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SHORT COMMUNICATION

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Drain secretion and seroma formation after immediate breast reconstruction with a biological and a synthetic mesh, respectively: A randomized controlled study

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Abstract

The aim of this study was to compare seroma production in breast reconstruction with a biological mesh with that of a synthetic mesh, in the same patient. The patients were randomized to biological mesh in one breast and synthetical in the other. Twenty-four breasts were included. The total drain production and the daily drain production were similar in the two groups. After drain removal, there were more seroma aspirations in the biological group. During the exchange to a permanent implant, there was significantly more seroma in the biological group. Seroma formation is different in synthetic and biological meshes.

KEYWORDS

acellular dermal matrix, immediate breast reconstruction, randomized controlled trial, seroma, synthetic mesh, TIGR®, Veritas®

1 | INTRODUCTION

One of the risk factors for high volume and prolonged seroma production after implant-based breast reconstruction is the usage of meshes/matrices.[1-4] The aetiology is unclear but it has been hypothesized that the extra foreign material incites a foreign body reaction in the poorly circulated mastectomy flaps.[1,5] Seroma formation could jeopardize the benefits with meshes and matrices as it may interfere with the process of integration and thereby the success of the reconstruction. Studies have indicated that the seroma formation varies with different types of matrices.[6,7] Nonetheless, most of the reports on seroma formation concern biological matrices[1] and there are no studies comparing seroma formation in biological and synthetic meshes. The aim of this study was to compare seroma production in implant-based immediate breast reconstruction with a biological mesh with that of a synthetic mesh, in the same patient.

2 | PATIENTS AND METHODS

The patients were recruited from the Gothenburg TIGR®/Veritas® Study (ClinicalTrials.Gov identifier NCT02985073). The Regional Ethical Committee of Gothenburg reviewed and approved the study (189-16). All patients gave their written informed consent to participate in the study. The primary outcome for the Gothenburg TIGR®/Veritas® Study is complication frequency, and therefore, no sample size calculation was performed for seroma production. All referrals for bilateral immediate breast reconstruction were assessed for inclusions. Inclusion criteria were 18 years of age or older and indication for a bilateral prophylactic mastectomy and immediate breast reconstruction. Exclusion criteria were inability to give informed consent, previous breast surgery, smoking, and BMI > 30 kg/m^2.

The surgical technique has been described previously[8,9] and was identical in the two breasts, with the exception of the mesh

used. During the operation, the patients were randomized, by the sealed envelope method, to synthetic mesh in one breast and biological in the other. Both meshes used are degradable. Biological Veritas® Collagen Matrix (Synovis Surgical Innovations) is a nonfenestrated non-cross-linked propylene oxide-treated acellular collagen matrix xenograft made of bovine pericardium.[10] Synthetic TIGR® Matrix Surgical Mesh (Novus Scientific) is knitted from two types of fibers: a fast degrading (4 months) copolymer between glycolide and trimethylene carbonate and a slow-degrading (36 months) copolymer between lactic and trimethylene carbonate.[11] In all cases, an anatomical tissue expander (TE) (CPX®, Mentor Worldwide LLC) was used. During the primary operation, two suction drains (Exudrain™, Mediplast), French gauge 14, were used for each breast. The drains were kept in place until the output was less than 30 mL per 24 hours, for a maximum of 14 days. Prophylactic antibiotics were given until the drains were removed. During the first two postoperative days, a continuous infusion of ropivacaine 2 mg/mL, 4 mL an hour, was given in each breast. The drain outputs were read once a day. After drain removal, clinically significant seromas were aspired with the aid of ultrasound or above the TE injection port. Seromas were classified according to Brzezienski et al[4] as class I-III, depending on the number of aspirations required. Seromas during the exchange to a permanent implant were classified as <1 deciliter and >1 deciliter.

Daily volume, as well as total drain output for each breast, was calculated. Descriptively, medians and ranges were given, except for daily volume which was given as a mean. Differences between samples from synthetic and biological meshes were analyzed using nonparametric Wilcoxon signed-rank test for related samples as the two samples came from the same patient. All tests were two-tailed, and a *P*-value of .05 or less was considered statistically significant. All analyses were performed with IBM SPSS version 25 for Mac (SPSS Inc).

3 | RESULTS

A total of 24 breasts, in 12 patients, were included. Patient demography and surgical details are presented in Table 1. The total drain production was a median of 579 mL (range 70-1460) in the biological group and 563 mL (range 345-2070) in the synthetic group ($P = .3$). The drains were kept in place for a median of 7.5 days (range 4-14) in the biological group and 8.5 days (range 2-14) in the synthetic group ($P = .9$). The daily drain production was similar in the two groups (Figure 1). After drain removal, there were no seroma aspirations in the synthetic group and two class III seromas, that is seromas requiring 3 or more aspirations, in the biological group ($P = .157$). There were no TE losses in the synthetic breasts and 1 in the biological breasts. The TE was lost due to infection, following wound edge healing problems. The patient had a total drain production of 980 mL on the biological side and 1245 on the synthetic side and did not require any seroma aspirations. During the exchange to a permanent implant, 11 synthetic mesh breasts had < 1 deciliter seroma and 1 breast > 1 deciliter. In the biological mesh breasts, 1 breast had < 1 deciliter seroma and 10 breasts had > 1 deciliter seroma ($P = .011$).

TABLE 1 Demography of participants and surgical details

	Participants	
	Median	Range
Age at operation (y)	50	32-65
BMI (kg/m^2)	22.9	19.1-29.6
Smoking (yes/no)	0/12	
Diabetes mellitus (yes/no)	0/12	
Preoperative radiation (yes/no)	0/12	
Neo-adjuvant chemotherapy (yes/no)	0/12	
Inframammary incision (yes/no)	24/0	
Resection weight synthetic side (g)	319	69-616
Resection weight biological side (g)	272	77-597
TE size (mL)	350	250-450
TE fill during operation (mL)	100	0-250
Fill ratio (%)	40	0-72
Time between primary op and first postoperative TE filling (d)	21	13-28
Time between first and last TE filling (d)	23	0-50
Time between primary op and exchange to a permanent implant (d)	114	42-157

Abbreviations: Op, operation; TE, tissue expander.

4 | DISCUSSION

This study compares seroma production in implant-based immediate breast reconstruction with a biological mesh with that of a synthetic mesh. Seroma formation is affected by patient-related factors, such as older age, higher BMI, and larger breast size (mastectomy weight),[6,12] by surgical factors, such as the size of TEs used and axillary lymph node dissection,[12,13] and by qualities of the mesh/matrix. The present study compares the right breast with left breast in the same patient, and the operations were performed in the same way, save the mesh/matrix used, in all patients. No axillary surgery was performed. Hence, patient-related factors and surgical factors other than the mesh should not have affected the results.

A mesh/matrix is sometimes described as a type of graft that revascularizes. As such, the matrix can be considered a xenograft/allograft whereas the mesh is more of a foreign material. Indeed, biopsies from early capsules from biological and synthetic meshes display different tissue reaction.[14] It has been hypothesized that additional synthetic material might lead to a prolonged inflammatory response contributing to a longer drain time.[12] However, this could not be seen in the present material as daily drainage outputs and drain times were similar. Nonetheless, there were more seroma aspirations and significantly more seroma formation present during the

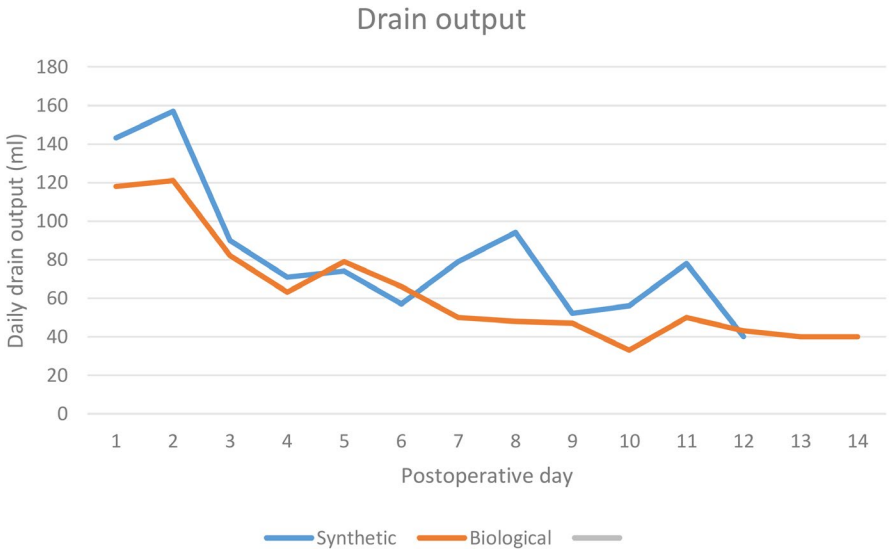

FIGURE 1 Daily drainage production. The drain outputs were higher as long as the continuous infusion of ropivacaine was given [Color figure can be viewed at wileyonlinelibrary.com]

exchange to permanent implants. This suggest that the significantly higher seroma production occurs late during the postoperative healing phase and contradicts the theory of an acute inflammatory reaction in the early stage of the wound healing process.[12] Even though the synthetic meshes provoke more inflammation and foreign body reaction,[14] it does not seem to be the deciding factor in the amount of seroma produced. The biological meshes seem to be more prone to produce seroma.

In addition, if a mesh/matrix is considered a type of graft, its qualities, such as meshing and thickness, could affect surface area between the mesh/matrix and the tissue and its potential to integrate. Previously, fenestration of biological meshes has been tried as a mean to reduce the risk for complications[7,15] and it specifically seems to reduce the incidence of seromas.[7] In analogy, skin grafts are often meshed to decrease the risk of seroma formation under them. In the present study, a nonfenestrated biological mesh was compared with a loosely knitted synthetic mesh. Theoretically, the ability of fluid to easily shift through the mesh could be one of the explanations to why the synthetic mesh is less prone to produce seroma in our study. Future studies comparing synthetic and biological meshes should include fenestrated biological meshes.

Previous studies have suggested that drains should be placed for a longer time after reconstruction with a mesh/matrix.[2,16]

However, our findings suggest that long drain times alone do not solve the problem as there seems to be a tendency for biological mesh to form late seromas, even if the drains are kept in place for up to 2 weeks postoperatively. In the present study, the frequency of seroma aspirations was low even in the biological breasts. However, this could be a reflection of conservative attitude to aspiration rather than a low occurrence of seromas. In fact, the evidence presence of substantial seromas during the stage two operation in the biological mesh group could indicate that more seromas could indicate that a more liberal attitude to seroma aspiration is warranted when biological meshes are used.

Weaknesses of the present study include a small sample size. Moreover, our strict inclusion criteria might have introduced a selection bias in the study with individual without other risk factors for seroma formation.[12,13] Theoretically, different risk factors could work in synergy and the use of matrices/meshes might therefore be a more important factor in high-risk patients. Further studies are needed specifically in individuals with an already high risk, such as patients who have received neo-adjuvant chemotherapy.[2] Another weakness is that the exact measurements of seroma during the second stage operation were unreliable, as some seroma ended up in the draping, some in the compresses, and some in the kidney dish. The reporting method <1 deciliter and >1 deciliter was chosen based on that there either was a minimal amount of seroma or a quite substantial amount of seroma. The exact amounts were considered subordinate due to their unreliable nature.

In conclusion, there was no difference in daily drainage outputs, total drainage volume, and days with drain between the synthetic and the biological mesh. The biological mesh required more seroma aspirations, and there was more seroma present during the exchange to a permanent implant. Clinically, our findings suggest that long drain times alone do not solve the problem and that a more liberal attitude to seroma aspiration could be warranted when biological meshes are used.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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