

Postoperative Monitoring of Free Flaps in Autologous Breast Reconstruction: A Multicenter Comparison of 398 Flaps Using Clinical Monitoring, Microdialysis, and the Implantable Doppler Probe

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ABSTRACT

Many techniques for flap monitoring following free tissue transfer have been described; however, there is little evidence that any of these techniques allow for greater rates of flap salvage over clinical monitoring alone. We sought to compare three established monitoring techniques across three experienced microsurgical centers in a comparable cohort of patients. A retrospective, matched cohort study of 398 consecutive free flaps in 347 patients undergoing autologous breast reconstruction was undertaken across three institutions during the same 3-year period, with a single form of postoperative monitoring used at each institution: clinical monitoring alone, the Cook-Swartz implantable Doppler probe, or microdialysis. Both objective and subjective measures of efficacy were assessed. Clinical monitoring alone, the implantable Doppler probe, and microdialysis showed statistically similar rates of flap salvage. False-negative rates were also statistically similar (only seen in the clinically monitored group). However, there was a statistically significant increase in false-positive alarms causing needless take-backs to theater in the microdialysis and implantable Doppler arms, $p < 0.001$. This study did not find any technique superior to clinical monitoring alone. New monitoring technologies should be compared objectively with clinical monitoring as the current standard in postoperative flap monitoring.

KEYWORDS: Breast reconstruction, deep inferior epigastric artery, DIEP flap, perforator flap, superficial inferior epigastric artery perforator flap, Cook probe

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J Reconstr Microsurg 2010;26:409–416. Copyright © 2010 by Thieme Medical Publishers, Inc., 333 Seventh Avenue, New York, NY 10001, USA. Tel: +1(212) 584-4662.

Received: December 10, 2009. Accepted after revision: January 21, 2010. Published online: March 10, 2010.

DOI: <http://dx.doi.org/10.1055/s-0030-1249607>.

ISSN 0743-684X.

Microsurgical free tissue transfer is widely used internationally, and many authors now consider fasciocutaneous flaps such as the deep inferior epigastric artery flap to be the gold standard in breast reconstruction. Increased experience with these procedures and advances in preoperative planning have potentiated published flap loss rates of lower than 2%.¹⁻⁵ Preoperative assessment of flap vasculature has been shown to be useful in improving surgical outcomes and flap selection,⁶ and the intraoperative evaluation of vascular pedicles has allowed for greater confidence in the viability of large free flaps.^{7,8}

Despite these advances, there is a low but significant risk with any such operation that arterial or venous compromise may occur, which will warrant a revision of the microsurgical anastomoses. With the potential for either flap salvage or flap loss, prompt and effective postoperative evaluation of flap viability is essential, and may potentiate early intervention. Whereas the no-reflow phenomenon will still mean that flaps are lost regardless of the microsurgeon's experience, optimal methods for postoperative monitoring of free flaps are being increasingly sought.

A broad range of different technologies have been discussed for postoperative monitoring, but few studies use a relevant clinical outcome as the primary endpoint of the trial, and as such there is little evidence for any single technique. This is reflected in the wide variety of techniques currently used in this role: clinical monitoring alone, pulse oximetry, near infrared spectroscopy, perfusion photoplethysmography, surface temperature measurement, fluorometry, microdialysis, ultrasound, the hand-held Doppler probe, implanted (Cook-Swartz) Doppler probes, laser Doppler flowmetry, impedance plethysmography, confocal microscopy, nuclear medicine, subcutaneous pH measurement, hydrogen clearance, externalization of part of a buried flap, and white light spectrometry. Surveys of plastic surgical units across the United Kingdom showed that there is substantial variation in the methods, organization, and implementation of monitoring techniques following free tissue transfer.⁹⁻¹¹

The need for the earliest possible detection of free flap compromise has been widely shown to be an essential element in salvage, with the no-reflow phenomenon, first described in 1978,¹² showing that flap salvage was closely related to ischemic time. Recent publications confirm that flap survival is dependent on ischemic time,^{3,13-16} reiterating the need for optimal methods for postoperative monitoring. Creech and Miller in 1975¹⁷ outlined the essential criteria for free flap monitoring:

- Simple and harmless to the patient and flap;
- Rapid, repeatable, reliable, recordable, and rapidly responsive;

- Accurate and inexpensive;
- Objective and applicable to all kinds of flaps; and
- Equipped with simple displays that could alert relatively inexperienced personnel.

Although operating techniques have changed since these criteria were first devised, they still aptly describe the issues that prospective monitoring techniques must address.

As yet, there is no proven method that satisfies all of these criteria, and thus surgeons currently choose techniques based on cost, availability, and the method that satisfies their priorities in postoperative care. A recent single surgeon cohort study comparing the implantable Doppler probe with clinical assessment demonstrated an improvement in outcome measures with the implantable Doppler probe,¹⁸ and we sought to further this analysis by comparing the use of three established monitoring techniques across three experienced microsurgical centers in a recent and comparable cohort of patients. Thus, this study, using the three different techniques (the implantable Cook-Swartz Doppler probe, microdialysis, and clinical monitoring alone) as the primary mode for postoperative monitoring, was designed. All these techniques have been previously shown to accurately predict the onset and existence of flap compromise.

METHODS

Study Design

A retrospective, matched cohort study of 398 consecutive free flaps in 347 patients undergoing autologous breast reconstruction was undertaken across three institutions during the same 3-year period, with a single form of postoperative monitoring used at each institution. Only fasciocutaneous flaps (per the Mathes and Nahai classification¹⁹) for breast reconstruction were included, all of which were suitable for monitoring with each of the techniques assessed. These comprised deep inferior epigastric artery perforator flaps (Types B and C fasciocutaneous flaps), superficial inferior epigastric artery flaps (Type A fasciocutaneous flaps), and superior gluteal artery perforator flaps (Type C fasciocutaneous flaps) (see Table 1). No buried flaps were included in the series. Of the 398 flaps monitored, 235 were monitored with clinical assessment only (Fig. 1), 121 were monitored with the Cook-Swartz implantable Doppler probe (Cook Medical, Cook Ireland Ltd, Limerick, Ireland) (Fig. 2), and 42 were monitored with microdialysis (CMA-Microdialysis AB, Solna, Sweden) (Fig. 3). Institutional ethical approval was obtained, with each patient consenting to the use of each monitoring technique.

Table 1 Patient Demographics Comparing the Three Monitoring Technique Groups

Patient Demographics	Clinical Assessment	Cook-Swartz Implantable Doppler Probe	Microdialysis
Number of patients	202	103	42
Number of breast reconstructions	235	121	42
Sex (% female)	100	100	100
Number of DIEP flaps	225	106	42
Number of SIEA flaps	10	15	0
Number of SGAP flaps	0	4	0

DIEP, deep inferior epigastric artery perforator; SGAP, superior gluteal artery perforator; SIEA, superficial inferior epigastric artery.

Each monitoring technique was applied according to criteria dictated by the individual unit, with no required standard in technique. Clinical monitoring was achieved through the assessment of the color, temperature, tactility, capillary refill, bleeding, and appearance of the flap. The Cook-Swartz probe silicone



Figure 1 Immediate postoperative photograph of a deep inferior epigastric artery perforator (DIEP) flap being monitored with clinical monitoring alone.



Figure 2 Immediate postoperative photograph of a deep inferior epigastric artery perforator (DIEP) flap being monitored with the Cook-Swartz implantable Doppler probe.

cuff was applied to the venous pedicle following successful venous anastomosis (per manufacturer and literature specifications). Application was always distal to the anastomosis, and microclips were used for attachment. The probe was left in situ for at least 1 week during the monitoring period and then removed. Microdialysis probes were applied to varying regions of the flap based on surgeon preference, with lactate, glucose, glycerol, and pyruvate measured.

A comparison between the three techniques for postoperative monitoring was performed. This included a comparison of demographic data, rates for return to theater (take-back rates), the salvage rates for those flaps returned to theater, and ultimate flap outcome in all cases. Of note, there were no logistical or other delays in returning to theater in any of the groups once the decision to return to theater had been made.

Data Analysis

The data were presented quantitatively, with all outcomes and the need to take-back recorded per flap, and the salvage rates recorded as the ultimate clinical outcome per flap. Each flap being monitored was recorded as either encountering a positive monitoring alarm or not encountering an alarm, with findings at theater noted



Figure 3 Photograph of a deep inferior epigastric artery perforator (DIEP) flap being monitored with microdialysis. The photograph is taken at the end of a reexploration performed on the third postoperative day based on microdialysis values.

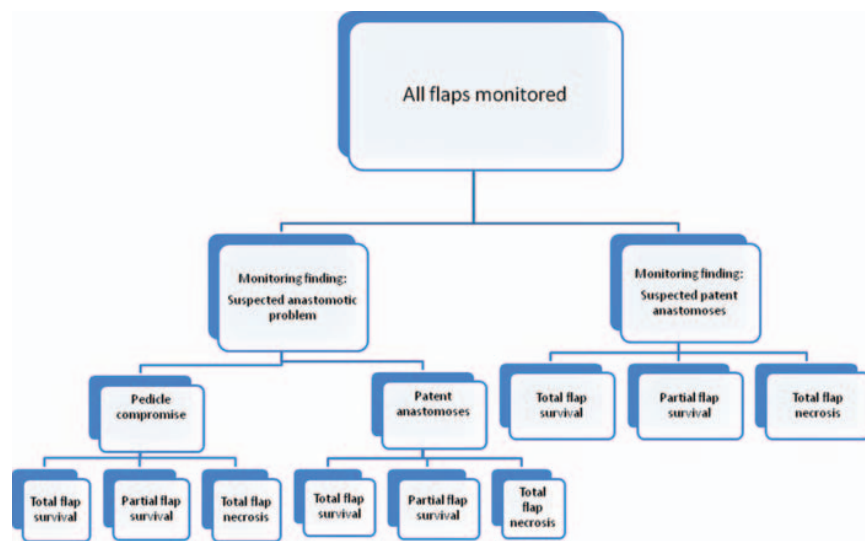


Figure 4 Flow chart for the recording of outcomes for each flap monitored, with each flap being recorded as either encountering a positive monitoring alarm or not encountering an alarm, with findings at theater noted, and ultimate outcomes recorded for each group.

and recorded in a flow chart (Fig. 4). True-positives comprised flaps in which positive monitoring alarms were found to have true pedicle compromise, false-positives comprised flaps in which positive monitoring alarms were found to have no pedicle compromise, true-negatives comprised flaps in which there were no alarms and flaps survived, and false-negatives comprised flaps in which there were no alarms but flaps ultimately failed.

Outcome Measures

The primary outcome measure in comparing techniques comprised “objective” assessments of monitoring efficacy, as previously outlined by Whitney et al and Lineaweaver.^{20,21} Unlike other diagnostic tests, in which sensitivity and specificity are the most useful measures of efficacy, monitoring is “time dependent,” in that *all* monitoring tests will eventually show a positive result; however, it is the time course to this result that affects free flap outcomes. As such, the “flap salvage rate” for flaps returned to theater (with early intervention resulting in flap salvage) and the false-positive rate (the limitation of a given technique being unnecessary returns to theater) are the two most important measures of efficacy. Of note, these calculations are true measures of efficacy because they are independent of surgeon decision making.

A secondary outcome measure comprised the false-negative rate, which although theoretically may be a measure of monitoring efficacy, is dependent on surgeon decision making because the decision to take a flap to theater for revision changes this measure (a failing flap could be categorized as either true-positive if taken back to theater or false-negative if not taken back).

Decisions such as this should clearly not influence an objective measure of monitoring efficacy, and thus such cases are more accurately represented by reducing the flap salvage rate of the given monitoring technique. Finally, the qualitative (subjective) benefits of the use of each monitoring technique were evaluated.

The flap salvage rate was calculated as a quotient of all flaps with true pedicle compromise that ultimately survived and all flaps with true pedicle compromise (all true-positives and all false-negatives). The false-positive rate was calculated as a quotient of all flaps with positive monitoring alarms that were found to have no pedicle compromise (false-positives) and all flaps with no pedicle compromise (all false-positives and all true-negatives). The false-negative rate was calculated as a quotient of all flaps without monitoring alarms that were found to have pedicle compromise (false-negatives) and all flaps with pedicle compromise (all false-negatives and all true-positives).

Data for each monitoring group were analyzed for statistical significance performed using the Fisher exact test. Statistical significance was considered at $p \leq 0.05$.

RESULTS

The three groups analyzed were comparable in terms of patient cohort and operative technique (Table 1). Although there were differences between institutions in patient volume and experience with breast reconstruction, all institutions were experienced microsurgical centers with significant experience in a range of microsurgical procedures.

There were 28 flaps in the series that required take-back to theater on the basis of positive monitoring

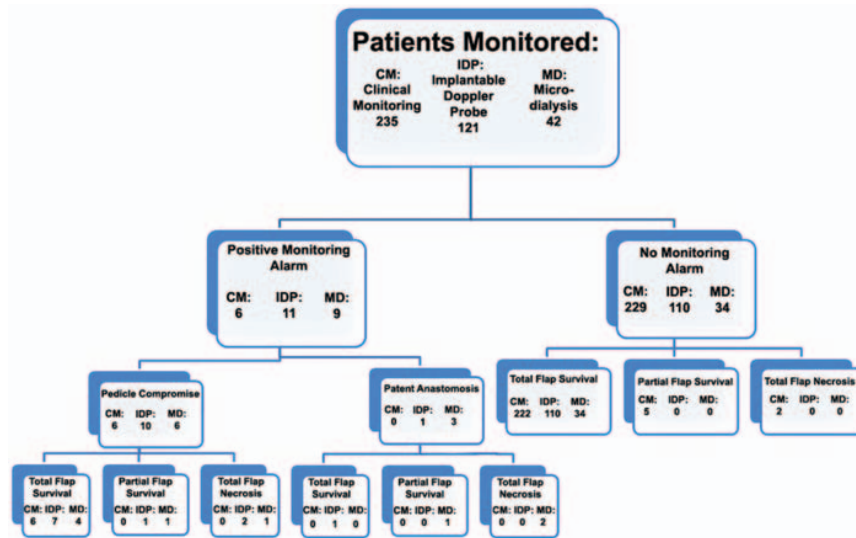


Figure 5 Flow chart for the recording of outcomes for each flap monitored. CM, clinical monitoring; IDP, implantable Doppler probe; MD, microdialysis.

test findings. Of the eight such cases that were monitored clinically (Fig. 5), two did not return to theater before there was evidence of flap necrosis (false-negatives), whereas six returned for venous compromise and were all salvaged. Of the 11 cases monitored with the implantable Doppler probe, 8 were revised and salvaged, 2 were unsalvageable, and 1 was a false-positive monitoring alarm. Of the nine cases monitored with microdialysis, five were salvaged, one failed, and three were false-positive alarms, with only territorial issues identified.

In terms of the primary outcome measure, there were statistically significant differences between the groups (Table 2). There was no significant difference in salvage rates between the three groups, with high salvage rates in all groups (range 75 to 83%, $p = 0.93$). However, a significant difference was found between groups in terms of false-positive rates: with no false-positives in the clinically monitored group (0%), 0.9%

false-positives in the implantable Doppler group, and 8.1% false-positives in the microdialysis group ($p < 0.001$). In these cases, a patent flowing pedicle was identified upon return to the theater, but territorial congestion was noted.

In terms of the secondary outcome measure, there was no statistically significant difference between groups for the false-negative rate (see Table 2). In the clinically monitored group, there were two false-negatives but no flaps that failed after reexploration; on the other hand, there were no false-negatives in the other two groups but there were failed flaps following reexploration. As mentioned, the decision to reexplore a flap is based upon individual surgeon preference, and is not a true test of the monitoring technique because a “false-negative” may be equivalent to a “true-positive, unsalvageable flap,” if the decision to reexplore is not made.

The third outcome measure, the secondary measure of qualitative assessment in the use of these techni-

Table 2 Primary Outcome Measures 1 and 2: Quantitative Assessment of the Efficacy of each Monitoring Technique by Primary Outcome Measure 1, Flap Salvage Rate, and False-Positive Rate, and Primary Outcome Measure 2, Timing of Flap Loss – Flap Loss Rate after Attempted Salvage, and the Rate of Missed Flap Losses (the False-Negative Rate)

	Clinical Assessment	Cook-Swartz Implantable Doppler Probe	Microdialysis	p Value
Primary Outcome Measures				
Flap salvage rate (salvaged flaps/compromised flaps) (n, %)	6/8 = 75%	8/10 = 80%	5/6 = 83%	0.93
False-positive rate (false-positives/uncompromised flaps) (n, %)	0/227 = 0%	1/111 = 0.9%	3/37 = 8.1%	<0.001
Secondary Outcome Measure				
False-negative rate (false-negatives/compromised flaps) (n, %)	2/8 = 25%	0/10 = 0%	0/6 = 0%	0.11

ques, demonstrated each technique to have positive and negative attributes. The particular benefits of clinical monitoring are cost and the ability to readily distinguish territorial compromise, whereas the implantable Doppler probe and microdialysis improve patient comfort during assessment and provide an objective monitor. The implantable Doppler probe uniquely avoids any physiologic or sampling delay in diagnosis by providing an instantaneous measure of pedicle flow.

DISCUSSION

The results of this study demonstrate both the utility and pitfalls of each different monitoring technique in the postoperative monitoring of free flaps. This study demonstrated that the use of microdialysis and the implantable Doppler significantly increases the rate of unnecessary take-backs to theater (the false-positive rate) over the use of clinical monitoring alone. This is in the context of both the implantable Doppler probe and microdialysis not significantly improving the salvage rate of free flaps or false-negative rate (although false-negatives were eliminated in these groups). Both benefits and pitfalls of each of the techniques evaluated were identified, and the evaluation of objective outcomes showed that neither adjunctive technique was superior to clinical monitoring alone.

Implantable Doppler Probe

The implantable Doppler probe manufactured by Cook has gained recent attention in the plastic surgery literature.^{5,22-30} The first attempts to utilize an implantable Doppler probe for free flap monitoring was in 1984, by Parker et al,²⁹ and soon thereafter the Cook-Swartz probe was developed in 1988 specifically for use in free flap operations.³⁰ It was initially used on the arterial pedicle, but subsequent studies showed it to be more sensitive when placed on the venous anastomosis, particularly for the detection of venous thrombosis.²³ A study by Kind et al²⁷ of 135 free flap operations in 1998 showed that the Cook-Swartz probe produced a high false-positive rate (20% of positive results, with a 2.9% false-positive rate as calculated by our method) and no false-negative results. All of the 16 compromised flaps were salvaged. The use of the probe was well received by all junior and senior medical staff and nursing staff. Results similar to those of Kind et al were seen in a separate analysis of the Cook-Swartz arm of our study.²⁵ The Cook-Swartz probe does have a small false-positive rate,^{25,27} and initial studies were associated with a low rate of probe malfunction, which was thought to be due to a learning curve for surgeons in applying the probe^{23,29,30} (problems pertaining particularly to probe placement). Rosenberg et al³¹ found a high false-positive rate of 88%, which was actually 37%

as calculated by our method, but no other trial has replicated a false-positive rate as high as this. It is difficult to ascertain why this result was so much higher than other reported rates, but the learning curve could play a part because only 20 cases of implanted Doppler monitoring were presented. These results by Rosenberg et al also applied to a diverse range of flap types and recipient sites making interpretation difficult. A recent large cohort study demonstrated an improvement in flap salvage rate with the Cook-Swartz probe over clinical monitoring alone, and a meta-analysis of the literature confirmed the statistically significant benefit of the Cook-Swartz probe over clinical monitoring.¹⁸

Microdialysis

This technique was first described in the setting of free flap monitoring by Udesen et al,³² who described the use of a double lumen catheter with a semipermeable membrane at the end. This catheter is placed within the flap to be monitored (see Fig. 3), and a small amount of fluid is pumped through the catheter. As this fluid passes through a semipermeable membrane, small molecules pass into the dialysate, which are then analyzed. The levels of certain metabolites within the transferred tissue are used to ascertain the metabolic state of that tissue. There are many molecules capable of being assessed with microdialysis, with typical metabolites comprising lactate, glucose, glycerol, and pyruvate.³²⁻³⁵ Udesen et al used a similar catheter placed elsewhere in the body for a reference comparison, whereas some later studies have simply compared results with reference values or used increasing lactate:pyruvate ratios as a measure of ischemia. Authors have generally agreed that microdialysis provides a timely and sensitive indication of flap ischemia. Studies comparing different flaps and regions within flaps have shown significant differences in microdialysis results,³³ an illustration of the sensitivity of this technique. Sorensen³⁵ successfully used microdialysis in buried free jejunal transfers to identify early flap compromise, salvaging two such transfers. Jyränki et al³⁴ reported a case series of free flaps monitored with microdialysis, and reported two cases in which metabolic change occurred before clinical signs; however, both flaps were unsalvageable upon reexploration.

The mechanisms of action of each technique assessed in this study may explain our findings. The implantable Doppler probe measures and records flow within the vascular pedicle, and is thus an immediate reflection of impaired flow.^{23,28} This occurs before clinical signs of ischemia become evident, and possibly earlier than the measurable biochemical markers of ischemia change. Microdialysis requires the biochemical markers of ischemia to rise, and requires a time delay (albeit small) for collection, testing, and the representation of results in graphical form. Clinical assessment can

demonstrate early changes in perfusion that may reflect flap ischemia; however, this occurs some time after flow is noted to be reduced on Cook-Swartz Doppler monitoring.²³ As such, there are intuitive benefits of the implantable Doppler probe over microdialysis, broadly categorized as physiologic error and sampling error. Physiologically, the Doppler probe can identify impaired pedicle flow substantially earlier in the course of venous compromise than the measurable effects of tissue necrosis as with microdialysis. In terms of sampling error, the implanted Doppler probe provides a continuous measurement of pedicle flow (although in practice it is often tested intermittently), compared with the static evaluation with clinical assessment (as it is usually performed) and microdialysis, at given points in time. This error is compounded with microdialysis because there is an "analysis" period even after the sample has been collected. These factors are all contributors to a reduction in the time to detection of flap ischemia, extending the time between ischemic onset and reexploration, which is known to be a key factor in the salvage rate for free flaps.^{3,12-16}

Although we have assessed these techniques on "objective" clinical criteria, in which we have explained the benefit of flap salvage rate and false-positive rate as the most objective, monitoring methods are not necessarily to be judged on a single set of clinical criteria alone. Other factors, such as ease of use, patient comfort, and cost come into play. In addition, the ability of clinical monitoring to distinguish between "territorial" compromise and "obstructive" compromise is a key factor in minimizing false-positives, and selecting those cases for which any intervention is appropriate.

The current trial does not identify either adjunctive method as producing a better clinical outcome when compared with subjective clinical monitoring alone. In fact, comparisons of large studies using different monitoring techniques have revealed similar flap success rates (98 to 99%) and salvage rates (up to 80%), regardless of the monitoring system used.¹⁻⁵ In our study, we compared the techniques as stand-alone measures; however, an additional use for objective monitoring techniques is as an adjunct to clinical monitoring, providing added reassurance to clinical assessment and potentially improving outcome measures. When used as stand-alone measures, the implantable Doppler probe and microdialysis are capable of being used without the need to wake the patient, and thus avoid the sleep deprivation of half-hourly flap observations.

A unique group of microvascular transfers are more difficult to assess and thus have lower salvage rates.³ This group of "buried" free flaps cannot be easily monitored clinically, and several authors have advocated the use of adjunctive monitoring techniques in such flaps.¹ It is in this group that the results of this study

and those of the future studies on advanced monitoring techniques will become particularly applicable.

CONCLUSION

Many objective and subjective techniques for flap monitoring have been described to monitor free tissue transfers,³⁶ and despite significant research efforts, there has been little evidence that any of these techniques allow for greater rates of flap salvage over clinical monitoring alone. This study has shown that in the participating three international units, clinical monitoring alone, the Cook-Swartz implantable Doppler probe, and microdialysis showed statistically similar rates of flap salvage and false-negative rates (only seen in the clinical group). However, there was a statistically significant increase in false-positive alarms causing needless take-backs to theater in the microdialysis and implantable Doppler arms, $p < 0.001$. This study, thus, did not show any technique to be better than clinical monitoring alone. Future monitoring studies with clinically relevant results are advised, rather than just the publication of uncontrolled data with a single method.

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