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Intraoperative Utility of the Implantable Doppler in Lower Extremity Reconstruction: A Matched Case-control Study

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Background: Patients with diabetes mellitus and peripheral vascular disease have high rates of thrombogenic vessels. The implantable (Cook) Doppler in lower extremity reconstruction can optimize microsurgical outcomes in this population.
Methods: Patients undergoing lower extremity free flap reconstruction who did not have an implantable Doppler probe placed were matched with patients who received an implantable Doppler probe. Groups were matched based on wound location, history of peripheral vascular disease, number of vessel runoffs, and number of venous anastomoses and postoperative outcomes compared.
Results: Thirty patients were included: 15 in the control group and 15 in the implantable Doppler group. Mean age was 60.2 ±10.2 years, and mean BMI was 28.7 ± 5.0 kg/m^2. There was a high prevalence of diabetes mellitus (13; 43.3%) and peripheral vascular disease (4; 13.3%). Takebacks due to vascular compromise were significantly higher in the control than in the implantable Doppler group (26.7% versus 0.0%, $P = 0.032$). Among flaps that required takeback to the operating room, the majority were muscle-based without a skin paddle (75.0%). Vascular compromise was due to arterial insufficiency in 2 cases and venous thrombosis in 1 case. The salvage rate among the takebacks of the non-implantable Doppler group was 0.0%, resulting in a 26.7% flap failure rate in the non-implantable Doppler group when compared with 0.0% flap loss in the implantable Doppler group ($P = 0.032$).
Conclusion: The implantable Doppler probe optimizes flap inset intraoperatively in lower extremity free flap reconstruction and can significantly decrease takebacks due to vascular complications, thereby increasing flap success. *(Plast Reconstr Surg Glob Open 2020;8:e3229; doi: 10.1097/GOX.0000000000003229; Published online 20 November 2020.)*

INTRODUCTION

Free tissue transfer has become a mainstay for limb salvage in patients suffering from chronic lower extremity wounds.[1] The introduction of healthy, well-vascularized tissue provides coverage, obliterates dead space, and decreases microbe inoculation from the wound bed.[1] Despite this, free flaps in the lower extremity continue to have the highest rates of flap failure when compared with other sites.[2–5] The chronic lower extremity wound population represents a particularly unique microvascular reconstructive challenge due to the high prevalence of diabetes mellitus and peripheral vascular disease (PVD), both of which increase the risk of having thrombogenic recipient vessels, as well as impaired venous return.[6–8] These microvascular conditions are further exacerbated by the dependent location of the wound and prolonged immobility.

Optimizing initial intraoperative flap inset and postoperative monitoring to ensure free flap success in this patient population is critical. Previous studies have demonstrated that clinical evidence of vascular compromise is most likely to declare itself between 24 and 72 hours postoperatively.[9–12] Furthermore, early intervention was correlated with higher salvage rates.[13] The implantable Doppler

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probe is commonly utilized for postoperative flap monitoring and has been shown to be superior at detecting early vascular compromise when compared with conventional clinical monitoring.[14,15] While the existing literature has focused on its utility in the postoperative monitoring period, particularly for intraoral head and neck free flaps or buried flaps, few studies evaluating its utility in lower extremity reconstruction exist.[16–19] Furthermore, in our experience, the implantable Doppler probe also proved useful as a tool for optimizing intraoperative flap inset, in addition to postoperative monitoring. Here, we present our institutional experience and outcomes using the implantable Doppler probe for lower extremity free flap reconstruction in a highly comorbid patient population.

PATIENTS AND METHODS

After obtaining institutional review board approval, we retrospectively reviewed our institutional database of lower extremity free flap reconstructions performed from April 2011 to December 2019. All free flaps performed before the use of the implantable (Cook) Doppler were identified (April 2011 to January 2012). They were matched with patients who had an implantable Doppler probe placed. Patients were matched according to wound location, history of PVD, number of vessel runoffs to the foot, and number of venous anastomoses (Table 1). Patients' gender and age were secondarily considered; however, cases with gender or age mismatch were still included in the study population. Utilizing these criteria, matches were assigned by one author who was blinded to surgical outcomes.

Data Collection

Information on patient demographics, comorbidities, defect characteristics (eg, location, vessel run-off) was collected for both groups. Operative details, including flap type (ie, muscle versus fasciocutaneous) and subtype, as well as anastomotic details (eg, end-to-end versus end-to-side arterial anastomosis, number of venous anastomoses) were included. Primary outcomes were partial and total flap failures as well as takebacks. A takeback was defined as an emergent return to the operating room due to suspected flap vascular compromise. Secondary outcomes encompassed peri-operative complications, including adverse events related to the implantable Doppler probe (eg, soft tissue infection).

Technique

The Cook–Swartz Venous Doppler (Cook Medical, Bloomington, Ind.) is an implantable 20-MHz ultrasonic probe with a portable monitor. The probe is placed on the venous pedicle using two micro clips, distal to the venous anastomosis. (**See Video 1 [online],** which displays how the implantable Cook Doppler provides the surgical team with real-time feedback on venous flow to optimize inset intraoperatively.)

Flap inset is guided by feedback from the Doppler signal to ensure that the venous outflow remains patent and the vascular pedicle is not inadvertently kinked in the process. Post-operatively, the implantable Doppler is utilized for flap monitoring. If there is an alteration in signal strength or quality, a clinical examination is also performed. Here, the second supplemental video shows a loss of signal with the placement of a singular staple for inset. (**See Video 2 [online],** which displays the application of the implantable Cook Doppler on the venous pedicle distal to the anastomosis using the two microclip technique.)

Statistical Analysis

To assess the matching procedure, differences in age, body mass index, and Charlson Comorbidity Index between the implantable Doppler and control groups were determined using paired *t*-tests or Wilcoxon signed rank sum tests, as determined by the Shapiro-Wilk normality test. Univariable associations between the case and control group and primary outcomes were analyzed using Pearson's chi-square test for categorical variables. $P < 0.05$ was considered significant. Descriptive and statistical analysis was performed using Stata 16 (StataCorp, College Station, Tex.).

RESULTS

Patient Demographics

A total of 30 free flaps in 30 patients were included (15 patients served as the control and 15 patients had implantable Doppler probes). Mean age was 60.2 ±10.2 years and mean BMI was 28.7 ± 5.0 kg/m^2. The majority of patients were men (16, 53.3%). There was a high prevalence of diabetes (13, 43.3 %) and peripheral vascular disease (4, 13.3 %) in both groups. There was no significant difference in patient's age, BMI, gender, or co-morbities between the control and implantable Doppler probe group (Table 2).

Table 1. Variables and Criteria for Assigning Matches

Primary Variables	
Wound location	Match location based on following categories: Plantar hindfoot Anterior ankle Posterior ankle Medial or lateral ankle
History of peripheral vascular disease	Exact match of yes versus no.
No. runoff vessels to foot	Exact match of number of runoff vessels to foot assessed by angiography. When applicable, match was assigned based on number of runoff vessels post-endovascular intervention.
No. venous anastomoses	Exact match of number of venous anastomoses performed for free flap.
Secondary Variables	
Age	Match age at time of free flap reconstruction ±5 years.
Gender	Exact match of men versus women.

Table 2. Patient and Wound Characteristics

Characteristic	Control Group No. (%)	Implantable Doppler Group No. (%)	P*
Mean age ± SD, y	59.4 ± 9.5	60.2 ± 10.2	
BMI, kg/m^2	28.3 ± 5.3	28.7 ± 5.0	
Gender			0.358
Men	9 (60.0)	7 (46.7)	
Women	6 (40.0)	8 (53.3)	
Co-Morbidities			
Diabetes mellitus	5 (33.3)	8 (53.3)	0.532
PVD	2 (13.3)	2 (13.3)	0.701
Osteomyelitis			0.227
Prior	1 (6.7)	1 (6.7)	
Active	0 (0.0)	4 (26.7)	
Smoking status			0.697
Prior	5 (33.3)	3 (20.0)	
Active	2 (13.3)	2 (13.3)	
Defect location			0.674
Proximal tibia	0 (0.0)	1 (6.7)	
Dorsal foot/ankle	12 (80.0)	11 (73.3)	
Plantar foot	3 (20.0)	3 (20.0)	
Flap type			0.358
Muscle-based	9 (60.0)	7 (46.7)	
Fasciocutaneous	6 (40.0)	8 (53.3)	

*$P < 0.05$ was considered statistically significant.

Table 3. Microvascular Anastomosis Characteristics

Characteristic	Control Group No. (%)	Implantable Doppler Group No. (%)	P*
Vessel runoff			0.566
3-vessel runoff	8 (53.3)	8 (53.3)	
2-vessel runoff	7 (46.7)	7 (46.7)	
1-vessel runoff	0 (0.0%)	0 (0.0%)	
Arterial anastomosis			
End-to-end	4 (26.7)	2 (13.3)	0.326
End-to-side	11 (73.3)	13 (86.7)	
Recipient artery			0.494
Anterior tibial	4 (26.7)	6 (40.0)	
Posterior tibial	9 (60.0)	9 (60.0)	
Peroneal	1 (6.7)	0 (0.0)	
Dorsalis pedis	1 (6.7)	0 (0.0)	
>1 venous outflow	11 (73.3)	11 (73.3)	1.000

*$P < 0.05$ was considered statistically significant.

Table 4. Comparing Complications between Control Group and Implantable Doppler Group

Complication	Control Group No. (%)	Implantable Doppler Group No. (%)	P*
Takeback	4 (26.7)	0 (0.0)	0.032
Hematoma	2 (13.3)	1 (6.7)	0.500
Seroma	0 (0)	0 (0)	0.701
Infection	2 (13.3)	2 (13.3)	0.701
Dehiscence	1 (6.7)	2 (13.3)	0.500

*$P < 0.05$ was considered statistically significant.

Operative Details

Most wound defects were located in the dorsal foot and ankle in both the control (80.0%) and implantable Doppler group (73.3%, $P = 0.647$). Overall, half of the defects were reconstructed with muscle-based flaps, and the remaining were fasciocutaneous, with no significant difference across flap type between the two groups. At the time of the free flap reconstruction, the majority of patients had 3 vessel run-offs in both groups (Table 3). The arterial anastomosis was performed in an end-to-side manner in most of the cases in both the control (73.3%) and the implantable Doppler group (86.7%, $P = 0.326$).

Flap Outcomes

There was no significant difference in minor complications between the two groups, including, hematoma, seroma, infection, and wound dehiscence (Table 4). Patients in the control group required a significantly higher rate of return to the operating room for vascular compromised when compared with patients who received an implantable Doppler group, intraoperatively (26.7% versus 0.0%, $P = 0.032$). Among flaps that required takeback to the operating room, the majority were muscle-based without a skin paddle (75.0%). Vascular compromise was due to arterial insufficiency in 2 cases and venous thrombosis in 1 case. Additional details on flaps requiring return to the operating room are outlined in Table 5.

DISCUSSION

Microvascular tissue transfer for the coverage of chronic lower extremity wounds represents a crucial component of limb salvage. Compared with free tissue transfer in other areas of the body, there is a higher risk of flap failure in the lower extremity.[2–4] Therefore, the value of effective flap monitoring that allows for timely and accurate detection of flap compromise is crucial.[11] While there have been previous reports on the use of the implantable Doppler for lower extremity free flaps, this study is the first to present its use for coverage of chronic wounds. Given the unique challenges associated with this patient population, we believe this reconstructive indication requires its own consideration. Furthermore, this is the first study investigating the utility of the implantable Doppler via a blinded matching process. Existing studies do not control for factors influencing flap failure, thereby decreasing the strength of the current evidence. In this study, we controlled for variables that inform free flap outcomes, including the presence of PVD, the number of runoff vessel, and the number of venous anastomoses.

In this lower extremity limb salvage population, we found that use of the implantable Doppler led to a zero-take back rate compared with a matched-cohort of patients who did not have implantable Doppler monitoring. Intraoperative use of the implantable Doppler optimizes positioning of the vascular pedicle before leaving the operating room. The implantable probe gives the operative team real-time feedback, which allows the surgeon to identify pedicle compression or kinking before definitive inset. Signal changes during inset indicate the need for exploration, either by removal of sutures securing the flap or by complete re-inset. The first supplemental video demonstrates how the implantable Doppler can detect signal changes incited by a single staple causing compression. (**See Video 1 [online],** which displays the application of implantable cook Doppler on venous pedicle distal to the anastomosis using two micro clip technique.) Often, the implantable Doppler is criticized for being cost-prohibitive, especially in the context of frequent flap monitoring

Table 5. Operative Details of Takebacks

Group	POD of Takeback	Flap Type	Intraoperative Finding	Salvage
No implantable Doppler	0	Muscle	Arterial thrombus, arterial revision	No
No implantable Doppler	1	Muscle	Explorative	No
No implantable Doppler	6	Muscle	Arterial thrombus	No
No implantable Doppler	7	Fasciocutaneous	Venous thrombus	No

POD, postoperative day.

by nursing and ICU levels of care.[20] However, in this patient population, the cost of the implantable Doppler wires and monitor are considerably less than the cumulative costs of takebacks for pedicle exploration, which include the cost of running and staffing an operative room for an additional unplanned procedure.[20]

Previous studies on the use of implantable Dopplers to monitor free tissue transfers have found a trend toward higher rates of flap salvage, with very few reaching significance.[17,21–23] In our cohort, all patients requiring salvage attempts were from the group that did not have implantable Doppler monitoring with a 0% successful salvage rate. Successful revision is contingent on timely recognition of vascular compromise and early anastomotic revision. Implantable Dopplers have been shown to improve flap salvage rate, likely through their ability to significantly reduce the time to detect inadequate flap perfusion when compared with clinical flap monitoring.[15,23] Rather than grappling with whether to return to the operating room in the immediate postoperative period, surgeons can use the baseline intraoperative signal to identify a concerning change that may indicate a need for re-exploration. This is especially meaningful for muscle-based flaps that lack a skin-paddle to demonstrate clinical signs of vascular compromise.[24] As a result, muscle-based flaps have later takebacks with lower rates of successful salvage attempts when compared with fasciocutaneous flaps.[5,24–26] In our study, 3 of the 4 flaps requiring takeback to the operating room were muscle-based. Therefore, the implantable Doppler may be uniquely valuable in the setting of muscle-based flaps that benefit more from direct pedicle monitoring.

The most common etiology for takebacks in our study was arterial insufficiency. This was initially counterintuitive because the implantable probe was placed on the venous anastomosis, which has long been considered the standard of care.[19] While arterial probes can detect an arterial compromise immediately, the literature suggests that there is a delay in its ability to recognize venous compromise.[27] Venous placement, on the other hand, not only detects venous problems immediately, but can also detect arterial compromise an average of six minutes after occlusion.[27] Therefore, even in a population with higher rates of arterial compromise, a venous implantable Doppler may confer an advantage in detection and revision.

There are theoretical risks associated with use of the implantable Doppler; however, in our experience, the implantable Doppler is a safe device for flap monitoring with a low complication profile. The most feared complications include compromise of the vascular pedicle due to shear from the probe wiring or compression of the pedicle due to tightness of the implantable cuff. We did not observe any such complications in this study. Additionally, we did not observe any instances of infection or bleeding due to placement of the probe. In the outpatient postoperative setting, the implantable wires are removed using gentle traction without disrupting the anastomosis. Allowing adequate time for healing of the pedicle to surrounding tissue decreases risk of disruption to the anastomosis during removal. This is consistent with Rozen et al.'s protocol, who describe removal of the device from over 200 patients in clinic with no reports of pedicle compromise.[18]

This study has several limitations, including the small sample size, which limits the strength of our conclusions. Furthermore, we are unable to provide results regarding the false-positive and false-negative rates from the use of the implantable Doppler due to the lack of takebacks in that group. While there is literature suggesting a high false-positive can result in unnecessary takebacks, other work has attributed this to the learning curve related to using the device.[10] At our institution, data were available only for 15 patients before widespread use of the implantable Doppler after free tissue transfer. By performing a matched-pair analysis, we provide the most reliable and statistically sound findings.[28] Within these limitations, we have demonstrated the intraoperative utility of the implantable Doppler for lower extremity reconstruction in a highly comorbid patient population, to significantly decrease takeback rates and, as a result, increase overall limb salvage rates.

CONCLUSIONS

Free flap reconstruction of chronic lower extremity wounds in patients with a high prevalence of microvascular disease represents a significant challenge. Technical success is contingent upon optimization of flap inset and early detection of flap compromise to increase chances of salvage. This is the first study to demonstrate the intraoperative utility of the implantable Doppler in this patient population. Our experience supports its use to significantly reduce takeback rates due to vascular compromise. This is particularly valuable in muscle-based flaps without a skin paddle.

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