

**Study summary**

**TiLOOP® Bra Studie (PRO-BRA):  
Patient Reported Outcome and  
cosmetic evaluation**

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**Patient reported outcome and cosmetic evaluation following implant based breast-reconstruction with a titanized polypropylene mesh (TiLOOP® Bra):  
A prospective clinical study in 269 patients**

▶ *Thill M., Faridi A., Meiré A., Gerber-Schäfer C., Baumann K., Blohmer J. U., Mau C., Tofall S., Nolte E., Strittmatter H. J., Ohlinger R., Paepke S. European Journal of Surgical Oncology 2020 Apr 15; S0748-7983(20)30407-8*

**Method**

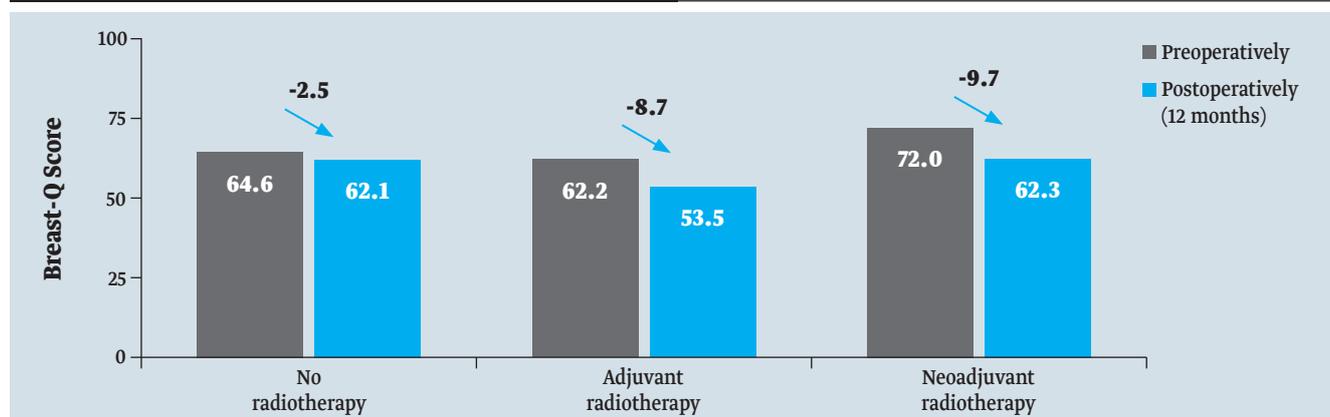
Between December 2013 and July 2016, 269 patients were enrolled in this prospective, single-arm, multicentre study. The patients underwent mastectomy and immediate or delayed breast reconstruction with the titanised mesh TiLOOP® Bra.

**Endpoints:**

- ▶ Patient Reported Outcome (PRO) 12 months postoperatively and the comparison to the preoperative assessment measured by the BREAST-Q questionnaire
- ▶ Cosmetic outcome assessed by two independent experts using photographs taken preoperatively and 12 months after surgery

The follow-up was 12 months.

**Impact of radiotherapy on “satisfaction with breasts”**



**Fig. 1:** Impact of radiotherapy on “satisfaction with breasts“ - measured by BREAST-Q questionnaire; comparison of the preoperative and postoperative evaluation (mean values); the higher the score, the higher the quality of life (score scale from 0 - 100 points)

**Impact of the patients' age on "satisfaction with breasts"**

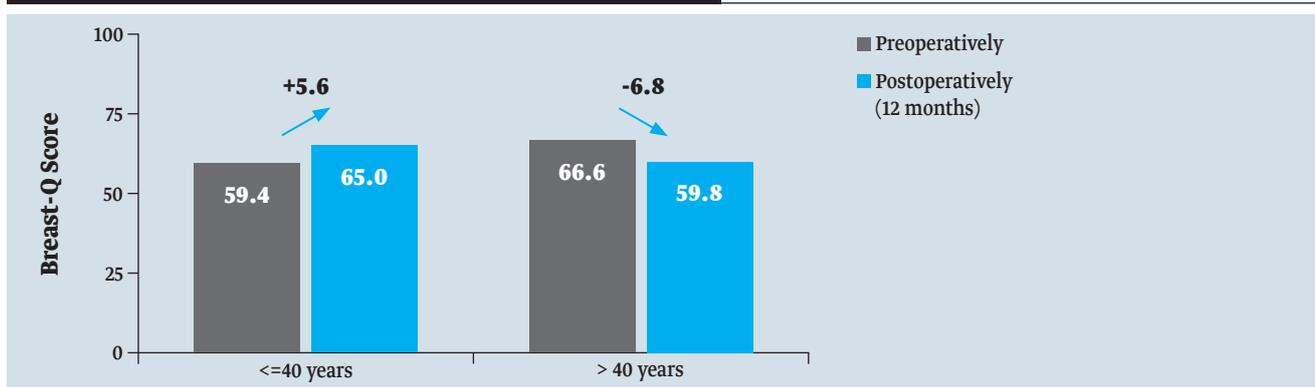


Fig. 2: Impact of patients' age on "satisfaction with breasts" - measured by BREAST-Q questionnaire; comparison of the preoperative and postoperative evaluation (mean values); the higher the score, the higher the quality of life (score scale from 0 - 100 points)

**Results**

- ▶ Out of a total of 269 patients, completed BREAST-Q data and photos for the evaluation of the cosmetic outcome were available from 210 patients.
- ▶ Of a total of 210 patients, 130 patients underwent unilateral and 80 patients bilateral surgery.
- ▶ Patients without adverse events (e.g. capsular contracture, seroma) were significantly more satisfied in terms of "sexual well-being" (p = 0.001), "satisfaction with breasts" (p < 0.05) and "psychosocial well-being" (p < 0.001) 12 months after surgery than patients with adverse events.
- ▶ The scale "psychosocial well-being" was significantly positively influenced (p < 0.01) in patients with at least one prior therapy (prior breast surgery, chemo- or radiotherapy).
- ▶ A unilateral surgery led to a significantly reduced "satisfaction with breasts" after 12 months follow-up compared to the preoperative evaluation (p < 0.01). In contrast, the "psychosocial well-being" was rated significantly higher.
- ▶ The cosmetic outcome was assessed differently by the patients and experts - the patients' assessment was significantly worse compared to the experts' (p < 0.001).

**Conclusion**

The results of the study show that the patients' quality of life is influenced by various factors, which can be either demographic (e.g. age) or therapy related (e.g. radiotherapy, previous therapies). This information can be used to improve the decision-making process for patients who will undergo implant-based breast reconstruction.

**References**



Further information:  
[www.pfmmedical.com/meshimplants-professionals](http://www.pfmmedical.com/meshimplants-professionals)

PubMed:  
[www.ncbi.nlm.nih.gov/pubmed/32336622](http://www.ncbi.nlm.nih.gov/pubmed/32336622)

**Contact**

Should you have any questions our Regulatory and Clinical Affairs Team will be glad to assist you.

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