

Study summary

Pre-pectoral breast reconstruction with TiLOOP® Bra

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Titanium-coated polypropylene mesh as innovative bioactive material in conservative mastectomies and pre-pectoral breast reconstruction

› Gentile P., Bernini M., Orzalesi L., Sordi S., Meattini I., Lessi F., Kothari A., Calabrese C., *Bioactive Materials*. 2021, 6(12): 4640-4653

Method

276 patients who underwent unilateral or bilateral mastectomy (328 mastectomies in total) between January 2012 and December 2018, were evaluated in this prospective observational study. In 163 patients a primary, implant-based pre-pectoral breast reconstruction (IBR) was performed with TiLOOP® Bra (study group). 113 patients received a secondary implant-based pre-pectoral breast reconstruction (control group). For 74.3% of the breast reconstructions in the control group TiLOOP® Bra was used, and 25.7% of breast reconstructions were performed without TiLOOP® Bra. The average follow-up period was 44 months (23-65 months).

Primary endpoints:

- › Clinical outcome: Incidence of perioperative and postoperative complications
- › Quality of Life (QoL) 24 months postoperatively and the comparison to the preoperative assessment measured by the BREAST-Q questionnaire
- › Aesthetic outcome, assessed by independent plastic surgeons and by the patients themselves
- › Capsular contracture rate evaluated by Baker scale

Secondary endpoint:

- › Histopathological assessment of the capsules in 11 patients chosen at random from both groups, in order to assess the tissue integration of TiLOOP® Bra

Results

Histological analysis shows complete mesh integration and normal healing*

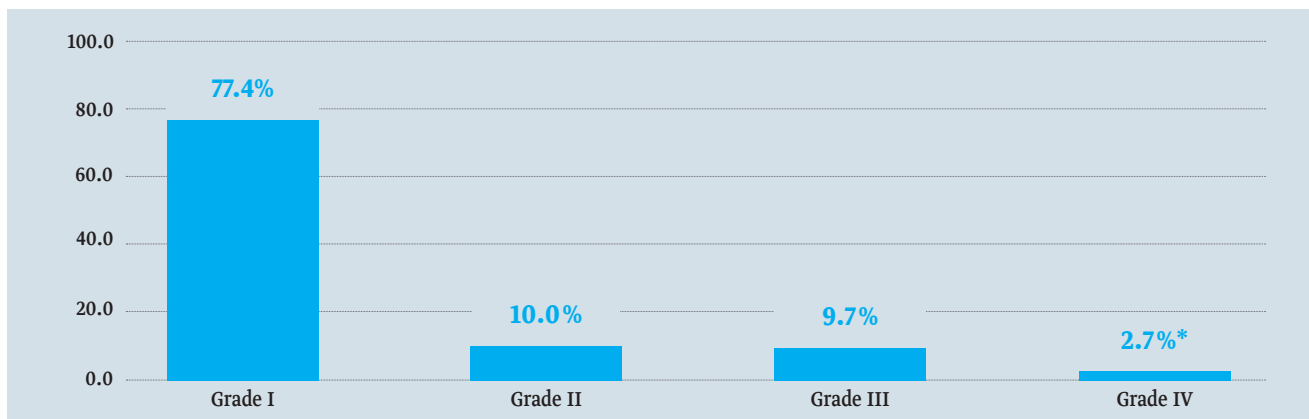
High level of satisfaction with the overall aesthetic result in primary breast reconstruction with TiLOOP® Bra**

Low rate of significant capsular contracture (Baker grade III and IV)

* Assessment based on inflammatory markers (number of lymphocytes) and collagen expression (collagen 1 and collagen 3, Figs. 3, 4, 7 in the study)

** Breast volume, breast shape, position of inframammary fold and appearance of the scars were assessed

Figure 1: Rate of capsular contracture according to Baker (related to operated breasts, n = 328)



Data taken from Table 3 of the study; presentation by pfm medical gmbh

* All patients received postoperative radiotherapy

Histological analysis of the incorporation of the TiLOOP® Bra mesh into the soft breast tissue

The expression of collagen 1 and 3 in tissue samples with and without TiLOOP® Bra is the same (no statistically significant difference). In the tissue samples, different layers containing collagen, capillaries and fibroblasts are visible, as well as the layer of adipocytes, in which lipofilling is possible. Overall, complete healing with newly formed dermal collagen is evident (Figs. 3, 4, 7 in the study).

Table 1: Complications (relative to operated breasts, n = 328)

Types of complications	Cases (%)
Skin and nipple necrosis	8 (2.4%)
Wound dehiscence	8 (2.4%)
Haematomas	3 (0.9%)
Infections	24 (7.3%)

Data taken from Table 3 of the study; presentation by pfm medical gmbh

Conclusion

According to the results of the study, skin- or nipple-sparing mastectomy followed by immediate pre-pectoral breast reconstruction with TiLOOP® Bra is oncologically safe. As the pectoral major muscle remains intact, it is less invasive than the sub-pectoral technique and leads to a high quality of life for the patients. Histological analysis shows complete incorporation of TiLOOP® Bra into the tissue. The expression of collagen types 1 and 3 shows no significant differences between samples with and without TiLOOP® Bra, which confirms complete integration of TiLOOP® Bra into the tissue and physiological healing.

References



Further information:
www.pfmmedical.com/meshimplants-professionals

PubMed:
<https://pubmed.ncbi.nlm.nih.gov/34095622/>

Contact

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