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CLINICAL ARTICLE

Comparison of venous couplers versus hand-sewn technique in 4577 cases of DIEP-flap breast reconstructions – A multicenter study

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Abstract

Introduction: Venous anastomosis remains to be a challenging step in microsurgical tissue transfer and venous complications constitute to a common reason for free flap failure. While several studies have compared mechanical vs. hand-sewn venous anastomoses, there is no large-series study comparing the type of anastomosis exclusively in DIEP flap breast reconstructions.

Patients and Methods: Between 2011 and 2019, 3926 female patients underwent 4577 free DIEP-flap breast reconstructions in 22 different breast cancer centers. Patient data was collected via an online database, files were screened and cases were divided into a hand- (HA) and a coupler-anastomosis (CA) group. Complications were accounted for and the two groups were then compared.

Results: Mean ischemia time was significantly shorter in the CA group (46.88 \pm 26.17 vs. 55.48 \pm 24.70 min; *p* < .001), whereas mean operative time was comparable (316 \pm 134.01 vs. 320.77 \pm 120.29 minutes; *p* = .294). We found no significant difference between both groups regarding the rate of partial (CA: 1.0% vs. HA: 1.3%) and total flap loss (CA: 2.2% vs. HA: 1.8%). However, revision rates were significantly higher in the CA group (CA: 10.5% vs. HA: 7.9%; *p* = .003), with higher numbers of arterial (2.3 vs. 0.9%; *p* < .001) and venous thromboses (3.4 vs. 1.8%; *p* = .001) accounting for this finding.

Conclusions: All taken into account, our findings do support the feasibility of venous coupler anastomoses in principle, however the inflationary use of coupler devices should be evaluated critically.

1 | INTRODUCTION

Microsurgical technique and a patent microvascular anastomosis are keys for free flap outcome. Venous anastomosis remains to be a chal-

lenging step in microsurgical tissue transfer and venous complications

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constitute to a common reason for free flap failure (Bui et al., 2007; Tran, Buchel, & Convery, 2007). Thus, efforts have been made to simplify the surgical technique. In this regard, Nakayama et al. developed the mechanical anastomotic coupling device in 1962 (Nakayama, Tamiya, Yamamoto, & Akimoto, 1962) which utilizes a metal ring with interlocking pins to perform a sufficient venous anastomoses.

Compared to conventional hand-sewn anastomoses, anastomoses using coupler devices are considered to be technically less complex, less operator dependent and less time consuming (Ardehali, Morritt, & Jain, 2014; de Bruijn & Marck, 1996; Grewal, Erovic, Strumas, Enepekides, & Higgins, 2012). Since studies have demonstrated the safety and efficacy of coupler anastomoses in a variety of fields including breast reconstruction (Grewal et al., 2012; Jandali, Wu, Vega, Kovach, & Serletti, 2010; Patel, Pang, Natoli, Gallagher, & Topham, 2013; Stranix et al., 2019; Zhang et al., 2012), they are routinely utilized for venous anastomoses in clinical practice.

Microsurgical breast reconstruction is one of the most common fields in plastic surgery and the free deep inferior epigastric artery perforator- (DIEP) flap has proven to be a working horse with acceptable donor site morbidity for autologous tissue transfer (Chang, 2012; Healy & Allen Sr, 2014). While several studies have compared mechanical vs. hand-sewn venous anastomoses in free flap breast reconstructions, there is no large-series study comparing the type of anastomosis exclusively in DIEP flap breast reconstructions (Bodin et al., 2015: Dimitropoulos, Efanov, Paek, Bou-Merhi, & Danino, 2019; Fitzgerald O'Connor et al., 2016; Jandali et al., 2010; Kulkarni et al., 2016). To our knowledge, the largest series compared 1123 DIEP flaps at a single surgical center with merely 319 flaps included in the coupler anastomoses group (Fitzgerald O'Connor et al., 2016).

To this end, we performed a retrospective analysis of the effect of microsurgical venous anastomotic technique on outcomes and complications of 4577 free DIEP free-flap breast reconstructions at 22 different breast cancer centers in Germany.

PATIENTS AND METHODS 2

The German Society of Plastic, Reconstructive and Aesthetic Surgeons (DGPRÄC) initiated a prospective online registry in 2011, in order to systematically collect and transparently present the structure and quality of breast reconstructions in Germany.(Fritschen, Grill, Wagner, et al., 2019) Prior to initiation, centers were certified, audited and monitored with regard to the quality and stringency of the data entered in comparison with the hospital's internal documentation. (Fritschen et al., 2019) A total of 30 centers entered data between January 2011 and January 2019. Of these, 22 centers performed DIEP flap reconstructions between January 2011 and January 2019 and were included in this study. Data was entered intraoperatively, or immediately postoperatively, in a prospective manner.

The registry has been utilized previously to determine different outcome parameters and risk factors of DIEP flap breast reconstruction (Prantl et al., 2020a, 2020b).

A total of 3926 female patients underwent 4577 free DIEP-flap breast reconstructions in 22 different breast cancer centers across Germany. A total of 629 Patients received a simultaneous bilateral DIEP-flap reconstruction. In case of a different flap procedure on the contralateral side, only the DIEP flap was included. The medical files and patient data were retrospectively screened for patients' demographics, perioperative details, flap survival, and surgical complications. There were no distinct exclusion criteria. However, a complete perioperative and follow-up dataset for every patient operated in the institution to be included was mandatory. The completeness of inclusion was verified by an auditing team.

The cases were divided into two groups according to the employed technique of venous anastomosis: a hand- (HA) and a coupler-anastomosis (CA) group. Surgical- (i.e. partial/ total flap loss, need for revision surgery, hematoma, and wound healing disturbances) and medical complications were accounted for and the two groups were then compared.

2.1 Statistical analysis

Data are shown as mean (standard deviation) or as absolute and relative frequencies. An analysis of variance (ANOVA) or a chi-squared test of independence was used to determine differences in free flap outcome between the groups. A p-value < .05 was considered statistically significant. No a-priori sample size calculation was performed for this study. On the one hand, the expected number of patients in the chosen time interval was high enough for detection of any clinically relevant difference without potentially being under powered. Further, there was no primary endpoint for a sample size calculation, since this is an exploratory trial with several different endpoints. All analyzes were performed using R, version 3.5.3 (The R Foundation for Statistical Computing).

RESULTS 3

The HA group included 1792 patients (2089 free flaps, mean age 51.25 ± 35.86 years) and the CA group included 2134 patients (2488 free flaps, mean age 51.34 ± 27.54 years).

Preoperative evaluation revealed no significant differences regarding perioperative risk factors (BMI, nicotine abuse, diabetes mellitus, coagulopathy, abdominal scars). In the HA group, a significantly higher prevalence of immunosuppressive therapy was observed (1.1 vs. 0.5%; p = .039). Etiology of the defects was similar between the groups.

The chemotherapy status within 6 months prior to the reconstruction (51.9 vs. 62.9% of cases; p < .001) and chemotherapy later than 6 months before reconstruction (40.8 vs. 57.0% of cases; p < .001) was significantly lower in the CA group. However, Tamoxifen therapy was significantly higher in the CA group (12.5 vs. 8.2% of cases; p < .001). Patient demographics are summarized in Table 1 and perioperative characteristic in Table 2.

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TABLE 1 Patient demographics according to microsurgical anastomotic technique

Patient demographics	Hand anastomosis	Coupler anastomosis	p value
Patients, n	1792	2134	
Free flaps, n	2089	2488	
Age, years			
Mean ± SD	51.25 ± 35.86	51.34 ± 27.54	.921
BMI, kg/m ²			
Mean ± <i>SD</i>	26.43 ± 4.29	26.16 ± 4.56	.042
Nicotine abuse, n (%)	212 (10.1)	264 (10.6)	.644
Diabetes mellitus, n (%)	59 (2.8)	66 (2.7)	.792
Coagulopathy, n (%)	25 (1.2)	46 (1.8)	.097
Abdominal scar >10 cm, n (%)	80 (3.8)	112 (4.5)	.291
Family history of breast and/or ovarian cancer in FDRs, n (%)	572 (27.4)	619 (24.9)	.059
Genetic disposition, n (%)	315 (15.1)	382 (15.4)	.829
Chemotherapy within last 6 months, n (%)	1313 (62.9)	1292 (51.9)	<.001
Chemotherapy later than 6 months, n (%)	1190 (57.0)	1016 (40.8)	<.001
Immunosuppressive therapy, n (%)	22 (1.1)	12 (0.5)	.039
Tamoxifen therapy, n (%)	172 (8.2)	312 (12.5)	<.001
Etiology (n)			<.001
Status after mastectomy	751 (44.6)	804 (37.3)	
DCIS	57 (3.4)	123 (5.7)	
Primary carcinoma	79 (4.7)	357 (16.6)	
Familial risk	90 (5.3)	172 (8.0)	
Complications after other reconstruction	455 (27.0)	358 (16.6)	
Benign tumor	17 (1.0)	30 (1.4)	
Status after BCT	145 (8.6)	176 (8.2)	
Tumor recurrence	32 (1.9)	90 (4.2)	
other	59 (3.5)	46 (2.1)	

Abbreviations: n, number; SD, standard deviation; BMI, body mass index; FDR, first degree relatives; BCT, breast conserving therapy; DCIS, ductal carcinoma in situ.

Mean ischemia time was significantly shorter in the CA group (46.88 ± 26.17 vs. 55.48 ± 24.70 min; p < .001), whereas mean operative time did not differ significantly (316 ± 134.01 vs. 320.77 ± 120.29 min; p = .294).

Mean length of hospital stay was significantly shorter in the CA group (7.91 \pm 9.14 vs. 9.15 \pm 13.61 days; p < 0.001).

Overall, there was no significant difference between the groups of patients regarding the rate of partial (CA: 1.0 vs. HA: 1.3% of cases) and total flap losses (CA: 2.2 vs. HA: 1.8% of cases) during our followup period. However, revision rates were significantly higher in the CA group (CA: 10.5% vs. HA: 7.9%; p = 0\.003). In depth analysis of reasons for emergent and unexpected revision surgery revealed that arterial (2.3 vs. 0.9%; p < .001) and venous thromboses (3.4 vs. 1.8%; p = .001) variated between the groups and were significantly higher in the CA group. The prevalence of other postoperative surgical- (infections, hematomas, or wound healing disturbances) and medical complications was similar between the groups (Table 3). A separate evaluation was performed for each individual center (Table 4). Total flap numbers ranged from 11 to 933 DIEP flaps. The number of annual DIEP flaps extended from 2.75 to 155.5. The rates of venous thrombosis depending on anastomotic technique ranged from 0%–4.76% for hand anastomoses and 0%–7.84% for coupler anastomoses. Due to the divergence in number of flaps performed by each site, we next investigated whether the rates of thrombosis (hand vs. coupler) differed according to the number of flaps performed. To this end, centers were divided into high (≥40 DIEP flaps per year) and low volume centers (≤40 DIEP flaps per year). For low volume centers, the rate of venous thrombosis showed no significant difference between the CA and HA group (2.79 vs. 2.28%; p = .561). Conversely, for high volume centers, venous thrombosis rates were significantly higher in the CA group (3.79 vs. 1.66%; p < .001) (Figure 1).

In the HA group we found that 2.8% (n = 59) of reconstructions were performed as teaching operations, compared to 4.4% (n = 109) in the CA group (p < .001).

Perioperative characteristics

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Free flaps, n	2089	2488	
Immediate reconstruction, n (%)	298 (14.3)	838 (33.7)	<.001
Secondary reconstruction, n (%)	1791 (85.7)	1650 (66.3)	<.001
Reconstructed side, n (%)			.884
right	713 (34.1)	847 (34.0)	
left	774 (37.1)	902 (36.3)	
both	602 (28.8)	739 (29.7)	
Operation time, min			
Mean ± SD	320.77 ± 120.29	316.78 ± 134.01	.294
Ischemia time, min			
Mean ± SD	55.48 ± 24.70	46.88 ± 26.17	<.001
Recipient vessels, n (%)			<.001
Internal mammary	1297 (62.1)	2386 (95.9)	
Thoracodorsal	674 (32.3)	30 (1.2)	
Other	118 (5.6)	72 (2.9)	
Flap monitoring, <i>n</i> (%)			
Clinically	2083 (99.7)	2445 (98.3)	<.001
Transcutaneous doppler probe	868 (41.6)	1178 (47.3)	<.001
Perivascular doppler probe (i.e. cook)	1 (0.0)	25 (1.0)	<.001
Transcutaneous HbO2 test (i.e. O2C)	1 (0.0)	9 (0.4)	.051
Warm touch preoperatively	93 (4.5)	129 (5.2)	.28
Warm touch postoperatively	763 (36.5)	1600 (64.3)	<.001
Postoperative mobilization, n (%)			<.001
Postop day 1	1711 (82.1)	1582 (63.6)	
Postop day 2	174 (8.3)	599 (24.1)	
Postop day 3	87 (4.2)	39 (1.6)	
Postop day 4	66 (3.2)	100 (4.0)	
Postop day 5	19 (0.9)	79 (3.2)	
Postop day 6	19 (0.9)	53 (2.1)	
Postop day 7	7 (0.3)	35 (1.4)	
Hospital stay, days			
Mean ± SD	9.15 ± 13.61	7.91 ± 9.14	<.001

Hand anastomosis

Coupler anastomosis

Abbreviations: n, number; SD, standard deviation; min, minutes.

4 | DISCUSSION

Sufficient venous anastomosis is vital for successful free flap surgery, and microvascular techniques have evolved constantly. Hand-sewn anastomoses have long been regarded as the goldstandard, but mechanical coupler devices have begun to challenge this status. On the one hand, this development can be attributed to the several down-sides of hand-sewn anastomoses. These include technical difficulty, operator dependence, time consumption and necessity of sufficient surgeon experience and impeccable technique (Ardehali et al., 2014; Nahabedian, Momen, & Manson, 2004). The technical ease of mechanical anastomosis using a coupler device, however, creates an anastomosis with a rigid circumference determined by the diameter of the ring, forces eversion of vessel edges prior to anastomotic connection and thus enables greater intimal contact as compared to hand-sewn anastomoses.(Chang, Lin, & Lai, 2007; Grewal et al., 2012; Jandali et al., 2010) Venous coupler anastomoses seem to be a long sought-after solution for overcoming the technical challenges of hand-sewn anastomoses. Backed by comprehensive literature they have thus gained widespread use in clinical practice.

However, some conclusive limitations of mechanical coupling devices have also been described. The process of vessel eversion onto the pins before coupling itself can cause intimal trauma, which in turn may lead to an increase of thrombotic events (Yap, Constantinides, & Butler, 2006). Additionally, several surgeons have come to reject mechanical device coupling given the loss of practice with hand-sewn anastomoses. They place an emphasis on hand-sewn anastomoses to TABLE 3 Postoperative complications according to microsurgical anastomotic technique

Postoperative complications	Hand anastomosis	Coupler anastomosis	p value
Free flaps, n	2089	2488	
Total flap loss (n)	38 (1.8)	54 (2.2)	.461
Partial flap loss (n)	27 (1.3)	24 (1.0)	.362
Unexpected/ emergent revision surgery, n (%)	165 (7.9)	260 (10.5)	.003
Venous thrombosis	38 (1.8)	85 (3.4)	.001
Arterial thrombosis	18 (0.9)	56 (2.3)	<.001
Infection donor site	8 (0.4)	15 (0.6)	.402
Infection recipient site	10 (0.5)	10 (0.4)	.867
Hematoma donor site	18 (0.9)	19 (0.8)	.839
Hematoma recipient site	73 (3.5)	75 (3.0)	.406
Woundhealing disturbances leading to revision surgery: donor site n (%)	28 (1.3)	52 (2.1)	.07
Woundhealing disturbances leading to revision surgery: recipient site n (%)	34 (1.6)	36 (1.4)	.708
Medical complications, n (%)	140 (6.7)	154 (6.2)	.482

increase proficiency and for teaching purposes (Frederick, Sweeny, Carroll, & Rosenthal, 2013), since conventional anastomoses are still frequently employed in difficult cases with small vessel diameters, or in irradiated tissue and for arterial anastomoses.

This study analyzed the impact of microsurgical venous anastomotic technique on outcomes and complications of DIEP free-flap based breast reconstructions, using the largest data base available in Europe. Overall, we found that coupler anastomoses showed a significantly higher incidence of venous thromboses compared with hand-sewn anastomoses, contrary to the predominant data found in the literature (Grewal et al., 2012; Jandali et al., 2010; Kulkarni et al., 2016; Rozen, Whitaker, & Acosta, 2010; Yap et al., 2006). Recently, Haug et al and Maruccia et al provided systematic reviews about venous couplers (Haug et al., 2020 (Online ahead of print); Maruccia et al., 2020). Haug et al reported comparable outcomes of venous couplers to those of hand-sewn anastomosis in lower limb reconstructions, specifically finding no difference in venous compromise (Haug et al., 2020 (Online ahead of print)). However, sample size and quality of data was limited. While the review of Maruccia et al included free flap transfers for breast reconstruction, analysis of flap outcome and thrombosis rates were based on pooled data across several defect sites (Maruccia et al., 2020). Their study group concluded that venous coupling devices do not decrease the risk of postoperative venous thrombosis significantly, yet they lead to a reduced risk of postoperative flap failure.

Notably, our data show that a significantly higher amount of reconstructions were teaching operations in the CA group. Arguably, this could account for the higher rate of thrombosis observed. However, all reconstructions including microvascular anastomoses were supervised by senior attending staff.

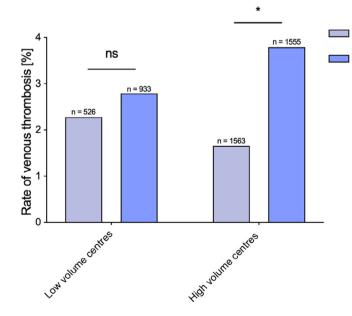
Venous thrombosis is a serious complication in microsurgery. It is accountable for a majority of revision surgeries and can result in complete flap loss (Hidalgo, Disa, Cordeiro, & Hu, 1998; Khouri et al., 1998; Novakovic, Patel, Goldstein, & Gullane, 2009). Contrary, in our patient population, the observed increase in venous thromboses did not translate into a significant increase of partial and total flap loss. This suggests that flap salvage rates after venous congestion in the CA group were high, although our study lacks data on the surgical strategy pursued after detection of thrombosis. Additionally, our data show significantly higher rates of arterial thrombosis, following coupler venous anastomosis, without providing proof of a causative relationship between the two. Possibly, at least in some cases, arterial thrombosis resulted from venous thrombosis and blood stasis back into the arterial pedicle.

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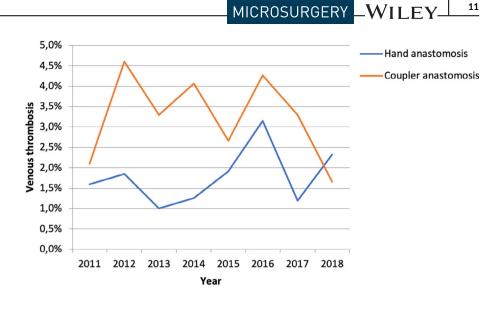
In depth evaluation of centers performing ≥40 DIEP flap breast reconstructions annually revealed a significantly higher rate of venous thrombosis in the CA group, while centers with low numbers of annual DIEP reconstructions showed comparable thrombosis rates between CA and HA groups. Hand-sewn anastomoses are technically challenging and require sufficient practice.(MacDonald, 2005; Zdolsek, Ledin, & Lidman, 2005) Our findings reflect this by showing significantly lower rates of venous thrombosis in the HA group for free flaps performed in high volume centers. While practice seems to make perfect in hand-sewn anastomoses, this does not seem to hold true for the use of coupler devices. Despite being an interesting finding, we cannot draw reliable conclusions from this, as a specific evaluation of venous thrombosis, with regard to the annual number of flaps performed, was beyond the scope of this study and the number of flaps performed in low volume centers is likely to be too low to allow detection of any significant difference. Interestingly, an analysis of the rates of venous thrombosis across all centers over time showed an unexpected turnover point in 2018 (Figure 2). Here, venous thrombosis rates sharply decreased in the CA group, falling below rates of thrombosis for hand-sewn anastomoses. Possibly this reflects that surgeons indeed need to familiarize themselves with the technique of mechanical anastomoses, although several articles oppose this theory TABLE 4 Detailed evaluation of number of DIEP flaps per center and thrombosis rates according to anastomotic technique

Klinik ID	Venous thrombosis HA (n)	Flaps HA (n)	Rate of thrombosis HA (%)	Venous thrombosis CA (n)	Flaps CA (n)	Rate of thrombosis CA (%)	Total flaps (n)	Years	Flaps per year (n)
1	1	148	0.68%	2	90	2.22%	238	2016-2019	59.5
2	0	5	0.00%	0	47	0.00%	52	2015-2019	10.4
3	0	21	0.00%	2	132	1.52%	153	2010-2017	21.9
4	0	19	0.00%	1	52	1.92%	71	2012-2017	11.8
5	0	11	0.00%	0	28	0.00%	39	2011-2014, 2018	7.8
6	0	0	0.00%	4	51	7.84%	51	2012-2016	10.2
7	22	636	3.46%	0	2	0.00%	638	2012-2018	91.1
8	2	56	3.57%	1	22	4.55%	78	2011-2016	13.0
9	0	10	0.00%	0	1	0.00%	11	2014-2017	2.75
10	0	34	0.00%	41	899	4.56%	933	2012-2017	155.5
11	0	8	0.00%	5	70	7.14%	78	2014-2018	15.6
12	0	16	0.00%	15	450	3.33%	466	2011-2019	51.8
13	2	86	2.33%	4	115	3.48%	201	2011-2017	28.7
14	0	1	0.00%	0	120	0.00%	121	2011-2018	15.1
15	0	44	0.00%	0	6	0.00%	50	2014-2017	12.5
16	0	5	0.00%	5	133	3.76%	138	2011,2013-2018	19.7
17	1	21	4.76%	0	52	0.00%	73	2011-2012, 2014-2018	10.4
18	2	63	3.17%	0	0	0.00%	63	2013-2017	12.6
19	3	729	0.41%	1	114	0.88%	843	2011-2017	120.4
20	5	163	3.07%	0	0	0.00%	163	2011-2018	20.4
21	0	1	0.00%	2	29	6.90%	30	2015-2017	10
22	0	12	0.00%	2	75	2.67%	87	2011–2012, 2014–2019	10.9
Total	38	2089	1.82%	85	2488	3.42%	4577		

Abbreviations: HA, hand anastomosis; CA, coupler anastomosis; n, number.



Hand anastomosis Coupler anastomosis FIGURE 1 Rate of venous thrombosis in hand-sewn and coupler venous anastomosis according to the type of center (high volume: ≥40 DIEP flaps per year; low volume: ≤40 DIEP flaps per year)



by stressing the technical ease (Chang et al., 2007; Grewal et al., 2012; Jandali et al., 2010).

Our data supports findings of previous studies showing that mean ischemia time can be significantly reduced using coupler anastomosis (Ardehali et al., 2014; Fitzgerald O'Connor et al., 2016; Grewal et al., 2012; Head & McKay, 2018), however not leading to a reduced mean operative time in this group. Thus, the significantly shorter mean length of hospital stay observed in patients of the CA group, cannot be attributed to the type of anastomosis.

All taken into account, while our findings do support the feasibility of venous coupler anastomoses in principle, the higher rates of venous thromboses indicate that the application is associated with specific challenges. To conclude, the inflationary use of coupler devices seen at many plastic surgical centers should be debated critically.

A strength of this study lies within the large sample size of 3926 female patients and 4577 DIEP flap breast reconstructions following resection of malignancies in 22 different breast cancer centers between January 2011 and January 2019. Patients were divided into two groups and compared 2089 hand-sewn anastomoses with 2488 coupler anastomoses. The large sample size allows to draw conclusions regarding the impact of anastomotic technique on outcomes. The fact that the procedures across the 22 breast cancer centers were performed by different microsurgeons arguably constitutes a strength and limitation at the same time. Quality of the anastomosis is regarded to be a key factor for free flap outcomes and can be influenced by the experience of the surgeon. On the other hand the results mirror the quality of care in a national setting. Since all procedures were performed by qualified, board certified plastic surgeons, we assume that a sufficient anastomotic technique was applied in all cases, although our data points towards a significant learning curve for coupler-anastomoses. Limitations of the study include the unequal distribution of immunosuppressive therapy, chemotherapy, or therapy with procoagulatory medication such as tamoxifen between the groups. The study is also greatly limited by the small number of thrombotic events in both groups, which prevents to perform multiple logistic regressions to eliminate confounding variables. Further limitations are based on the database search nature of the study. Exemplary, it would have been informative to investigate the surgical strategy pursued after detection of thrombosis in both groups, to determine whether a greater number of vein grafts was required in the CA group.

CONCLUSIONS 5

This study analyzed the largest series of microsurgical breast reconstructions in Germany using DIEP flaps, with a focus on the impact venous anastomotic technique. While flap failure was comparable between anastomoses performed using a venous coupler and those performed with conventional suturing techniques, we found a significantly higher number of overall venous thromboses in the CA group. Based on these results, microsurgeons should bear in mind that these devices involve specific technical challenges usually not seen in hand sewn anastomosis. Especially at the beginning of the learning curve, the application should be critically questioned and limited to clearly laid out situations.

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CONFLICT OF INTEREST

The authors declare no potential confict of interest.

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