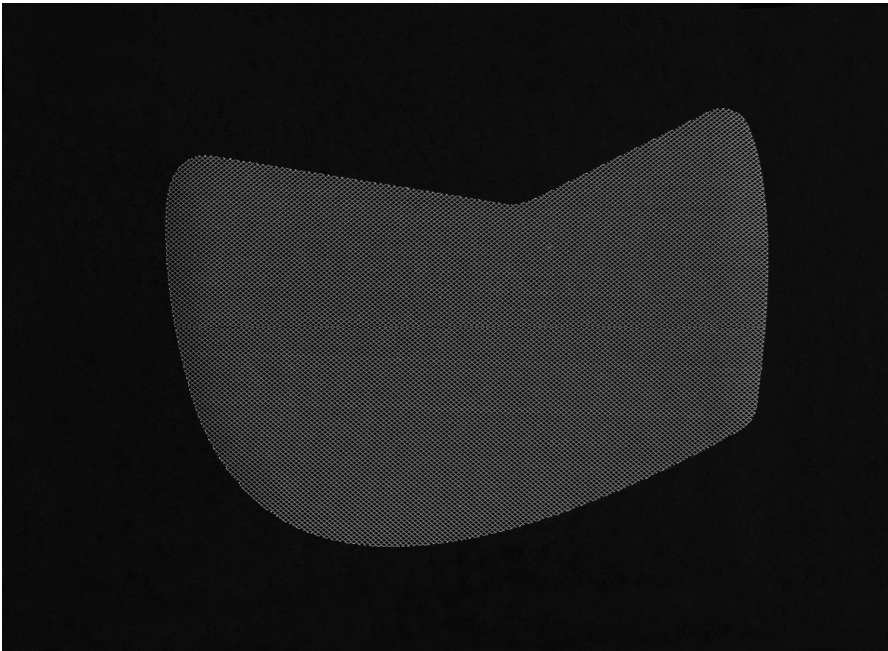
However, as is often the case in operative therapies, there is a lack of corresponding standards that are grounded in prospective studies.

The feasibility argument based on new advances with tested and approved medical devices often represents the first step towards introduction in clinical practice. It is therefore left to the discretion and experience of breast cancer center and clinic surgeons to select the appropriate course of action, and to assess these procedures over the course of their implementation by way of intensive consultation with patients and through constant critical scrutiny.

The 2010 AGO guidelines evaluate the application of tissue-supporting extraneous materials with “+/-”; the clear surgical benefits are, as is often the case in largely non-standardizable surgery, pitted against the already highlighted absence of established research results.

Although randomized studies in the field of oncoplastic surgery are difficult to implement, the contrasting experiences of surgeons should be collected in a central register as the use of extraneous materials increases, to facilitate a more evidence-based approach to surgical recommendations than has been the case to date.

Figures





## Literature

1. Bezuhly M. et al.: Immediate postmastectomy reconstruction is associated with improved breast cancer-specific survival. *Cancer* 115(2009): 4648-4654
2. Albain K, Barlow W, Shak S et al.: Prognostic and predictive value of the 21-gene recurrence score assay in postmenopausal, node-positive, ER-positive breast cancer. Abstract 10
3. Mook S, Schmidt MK, Viale et al.: Breast cancer patients with 1-3 positive lymph nodes and a low risk 70-gene profile have an excellent survival. Abstract 50
4. Brunnert, K. and Warm, M. (2008) *gynäkol. prax.* 32, 479-493
5. Scheidbach, H., Tamme, C., Tannapfel, A., Lippert, A., and Köckerling, F. (2003) Biokompatibilität verschiedener Polypropylen-Netze unter Berücksichtigung der Handhabbarkeit bei der totalen extraperitonealen Patchplastik (TEP). In Köckerling, F., Bittner, R., Gastinger, L., and Lippert, H., editors. *Minimal Invasive Chirurgie*, Science Med, Hannover
6. Scheidbach, H., Tannapfel, A., Schmidt, U., Lippert, H., and Köckerling, F. (2004) *Eur Surg Res* 36, 313-317
7. Scheidbach, H., Tamme, C., Tannapfel, A., Lippert, H., and Köckerling, F. (2004) *Surg Endosc.* 18, 211-220
8. Tamme, C., Garde, N., Klingler, A., Hampe, C., Wunder, R., and Köckerling, F. (2005) *Surg Endosc.* 19, 1125-1129
9. Horstmann, R., Hellwig, M., Classen, C., Rottgermann, S., and Palmes, D. (2006) *World J Surg* 30, 1742-1749
10. Schardey, H. M., Schopf, S., Rudert, W., Knappich, P., and Hernandez-Richter, T. (2004) *Zentralbl. Chir* 129, 363-368