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Are patients most satisfied with a synthetic or a biological mesh in dual-plane immediate breast reconstruction after 5 years? A randomized controlled trial comparing the two meshes in the same patient

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Summary Biological or synthetic meshes are commonly used in implant-based immediate breast reconstruction (IBR). The aim of this study was to compare patient-reported outcome measurements (PROMs) after IBR with a synthetic mesh and a biological mesh, in a single-blinded randomized controlled trial, using the compared materials in the same patient, thereby eliminating patient-related confounders. Twenty-four patients were recruited, and all patients had a prophylactic bilateral mastectomy and a dual-plane reconstruction using anatomical breast implants.

The patients' two breasts were randomized preoperatively to a biological or a synthetic mesh, using a simple approach with a parallel design. PROMs were measured with BREAST-Q. Twenty-one patients answered (88%). Most participants were equally satisfied/dissatisfied with the synthetic and the biological mesh sides regarding size of bra, softness, feel to touch, natural part of body, appearance compared with preoperatively, and palpable wrinkles, and about half

Abbreviations: IBR, immediate breast reconstruction; PROM, patient reported outcome measure; BMI, body mass index; GCP, good clinical practice; MDT, multidisciplinary team; TE, tissue exxpander; SD, standard deviation; NAC, nipple areola complex; GA, general anaesthetics; LA, local anaesthetics; ASA, American Society of Anaesthesiologists'classification.; IQR, interquartile range; NR, not reported.

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of the patients regarding shape of bra, natural appearance, and visible wrinkles. The frequency of capsular contracture rate was zero in both groups at 5 years. One mesh type was not clearly superior to the other regarding PROMs, but biological and synthetic meshes seem to give rise to different types of reconstructed breasts, and more studies are needed regarding whether knowledge about the effects of different meshes can be used to tailor breast reconstructions to individual patients' wishes. The rate of complications and corrections in the biological mesh breasts was higher, and this must be considered when the type of mesh is chosen.
Trial registration number: ClinicalTrials.Gov identifier NCT02985073

Introduction

Biological or synthetic meshes are commonly used in implant-based immediate breast reconstruction (IBR).[1] They were introduced as an adjunct in secondary esthetic breast surgery and later established in breast reconstructions after breast cancer to give a better control of the reconstructed breast footprint, decrease the risk for capsular contracture, and allow for single-stage reconstruction with a fixed volume implant.[2] However, scientific studies have thus far failed to support some of the benefits,[3] and meshes seem to give rise to more complications than traditional muscle-cover,[1,3,4] although the frequencies vary considerably depending on the type of mesh used.[5] Complications seem to be lower for synthetic than biological meshes.[3,6]

The frequency of complications is only one of the outcomes that are important when breast reconstruction technique is chosen. The BRAVO study[7] has developed a core outcome set, which comprises major complications, unplanned surgery, donor site morbidity, normality, quality of life, and women's cosmetic satisfaction (important for both professionals and patients); implant- and flap-related complications (important for professionals alone); and self-esteem, emotional well-being, and physical well-being (important for patients alone).[7] The outcomes normality, quality of life, women's cosmetic satisfaction self-esteem, emotional well-being, and physical well-being can be measured with patient-reported outcome measurements (PROMs).[8] The dimensions measured with PROMs are complex concepts influenced by body image, social networks, psychological factors,[9-11] and attitudes to the care given,[12] in addition to by body mass index (BMI),[13] tobacco use,[14,15] and other diseases.[16] Therefore, the measurement of PROMs is infested with confounders, and it is difficult to single out one factor, such as type of mesh, to compare.

The aim of this study was to compare PROMs in IBR with a synthetic mesh and a biological mesh, in a randomized controlled trial, using the compared materials in the same patient, thereby eliminating patient-related confounders. We hypothesize that the biological mesh has better stretch properties and therefore gives rise to reconstructed breasts that appear more natural and are softer, and thereby more appealing, to the patient.

Patients and methods

Study design, protocol, and ethics

This study is a clinical, randomized, and prospective trial comparing synthetic and biological mesh in the same patient. It is one of the studies described in the Gothenburg TIGR® /Veritas® Study protocol (ClinicalTrials.Gov identifier NCT02985073). The study is reported according to the CONSORT guidelines.[17] Previously, complications,[6] drain secretion,[18] and histological findings[19] have been reported for the participants. The study was vetted and approved by the Regional Ethical Committee of Gothenburg (189–16) and conducted in accordance with the Helsinki Declaration and the Good Clinical Practice (GCP) guidelines. All participants gave their informed consent to participation, chart review, and publication of the results.

Setting

The study was conducted in the second largest city of Sweden, Gothenburg, in one of the country's seven public departments of plastic and reconstructive surgery. Sahlgrenska University Hospital performs about 350 breast reconstructions a year, of which about 40 are prophylactic mastectomies and IBRs performed mainly in mutation carriers.

Inclusion and exclusion criteria, recruitment, and sample size

All referrals for bilateral prophylactic mastectomy and IBR were assessed for inclusion, and patients who met the inclusion criteria were asked for participation consecutively. Inclusion criteria were 18 years of age or older and indication for bilateral prophylactic mastectomy and IBR. Exclusion criteria were inability to give informed consent, previous breast surgery, active smoking (6 weeks of abstinence were required before and after surgery), and a BMI > 30 kg/m^2. Indication and surgical techniques were discussed at a multi-disciplinary team (MDT) conference in all cases. The sample size in the Gothenburg TIGR® /Veritas® Study protocol was calculated based on complications, as described previously.[6]

Interventions and randomization

The surgical protocol has been described in detail previously.[6] The mastectomies were performed by oncological breast surgeons (general surgeons) and the reconstructions by plastic surgeons (HH or EH). The techniques, expanders, and implants used were identical on the two sides, except for the mesh used. In big and/or ptotic breasts, a Wise pattern incision and skin-reducing mastectomy were performed, and in breasts, where a skin reduction was not necessary, a submammary incision was used. All mastectomies were nipple-sparing. A dual-plane approach was used; hence, the inferior medial and inferior attachment of the major pectoralis muscle were released, and the expanders/implants were partially covered by the muscle. The meshes were sutured with 2.0 Maxon™ (Covidien, Dublin, Ireland) to the pectoralis muscle and to the chest wall laterally and in the inframammary fold. The reconstructions were performed in two stages, and an anatomical tissue expander (TE) (CPX®, Mentor Worldwide LLC, CA, USA) was placed during the first operation. Preoperatively, the breasts were randomized, by sealed envelope, to a biological or a synthetic mesh. The allocation sequence was concealed, and a simple randomization approach, with a parallel design and an intended allocation ratio of 1:1, was used. The patients were blinded to which side a biological and a synthetic mesh had been used. The first TE filling was performed during the operation, and the second two to three weeks postoperatively, and then once a week until the target volume had been reached. The second-stage operation was performed about three months after the first operation, and the TE was then exchanged for a permanent implant (CPG®, Mentor Worldwide LLC, CA, USA). During the second stage, the same skin incision was used as during the first operation, and the implant pocket was modified if needed.

Meshes

Two degradable materials that have been used previously in breast reconstruction [5,20-25] were utilized. The biological matrix was Veritas® Collagen Matrix (Synovis Surgical Innovations, St. Paul, MN, USA), which is a non-fenestrated xenograft manufactured from bovine pericardium and composed of non-cross-linked propylene oxide-treated acellular collagen matrix.[24,26,27] The synthetic mesh was TIGR® Matrix Surgical Mesh (Novus Scientific, Uppsala, Sweden), which is made from a fast-degrading copolymer between glycolide and trimethylene carbonate and a slow-degrading copolymer between lactic and trimethylene carbonate. The fast-degrading part is fully absorbed after approximately four months and the slow-degrading part after three years.[28]

Patient-reported outcome measurements

The patients were sent a breast reconstruction-specific health-related quality of life questionnaire preoperatively and 4 to 6 years postoperatively, in February and March 2022. The BREAST-Q reconstruction questionnaire, which has been developed in North America,[29] validated,[30,31] and translated to Swedish, was used. The use of BREAST-Q, authored by Drs. Klassen, Pusic, and Cano, was made under license from Memorial Sloan Kettering Cancer Center, New York, USA. The following domains were analyzed: Satisfaction with breast/s (16 items), satisfaction with outcome (7 items), satisfaction with implants (2 items), psychosocial well-being chest (10 items), sexual well-being (6 items), physical well-being chest (16 items), and satisfaction with information (15 items). The patient rates the items on a Likert scale (1–3/4/5), and a score is calculated and transformed to a standardized score between 0 and 100 for each domain. A higher score indicates a better outcome. In the satisfaction with breast/s domain, the participants were postoperatively asked to rate breast-specific items for the left and right breast separately. Normative scores have been described for two North American[13,32] and one Australian[33] population. Mean normative scores and standard deviations (SDs) for the different BREAST-Q domains are as follows[13,32,33]: Satisfaction with breasts 58 ± 18/59±21/50 ± 15, psychosocial well-being 71±18/79±19/55 ± 16, sexual well-being 56±18/57±19/42 ± 21, physical well-being chest 93±11/84±13/79 ± 15.

Complications and corrections

Data on complications and corrections were registered prospectively and have been defined previously[6] (Table 1).

Statistics

Descriptive data were given as median and ranges, means and SDs, and frequencies, when applicable. BREAST-Q data were treated as described in the manual, and QScore™ was used to calculate summary scores. Preoperatively, the questionnaire was used in the traditional way. Postoperatively, the participants were asked to rate breast-specific items for the left and right breast separately in the satisfaction with breast/s domain. To calculate, a total postoperative score for the domain satisfaction with breasts average item scores for the right and left breast was used. To compare the breasts reconstructed with a synthetic mesh and a biological matrix, paired, non-parametric Wilcoxon signed-rank test was used to compare preoperative and postoperative domain scores and McNemar's test to compare single items. All tests were two-tailed, and a p-value of 0.05 was considered to indicate a statistically significant difference. Statistical analyses were performed using SPSS® version 27.0.0.0 for Mac (IBM, Armonk, New York, USA).

Results

Participants

Forty-two breasts (21/24 participants, 88%) were included in the analysis, 21 reconstructed with synthetic mesh and 21 with biological mesh (Figure 1). All procedures were prophylactic, but one patient had breast cancer during the follow-up period. Hence, one biological mesh breast has been

Table 1 Definitions of complications. The table has been published previously in Journal of Surgical Oncology.[6] It is distributed under the terms under the Creative Common CC BY license.

Complication	Definition
Local wound complications	Seroma, red breast syndrome, burn wound in mastectomy flap, delayed wound healing/wound dehiscence, infection, skin necrosis, NAC necrosis
Seroma	A seroma requiring aspiration or leading to the second stage was brought forward or significant seroma during the stage II operation (>1 dl)
Red breast syndrome	A noninfectious, self-limited erythema of the reconstructed breast
Brun wound in mastectomy flap	Burn wounds were defined as clinically visible burn scars at the first follow-up visit
Infection	Any local surgical site condition requiring treatment with antibiotics. Prophylactic antibiotics given perioperatively or until drains were drawn were not included
Delayed wound healing/wound dehiscence	Any wound healing problems, found on clinical examination, not requiring an intervention in GA or LA. If antibiotics were given the complication was registered as both 'delayed wound healing' and 'infection.' Revision bedside was noted separately
Wound revision bedside	Partial necrosis of the skin or NAC revised bedside in LA
NAC loss	NAC loss that required later NAC reconstruction in LA
Unplanned re-operations	
Necrosectomy	Reoperation in GA due to hematoma, removal of TE/implant, and necrosectomy
Hematoma evacuation	Any hematoma requiring surgical exploration
TE loss	A complication that required that the TE was removed.
Implant loss	A complication that required that the implant was removed. n

Abbreviations: GA, general anaesthetics;.
LA, local anaesthetics;.
NAC, nipple-areola complex;.
TE, tissue expander.

treated with tumor resection followed by radiotherapy. All mastectomies were nipple-sparing mastectomies, and the majority were skin-sparing mastectomies with a submammary incision (Table 2). Details regarding the operations and expanders and implants used are given in Table 2. The participants were followed for a median of 5 years and a minimum of 3 years. There were expander/implant losses in four biological mesh breasts (19%) and in one (5%) synthetic mesh breasts. Details about complications are given in Table 2. All patients were re-reconstructed in two stages with an expander followed by a permanent implant (Table 2). There were no capsular contractures in any of the groups. The frequencies of corrections were 33% in the biological group and 14% in the synthetic group (Table 3). The most common type of correction was lipofilling (Table 2). Preoperative and postoperative BREAST-Q scores were similar, except for the domain of physical well-being where the scores were lower after surgery than before (Table 4).

Satisfaction with biological and synthetic mesh breasts

One mesh type was not clearly superior to the other regarding patient-reported satisfaction of individual items of the satisfaction with breast/s domain of BREAST-Q. A majority of the participants were equally satisfied/dissatisfied with the synthetic and the biological mesh sides regarding size of bra, softness, natural part of body, appearance compared with preoperatively, and palpable wrinkles, and about half of the patients regarding shape of bra, natural appearance, feel to touch, and visible wrinkles (Figure 2, Table 5). The aspect in which the most participants experience a difference between the synthetic and the biological mesh breast was a natural appearance, visible wrinkles, and feel to touch (Table 5, Figure 2). Among the participants who experienced differences between the two sides, more participants were more satisfied with the biological mesh regarding natural appearance and appearance compared with preoperatively. A few biological mesh breasts had bottoming out (Table 2). Among participants who experienced a difference between the two breasts, a predominance was more satisfied with the synthetic mesh size of bra and natural part of body (Table 5, Figure 2). Half of the participants who experienced a difference between the synthetic and the biological mesh were more satisfied with the synthetic mesh and half with the biological mesh regarding feel to touch, softness, and palpable wrinkles (Table 5, Figure 2).

Discussion

This randomized controlled study explores differences in patient satisfaction with IBR with a synthetic and a biological mesh, in the same patient. One mesh type is not generally superior to the other, regarding patient-reported outcomes.

Our findings are in accordance with previous studies. There are four previous studies comparing PROMs in synthetic and biological mesh in partially muscle-covered (dual

Table 2 Demography of included participants.

	Patients ($n = 21$)	Synthetic mesh breasts ($n = 21$)	Biological mesh breasts ($n = 21$)
Follow-up, years	5 (3-5)		
Age at operation, years (median (range))	44 (28-65)		
Age at questionnaire, years (median (range))	49 (33-68)		
BMI at operation, kg/m^2 (median (range))	23.4 (19.—29.6)		
Previous smokers*	4		
ASA 1	19		
ASA 2	2		
Neoadjuvant chemotherapy	0		
Postoperative chemotherapy	1		
Postoperative radiotherapy	0	1*	0
Nipple-sparing mastectomy		19	19
Inframammary incision, skin-sparing mastectomy		18	18
Wise pattern incision, skin-reducing mastectomy		4	4
Resection weight (grams)		272 (68-616)	270 (77-597)
TE size, ml		350 (250-450)	350 (250-450)
TE fill during operation, ml		100 (0-250)	100 (0-250)
Fill ratio (%)		34 (0-72)	34 (0-72)
Time between stage I and stage II (months)	3.8 (1.4-13.5)		
Permanent implant size (ml)		370 (270-440)	370 (270-440)
Unplanned operations stage I (n (%))			
Hematoma evacuation		0	0
Wound revision			
Expander loss			
		0	0
		1 (4.8%)	3 (14%)
Unplanned operations stage II (n (%))			
Hematoma evacuation		0	0
Wound revision			
Implant loss			
		0	0
		0	1 (4.8%)
Re-reconstruction with new expander		1	4
Radiotherapy due to cancer		0	1**

Abbreviations: ASA, American Society of Anaesthesiologists' classification.
BMI, body mass index.
N, number of patients/breasts.
TE, tissue expander.
1The patients had to abstain from smoking 6 weeks before and 6 weeks after the operation.
* The patients had to abstain from smoking 6 weeks before and 6 weeks after the operation.
** The patient has not yet required any re-operations or corrections after the radiotherapy.

plane) implant-based IBR (Table 6). All of them are non-randomized cohort studies,[34-37] and three of them are retrospective.[34,35,37] In the prospective study,[36] there is no information on the types of synthetic and biological meshes used. None of the studies have been able to demonstrate any difference in PROMs between the meshes (Table 6). BREAST-Q domain scores in the present study were on the same level as previous studies (Tables 4 and 6) and similar to the previously published norms.[13]

Considerations regarding the results

In accordance with our hypothesis, the biological mesh appears to have more stretch and therefore gives rise to a more ptotic breast with a more flexible implant pocket. However, this is not always appreciated by the patients, as some of them seem to prefer the more rigid softness of the synthetic mesh breast (Figure 2, Table 5). It has been discussed that a mesh with more stretch capacity accommo-

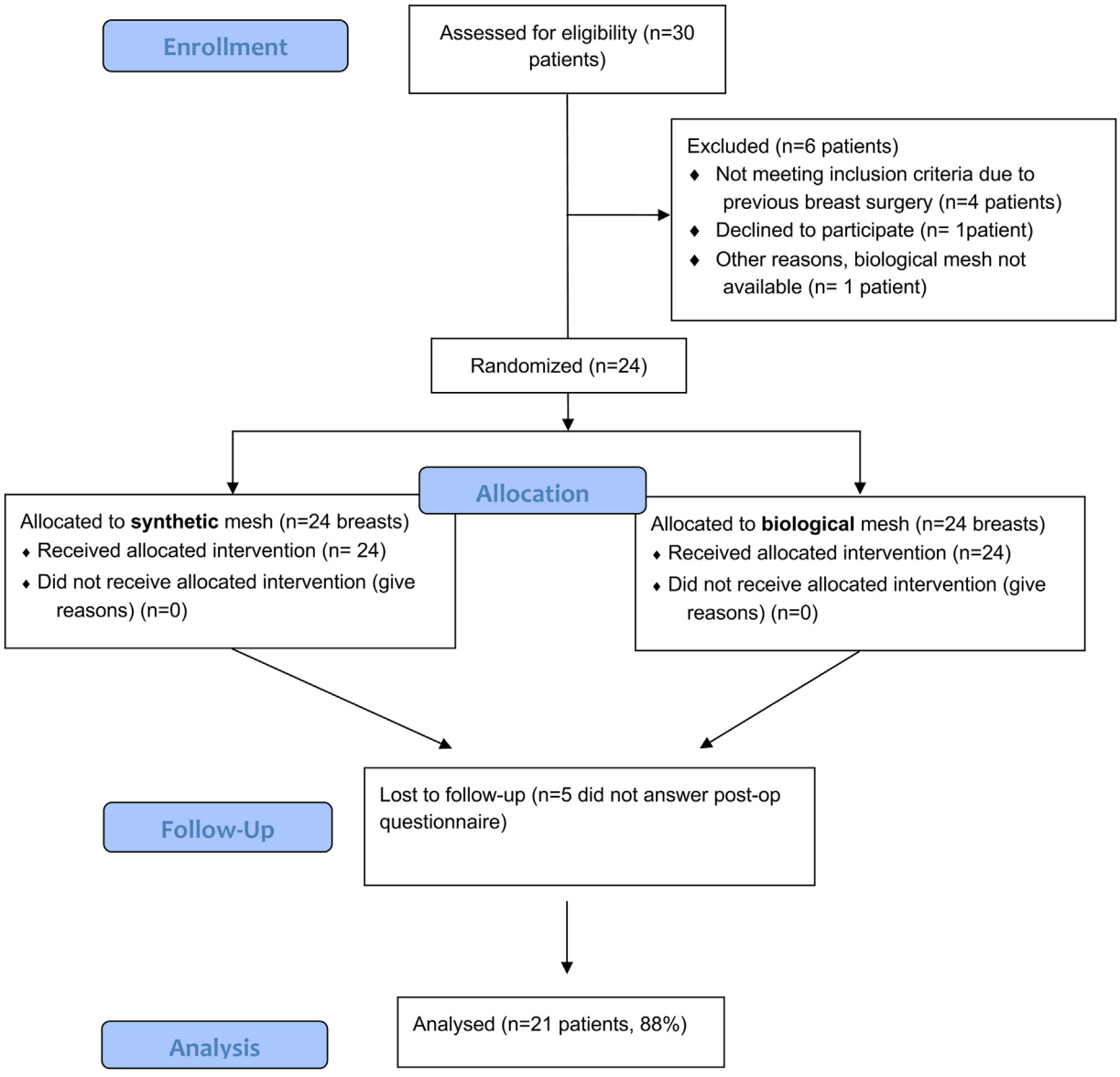

Figure 1 Consort diagram.

Table 3 Corrections.

	Synthetic mesh - total $n = 21$	Biological mesh - total $n = 21$	Synthetic mesh - re-reconstructed excluded$n = 20$	Biological mesh - re-reconstructed excluded$n = 17$
Implant changes - too small	0	1	0	1
Implant changes - too big	1	1	1	1
Operation due to capsular contracture	0	0	0	0
Correction due to bottoming out	0	2	0	1
Liposuction	1	0	1	0
Lipofilling	1	3	0	1

Table 4 Preoperative and postoperative BREAST-Q scores.

	Preoperative score	Postoperative score	Preoperative vs. postoperative score (p-value)Wilcoxon signed-rank test
BREAST-Q	Mean (SD) Median (range)	Mean (SD) Median (range)	
Satisfaction with breast	63 (15) 58 (38–100)	59 (14) 59 (30–90)	$p = 0.14$
Psychosocial well-being	75 (12) 79 (57–100)	76 (21) 73 (41–100)	$p = 0.80$
Sexual well-being	64 (18) 57 (39–100)	60 (23) 54 (16–100)	$p = 0.18$
Physical well-being chest	86 (11) 85 (68–100)	78 (14) 74 (50–100)	$p = 0.012$
Satisfaction with information	-	67 (20) 66 (38–100)	
Satisfaction with outcome	-	67 (13) 67 (39–100)	

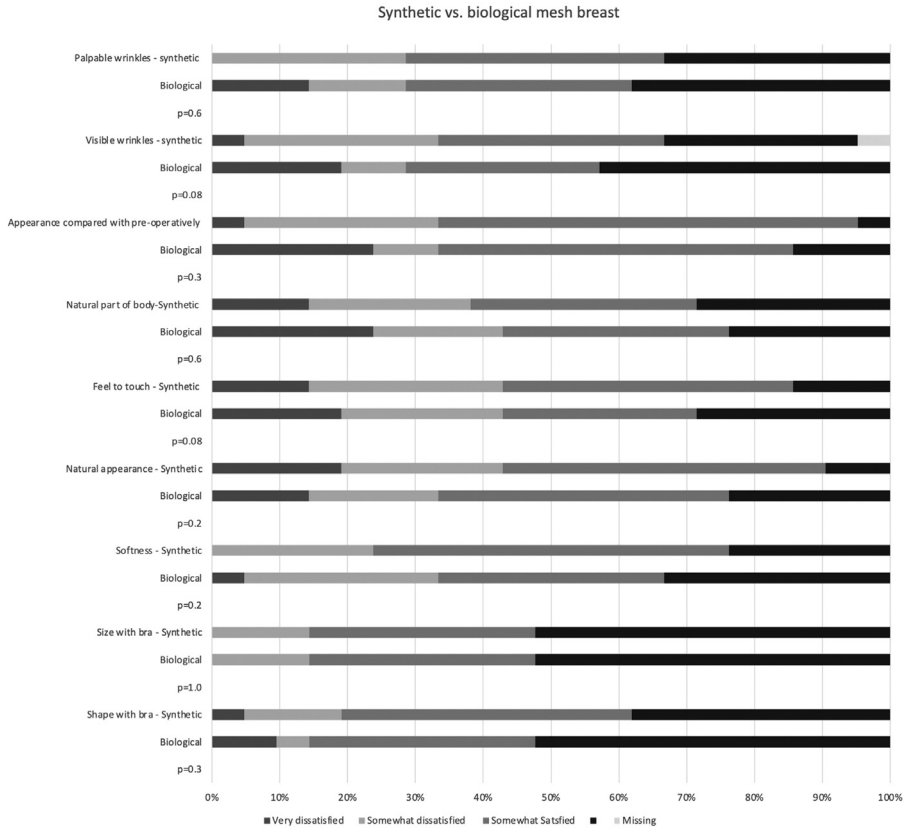

Figure 2 Satisfaction with breasts reconstructed with synthetic and biological meshes.

dates an implant better and causes fewer problems with pain and discomfort.[38] Our results contradict this as too much flexibility of movement in the implant pocket might give rise to discomfort and seem to result in more palpable wrinkles (Figure 2, Table 5). Too much stretch might also counteract the mesh advantage of the proposed rigorous control of the implant pocket borders and the intramammary fold.

Contrary to our hypothesis, the majority of patients do not seem to find biological mesh more appealing. This is also reflected in the higher rate of cosmetic corrections seen in the biological mesh breasts (Table 3). Thus, theoretically, attractive mesh properties might not give the most patient-pleasing result, demonstrating the well-known fact that surgeons and patients often evaluate breast reconstruction differently and that there often is a lack

Table 5 Difference in item scores between synthetic and biological mesh breasts.

	Same score	One point difference	Two points difference	Three points difference	More satisfied with synthetic mesh	More satisfied with biological mesh
Shape of bra	12 (57%)	8	1	0	3/9 (33%)	6/9 (67%)
Size of bra	14 (67%)	4	2	0	4/6 (67%)	2/6 (33%)
Softness	14 (67%)	4	3	0	4/7 (57%)	3/7 (43%)
Natural appearance	10 (48%)	5	4	2	4/11 (36%)	7/11 (64%)
Feel to touch	12 (57%)	67	1	1	4/9 (44%)	5/9 (56%)
Natural part of body	13 (62%)	5	2	1	5/8 (63%)	3/8 (38%)
Appearance compared with preoperatively	12 (57%)	6	2	1	1/9 (11%)	8/9 (89%)
Visible wrinkles[1]	11 (55%)	5	4	0	4/9 (44%)	5/9 (56%)
Palpable wrinkles	13 (62%)	6	2	0	4/8 (50%)	4/8 (50%)

[1] One missing answer. $N = 20$.

of correlation between objectively desirable results and patient-reported outcomes.[12,39,40] The biological and synthetical meshes seem to give rise to different effects and patients' diverging preferences might explain the scattering results. More studies are needed to further explore how knowledge about the effects of different meshes can be used to tailor breast reconstructions to individual patients' wishes.

The patient-reported satisfaction and health-related quality of life constructs are also affected by different factors, unrelated to the result of the breast reconstruction, such as psychosocial circumstances and body image,[9-11] sociodemographic and lifestyle aspects,[14,15] and comorbidity.[16] However, such factors could be controlled for in the present study as the participants were their own controls, and they all had one synthetic mesh and one biological mesh breast. Nonetheless, the result could have been affected by different conditions on the two sides. Complications might themselves lead to dissatisfaction with the reconstruction,[41,42] which have affected the scores of the biological mesh breasts negatively. Moreover, complications might also have influenced the overall scores of both breasts as attitudes to the care given [12] seem to have an important role in patient-reported outcomes. As demonstrated previously,[3,6] the biological mesh seems to give rise to more complications as well as more corrections than the synthetic mesh (Tables 2 and 3), and this could have decreased patient satisfaction with the biological mesh. The impact of possible complications must be taken into consideration when the reconstructive method is chosen. A mesh should give a very superior result and have clear advantages compared to another to warrant a higher complication rate.

One of the most important stated advantages of meshes is a lower capsular contracture rate, especially biological meshes.[43] However, there are no high-quality clinical studies comparing capsular contracture rates of synthetic and biological meshes. In the present study, no capsular contractures were seen in any of the groups. More studies are needed to elucidate whether the difference seen in histological reactions between the two meshes has a clinical effect on the capsular contracture rate.[19] A clear reduction in the need for operations to correct capsular contracture would be needed to outweigh the increased biological mesh created a need for un-planned operations due to complications. A decreased rate of revisions is another of the proposed benefits of meshes.[2] According to the result of the present study (Table 3), the decreased rate of correction is greater when synthetic meshes are used.

Other postulated advantages of using meshes in breast reconstruction include an elimination of the need to use TEs, and thereby a faster time to completion of reconstruction and fewer operations.[2] Other than direct advantages for the patients, this could potentially also lower health care and societal costs for breast reconstruction. However, the possible lowering of costs for operations must be put in relation to the cost of the mesh itself. Biological meshes are considerably more expensive than synthetic meshes, and therefore a clear superiority has to be demonstrated to warrant their use. Based on the present results, such a superiority, warranting the increased costs, is uncertain.

Considerations regarding study methodology

The generalizability of the present study is limited by the small sample size as well as the surgical techniques and meshes used. The original power calculation was based on complication frequencies, assumed a target difference of 35 percent in overall complication rates between the two meshes, and stated that 32 breasts would be needed in each group to give a power of 80 percent for a type I error rate of 5 percent.[6] However, the study was terminated when it became clear that patients experienced an asymmetry that could be related to the usage of different meshes on the two sides. Nonetheless, a clear aesthetic superiority of one of the meshes would have been detectable, despite the low sample size. A bigger sample would have allowed for a more detailed analysis regarding specific properties that make the patient more or less satisfied with a reconstructed breast. There are many different types of biological and synthetic meshes on the market, and specific studies are needed for more mesh types to

Table 6 Previous studies comparing synthetic and biological mesh in implant-based immediate breast reconstruction.

Study	Sewart et al., UK [36] *Prospective non-randomized cohort*		Gao et al., China [35] *Retrospective non-randomized cohort*		Ohlinger et al., Germany [37] *Retrospective non-randomized cohort*			Hallberg et al., Sweden [34] *Retrospective non-randomized cohort*	
	Synthetic	Biological	Synthetic	Biological	Synthetic		Biological	Synthetic	Biological
Number of patients	95	495	32	68	55	52	14	41	53
Mesh	NR	NR	TiLOOP Bra/TiMesh®-non-resorbable polypropylene with titanized surface	Surgisis®-acellular porcine small intestinal submucosa	TiLOOP Bra/TiMesh®-non-resorbable polypropylene with titanized surface	SERAGYN® - partially absorbable polypropylene	Strattice®-acellular porcine dermis	TIGR® - resorbable glycolide and trimethylene carbonate and lactic and trimethylene carbonate	Surgisis®-acellular porcine small intestinal submucosa
BREAST-Q	Median (IQR; range)	Median (IQR; range)	Mean (SD) or Median (IQR)	Mean (SD) or Median (IQR)	Mean	Mean	Mean	Mean (SD) Median (range)	Mean (SD) Median (range)
Satisfaction with breast	56 (47-71; 0-100)	61 (48-73; 0-100) p=NR	54 (46-59)	58 (53-65) $p = 0.051$	60	58	63 $p = 0.90$	61 (16.1) 61 (25-100)	57 (15) 57 (16-100) $p = 0.035$
Satisfaction with outcome	67 (61-86; 0-100)	73 (55-86; 0-100) p=NR	NR	NR	73	74	62 $p = 0.32$	67 (18.7) 67 (35-100)	70 (20.5) 67 (0-100) $p = 0.24$
Psychosocial well-being	67 (52-86; 0-100)	67 (53-86; 0-100) p=NR	65 (58-93)	74 (60-87) $p = 0.491$	71	70	68 $p = 0.33$	72 (19.8) 70 (26-100)	72 (23.1) 75 (23-100) $p = 0.96$
Sexual well-being	50.5 (30.5-63; 0-100)	47 (34-63; 0-100) p=NR	36 (18.1)	40 (17.4) $p = 0.424$	54	53	57 $p = 0.93$	53 (21.9) 49 (0-100)	54 (24.1) 54 (0-100) $p = 0.66$
Physical well-being chest	74 (63-81; 33-100)	74 (66-85; 13-100) p=NR	56 (41-66)	43 (36-68) $p = 0.282$	64	68	63 $p = 0.35$	79 (15) 81 (50-100)	78 (16) 77 (33-100) $p = 0.88$

Abbreviations: IQR=interquartile range.
N= number of participants.
NR= not reported.
SD= standard deviation.

make the results generalizable to biological and synthetic meshes in general. Similarly, all the reconstructions in the present study were two-stage reconstruction using a partially muscle-covered and partially mesh-covered TE that was later exchanged to a permanent implant. In recent years, a pre-pectoral surgical approach with mesh-covered implants has emerged.[44] More studies are needed regarding the differences in patient-reported outcomes of biological and synthetic meshes using this approach.

Another methodological flaw of the study is that, although BREAST-Q is an extensively validated questionnaire, it has never been validated to use separately for the right and left breast of the same patient, which it was postoperatively in this study. There are no existing questionnaires that have been validated for such a use. It would be ideal if BREAST-Q domain scores could be compared for the synthetic and the biological meshes, but this is not possible as both breasts belong to the same individual, and most BREAST-Q items are not breast specific. Nonetheless, the unvalidated application of BREAST-Q limits the scientific rigor of the results.

The varying follow-up time of the study, ranging from three to five years, is a methodological weakness. The original follow-up time of three years was not adhered to due to a problem with conducting studies during the pandemic. However, the great majority of participants were followed-up after five years instead, and the scores of the few patients with a shorter follow-up did not deviate from the scores achieved in the group that was followed for five years. This indicates that the BREAST-Q scores could be stable when a certain time has elapsed after the breast reconstruction.

Conclusions

One mesh type is not generally superior to the other, regarding patient-reported outcomes. Biological and synthetic meshes seem to give rise to different types of reconstructed breasts, and more studies are needed regarding whether knowledge about the effects of different meshes can be used to tailor breast reconstructions to individual patients' wishes. The rate of complications and corrections in the biological mesh breasts is higher, which must be considered when the type of mesh is chosen.

Conflict of interest

None.

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Ethical permit

The study was approved by the Regional Ethical Committee of Gothenburg, Sweden (189-16).

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