The Efficacy of Clinical Assessment in the Postoperative Monitoring of Free Flaps: A Review of 1140 Consecutive Cases

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Background: Effective postoperative monitoring of the vascular pedicle to a free flap can potentiate rapid return to the operating room in the setting of compromise, allowing for the potential to salvage the flap. The only ubiquitous method for postoperative monitoring of free flaps is clinical bedside monitoring, but although the use of clinical monitoring may be inferred in large reported series of free flaps, there has been little discussed in the literature of specific clinical outcome measures.
Methods: The authors present their experience with 1140 consecutive cases of free tissue transfer and the use of clinical monitoring as a sole method of monitoring, and subgroup analysis of different recipient sites.
Results: There were 94 take-backs, four of which had no pedicle compromise (false-positives) and there were four false-negatives. The overall flap salvage rate was 62.8 percent and the false-positive rate was 0.4 percent. Subgroup analyses demonstrated statistically significant differences between recipient sites for the false-positive rates: fewer false-positives with breast reconstruction cases ($p < 0.05$) and significantly more false-positives in the extremity group ($p < 0.05$). There was an improved flap salvage rate in cases of venous compromise compared with arterial compromise (69 percent versus 51 percent, $p = 0.015$).
Conclusions: This largest reported series to date provides an outcome-based analysis of postoperative monitoring for free flaps, providing a benchmark standard against which adjunctive monitoring techniques can be compared. Future studies need to be assessed in the context of individual recipient sites, with significant differences in monitoring outcomes between sites. (*Plast. Reconstr. Surg.* 125: 1157, 2010.)

The vascular pedicle of a free flap needs to be monitored postoperatively because of the risk of an occlusive event, such as arterial or venous thrombosis, external compression, or kinking of the pedicle. Such an event plays a pivotal role in dictating the success of a free flap, and the length of time for which the flap remains compromised dictates the ultimate survival of that flap.[1–6] Effective monitoring of the vascular pedicle to a flap can potentiate rapid return to the operating room in the setting of compromise, allowing for the potential to salvage the flap.

The only ubiquitous method of monitoring free flaps postoperatively is the use of clinical bedside monitoring.[7,8] This practice involves the subjective evaluation of a range of factors, including flap appearance and color, capillary refill, temperature, bleeding time, and in selected cases, the use of a handheld Doppler ultrasound device. The fact that this is the only type of monitoring used by many centers clearly demonstrates the confidence that many surgeons have in the usefulness of clinical monitoring for early detection and intervention in the case of flap compromise.

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Some small studies have shown that several techniques allow for greater success than clinical monitoring in terms of the clinically relevant outcome of flap salvage rate,[9–11] but there are no larger scale trials supporting these studies. The paucity of high-level evidence for the use of expensive and sometimes invasive techniques has led to the noted widespread use of bedside monitoring, with some units using adjunctive techniques at the discretion of the surgeon.[7,8]

Monitoring on a regular basis with clinical monitoring for the first few days postoperatively has allowed some units to produce flap salvage rates of up to 80 percent and overall success rates of up to 99 percent.[1,12] The review of multiple large case series shows that salvage rates range from 40 to 80 percent and overall success rates range from 94 to 99 percent.[1,12–18] However, most of these case series have used adjunctive monitoring in some cases and, in some series of buried flaps, have elected to use no monitoring at all. In addition, they have not analyzed their data with objective measures of the success of their monitoring techniques.

Although the use of clinical monitoring may be inferred in reports of large series of free flaps, there has been little discussed in the literature regarding the specific clinical outcome measures with the use of clinical monitoring. We present our experience with free tissue transfer and the use of clinical monitoring as a sole method of monitoring, and subgroup analysis of different recipient sites.

PATIENTS AND METHODS

A retrospective analysis of a consecutive series of patients from two plastic surgical units was undertaken. All patients who underwent free flap operations that had been monitored clinically were included in the study. Patients who had been monitored using techniques other than those described above or who were not monitored at all were planned exclusions from our analysis, and this comprised five cases of buried flaps for head and neck reconstruction. The analysis was achieved by chart review.

Clinical monitoring comprised the bedside assessment of the color, temperature, tactility, capillary refill, bleeding, and appearance of the flap. Assessment began intraoperatively and was continued by both medical and nursing staff postop-

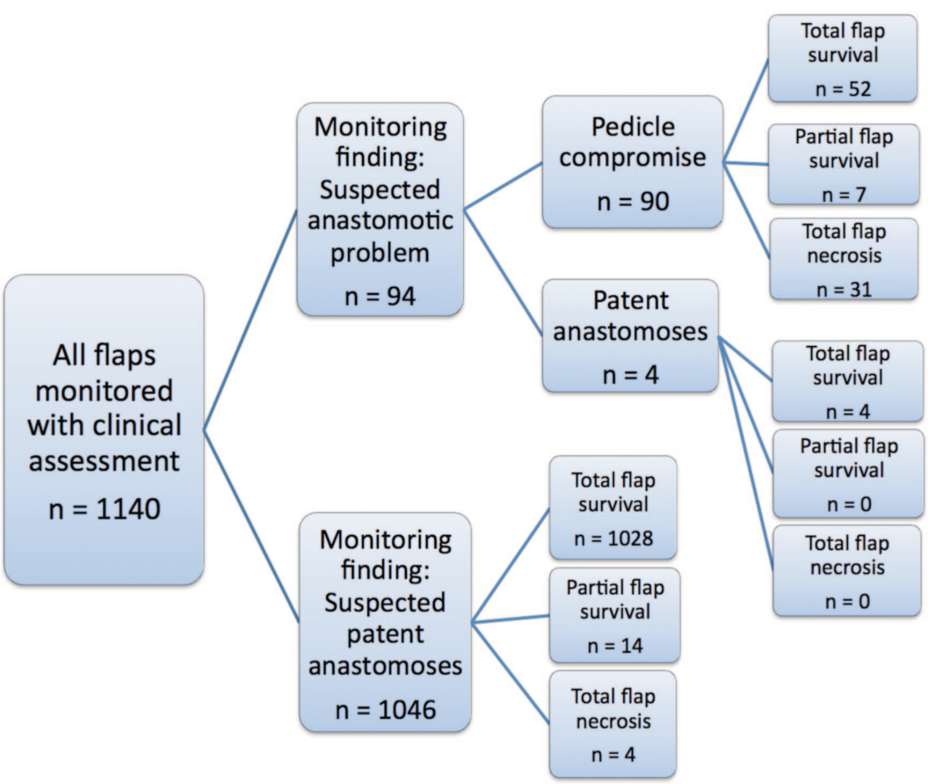

Fig. 1. Flow chart for the recording of outcomes for all free flaps monitored with clinical monitoring. Each flap being monitored is recorded as either encountering a positive monitoring alarm or not encountering an alarm, with findings in the operating room noted and ultimate outcomes recorded for each group.

eratively. The standard frequency of flap monitoring in all cases was half-hourly 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. Suspicion of flap compromise by either nursing or more junior medical staff resulted in consultation with senior medical staff, who bear the ultimate responsibility for decisions to reexplore the flap. No adjunctive monitoring tests were undertaken at any stage of the monitoring process or before a decision to reexplore the flap.

Patient records were assessed to determine the postoperative course after free flap surgery. Several factors were identified for each patient, including whether they were taken back to the operating room for presumed pedicle compromise, reoperative findings, and final outcomes of their operations.

Algorithm and Analysis

Each monitored flap was stratified according to the algorithm in Figures 1 through 4. Monitored flaps were identified as triggering a positive monitoring "alarm" (i.e., the clinical monitoring suggested an event of pedicle compromise requiring a return to the operating room for pedicle revision). Of the positive alarms, the findings in the operating room were then able to stratify these flaps into those cases with confirmed pedicle compromise and those without any pedicle compromise. Final flap outcomes were then documented.

Two primary outcome measures were assessed, comprising only the *objective* measures of monitoring outcomes, namely, the flap salvage rate and the false-positive rate. The flap salvage rate calculates the rate of salvaging those flaps for which there was a preventable outcome (i.e., the benefit of using a monitoring technique), and the false-positive rate calculates the rate of taking back flaps for which there was no need for intervention (i.e., the weakness of using a monitoring technique). The flap salvage rates and false-positive rates were calculated based on the algorithm shown, with the flap salvage rate calculated as the number of reexplored flaps that survived (total or partial survival) of the total number of reexplored flaps *plus* the number of failed flaps among those that were

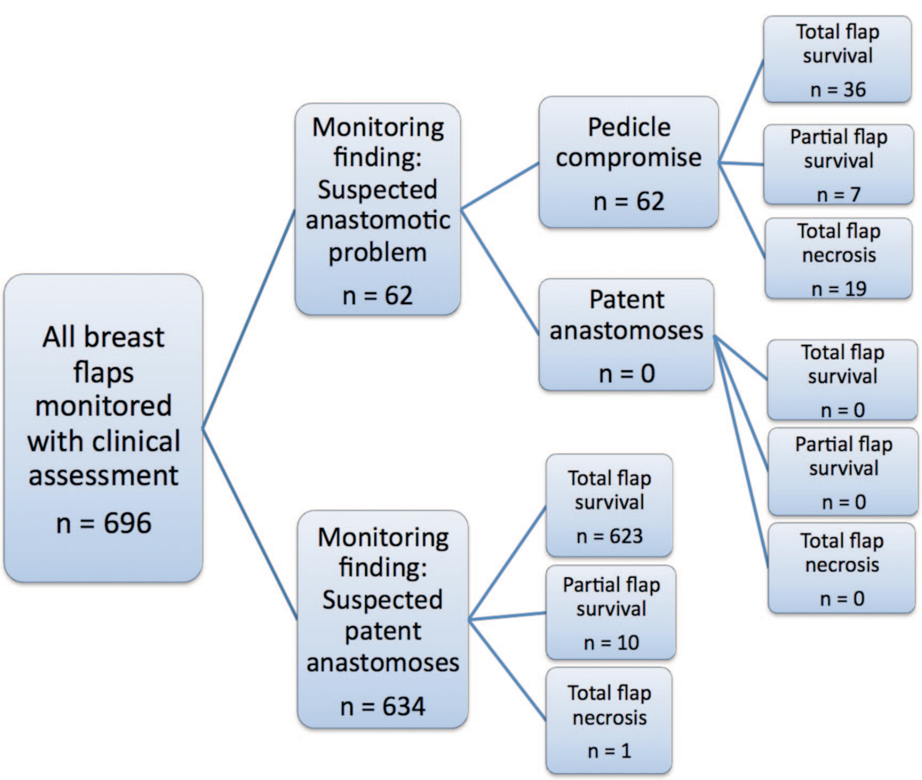

Fig. 2. Flow chart for the recording of outcomes for all breast reconstruction flaps monitored with clinical monitoring. Each flap being monitored is recorded as either encountering a positive monitoring alarm or not encountering an alarm, with findings in the operating room noted and ultimate outcomes recorded for each group.

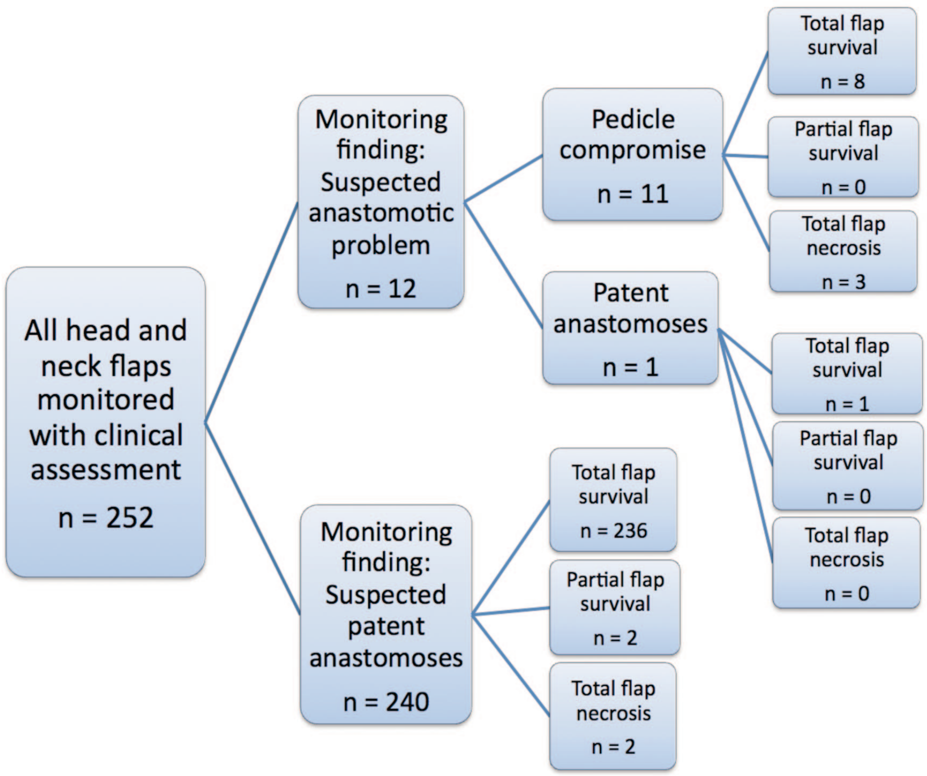

Fig. 3. Flow chart for the recording of outcomes for all head and neck flaps monitored with clinical monitoring. Each flap being monitored is recorded as either encountering a positive monitoring alarm or not encountering an alarm, with findings in the operating room noted and ultimate outcomes recorded for each group.

not reexplored. The false-positive rate is calculated as the number of false-positive flaps of the total number of flaps for which there was never a pedicle problem (false-positives *plus* true-negatives). Both of these measures are aimed at demonstrating the effectiveness of the monitoring technique when compared with no monitoring at all.

The false-negative rate was *not* included, as this calculation is dependent on surgeon decision making; that is, if a flap is ultimately failing because of pedicle compromise (and not salvaged), the decision to take the flap to the operating room for revision would yield a *true-positive* result but the decision to not take it back to the operating room would yield a *false negative* result. This decision clearly should not influence the objective measure of monitoring efficacy, and thus the case is more accurately represented by reducing the *flap salvage rate* of the given monitoring technique, regardless of decision.

RESULTS

The study comprised 1140 consecutive free flaps for a range of reconstructive procedures (Table 1). These procedures were classified by recipient site into breast reconstruction (696 flaps), head and neck reconstruction (252 flaps), and extremity reconstruction (192 flaps). The donor site and flap type for each case are listed in Table 1, with the deep inferior epigastric artery perforator flap constituting a majority of the breast reconstruction cases; the anterolateral thigh, radial artery forearm, and fibula flaps being the more common flaps for head and neck reconstruction; and the latissimus dorsi and anterolateral thigh flaps being more common for extremity reconstruction. Of the 1140 flaps, 94 were taken back to the operating room; four of these had no pedicle compromise (false-positives). There were four false-negative results in our study. Of the 94 flaps with pedicle compromise, 59 (66 percent) were salvaged, with an overall success rate of 97 percent (Table 2).

Subgroup analyses were then performed, comparing groups based on the flap recipient site (Figs. 1 through 4). The analysis of flap subtype demonstrated no significant difference between subgroups in flap salvage rate. However, there

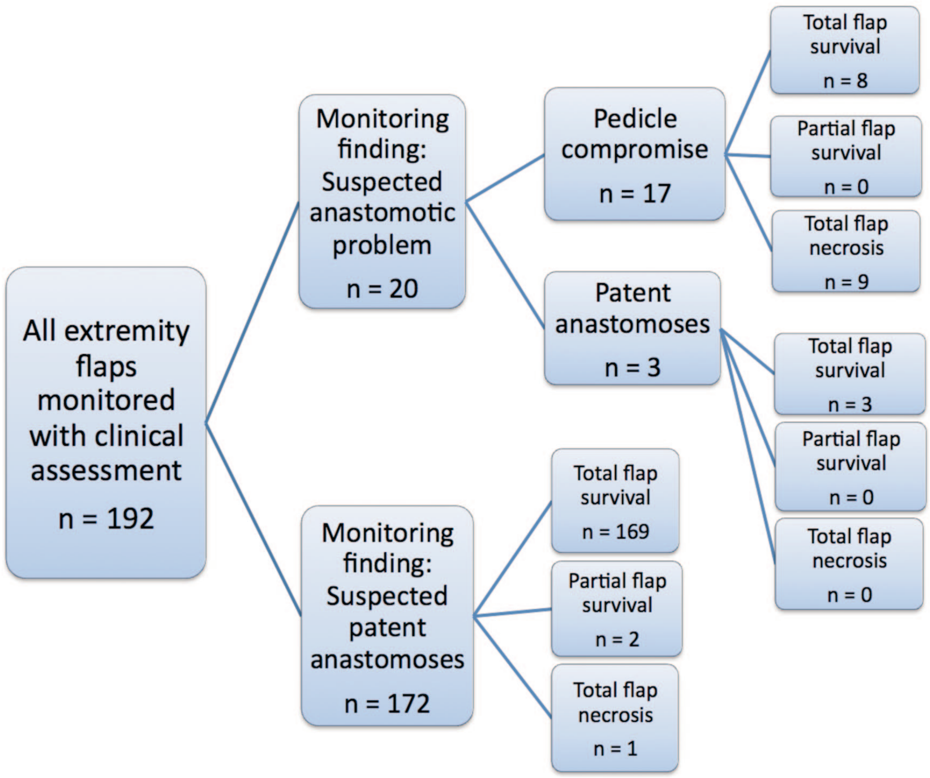

Fig. 4. Flow chart for the recording of outcomes for all extremity flaps monitored with clinical monitoring. Each flap being monitored is recorded as either encountering a positive monitoring alarm or not encountering an alarm, with findings in the operating room noted and ultimate outcomes recorded for each group.

were statistically significant differences between recipient sites for the false-positive rates; there were significantly fewer false-positives for breast reconstruction flaps (0 percent versus 0.4 percent, $p < 0.05$) and significantly more false-positives in the extremity group (1.7 percent versus 0.4 percent, $p < 0.05$). Table 2 summarizes the operative and reoperative outcomes.

A further subgroup analysis was performed, comparing groups based on the ultimate cause for pedicle compromise. Table 3 demonstrates the range of causes for pedicle compromise overall and when cases were stratified by flap recipient site, and Table 4 compares the flap salvage rates for each cause of pedicle compromise. Overall, there were no differences between the groups for the incidence of arterial and venous compromise (Table 5). However, there was an improved flap salvage rate in cases of venous compromise compared with arterial compromise (69 percent versus 51 percent, $p = 0.015$).

DISCUSSION

The results of the current study represent the largest reported series of the use of clinical monitoring in the literature and are in line with previously reported data in terms of take-back rates, salvage rates, and overall flap survival. We feel that they give a clear picture of the effectiveness of clinical monitoring in our units and that they are similar to the experience of other units that have predominantly used clinical monitoring.[12] The differences in salvage rates between recipient sites have been reported previously, although the differences were not as pronounced.[1]

These results highlight some problems with clinical monitoring. First, buried flaps are not amenable to many aspects of clinical monitoring, meaning that adjunctive techniques are more likely to be useful in this setting. We have also confirmed that extremity recipient sites are more likely to have problems associated with their monitoring. There was a statistically insignificant trend toward lower flap salvage rate in this subgroup, although the false-positive rate (and subsequent erroneous reoperation) was significantly higher. It is likely that the false-positive cases encountered were caused by mistaking dependent venous congestion of lower extremity flaps for pedicle com-

Table 1. Breakdown of Flap Donor Site for Each of the Flaps Included in the Study, Stratified According to Flap Recipient Site

Donor Site/Flap Type	Breast Reconstruction	Head and Neck Reconstruction	Extremity Reconstruction
Deep inferior epigastric artery perforator	643	1	4
Superficial inferior epigastric artery	20	—	2
Rectus abdominis myocutaneous	—	24	3
Groin	—	—	5
Inferior gluteal artery perforator	4	—	—
Superior gluteal artery perforator	25	—	—
Transverse upper gracilis myocutaneous	2	—	—
Gracilis	—	9	6
Anterolateral thigh perforator	2	45	43
Anteromedial thigh perforator	—	8	9
Fibula osteocutaneous	—	43	13
Deep circumflex iliac artery	—	15	2
Helical rim	—	3	—
Latissimus dorsi	—	15	43
Serratus anterior	—	2	6
Thoracodorsal artery perforator	—	—	1
Parascapular artery	—	5	9
Scapular artery	—	4	7
Circumflex scapular artery	—	2	—
Intercostal artery perforator	—	1	—
Jejunum	—	17	—
Toe	—	—	9
Fillet of sole	—	—	1
Dorsalis pedis	—	—	2
Medial gastrocnemius	—	2	—
Finger	—	—	1
Radial artery forearm	—	49	8
Lateral arm	—	7	18
Total	696	252	192

promise, and that the lower flap salvage rate of these flaps is attributable to the opposite problem, where dependant congestion is falsely assumed to be venous compromise. Clearly, this is a situation where careful monitoring is paramount and possibly another area where adjunctive monitoring can produce improved results. Extremity cases were also less likely to be elective cases, with trauma and infection often contributing to damaged microvasculature and macrovasculature. This highlights some other important factors involved in monitoring in addition to the test alone, including the level of surgical expertise, level of expertise with flap monitoring, and frequency of flap monitoring.

Our outcome-based data, which are based on clinical monitoring alone, allow for a benchmark standard against which monitoring techniques can be compared. These results allow scope for the evaluation of different adjunctive monitoring techniques. Future studies might use these results as a basis for power analyses to determine the number of failed flaps that need to be monitored before statistically significant results of different magnitudes would be detected.

Diagnostic tests used for many other fields are judged on specific criteria. These criteria include the sensitivity, specificity, false-positive rate, false-negative rate, positive predictive value, and negative predictive value. Sensitivity is defined as the proportion of tests on specimens that are affected by the disease in question (disease-positive) that return a positive result, whereas specificity is the proportion of disease-free specimens that return a negative result. False-negative rates and false-positive rates are, respectively, the inverse of sensitivity and specificity. Positive predictive value is calculated as the proportion of positive tests that are a true-positive result, whereas negative predictive value is the proportion of negative tests that are true-negative results.[19]

The use of appropriate analytical tools that measure the success of monitoring techniques is of paramount importance to any study of these techniques. Commonly used statistical analyses may not prove to be particularly useful comparators because of several factors. First, it is difficult to discriminate between false-negative results and late "true-positive" results, because in both of these groups, a failed or failing flap with the same ultimate outcome may be taken back to the operating room for attempted salvage or not be taken back at all. With the results of monitoring in

Table 2. Data and Outcomes from the Use of Clinical Monitoring, Both Overall and Stratified According to Flap Recipient Site*

	All Free Flaps (%)	Breast Reconstruction Flaps (%)	Head and Neck Reconstruction Flaps (%)	Extremity Reconstruction Flaps (%)
Raw data				
True-positives	90/1140 (7.9)	62/696 (8.9)	11/252 (4.4)	17/192 (8.9)
False-positives	4/1140 (0.4)	0/696 (0)	1/252 (0.4)	3/192 (1.6)
True-negatives	1042/1140 (91.4)	633/696 (90.9)	238/252 (94.4)	171/192 (89.1)
False-negatives	4/1140 (0.4)	1/696 (0.1)	2/252 (0.8)	1/192 (0.5)
Outcomes				
Overall success	1105/1140 (97)	676/696 (97) $p = 0.72$	247/252 (98) $p = 0.31$	182/192 (95) $p = 0.07$
Flap salvage rate (salvaged flaps/compromised flaps)	59/94 (62.8)	43/63 (68.3) $p = 0.29$	8/13 (61.5) $p = 1.0$	8/18 (44.4) $p = 0.10$
False-positive rate (false-positives/uncompromised flaps)	4/1046 (0.4)	0/633 (0) $p \leq 0.05$†	1/239 (0.4) $p = 1.0$	3/174 (1.7) $p \leq 0.05$†

*Overall success rates are compared, as are the primary outcome measures of efficacy (flap salvage rate and false-positive rate).
†Significance determined by Fisher's exact test, with the test performed between the comparison group and all flaps other than that group. Statistically significant findings are highlighted.

both cases resulting in the same outcome (flap failure), assigning either of these results to the monitoring technique becomes clinically irrelevant: it is a surgical decision and not a measure of the monitoring method. As a result, the use of sensitivity as a measure of successful monitoring becomes useless. The measures of positive predictive value and negative predictive value in this setting also require the inclusion of false-negatives and true-positives, both of which hinge on the prevalence of flap compromise and surgical decision making as described. The broad range of flap survival and flap reexploration rates among different units makes the use of positive predictive value and negative predictive value irrelevant as measures of a monitoring technique.

Despite these problems, there are two useful ways of evaluating the efficacy of a monitoring technique. The flap salvage rate is a measure of the benefit of the monitoring technique, calculating the rate of salvaging those flaps for which there was a preventable outcome. The false-positive rate is a measure of the weakness of incorporating a monitoring technique, calculating the rate of taking back viable flaps for which there was no need for intervention. The flap salvage rate was calculated as the number of reexplored flaps that survived (total or partial survival) of the total number of reexplored flaps *plus* the number of failed flaps among those that were not reexplored. The false-positive rate was calculated as the number of false-positive flaps of the total number of flaps for which there was never a pedicle problem (false-positives *plus* true negatives).

A simple analogy that has been discussed previously and that highlights the need to use objective outcome measures for the evaluation of monitoring techniques is the "green bean" hypothesis, proposed by Lineaweaver in his criticism of reports of monitoring technique "successes."[20] In discussing this hypothesis, a green bean is hypothetically placed on the surface of the flap, which is said to turn red if the flap becomes compromised. Clearly, this will never occur, and thus a nonfunctioning monitor is created. As a result, the green bean monitor will never result in a takeback, and will produce a 0 percent false-positive rate. However, as with other case series of nonmonitored flaps such as buried flaps,[12] there would be a concurrent 0 percent flap salvage rate as well. The aim of any monitoring technique should be to "beat the green bean" by allowing for timely attempts at flap salvage but ideally not at the expense of a high rate of unnecessary reexplorations. Although other attributes of monitoring

Table 3. Incidence of Each Cause of Pedicle Compromise, Stratified According to Flap Recipient Site*

	Incidence of Complication			
	All Free Flaps (%)	Breast Reconstruction (%)	Head and Neck Reconstruction (%)	Extremity Reconstruction (%)
Arterial compromise (overall)	53/1140 (4.6)	37/696 (5.3)	4/252 (1.6)	12/192 (6.3)
Arterial thrombosis	37/1140 (3.2)	27/696 (3.9)	3/252 (1.2)	7/192 (3.6)
Arterial spasm/kink/damage	5/1140 (0.4)	2/696 (0.3)	—	3/192 (1.6)
Combined arterial and venous thromboses	9/1140 (0.8)	6/696 (0.9)	1/252 (0.4)	2/192 (1.0)
Combined arterial and venous avulsion	2/1140 (0.2)	2/696 (0.3)	—	—
Venous compromise (overall)	52/1140 (4.6)	34/696 (4.9)	10/252 (4.0)	8/192 (4.2)
Venous thrombosis	34/1140 (3.0)	20/696 (2.9)	8/252 (3.2)	6/192 (3.1)
Venous compression	7/1140 (0.6)	6/696 (0.9)	1/252 (0.4)	—
Combined arterial and venous thromboses	9/1140 (0.8)	6/696 (0.9)	1/252 (0.4)	2/192 (1.0)
Combined arterial and venous avulsion	2/1140 (0.2)	2/696 (0.3)	—	—

Table 4. Flap Salvage Rate for Each Cause of Pedicle Compromise, Stratified According to Flap Recipient Site*

	All Free Flaps (%)	Breast Reconstruction (%)	Head and Neck Reconstruction (%)	Extremity Reconstruction (%)
	Overall Flap Salvage Rate (salvaged flaps/compromised flaps)			
Arterial compromise (overall)	27/53 (51)	21/37 (57)	0/4 (0)	6/12 (50)
Arterial thrombosis	19/37 (51)	16/27 (59)	0/3 (0)	3/7 (43)
Arterial spasm/kink/damage	5/5 (100)	2/2 (100)	—	3/3 (100)
Combined arterial and venous thromboses	1/9 (11)	1/5 (20)	0/1 (0)	0/2 (0)
Combined arterial and venous avulsion	2/2 (100)	2/2 (100)	—	—
Venous compromise (overall)	36/52 (69)	25/34 (74)	8/10 (80)	3/8 (38)
Venous thrombosis	26/34 (76)	16/20 (80)	7/8 (88)	3/6 (50)
Venous compression	7/7 (100)	6/6 (100)	1/1 (100)	—
Combined arterial and venous thromboses	1/9 (11)	1/5 (20)	0/1 (0)	0/2 (0)
Combined arterial and venous avulsion	2/2 (100)	2/2 (100)	—	—

Table 5. Statistical Comparison between Arterial and Venous Causes of Pedicle Compromise

	Overall Arterial Compromise (%)	Overall Venous Compromise (%)	*p**
Incidence of complication, no./total cases	53/1140 (4.6)	52/1140 (4.6)	0.920
Overall flap salvage rate, salvaged flaps/compromised flaps	27/53 (51)	36/52 (69)	
Incidence of complication, no./total cases	53/1140 (4.6)	52/1140 (4.6)	0.920
Overall flap salvage rate, salvaged flaps/compromised flaps	27/53 (51)	36/52 (69)	0.015†

*Significance determined by Fisher's exact test, with the test performed between the comparison group and all flaps other than that group.
†Statistically significant findings.

such as cost and ease of use are important, the green bean test is the simplest way of assessing the true efficacy of flap monitoring. There is a notable paucity of studies that use clinically relevant outcomes as their primary endpoints. Only three methods have demonstrated their efficacy through the use of flap salvage rate as a primary outcome: laser Doppler flowmetry, fluorometry, and implanted Doppler probes.[9–11] These studies were all of relatively small series of reexplored flaps ($n = 16$ in the largest case) that demonstrated higher salvage rates than the historical salvage rates for the particular unit managing the study.

The current study provides a detailed appraisal of the use of clinical monitoring. It is clear from our results that clinical monitoring can successfully salvage a substantial proportion of free flaps, without many unnecessary take-backs. Our study shows that the false-positive rate for clinical monitoring is very low, with less than 1 percent of all free flaps monitored explored unnecessarily. Our units have an overall salvage rate of 60 percent and, although this is not the highest reported salvage rate in the literature, matches many reported salvage rates in large case series.[1,12–18] No large studies using any technique have reported salvage rates above 80 percent. This reinforces our view that the best positive comparator of monitoring techniques is the flap salvage rate, as it is clearly the measure by which significant improvements can be made, and should be compared with the false-positive rate for any given monitoring technique.

The difference in salvage rates between venous and arterial thromboses was a notable finding in the current study, with the improved salvage of venous thromboses over arterial thromboses a finding similar to that reported in the literature.[1] Although our study could not definitively explain this phenomenon, there were several factors that we identified to likely be involved and that have also been identified in the literature previously. Venous thrombosis results in a dark, congested flap that is likely to be identified more easily and at an earlier time than the pale, ischemic flap that occurs with arterial thrombosis.[15,18] The edema and hematoma that may accompany venous congestion can also aid early diagnosis.[1] These clinical signs are likely to potentiate an earlier detection of flap compromise in cases of venous thrombosis and an earlier return to the operating room for exploration, with this earlier time course shown in the literature to improve salvage rates.[1,2,5,6]

Another major factor influencing operative success rates is the level of expertise within and between units. Large trials in experienced units have demonstrated salvage rates that vary between 40 and 80 percent,[1,12–18] although many units have reported gradual increases in success rates alongside increasing experience within the unit. This contributes to the difficulty in designing useful trials of monitoring techniques, and although ideal studies would be randomized trials, cohort studies can provide sufficient evidence to demonstrate the usefulness of a technique. Our results provide information that enables comparison of monitoring technique results from different units with our clinically monitored results. They also highlight the recipient sites that are generally not monitored as successfully as others and that may be more likely to show an improvement in salvage rates with the use of adjunctive monitoring techniques.

CONCLUSIONS

In the largest reported series to date, an outcome-based analysis of postoperative monitoring for free flaps demonstrates that clinical monitoring provides a flap salvage rate of over 60 percent in the context of a false-positive rate of 0.4 percent. This benchmark enables a standard against which adjunctive monitoring techniques can be compared. These studies need to be assessed in the context of individual recipient sites, with significant differences in monitoring outcomes between sites.

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