POSTOPERATIVE MONITORING OF LOWER LIMB FREE FLAPS WITH THE COOK–SWARTZ IMPLANTABLE DOPPLER PROBE: A CLINICAL TRIAL

WARREN M. ROZEN, M.B.B.S., B.Med.Sc., P.G.Dip.Surg.Anat., Ph.D.,[1] MORTEZA ENAJAT, B.A.,[2]
IAIN S. WHITAKER, B.A. (Hons), M.A. (Cantab), M.B.B.Chir., M.R.C.S.,[3] ULRICA LINDKVIST, B.Physio.,[2]
THORIR AUDOLFSSON, M.D.,[2] and RAFAEL ACOSTA, M.D., EBOPRAS[2*]

Background: Free flaps to the lower limb have inherently high venous pressures, potentially impairing flap viability, which may lead to limb amputation if flap failure ensues. Adequate monitoring of flap perfusion is thus essential, with timely detection of flap compromise able to potentiate flap salvage. While clinical monitoring has been popularized, recent use of the implantable Doppler probe has been used with success in other free flap settings. *Methods:* A comparative study of 40 consecutive patients undergoing microvascular free flap reconstruction of lower limb defects was undertaken, with postoperative monitoring achieved with either clinical monitoring alone or the use of the Cook-Swartz implantable Doppler probe. *Results:* The use of the implantable Doppler probe was associated with salvage of 2/2 compromised flaps compared to salvage of 2/5 compromised flaps in the group undergoing clinical monitoring alone (salvage rate 100% vs. 40%, $P = 0.28$). While not statistically significant, this was a strong trend toward an improved flap salvage rate with the use of the implantable Doppler probe. There were no false positives or negatives in either group. One flap loss in the clinically monitored group resulted in limb amputation (the only amputation in the cohort). *Conclusion:* A trend toward early detection and salvage of flaps with anastomotic insufficiency was seen with the use of the Cook–Swartz implantable Doppler probe. These findings suggest a possible benefit of this technique as a stand-alone or adjunctive tool in the clinical monitoring of free flaps, with further investigation warranted into the broader application of these devices. © 2009 Wiley-Liss, Inc. Microsurgery 30:354–360, 2010.

Free flap coverage to lower limb defects are required in a range of clinical settings. These flaps are unique in that there are inherently high venous pressures in the lower limb due to gravitational effects, potentially incompetent veins and relative dependant edema.[1,2] Additionally, both dressings and mobilization can further increase these pressures, potentially impairing flap viability, which in the lower limb setting may lead to limb amputation if flap failure ensues. Adequate monitoring of flap perfusion is thus essential to avoid these complications, with timely detection of flap compromise able to potentiate flap salvage.

To date, clinical monitoring has formed the basis for monitoring lower limb free flaps across institutions and throughout the literature, with signs such as skin color, capillary refill, bleeding, and temperature the key features assessed. The Doppler probe has also been used as an adjunct to clinical monitoring,[3,4] with Doppler shown to be noninvasive, inexpensive, easy to perform, and reproducible.[5,6] However, limitations to these techniques include a degree of inaccuracy due to the subtle nature of the signs of vascular compromise, the inability to perform continuous monitoring, and the need for flap exposure to perform the tests. This is compounded in the setting of early mobilization, which increases venous pressures and may threaten the venous drainage of flaps. However guidelines for mobilizing these flaps and the means for flap monitoring in this setting have not been described.

The implantable Doppler probe has been described as an additional tool for flap monitoring, shown to be highly beneficial in a range of clinical settings.[7–11] An internal Doppler cuff is attached to an external monitor, which allows continuous monitoring of pedicle flow. In the settings of buried flaps and in breast reconstruction, these probes have shown distinctive benefits, but the unique scenario of lower limb flaps warrants particular attention. Our experiences with implantable probes for lower limb free flaps have demonstrated unique benefits from the time of flap in-insetting, to the immediate postoperative period, and particularly during limb elevation, the application of pressure dressings, mobilization, and during physiotherapy. We thus undertook a study to comparing the implantable Doppler probe to clinical monitoring alone in the monitoring of free flaps to the lower extremities, the first such study to compare clinical outcomes of this adjunctive monitoring tool in this setting.

METHODS

A prospectively entered, retrospectively reviewed cohort study was undertaken comprising 40 consecutive patients undergoing microvascular free flap reconstruction

[1]Jack Brockhoff Reconstructive Plastic Surgery Research Unit, Room E533, Department of Anatomy, University of Melbourne, Grattan St, Parville, 3050, Victoria, Australia
[2]Department of Plastic Surgery, Uppsala Clinical Hospital, Uppsala, Sweden
[3]Department of Plastic, Reconstructive and Burns Surgery, The Welsh Centre for Burns and Plastic Surgery, Morriston Hospital, Swansea, SA6-6, UK
*Correspondence to: Rafael Acosta, M.D., EBOPRAS, Department of Plastic Surgery, Uppsala Clinic Hospital, Uppsala, 75185, Sweden.
E-mail: rafael.acosta.rojas@akademiska.se
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Table 1. Patient Demographics, Comparing the Cook–Swartz Implantable Doppler Probe and Clinical Assessment Groups

Patient demographics	Cook-Swartz implantable Doppler	Clinical assessment	*P* value
Sex (% male)	70	60	0.74
Mean age (years)	45.6, range: 15–73	43.3, range: 1–80	0.70[a]
Smoking (%)	15	30	0.45
Corticosteroid use (%)	0	15	0.23
Hypertension (%)	15	0	0.23
Diabetes Mellitus (%)	5	0	1
Mean ischaemia time (minutes) (SD)	80.10 (22.17)	83.35 (26.06)	0.67[a]

SD, standard deviation.
P values are calculated with the two-tailed Fisher's exact test.
[a]*P values are calculated with a two tailed Student's t-test.*

Table 2. Presentation of Patients, Comparing the Cook–Swartz Implantable Doppler Probe and Clinical Assessment Groups

Presenting problem (*n*)	Cook-Swartz implantable Doppler probe	Clinical assessment	*P* value
Open fracture	10	10	1.00
Wound Infection	7	6	1.00
Stump coverage postamputation	1	2	1.00
Traumatic degloving injury	2	1	1.00
Burn	0	1	1.00

P values calculated with the two-tailed Fisher's exact test.

of a lower limb defect in the period from September 2004 to September 2008. Of these, the first 20 patients were monitored postoperatively with clinical assessment only, while the subsequent 20 patients were monitored with the Cook–Swartz implantable Doppler probe (Cook Medical®, Cook Ireland Ltd, Limerick, Ireland). All patients were recruited through a single surgeon (RA), with patient demographics (see Table 1) and flap details (see Table 2) all recorded. Complications, reoperations, and clinical outcome measures were compared between groups.

In the "clinical assessment only" group, postoperative flap perfusion was monitored through a range of clinical bedside tests, including the assessment of the color, temperature, tactility, capillary refill, bleeding, and appearance of the flap. Topical temperature monitors and the hand-held Doppler probe were used adjunctively.

The 'implantable Doppler probe' group of flaps was monitored with the Cook–Swartz implantable Doppler probe alone (see Fig. 1). The Cook–Swartz venous Doppler system comprises an implantable 20 MHz ultrasonic probe and a battery operated portable monitor (see Fig. 2). As per manufacturer and literature specifications, the probe is always used on the venous pedicle (as arterial compromise causes venous changes within minutes), with the probes attached distal to the venous anastomosis in all cases. Microclips are used to secure the silicone cuff around the vessel adventitia, rather than sutures or glue (see Fig. 3). The tension of the silicone cuff is important, as a tight cuff may cause venous outflow obstruction, while a loose cuff may be prone to false-positive or false-negative results. The use of microclips in our experience minimizes these problems. Multiple venous anastomoses can be monitored simultaneously with a single Cook–Swartz system, by the simple connection of each wire attachment to each of the two channels on the right of the monitor (see Fig. 2) and pressing an alternating switch on the monitor. The probes were turned on immediately intraoperatively, both to ensure proper application of the probe and to check anastomotic patency during flap insetting. Any problems detected intraoperatively can then be re-explored immediately. Continuous monitoring proceeded into the recovery room.

Monitoring was performed for the first 7 days postoperatively on the ward during inpatient stay, and continued for 4 weeks postoperatively. Audible Doppler abnormalities were assessed by the nursing and medical teams, as well as by the patient themselves. Loss of signal and significant changes in the signal were the primary alerts for further investigation or intervention. In such cases of abnormal Doppler signal, clinical assessment was also performed adjunctively. Probes were removed in the outpatient department after 4 weeks by medical staff by gentle traction on the external component of the wire. Gentle traction causes release of the wire attachment from the cuff, without any pedicle damage in our experience of over 200 cases of using the system in multiple body regions. A hand-held Doppler probe can be used to confirm pedicle flow after removal of the implanted system.

The standard frequency of flap monitoring in all cases (both groups) comprised half-hourly monitoring for the first postoperative day, hourly for the second day, 2-hourly for the third day, and 4-hourly thereafter until planned discharge on day 7. Postoperatively, all lower extremity flaps were elevated to at least 10 cm above heart level for the first postoperative week, and further elevated in cases of suspected venous congestion. Compression bandages were applied cautiously after 4 postoperative days and increased during mobilization at the end of the first postoperative week. Postdischarge monitoring with the probe was performed throughout the early physiotherapy and rehabilitation process. Changes in Doppler signal were recorded and patients reviewed in such instances for the degree of bandage compression and the need for limb elevation. In all cases (both groups), any positive monitoring finding suggestive of pedicle compromise precipitated an immediate return to theater, with no delays in theater experienced in either group.

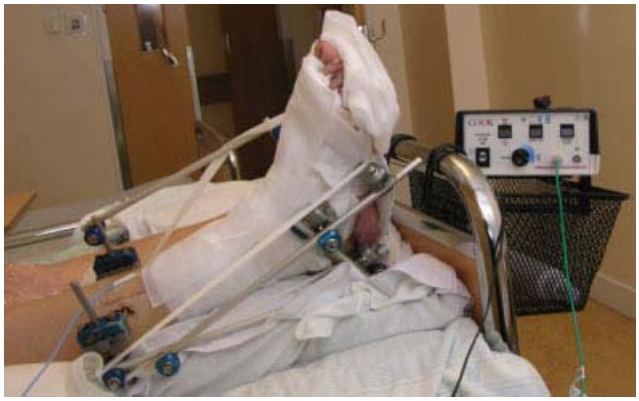

Figure 1. Postoperative photograph after lower limb free flap coverage, demonstrating the Cook–Swartz implantable Doppler probe in situ, with the flap able to be monitored at the end of the bed, without the need to remove overlying dressings. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

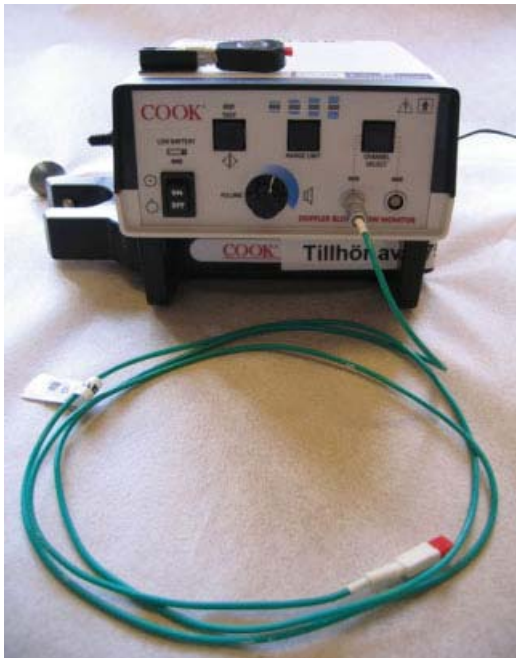

Figure 2. The Cook–Swartz implantable venous Doppler system, comprising the implantable 20 MHz ultrasonic probe, wire connections, and battery operated portable monitor. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

Outcomes assessed for each group included complications, take-backs to theater, false positives and negatives, and the rates of salvage of these take-backs. Student's *t*-test was used to compare the means of continuous outcome variables in the independent groups, calculated at 95% confidence intervals with two-tailed *P* values given. The testing of statistical significance for nominal data was done by means of a two-tailed Fisher's exact test. Statistical significance was considered at $P < 0.05$. Statistical analysis was done using Statistical Package for the Social Sciences (SPSS) for Windows (version 16.0, SPSS Incorporated, Chicago, IL).

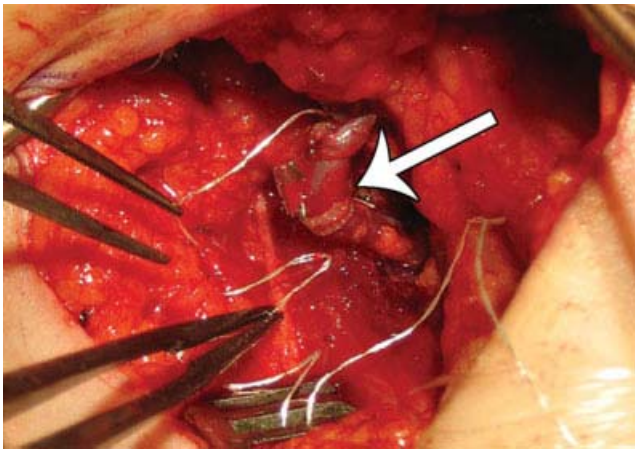

Figure 3. Intraoperative photograph, demonstrating application of the Doppler probe silicone cuff (arrow) distal to the venous anastomosis, with microclips used to secure the cuff around the vessel adventitia. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

RESULTS

The study comprised 40 consecutive patients, in which 20 patients were monitored with the Cook–Swartz implantable Doppler probe and 20 were monitored with clinical monitoring alone. There were no statistical differences between the groups in any demographic factors, including sex, age, smoking habit, comorbidities or presenting complaint/indication for reconstruction (see Tables 1 and 2). Similarly, they were highly comparable for flap type, donor and recipient vessels used and flap ischemia time (see Tables 1 and 3). All reconstructed defects were located below the knee, with the flap most frequently used being the latissimus dorsi musculocutaneous flap, and the vessels most frequently used as recipient vessels being the posterior tibial vessels.

While a range of complications were encountered, these were statistically similar between groups (see Table 4). The overall success rate was 37 of 40 flaps (93%), with no significant differences in overall flap survival between groups. Comparable outcomes included rates of take-back (10% vs. 25%, $P = 0.41$), partial flap loss (no cases in either group) and complete flap loss (0% vs. 15%, $P = 0.23$). Monitoring findings suggestive of anastomotic insufficiency occurred in two cases in the group with Cook-Swartz probe (10%) and in five cases in the group without the Cook-Swartz probe (25%) ($P = 0.41$).

Re-explorations were carried out in all such cases of anastomotic insufficiency, and confirmed the presence of vessel thrombosis (venous thrombosis in all cases, and one case of both arterial and venous thrombosis). There were no false positives or false negatives in either group.

Table 3. Flap Type and Anastomotic Details, Between the Cook–Swartz Implantable Doppler Probe and Clinical Assessment Groups

	Cook–Swartz implantable Doppler probe	Clinical assessment	*P* value
Flap type (*n*/%)			
Anterolateral thigh (ALT)	2 (10)	4 (20)	0.66
Parascapular	1 (5)	1 (5)	1.00
Latissimus dorsi	12 (60)	10 (50)	0.75
Gracillis	0	1 (5)	1.00
Serratus	0	1 (5)	1.00
Lateral arm	4 (20)	3 (15)	1.00
Radial	1 (5)	0	1.00
Recipient artery (*n*/%)			
Posterior tibial	13 (65)	10 (50)	0.52
Anterior tibial	3 (15)	8 (40)	0.16
Dorsalis pedis	1 (5)	0	1.00
Peroneal	1 (5)	0	1.00
Poplitial		0	1.00
Superficial femoral	1 (5)	1 (5)	1.00
Profunda femoris	0	1 (5)	1.00
Recipient vein (*n*/%)			
Posterior tibial	12 (60)	10 (50)	0.75
Anterior tibial	4 (20)	8 (40)	0.30
Dorsalis pedis	1 (5)	0	1.00
Peroneal	1 (5)	0	1.00
Poplitial	1 (5)	0	1.00
Superficial femoral	1 (5)	1 (5)	1.00
Profunda femoris	0	1 (5)	1.00

P values are calculated with the two-tailed Fisher's exact test.

Of the take-backs to theater, there was a substantially higher percentage of compromised flaps able to be salvaged with the use of the Cook–Swartz implantable Doppler probe. In the Cook–Swartz probe group, none of the anastomotic insufficiencies resulted in flap failure (two of two flaps salvaged), compared with the clinical group in which three of the five anastomotic insufficiencies resulted in flap failure (two of five flaps salvaged), equating to an overall flap salvage rate of 100% vs. 40%, $P = 0.28$. The improved flap salvage reflects an earlier detection of flap compromise, return to theater, and improved ability to reverse ischemia by returning pedicle flow with the use of the Cook–Swartz implantable Doppler probe. This earlier time course to detection was also evident when analyzing the time of detection of flap compromise within the Cook–Swartz probe group, with the detection of anastomotic insufficiency occurring with the implantable Doppler probe up to several hours before clinical signs were evident. Of the two cases, both anastomotic thromboses were detected by the Cook–Swartz implantable Doppler probe and reversed without any clinical signs ever becoming evident, and two displayed clinical signs only by the time the flaps were returned to theater 3–4 hours later. In addition to these factors for early intervention, the time from operation that flap compromise was detected was uniformly earlier in the Cook–Swartz probe group than the clinical group: several days after surgery in the clinical assessment group (mean 2.0

Table 4. Operative Outcomes and Complications, Comparing the Cook–Swartz Implantable Doppler Probe and Clinical Assessment Groups

	Cook–Swartz implantable Doppler probe	Clinical assessment	*P* value
Raw data (*n*/%)			
True positives	2/20 = 10%	5/20 = 25%	N/A
False positives	0/20 = 0%	0/20 = 0%	N/A
True negatives	18/20 = 90%	15/20 = 75%	N/A
False negatives	0/20 = 0%	0/20 = 0%	N/A
Outcomes (*n*/%)			
Overall survival rate	20/20 = 100%	17/20 = 85%	0.23
Flap salvage rate (salvaged flaps/compromised flaps)	2/2 = 100%	2/5 = 40%	0.28
False-positive rate (false positives/uncompromised flaps)	0/18 = 0%	0/15 = 0%	1.00
False-negative rate (false negatives/compromised flaps)	0/2 = 0%	0/5 = 0%	1.00
Total re-explorations (*n*/%)	2 (10%)	5 (25%)	0.41
Complications (*n*/%)	4 (20%)	7 (35%)	0.48
Wound dehiscence	0	1 (5%)	1.00
Hematoma	0	0	1.00
Infection	2 (10%)	3 (15%)	1.00
Seroma	0	0	1.00
Anastomotic insufficiency	2 (10%)	5 (25%)	0.41
Partial flap loss/necrosis	0	0	1.00
Total flap loss	0 (0%)	3 (15%)	0.23
Amputation of limb	0	1 (5%)	1.00

P values calculated with Fisher's exact test.

days), and minutes to hours postoperatively in the Cook–Swartz probe group (mean 0.5 days). These three factors all point to an earlier time course to the detection of anastomotic insufficiency with the Cook–Swartz probe over clinical monitoring alone. Of further note, is that one of the flap failures in the clinically monitored group resulted in amputation of the limb (the only amputation in the cohort). There were no limb amputations in the implantable Doppler probe group.

DISCUSSION

Free microvascular tissue transplantation to the lower limb is associated with higher rates of thrombotic complications when compared with other body regions.[12–14] In addition to the nature of the injuries requiring reconstruction (contaminated, infective, traumatized tissues), the inherently high venous pressures in the lower limb and the use of compression dressings and mobilization can further increase these pressures.[1,2] The potential impairment to flap viability can thus result in partial or complete flap loss.[15,16] Flap loss in this setting can necessitate amputation of the limb, with amputation rates as high as 18% reported.[17] While the success of elective free flaps in other body regions frequently reaches 98%, such as in autologous breast reconstruction,[18] failure rates as high as 20% have been reported for free flaps to the lower extremity.[19,20] The failure rates in the current study are thus highly comparable with the literature, with an overall flap survival of 93%.

By monitoring the vascular pedicle of these free flaps, occlusive events (such as arterial or venous thrombosis, external compression, or kinking of the pedicle) can be detected at an early stage and rapid return to theater potentiated. Occlusive events can risk the success of a free flap, and there is good evidence that the length of time that a flap remains compromised dictates the ultimate survival of that flap.[21–25] Although it is not possible in this clinical study to identify the exact time that pedicle occlusion began in any single case, there is ample evidence in these studies to show that early identification of impaired flap viability can potentiate return to theater and an improved rate of flap salvage.[21–25] Effective monitoring of a flap will further improve this, causing an earlier detection of pedicle compromise and resulting in an improved flap salvage rate. In the current study, the improved flap salvage rate seen in the Cook–Swartz implantable Doppler probe group thus reflects an earlier detection of flap compromise, earlier return to theater and improved ability to reverse ischemia by returning pedicle flow.

Clinical monitoring has formed the basis of such monitoring techniques in the past, and is still largely the gold standard even today. Temperature, skin color, capillary refill, active bleeding, tissue turgor, and the use of the handheld Doppler probe are all useful for monitoring flaps.[3,4] These techniques are simple to use, inexpensive, non-invasive and reproducible. However these techniques require interpretation by experienced staff, and require the same staff member to repeat the examination in order to avoid interobserver variability. Overnight particularly, subjective interpretation and varying levels of experience of medical and nursing personnel can contribute to inaccuracies in monitoring. The subtle nature of these signs is certainly a factor in late presentations, and timely detection even by experienced staff is often missed.

In addition to observer-based inaccuracies with clinical assessment, there are inherent problems with clinical assessment. Interpretation of skin color is subjective, and is influenced by pigmentation and lighting conditions.[26] Differences in the skin color between donor and recipient sites can also confound. Furthermore, the monitoring of capillary refill can be difficult with darker skin. Surface skin temperature can be influenced by environmental factors, core temperature, and dressings, with temperature often considered an unreliable indicator of flap perfusion.[27] If flaps lose their sensory innervation, central thermoregulation to the flap is lost, further contributing to dissimilarities between flap temperature and surrounding tissues.[28] Clinical assessment is performed intermittently, often used 0.5–1 hourly for the first 24–48 hours and reducing thereafter.

The Cook-Swartz implantable probe provides an alternative to clinical assessment. In theory, the implantable Doppler detects impairment to pedicle flow, and may detect flap compromise before clinical ischemia becomes evident. The Doppler signal is a continuous monitor, and can be assessed continuously or intermittently, without any need for waking the patient or any contact with the patient. While other studies have demonstrated the value of the Cook–Swartz Doppler probe in the salvage of failing flaps, the current study has demonstrated this effect in the unique setting of lower limb free flaps.[7–11] As discussed, lower limb flaps comprise a distinctive group in that these are often emergency cases, in the presence of trauma, vascular injury or infection, and may be associated with peripheral vascular disease. In addition, the physiology of these flaps include inherently high venous pressures in the lower limb due to gravitational effects, potentially incompetent veins and relative dependant edema.[1,2] Both dressings and mobilization (dependency) can further increase these pressures, potentially impairing flap viability, which in the lower limb setting may lead to limb amputation if flap failure ensues.

In our series, the probe was applied to the venous pedicle, with previous studies showing that the venous signal is lost within minutes of loss of either venous or

arterial flow.[10,29] As a routine, we only perform clinical assessment in cases of impaired Doppler signal, and we have never had a false negative in over 200 cases of the use of the Cook–Swartz probe. We use continuous monitoring intraoperatively, during flap insetting and closure, and as shown in the case described, this has potentiated revision in the setting of any changes in character or intensity of the signal. In such cases, kinking, compression or suturing of the pedicle may have occurred, and signal changes can precipitate the removal of sutures and inspection of the anastomosis. We continue continuous monitoring in the immediate postoperative period, and use intermittent audible signals as the basis for clinical flap monitoring for the first postoperative week. There is a short learning curve for medical and nursing staff, and even patients can actively participate in their own flap monitoring. We have found patients find reassurance in the clear audible signal of the Doppler, and use the signal in-between monitoring times. The strong trend towards early flap salvage (an improvement from 40% to 100% salvage) was limited in statistical significance by the power of the study (only seven take-backs). With larger numbers potentially proving the effect of improved flap salvage, further study is ongoing.

There are few disadvantages described in using an implantable Doppler probe. The cuff itself has the potential to be applied incorrectly, as mentioned previously, with a tight cuff potentially causing venous outflow obstruction, while a loose cuff potentially causing false-positive or false-negative results. Experience is the most important factor in minimizing application problems, and we have found the use of microclips to be highly useful to achieve the appropriate tightness during application. The major limitation of the use of the implantable Doppler probe is the increased financial cost associated with its use. The Cook–Swartz implantable Doppler system itself costs US$3,000 (reusable) and the disposable probes cost US$250 per patient. Of course, this needs to be evaluated in the context of the cost savings associated with potentially salvaging 60% more flaps.

The complete loss of the Doppler signal occurred in two patients in the current series, and in both cases the early detection of compromise enabled flap salvage. In both cases, the probe detected flow abnormalities before clinical signs were evident. As we leave the implantable probe in situ for 4 weeks postoperatively, we have encountered additional benefits of the probe. During dressing changes, both inpatient and outpatient, the probe is used as a direct monitor for the degree of compression to be used in dressings. In many cases, the signal has become markedly altered or lost by overly tight dressings and we have been able to adjust accordingly. Similarly, during physiotherapy and rehabilitation, the probe is able to guide the degree of knee and ankle movement, the amount of weight bearing and the degree of mobilization. With these techniques we have been able to mobilize patients earlier than previously in a safe fashion due to the ability of direct pedicle monitoring. In addition, the implantable probe is useful for buried flaps, where there is no skin paddle available for monitoring.

CONCLUSION

The current study presents our experience with the use of the Cook–Swartz implantable Doppler probe for the monitoring of lower limb free flaps, comparing this group with an equivalent group of patients in whom routine clinical assessment was used. Although not statistically significant, a trend toward early detection and salvage of flaps with anastomotic insufficiency was seen with the use of the implantable Doppler probe. One flap loss in the clinically monitored group resulted in limb amputation (the only amputation in the cohort), with no amputations in the implantable Doppler probe group. These findings suggest a benefit of this technique as a stand-alone or adjunctive tool for the clinical monitoring of free flaps, and suggests that further investigation is warranted into the broader application of these devices.

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