VENOUS COUPLER SIZE IN AUTOLOGOUS BREAST RECONSTRUCTION—DOES IT MATTER?

P. NICLAS BROER, M.D.,[1] KATIE E. WEICHMAN, M.D.,[1] NEIL TANNA, M.D. M.B.A.,[2,3] STELIOS WILSON, B.A.,[1] REUBEN NG, Ph.D.,[4] CHRISTINA AHN, M.D.,[1] MIHYE CHOI, M.D.,[1] NOLAN S. KARP, M.D.,[1] JAMIE P. LEVINE, M.D.,[1] and ROBERT J. ALLEN, M.D.[1]*

Background: Autologous microvascular breast reconstruction is an increasingly common procedure. While arterial anastomoses are traditionally being hand-sewn, venous anastomoses are often completed with a coupler device. The largest coupler size possible should be used, as determined by the smaller of either the donor or recipient vein. While its efficacy has been shown using 3.0-mm size and greater couplers, little is known about the consequences of using coupler sizes less than or equal to 2.5 mm. *Methods:* A retrospective chart review of patients undergoing autologous breast reconstruction was conducted at NYU Medical Center between November 2007 and November 2011. Flaps were divided into cohorts based on coupler size used: 2.0 mm, 2.5 mm, and 3.0 mm. Outcomes included incidence of arterial or venous insufficiency, hematoma, fat necrosis, partial flap loss, full flap loss, and need for future fat grafting. *Results:* One-hundred ninety-seven patients underwent 392 flaps during the study period. Patients were similar in age, type of flap, smoking status, and radiation history. Coupler size less than or equal to 2.0 mm was found to be a significant risk factor for venous insufficiency ($P = 0.038$), as well as for development of fat necrosis ($P = 0.041$) and future need for fat grafting ($P = 0.050$). In multivariate analysis, body mass index was found to be an independent risk factor for skin flap necrosis ($P = 0.010$) and full flap loss ($P = 0.035$). *Conclusions:* Complications were significantly increased in patients where couplers of 2.0 mm or less were used, therefore to be avoided whenever possible. When needed, more aggressive vessel exposure through rib harvest, the use of thoracodorsal vessels or hand-sewing the anastomosis should be considered in cases of internal mammary vein caliber of 2.0 mm or less. *Clinical Question:* Therapeutic *Level of Evidence:* Level III. © 2013 Wiley Periodicals, Inc. Microsurgery 33:514–518, 2013.

Traditionally, throughout the United States and the world both the arterial and venous microvascular anastomoses have been performed in a hand-sewn fashion. However, since the venous anastomoses are known to be more challenging given the thin vessel walls and tendency to collapse, several non-suture alternatives have been developed. These alternatives not only overcome the vessel limitations but also increase operative efficiency. The most widely used device remains the Synovis microvascular anastomotic device (GEM coupler, Synovis Micro Companies Alliance, Birmingham, AL).[1] It has gained popularity throughout the United States and is the device used for the majority of venous anastomoses at our institution.[2]

The coupler works by feeding the cut ends of the veins through a single-use implantable polyethylene ring with several mirror imaged steel pins (Fig. 1, top left). The veins are then everted over these rings (Fig. 1, top right and middle left) and the coupler device closed (Fig. 1, middle right), which completes the anastomosis (Fig. 1, bottom).[3] This can also be performed in an end-to-side fashion.[4] The coupler rings are available in several sizes with inner diameters ranging from 1.0 mm to 4.0 mm. This coupler system has been in use for almost 20 years now with universally excellent results and patency rates, which are comparable to traditional hand-sewn venous anastomoses.[5–7] The coaptation is fast and allows for precise intima to intima approximation of donor and recipient vessels.[8] Further, no thrombogenic material (like sutures for example) remains retained in the vessel lumen and the ring prevents collapse of the vein by acting as an external splint.[9]

While under ideal circumstances the diameter of donor and recipient vessels should be matching in diameter and of largest size possible, clinically size discrepancies are common. Given the design of the coupler device, the smaller of the two veins becomes the limiting factor in ring diameter size selection. Several techniques, including beveling and fish-mouthing, have thus been described to aid in overcoming such size discrepancies and allow using the largest diameter coupler possible. Theoretically, these techniques provide a two-fold advantage. First, improved venous drainage will result from the larger diameter anastomosis[10] and second, accumulation of redundant vein within the ring (which may lead to obstruction)[11] is minimized. While the efficacy of the coupler device has been widely shown using 3.0 mm and greater couplers, little is known about the consequences of using small coupler sizes of 2.0 mm and below.[12] The purpose of this investigation is to evaluate the effect of coupler size on outcomes of microvascular breast reconstruction.

[1]Institute of Reconstructive Plastic Surgery, New York University, New York, NY

[2]Department of Surgery, Long Island Jewish Hospital, Manhasset, NY

[3]Department of Surgery, North Shore University Hospital, Manhasset, NY

[4]Department of Epidemiology and Biostatistics, Yale University, New Haven, CT

*Correspondence to: Robert J. Allen, M.D., New York University Medical Center, Institute of Reconstructive Plastic Surgery. E-mail: Robert.Allen@nyumc.org

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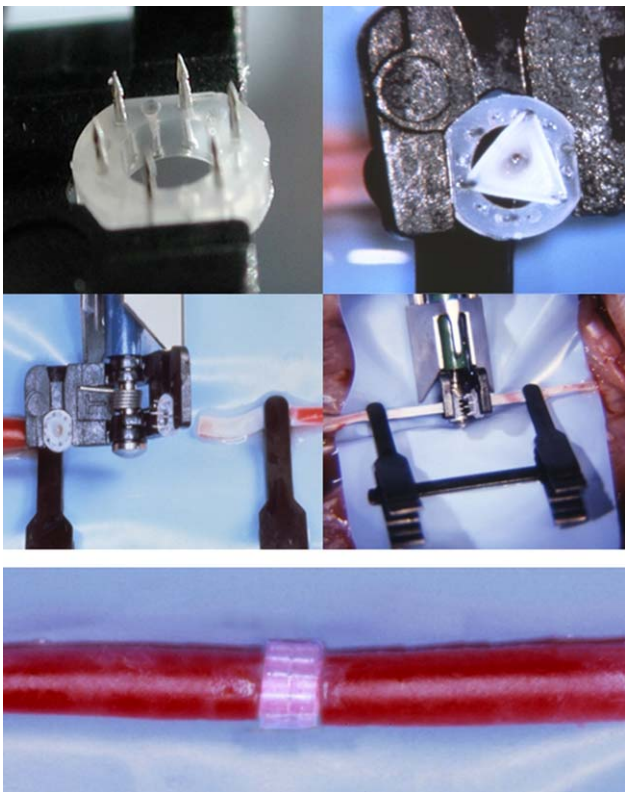

Figure 1. Plastic ring with steel pins over which the vessel ends are to be everted (top left). The cut vessel ends are fed through the plastic ring and secured over the steel pins with aid of a special forceps (top right). Positioning of the coupler and vessels (middle left). The coupler device is being closed, adapting the two rings which are then held in place by the pins (middle right). Completed anastomosis (bottom). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

PATIENTS AND METHODS

After obtaining an IRB waiver, a retrospective chart review of all patients undergoing autologous breast reconstruction at New York University Medical Center between November 2007 and November 2011 was conducted. Both electronic hospital medical records and office charts were reviewed for pertinent information. All patients undergoing autologous microvascular breast reconstruction were included and bilateral reconstructions were considered two distinct breasts. Breasts were excluded from the investigation if a venous coupler was not used in the reconstruction and if there was no documentation of coupler size used in the operative report.

Breasts meeting inclusion criteria were then divided into cohorts based on coupler size: 2.0 mm, 2.5 mm, and 3.0 mm. Patient characteristics including demographic information, age, body mass index (BMI), mastectomy specimen weight, flap weight, flap choice, recipient vessels, medical comorbidities, history of recent or remote breast surgery, smoking status, the use of adjuvant/neoadjuvant chemotherapy and radiation, breast cancer stage, indication for mastectomy (therapeutic versus prophylaxis), and timing of reconstruction were analyzed in comparison. The procedures were all performed by one of the senior authors of the study (R.A., J.P.L., M.C., N.S.K.).

Outcomes were then analyzed based on incidence of arterial insufficiency, venous insufficiency, hematoma requiring reoperation, fat necrosis, partial flap loss, full flap loss, and future need for fat grafting. Venous insufficiency was defined as venous congestion requiring reoperation and subsequent revision of the venous anastomosis (i.e., acute thrombosis occurring within the first 24 hours). Partial flap loss was defined as acute flap loss postoperatively, including flap skin and subcutaneous tissue. Fat necrosis was defined by physical examination identifying fat necrosis, excision during revision surgery, or postoperative imaging (MRI/CT) documenting fat necrosis.

Data were then analyzed using Statistical Package for the Social Sciences (SPSS) software (Armonk, NY) for regression analysis. For all cases, a P-value of less than 0.05 was considered to be statistically significant.

RESULTS

During the study period, 197 patients underwent 392 flaps. Eight reconstructions (0.8%) were performed using a 3.5-mm coupler, ninety (22.9%) of reconstructions were performed using a 3.0-mm coupler, two-hundred eighteen (55.6%) with a 2.5-mm coupler, and 75 (19.1%) with a 2.0-mm coupler. The different cohorts of patients were similar in age, type of flap, indication for reconstruction, smoking history, and radiation history. (Table 1)

Overall, the most common flap used for reconstruction was the deep inferior epigastric perforator (DIEP) flap (n = 241, 61.5%), followed by the muscle-sparing free transverse rectus abdominis myocutaneous (MS-TRAM) (n = 103, 26.2%), profunda artery perforator (PAP) (n = 29, 7.4%), transverse upper gracilis (TUG) (n = 13, 3.3%), superficial inferior epigastric artery (SIEA) (n = 5, 1.3%), and superior gluteal perforator (SGAP) (n = 1, 0.3%) flaps. Internal mammary vessels (n = 379, 96.7%) were most commonly used as recipient vessels, but thoracodorsal vessels (n = 9, 2.3%) and internal mammary perforators (n = 5, 1.3%) were used occasionally. All anastomoses were performed in an end-to-end fashion (Table 1).

Breasts undergoing reconstruction with 2.0-mm coupler were more likely to suffer venous insufficiency at 6.7% (n = 5) when compared with 2.5-mm coupler at 2.3% (n = 5) and 3.0-mm coupler at 1.1% (n = 1). In Addition, partial flap loss, fat necrosis, and need for

Table 1. Patient Demographics and Operative Details

	1.5 coupler	2.0 coupler	2.5 coupler	3.0 coupler	3.5 coupler	Total
Flaps	1 (0.03%)	75 (19.1%)	218 (55.6%)	90 (22.9%)	8 (2.0%)	392
Age	42 ± 0	47.14 ± 9.5	49.19 ± 8.65	49.9 ± 8.93	44 ± 11.95	N/A
BMI (kg/m^2)	22 ± 0	27.5 ± 5.5	26.4 ± 4.40	26.9 ± 4.07	21.67 ± 1.03	N/A
Immediate	1 (100%)	53 (70.6%)	160 (73.4%)	63 (70%)	6 (75%)	283
Delayed	0 (0%)	22 (29.3%)	58 (26.6%)	27 (30%)	2 (25%)	109
NAS	0 (0%)	8 (10.6%)	60 (27.5%)	16 (17.8%)	6 (75%)	90
Rib resection	0 (0%)	44 (58.6%)	131 (60.9%)	51 (56.6%)	6 (75%)	232
IMA/IMV	1 (100%)	70 (93.3%)	211 (96.7%)	88 (97.7%)	8 (100%)	378
Thoracodorsal	0 (0%)	3 (4%)	4 (1.8%)	2 (2.3%)	0 (0%)	9
Perforators of IMA	0 (0%)	2 (2.6%)	3 (1.4%)	0 (0%)	0 (0%)	5
MS-TRAM	1 (100%)	18 (24%)	51 (23.4%)	31 (34.4%)	2 (25%)	103
DIEP	0 (0%)	48 (64%)	139 (63.7%)	50 (55.5%)	4 (50%)	241
PAP	0 (0%)	6 (8%)	19 (8.7%)	4 (4.4%)	0 (0%)	29
TUG	0 (0%)	2 (2.6%)	5 (2.3%)	4 (4.4%)	2 (25%)	13
SIEA	0 (0%)	1 (1.3%)	3 (1.4%)	1 (1.1%)	0 (0%)	5
SGAP	0 (0%)	0 (0%)	1 (0.45%)	0 (0%)	0 (0%)	1
SLNB	1 (100%)	12 (16%)	50 (23.0%)	21 (23.3%)	0 (0%)	83
ALND	0 (0%)	12 (16%)	16 (7.4%)	5 (5.5%)	0 (0%)	33
Neo-adjuvant chemotherapy	0 (0%)	8 (10.6%)	22 (10.9%)	9 (10%)	1 (12.5%)	50
Neo-adjuvant radiation	0 (0%)	2 (2.6%)	16 (7.3%)	7 (7.7%)	1 (12.5%)	26
Adjuvant chemotherapy	0 (0%)	10 (13.3%)	32 (14.7%)	8 (8.8%)	0 (0%)	50
Adjuvant radiation	0 (0%)	7 (9.3%)	16 (7.3%)	9 (10%)	0 (0%)	32
Cancer indication	1 (100%)	50 (66.6%)	144 (66.1%)	61 (67.7%)	2 (25%)	258
Prophylactic indication	0 (0%)	25 (33.3%)	74 (33.9%)	29 (32.2%)	6 (75%)	134
Smoking	0 (0%)	1 (1.3%)	0 (0%)	1 (1.1%)	0 (0%)	2
Former smoking	0 (0%)	5 (6.6%)	20 (9.1%)	11 (12.2%)	0 (0%)	36
Fat grafting	0 (0%)	22[a] (29.3%)	50 (23.8%)	20 (22.2%)	2 (25%)	94
Average volume fat grafting	N/A	138.75 ± 77.7 mL (range: 50–320 mL)	159.34 ± 135.8 mL (range: 22–425 mL)	104.53 ± 79.0 mL (range:20–350 mL)	75 ± 42.4 mL (range: 45–105 mL)	N/A

[a]*Statistically significant.*

ALND: axillary lymph node dissection; BMI: body mass index; DIEP: deep inferior epigastric perforator; IMA/IMV: internal mammary artery/ internal mammary vein; MS-TRAM: muscle sparing- transverse abdominis; NAS: nipple areolar sparing; PAP: profunda artery perforator; SGAP: superior gluteal artery perforator; SIEA: superficial inferior epigastric artery; SLNB: sentinel lymph node biopsy; SMOKING: number of patients who smoke; TUG: transverse upper gracilis.

future fat grafting were more likely in the 2.0-mm coupler group when compared with the larger couplers. Those comparisons proved to be statistically significant for venous insufficiency and fat necrosis. Coupler sizes less than or equal to 2.0 mm was found to be a significant risk factor for venous insufficiency ($P = 0.038$; risk reduction with coupler size greater than or equal to 2.5 mm 87%) as well as for development of fat necrosis ($P = 0.041$; 73% risk reduction when using coupler sizes greater than or equal to 2.5 mm) and future need for fat grafting ($P = 0.050$; 45% risk reduction when using coupler sizes greater than or equal to 2.5 mm). There were no differences in respect to arterial insufficiency, hematoma, mastectomy skin flap necrosis, and full flap loss when comparing coupler sizes (Table 2).

After controlling for adjuvant radiation, smoking and BMI, coupler size was a significant risk factor for venous insufficiency ($P = 0.038$), fat necrosis ($P = 0.041$), and future need for fat grafting ($P = 0.050$). Specifically, a 0.5-mm increase in coupler size is associated with marked risk reductions for venous insufficiency (87% risk reduction), fat necrosis (73% risk reduction), and future need for fat grafting (45% risk reduction). Practically, a coupler size of 2.0 mm or less is associated with higher risk of complications and should be avoided if possible. Coupler sizes of 2.5 mm or greater reduce the risk of complications significantly. Coupler size did not affect the risk of other complications including hematoma, arterial insufficiency, and partial or full flap loss.

Table 2. Complications

	1.5 coupler (n = 1)	2.0 coupler (n = 75)	2.5 coupler (n = 218)	3.0 coupler (n = 90)	3.5 coupler (n = 8)	Total (n = 392)
Arterial insufficiency	0 (0%)	2 (2.6%)	3 (1.3%)	0 (0%)	0 (0%)	5 (1.2%)
Venous insufficiency	0 (0%)	5 (6.7%)[a]	5 (2.3%)	1 (1.1%)	0 (0%)	11(2.8%)
Hematoma	0 (0%)	3 (4%)	9 (4.1%)	1 (1.1%)	0 (0%)	13 (3.3%)
Partial flap loss	0 (0%)	3 (4%)	8 (3.7%)	3 (3.3%)	0 (0%)	14 (3.6%)
Full flap loss	0 (0%)	1 (1.3%)	1 (0.4%)	0 (0%)	0 (0%)	2 (0.5%)
Fat necrosis	0 (0%)	11 (14.7%)[a]	14 (6.3%)	5 (5.5%)	0 (0%)	30 (7.7%)
Mastectomy skin flap necrosis	0 (0%)	4 (5.3%)	11 (5.1%)	3 (3.3%)	0 (0%)	18 (4.6%)

[a]*Statistically significant.*

Interestingly in multivariate analysis, BMI is an independent risk factor for skin flap necrosis ($P = 0.010$) and full flap loss ($P = 0.035$).

DISCUSSION

Breast reconstruction using microvascular free flaps has become a routine procedure. Preferred recipient vessels are the internal mammary or thoracodorsal vessels. Historically, acute intraoperative complications resulting from hand-sewn venous anastomoses were found to be as low as 3%.[13] Similar rates have been reported using the coupler device, with time needed for anastomoses being significantly less.[14] The venous anastomosis can be coupled in 2–3 minutes, while a hand-sewn anastomosis usually takes 10–15 minutes. Further, employing the coupler device is easier.[15] However, with increasing popularity of this type of reconstruction and increasing ease of the venous coupler, use of smaller coupler size has become commonplace in our practice. While there is copious evidence in the literature showing efficacy at sizes greater than 3.0 mm, the literature is deplete when looking at outcomes of venous couplers sizing 2.0 mm and less. Further, most of the existing literature is not solely focused on free flap breast reconstruction. One of the largest other series of employing the coupler in autologous breast reconstruction by Serletti et al. showed lower complication rates in the group of patients that received 2.0-mm couplers, however, in their series the total number of patients in that group was only 14/1,000 (1.4%) vs. 19.1% in our group.[16] Further, given the fact that Serletti et al. as well as other groups have performed the vast majority of anastomosis with coupler sizes of 2.5 mm or greater goes to show that this should be feasible and according to our data also desired in most patients. As pointed out in the discussion, more aggressive vessel exposure or other means of vessel modification such as beveling the cut ends should be the consequence in order to accommodate for a larger coupler size. Hand sewing the veins could be another option when a 2.5 mm coupler is not possible, however, we lack data in this respect due to the very low number of patients in that group. We will continue to evaluate the outcomes of those particular cases in a prospective fashion.

Our investigation is the largest single institution evaluations on the influence of coupler size on short- and long-term outcomes in autologous breast reconstruction.

The main limitations of this investigation are its retrospective study design, as well as the lack of control for flap outflow and recipient vein size, which clearly represent confounding variables. While in our study smaller couplers were only used when smaller vessels had to be anastomosed, a study design that controls for vessel size would be ideal, because in the end the small vasculature, and not the couplers themselves, could be the etiology of the increased complication rate. Given that any increase in vessel or coupler diameter allows for an exponentially higher flow rate according the Hagen-Poiseuille equation, an increase in risk to develop venous congestion with smaller coupler sizes seems somewhat logical however.

A retrospective study from M.D. Anderson over a 40-months period by Yap et al. compared anastomotic coupling devices with hand-sewn anastomoses and found that venous thrombosis rates were not statistically different between the coupled (1.4%, 2/139 cases) and sutured (3.3%, 19/585 cases) groups. Further, they also found that salvage rates following venous thrombosis were not statistically different for the anastomoses performed with a coupler (50%, 1/2 cases salvaged) and the hand-sewn group (68.4%, 13 of 19 cases salvaged).[6] As such, the safety of the coupler has been reported for venous and even arterial anastomoses in head and neck-, extremity-, and breast reconstruction.[17–19]

Overall, the success rate varies from 94 to 100% for venous, and between 87 and 100% for arterial anastomoses.[20] Knight et al. published a series of 117 patients where the majority of flaps were anastomosed to the internal mammary vessels (65.3%) and with 2.5-mm couplers (65.3%) with a total rate of anastomotic revision (arterial and venous) of 4.9%. Serletti et al. provide the to date largest series on using the coupler device in autologous free flap breast reconstruction and quote a thrombosis rate of 0.6%, which is favorably low. In their

report, the rate of thrombosis was not clearly linked to coupler size. In the total of 1,000 flaps analyzed, the majority of thrombosis occurred in the 3.0-mm group ($n = 852$) and the 2.5-mm group ($n = 130$), with 0.9 and 0.8%, respectively. The authors did not report any incidences of thrombosis or partial flap loss in the group of 2.0 mm or below, however this group only included 15 patients.

Our data is somewhat different in that we have a significantly higher rate of 2.0 mm ($n = 75$) couplers used, in total approximately 20% of all couplers. We found that using couplers this size significantly increases the chances of development of venous insufficiency in form of acute thrombosis, as well as for development of fat necrosis and consequently future need for fat grafting. Using couplers of larger size offered a significant risk reduction.

Overall we found that the venous coupling device allows for fast and efficient venous anastomoses in autologous breast reconstruction, however, internal diameters of 2.0 mm or less increased acute and chronic complications significantly.

CONCLUSIONS

Small coupler size of 2.0 mm and less increases complications significantly, and hence the largest diameter coupler possible should be used. Vessel modification via beveling or fish-mouthing as well as more aggressive vessel exposure through rib harvest and possible use of thoracodorsal vessels should be considered in cases of IMV caliber of 2.0 mm or less.

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