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Overall complication rates of DIEP flap breast reconstructions in Germany – a multi-center analysis based on the DGPRÄC prospective national online registry for microsurgical breast reconstructions

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Abstract: While autologous breast reconstruction has gained momentum over recent years, there is limited data on the structure and quality of care of microsurgical breast reconstruction in Germany. Using the breast reconstruction database established by the German Society of Plastic, Reconstructive and Aesthetic Surgeons (DGPRÄC), the presented study investigated overall outcome of DIEP flap reconstructions in Germany. Data of 3926 patients and 4577 DIEP flaps performed by 22 centers were included in this study. Demographics, patient characteristics, perioperative details and postoperative outcomes were accounted for. Centers performing < Ø 40 (low-volume (LV)) vs. ≥ Ø 40 (high-volume (HV)) annual DIEP flaps were analyzed separately. Overall, total and partial flap loss rates were as low as 2.0% and 1.1% respectively, and emergent vascular revision surgery was performed in 4.3% of cases. Revision surgery due to wound complications was conducted in 8.3% of all cases. Mean operative time and length of hospital stay was significantly shorter in the HV group (LV: 385.82 min. vs. HV: 287.14 min.; LV: 9.04 (18.87) days vs. HV: 8.21 (5.04) days; both $p<0.05$). The outcome and complication rates deduced from the national registry underline the high standard of microsurgical breast reconstruction on a national level in Germany.

Keywords: Breast Reconstruction; DIEP Flap; Breast Cancer; Microsurgery; Plastic Surgery, Reconstructive Surgery

1. Introduction

Since its first description in 1979 [1], autologous breast reconstruction has evolved as a safe and viable option. More than that, it is now regarded as the international gold-standard in reconstructive breast surgery [2]. Breast reconstruction was revolutionized in 1989, when Koshima et al. introduced perforator-based reconstruction using the deep inferior epigastric perforator (DIEP) flap [3], thus significantly reducing donor site morbidity while at the same time maximizing clinical outcome and generating aesthetically pleasing results. Since then, the DIEP flap has emerged as a workhorse in reconstructive breast surgery [4-8].

Currently, breast reconstruction is performed either by plastic surgeons or gynecologists. Both specialties often differ significantly in regard to the reconstructive approach preferred and no clear international, or interdisciplinary guidelines exist to support the decision-making process. While superior results are reported for autologous breast reconstruction in terms of aesthetic and natural outcome, longevity of postoperative results, long-term patient satisfaction and quality of life [9-11], implant-based reconstructions are still, by far, the most commonly performed procedure after breast cancer surgery. In fact, rates of autologous reconstruction have continued at a stable, rather than increasing level, for many years [12-14].

For various reasons, the introduction of microsurgical breast reconstruction into patient care has yet to gain strong momentum in Germany [15]. To further improve the standpoint of modern microsurgical reconstructive procedures within interdisciplinary treatment concepts, the German Society of Plastic, Reconstructive and Aesthetic Surgeons (DGPRÄC) introduced a national online registry to underline the structure and quality of care of microsurgical breast reconstruction in Germany.

Using this prospectively maintained free flap breast reconstruction database, the presented study investigated overall complication rates of DIEP flap breast reconstructions in Germany, based on a large patient cohort of 3926 female patients. By demonstrating flap success rates of over ~ 97%, this study underlines that successful microsurgical breast reconstruction can be achieved as successful on a national level in Germany, as described in international literature.

2. Materials and Methods

Patient data were obtained from the DGPRÄC national online registry for microsurgical breast reconstructions, including data sets from January 2011 - July 2018. Parts of this database have been previously investigated by our study group [16-19]. Fritschen et al. have described the purpose and design of the registry in detail [15]. All elements of the study were performed in accordance to institutional guidelines and regulations. Ethical board approval was obtained prior to study initiation (Bavarian State Medical Association (156/17 S) and Berlin Chamber of Physicians (Eth-V-Q/17)). Patient data were entered anonymously.

Data were entered prospectively, sorted and tagged to the individual plastic-surgical department and surgeon. Data acquired included clinical outcome, relevant individual patient parameters and characteristics, as well as prior therapeutic steps such as systemic breast cancer therapy or previous surgery. Intra- and perioperative details as well as data regarding surgical technique were also entered. Outcome was assessed and follow-up data generated up to three months postoperatively.

The database was open to plastic surgical units in Germany. To assure high quality conclusions, only data points from centers previously certified by the DGPRÄC according to especially defined criteria (Table 1) were analyzed in the study.

Audit monitoring visits were performed by qualified monitors according to a defined protocol and checklist, in order to ascertain the quality of entered data in comparison to the hospital´s documentation.

Table 1: Criteria defined by the German Society of Plastic, Reconstructive and Aesthetic Surgeons (DGPRÄC) for certification of plastic-surgical centers that entered data into the national online registry for microsurgical breast reconstructions. Criteria translated from German, originally published in Fritschen et al [15].

Criteria for DGPRÄC certification
Centers must perform at least 100 annual breast procedures
At least 20 microsurgical breast reconstructions performed by a single surgeon
5 of these procedures may be performed as teaching operations
Procedures performed as an assistant surgeon in teaching operations are not counted

2.1 Patient cohort

To investigate a homogenous group of breast reconstructions, merely female patients receiving uni- or bilateral DIEP flap breast reconstruction were included in this study. Thus, data of 3926 patients and 4577 DIEP flaps were included in this study. The data were generated by a total of 22 plastic surgical centers. Cases were divided into two groups, depending on the experience of centers with DIEP flap surgery: a high-volume group (≥ Ø 40 DIEP flaps per year of data entry) vs. a low-volume group (< Ø 40 DIEP flaps per year of data entry). Surgical complications were then compared between both groups. The following outcomes were investigated: total flap loss, partial flap loss (10-20% of free flap tissue), unexpected or emergency revision surgery (vascular revision i.e., arterial and venous thrombosis; wound revision i.e., infection, hematoma and wound healing disturbances at donor and recipient site) and medical complications.

2.2 Statistical Analysis

Differences between groups were determined using ANOVA or chi-squared test of independence. Statistical analyses were performed using SAS (Version 9.4, The SAS institute, Cary, NC), and results were considered statistically significant for values of $p \leq 0.05$ to guide conclusions.

3. Results

3.1 Descriptive Data (Table 2)

The investigated study sample consisted of 3926 female patients, with a mean age of 51.30 (SD 31.61) years and mean body mass index (BMI) of 26.28 (SD 4.44) kg/m2, that received 4577 free DIEP flap breast reconstructions. 3236 free flaps (70.7%) were unilateral breast reconstructions, while 1341 flaps (29.3%) were bilateral breast reconstructions. Immediate breast reconstructions were performed in 24.8% of cases.

Reconstructions were performed at 22 plastic-surgical centers. Five of these centers performed an average of ≥ 40 DIEP flaps per year of data entry and were thus classified as high-volume clinics. A majority of 17 centers performed < 40 DIEP flaps per year and were thus classified as low-volume clinics.

476 (10.4%) patients reported a history of smoking. Further details with regard to number of pack years were not available. Patient comorbidities assessed within the database showed a total of 125 (2.7%) cases with diagnosed diabetes mellitus. 71 (1.6%) cases showed a clinical history of deranged hemostasis with impaired clot formation. 192 (4.2%) free flaps were performed in patients with a prior abdominal scar >10 cm. A positive family history of breast and/or ovarian cancer in first degree relatives (FDRs) was found in 1191 (26.0%) cases. 697 (15.2%) cases were associ-

ated with a genetic disposition for breast cancer.

More than half of all cases (2605, 56.9%) received chemotherapy within the last six months prior to breast reconstruction, while 2206 (48.2%) cases received chemotherapy more than six months prior to reconstruction. Immunosuppressive therapy using targeted antibodies was merely administered in 34 (0.7%) cases, whereas 484 (10.6%) cases received Tamoxifen therapy prior to surgery.

The most common indication for breast reconstruction was status after mastectomy (40.5%), followed by DIEP flap breast reconstruction after complications associated with other reconstructive techniques (21.2%; including implant or other flap type based reconstructions), primary carcinoma (11.4%), and status after breast conserving therapy (8.4%). Prophylactic mastectomy due to positive familial history certified by a genetic test accounted for 6.8% of all reconstructions.

Table 2: Demographics and patient characteristics. Percentages calculated based on the number of free flaps. * clinical history of deranged hemostasis; ** Family history of breast cancer without a positive genetic test *** Chemotherapy less than 6 months prior to DIEP flap; **** Chemotherapy more than 6 months prior to DIEP flap; + Immunotherapy with targeted antibodies; ++ Tamoxifen therapy for women with hormone-receptor positive breast cancer; +++ Risk-reducing mastectomy performed in patients with a genetic mutation for familial/ hereditary breast cancer; ++++ Complications after previous reconstructive breast cancer surgery (i.e. implant, other pedicled/ free flap transfer)

Variable	
Patients, n	3926
Free flaps, n	4577

Age, years	
Mean (SD)	51.30 (31.61)
BMI, kg/m2	
Mean (SD)	26.28 (4.44)
Immediate reconstruction, n (%)	1136 (24.8)
Secondary reconstruction, n (%)	3441 (75.2)
Reconstructed side, n (%)	
right	1560 (34.1)
left	1676 (36.6)
both	1341 (29.3)
Smoking history, n (%)	476 (10.4)
Comorbidities, n (%)	
Diabetes mellitus	125 (2.7)
Coagulopathy*	71 (1.6)
Abdominal scar >10cm, n (%)	192 (4.2)
Family history of breast and/or ovarian cancer in FDRs, n (%)	1191 (26.0)
Genetic disposition, n (%)**	697 (15.2)
Chemotherapy within last 6 months, n (%)***	2605 (56.9)
Chemotherapy later than 6 months, n (%)****	2206 (48.2)
Immunosuppressive therapy, n (%)+	34 (0.7)

Tamoxifen therapy, n (%)++	484 (10.6)	145
Indication, n (%)		146
Status after mastectomy	1555 (40.5)	147
DCIS	180 (4.7)	148
Primary carcinoma	436 (11.4)	149
Familial risk+++	262 (6.8)	150
Complications after other reconstruction++++	813 (21.2)	151
Benign tumor	47 (1.2)	152
Status after BCT	321 (8.4)	153
Tumor recurrence	122 (3.2)	154
other	105 (2.7)	155

156

157 n, number; SD, standard deviation; BMI, Body Mass Index; FDR, First degree relatives; BCT, Breast conserving therapy;
158 DCIS, Ductal Carcinoma in Situ.

159

160 *3.2 Perioperative details (Table 3)*

161 The mean duration of DIEP flap reconstruction was 318.60 (SD 127.94) minutes and mean ischemia time was 50.81 (SD
162 25.86) minutes. The internal mammary artery was used for anastomosis in the majority of cases (3683 flaps, 80.5%).
163 Perioperative antibiotics (single-shot) were administered in almost all cases (4399, 96.1%). Mobilization was begun at
164 the first postoperative day in almost three quarters of all cases (3293, 72.0%). Mean hospital stay was 8.47 (SD 11.42)

165 days.

166 **Table 3:** Perioperative details. Percentages calculated based on the number of free flaps.

167

Variable	
Free flaps, n	4577
Operation time, min	
Mean (SD)	318.60 (127.94)
Ischemia time, min	
Mean (SD)	50.81 (25.86)
Recipient, n (%)	
Internal mammary	3683 (80.5)
Thoracodorsal	704 (15.4)
other	190 (4.2)
Perioperative antibiotics, n (%)	4399 (96.1)
Postoperative mobilization, n (%)	
Day 1	3293 (72.0)
Day 2	773 (16.9)
Day 3	126 (2.8)
Day >3	378 (8.3)
LOS, days	
Mean (SD)	8.47 (11.42)

n, number; SD, standard deviation; min, minutes; LOS, Length of hospital stay.

3.3 Postoperative Complications and comparison of low- and high-volume centers (Tables 4, 5 and 6)

The overall flap success rate was 96.9%. Total flap loss was seen in 92 (2.0%) cases, whereas partial flap loss occurred in 51 (1.1%) cases. Emergent vascular revision surgery was performed in 4.3% of cases. In 2.7% of all cases, vascular revision surgery was necessary due to venous thrombosis, compared to 1.6% of cases with arterial thrombosis. Revision surgery due to wound complications was necessary in 8.3% of all cases, with hematoma at the recipient site being the most common reason (3.2%), followed by woundhealing disturbances at the donor (1.7%) and recipient site (1.5%). Medical complications occurred in 294 (6.4%) cases.

Table 4: Postoperative complications and free flap outcome over a follow-up period of three months. Percentages calculated based on the number of free flaps.

Variable	
Free flaps, n	4577
Total flap loss, n (%)	92 (2.0)
Partial flap loss, n (%)	51 (1.1)
Emergent vascular revision surgery, n (%)	197 (4.3)
Venous thrombosis	123 (2.7)
Arterial thrombosis	74 (1.6)
Revision due to wound complications, n (%)	378 (8.3)

Infection donor site	23 (0.5)
Infection recipient site	20 (0.4)
Hematoma donor site	37 (0.8)
Hematoma recipient site	148 (3.2)
Woundhealing disturbances donor site	80 (1.7)
Woundhealing disturbances recipient site	70 (1.5)
Medical complications, n (%)	294 (6.4)

n, number.

To evaluate potential differences in complications rates with regard to the volume of DIEP flaps performed and thus the experience of the individual centers with this operative technique, we separately evaluated low vs. high-volume centers in detail. 1260 females receiving 1459 DIEP flaps were included in the low-volume (LV) group, 2653 females receiving 3118 DIEP flaps were included in the high-volume (HV) group. (Table 5) Mean operation time was significantly shorter in the HV group (LV: 385.82 min. vs. HV: 287.14 min.; $p<0.001$). Mean ischemia time, however, was comparable between both groups ($p=0.073$). Postoperative mobilization commenced significantly earlier in the HV group ($p<0.001$). In addition, LOS was significantly shorter in the HV group (LV: 9.04 (18.87) days vs. HV: 8.21 (5.04) days; $p=0.023$).

Table 5: Perioperative details according to the average number of DIEP flaps performed per year per center (high-volume group: ≥ Ø 40 DIEP flaps per year of data entry vs. low-volume group < Ø 40 DIEP flaps per year of data entry). Percentages calculated based on the number of free flaps.

193

Variable	LV-centers	HV-centers	p value
Patients, n	1260	2653	
Free flaps, n	1459	3118	
Operation time (min)			
Mean (SD)	385.82 (142.31)	287.14 (107.01)	<0.001
Ischemia time (min)			
Mean (SD)	51.81 (27.36)	50.34 (25.12)	0.073
Recipient, n (%)			<0.001
Internal mammary	1312 (89.9)	2371 (76.0)	
Thoracodorsal	60 (4.1)	644 (20.7)	
other	87 (6.0)	103 (3.3)	
Postoperative mobilization, n (%)			<0.001
Day 1	472 (32.4)	2821 (90.6)	
Day 2	488 (33.5)	285 (9.1)	
Day 3	118 (8.1)	8 (0.3)	
Day 4	166 (11.4)	0 (0.0)	
Day 5	98 (6.7)	0 (0.0)	
Day 6	72 (4.9)	0 (0.0)	
Day 7	42 (2.9)	0 (0.0)	
LOS, days			

Mean (SD)	9.04 (18.87)	8.21 (5.04)	0.023

194 n, number; SD, standard deviation; min, minutes; LOS, Length of hospital stay; LV, low-volume; HV, high-volume.

195

196 Interestingly, outcome analysis showed a significantly higher rate of total flap loss within the HV-group (LV: 1.2% vs.
197 HV: 2.4%; p=0.014), whereas partial flap loss was comparable between groups (p=0.327). Emergent vascular revision
198 was performed in 4% (LV) and 4.5% (HV) of cases, without showing statistical significance (p=0.453). Revision surgery
199 due to wound complications was, however, performed significantly more often in the LV-group (LV: 10.8% vs. HV:
200 7.1%; p<0.001). This was related to a significantly higher number of woundhealing disturbances at the recipient site
201 requiring revision surgery in this group (LV: 2.7% vs. HV: 1.0%).

202 **Table 6:** Postoperative complications according to the average number of DIEP flaps performed per year per center
203 (high-volume group: ≥ Ø 40 DIEP flaps per year of data entry vs. low-volume group < Ø 40 DIEP flaps per year of data
204 entry). Percentages calculated based on the number of free flaps.

205

Variable	**LV-centers**	**HV-centers**	**p value**
Free flaps, n	1459	3118	
Total flap loss, n (%)	18 (1.2)	74 (2.4)	0.014
Partial flap loss, n (%)	20 (1.4)	31 (1.0)	0.327
Emergent vascular revision surgery, n (%)	58 (4.0)	139 (4.5)	0.453
Venous thrombosis	38 (2.6)	85 (2.7)	0.889

Arterial thrombosis	20 (1.4)	54 (1.7)	0.437
Revision due to wound complications, n (%)	158 (10.8)	220 (7.1)	<0.001
Infection donor site	9 (0.6)	14 (0.4)	0.6
Infection recipient site	6 (0.4)	14 (0.4)	1
Hematoma donor site	15 (1.0)	22 (0.7)	0.338
Hematoma recipient site	56 (3.8)	92 (3.0)	0.136
Woundhealing disturbances donor site	33 (2.3)	47 (1.5)	0.09
Woundhealing disturbances recipient site	39 (2.7)	31 (1.0)	<0.001
Medical complications, n (%)	105 (7.2)	189 (6.1)	0.144

n, number; LV, low-volume; HV, high-volume.

4. Discussion

Despite the evident advantages of autologous breast reconstruction, it is often underrepresented as treatment of choice for many breast cancer patients. Several reasons might account for this phenomenon: First, autologous breast reconstruction is associated with higher procedural and hospital costs, due to extensive operative time, longer postoperative morbidity and hospital stay, although recent studies found similar long-term total cost of care compared to implant-based reconstruction [20, 21]. Second, patient awareness and information of the different reconstructive options available plays an important role and might need improvement [22]. In Germany, the therapy of breast cancer is often integrated into specialized interdisciplinary breast cancer centers, which are most commonly managed by gynecologists. While the certification criteria stipulate that patients must be offered all available reconstructive techniques, by

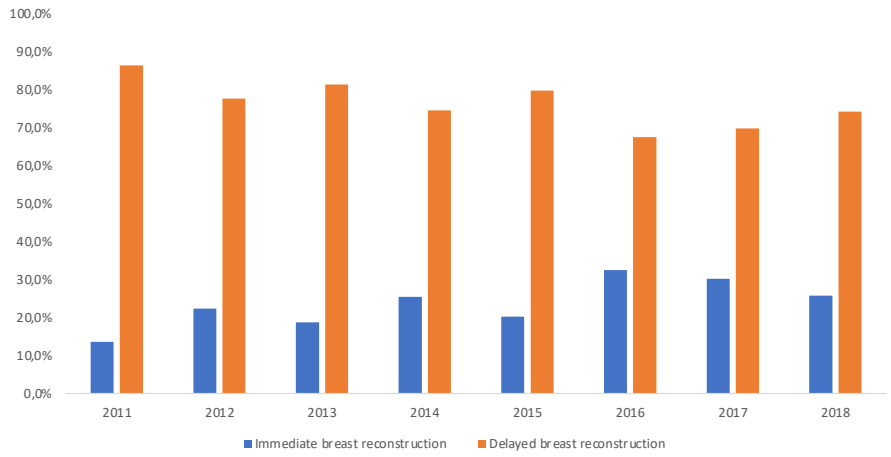
providing plastic-surgical care if needed, implementation into clinical practice still needs significant improvement [15]. The structural, professional and political issues within breast cancer centers might drive patient care toward implant-, rather than autologous breast reconstruction. In line with this, Albornoz et al. identified that sociodemographic variables and hospital characteristics may influence the method of breast reconstruction [23]. Last but not least, gynecologically managed breast cancer centers have doubted the quality of care of microsurgical breast reconstruction in Germany and questioned whether it can meet international standards and outcomes particularly outside of specialized centers in a national setting. While international studies show increasingly good outcome rates after autologous tissue breast reconstructions, reaching excellent levels of an average flap loss rate of merely up to 3%,[24] no data existed concerning the situation of care in Germany.

The DGPRÄC online registry was designed to tackle this problem and to shed further light onto the structure and the quality of microsurgical autologous breast reconstruction in Germany. Overall, the presented data show that free DIEP transfer for breast reconstruction is performed under high quality standards over a broad number of centers in Germany, with total and partial flap loss rates as low as 2.0% and 1.1% respectively, and emergent vascular revision surgery being performed in 4.3% of cases. The outcome and complication rates deduced from the national registry compare to recent large-scale international studies and show no significant disparity in this regard [25-28]. The study population of Vemula et al. (478 DIEP flaps) showed overall DIEP flap success rates of 98.2% at specialty surgery hospitals and 96.4% at tertiary care facilities [25]. Unukovych et al. found a reoperation rate of 15.9% in a study population of 503 DIEP flaps. Mirroring our results, flap failure was encountered in 2.0% of cases, while partial flap loss was found in 1.2% of all cases [26]. Depypere et al. report revision surgery in 5% (48/965) of all DIEP flaps investigated [27]. The study group of Vanschoonbeek et al. investigated a total of 1330 DIEP free flaps, of which 3.38% required urgent exploration. In accordance to our study results, venous insufficiency was the main reason for revision of DIEP flaps. The flap failure rate reported was 1.28%, thus being slightly lower than the one presented in this manuscript [28]. Notably, these studies investigated a study population significantly smaller than the one presented within this manuscript.

Descriptive data and demographical variables of the investigated study population were comparable to international literature. Exemplary, mean age of patients receiving DIEP flap transfer was 51.30 years, compared to a median age of

51.6 years in the study population investigated by Kamali et al. [14], and 46.7 years in the study population evaluated by Depypere et al [27]. Mean BMI was 26.28 kg/m2 and therefore slightly higher as compared the population investigated Vanschoonbeek et al. (24.9 kg/m2) [28], and almost equal to the mean BMI of the study population investigated by Unukovych et al. (26.2 kg/m2) [26]. Neoadjuvant chemotherapy was administered in approximately 50% of all cases, complying with numbers found in the studies of Vemula et al. [25] and Unukovych et al [26]. Overall, immediate breast reconstruction (IBR) was performed in ~25% of all cases which seems relatively low, compared to international literature [12, 29, 30]. Several studies have reported a continuous increase in IBR, which, however, can also be traced back to an increased amount of implant-based immediate breast reconstructions [31]. Importantly, our data show a significant increase in autologous IBR between years 2011 and 2018 (Figure 1; $p < 0.001$ between years and type of reconstruction immediate vs. delayed breast reconstruction).

Figure 1: Increasing trend of immediate breast reconstruction performed between 2011-2018, pooled across all 22 centers ($p<0.001$ between years and type of reconstruction immediate vs. delayed breast reconstruction).



Compared to international standards, especially in the U.S., LOS was significantly longer in the patient population investigated in this study. While patients after DIEP flap reconstruction stay hospitalized for 3-4 days in the U.S. [31], we found LOS to be as high as 8.47 (SD 11.42) days. This complies with findings of Ridic et al. who compared overall LOS in health care systems in the U.S. and Germany. According to their study, the average LOS in Germany is gener-

ally much longer than in the United States (12.0 vs 7.1 days) which can be related to significant larger capacity in the number of hospital beds relative to the population [32]. In addition, the structure of outpatient care and overall remuneration differs largely.

Importantly, when comparing high vs low-volume centers, the data presented in this manuscript show a significant reduction of LOS for centers performing more than an average of 40 DIEP flaps annually. Probably, this relates to the significantly earlier postoperative mobilization and shorter operation time by the factor 0.74 observed in these centers. Unexpectedly, ischemia time was comparable between the HV and LV group, rather than being significantly shorter within the HV group. The data suggest that the reduced operation time could result from significantly quicker and more efficient flap harvest rather than faster microsurgical anastomosis at the recipient site. Surprisingly, while generally being at a low ~2%, flap loss rates were higher in HV-centers. The data provides no conclusive evidence to explain this result, which is why future studies need to elaborate on this finding.

By publicizing and evaluating data from the DGPRÄC national online registry for microsurgical breast reconstruction, the authors hope to increase visibility and transparency of the standard and quality of care in breast reconstruction. By doing so, and in the best interest of our patients, we aim to improve the cooperation between oncologic and reconstructive surgeons, increase patients´ awareness for the reconstructive measures available and strengthen the role of microsurgical breast reconstruction in breast cancer treatment.

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