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# A biological or a synthetic mesh in immediate breast reconstruction? A cohort-study of long-term Health related Quality of Life (HrQoL)

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ABSTRACT

*Objectives:* Meshes/matrices are commonly used in immediate breast reconstruction. There are few studies comparing biological and synthetic meshes and it is unknown what type of mesh gives the best long-term results. The aim of this study was to compare long-term health-related quality of life (HrQoL) and patient satisfaction in implant-based immediate breast reconstruction with a biological mesh (Surgisis®) with that of patients reconstructed with a synthetic mesh (TIGR ® Matrix Surgical Mesh).
*Material and methods:* Both cohorts were prospectively included and consecutively operated. Clinical data was collected. HrQoL was evaluated with EuroQoL-5 dimension – 3 levels questionnaire (EQ-5D-3L) and the Hospital Anxiety and Depression Scale (HADS) and the Breast-Q.
*Results and conclusion:* Seventy-one patients were operated on in the biological group and 49 in the synthetic group. The response rates were 75 and 84 per cent, respectively. Mean follow-up time was 74 months and 23 months, respectively. There were no statistical differences in satisfaction and quality of life between the two groups. Complications and radiation seem to lead to a lower satisfaction. Our findings could indicate that biological and synthetic meshes give an equal long-term result as regards patients' perceived quality of life.


## Introduction

As breast cancer survival has increased in Western countries focus of care has shifted towards quality of life (QOL) after cancer treatment. When meshes were introduced in breast reconstruction in 2005 [1], a number of advantages were postulated. However, there are limited data supporting that they are superior to traditional muscle coverage [2]. The first meshes were biological and called acellular dermal matrices (ADM). In recent years, synthetic meshes have also been introduced on the market [3]. However, there are few studies comparing biological and synthetic meshes and it is unknown what type of mesh gives the best long-term result [4,5], especially regarding Health related Quality of Life (HrQoL) and patient satisfaction. There is only one previous study comparing HrQoL between a synthetic (TiLOOP®) and a biological (Protexa®) mesh [6]. That prospective randomized study included 48 randomized patients and concluded that there were no differences in patient satisfaction with cosmetic results between the groups at two weeks, 3 months and 6 months after the operation. Judged on standardized photographs by surgeon and external specialists, there was a significantly better outcome with TiLOOP®. However, when patients with failed reconstructions where excluded similar cosmetic results were found. The Protexa® group had more severe complications with 30.4 per cent implant losses compared to the TiLOOP® group with 7.7 per cent implant losses ($p = 0.0001$) and showed worse QOL results, as measured with the EORTC QLQ C30 and the BR23 questionnaires.

The aim of this study was to compare long-term HrQoL and patient satisfaction in implant-based immediate breast reconstruction with a biological mesh (Surgisis®) with that of patients reconstructed with a synthetic mesh (TIGR ® Matrix Surgical Mesh).

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## Patients and methods

### Patient cohorts

Two groups were included in the study: patients who had their breast reconstructed with Surgisis®, called the biological mesh group (BMG), and patients reconstructed with TIGR ® Matrix Surgical Mesh, called the synthetic mesh group (SMG). Both cohorts were prospectively included and consecutively operated. Inclusion criteria were 18 years of age or older and indication for a unilateral or bilateral mastectomy, either for oncological or prophylactic reasons, and an immediate breast reconstruction. Exclusion criteria were inability to give informed consent and to answer questionnaires in Swedish. Indication and surgical technique were discussed at a multi-disciplinary team conference in all cases. If postoperative radiation was anticipated the patient was recommended a secondary autologous reconstruction. However, there were unanticipated postoperative irradiation in 21 per cent in the BMG and 10 per cent in the SMG (Table 1). The biological mesh group were consecutively operated on between 2005 and 2014 and the synthetic mesh group between 2015 and 2016 in our department. Procedures followed were in accordance with the Helsinki Declaration of 1964, as revised, and the Good Clinical Practice (GCP) guidelines. All patients gave their informed consent to participate (GU-043-08).

### Surgical technique and meshes

The surgical technique has been described previously and was identical in the two groups, with the exception of the mesh used [2,7]. Both meshes are degradable. Surgisis® (Cook Inc, West Lafayette, USA) is a biological mesh composed of a multi-layered

**Table 1**
Unadjusted and adjusted analysis of biological vs. synthetic mesh with respect to patient characteristics and HrQoL.

| | Surgisis (n = 53) | TIGR (n = 41) | p-value | Adjusted p-value* |
|---|---|---|---|---|
| Age (years) | 45.2 (8.8)<br>43.1 (29.5; 67.4)<br>n = 53 | 45.6 (9.8)<br>45.5 (26.6; 71.0)<br>n = 41 | 0.73 | |
| Weight (kg) | 67.2 (9.6)<br>65.0 (54.0; 96.0)<br>n = 53 | 65.0 (8.3)<br>64.0 (49.0; 84.0)<br>n = 41 | 0.38 | |
| Body mass index (kg/m2) | 23.7 (3.1)<br>22.7 (18.9; 32.7)<br>n = 53 | 23.1 (2.6)<br>23.0 (17.9; 28.4)<br>n = 41 | 0.65 | |
| Unilateral/Bilateral | | | | |
| Unilateral | 20 (37.7%) | 28 (68.3%) | | |
| Bilateral | 33 (62.3%) | 13 (31.7%) | 0.0060 | |
| Radiation (preop/postop) | | | | |
| No radiation | 42 (79.2%) | 37 (90.2%) | | |
| Radiation | 11 (20.8%) | 4 (9.8%) | 0.24 | |
| Years between surgery and QoL answer | 5.54 (1.56)<br>5.33 (3.28; 12.75)<br>n = 53 | 1.68 (0.34)<br>1.63 (1.13; 2.61)<br>n = 41 | <.0001 | |
| Breast-Q - Satisfaction with breasts | 57.0 (15.3)<br>57.0 (16.0; 100.0)<br>n = 52 | 60.9 (16.1)<br>61.0 (25.0; 100.0)<br>n = 41 | 0.35 | 0.39 |
| Breast-Q - Satisfaction with outcome | 69.7 (20.5)<br>67.0 (0.0; 100.0)<br>n = 53 | 66.6 (18.7)<br>67.0 (35.0; 100.0)<br>n = 41 | 0.24 | 0.46 |
| Breast-Q - Psychosocial well-being | 71.7 (23.1)<br>74.5 (23.0; 100.0)<br>n = 52 | 72.2 (19.8)<br>70.0 (26.0; 100.0)<br>n = 41 | 0.96 | 0.84 |
| Breast-Q - Sexual well-being | 54.0 (24.1)<br>54.0 (0.0; 100.0)<br>n = 53 | 53.1 (21.9)<br>49.0 (0.0; 100.0)<br>n = 41 | 0.66 | 0.70 |
| Breast-Q - Physical well-being - chest | 77.7 (15.6)<br>77.0 (33.0; 100.0)<br>n = 53 | 79.0 (15.1)<br>81.0 (50.0; 100.0)<br>n = 41 | 0.88 | 0.96 |
| EQ5D | 0.883 (0.152)<br>1.000 (0.291; 1.000)<br>n = 38 | 0.831 (0.193)<br>0.848 (−0.066; 1.000)<br>n = 41 | 0.16 | 0.19 |
| VAS | 78.4 (13.8)<br>80.0 (30.0; 100.0)<br>n = 38 | 78.4 (16.2)<br>80.0 (20.0; 100.0)<br>n = 41 | 0.73 | 0.82 |
| HAD - Anxiety | 5.66 (4.90)<br>5.00 (0.00; 19.00)<br>n = 35 | 5.44 (4.26)<br>5.00 (0.00; 14.00)<br>n = 41 | 0.95 | 0.78 |
| HAD - Depression | 2.83 (3.46)<br>1.00 (0.00; 13.00)<br>n = 36 | 2.95 (3.02)<br>2.00 (0.00; 11.00)<br>n = 41 | 0.68 | 0.88 |

For categorical variables n (%) is presented.
For continuous variables Mean (SD)/Median (Min; Max)/n = is presented.
For comparison between groups Fisher's Exact test (lowest 1-sided p-alue multiplied by 2) was used for dichotomous variables and the Mann-Whitney *U* test was used for continuous variables.*) Adjusting for Age (years), Body mass index (kg/m$^2$), Unilateral/Bilateral and Radiation (preop/postop) using Logistic regression.

non-cross linked collagen (types I, III and V), glycosaminoglycans, proteoglycans, glycoproteins, and growth factors [8–12]. TIGR ® Matrix Surgical Mesh (Novus Scientific, Uppsala, Sweden) is knitted from two types of fibres: a fast degrading copolymer between glycolide and trimethylene carbonate and a slow-degrading copolymer between lactic and trimethylene carbonate. The fast degrading part gives extra strength during the healing phase (4 month) and gradually becomes softer and more flexible. The slow-degrading part is completely resorbed after about three years [13].

*Clinical data collection*

Patients were evaluated clinically one week, three weeks and twelve months post-operatively as well as at later time if it was needed. Collected demographic data included age at surgery, weight, body mass index (BMI), smoking, follow up time in months from first operation to last follow-up visit, radiation, type of surgery, and complications. Definitions of complications have been published previously [7]. Complications were divided into early (≤30 days) and late (>30 days). A clinical case report form (CRF) was used to ensure that all patients were evaluated for all studied complications in a standardized fashion.

*Outcomes measures: quality of life questionnaires*

In 2018, the questionnaires were distributed per mail including an envelope for return and a reminder was sent after two weeks to non-responders. In this study, two generic instruments, the EuroQoL-5 dimension − 3 levels questionnaire (EQ-5D-3L) [14,15] and the Hospital Anxiety and Depression Scale (HADS) [16,17] and one disease-specific instrument, the Breast-Q [18] were used.

The EQ-5D-3L was developed for economic and clinical evaluation of health care. It has a 5-dimension, 3-level descripting system comprising mobility, self-care, usual activities, pain/discomfort and anxiety/depression. A global score, where 1 indicates “perfect health” and 0 “death”, is calculated. The EQ-5D-3L also includes a visual analogue scale (VAS) where the patient marks his/her current health state, from 0 (“worst imaginable”) to 100 (“best imaginable”). The instrument has been validated for Swedish language [19] and for breast reconstruction [20].

The HADS comprises 14 questions: seven covering anxiety and seven covering depression during the previous week. Each question is scored from 0 (“never, no intensity”) to 3 (“every day, very intense”). A total score is calculated for each scale. A total score less or equal to 7 is judged as no depression or anxiety, a score between 8 and 9 equals that depression or anxiety might be present and a score over 9 means that the presence of depression or anxiety is plausible. The instrument has been translated to Swedish [21] and has previously been used to evaluate breast reconstruction [22,23].

The Breast-Q specifically measures patient's satisfaction and QOL after breast surgery [24] and is widely used [25]. In this study the breast reconstruction module was used. Only domains relevant for the aim of the study were analysed: QOL domains: (1) psychosocial well-being, (2) sexual well-being and (3a) physical well-being (chest and upper body) and Satisfaction domains: (1) satisfaction with breasts and (5) satisfaction with outcome. The QScore Scoring Software was used to convert Breast-Q scores to a score between 0 and 100 for each domain. A higher score indicates a better outcome. The Breast-Q has been translated to Swedish and used in many previous studies on breast reconstruction [25].

*Statistics*

Descriptively, number and percentage were shown for categorical variables, and mean, standard deviation, median and range for continuous variables. Scores from the three instruments were calculated according to their respective manuals [17,26–28]. For test between two groups Fisher's exact test was used for dichotomous variables and Mann-Whitney *U* test for continuous variables. The relation between two continuous variables was described and tested by Spearman correlation. The adjusted analysis of test between the biological and synthetic mesh groups with respect to different Breast-Q domains was performed using logistic regression with group as dependent variable and each domain at the time as main effect variable, with adjustment for age, body mass index, unilateral/bilateral surgery and radiation. All analyses were performed using SAS Software version 9.4 (SAS Institute Inc., Cary, NC, USA). All tests were two-tailed and conducted at a 0.05 significance level.

## Results

During the study period 71 patients (116 breasts, 26 unilateral and 45 bilateral) were operated on in the BMG and 49 patients (65 breasts, 16 bilateral and 33 unilateral) in the SMG. The response rates in the BMG was 75 per cent (54/71) and 84 per cent (41/49) in the SMG (Electronic supplement 1). There were very few missing values in both groups (Table 1, Electronic supplement 1). Mean follow-up time was 74 months (43–162) and 23 months (17–34) respectively ($p > 0.001$). The groups were similar regarding age and BMI (Table 1). There were significantly more bilateral operations in the BMG (62% vs. 32%, $p = 0.0060$) as well as more patients with a history of radiation (21% vs. 10%, $p = 0.24$) (Table 1). There were no statistical differences in satisfaction and QOL, as measured with BREAST-Q, EQ5D or HAD (Table 1) between the two groups. However, the SMG had fewer overall complications, 29.3 per cent compared to 35.8 per cent in the BMG. In the BMG, patients with a previous history of irradiation had a high but not significantly increased risk for implant loss. Four out of eleven patients had an implant loss, 36.4 per cent compared to 9.5 per cent ($p = 0.096$) in non-irradiated patients in the BMG. In the SMG there were a lower implant loss rate of 4.9 per cent in the whole group (Table 2). When the analysis was adjusted for complications, there was a significantly lower satisfaction with outcome ($p = 0.028$) in the BMG but no differences were found in the other Breast-Q sub-themes.

## Discussion

In this cohort study QOL and patient satisfaction in immediate breast was compared in patients reconstructed with a biological and a synthetic mesh. There were no differences in perceived QOL between the groups, as measured with EQ-5D, HADS, and Breast-Q (Table 1). The accordance between the three instruments might strengthen that there truly is no difference in long-term QOL between biological and synthetic meshes. However, when taking complications into account, the BMG with higher complication rates compared to the SMG scored significantly lower for satisfaction with outcome (Table 2, Electronic supplement 2). There were no differences in Breast-Q regarding the other sub-themes.

One of the stated advantages of biological meshes is a decreased risk for capsular contracture [3]. Nonetheless, in this study there was a similar capsular contraction rate in the two groups (Table 2). If there had been a great difference in capsular formation between synthetic and biological meshes, a difference in patient-reported satisfaction would also be expected. In brief, our results might contradict that biological meshes give a superior long-term result to synthetic meshes. Moreover, the Breast-Q scores in this study are at a similar level as the American normative Breast-Q scores and those of the only Breast-Q study on mesh-assisted breast reconstruction [29] (Table 3). There is one study [20] using EQ-5D in

**Table 2**
Early and late complications in respondents vs. non-respondents.

| | Biological mesh - respondents | Biological mesh non-respondents | Synthetic mesh - respondents | Synthetic mesh non-respondents |
|---|---|---|---|---|
| **No. of patients (%)** | 53 (75%) | 18(25%) | 41(84%) | 8(16%) |
| **Early complications ≤ 30 days** | n(%) | n(%) | n(%) | n(%) |
| Overall | 19(35.8%) | 7(38.9%) | 12(29.3%) | 0 |
| Major complication | 0 | 0 | 1[b](2.4%) | 0 |
| Implant loss: | 8(15.1%) | 4(22.2%) | 2(4.9%) | 0 |
| Irradiated | 4/11(36.4%) | | 1/4(25%) | |
| Non-irradiated | 4/42(9.5%) | | 1/37(2.7%) | |
| Minor complication | 11(20.7%) | 3(16.7%) | 8(19.5%) | 0 |
| **Late complications >30 days** | n(%) | n(%) | n(%) | n(%) |
| Lipofilling (e.g. due to rippling) | 17(32.1%) | 0 | 6(14.6%) | 1(12.5%) |
| Correction of implant position | 6(11.3%) | 1(5.6%) | 0 | 0 |
| Minor skin correction | 5(9.4%) | 0 | 2(4.9%) | 1(12.5%) |
| Capsular contracture requiring operation | 3[a](5.5%) | 0 | 2(4.9%) | 0 |
| Reconstruction removed due to relapse | 1(1.8%) | 0 | 0 | 0 |

[a] One patient needed bilateral operation and is counted as one as this is a per-patient table.
[b] One patient had both a pulmonary embolus and reoperation due to.

**Table 3**
Normative values for Breast-Q and Breast-Q scores from previous studies on quality of life in mesh-assisted immediate breast reconstruction.

| First author, year<br>Patients | Mundy, 2017 [45]<br>n = 1018 | Negenborn, 2018 [38]<br>n = 208 | Walia, 2018 [46]<br>n ~ 50[a] |
|---|---|---|---|
| | Mean (SD) | Mean (SD) | Median, min-max |
| Satisfaction with breasts | 58 (18) | 70.6 (20.2) | 47 (40–58) |
| Satisfaction with outcome | | 78.0 (20.5) | 75 (61–100) |
| Psychosocial well-being | 71(18) | 79.5 (22.7) | 63 (50–82) |
| Sexual well-being | 56(18) | 60.8 (23.7) | 47 (34-609) |
| Physical well-being, chest | 78 (20) | 80.5 (16.7) | 71 (63–81) |

[a] Follow-up 60 days.

immediate breast reconstruction, irrespective of surgical technique (n = 103). In that study, the mean EQ-5D score was 0.851 (SD 0.17), which is similar to the scores in this study (Table 1). There is one study [22] giving HADS total scores in immediate breast reconstruction, irrespective of surgical technique (n = 153). In that study the mean score (SD) for anxiety was 3.99 (4.301) and for depression 2.90 (4.320) [22]. Those scores are slightly lower than the scores seen in the present study (Table 1). In summary, the level of the QOL scores and complications rates in this study seem to be comparable to those of similar studies.

The results of the study could have been affected by a base line difference between the two groups. The inclusion of patients was started before the Swedish Breast-Q was developed and we therefore have no pre-operative Breast-Q scores from the patients. Such baseline data would make it possible to evaluate the results in the light of the patients' original QOL and it would also make it possible to investigate if there were any differences in base line QOL between the biological mesh group and the synthetic mesh group. Furthermore, the results could have been influenced by the difference in follow-up time between the two groups, ($p > 0.0001$) (Table 1). It is a known fact that patients' answers to QOL questionnaires might be adapted over time; that is, there is a *response shift* [30], which may introduce an uncertainty in the measurement. Since baseline data and data on changes in the patients' general health status are missing in this material, no tests for response shift could be performed. Furthermore, previous studies have indicated that the patients' satisfaction with their breast reconstruction changes during the first year, but then stabilizes [31]. Hence, it should not be a problem to compare two-year data (SMG) with six-year data (BMG). Still, a difference in changes in general health between the groups potentially could have affected the results. The response rate can affect the result of questionnaire studies. The response rate was slightly lower in the BMG which might be explained by that the operations were performed many years ago and the patients may therefore be less likely to respond. The level of satisfaction could have been affected by the occurrence of complications, especially in combination with radiation [32]. However, there were more complications and corrections in the responding groups than in the non-responders (Table 2), which indicates that not only the most content patients answered the questionnaire.

In summary, we detected no statistically significant differences in reported QoL when comparing immediate breast reconstruction with either a synthetic mesh or a biologic mesh, with the exception for complications, for which the BMG scored higher, especially in irradiated patients. Our findings could indicate that biological and synthetic meshes give an equal long-term result as regarding patients' perceived QOL.

## Conflict of interest statement

The authors report no conflicts of interests. The authors alone are responsible for the content and writing of this article.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejso.2019.03.013.

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