Article

Long-term Results after Autologous Breast Reconstruction with DIEP Versus PAP Flaps based on Quality of Life and Aesthetic Outcome Analysis

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Abstract: (1) Background: This work aimed to conduct the first comparative study providing long-term data about patient reported outcome measures as well as donor-site scar assessment and aesthetic evaluation of the reconstructed breasts in patients with DIEP versus PAP flap breast reconstruction. (2) Methods: This prospective, single-center, matched cohort study included a total of 36 patients after DIEP and PAP flap breast reconstruction. Evaluation was done using the Breast-Q and POSAS questionnaire as well as the Breast Aesthetic Scale for cosmetic analysis by four plastic surgeons. (3) Results: Post-operative Breast-Q evaluation revealed no significant differences between both patient groups for the categories physical well-being donor-site, physical well-being breast and satisfaction with the breast. Scar evaluation of the donor-site region showed equivalent results for the thigh and the abdomen concerning the overall opinion of patients and observers. There was no significant difference between both methods of reconstruction for all aspects of breast aesthetics. (4) Conclusions: Similar results of donor-site morbidity, scar quality and aesthetic outcome of the breast in both the DIEP and PAP patient group have been demonstrated. Hence, in cases suitable for both types of reconstruction, the decision can be based on factors such as patients' lifestyle, leisure activities and preferences.

Keywords: breast cancer; mastectomy; autologous breast reconstruction; PAP flap; DIEP flap; donor-site morbidity; quality of life; aesthetic outcome; scar quality; Breast-Q

1. Introduction

Breast Cancer is the leading cancer entity in women with a lifetime risk of approximately 12.9% in industrialized countries [1]. Increasing survival rates over the last four decades changed and diversified the treatment challenges with aesthetic demands and life quality claims being of increasing importance [2,3]. Despite significant therapeutic advances NSME and SSME still remain an inherent part of the therapeutic options and have an even broadened ambit with bilateral and prophylactic mastectomies rising in numbers [4,5]. Women clearly benefit from post-mastectomy breast reconstruction in their long-term survivorship period [6]. Among different methods of reconstruction, autologous techniques have proven their superiority, due to their permanent and natural aesthetic results and high patient satisfaction, compared to implant based techniques [6–9]. Free flap reconstruction with tissue from the abdomen has long been favored and the deep inferior epigastric perforator (DIEP) flap is nowadays considered as gold-standard [10,11]. However, the thigh has proven to be a safe alternative donor-site, more precisely the profunda artery perforator (PAP) flap has evolved as reliable option especially for the reconstruction of small- to medium-sized breasts [12,13]. Since microsurgical safety has been

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proven for both perforator flaps, considerations about long-term results, donor-site morbidity and recovery time come to the fore. This necessitates detailed work-up of autologous techniques to help surgeons in their decision making process and, in further consequence, to permit thorough patient counseling. In order to allow informed consent, all reconstructive options must be well discussed. Moreover, quality of provided information in the counseling process is crucial for post-operative patient satisfaction [14]. Literature review revealed three comparative studies about patient reported donor-site morbidity in autologous perforator flap breast reconstruction, with diverging patients' preferences being reported [15–17]. This work aimed to conduct the first comparative study providing long-term results about patient reported outcome measures as well as donor-site scar assessment and aesthetic evaluation of the reconstructed breasts in patients with DIEP versus PAP flap autologous breast reconstruction.

2. Materials and Methods

2.1. Study Design

This prospective, single-center, cohort study of 36 patients after autologous breast reconstruction was approved by the Institutional Ethics Committee of MEDICAL UNIVERSITY INNSBRUCK (protocol code 1058/2020, 28 October 2020). Two matched patient groups of each 18 patients after PAP and DIEP flap reconstruction were evaluated.

Informed consent for photo documentation, the operation and anonymized evaluation and publication of data was obtained in written form from all patients. Inclusion criteria were defined as age > 18 years, breast cancer diagnosis, high-risk genetic disposition or recurrent infections of the breast, uni- or bilateral breast reconstruction and post-operative course longer than 12 months. We excluded patients with metastatic disease, severe psychiatric disorders and follow-up less than 12 months. Patient demographics including age, body mass index (BMI), smoking habits and comorbidities as well as post-operative complications were documented.

Prospective evaluation was done using two validated questionnaires, translation to German language was conducted in accordance with the copyright owners. Patient reported outcome and quality of life was assessed using the post-operative Breast-Q version 2.0 (Copyright ©2017, Memorial Sloan Kettering Cancer Center and the University of British Columbia). Evaluation of the questionnaire was done using the provided conversion tables. The scores range from 0 to 100, the higher the scores, the more favorable the results. Patients with missing responses to specific questions were removed from the analysis of the referred question, but kept for the analysis of completed questions.

Evaluation of the scar quality in the donor-site region was done with the POSAS version 2.0 (The Patient and Observer Scar Assessment Scale, https://www.posas.nl/) [18]. The patient and the observer scale contain of 6 items each, all of them are rated on a 10-point score. The lowest score is '1', which corresponds to the situation of normal skin, while score 10 equals the largest difference from normal skin. Additionally, there is for each scale a rating for the overall opinion about the scar.

Cosmetic evaluation of the breast reconstruction for both patient groups was conducted by a gender-balanced panel of four independent plastic surgeons (two seniors, two residents) based on standardized post-operative photo documentation in frontal and oblique views using a German translation of the Breast Aesthetic Scale [19]. Nine questions of this validated tool were used to evaluate the aesthetic result of the breast reconstruction, questions about the nipple-areola reconstruction were omitted, since this was not aim of this study. Every question is graded from 1 to 5, with 5 points representing the perfect aesthetic result. In the DIEP group only 17 patients were included for aesthetic evaluation since one patient did not complete photo documentation.

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2.2. Patients

All patients with a PAP flap breast reconstruction from January 2016 to November 2019 at our Department were identified. In this period 18 patients, of whom nine underwent bilateral PAP flap reconstruction, met our inclusion criteria and consented to participate. Evaluation data of the PAP cohort was recently published by our group [20]. Consequently, our Departments' patient database was searched retrospectively from January 2011 to December 2020 and 18 patients after DIEP flap breast reconstruction were matched with this PAP cohort according to the criteria age, clinical diagnosis and concomitant oncologic therapy. All except one patient were matched according laterality as well. In both groups one patient with recurrent infections was included but only the patient in the DIEP group had bilateral reconstruction. Therefore in the DIEP group 28 flaps and 18 donor-sites were evaluated with a mean follow up of 69.8 (± 34.7) months (Figure 1a). The mean post-operative follow up in the PAP group was 34.0 (± 15.8) months (Figure 1b).

Figure 1. (Left) Pre-operative and (right) post-operative views of bilateral autologous breast reconstruction with (a) DIEP and (b) PAP flaps.

2.3. Statistical analysis

Statistical analysis was performed using ©Microsoft Excel 2016 (Microsoft Corporation. https://office.microsoft.com/excel; accessed August 20, 2022) and ©MedCalc Statistical Software Ltd. (MedCalc Software Ltd. Fisher exact probability calculator. https://www.medcalc.org/calc/fisher.php, version 20.115; accessed September 27, 2022). Chi-square or Fisher exact tests and Student t-test were used to test for differences between the PAP versus DIEP groups; statistical significance was set at a p-value less than 0.05 for all tests.

3. Results

3.1. Patient characteristics

In both groups 18 patients were evaluated after autologous breast reconstruction with PAP and DIEP flaps, respectively. Bilateral reconstruction was performed in the PAP group in 9 patients (n = 27 flaps) and in the DIEP group in 10 patients (n = 28 flaps). Patient information is listed in Table 1. Matching of the patient groups was done based on age, indication for mastectomy and adjuvant oncologic therapies, therefore there were no sig-

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nificant differences between the PAP versus DIEP group in terms of radiation and chemotherapy. Average BMI was significantly higher in DIEP patients (25.3 kg/m²) compared to PAP patients (21.6 kg/m²; p = 0.001). Also flap volume (565.2 ± 207.4 vs. 327.7 ± 108.2; p < 0.0001) and mastectomy volume (518.1 ± 167.3 vs. 274.8 ± 132.8; p < 0.0001) was significantly higher in DIEP patients.

Table 1. Patient characteristics.

Characteristic	DIEP		PAP		p-value
	mean	**(± std)**	**mean**	**(± std)**	
Age (years) *	41.3	(± 6.7)	43.6	(± 7.4)	0.3660
Follow-up (months) *	69.8	(± 34.7)	34.0	(± 15.8)	0.0005
BMI (kg/m²) *	25.3	(± 3.7)	21.6	(± 2.3)	0.0010
Flap volume (cc) †	565.2	(± 207.4)	327.7	(± 108.2)	< 0.0001
Mastectomy volume (cc) †	519.1	(± 167.3)	274.8	(± 132.8)	< 0.0001
	n	**(%)**	***n***	**(%)**	
Active smoker *	4	(22.2)	1	(5.6)	0.3377
Time of reconstruction †					0.0515
Primary	28	(100)	23	(85.2)	
Secondary	0	(0.0)	4	(14.8)	
Indication for mastectomy †					0.4182
Breast cancer	14	(50.0)	17	(63.0)	
Non-Malignant	14	(50.0)	10	(37.0)	
Prophylactic	12	(42.9)	9	(33.3)	
Mastitis	2	(7.1)	1	(3.7)	
Positive genetic testing *	4	(22.2)	4	(22.2)	> 0.99
Radiotherapy *					> 0.99
Yes	9	(50.0)	10	(55.6)	
Previous radiotherapy	1	(5.6)	3	(16.7)	
Adjuvant	8	(44.4)	7	(38.9)	
No	9	(50.0)	8	(44.4)	
Chemotherapy *					
Yes	12	(66.7)	11	(61.1)	> 0.99
Previous chemotherapy	9	(50.0)	7	(38.9)	
Adjuvant	3	(16.7)	4	(22.2)	
No	6	(33.3)	7	(38.9)	

100%: * *n* = patients, † *n* = flaps.

Post-operative complications were defined as events classified as Grade 3b according to the Clavien-Dindo Classification, necessitating operative revision under general anesthesia [21]. Such events (hematoma, seroma, wound dehiscence, wound infection) occurred in 29.6% (8/27) of operated thighs and 5.5% (1/18) of abdominal donor-sites (p = 0.0479). One flap loss was observed in each group due to venous failure. Evaluation of post-operative complications in the breast as well as rates of secondary corrections in the breast or donor-site did not reveal significant differences between both patient groups, detailed results are shown in Table 2.

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Table 2. Post-operative complications (Clavien-Dindo 3b) and secondary corrections.

Characteristic	DIEP *n*	(%) *	PAP *n*	(%) †	p-value
Complications breast	4	(14.3)	6	(22.2)	0.5027
Complications donor-site	1	(5.5) ˣ	8	(29.6)	0.0479
Secondary corrections breast	5	(18.5) ≈	9	(34.6) ~	0.2238
Secondary corrections donor-site	5	(27.8) ˣ	3	(11.1)	0.2351

100%: * *n* = 28 DIEP flaps, ˣ *n* = 18 DIEP donor-sites, ≈ *n* = 27 DIEP flaps (1 flap loss). † *n* = 27 PAP flaps, ~ *n* = 26 PAP flaps (1 flap loss).

3.2. Breast Q

All included patients completed the Breast-Q form at least 12 months post-operatively. Patients who underwent bilateral surgery answered one questionnaire for each reconstructed breast and in the PAP group also for each donor-site. Results are shown in Figure 2. Post-operative Breast-Q evaluation revealed no significant differences between both patient groups in the categories; physical well-being donor-site (p = 0.9478), physical well-being breast (p = 0.1840) and satisfaction with the breast (p = 0.0745) (Figure 2a). The section about the satisfaction regarding the donor-site contains three questions, namely about the appearance of the scar, the position of anatomic landmarks (umbilicus / gluteal crease) and how the donor-site looks without clothes. Rating is done from 1 (very unsatisfied) to 4 (very satisfied). Comparison of both patient groups did not reveal significant differences regarding donor-site satisfaction. Scores are shown in Figure 2b. Evaluation of the categories, psycho-social well-being (p = 0.0031) and sexual well-being (p = 0.0469), revealed significant higher Q-scores in the DIEP group (Figure 2a).

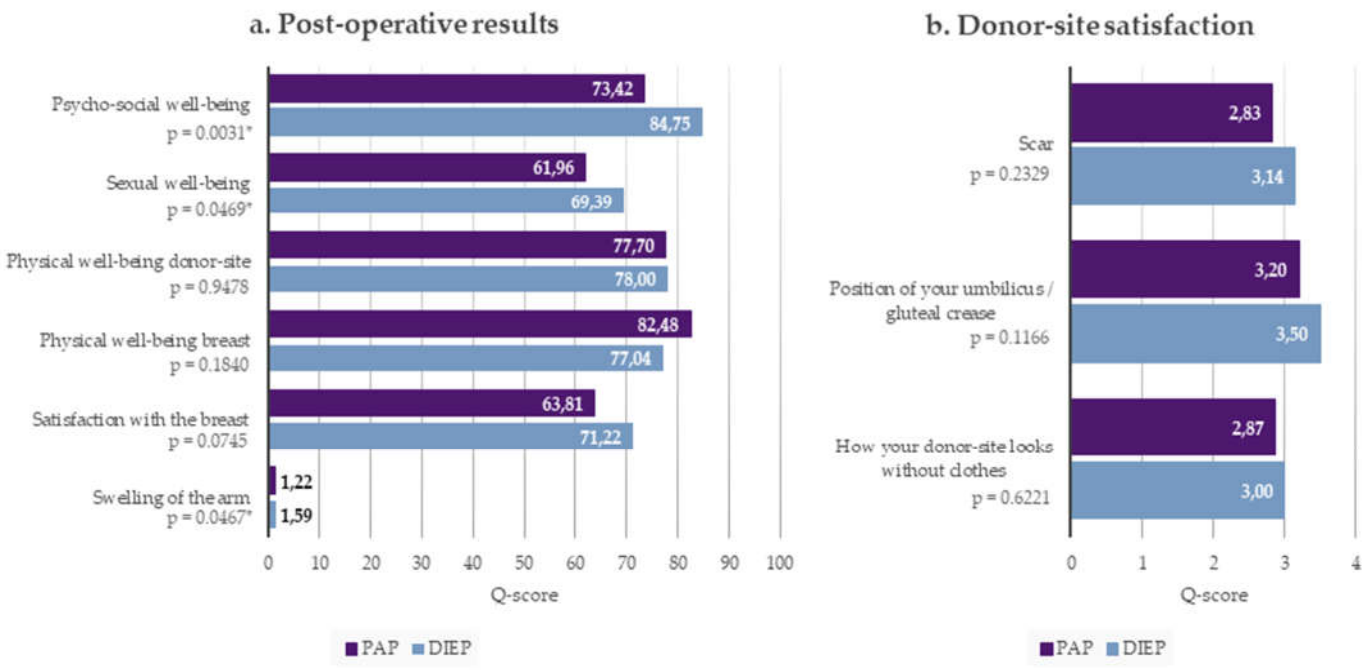

Figure 2. Breast-Q Evaluation. (a) Post-operative results, (b) donor-site satisfaction. * p < 0.05.

3.3. POSAS

All included patients in this study completed the POSAS questionnaire for donor-site scar evaluation at least 12 months post-operatively. All parameters were scored from 1 to 10, with the lowest score 1 corresponding to the normal skin situation, results are given in Table 3.

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Table 3. POSAS – patient and observer scale of donor-site scar.

POSAS score	DIEP		PAP		
Patient scale	**mean**	**(± std)**	**mean**	**(± std)**	**p-value**
Has the scar been painful the past few weeks?	1.33	(± 1.15)	1.93	(± 1.88)	0.2498
Has the scar been itching the past few weeks?	2.39	(± 1.77)	1.26	(± 0.84)	0.0076
Is the scar color different from the color of your normal skin?	4.00	(± 1.83)	4.52	(± 2.44)	0.4556
Is the stiffness of the scar different from your normal skin?	4.06	(± 2.55)	4.52	(± 2.56)	0.5635
Is the thickness of the scar different from your normal skin?	3.94	(± 2.63)	4.19	(± 2.40)	0.7585
Is the scar more irregular than your normal skin?	4.00	(± 2.67)	4.37	(± 2.74)	0.6627
Total score	19.72	(± 8.50)	20.78	(± 9.94)	0.7198
Overall opinion	**3.67**	**(± 2.08)**	**4.72**	**(± 2.41)**	**0.1453**
Observer scale					
Vascularity	2.39	(± 1.64)	2.42	(± 1.11)	0.9495
Pigmentation	3.11	(± 1.63)	3.80	(± 1.72)	0.2032
Thickness	2.33	(± 1.49)	3.08	(± 1.09)	0.0714
Relief	2.28	(± 1.52)	3.40	(± 1.41)	0.0196
Pliability	3.00	(± 1.70)	2.36	(± 0.79)	0.1150
Surface area	2.89	(± 1.97)	3.12	(± 1.39)	0.6623
Total score	15.16	(± 9.30)	18.08	(± 6.32)	0.2329
Overall opinion	**2.72**	**(± 1.41)**	**3.16**	**(± 1.29)**	**0.3074**

The patients' rating regarding the overall opinion on their donor-site scars indicated a mean value of 3.67 (± 2.08) in the DIEP group and 4.72 (± 2.41) in the PAP group ($p = 0.1453$) and therefore did not show significant differences (Figure 3a). The observers' rating regarding the overall opinion on the donor-site scars resulted in a mean value of 2.72 (± 1.41) in DIEP patients and 3.16 (± 1.29) in PAP patients ($p = 0.3074$), not showing differences between both groups either (Figure 3b). However, in both patient groups the overall opinion about the donor-site scar showed improved ratings in the observers' assessment compared to the patients' results, with a significant difference in the PAP group ($p = 0.0068$) (Table 3, Figure 3c and 3d).

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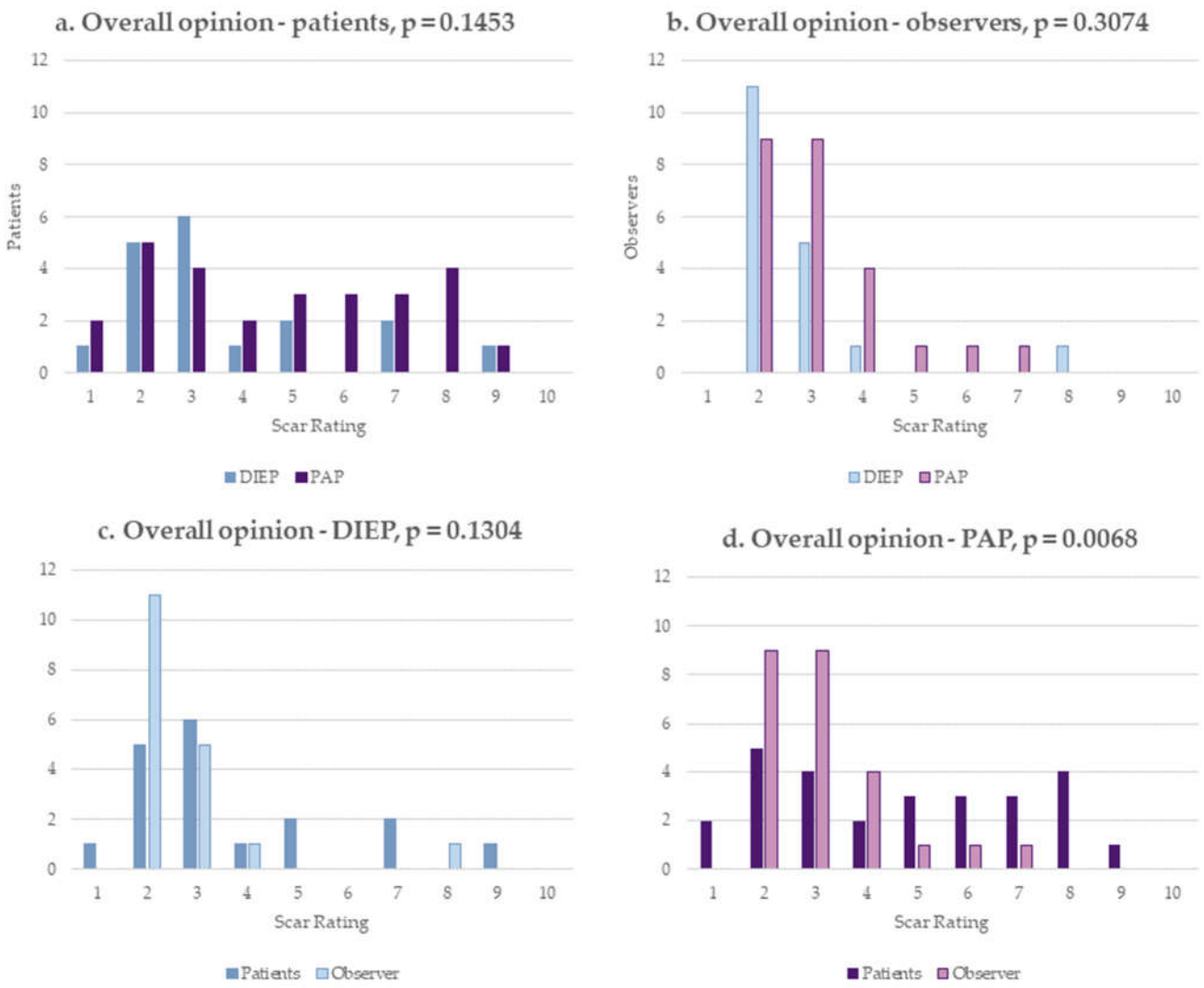

Figure 3. POSAS - overall-opinion on donor-site scar. (a) Patient scale, (b) observer scale, (c) DIEP cohort, (d) PAP cohort.

The POSAS score is calculated by summing up the scores of all six items, not including the overall opinion. The patient form asks about pain, itching, color, stiffness, thickness and irregularities, the observer form asks about vascularity, pigmentation, thickness, relief, pliability and surface area. Comparison between the DIEP patient group (19.72 ± 8. points) and the PAP patient group (20.78 ± 9.94 points) did not reveal differences concerning the total score ($p = 0.7198$). Still, the DIEP group reported significantly more itching of the scar than the PAP group (2.39 ± 1.77 points versus 1.26 ± 0.84 points; $p = 0.0076$).

Comparison of the two study groups also showed equivalent results concerning the observer total score ($p = 0.2329$). However, scar relief was significantly better rated in the DIEP group (2.28 ± 1.52 points versus 3.4 ± 1.41 points in the PAP group; $p = 0.0196$).

3.4. Cosmetic results

Comparison of the two study groups showed equivalent results concerning the overall opinion about the aesthetic outcome with a mean of 3.41 points in the PAP group and 3.61 points in the DIEP group ($p = 0.4771$). Likewise, there was no significant difference between both methods of reconstructions for all other aspects of breast aesthetics, details are given in Table 4.

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Table 4. Breast aesthetic scale.

Questions	DIEP		PAP		
Breast	**mean**	**(± std)**	**mean**	**(± std)**	**p-value**
Breast symmetry	3.22	(± 0.92)	3.21	(± 1.14)	0.9733
Breast position	3.66	(± 0.75)	3.67	(± 1.01)	0.9496
Inframammary fold	3.82	(± 0.8)	3.68	(± 0.98)	0.5954
Volume	3.58	(± 0.75)	3.51	(± 1.09)	0.7995
Shape and contour	3.21	(± 1.03)	3.11	(± 1.12)	0.7297
Scar					
Appearance	4.22	(± 0.65)	3.99	(± 0.67)	0.2183
Nipple-Areola Complex					
Nipple symmetry	3.57	(± 0.91)	3.46	(± 1.06)	0.7416
Nipple position	3.57	(± 0.82)	3.65	(± 0.91)	0.7484
Overall Appearance	**3.58**	**(± 0.93)**	**3.38**	**(± 1.02)**	**0.4907**

4. Discussion

The rising number of patients seeking autologous breast reconstruction after mastectomy leads to steadily growing experience with a variety of surgical options [22]. Patients need to be evaluated and counseled thoroughly to allow a distinct selection process of the individual patient's best choice. The abdominal DIEP flap is now considered as gold-standard for perforator flap reconstruction, but also the thigh-based PAP flap has proven to be a safe alternative [10,12,23,24]. The PAP flap is particularly favored in patients with a rather low BMI and lack of abdominal tissue and in patients with previous abdominal surgery potentially compromising perforator vessels [11]. Comparative evaluation of the two perforator flaps is necessary to support the process of decision-making in patients suitable for both options.

In this study matching of the patient groups was performed according to age, indication for mastectomy and adjuvant therapy, with the aim of minimizing the bias on the aesthetic outcome and the patients' perception about their illness. The patient groups did significantly differ concerning their average BMI with a higher BMI in the DIEP group. Average BMI in the PAP group was 21.6 kg/m², these patients often did not provide sufficient abdominal fat for reconstruction. Furthermore, also feasible reconstruction volume is limited with thigh-based reconstructions since the PAP flap presents a lower average flap volume [17,25]. This often limits PAP reconstruction to small- to medium-sized breasts. These known disadvantages do also correspond to our findings of a significantly lower flap volume and lower mastectomy volume in the PAP cohort [13]. Besides flap characteristics, donor-site morbidity must be well considered for evaluation of surgical methods. Preliminary studies demonstrate that functional deficits are rare in thigh donor-sites, but they may concern the ability to sit for prolonged periods or restriction in leisure activities such as bike-riding, stretching, hiking and climbing [26]. Haddock reports a return to normal lower extremity musculoskeletal condition by six months and high patient satisfaction after PAP harvesting [24]. More literature is available about the long-term morbidity of the abdominal DIEP donor-site, where abdominal wall hernia and bulge occur in 2-7 % and abdominal weakness represents the leading functional impairment in a wide range of 7 to up to 64 % [27–33]. In this study post-operative donor-site complications necessitating operative revision were found significantly more often in the PAP group, this is inconsistent with recent literature where comparable incidences of surgical site complications in DIEP and PAP donor-sites are described [15,25,34]. We observe that with increasing experience and familiarity with the PAP flap complication rates in thighs are decreasing as well at our Department which might hint for the learning curve as the main cause. Evaluation showed that secondary corrections of the donor-site due to aesthetic or functional deficits were more frequent in the DIEP group where 27.8 % of patients

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had staged touch-up procedures, compared to 11.1 % in the PAP group, though this difference was not significant. We hypothesize that patients may put higher aesthetic demands on the well-visible abdominal donor-sites. Therefore, DIEP patients might be more alive to surgical corrections. We believe that information about the potential need of follow-up procedures should be part of initial patient counseling in order to build up adequate expectations about the final result (*Figure 4*).

Figure 4. Post-operative views of donor-sites of (a) DIEP and (b) bilateral PAP flap.

Despite these differences in the post-operative and follow-up period concerning complications and secondary corrections, evaluation of the Breast-Q in our study showed that comparison of both patient groups did not reveal significant differences regarding donor-site satisfaction and physical well-being of the donor-site. Notably, the significantly higher post-operative complication rate in the PAP group does not compromise the long-term patient satisfaction and quality of life concerning the donor-site region. Comparative evaluation of donor-site satisfaction in literature reports diverging results so far. Lee reports similar levels of satisfaction for the abdomen and the thigh, whereas Murphy found a superiority of the PAP donor-site and Haddock a patients' preference for the DIEP donor-site [15–17]. Furthermore, Breast-Q evaluation of the categories physical well-being breast and satisfaction with the breast revealed no significant differences between both patient groups. However, post-operative Breast-Q evaluation revealed significant higher Q-scores in the DIEP group for the categories psycho-social well-being and sexual well-being. We hypothesize that this may be biased by our study schedule; evaluation of the DIEP patients was done in 2022, whereas PAP patients were questioned 2020, coinciding with the first COVID wave in Austria. During this time population faced long periods of governmentally dictated home quarantine. Impact of this psychologically exceptional situation must be considered, since a decrease in people's quality-of-life, with poorest levels among females, has been reported in conjunction with the pandemic's consequences [35].

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An inferiority in psycho-social well-being in the PAP group may therefore not essentially be linked to the technique of breast reconstruction.

POSAS evaluation showed, that the patients' as well as the observers' rating regarding the overall opinion on the donor-site scars did not show significant differences between the abdomen and the thigh. Itching was the only scar symptom experienced significantly more often in the abdomen compared to the thigh. So far, two studies using the POSAS have been completed for DIEP scar evaluation after breast reconstruction. POSAS scores were inferior in both studies compared to our results, but Siegwart reports a better patients' and observers' overall opinion about scar quality in the DIEP group without mesh [14,36]. Patient information about donor-site scar outcome is crucial to maximize post-operative scar appraisal [14]. Some patients might have the preconception that flap harvesting is equivalent to widely known body-contouring procedures since similar surgical incisions are made, but aesthetic outcome after abdominoplasty has been described as superior to the abdominal donor-site after autologous breast reconstruction [37]. Such diverging presumptions might also contribute to our findings of a better donor-site scar rating among observers compared to patients in the POSAS evaluation (Figure 3c and d). Surgeons know about the challenges of flap harvesting for autologous breast reconstruction. In body contouring procedures surgical resection is limited to the excess skin and fat. On the contrary, especially in thin patients, sufficient flap volume for autologous breast reconstruction can only be gained by extensive tissue harvesting. As a result, closure of the donor-site is sometimes only achieved under tension even using wide mobilization. This represents a major difference of the reconstructive surgery and information must be provided beforehand to patients. At our Department, we use pre- and post-operative photographs of selected cases in the first counseling, in order to build up expectations as realistic as possible about the results. Still, our data show that these challenges are independent from the choice of donor-site.

In this study, there was no difference between the DIEP and the PAP patients in long-term aesthetic outcome of the breast. Although flap volume was significantly lower in our PAP patients, both patient groups showed equivalent rating of the breast reconstruction being proportional to their body habitus. However, selection bias is evident since PAP reconstruction was mainly performed in thin patients. We believe that the equality of the PAP and DIEP flap concerning aesthetic outcome is also stressed by the rate of staged secondary corrections of the breast, where our evaluation showed comparable numbers in both patient groups.

There are several limitations to our study. The single-institution design allows only insight in results from our Department. Reconstructive surgery was performed by three senior surgeons in the PAP group, in the DIEP group further two senior surgeons were involved. Therefore, differing surgeon-related outcome cannot be excluded completely. Another limitation might be the patient sample size, however a clear strength of the study is the matching of patients, creating a homogeneity between both groups included in the study.

5. Conclusions

This study provides extensive information on long-term results after autologous perforator flap breast reconstruction. Similar results of donor-site morbidity, scar quality and aesthetic outcome of the breast in both the DIEP and PAP patient group have been demonstrated. This allows, in cases suitable for both types of reconstruction, to choose the method of reconstruction based on patients' lifestyle, leisure activities and preferences. Our data will support surgeons and patients in the complex decision-making process of breast reconstruction.

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W.D.; project administration, W.D. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Ethics Committee of MEDICAL UNIVERSITY INNSBRUCK (protocol code 1058/2020, 28 October 2020).

Informed Consent Statement: Written informed consent has been obtained from the patients to publish this paper.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

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Conflicts of Interest: The authors declare no conflict of interest.

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