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Shoulder-related donor site morbidity after delayed breast reconstruction with pedicled flaps from the back: An open label randomized controlled clinical trial

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Summary *Background:* This randomized controlled trial (RCT) investigates differences in shoulder-related morbidity after delayed breast reconstruction by either a latissimus dorsi (LD) flap or a thoracodorsal artery perforater (TAP) flap.
Material and methods: In accordance with the CONSORT guidelines, we included women for unilateral delayed breast reconstruction. Patients were randomized to reconstruction by either of the two flaps. Shoulder-function was assessed at baseline and at 3, 6 and 12 months after surgery. The primary endpoint was patient-reported shoulder-related pain. A further objective assessment by the Constant Shoulder Score (CSS) was included as secondary endpoints.
Results: A total of 50 women were enrolled over a two-year period and allocated to reconstruction, with 25 patients in each group. Patient-reported shoulder-related pain was significantly lower in the TAP group at 12 months after surgery when adjusting for pain at baseline: OR = 0.05 95%CI(0.005-0.51), *p*-value = 0.011.

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The estimated effect on the total CSS at 12 months, when applying the TAP flap instead of the LD flap and adjusting for the baseline score, was 6.2 points with 95%CI(0.5–12.0), *p*-value 0.033. The TAP flap seems to have a statistically significant positive effect on pain and activity in daily life (ADL), while there were no significant effect on range of motion and strength after one year.

Conclusion: Patient reconstructed by the TAP flap are less likely to experience shoulder-related pain and have a better shoulder-function one year after the reconstruction. Harvest of the LD flap carries a higher risk of shoulder-function impairment, chronic pain and reduced ADL.

Introduction

Today, breast reconstruction is an integral part of breast cancer treatment, and the focus on providing patients with good reconstructive options has increased.[1] When autologous tissue transfer is required, the flaps used are not only evaluated on their ability to reconstruct a naturally appearing breast, but also on their associated donor site morbidity.[2]

The pedicled thoracodorsal artery perforator flap (TAP flap) has been established as a feasible alternative to the conventional latissimus dorsi flap (LD flap)[3-13] based on the hypothesis that leaving the muscle undissected will result in lower donor site morbidity of the upper extremity (Figure 1). Evidence of this is, however, still scarce and ambiguous.[14-18]

A previous retrospective study compared shoulder-related donor site morbidity following delayed breast reconstruction by the two flaps and found a significantly higher level of postoperative pain and restricted range of motion (ROM) after LD flap harvest.[19]

The aim of this randomized clinical trial was to further investigate the differences in shoulder-related morbidity associated with delayed breast reconstruction by the two flaps, in order to establish whether there is sufficient evidence to support the hypothesis that TAP flap-based reconstructions provide better postoperative shoulder function.

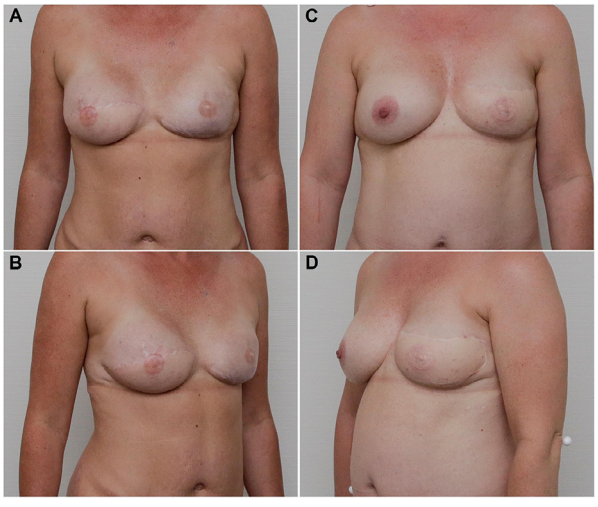

Figure 1 Patients reconstructed by the LD flap (A/B) and the TAP flap (C/D).

Material and methods

We conducted a multicentre, randomized controlled trial (RCT) in accordance with the CONSORT guidelines.[20] The study was designed as a superiority trial with two parallel study-arms, as patients were allocated to breast reconstruction by either a LD or a TAP flap in a ratio of 1:1.

Prior to commencement of the trial, we conducted a sample size calculation based on the assumption that 60% of the patients in the LD group would report shoulder-related pain one year after reconstruction compared to only 10% in the TAP group. Using Fischer's exact test for small samples, setting the rate of type I error at 0.05 and type II error at 0.20, we determined a sample size of 32 patients with 16 in each intervention group. To account for an expected attrition rate of up to 30%, we set a total study population of 50 women with 25 in each group.

All Danish centres performing delayed breast reconstruction were invited to participate in the trial. Three out of eight centres wished to contribute to patient enrolment. Furthermore, one Norwegian center, which had adopted the TAP flap for breast reconstruction, offered to enroll patients.

Patients were planned for enrolment in the two-year period between 1 September 2013 and 31 August 2015, or until a minimum of 50 participants were included. Inclusion criteria were all women over 18 years referred for unilateral, delayed breast reconstruction, who were found best suited for, and opted for, breast reconstruction with a pedicled flap from the back. Exclusion criteria were patients who were found better suited for reconstruction by another method, i.e. abdominal free flaps, and patients where a suitable perforator of the thoracodorsal artery could not be identified by color Doppler ultrasonography.

All referred women were assessed for eligibility at the first consultation in the outpatient clinic by one of the consultants associated with the trial. Those meeting the eligibility criteria were invited to participate, and informed consent was obtained. Enrolled patients were subsequently seen for baseline evaluation, including interview and physical examination. All relevant demographic and medical data were recorded and validated by a review of medical records.

Hereafter, patients were randomized to breast reconstruction by either the LD flap or the TAP flap. The randomization was conducted by drawing an envelope containing the allocation to one of the two intervention groups. The principal investigator (PI) generated the allocation sequence prior to initiation of the trial, by making 50 envelopes – 25 containing allocation to each treatment. The envelopes were sealed and then shuffled independently by two persons, unconnected to the study group. Finally, the envelopes were numbered from 1–50. The envelopes were drawn consecutively for randomization, starting with number 1. Neither participants nor investigators were blinded for the allocated treatment.

The breast reconstructions were performed by 1–2 consultant plastic surgeons at each center. To ensure comparability, all procedures were performed in a standardized fashion: For the LD flap-based reconstructions, a horizontally placed skin paddle was raised on the entire underlying LD muscle, releasing its insertion on the thoracic vertebrae, the thoracolumbar fascia, and the iliac crest. The humeral insertion was not divided, if possible, and the thoracodorsal nerve was not transected. The flap was then transposed to the anterior thorax and draped over a prepectorally placed implant.

The TAP flap-based reconstructions was performed in accordance with the TAPIA-concept previously described by the authors.[4]

All patients followed the same postoperative regime and rehabilitation program, focusing on shoulder function, which was handled by specialized physiotherapists.

The patients were seen in the outpatient clinic for follow-up at 3, 6 and 12 months after surgery, where evaluation identical to baseline was performed.

In Denmark, all evaluations were performed by the PI. In Norway, evaluation was conducted by a deputy, who was trained accordingly to ensure uniformity.

The presence of shoulder-related pain at baseline and follow-up was evaluated by a standardized question with the phrasing: *"Have you within the last 24 h experienced pain in your shoulder, upper arm or upper part of the back?"*. Patients were asked indicated the answer with yes/no only. The shoulder function was further assessed and objectified by the Constant Shoulder Score (CSS) in accordance with the published guidelines.[21] The test evaluates four parameters: pain, activity in daily life (ADL), ROM, and strength. It yields a total score of 1–100, with a higher score indicating good shoulder function.

Data were recorded on paper forms and later entered into the REDCap Database System by double data entry.[22] Data management and statistical analysis were conducted in STATA (Vers. 14.2 – STATA Corp. College Station TX, USA). As outlined in the data management plan before initiation of the trial, the primary endpoint would be shoulder-related pain one year after surgery. Differences in total CSS at baseline and 1-year follow-up as well as differences in subscores would constitute secondary endpoints. Furthermore, changes in total CSS and sub-scores during follow-up would be included as exploratory endpoints.

All statistical analyses were performed on a modified intention-to-treat (ITT) population, including only patients who completed both reconstruction and follow-up. For the primary endpoint, we applied a logistic regression model adjusting for pain at baseline, whereas a simple linear regression model adjusted for baseline was applied for both secondary and tertiary endpoints. All statistical analyses were approved by a professional statistician, specialized in health research.

The method of this study, including eligibility criteria and outcome measures, were kept constant during the trial. The study was registered on clinicaltrials.gov (NCT02169011) and approved by The Danish Committee on Health Research Ethics (S-20120207) as well as the Danish Data Protection Agency (18/47953).

Results

A total of 156 women were assessed for eligibility during the inclusion period (Figure 2). Of these, 101 were deemed non-eligible for participation because they did not meet the criteria of the trial. A further five women declined to participate. During the two-year period, we enrolled 50 who were allocated to the two interventions, with 25 patients in each group.

In the LD group, four patients left the trial prior to reconstruction, either because they did not want reconstruction with the allocated flap (3) or because of sudden death (1). For the TAP group, two patients left after randomization, both because they did not want reconstruction with the allocated flap.

The remaining 21 women in the LD group and 23 women in the TAP group received the allocated reconstruction and proceeded to follow-up. Before completion of the 12-months follow-up, one additional patient from each group left the trial and were lost to follow-up. A further two women from the LD group died due to recurrence of their cancer. This left 18 women in the LD group and 22 in the TAP group, who completed the trial and were included in the modified ITT population.

Demographics and data for breast cancer treatment were comparable between the groups (Table 1). Data related to the course of breast reconstruction, the following hospitalization and complication rates were also without statistically significant differences between the groups (Table 2). In the TAP group, six patients experienced complications, four of which required surgical intervention (haematoma, major flap necrosis and minor flap necrosis). In the case of major necrosis, the flap was revised, and the implant was changed to an expander. There were no cases of failure.

Data on patient-reported shoulder-related pain showed a significant difference at 12 months after surgery (Table 3). When applying the logistic regressions model to adjust for pain at baseline, we found a significantly decreased risk of experiencing pain when reconstructed by the TAP flap, OR = 0.05 95%CI(0.005-0.51), p-value = 0.011 (Table 4).

The estimated effect on the total CSS at 12 months, when applying the TAP flap instead of the LD flap and adjusting for differences in the baseline score, was 6.2 points with 95%CI(0.5–12.0), which was statistically significant, p-value 0.033 (Table 5). Furthermore, there was a statistically significant positive effect on the total CSS at six months after the reconstruction of 5.6 points 95%CI(0.1–11.0), p-value 0.047. The total CSS did not differ significantly at three months.

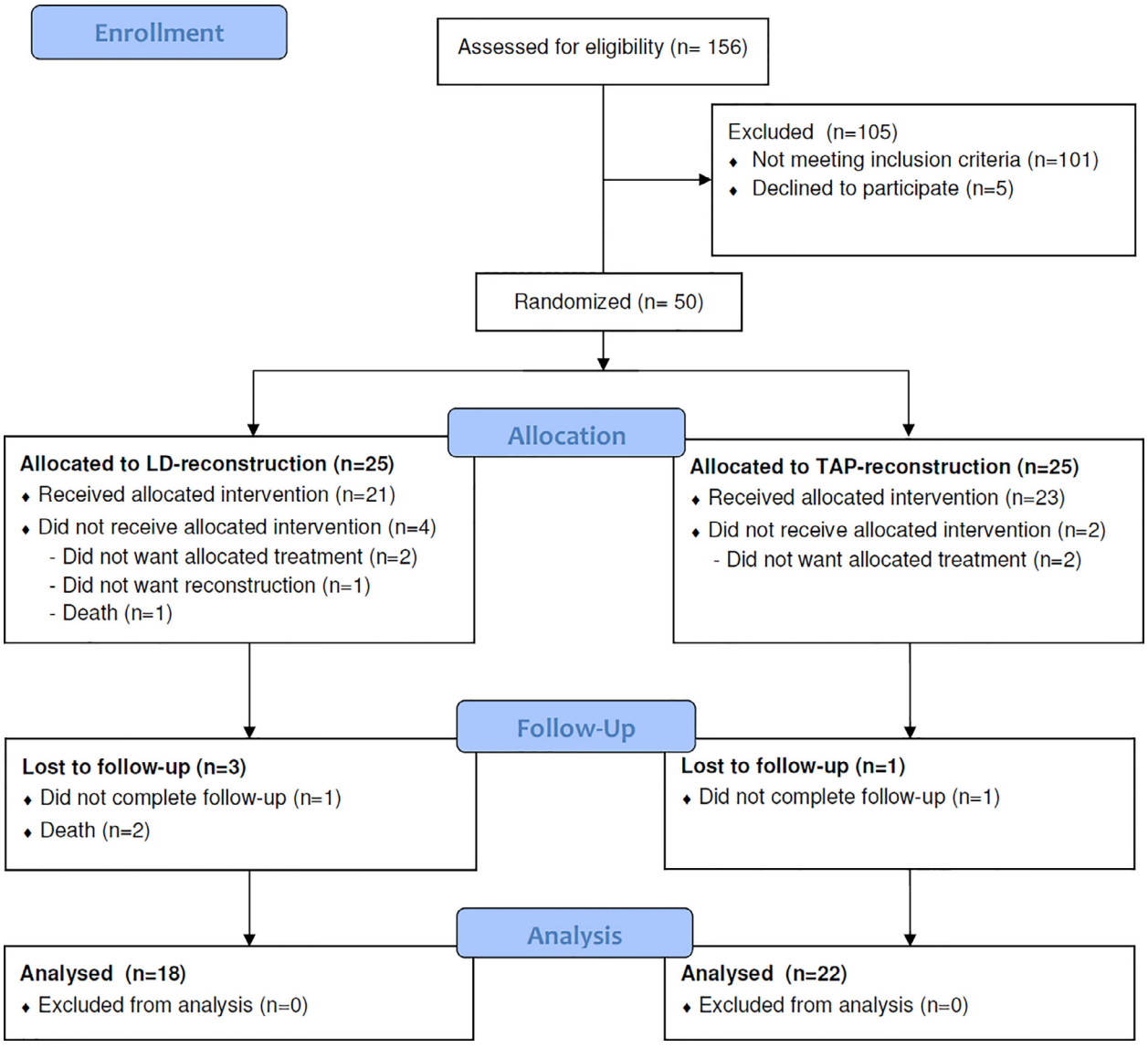

Figure 2 Flowchart illustrating patient enrolment.

The TAP flap seems to have a statistically significant positive effect on pain and ADL, while there is no significant effect on ROM and strength after one year of follow-up (Table 6). The same effect can be found at six months after the surgery, where strength also shows to be an average of two points higher in the TAP group. At three months, only ADL shows a significant difference, with a higher score amongst the TAP patients.

Discussion

This RCT confirms that there is a significant difference in patient-reported shoulder-related pain, as patients reconstructed by the TAP flap are less likely to report pain one year after the reconstruction. This is further supported and objectified by the differences in CSS which also shows an advantage to TAP patients.

Analysis of the sub-scores further indicates that it is mainly the two subjective parameters pain and ADL that are affected. Patients reconstructed with the LD flap experience a higher level of shoulder-related pain and a reduced ability to perform normal daily functions, including household chores and spare time activities. Their range of motion and strength of the shoulder do, however, not seem influenced significantly by the procedure.

The trial thus confirms our hypothesis that breast reconstruction with the TAP flap results in reduced shoulder-related morbidity and better postoperative shoulder function. It supports and confirms the findings of our retrospective study[19] and lends more evidence to the theory that harvest of the latissimus dorsi muscle has a detectable, negative effect on the overall shoulder function.

In both studies, the frequency and level of daily pain are found to be significantly higher amongst the LD patients. Quite interestingly, there is no detectable difference at three months after the surgery, but significantly so after six

Table 1 Demographic data and data on breast cancer treatment.

	LD flap (range) $n = 18$		TAP flap (range) $n = 22$	
Age	54.2 years (41-71)		55.8 years (35-70)	
BMI	26.2 (18.8-34.0)		25.4 (19.4-31.6)	
Smoking status	Current	0	Current	2
	Former	7	Former	6
	Never	11	Never	14
Comorbidity	Hypertension	1	Hypertension	5
	Diabetes	1	Diabetes	0
Mastectomy (indication)	Cancer	17	Cancer	22
	DCIS	1	DCIS	0
Axillary surgery	SNB[a]	10	SNB[a]	7
	ALND[b]	8	ALND[b]	15
Adjuvant therapy	Chemo	14	Chemo	15
	Radiation	9	Radiation	17
	Antihormone	11	Antihormone	14
Time to reconstruction (From mastectomy)	19 months (10-242)		22 months (6-127)	

[a] SNB = Sentinel Node Biopsy.
[b] ALND = Axillary Lymph Node Dissection.

Table 2 Breast reconstruction data.

	LD flap (range) $n = 18$		TAP flap (range) $n = 22$		p-value
Operating time	164 min (110-205)		169 min (75-250)		*0.741*
Use of implant	No implant	0	No implant	2	*0.189*
	Silicone	17	Silicone	15	
	Permanent expander	1	Permanent expander	2	
	Expander	0	Expander	3	
Implant size	275 cc (140-420)		300 cc (165-450)		*0.321*
Hospitalization	6.4 days (3-12)		6.5 days (4-14)		*0.875*
Complications	Total	2	Total	6	*0.204*
	Major[a]/minor[b]	0/2	Major[a]/minor[b]	4/2	*0.102*
Complications by type	Haematoma	0	Haematoma	1	
	Infection	1	Infection	1	
	Seroma	1	Seroma	0	
	Minor necrosis[c]	0	Minor necrosis[c]	3	
	Major necrosis[d]	0	Major necrosis[d]	1	

[a] Major = Complications requiring surgical intervention.
[b] Minor = Complications treated conservatively.
[c] Minor necrosis = Epidermolysis and small necrosis of the most distal part of the flap.
[d] Major necrosis = Necrosis requiring removal of the implant).

Table 3 Patient-reported shoulder-related pain.

	LD flap (Prop.) $n = 18$	TAP flap (Prop.) $n = 22$	p-value[a]
Baseline	7 (39%)	9 (40%)	*0.987*
12 months	13 (72%)	7 (32%)	***0.011***

[a] Chi^2-test.

Table 4 Risk of shoulder-related pain adjusted for baseline.

	OR	95%CI	p-value[a]
Pain at 1 year (TAP vs. LD)	0.05	(0.005-0.51)	***0.011***

[a] Logistic regression.

and twelve months. This may indicate that the pain is not directly related to transfer of the muscle itself, but rather to some late effects of the more extensive surgery i.e. scar tissue formation and altered biomechanics of the joint.

ADL is shown to be affected only in the current, prospective trial. The LD patients report a lower level of functioning at all follow-up visits, contrary to the findings in the retrospective study.[19] One explanation for this discrep-

Table 5 Total constant shoulder score at follow-ups.

	CSS score	LD flap (95%CI)	TAP flap (95%CI)	ATE[a] (95%CI)	*p*-value
Total CSS (0-100)	**Baseline**	76.3 (68.9-83.7)	80.1 (73.5-86.8)		
	3 months	68.3 (60.5-76.1)	76.4 (68.3-84.6)	4.4 (−1.4-10.2)	*0.135*
	6 months	70.6 (62.3-78.8)	81.2 (75.9-86.6)	5.6 (0.1-11.0)	***0.047***
	12 months	68.1 (58.2-79.9)	78.7 (70.9-86.4)	6.2 (0.5-12.0)	***0.033***

[a] AET = Average Treatment Effect.

Table 6 Constant shoulder score - subscore analysis.

	CSS score	LD flap (95%CI)	TAP flap (95%CI)	ATE[a](95%CI)	*p*-value
Pain (0-15)	**Baseline**	13.1 (11.7-14.5)	13.8 (12.6-15.0)		
	3 months	11.6 (9.7-13.5)	13.3 (11.9-14.7)	1.1 (−0.5-2.6)	*0.170*
	6 months	12.4 (10.8-14.0)	14.2 (13.3-15.0)	1.1 (0.3-1.9)	***0.007***
	12 months	11.6 (9.8-13.4)	14.0 (12.8-15.2)	1.8 (0.2-3.4)	***0.023***
ADL (0-20)	**Baseline**	18.6 (17.4-19.8)	17.7 (15.8-19.5)		
	3 months	16.6 (14.8-18.3)	18.0 (16.4-19.5)	2.2 (1.1-3.4)	***<0.0001***
	6 months	17.5 (16.0-19.0)	19.9 (18.2-19.7)	1.7 (0.8-2.6)	***<0.0001***
	12 months	17.1 (14.9-19.2)	18.7 (17.3-20.0)	2.6 (1.1-4.2)	***<0.0001***
ROM (0-40)	**Baseline**	32.6 (28.3-36.8)	36.4 (33.5-39.3)		
	3 months	29.9 (25.9-33.9)	33.9 (30.0-37.9)	0.3 (−2.5-3.1)	*0.849*
	6 months	31.1 (26.6-35.6)	36.3 (33.4-39.2)	0.6 (−3.0-4.1)	*0.763*
	12 months	29.6 (24.6-34.5)	34.8 (31.0-38.6)	0.9 (−1.4-3.2)	*0.451*
Strength (0-25)	**Baseline**	12.1 (10.1-14.1)	12.3 (10.4-14.2)		
	3 months	10.2 (8.3-12.2)	11.3 (9.3-13.2)	0.9 (−0.8-2.6)	*0.325*
	6 months	9.6 (7.9-11.3)	11.8 (10.1-13.5)	2.0 (0.3-3.6)	***0.018***
	12 months	9.9 (7.8-12.0)	11.2 (9.3-13.1)	1.2 (−1.0-3.3)	*0.285*

[a] AET = Average Treatment Effect.

ancy may be that follow-up in the retrospective study was performed long after the breast reconstruction. The patients in the current trial were seen closer to their pre-reconstructive condition and were asked frequently to evaluate their level of function. They were thus more likely to compare their current level to their pre-reconstructive level. Patients from the retrospective cohort had more time to adapt, which is why they may not have assessed ADL with the same reference to their previous abilities or perhaps the retrospective study did not have enough statistical strength to detect such difference.

In contrast, ROM was not found to be affected at any point in the prospective trial but was significantly reduced for the LD patients in the retrospective study by a mean of 5.5 points.[19] Strength was not significantly reduced between treatment groups in any of the cohorts. Both of these findings could once again indicate that any impairment of the shoulder is not a direct result of the dissection and loss of LD muscle function, but rather a consequence of the subsequent processes that occur around and in the shoulder.

The LD muscle is important for stability and movement in the glenohumeral joint. The fact that strength, and to some extend ROM, is preserved after release of the muscle clearly suggests that activation of agonistic muscles allows patients to regain close to normal function in terms of movement. However, transfer of the LD muscle may impact the stability of the shoulder and affect the joint's biomechanical properties. Over time, this can affect function and account for development of pain, and subsequently reduced ROM.

Furthermore, dissection of the entire LD muscle results in a much larger donor-site defect, than when raising a TAP flap, which causes formation of scar tissue and fibrosis. Contracture of this tissue and the resulting restrictions to movement around the shoulder could contribute further to the development of chronic pain.

One important difference between the retrospective study and the current prospective trial is that most retrospective patients had the LD released from its humeral insertion, contrary to women in the RCT. The more extensive dissection around the shoulder joint may account for the higher level of pain and reduced range of motion found in that study.

The clinical relevance of the findings of this RCT should, of course, be evaluated. As demonstrated patients reconstructed by the LD flap are much more likely to experience pain from the shoulder, upper arm or back than TAP patients. This fact cannot be disregarded as irrelevant as chronic pain can influence quality-of-life significantly.[23] The mean value of the total CSS for women between 51-60 years is 73 points.[21] The baseline score in both treatment groups is a little higher, but falls rather close to the expected score when looking at the confidence intervals. The statistical analysis takes the baseline score into account, and the difference is an estimation of the average effect of applying the TAP flap instead of the LD flap. This too cannot not be regarded as clinically irrelevant, especially as shoulder function decreases further with age. However, longer follow-up is needed to establish whether the function decreases more

with time, as this may impact decision-making when choosing a pedicled flap for breast reconstruction. With the data at hand, the difference demonstrated at one year is not sufficient to discourage use of the LD flap. This flap still has a place in breast reconstruction, but potential morbidity should be considered and discussed with the patient.

The economic aspects of implementing a new procedure are important. As shown, theater-time, duration of hospitalization as well as type and size of the implants used was comparable between the groups. With regard to complications, there was no statistically significant difference, but the TAP flap seems more prone to suffer from minor necrosis of the distal part of the flap. As demonstrated previously, there is a learning curve on the procedure, and the design of the flap is paramount in achieving a good result without major complications.[7] Presumably, the TAP flap has a somewhat less predictable blood supply, which may impact decision making when choosing the flaps for i.e. salvage reconstructions.

One economic aspect that needs to be considered is that breast reconstruction with the TAP flap requires a mesh to support the implant to reduce the risk of complications. To ensure uniformity, we used an ADM (Strattice®) for all patients in the TAP group. This of course increases the procedural cost, but as more types of meshes emerge and prices develop this expense diminishes. Based on the above, the additional costs of applying the TAP flap are acceptable.

In terms of patient flow, there was a larger dropout in the LD group. However, as demonstrated in the flowchart, the number of drop-outs, which was not caused by death was comparable between groups (Figure 2). Based on this, we do not believe that the difference in women who left the trial before conclusion introduced any selection bias.

We considered blinding patients and/or investigators to improve the quality of the study. However, patients could not be blinded, due to the fact that TAP patients had to be informed about the implantation of a biological mesh. Furthermore, clinicians could not be blinded, as the donor-site scarring is different between the two techniques, which would reveal the type of procedure at follow-up. Blinding was thus deemed unfeasible, which of course introduces a small risk of bias in relation to both patients and investigators. All patients did, however, receive the same information before inclusion, and the fact that patients from both intervention groups left the trial after randomization suggests that none of the procedures was presented as superior to the other.

Despite a rather small study population and relatively wide confidence intervals, the difference in postoperative shoulder function still reached significance. This emphasizes the strength of our results. Furthermore, the study was conducted as a multicenter trial, which supports the assumption that the results are representative for reconstructed women in general and will be reproducible anywhere.

This is the first randomized trial comparing shoulder function after breast reconstruction by different pedicled flaps from the back. The study supports previous findings; however, the published evidence on this subject is scarce. Only three papers representing the highest level of evidence on shoulder function following LD muscle transfer exist. The latest is a systematic review and meta-analysis by Steffensen and colleagues published in 2019.[14] The study included 26 articles with 1045 patients. The overall conclusion was that there is a tendency that latissimus dorsi flap transfer does affect shoulder function and that the impact seems to be influenced by the thoracodorsal vessel-based flap. However, they find that limitations seem minimal. Furthermore, they find the existing literature to be insufficient to draw any final conclusion, and they advocate further studies with higher levels of evidence.

These findings fall well in line with the reviews published by Blackburn et al. and Lee et al.[15,16] The conclusion of both papers was that the quality of evidence is low and ambiguous, but that some degree of functional impairment can develop after transfer of the LD flap.

Similarly, the evidence on donor-site morbidity following harvest of the TAP flap is limited. In 2008 Hamdi and colleagues published a retrospective study including 22 patients, who underwent breast reconstruction with a pedicled TAP flaps.[18] Neither muscle strength nor LD thickness was found to be affected, but flexion and abduction of the arm was reduced significantly. The conclusion was, however, that donor site morbidity is low, and that the flap presented a good alternative to the LD flap.

Another retrospective study by Lee and colleagues analysed 293 patients, who had various reconstructions with a free TAP flap.[17] The overall conclusion was that donor site morbidity and functional impairment, objectified by the Quick-DASH-score, was low.

Conclusion

The results of this RCT show a difference in shoulder-related donor site morbidity between the two flaps, demonstrating a clear advantage to the TAP flap. Patient reconstructed by the TAP flap are thus less likely to experience shoulder-related pain and have a better function of the shoulder one year after the reconstruction. The TAP flap is thus superior to the LD flap as harvest of the latter carries a higher risk of shoulder function impairment, chronic pain and reduced ADL. A longer follow-up period is needed to establish whether this difference change and perhaps becomes even more significant over time. Further investigation into differences in patient satisfaction and esthetic outcome of the two procedures is also warranted.

Declaration of Competing Interest

The first author has received a donation of ADM (Strattice®) from Acelity™ to be used in this randomized clinical trial. Apart from this none of the authors have any disclosures in terms of financial and/or personal relationships with people or organizations that could influence this published work. This study did not receive any funding.

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