



Evaluation of Breast Animation Deformity following Pre- and Subpectoral Direct-to-Implant Breast Reconstruction: A Randomized Controlled Trial

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Abstract

Background The incidence of breast animation deformity (BAD) is reported to be substantial after direct-to-implant breast reconstruction with subpectoral implant placement. It has, however, never been examined if BAD can occur following prepectoral implant placement. Our primary aim was to compare the incidence and degree of BAD after direct-to-implant breast reconstruction using either subpectoral or prepectoral implant placement. Secondary aim of this study was to assess and compare the level of pain between sub- and prepectoral reconstructed women.

Methods In this randomized controlled trial, patients were allocated to reconstruction by either subpectoral or prepectoral implant placement in accordance with the CONSORT guidelines. The degree of BAD was assessed by the “Nipple, Surrounding skin, Entire breast (NSE)” grading scale 12 months after surgery. The level of postoperative pain was assessed on a numerical pain rating scale.

Results We found a significant difference in the degree of BAD favoring patients in the prepectoral group (23.8 vs. 100%, $p < 0.0001$; mean NSE grading scale score: 0.4 vs. 3.6, $p < 0.0001$). The subpectoral reconstructed group reported higher levels of pain on the three subsequent days after surgery. No significant difference in pain levels could be found at 3 months postoperatively.

Conclusion The incidence and degree of BAD was significantly lower in women reconstructed by prepectoral direct-to-implant breast reconstruction. Unexpectedly, we found mild degrees of BAD in the prepectoral group. When assessing BAD, distortion can be challenging to discern from rippling.

Keywords

- ▶ breast reconstruction
- ▶ breast deformity
- ▶ breast implant
- ▶ treatment outcome
- ▶ incidence

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Introduction

Breast animation deformity (BAD) is characterized by movement/deformation/distortion of the whole breast, the breast skin or the nipple areolar complex (NAC).¹ The distortion is caused by the compressing action of the pectoralis major muscle (PMM) when activated above an underlying implant. The distortion may lead to varying degrees of skin wrinkling, widened cleavage and upward or superolateral implant malposition and asymmetry.² Besides cosmetic challenges, some women experience BAD as a nuisance occurring under activities of daily living which is aggravated during exercise. Functional problems such as muscle twitching, pain, and impaired shoulder function may affect patient's quality of life.¹

Implant-based breast reconstruction can be performed using various pocket planes.³ Subpectoral implant placement has been the gold standard of implant-based breast reconstruction and when using the PMM as a vascularized cover, rippling, implant visibility, and the incidence of capsular contracture are reduced.^{4,5} However, BAD is a significant challenge when using the subpectoral plane and several studies have indicated that the incidence of pain is significantly higher after subpectoral implant placement.^{1,6-8}

The lack of soft tissue after a skin- or nipple-sparing mastectomy predisposes women reconstructed with a subpectoral placed implant to suffer from severe BAD in comparison to breast augmentation. In a recent retrospective cohort study, we found that 100% of the patients being reconstructed by subpectoral direct-to-implant breast reconstruction experienced some degree of BAD.⁹

The esthetic outcome of prepectoral implant placement has been found comparable to the subpectoral techniques while utilizing the advantages of less postoperative pain and a possible prevention of BAD.^{10,11} Disadvantages of this pocket plane can, however, be visible wrinkling, secondary ptosis, bottoming out, and an increased incidence of capsular contracture.^{12,13} Furthermore, it seems that placing the implant solely prepectorally does not eliminate BAD totally. In a retrospective study, we found a prevalence of BAD on 10.5% in the prepectoral reconstructed group by using the "Nipple, Surrounding skin, Entire breast (NSE)" grading scale for assessment of BAD. In this study, we introduced the NSE grading scale that focuses on distortion of three features of the breast: distortion of the top of the breast mound/nipple areolar complex (NAC), distortion of the breast skin surrounding the NAC, and movement of the entire breast (→ **Table 1**). The NSE scale provides a score from 0 to 2 (no distortion, visible distortion, and severe distortion) at each feature adding up to a summed score from 0 to 6 and was validated and found easy-to-use in a clinical setting.⁹ The interpretation has since been further developed for a more consistent and comparable categorization as follows: (1) mild BAD, (2) moderate BAD, and (3) severe BAD (→ **Videos 1-3**, available online only).¹⁴

Table 1 The Nipple, Surrounding skin, Entire breast (NSE) grading scale

TBM/NAC
0) No distortion 1) Visible distortion 2) Severe distortion
Breast skin surrounding TBM/NAC
0) No distortion 1) Visible distortion 2) Severe distortion
Entire breast
0) No movement 1) Visible movement 2) Severe movement
Total (0-6)
1-2: mild BAD 3-4: moderate BAD 5-6: severe BAD

Abbreviations: BAD, breast animation deformity; NAC, nipple areolar complex; TBM, top of the breast mound.

Video 1

Video of mild BAD in a subpectoral reconstructed women assessed by the NSE grading scale. BAD, breast animation deformity; NSE: Nipple, Surrounding skin, Entire Breast. Online content including video sequences viewable at: <https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0042-1756337>.

Video 2

Video of moderate BAD in a subpectoral reconstructed women assessed by the NSE grading scale. BAD, breast animation deformity; NSE: Nipple, Surrounding skin, Entire Breast. Online content including video sequences viewable at: <https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0042-1756337>.

Video 3

Video of severe BAD in a subpectoral reconstructed women assessed by the NSE grading scale. BAD, breast animation deformity; NSE: Nipple, Surrounding skin, Entire Breast. Online content including video sequences viewable at: <https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0042-1756337>.

In the literature, there is a lack of high-quality data comparing sub- and prepectoral reconstructed women regarding BAD. Only a few studies with a clear description of design, participants, and validated grading systems have been published.^{14,15}

In this randomized controlled trial (RCT), our primary aim was to compare the incidence and degree of BAD in patients having a direct-to-implant breast reconstruction by either subpectoral or prepectoral implant placement using the validated NSE grading scale for assessment. Our second aim was to investigate and compare differences in pain between sub- and prepectorally reconstructed groups.

Methods

The RCT was conducted in accordance with the CONSORT guidelines.¹⁶ The study was designed as a superiority trial with two parallel study arms. Patients were allocated to either a sub- or prepectoral implant placement in a ratio of 1:1 following skin- or nipple-sparing mastectomy. Prior to initiation of the trial, the main supervisor generated the allocation sequence indicating either sub- or prepectoral implant placement. The envelopes were then sealed and shuffled independently by a single person unconnected to the trial. Finally, the envelopes were numbered consecutively and stored in a secure locker.

This study was a collaboration between two departments of plastic surgery in Denmark. Patients were planned for enrolment in a 3-year period from April 2017 to March 2020. Inclusion criteria included women over 18 years who are eligible for unilateral or bilateral direct-to-implant breast reconstruction after a therapeutic or prophylactic skin- or nipple-sparing mastectomy. Exclusion criteria were prior or planned radiation therapy to the breast, tobacco usage, hypertension treated with more than one drug, breast ptosis >2 measured by Regnault's ptosis scale,¹⁷ body mass index (BMI) <22 or >32 kg/m², dementia, or psychiatric disorders making patients incapable of providing informed consent.

All referred women were assessed for eligibility in the outpatient clinic and recruited by a plastic surgeon. Those meeting the criteria were invited to participate in the trial and received oral and written information. Each patient was given time for reflection prior to informed consent. The patients were informed that the final screening for eligibility would be carried out during surgery following mastectomy and prior to reconstruction.

During surgery, the mastectomy flaps were assessed for thickness and viability securing that the tissue was suitable for reconstruction by both sub- and prepectoral implant placement. If evaluated eligible, patients were randomized by drawing an envelope containing the allocation to one of the two interventions groups. At randomization, envelopes were drawn consecutively starting with number one. Neither participants nor investigators were blinded after surgery.

Skin- or nipple-sparing mastectomy were carried out by four different breast surgeons. Breast reconstructions were performed by two different consultant plastic surgeons at each center. The procedures were performed in a standard-

ized fashion. For the subpectoral reconstruction technique, the PMM insertion was divided inferomedially using monopolar cautery and a pocket was created underneath the muscle allowing for partial muscle coverage of the implant. The inferior part of the implant was covered/supported by an acellular mesodermal matrix (AMM; Meso BioMatrix size 10 × 16 cm) as a hammock which was sutured to the edge of the muscle and the inframammary crease (IMM).

When performing prepectoral reconstruction, two pieces of AMM was used as a full hammock and sutured circumferentially along the breast footprint to the PMM creating a prepectoral implant pocket. Both techniques have been described in detail in an earlier publication.¹⁸

After surgery, the patients followed the same postoperative regime and approximately 3 and 12 months after surgery, each patient was seen in the outpatient clinic by the principal investigator (PI). After surgery and during these clinical visit, information on levels of postoperative pain would be obtained and evaluation of BAD would be made. Furthermore, incidences of major and minor complications, such as skin necrosis, wound dehiscence, infection, seromas, bleeding, and explantation of implants, were recorded. Complications would be classified as either major or minor depending on the need for surgical revision in general anesthesia.

When assessing the incidence and degree of BAD, each patient would be placed in a standing position, relaxed, and then performing maximal contraction of the PMM by pressing the palms of their hands together in the midline in front of their waist. For later assessment of BAD, each patient would have photographs and video-recordings taken in a standardized manner by a professional photographer. Again, each patient would perform the above-mentioned practice for contraction of PMM. Videos would be saved and used for later assessment of the degree of BAD by the NSE grading scale⁹ by two blinded consultant plastic surgeons individually scoring each patient from 0 to 6. In cases of disagreement, a consensus would be reached. In bilateral cases, the most severe side would be used for comparison.

When assessing postoperative pain, each patient scored the level of pain on a numerical pain rating Scale (NPRS) with 1 being no pain and 10 as the worst pain possible. Scoring was done immediately after surgery (day 0), on each of the subsequent 3 days at 12 o'clock, and finally after 3 months during a planned visit in the outpatient clinic.

All data were recorded on the REDCap Database System by double data entry.¹⁹ The photographs and video recordings were stored on a secure server in our Patient Data Explorative network (<https://open.rsyd.dk>).

Prior to the initiation of the trial, we conducted a nonparametric calculation of the sample size using Fisher's exact test for small sample sizes. The calculation was based on the assumption that 60% of the patients who reconstructed by subpectoral implant placement would suffer from some degree of BAD 1 year after reconstruction as opposed to 20% of the women reconstructed by prepectoral implant placement. Using these assumptions in combination with a significance level of 0.05 (one sided) and a power of 0.95, we determined a sample size of 70

patients with 35 in each intervention group. During the enrolment period, we conducted a retrospective cohort study in women who had a unilateral or bilateral immediate breast reconstruction between November 2011 and December 2017 that suggested that the above sample size assumptions were too conservative.⁹ An interim analysis was therefore conducted with 60% of patients included (i.e., $0.6 \times 70 = 42$) in the sense of a sequential test strategy, and the primary hypothesis was tested conservatively applying an O'Brien–Fleming type- α spending function (i.e. $\alpha_1^* \text{ in }^{20}$). If the significance level was under the threshold <0.0114 at interim, the trial would be terminated before full enrollment. After analysis, we found a $p < 0.0001$, and the trial was therefore terminated following interim analysis.

We used baseline variables to describe the characteristics of the trial participants. Continuous variables were expressed as means and standard deviations or as median and interquartile range (25th–75th percentiles) if the distributions found were asymmetrical. Respective inferential statistics were performed with the unpaired t -test or Wilcoxon's rank sum test. Categorical variables were summarized as numbers and percentages. Comparisons between

groups were done with Fisher's exact test, and a two-sided p -value of less than 0.05 was considered significant. The primary analysis was the comparisons of proportions of patients with BAD in the two groups. This was done with Fisher's exact test. The adjusted significance level for the interim analysis of the primary endpoint was 0.0114 (see previous section for details). For comparison of the different assessments of BAD between raters, proportion of agreement is expressed in percentages with 95% confidence intervals.²¹ Regarding assessment of postoperative pain on a continuous scale, a graphical visualization of potential interaction between type of reconstruction and time point was based on a repeated measures Analysis of Variance with pooled error term. Data management and statistical analysis were conducted using STATA/IC 16, (StataCorp, College Station, TX).

Results

During the inclusion period, we assessed 69 women for eligibility (→ Fig. 1). Of these 69 women, 53 were included and allocated to the two interventions. Sixteen were

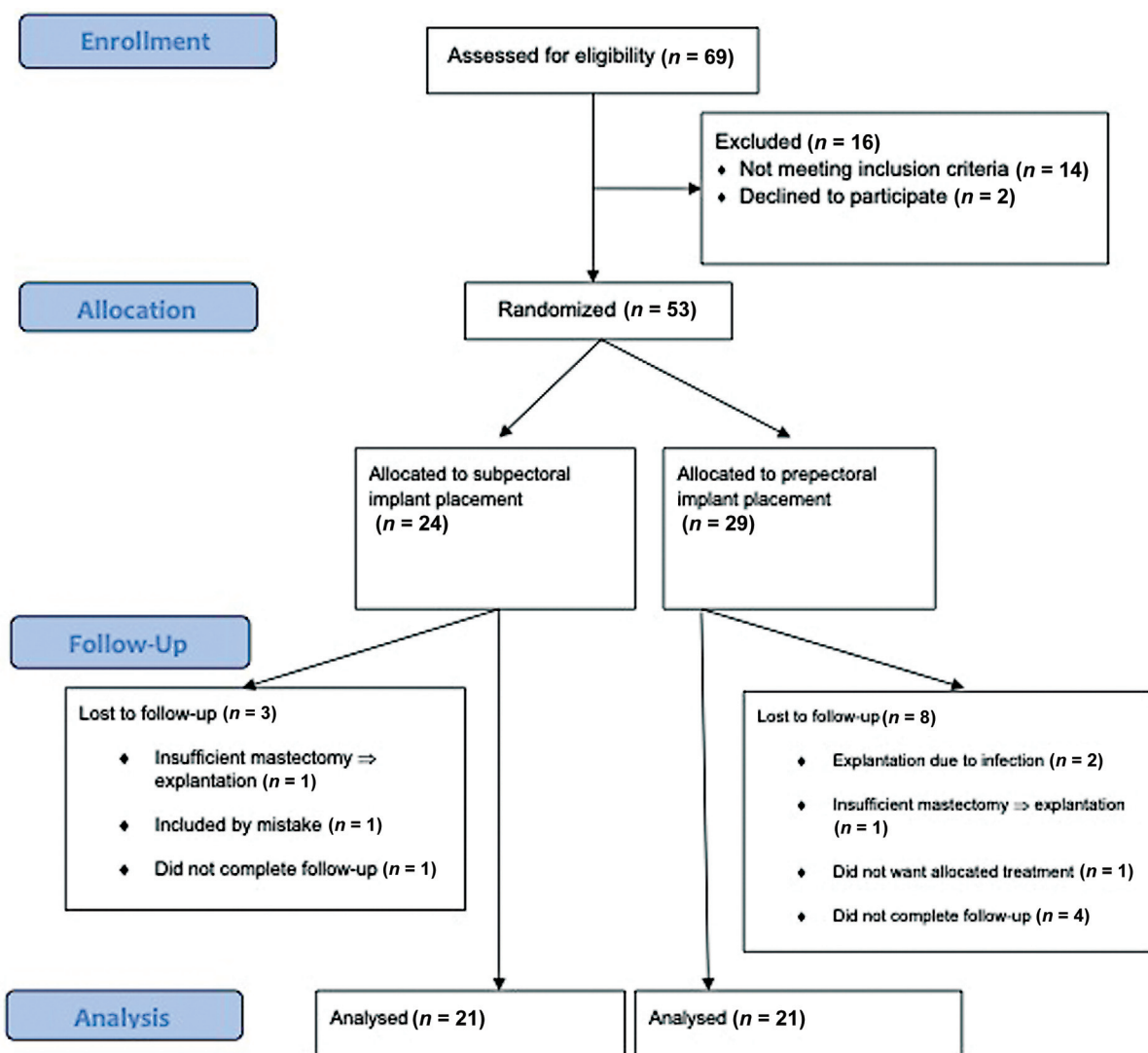


Fig. 1 Flowchart illustrating enrolment, allocation intervention, follow-up and data analysis of the included patients.

Table 2 Descriptive statistics

	Subpectoral n/n (%) / mean \pm SD / median (IQR)	Prepectoral n/n (%) / mean \pm SD / median (IQR)	p-Value
No. of breast	27	33	
Mastectomy indication			
Therapeutic	18 (66.7)	20 (60.6)	0.79
Prophylactic	9 (33.3)	13 (39.4)	
No. of patients	21	21	
Age (y)	50.0 \pm 10.2	49.4 \pm 10.9	0.84
BMI (kg/m ²)	26.8 \pm 2.25	25.5 \pm 2.4	0.083
Laterality of reconstruction			
Unilateral	15 (71.4)	9 (42.9)	0.12
Bilateral	6 (28.6)	12 (57.1)	
Duration of surgery,	176 (152–200)	184 (151–231)	0.61
Use of implant			
Silicone	19 (90.5)	21 (100)	0.49
Expander	2 (9.5)	0	
Implant volume (cc)	415 (375–490)	440 (370–520)	0.79
Chemotherapy	10 (47.6)	6 (28.6)	0.34
Length of follow-up (d)	399.4 \pm 36.7	390.4 \pm 34.5	0.42

Abbreviations: BMI, body mass index; IQR, interquartile range; SD, standard deviation.

excluded before randomization because of the following circumstances: seven were deemed noneligible due to thin or poorly vascularized skin flaps following mastectomy, and two were excluded due to metastatic disease. Another two was found noneligible because of comorbidities, one had a BMI that was too low (20.7 kg/m²), one was excluded because of smoking and medication intake, and one suffered from hypertension treated with more than one drug. Finally, two possible participants declined to participate.

Of the 53 included patients, 24 were allocated to subpectoral implant placement and 29 were allocated to prepectoral implant placement. In the subpectoral group, three patients were lost to follow-up: one patient had an insufficient mastectomy and needed reoperation, another did not complete follow-up, and one patient had been included by mistake and no baseline data had been obtained. In the prepectoral group, eight patients were lost to follow-up, two suffered from infection with the need for explantation, one regretted the reconstruction and requested an explantation, and four patients did not complete follow-up. This left a total of 42 women at 12-month follow-up who had completed the trial and were eligible for analysis. The women were distributed with 21 in the subpectoral group and 21 in the prepectoral group (**► Fig. 1**).

Of the 21 women reconstructed with subpectoral implant placement, 71.4% were unilateral reconstructed, 28.6% were bilateral reconstructed and in 66.7% of the patients, the indication for performing a mastectomy were therapeutic. In the prepectorally reconstructed group, 42.9% were unilateral and 57.1% were bilateral. In 60.6% of the cases, the indication of mastectomy was therapeutic. Age and BMI

were comparable between the sub- and prepectorally reconstructed groups (**► Table 2**). No patients received pre- or postoperative radiation therapy to the breast. Follow-up was conducted at a mean of 13 months and there was no difference between groups (**► Table 2**).

During follow-up, complications were registered in a total of nine patients, five (24%) in the subpectorally reconstructed group and four (19%) in the prepectorally reconstructed group (**► Table 3**). One major complication (4.8%) was registered in the subpectorally reconstructed group; one patient who was bilaterally reconstructed suffered from an infection that required a unilateral explantation of the implant. Likewise, in the prepectorally reconstructed group, one bilaterally reconstructed patient (4.8%) suffered from a major infection that required a unilateral explantation of the implant. Additionally, we had four (19.2%) minor complications in the subpectoral

Table 3 Postoperative complications

	Subpectoral (n = 21) n (%)	Prepectoral (n = 21) n (%)
Total	5 (24)	4 (19)
Complications by type		
Seroma	1 (4.8)	0
Infection, minor	2 (9.5)	2 (9.5)
Infection, major	1 (4.8)	1 (4.8)
Skin flap necrosis, minor	1 (4.8)	1 (4.8)
Skin flap necrosis, major	0	0

Table 4 Incidence of BAD assessed using the NSE grading scale

	Subpectoral (n = 21)	Prepectoral (n = 21)	Difference	p-Value
NSE total (0–6) ^a	3.6 (3.0–4.2)	0.4 (0.04–0.7)	3.2 (2.5–3.9)	<0.0001
NSE total of 1 or more	21 (100%)	5 (23.8%)	76.2% (58.0–94.4%)	<0.0001
Mild ^{1,2}	4 (19.1%)	5 (23.8%)	N/A	<0.0001
Moderate ^{3,4}	11 (52.4%)	0 (0%)		
Severe ^{5,6}	6 (28.6%)	0 (0%)		

Abbreviations: BAD, breast animation deformity; N/A, not applicable; NSE: Nipple, Surrounding skin, Entire Breast.

^aNSE total are presented as means with 95% confidence intervals.

group and three (14.4%) minor complications in the prepectoral group. All healed uneventfully by conservative treatment.

We found a significant difference in the degree of BAD in favor of patients reconstructed by prepectoral implant placement compared to the subpectoral group (23.8 vs. 100%, $p < 0.0001$). Overall, 100% in the subpectoral reconstructed group was assessed to have some degree of BAD compared to 23.8% in the prepectoral group. This difference was also mirrored in the mean differences in the NSE grading scale scores (0.4 vs. 3.6, respectively; $p < 0.0001$; ► **Table 4**). The distribution on the different categories of mild, moderate, and severe BAD is shown in ► **Table 4**. For the subpectorally reconstructed women, the majority was categorized with having moderate or severe BAD (81%), whereas in the prepectoral group, all BAD assessments were in the mild category. When further exploring the assessments of BAD in the prepectoral group, none were categorized with distortion in the subfeature “distortion of the top of the breast mound/nipple areolar complex (NAC),” and none were assessed having more than 1 point (visible distortion) in subfeatures 2 and 3 (► **Table 1**).

The above-mentioned incidences and degrees of BAD were scored by two consultant plastic surgeons assessing each patient by the NSE grading scale. In terms of agreement between raters, when comparing the total summed scores from 0 to 6, the two raters agreed in 57.1% of the patients (95% confidence interval [CI]: 41–72.3) and consensus was therefore necessary to reach in 42.9% of the patients. When comparing the agreements between the two raters on different categories of BAD (mild, moderate, and severe), the agreement was 81% (95% CI: 65.9–91.4). Furthermore, when looking at agreements in the subfeatures of the NSE grading scale (breast mound/NAC, skin, and entire breast) agreements were 83.3% (95% CI: 68.6–93), 81% (95% CI: 65.9–91.4), and 71.4% (95% CI: 55.4–84.3), respectively (► **Table 5**).

Table 6 Postoperative pain assessed by numerical pain rating scale: 1, no pain and 10, worst pain possible

	Day of surgery	Day 1	Day 2	Day 3	3-month postoperatively
Subpectoral (mean ± SD)	4.2 ± 2.5	5.3 ± 2.2	4.5 ± 2.3	4.0 ± 2.3	1.1 ± 0.4
Prepectoral (mean ± SD)	3.3 ± 2.0	3.7 ± 1.9	3.0 ± 1.5	2.3 ± 1.3	1.0 ± 0.2
Difference (95% CI)	0.8 (–0.5 to 2.2)	1.6 (0.3–2.8)	1.4 (0.2–2.6)	1.8 (0.6–2.9)	0.1 (–0.1 to 0.3)
p-Value	0.22	0.017	0.023	0.003	0.30

Abbreviations: CI, confidence interval; SD, standard deviation.

Table 5 Proportion of agreements on subscale assessments of BAD

NSE scale	Proportion, in % (n)	95% CI
1. Breast mound/NAC	83.3 (35)	68.6–93.0
2. Breast skin	81.0 (34)	65.9–91.4
3. Entire breast	71.4 (30)	55.4–84.3

Abbreviations: BAD, breast animation deformity; CI, confidence interval; NAC, nipple areolar complex; NSE: Nipple, Surrounding skin, Entire Breast.

When analyzing and comparing the differences in pain between the sub- and prepectorally reconstructed groups, we found that there was no significant difference on the day of surgery ($p = 0.22$, see ► **Table 6**). On days 1, 2, and 3 after surgery, we found a significant difference in reported pain levels between the groups, as the subpectorally reconstructed group reported higher levels of pain ($p = 0.017$, 0.023, and 0.003). There was, however, no difference at 3 months after surgery where the level of pain was close to none in each group (1.1 vs. 1.0, $p = 0.30$). Furthermore, an interaction between type of reconstruction and time point was not apparent (► **Fig. 2**).

Discussion

Over the last years, there has been increased focus on BAD and several studies have been conducted to assess the etiology, treatment, and grading.^{3,13,22–24} This randomized controlled trial is, to the best of our knowledge, the first evaluating and comparing sub- and prepectoral implant placement when performing direct-to-implant breast reconstruction. We found a significant difference in the incidence and degree of BAD between sub- and prepectorally

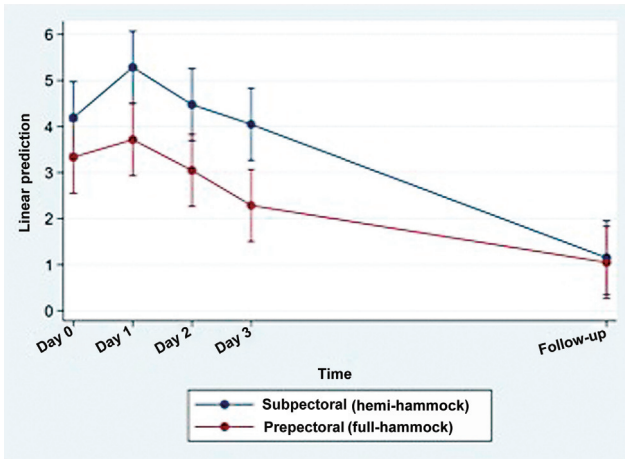


Fig. 2 Pain assessed by the numeric rating scale over time between sub- and prepectorally reconstructed groups.

reconstructed groups when evaluating the patients by the NSE grading scale 12 months after surgery (►Table 4). All (100%) of the patients reconstructed with subpectoral placed implants experienced some degree of BAD. This is higher than the value reported by Spear et al in an augmented population (77.5%)²² but conforms to our findings in a retrospective study⁹ and furthermore in Kim et al findings in a cross-sectional prospective study.²³

Through the last 5 years, several other assessment methods/grading scales have been proposed.^{1,13,23,25} However, only a few have been standardized and reproducible and therefore difficult to use for comparison.¹⁴ In 2019, we presented the NSE grading scale focusing on three esthetic features of the breast as follows: (1) the top of the breast mound/nipple areolar complex (NAC), (2) the breast skin surrounding the NAC, and (3) the entire breast. By using video recordings for assessment of BAD, we found moderate (75) to strong (88%) inter- and intraobserver agreement.⁹ It has since this study come to our knowledge that agreement parameters are preferable to use in medical research in which an instrument will be used for evaluation purposes. Therefore, the proportion of agreement is more characteristic of the measuring scale itself compared to reliability measures.²⁶ We therefore chose to compare the assessment of BAD in this manner and found the overall proportion of agreement was 57%. A reason for this modest agreement is probably caused by the many (0–6) options when using the NSE grading scale. Conformingly when looking at the different categories of BAD grading (mild, moderate, or high), the agreement was high 81% (95% CI: 65.9–91.4) and the same applied when assessing each subscale of the NSE grading scale; NAC (83%), skin, (81%), and entire breast (71%). A possible explanation for the slightly lower proportion of agreement with “the entire breast” (71%) is that it can be difficult to interpret whether movement/deformity is related to a compressing action of the PMM on the underlying implant or simply a “normal” breast movement that most women are capable of naturally. Furthermore, the lack of tissue thickness in the upper quadrants and a possible adherence of the skin to the muscle fascia might make it



Fig. 3 Patient with severe BAD following subpectoral direct-to-implant breast reconstruction. BAD, breast animation deformity.

difficult to differ skin contraction from entire movement in some cases.

Reconstructed patients might have a greater risk for developing severe BAD. After a skin- or nipple-sparing mastectomy, lesser soft tissue is present to camouflage a distortion. Our findings substantiate this, in the subpectoral group, where we found 52.4% in the moderate and 28.6% in the severe categories (►Table 4). Correspondingly Kim et al found 22% in the severe category, whereas Fracol et al found 29% by using the three-pointed grading system stated by Kim et al.^{23,24} When using their own quantitative grading system, Becker and Fregosi found 24% in the moderate-to-severe category and 12% in the severe category.¹ In spears augmented population, only 15% of the patients were evaluated to be in the severe BAD group²² which might be a result of a thicker, soft tissue cover.

Surprisingly, we found 23.8% in the prepectoral reconstructed group assessed with some degree of BAD. Of the 23.8%, all were assessed with mild^{1,2} BAD and scored solely in the subscale categories 2 and 3, breast skin, and entire breast distortion, respectively. A well-known downside of prepectoral implant placement is the possibility of rippling which can be worsened in the reconstructed population because of thinner skin cover.³ We believe, it can be difficult to discern rippling from skin movement which can cause a deteriorating in the BAD assessments in the prepectoral group (►Figs. 3 and 4). Furthermore, the lower proportion of agreements in the subscale 3 “entire breast” might also play an essential role in wrongfully assessing the prepectoral group with mild distortion. No studies regarding BAD assessment in prepectoral reconstructed women could be found for comparison but in the light of our findings, it is a limitation that we did not evaluate on the degree of rippling between groups. This limitation caused us to look through our video material once more with the purpose of assessing rippling in the sub- and prepectoral reconstructed group. In the prepectoral group 10 of 21 (47.6%) was assessed having some degree of rippling. In the subpectoral group, 6 of 21 (28.6%) had some degree of rippling. When applying Fisher’s exact test, we did not find a significant difference between groups ($p = 0.557$).

Regarding postoperative pain, we found significant differences in favor of the prepectorally reconstructed group on the first, second, and third postoperative days (►Table 6). In a nonrandomized prospective study, Cattalani et al evaluated 84 patients after direct-to-implant breast reconstruction (DIR). Pain was assessed by the Brief Pain Inventory-Short form (BPI-sf) administered postoperatively on days 1 and 7. Correspondent to our findings, they found significantly lower

pain intensity in the prepectoral group compared to the subpectoral group.²⁷ Contrary to our findings, a prospective study by Baker et al assessed postoperative pain the first 7 days after acellular dermal matrix (ADM)-assisted pre- or subpectoral DIR. By utilizing the Likert's pain chart, they found no significant difference in cumulative pain over the first 7 postoperative days, neither at any individual postoperative time point.²⁸ Baker et al speculated that maybe the prepectoral reconstructed patients experiences the same degree of discomfort when the ADM is sutured circumferentially to the chest or maybe the discomfort is primarily related to pain from the mastectomy. Postmastectomy related pain could also be a factor in our study on day 0, where there was no difference in pain levels in the two groups. The study sample by Baker et al is, however, small, with an uneven distribution between sub- and prepectoral groups (12 vs. 28). The sample size is also a possible limitation in our study. Nonetheless, the distribution between groups is equal and the response rate is 100% which we believe is a strength. Another limitation is the fact that we did not compare the need for analgesics between sub- and prepectorally reconstructed groups. We did not record if some of the patients needed more potent analgesics besides the basics of ibuprofen and paracetamol. The level of pain was however monitored at noon, right before intake of mid-day analgesics to evaluate each patient equally.

We found a total major and minor complication rate of 24% in the subpectorally reconstructed group and 19% in the prepectorally reconstructed group (► **Table 3**). In a recent retrospective study by Manrique et al, total complication rates were 7.2 and 11.6% between pre- and subpectoral reconstructed groups.²⁹ In comparison, our findings are moderately high but with the same tendency of higher complication rates in the subpectoral group. When addressing only major complications our findings are, however, comparable to other studies. In both the subpectorally- and prepectorally reconstructed groups, the major complication rates were 4.8%. Correspondingly, Riggio et al had a major complication rate at 4.3% in a patient population with 70 women who underwent direct-to-implant breast reconstruction.³⁰ Furthermore, Sbitany et al found prepectoral reconstruction superior to subpectoral regarding implant loss, and reported major complication rates at 1.2 and 4.3%, respectively.⁶ In this study, we believe that our higher complications rates and small discrepancies between groups can be a consequence of our small cohort which is a limitation in this study. It is furthermore difficult to truly compare our findings since no other RCT has been made comparing sub- to prepectoral breast reconstruction.

Follow-up was comparable between groups. Besides our small population another limitation of this RCT might be the follow-up time. Patients were seen 12 months after surgery, but we do not know if BAD changes over time. It might be worsened in the subpectoral reconstructed group 5 years after surgery. We must also keep in mind that even though the incidence and degree of BAD seems minimized using the prepectoral plane, disadvantages, such as rippling, bottoming out, visible implant edges, and possible ptosis over time,



Fig. 4 Patient with mild BAD following prepectoral direct-to-implant breast reconstruction. BAD, breast animation deformity.

might dissolve the many advantages. For this purpose, studies on long-term follow-up assessing these cosmetic challenges are needed.

Finally, the patient's perception of BAD is the most important. We might as surgeons find advantages using the prepectoral plane but do the patients feel more satisfied after a prepectoral breast reconstruction? Future studies evaluating and comparing patient-related outcome measures (PROM) between sub- and prepectoral reconstructed groups are needed.

We started our investigation with the perception that prepectoral implant placement carried the benefits of less BAD and less postoperative pain compared to subpectoral implant placement. Our results did substantiate this, as we found a significant difference in the incidence of BAD between subpectoral and prepectoral reconstructed groups with some degree of BAD in all cases of subpectoral direct-to-implant breast reconstruction. Even though the severity of BAD was mainly moderate-to-high in the subpectoral group, mild BAD was surprisingly found in a quarter of the prepectoral reconstructed women. Distortion can be difficult to discern from rippling, and it seems that skin flaps thickness is not only crucial for an acceptable cosmetic outcome, but maybe also for a true evaluation on BAD.

We found higher levels of pain in the subpectoral group on the three subsequent days after surgery. This difference was, however, vanished 3 months postoperatively. We believe that this is an important finding, because if the higher levels of pain in the subpectoral group is limited to the time right after surgery, then may be pain should not be a factor influencing the choice of pocket plane for breast reconstruction. Nevertheless, the postoperative analgesics should probably be tailored to the different reconstructions. Complication rates were moderately high but comparable between groups, supporting both methods for implant-based reconstruction, can be offered, however, after careful patient selection. Patients' lifestyle, daily activity level, and routines must be kept in mind when planning the course of breast reconstruction. Further studies on PROM comparing subpectoral and prepectoral reconstructed groups are needed to support proper patient selection in the future.

Ethical Approval

The study was approved by the Regional Committees on Health Research Ethics for Southern Denmark (approval no.: S-20160160) and performed in accordance with the principles of the Declaration of Helsinki. Written

informed consent was obtained from the included participants. The study has been prospectively registered at clinicaltrials.gov (identifier: NCT03143335) and the protocol has been published in trials (Direct-to-Implant Extracellular Matrix Hammock-based Breast Reconstruction; Prepectoral or Subpectoral? Doi:10.1186/s13063-020-4125-6).

Authors' Contributions

Conceptualization: D.L.D., J.B.T., and C.B.; data curation: D.L.D.; formal analysis: O.G. and D.L.D.; investigation: D.L.D.; methodology: J.B.T. and C.B.; project administration: D.L.D., J.B.T., and J.A.S.; supervision: J.B.T., C.B., J.A.S., and V.K.; writing the original draft: D.L.D. and J.B.T.; and writing and review and editing: all authors.

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Conflict of Interest

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