The effect of peri-operative innovations in free flap reconstruction

Smit, Jeronimus Maria

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STELLINGEN

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Stellingen

1) Computer tomografie angiografie en magnetische resonantie angiografie zijn momenteel de beste methoden om de vasculatuur van lappen met een minder voorspelbare anatomie pre-operatief in kaart te brengen.

2) Bij lappen met een voorspelbare anatomie of een oppervlakkige vaatsteel, blijven de hand Doppler of zelfs geen aanvullend onderzoek de voorkeur houden om de vasculatuur in kaart te brengen.

3) De introductie van computer tomografie angiografie als onderdeel van de work-up van de perforatorlap borstreconstructies in plaats van enkel de hand Doppler kan een significante vermindering van de operatietijd opleveren.

4) Er zijn concrete aanwijzingen dat de drukverandering in de oppervlakkige vene van DIEP lappen na dissectie van de lap van voorspellende waarde is voor veneuze stuwing.

5) In de literatuur wordt het gebruik van enkel conventionele monitor methoden niet aangeraden in verband met de langere reactietijd en een verminderde betrouwbaarheid.

6) Bij bestudering van de literatuur, lijken het implanteerbare Doppler systeem, near infrared spectroscopy en laser Doppler flowmetry de beste monitor methoden die op dit moment beschikbaar zijn.

7) Ondanks de goede negatief voorspellende waarde van het implanteerbare Doppler systeem ten aanzien van het aantonen van arteriële en veneuze complicaties na reconstructie van de borst, zou de positief voorspellende waarde nog beter kunnen en daarmee is de zoektocht naar de ultieme monitor methode nog niet beëindigd.

8) De invoering van het implanteerbare Doppler systeem leidt niet tot een significante toename in het succes percentage van gereviseerde lappen ten opzichte van conventionele monitor methoden.

9) Het implanteerbare Doppler systeem maakt het monitoren van vrije lappen voor personeel niet gemakkelijker.

10) Budgetkortingen en bevriezing van het Budgetkaderzorg zijn geen effectieve manieren om de stijgende kosten van de zorg te beteugelen. Er zullen keuzes gemaakt moeten worden over de zorg die aangeboden wordt.

11) Het is in het belang van de patiënt dat de oncologische resectie en de daaropvolgende reconstructie door twee separate teams wordt uitgevoerd.

12) De wetenschappelijke ontwikkelingen, de technische vooruitgang en de steeds hoger wordende eisen met betrekking tot de kwaliteit van zorg maken het nodig dat de rolverdeling van de verschillende specialismen herzien wordt. De rol van de generalist zal hierbij verdwijnen.

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CONTENTS

Chapter 1

Design and rationale of the thesis

Design and rationale of the thesis

Defects, depending on their size, location and cause, can create a challenge for closure. If this is indeed the case, the reconstructive ladder needs to be considered. On top of that ladder is the free flap or free microvascular tissue transfer. A free flap is an organ-like piece of tissue, which can be isolated on a vascular pedicle and moved from one site on the body to another site. During this transfer its blood supply is detached from its donor site and later attached or anastomosed at or near the recipient site. As the artery and vein(-s) of such a flap are of relatively small caliber (usually smaller than 2-3mm), the anastomes are made with microsurgical techniques. The most common indications for a free flap are reconstructions after tumor resection and trauma. Other indications include defects following infections, congenital deformities and burns.

The origins of microvascular surgery can be traced back to the early 1900's. Alexis Carrel[1] illustrated reproducible methods of suturing vessels together with high patency rates, and in the 1920's the operating microscope was introduced by ENT-doctor Nylen.[2] It took until 1957 before free vascularized human tissue transfer was accomplished when an esophagus was reconstructed with a free jejunal segment.[3] However due to the popularity of other regional flap techniques and lack of fine sutures and instruments, it took until the 1970s before further large microvascular advances were made. During that period multiple reports of free fasciocutaneous flaps[4-7] as well as other flaps[8,9] were published. In the decennia thereafter more and more flaps were developed with different constitution and characteristics.

For a successful free flap reconstruction three stages are important; the preoperative planning of the flap, the surgery itself and the post operative care. All advancements within these three different stages may contribute to a safer, faster and easier to perform free flap procedure. Initially, research concerning flaps focussed predominantly on the operative procedure itself, investigating which flaps to use in what type of defects,[10-12] the number and type of pedicles,[13-15] the innervation of flaps,[16,17] how to treat venously compromised flaps,[18,19] and the kind of anastomotic material to be used.[20-22] As a result, it has become very clear which measures are essential to make the procedure more reliable.

Although the preoperative planning of the flap and the post operative care have been addressed in earlier investigations, special attention has been given to them in recent years. The introduction of computed tomography angiography (CTA) in the planning of perforator flaps in 2006 by Masia et al.[23] for example showed the potential of new preoperative vascular mapping techniques, while the awareness of the limitations of conventional monitoring methods[24,25] led to the introduction of new continuous monitoring methods.

A decent preoperative planning of the flap can improve surgery by giving the surgeon insight of the vascular anatomy and its surrounding before the surgery has begun. With this information at least in theory the surgeon may be able to select the best perforator prior to surgery and thereby make the surgery more straightforward.

A variety of mapping methods exist, and the most commonly used are handheld Doppler, color duplex sonography, conventional digital subtraction angiography, computed tomography angiography (CTA) and magnetic resonance angiography (MRA). Of these techniques CTA[23,26] and MRA[27,28] seem to have the most potential. It has been shown that they can produce a good 3D image of the vessels and their surrounding structures. It is however not known how the depiction of these 3D images of the vessels and their surrounding structures may influence clinical practice, and this has been one of the reasons to start this research. Post-operative monitoring is of importance because the sooner a vascular occlusion of the pedicle of a flap is detected and acted upon, the higher the chances on flap survival are.[29,30] The most commonly applied monitoring methods are conventional techniques, such as clinical assessment of skin color, turgor and temperature of the flap, capillary refill and hand-held Doppler. In only approximately 10% of the cases other methods are used.[31,32] Limitations of the aforementioned methods however, are that they do not monitor the blood flow of the flap continuously. The latest continuous measuring devices that have emerged on the market are an implantable Doppler system, near infrared spectroscopy and laser Doppler flowmetry. Although all these techniques show potential, an implantable Doppler system has some advantages others do not have: this system monitors the venous flow directly and therefore alterations in flow can be detected immediately when they occur, furthermore it has been suggested that the system's reading is easy to interpret, making it friendly in use.[33] Evidence however is lacking.

Therefore, the general aim of this thesis was to investigate if innovations in free flap surgery are indeed able to improve the outcome of free flap reconstructions. In line with the recent developments as described above, the focus of this thesis is the role of preoperative investigations of the vasculature of the flap and the postoperative monitoring. The improvement of these two stages of free flap reconstruction, should ultimately lead to an optimal result for the patient and a more profitable procedure for the hospital.

Specific aims

1. To create an overview of the methods used in the pre-operative planning of free flaps.
2. To investigate if computed tomography angiography makes the harvesting of the deep inferior epigastric perforator flap in breast reconstruction faster and easier.
3. To find an easy and objective method to predict or test venous congestion.
4. To create an overview of the most commonly used flap monitoring methods available today.
5. To test the reliability of an implantable Doppler system in the monitoring of free flap breast reconstructions.
6. To investigate the efficiency of an implantable Doppler system.
7. To test which method, the implantable Doppler system or the conventional monitoring methods, gives medical and nursing staff most confidence while monitoring free flaps.

Outline of this thesis

Chapter two is a review of the preoperative methods currently used in the planning of flaps. The pro's and con's of the hand-held Doppler, color duplex and computed tomographic angiography (CTA) will be reviewed and future developments, such as magnetic resonance angiography (MRA), discussed.

In *Chapter three* the influence of preoperative planning with CTA and conventional handheld Doppler in the planning of the DIEP flap are compared. Outcome parameters are duration of surgery and complications, including flap failure.

A known problem during and after surgery can be venous congestion, which sometimes for example occurs when there is a preferential draining of a DIEP flap through its superficial system. *Chapter four* describes investigations on the venous pressure in the superficial venous system in 26 DIEP cases during flap harvest and the correlation with venous congestion.

In *Chapter five* a review on monitoring techniques for free flaps is presented. Conventional methods, the handheld Doppler, the implantable Doppler system, microdialyses, near infrared spectroscopy, color duplex sonography and laser Doppler flowmetry, their advantages and disadvantages will be discussed.

In *Chapter six* the reliability of an implantable Doppler system for monitoring of the blood flow in the flap pedicle is presented. The device consists of an implantable Doppler crystal mounted on a silicone cuff that is wrapped around the vein and this crystal registers flow through the flap.

Chapter seven investigates the influence of using an implantable Doppler system on the success rate in free flap reconstructions. Based on these numbers a financial analysis will be given.

Chapter eight is a study on the confidence an implantable Doppler system offers compared to conventional monitoring methods. From these findings the ease of use of the system can be derived.

The findings of the preceding chapters are summarized and discussed in *Chapter nine*.

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Chapter 2

An overview of methods for vascular mapping in the planning of free flaps

J.M. Smit, MD, S. Klein, MD, P.M.N. Werker, MD, PhD

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Summary

Introduction: The aim of this overview is to describe the various methods for vascular mapping of flaps together with their advantages and drawbacks.

Materials and methods: The PubMed database was used. Relevant search terms included 'flap' in combination with 'hand-held Doppler' (HHD), 'color duplex sonography' (CDS), 'digital subtraction angiography' (DSA), 'computed tomography angiography' (CTA) and 'magnetic resonance angiography' (MRA). All studies found between January 2000 and January 2010 were evaluated.

Results: A total of 72 articles were found. Of these, 62 were usable for this overview. Recommendations could not be found for all types of flaps. Therefore, no uniform guidelines can be provided; some findings are, however, unequivocal. In general, HHD is cheap and easy to use, but relatively unreliable in determining the exact site of emergence at fascia level of perforators. CTA and MRA provide the best three-dimensional images. CTA offers more detailed images, MRA has the advantage however of not using radiation. CDS can be of value to offer information about the amount of flow in vessels or in cases in which CTA or MRA are contraindicated. DSA appears to be fading out slowly.

Conclusion: CTA and MRA are currently the best methods available to map the vasculature of donor sites of perforator flaps with variable anatomy such as anterolateral thigh (ALT) and deep inferior epigastric perforator (DIEP). In flaps with standard anatomy and superficial vasculature, HHD or no mapping at all remains the method of choice.

Introduction

Reconstructive surgery has seen great development since the early 1960s, when the concept of axial vessels became mainstay.[1-10] The first generation of axial pattern flaps was based on well-known vessels from the anatomy book, such as the radial artery for the radial forearm flap and the thoracodorsal vessels for the latissimus dorsi flap. The harvest of these flaps, although in that time revolutionary, is nowadays looked upon as relatively straightforward, due to their constant anatomy. Only in instances where previous surgery or trauma might have damaged the vascular pedicle, further investigation of the vasculature is deemed indicated. In the past 20 years, enormous progress has been made in flap design and more and more flaps are based on perforating vessels that branch off and are traced back to well-known vessels, thereby limiting donor-site morbidity. The exact location of perforators, however, varies significantly, and preoperative vascular mapping has been introduced to help identify the dominant perforator and its course and, as such, speed up flap harvest.

A variety of methods is available for this purpose, the most commonly used being hand-held Doppler (HHD),[2-4] color duplex sonography (CDS),[5,11-13] digital subtraction angiography (DSA),[14,15] computed tomography angiography (CTA)[6-8,16] and magnetic resonance angiography (MRA).[8,9,17] HHD was already reported in the planning of flaps in 1975, when it was described for the localisation of the donor and recipient vessels in facial reconstructions.[18] Around the same period, angiography, later replaced by DSA, was introduced to assess the vascular anatomy of flaps, mainly in the lower extremities.[19,20] The use of CDS in the planning of flaps was first described in the 1980s and became a common mapping method in the 1990s.[21,22] In the last decade, major progress has been made in the applicability of, especially, CTA and MRA. The purpose of this overview is to describe the various vascular mapping systems in detail, together with their advantages and drawbacks to assist beginning micro-surgeons in their planning of free flaps.

Although other mapping methods such as indocyanine green[23] and near infrared imaging[24] exist, these can only be used for intra-operative flap design and are therefore beyond the scope of this overview.

Materials and methods

A literature search was conducted, using the PubMed database. The following search terms were used: 'flap' in combination with 'hand-held Doppler', 'color duplex sonography', 'digital subtraction angiography', 'computed tomography angiography' and 'magnetic resonance angiography'. All studies found between January 2000 and January 2010 was evaluated. Only studies written in the English language were included. Manual cross-referencing was also performed. For historical and technical backgrounds, reports prior to 2000 were used whenever necessary. In selecting data regarding the reliability of the mapping method, studies with the highest level of evidence were preferred over others.

Results

Our query led to 18 studies on HHD, eight on CDS, 10 on DSA, 31 on CTA and 12 on MRA.

Hand-held Doppler sonography (HHD)
A pencil-type Doppler probe registers moving erythrocytes by sending out and detecting reflected ultrasound. Depending on the depth and the diameter of the vessels to be investigated, various probes with different frequencies can be used. The two most commonly used frequencies, 8 and 10 MHz, have a peak sensitivity of only 20 and 15 mm, respectively. Gel must be used at the interface of skin and the probe to improve ultrasound conduction. When searching for perforators, it has been advised to vary the amount of pressure applied with the Doppler probe to the skin surface. If the detected sound comes from a perforator that runs directly towards the HHD, the loudness of the pulsating sound will reduce with increasing pressure.[25]

Reported advantages of the HDD are its non-invasiveness, small size, low costs, portability and the ease to perform the examination. In addition, there are special probes available, which can be sterilised, making the technique available intra-operatively to finalise the planning and check the pulsation of a vessel during the surgical procedure.[2,4,25,26]

The main disadvantages of the most widely used Doppler probe (8 MHz) is that it only detects vessels to a depth of 20 mm. This makes the technique less reliable for the detection of the site of emergence of perforators through the fascia, whenever the thickness of skin and subcutaneous tissue exceeds this amount.[2] Besides, one can never know for sure what vessel is producing the Doppler signal picked up by the HHD. Furthermore, this technique does not create a three-dimensional (3D) image of the vasculature and its surrounding anatomy than can be stored and retrieved later.

The use of HHD has predominantly been reported to locate perforators on the trunk and extremities.[2-4,28] A relatively new field in reconstructive surgery, in which the HHD is being used, is in free-style perforator free flaps[27,29-33] and in pedicled perforator flaps.[34-36]

The use of HDD has been reported with variable success: In the study by Yu and Youssef[2] of 2006, in which they included 100 patients undergoing an anterolateral thigh (ALT) reconstruction, the locations of HHD signals of an 8-MHz and a 10-MHz probe were compared to the intraoperative findings. The positive predictive value for the 8-MHz probe in detecting the perforator was 89%, while no false-negative results were found. For the 10-MHz probe, a positive predictive value of 94%

and negative predictive value of 43% were found. The study by Shaw et al.[28] compared HHD to intra-operative findings in 30 patients undergoing an ALT reconstruction. They found a large underestimate (30%) to an overestimate (150%) for the HHD findings. In a study of 32 deep inferior epigastric perforator (DIEP) and eight superior gluteal artery perforator (SGAP) flaps in which HHD findings were compared with intraoperative findings, a positive predictive value of only 52.4% was found for DIEP and SGAP flaps combined.[4]

Color duplex sonography (CDS)
CDS relies on the same working principle as HHD. Blood flow in vessels is detected by the physical principle of a direct relationship between the recorded Doppler frequency shift and blood-flow velocity. In addition, different velocities and directions of moving blood streams can be displayed on a screen in the color duplex mode. As such, CDS does not only offer information about the internal vessel diameter and their course, but also depicts the 3D footprint of the perivascular anatomy.[37] As with HHD, gel must be used at the interface of skin and the probe to improve ultrasound conduction.

Similar to HHD, CDS is non-invasive. An advantage compared with the HHD is its ability to offer more information about anatomy of the vessel and its perforators in reference to its surrounding tissues, and it can quantitatively analyse which perforator is the dominant one.[38]

The disadvantage of CDS is, however, that the investigation can only be performed by skilled personnel, who also have knowledge of free-flap anatomy. In addition, it is less reproducible because of its real-life dynamics. Another disadvantage in comparison to CTA, MRA and DSA is that CDS just as HHD does not reproduce a 2D or 3D image of the complete vascular anatomy, which can be used by the surgeon during flap design or flap elevation.[7,8,16]

CDS has been successfully used to preoperatively assess flaps for reconstructions in the head and neck, trunk[5,11,13,38,40] and extremities.[12,37] Tsukino et al.[37,39] investigated the reliability of CDS in 10 patients prior to ALT flap harvesting. Comparison of CDS findings to intra-operative findings showed a concordance of 100%. This was confirmed for DIEP flaps in a report of six cases.[11] CDS has been found to be of value in cases in which the perforating vessels might have been damaged, for example, after liposuction, as it can give information about the amount of flow in vessels or in cases where the radiation dose of CTA is undesirable.[11]

Digital subtraction angiography (DSA)
In traditional angiography, an iodine-containing contrast medium is administered intra-arterially while X-rays are taken. In DSA, these contrast-enhanced pictures are digitally subtracted from the pre-contrast mask X-ray to depict the vascular anatomy (*Figure 1*). This investigation technique generates 2D images and, therefore, generally has to be performed in two directions.

The reported advantages of DSA include the facts that it gives an image of the intraluminal vascular anatomy and information about atherosclerotic changes. A disadvantage of DSA is that it is a time-consuming, invasive technique necessitating the use of iodinate-contrast medium, which may cause vascular or renal damage as well as allergic reactions.[41] In addition, there is a radiation dose to be considered.[6,42-45] Another disadvantage is the vasoconstricting effect of the contrast medium, making exact measurement of the vascular diameter and the assessment of small-calibre vessels unreliable. Furthermore, the patient has to stay in supine position after the angiography for several hours, to allow the puncture site to heal. This makes hospital admission often mandatory and this imaging modality relatively expensive. Finally, there is a 4.5% chance for the development of false aneurysms at the puncture site.[46]

DSA in free-flap planning is predominantly reported in fibula flaps, where it is essential to be informed about the continuity of the three lower leg vessels, the level of bifurcation of the tibiofibular trunk and about arteriosclerotic plaques.[15,42,43]

Angiography has been found to provide a more accurate assessment of the patency of vessels compared with conventional tests such as ankle-arm index and HHD examination.[15,42,43,47]

The use of DSA has also been reported in the planning of transverse45 and oblique44 rectus abdominis musculocutaneous flaps. It has been reported to have been used during surgery to visualise the vascular architecture of a flap after its harvest. This can show its perforator and its connection to the axial flap vessel, which can help the surgeon to safely thin and separate the flap during secondary procedures.[44,45] This is, however, not a commonly reported technique.

Figure 1; Digital subtraction angiography imaging of the left lower leg, showing a normal branching pattern of the vessels.

Computed tomography angiography (CTA)
CTA combines the use of X-rays with computerised 3D analysis of the images. The number of detector rows decide how fast a scan can be performed and to what extent details can be revealed. A great variety of CT scanners and software is currently available, making a comparison of the results of various studies difficult. The number of multidetector rows used in different studies varies from 416 to 64,48 enabling the generation of slices of approximately 1 mm or thinner, depending on the CT scanner used. The actual scan is performed in concert with a high-speed venous contrast-medium injection to enhance the staining of vessels. A bolus of 80e100 ml of contrast medium is given intravenously at a rate of 4 ml/s. After the scanning, the data need to be processed into maximum intensity projection and 3D volume-rendered reconstructions. A great variety of software packages are available for this purpose (e.g., Siemens InSpace,[48] Vitrea version 3.0.1,7 VoNavix[49] VirSSPA50 and Virtual Place 2151). Based on the software used, 2D pictures in three planes or 3D reconstruction in multiple planes can be provided. The processing of the images by the radiologist and the preoperative selection of the right vessels/perforators by the surgeon has been reported to take up to 30 min in perforator flaps.[16,49]

The advantage CTA offers is that it provides an image with accurate visual details on the calibre and course of the vessels and their relationships with other anatomic structures (*Figures 2 and 3*). This allows surgeons to develop a dissection strategy and opt for a certain perforator prior to surgery, making the actual dissection safer and swifter.[7,8,16,49,52-54]

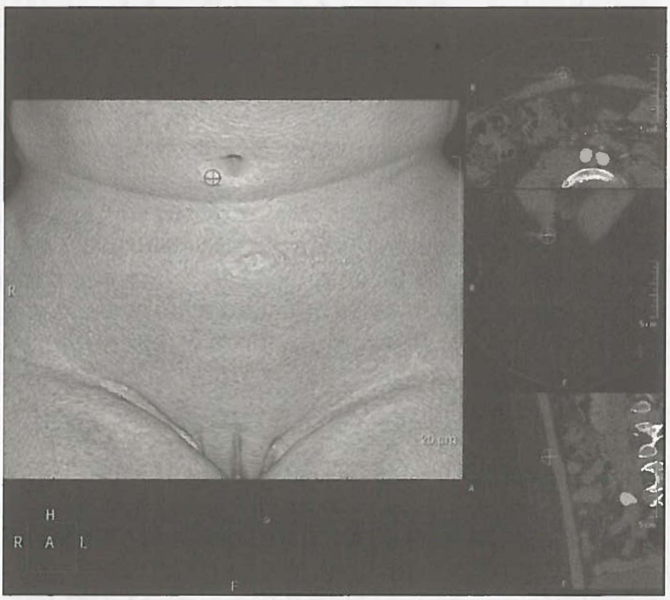

Figure 2; Reconstructions of CTA images in the sagittal, coronal and axial planes (right), and the VRT coronal image of a deep inferior epigastric perforator flap.

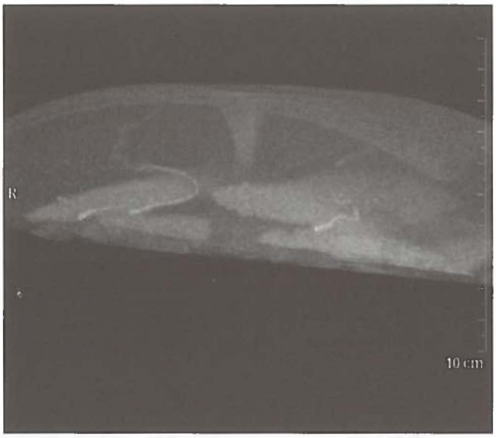

Figure 3; 3D CTA image of a deep inferior epigastric perforator flap through which can be scrolled, which enables the user to view the vasculature from any direction. The direction of viewing is predominantly cranial as indicated by the green cube on the bottom left. The trunk of the umbilicus and the rectus abdominis muscles can be seen. On the left sight of the umbilicus a perforator can be seen going medially around the rectus muscle and branching off towards the skin.

The disadvantages of CTA are its radiation dose, which is reported to be 5.6 mSv,[7] and the necessity to use iodinated contrast medium with its previously listed disadvantages.[7,16] Especially, the vasospastic action is a serious drawback, because it can make the accurate assessment of small-calibre vessels difficult.[55]

CTA has been predominantly used in the planning of perforator flaps in breast reconstructions (DIEP and SGAP),[7,8,16,48,49,56,57] and has also been reported to assess the vasculature of ALT flaps[54,58] and fibula flaps.[6]

Furthermore, it has been described to map the internal mammary artery perforator59 and the deep circumflex iliac artery perforator flap[60] in cadaver studies. CTA may also have additive value to preoperatively assess the recipient site.[6,61,62] However, the spurting test should be used in addition to confirm blood flow in the recipient site. In the initial reports of Masia et al.[7] and Alonso-Burgos et al.[16] regarding CTA in DIEP breast reconstructions, a 100% correlation was found between the CTA findings and the intra-operative findings. This included the location of the perforators, their estimated size, the course of the pedicle and its relationship with other anatomic structures. This was later confirmed by other studies.[8,48,56,57] Compared with MRA, the depiction of smaller perforators is more accurate with CTA (vessels up to 0.3 mm in CTA vs. 1.0 mm in MRA).[63,64] The introduction of CTA in DIEP in breast reconstructions led to a reduction of operating times of 90e100 min in flaps previously examined by HHD,[8,57,65] and 76 min in flaps previously mapped by CDS.[56] In the planning of ALT flaps, a 100% correlation was found between CTA findings and intra-operative findings as well.[58]

Magnetic resonance angiography (MRA)

MRA imaging uses a powerful magnetic field to align the nuclear magnetisation of hydrogen nuclei in the body. Radio-frequency pulses are used to tip the alignment of the hydrogen nuclei away from the main magnetic field, causing the hydrogen nuclei to produce a radio-frequency signal that is detectable by the scanner. Analysed by a computer, this yields detailed pictures of organs, soft tissues, bone and virtually all other internal body structures. By injection of a paramagnetic contrast agent (gadolinium), the vessels enhance. Since magnetic resonance imaging (MRI) has no radiation exposure, a picture of the vessels is typically obtained in the arterial phase and subsequently in the blood-pool phase to selectively visualise only arteries and to also see the larger artery/vein combination. Recently, a new blood-pool gadolinium contrast agent, gadofosveset trisodium, has become available that is optimised for imaging both the arterial and blood-pool phases of contrast enhancement without interference from soft-tissue enhancement. There is also the possibility to visualise vessels without the injection of contrast, albeit with lower resolution.[66]

Just as with CTA, a great variety of magnetic resonance scanners and software are being used, making comparison of the results of different studies once again difficult. The scanners used varied from 1.563,[68-70] to 3 T.[9,17] However, in recent perforator flap studies, the 1.5-T scanners are preferred over 3 T because of the better image quality. The 1.5-T scanners suppress signals from fat more homogeneously than the 3-T machines.[66,69,70] The contrast medium administered varied from none66 to 60 ml[67] per scan. With the introduction of newer devices, the procedure time of an MRA scan has been reduced to approximately 20 min, and with actual scan acquisition times of about 20 seconds.[68]

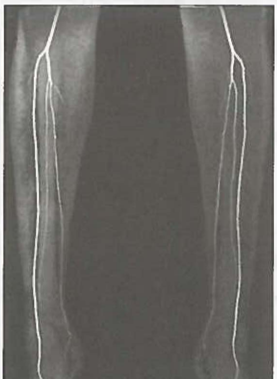

Figure 4; MRA image of the lower legs, showing a normal branching pattern of the vessels.

Figure 5; MRA image in the axial plane of a deep inferior epigastric perforator flap. Showing a perforator left from the centre and its course through the muscle.

Feature	HHD	CDS	DSA	CTA	MRA
Three dimensional imaging	-	-	-	+	+
Operator dependant	+	+	-	+	+
Use of radiation	-	-	+	+	-
Invasiveness	-	-	A	V	V/-
Images superficial vessels/ perforators	+	+	-	+	+
Images vessels in deeper layers	-	+	+	+	+
Reproducibility	-	-	+	+	+
Information on surrounding tissues and anatomy	-	+	-	+	+
Additional costs per investigation*	-	€75	€325**	€ 250	€ 250

*Table 1; The characteristics of each mapping method compared to one other. HHD; hand-held Doppler, CDS; colour duplex sonography, DSA; digital subtraction angiography, CTA; computed tomography angiography, MRA; Magnetic resonance angiography, A; arterial, V; venous. * The prices given in this overview only represent a rough indication; prices can vary between countries and hospitals.** The costs of the hospital admission often mandatory are not included.*

There are several advantages of MRA. It works with magnetism instead of radiation and, depending on the software used, can be used without a non-iodine contrast medium, making it a relatively safe procedure for the patient.[67] MRA produces a 3D image, which allows surgeons to accurately assess the course and diameter of the vessels and their relation to other surrounding structures, prior to surgery (*Figure 4*).[9,10,67,71] MRA can be obtained both prone and supine to have images in which the normal contours of the abdominal and buttock fat are not distorted by the pressure of lying against a flat surface.

The reported disadvantages of MRA are its relatively high costs. Besides, it cannot be used in claustrophobic patients or patients with implants containing ferrous metals because these produce scattering or can cause severe damage to the scanner, if they are magnetic. Further, compared with CTA, the depiction of smaller perforators is less accurate with MRA (vessels up to 1.0 mm in MRA vs. 0.3 mm in CTA).[63,64]

MRA has predominantly been used in the planning for free fibula flaps[9,10,67,72] but more recently for the mapping of perforator flaps in breast reconstructions as well.[17,63,66,68-70] MRA, as a single test in the planning of fibula flaps, has been reported to provide all the goals addressed by Doppler, combined with conventional angiography. Furthermore, it adds important data concerning the septocutaneous perforators that neither test can provide.[10]

For DIEP flaps, Masia et al.[66] found a 100% correlation between MRA and intra-operative findings in a study including 56 patients. Greenspun et al.[70] reported a positive predictive value of 100% but a negative predictive value of 96% in a series including 31 patients and using MRA with contrast. For fibula flaps, it is unfortunately more difficult to draw conclusions about the positive and negative predictive values based on currently available literature. The reports that correlate the preoperative images to operative findings consist of only small populations and are not unambiguous.[10,63,64,67,68,71] *Table 1* summarises all the characteristics found in the literature of the individual mapping methods such as use of radiation, invasive nature of the investigation and the type of vessels they are able to image.

Discussion

This study was undertaken to create a contemporary overview of the preoperative mapping methods for (free) flap planning. A serious limitation of this study is that the use of the discussed methods of mapping has not been reported for all currently used flaps. Therefore, only an extrapolation of the findings in this study to other flaps can be given. Furthermore, the studies found were mostly large case series and have low levels of evidence. For this reason, it is not possible to draw concrete conclusions based on the current literature; nevertheless, some findings are unequivocal and guidelines for clinical practice can be distilled.

While interpreting these data, it is important to realise that anatomical knowledge still remains the cornerstone to successful flap harvest and that preoperative mapping methods only serve as an adjunct to surgery. Furthermore, with some of the methods described above, it might be difficult to detect discrepancies between the perforating artery and the committante vein. Therefore, it is always good to have a back-up plan. In addition, readers should be aware that most studies took place in specialised units and the achieved results might not be obtainable in less specialised units in which a specific mapping method might not be available. Finally, it is important to realise that collective collaboration between radiologist and surgeon is key in order to maximally exploit the more advanced preoperative mapping possibilities.

This report shows that, in such settings, CTA[7,8,16,48,49,56,57] and MRA[9,10,41,67,71] can produce the best 3D image of the vessels and their surrounding structures. The advantage of CTA over MRA is that it is able to depict small vessels and especially perforators more accurately.[63,64] This is why CTA, at present, is predominantly being used in the scanning of perforator flaps, in which the size and the course of the perforators are of great importance for surgery.[7,8,16,48,49,56,57] The main advantages of MRA over CTA are its lack of exposure of the patient to ionising radiation and the necessity to use a potentially nephrotoxic contrast medium (if used at all).[66,67]

Although HHD has proven to be less accurate in locating perforators compared with CDS[2,3] and CTA,[7,16,26,48] it will probably remain of importance in clinical practice. This is because the device is portable and the examination inexpensive and relatively easy to perform and interpret. In contrast to most other mapping methods, it can be made available during surgery.[2,4,25,26] Furthermore, it can be used as primary mapping device in thin flaps and in flaps, which do not rely on a specific perforator such as the radial forearm flap or as a complementary device to CTA or MRA in the planning of, for example, DIEP and fibula flaps.

CDS is a readily available non-invasive mapping device in most vascular units that, to some extent, also offers information about the 3D anatomy around the vasculature.[37] The disadvantage of CDS is that the investigation can only be performed by skilled personnel, who also need to have knowledge of flap surgery. In addition, it is less reproducible because of its real-life dynamics.[8,9] This is why we believe CDS should only be used as primary mapping modality in selected cases, as for instance, in cases in which CTA or MRA are contraindicated or in which there is a special interest in flow within the vessels.

With the introduction of CTA, MRA and CDS, the need for DSA in free-flap planning as a primary mapping device seems to fade. Compared with CDS and MRA, it is more invasive, necessitates a radiation dose and the use of iodinate-contrast medium. Furthermore, the images it produces are only 2D and finally, false aneurysms may occur.

Future developments in the planning of free flaps should focus on the refining of 3D reconstructions and in a further elimination of the use of invasive diagnostic tests that rely on contrast media, which may cause co-morbidity. Because MRA has most of these characteristics, we believe that MRA has the greatest potential for the future, especially if future developments make it as accurate as CTA. Nevertheless, HHD will always keep a place in (free) flap planning because of its ease of use and intra-operative availability. Future research should also focus on the comparison between the different mapping methods and should prospectively compare the findings of the diagnostic tests with intra-operative findings.

Conclusion

CTA and MRA are currently the best methods available to map the vasculature of flaps that rely on perforators and their surrounding anatomy. In the planning of thin pedicled flaps that are planned close to a defect, in flaps with a more straightforward anatomy and for intra-operative use, the HHD remains to be mapping method of choice. DSA is slowly fading out and CDS can be used as an alternative, whenever there are contra-indications to the use of the other methods of investigation.

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Chapter **3**

The preoperative use of computer tomographic angiography reduces surgery time in perforator flap reconstructions

J.M. Smit, MD, A.G. Liss, MD, PhD, A. Dimopoulou, MD,
C.J. Zeebregts, MD, PhD, M. Kildal, MD, PhD,
I.S. Whitaker, B.A. (Hons), M.A. Cantab, MBBChir, M.R.C.S,
A. Magnusson, MD, PhD, R. Acosta, MD

J Plast Reconstr Aesthet Surg. 2009 Sep;62(9):1112-7

Summary

Introduction: The use of perforator flaps in breast reconstructions has increased considerably in the past decade. A disadvantage of the perforator flap is difficult dissection, which results in a longer procedure. During spring 2006, we introduced CT angiography (CTA) as part of the diagnostic work-up in perforator flap reconstructions to visualise each perforator more accurately. The main objectives were to reduce surgery time and the number of complications. A chart review was conducted 1 year after CTA introduction to investigate if these objectives were met.

Materials and methods: Patients with a deep inferior epigastric perforator (DIEP) flap who underwent preoperative analysis through CTA were retrospectively evaluated. The population <1 year before CTA introduction were the control group. The two groups were compared with respect to surgery time and complications (including flap failure).

Results: One hundred and thirty-eight DIEP breast reconstructions were done; 70 underwent preoperative CTA analysis, and 68 had preoperative Doppler investigation. Surgery time in the CTA group was significantly lower ($P < 0.001$) than in the control group, 264 min (SD ± 62) versus 354 min (SD ± 83), respectively. There was a tendency for fewer complications in the CTA group compared with the control group. All flaps were successful in the CTA group.

Conclusion: CTA in the assessment of perforator flaps helps to reduce surgery time.

Introduction

The use of perforator flaps for breast reconstruction has increased considerably during the past decade. They offer less postoperative pain, low morbidity, and preservation of muscles at the donor site compared with conventional musculocutaneous flaps. The variety of donor sites allows most patients to be suitable for this procedure.[1] The disadvantage of perforator flaps is that they are more difficult to harvest, which results in a longer procedure.[2] Some surgeons fear that without the protective muscle bulk, the pedicle will kink or be compressed.[3]

Complications during perforator flap reconstruction can be reduced by preoperative assessment of vascular anatomy. The commonest method is unidirectional Doppler sonography.[1,4] It is an accessible and inexpensive tool that can be used to investigate the location and flow of perforators, but is highly sensitive. It locates not only the perforators suitable for anastomosis, but also the very small perforators that are not. False-positive results for unidirectional Doppler sonography can be up to 50%. The number of false-negative perforators detected with unidirectional Doppler sonography is lower (e.g. 11% for the deep inferior epigastric perforator flap).[5,6] Unidirectional Doppler sonography is therefore not ideal for accurate preoperative assessment of vascular anatomy.

CT angiography (CTA) has been used in our centre for the planning of perforator flaps for breast reconstructions since spring 2006. The aim of its introduction was to better map the perforators to reduce the dissection time of the flap, and to reduce the number of complications. A chart review was conducted to investigate if this aim was successful.

Patients and methods

Study design

One year after the introduction of CTA before free microvascular tissue transfer in our clinic, a chart review was conducted of all patients who had free microvascular breast reconstruction. The patients who had breast reconstruction with a deep inferior epigastric perforator (DIEP) flap and who also had a CTA in their diagnostic work-up were further analysed. Patients who underwent the same reconstruction in the year before the introduction of CTA were the control group. The study was done from a prospectively maintained database, but was retrospective.

Setting

The section of microsurgery of Uppsala University Hospital, Sweden, consists of three plastic surgeons, one surgical fellow, and one resident on surgical rotation. The number of DIEP flaps done since 2000 is about 60-80 per year.

Data

Age, indication for surgery, date of surgery, ASA-classification, nicotine use, administration of radiotherapy, defect location, flap type, surgeon, surgery time, anastomosis type, type of anastomotic material used, receiving vessels, ischaemia time, vessel-suturing time, complications, need for revision, revision indication, and surgical outcome of all patients were noted.

The two groups mentioned above were compared with respect to surgery time, complications, and flap failure. In the comparison of surgery time, only patients who underwent delayed unilateral reconstruction were selected and compared. Selection was made to prevent a mismatch in surgery time because of different types of reconstruction (e.g. unilateral versus bilateral).

Imaging

CTA was done using a Somatom Sensation 16 machine (Siemens, Forchheim, Germany). Patients were examined in the supine position. A catheter was placed in the antecubital vein of one arm, and a bolus injection of 80 ml contrast medium (Omnipaque 300 mg I/ml, GE Healthcare, Oslo, Norway) was administered through a power injector (Stellant Medrad, Indianola, USA) at 4 ml/s. The scanning delay was approximately 30 s. Bolus tracking was done with the region of interest (ROI) on the aorta, just above the aortic bifurcation. Scanning was initiated approximately 10 s after the ROI reached 100 Hounsfield units. Imaging was in a caudo-cranial direction from the femoral head to approximately 5 cm cranially of the umbilicus. Images were acquired during a single arterial phase with the following scan parameters: 0.5 s gantry rotation speed, 0.75 mm collimation, 10.5 feed/rotation (pitch ≤ 1), and image reconstruction of 1 mm with an increment of 0.6 mm.

Post-processing of images

Post-processing of three-dimensional images was done on a Siemens Leonardo Workstation (Siemens, Forchheim, Germany). Volume rendering technique (VRT) and multi-planar reformation (MPR) images were reproduced. Perforators could be identified simultaneously in axial, coronal, sagittal planes using a coordinate system with a MPR cursor. In a VRT coronal image of the scanned volume, a grid was placed with the umbilicus as zero point, and the best perforators could easily be marked. The suitability of each perforator was then analysed.

Surgical procedure

The surgery team comprised two surgeons and two nurses. One surgeon started with flap dissection, while the other surgeon dissected and prepared the receptor site. After dissecting the flap and preparing the receptor site, a pause of 15 min was often taken to see if the chosen perforator was appropriate. If the pedicle remained well perfused, it was harvested and anastomosed to the receiving vessels (often the internal mammary vessels). Anastomoses were made with sutures, clips or rings, depending on the diameter and quality of the vessels. Technical details of the anastomotic procedures have been previously described.[7] After re-establishment of blood flow in the flap, the defect at the donor site was closed, and the flap modified and sutured to match the contralateral breast.

Definitions
Surgery time was defined as the time between the first incision and wound closure. A complication was classified as haematoma, infection, superficial necrosis, seroma, anastomotic failure, or a combination of these. Surgical outcome was rated as success, partial necrosis (>10% tissue loss) or failure.

Data assessment
Data are represented as means ± standard deviation. Student t-test and chi-square tests were used to compare the groups. Significance was set at $P < 0.05$. Statistical analyses was done using a Statistical Package for the Social Sciences (SPSS 13.0, SPSS Benelux bv, Gorinchem, The Netherlands).

Results

Population
In the period reviewed, 138 DIEP breast reconstructions were done; 70 cases underwent preoperative CTA, and 68 underwent preoperative Doppler investigation.

In the CTA group, the mean age was 49.7 years (SD ± 9.3). The mean ASA-classification was 1.7 (4 patients were treated for hypertension, 3 used corticosteroids, 1 had cardiovascular problems, and 1 had diabetes mellitus). One patient smoked during admission for surgery, and 44.3% of patients received preoperative radiotherapy.

Reconstructionswere done after mastectomy due to breast cancer (26% primary and 74% delayed). Forty-eight patients had unilateral reconstruction, 11 had bilateral reconstructions. The internal mammary vessels were used as receptor site in 87% of cases; the circumflex scapular or the thoracodorsal vessels were used in the rest. The cephalic vein was anastomosed to the superficial vein of the flap in 31% of cases. The anastomoses were end-to-end in all but two cases. Sutures were used in 47%, clips in 47%, and rings in 6% of anastomoses. Mean ischaemia time was 60.6 min (SD± 25).

In the control group, the mean age was 49.9 years (SD ± 7.0).The mean ASA-classification was 1.7 (6 patients were treated for hypertension, none of the patients had cardiovascular problems, diabetes or had previously used corticosteroids). None of the patients smoked during admission for surgery, radiotherapy had been given in 63.2% of cases.

Reconstructions were carried out because of breast cancer in 94.1% of cases (20% primary and 80% delayed); two patients had reconstructions because of Poland's syndrome, and another two patients had extreme deformities after an infected prosthesis had been removed. Unilateral reconstruction was done in 50 cases; nine patients underwent bilateral reconstruction. The internal mammary vessels were used as receiving artery and vein in 74% of cases; the circumflex scapular vessels were used in the rest. The superficial vein of the flap was anastomosed to the cephalic vein in 60% of cases. All anastomoses were made in an end-to-end fashion. Sutures were used in 50%, clips in 30%, and rings in 20% of anastomoses. The mean ischemia time was 61.9 min (SD± 26).

Surgery time

The mean surgery time in the CTA group was 313 min (SD ± 107) compared with 395 min (SD ± 109) in the control group. Mean surgery time in the CTA group was significantly lower ($P < 0.001$).

The number of patients who had unilateral delayed reconstruction because of breast cancer was 41 in the CTA group, and 44 in the control group. The time needed for surgery was significantly lower ($P < 0.001$) in the CTA group. Mean surgery time in this group was 264 min (SD ± 62) compared with 354 min (SD ± 83) in the control group (*Figure 1*).

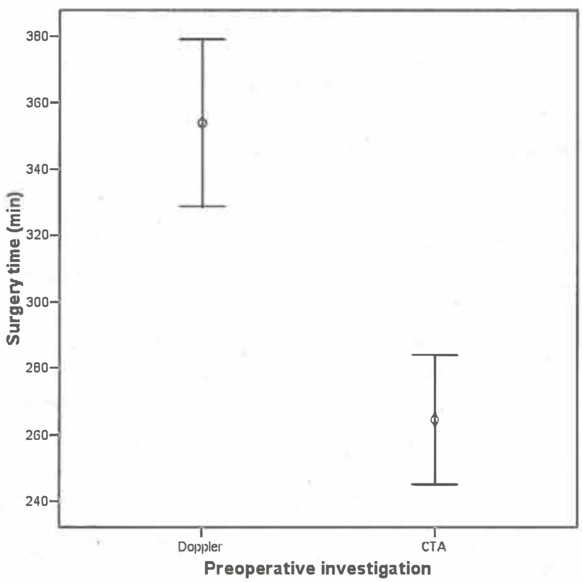

Figure 1; Mean surgery time per preoperative screening facility. Error bars represent the confidence interval of the mean (CI: 95%).

Complications
Fewer complications occurred in the CTA group than in the control group: 20.0% versus 25.0%. In the CTA group, infection was observed six times, haematoma four times, and superficial necrosis and seroma both twice. Revision of the anastomoses was needed in two cases. In the control group, a haematoma occurred four times, whereas infection and superficial necrosis were both observed six times. Revision of the anastomosis was needed because of an arterial or venous occlusion in six cases. Differences between the two groups were not sufficiently large to reach statistical significance.

Flap failure
All flaps were successful in the CTA group. One flap failed, and partial necrosis occurred in three flaps in the control group.

Discussion

We observed that preoperative CTA of the donor site in microvascular perforator flap reconstruction diminishes surgery time. A tendency to less morbidity was noticed during follow-up, including fewer partial and complete flap failures. We could decrease the total cost of DIEP breast reconstruction by reducing surgery time. The costs of one CTA were approximately 350 pounds; the reduction in surgery time led to a mean saving of 1750 pounds per patient.

A limitation of this study was the selection criteria; the complete CTA group had surgery after the control group. Whether our results are due to the introduction of CTA or other factors (e.g. increased technical know-how) is unknown. Before the introduction of CTA, >380 DIEP breast reconstructions had been done in our clinic. During this period, no significant decrease in surgery time or the number of complications was observed. Taking this into account, it seems more credible that the current decrease in operating time can be attributed to CTA introduction.

CTA provides a three-dimensional view of the vascular anatomy of the perforator flap and its surroundings. It gives precise information about the location, size, position and course of perforators. With a positive predictive value of 100%, CTA proved to be a reliable method to assess the perforator vessels before surgery.[8,9] CTA helped to determine if a patient was suitable for a DIEP flap. It also helped flap design, and the planning of incisions; the surgeon could determine how long the dissection would be.

Color duplex ultrasound offers precise information on the number of perforators and their diameter with a positive predictive value of 100%.[6] Compared with CTA, color duplex ultrasound offers more information about flow velocity inside the vessel, the condition and the thickness of the layer of subcutaneous fat, and the anatomical characteristics and status of the underlying skeletal muscles and fasciae. This gives the surgeon a detailed 'roadmap' that can be used in flap design for the individual patient.[6] The disadvantage of color duplex ultrasound is that it is a time-consuming technique for hospital staff and patients. The investigation takes ±45-60 min, and can be carried out only by highly skilled personnel who also have knowledge of perforator flap surgery. The information obtained is less reproducible because of real-time dynamics.[6,10]

CTA is easier to interpret than color duplex ultrasound. It took our radiologists an average of 15 min to post-process images. Post-processing included sagittal, axial and coronal slices, as well as three-dimensional reconstruction (*Figures 2, 3 and 4*).

The disadvantages of CTA are radiation exposure and the more invasive character of the examination. Radiation exposure was minimised by scanning only the donor site. Intravenous contrast material did not cause adverse reactions, but patients with known contrast allergy or impairment of renal function must be excluded.

CTA is used experimentally in complicated microsurgical fibula transfers.[11] Our study shows that CTA can also play an important part in microvascular perforator flap reconstructions. It provides high-resolution images and three-dimensional reconstruction of the vasculature. The ability to selectively add and subtract soft tissue and bones from images provides useful landmarks and important information about the zone of perfusion.

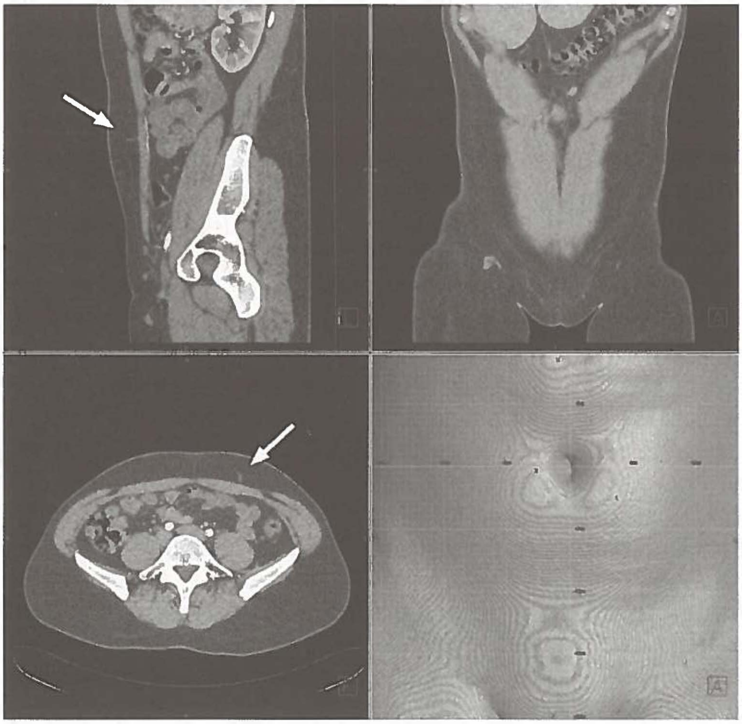

Figure 2; Reconstructions of CTA images in the sagittal, coronal and axial planes, and the VRT coronal image with a grid. The best perforator is marked with an arrow.

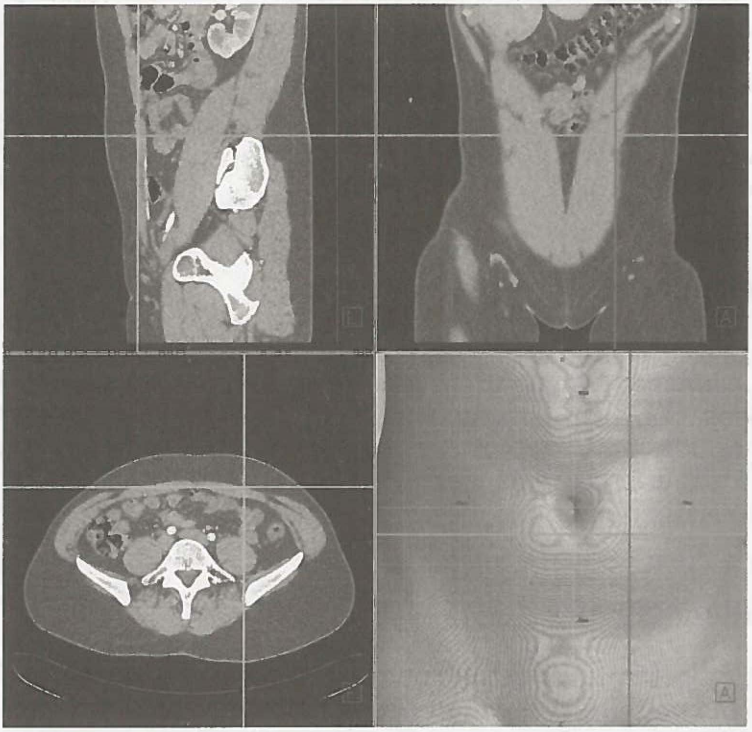

Figure 3; MPR cursor. Thick coloured lines mark the location of the perforator in the sagittal, coronal and axial planes, and the VRT coronal image with a grid and cursor.

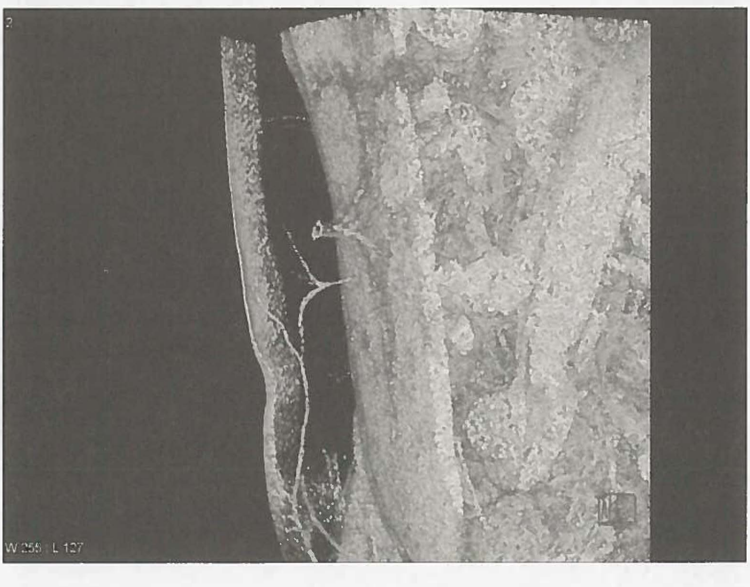

Figure 4; Three-dimensional reconstruction of the perforator arising from the abdominal muscle.

Conclusion

CTA in the assessment of perforator flaps was proved to be safe and reliable. It can help reduce surgery time. There are also indications that it positively influences the survival rate of flaps, but larger series are needed to confirm this.

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Siemens Leonardo Workstation (Siemens, Forchheim, Germany); Somatom Sensation 16 (Siemens, Forchheim Germany); Contrast Medium Omnipaque 300 mg I/ml (GE Healthcare, AS, Oslo Norway); Statistical Package for the Social Sciences (SPSS 13.0, SPSS Benelux bv, Gorinchem, The Netherlands).

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Chapter 4

Measuring the pressure in the superior inferior epigastric vein to monitor for venous congestion in DIEP breast reconstructions: A pilot study

J.M. Smit, MD, T. Audolfsson, MD, I.S. Whitaker, B.A. (Hons), M.A. Cantab, MBBChir, M.R.C.S, P.M.N. Werker, MD, PhD, R. Acosta, MD, A.G. Liss, MD, PhD

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Summary

Introduction: During deep inferior epigastric artery perforator (DIEP) flap dissection, we noted that in many cases the superficial vein on the ipsilateral side of the flap was engorged and tense, and in others, it was empty. This led us to believe that the pressure is increased as the result of preferential outflow through the superficial vein in some cases, which could result in venous congestion of the flap if this vessel was not anastomosed. To test this hypothesis, we measured the venous pressure in the superficial venous system before and after flap dissection.

Materials and methods: The pressure in the superficial inferior epigastic vein of a DIEP flap was measured in 26 consecutive flaps to investigate the correlation between the pressure and venous congestion of the flap. The first measurement was performed at the beginning of the dissection, and the second measurement was taken after the flap had been completely raised on a single perforator.

Results: The mean increase in pressure after flap dissection was 10.6 mm Hg (μ=10.6; range -1 to 31; σ ±7.0 mm Hg). Clinical signs of venous congestion were observed in one case. In this case, the increase in venous pressure was with 31 mm Hg, also the highest.

Conclusion: Although the results of this report are preliminary, they indicate that the pressure in the superficial vein of DIEP flaps might be of predictive value for venous congestion.

Introduction

Since its introduction by Koshima and Soeda,1 the deep inferior epigastric artery perforator (DIEP) flap has developed into a reliable option in breast reconstructions. The flap provides a large bulk of autologous tissue, while maintaining minimal donor site morbidity.[2–6]

Despite the fact that the reliability of the flap has increased as the result of technical improvements over the last decade,[7,8] complications still occur. One of these complications is venous congestion, which may occur when outflow of the flap through the perforator vein is insufficient compared with the blood inflow. Venous congestion has been reported to occur in 5% of the flaps.[8] This problem usually can be solved by creating an additional venous drainage, using the superficial epigastric vein.[9,10]

Accurate assessment of the perfusion of free tissue transfers has always been a challenge for surgeons undertaking microvascular reconstructive procedures, and there are a range of contemporary techniques in clinical use and currently in development.[11] It is well recognized that surgical experience is an important predictor for flap survival,[12] and recent advances in technology and improvements in surgical technique have led to reported success rates between 95 and 98%.[13,14] Taking into account that DIEP flaps are considered as time-consuming and complex procedures with inherent risks and psychological ramifications to the patient, it is crucial to optimize chances of a successful outcome.

Clinical tests used to detect venous congestion such as inspection (to assess color), palpation (to assess turgor and temperature), and capillary refill of the flap are still commonly used,[15,16] although animal tests have shown that change in color and increased refill are relatively late signs of venous congestion.[17] Because these tests often only becomes positive after the microsurgical anastomosis is completed, this potentially increases operative times.

Adjunctive techniques used to monitor flaps postoperatively include near-infrared spectroscopy,[18–20] indocyanine-green fluorescence video angiography,[21] simultaneous noninvasive laser Doppler flowmetry and tissue spectrophotometry,[22] and modified oxygen microelectrode combined with laser Doppler flowmetry.[17]

At the end of the DIEP flap dissection, we noted that in many cases the superficial vein on the ipsilateral side of the flap was engorged and tense, and in others, it was empty. This led us to believe that the pressure might be increased in some cases and could eventually result in venous congestion. To test this hypothesis, we measured the venous pressure in the superficial venous system before and after flap dissection.

Materials and methods

Design of study

The venous pressure in the ipsilateral superficial inferior epigastic vein (SIEV) of a DIEP flap was measured in 26 consecutive flaps. The first measurement was performed at the beginning of the dissection of the flap and was regarded as the normal pressure in the superficial venous system. The second measurement was taken after the dissection of the flap had been completed and the flap was raised on a single deep inferior epigastric perforator.

To investigate if there was a correlation between the change in pressure and venous congestion, the flaps were evaluated during surgery (prior to pedicle division and after the microsurgical anastomosis was completed) as well as a week postoperatively for any signs of venous congestion. The pressure measurements of the SIEV were only performed during surgery, so no measurements were performed during the postoperative checkups.

Because this is a pilot study, the criteria used to connect the superficial system to the cephalic vein were any sign of venous congestion or a caliber of 1.5 mm or larger of the SIEV. The results of our measurements did not influence this decision.

Preoperative computer tomographic angiography was performed to decide which perforator was best suited to base the flap on.

Patient characteristics

The age, sex, indication for surgery, American Society of Anesthesiologists (ASA) classification, nicotine use, received radiotherapy, type of anastomosis, receiving vessels, ischemia time, anastomotic time, surgery time, need of a revision, and surgical outcome of all patients were noted.

The study included 20 unilateral and three bilateral reconstructions. The age of the patients included ranged from 38 to 63 years ($\mu=50$; σ ± 6.0). The ASA classification ranged from one to three (m=2). Two patients were treated for hypertension. No patients used corticosteroids or had cardiovascular problems or diabetes mellitus. None of the patients smoked during admission for surgery, and 54% of patients received preoperative radiotherapy. All breast reconstructions were for oncological reasons, with four immediate breast reconstructions and 22 delayed reconstructions.

The internal mammary artery was the recipient site in the majority of cases (n=24). The circumflex scapular artery was the recipient vessel in two cases (n=2). The respective vein was used for the venous anastomosis. All arterial and venous anastomoses were done in an end-to-end fashion. In five flaps, a second venous anastomosis was performed as the diameter of the SIEV was 1.5 mm or larger, and in one case, signs of venous congestion were observed. The cephalic vein was used in all cases as the recipient vessel for the secondary anastomosis. The mean ischemia time was just under 1 hour (μ=56; range 31 to 160; σ ± 26 minutes). The mean anastomotic time was 14 minutes (μ=14; range 7 to 28; σ ± 6 minutes) and 8 minutes (μ=8; range 2 to 23; σ ± 5 minutes) for the artery and vein, respectively. The mean operative time was 6 hours and 6 minutes (μ= 366; range 210 to 510; σ ± 79 minutes). There were no flap losses, either partial or complete (overall success rate 100%; *Table 1*).

Mean age (years)(SD)	50, range 38 – 63 (6.0)
Mean ASA classification	2, range 1 – 3
Number of uni- and bilateral reconstructions	20 / 3
Number of primary and secondary reconstructions	4 / 22

Table 1; Patient demographics and variables of the 26 flaps used for this research. ASA; American society of anesthesiologists, SD; standard deviation.

Venous pressure measurement

To measure the pressure in the SIEV, a 22-gauge venflon (Becton Dickinson, Helsingborg, Sweden) was connected to a disposable pressure transducer (Becton Dickinson). The tip of the venflon was inserted into the vein, which had been isolated, securing the vein around it by gentle manipulation of the hand. After the tip was inserted, the microvascular clamp (S&T, Neuhausen, Switzerland) was removed and the pressure was measured (see *Figure 1*).

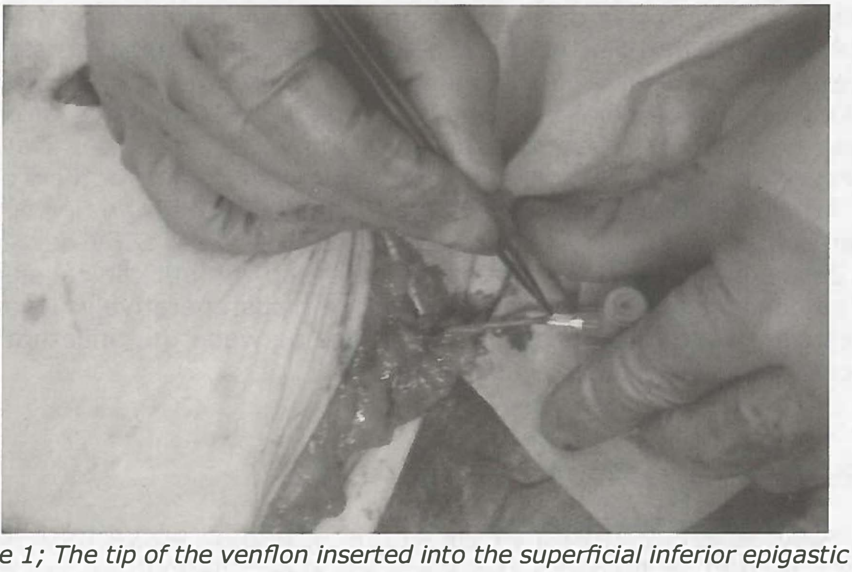

Figure 1; The tip of the venflon inserted into the superficial inferior epigastic vein, which had been isolated. The vein is being manipulated around the tip of the venflon using microsurgical forceps.

	Prior to flap dissection (n=25)*	After flap dissection (n=25)*	Difference (n=25)*
Mean pressure			
(cmH2O)	2.2	12.8	10.6
Range (cmH2O)	0 - 4	0 – 32	-1 – 31

*Table 2; The mean pressure in the superficial inferior epigastric vein prior to and after flap dissection. * In one case, no measurement was performed because of the minimal caliber of vein.*

Results

Of the 26 flaps used for this study, the pressure in the ipsilateral SIEV could be measured in 25. In one case, the pressure could not be measured as the caliber of the vein was too small to allow insertion of the cannula.

Venous pressure measurements
The mean pressure in the SIEV at the start of flap dissection was 2.2 mm Hg (μ=2.2; range 0 to 4; σ ± 1.1 mm Hg). The mean pressure after completion of flap dissection was 12.8 mm Hg (μ=12.8; range 0 to 32; σ ± 6.8 mm Hg). The mean increase in pressure after flap dissection was 10.6 mm Hg (μ=10.6; range -1 to 31; σ ± 7.0 mm Hg; *Table 2*).

Clinical signs of venous congestion were observed in one case out of the 26 (4%). In this case, the increase in venous pressure was also the highest, 31 mm Hg. At the time of this measurement, no signs of congestion were visible. The clinical signs (increasing turgor, delayed capillary refill, blue coloration) became apparent 10 minutes after the pressure in the SIEV was measured. In this case, the superficial vein was anastomosed to the cephalic vein to augment venous outflow of the flap. After the superficial vein was anastomosed, the signs of venous congestion resolved. In one case, the pressure in the SIEV decreased to 0. In the other cases, the pressure increased without clinical signs of venous congestion, either during surgery or postoperatively. No differences were seen in the increased pressure between the unilateral and bilateral reconstructions.

Discussion

This study was undertaken to try to find a simple, accurate, and objective method to measure the pressure in the superficial system to identify those at risk of venous congestion that requires an additional venous anastomosis. We describe a simple technique using a 22-gauge venflon connected to a disposable pressure transducer, which are both commonly used by anesthetists.

In our pilot study of 26 flaps, one episode of intraoperative venous congestion was observed. In this case, the increase of venous pressure after dissection was the highest at 31 mm Hg. After we had performed a second venous anastomosis (superficial epigastric vein to the cephalic vein), as expected, the signs of venous congestion resolved. In the case that read a pressure in the SIEV of 0, there was an exceptionally large-caliber vein in the deep system. In the other cases where the pressure increased, no signs of venous congestion were observed either intra- or postoperatively.

In 1999, Villafane et al[9] reported the importance of the superficial system. They used the SIEV as a lifeboat in a complicated case. After a thrombus formed twice in the deep inferior epigastric vein, it was no longer useable for drainage. The flap was saved by anastomosing the SIEV via a vein graft to the circumflex scapular vein.[9] Blondeel et al10 investigated the SIEV in an anatomic study in 15 fresh cadavers and three abdominoplasty specimens and retrospectively reviewed 249 DIEP and 279 transverse rectus abdominal muscle microvascular breast reconstructions. They recommended using the SIEV if it is wider than 1.5 mm as secondary if not primary venous anastomoses.[10] This was affirmed by other clinical and anatomic studies.[18,23,24] Although this criterion is widely applied today, the diameter of the SIEV might not be an absolute predictor for venous congestion. A recent study did not show a direct correlation between vessel diameters of superficial and deep inferior epigastric systems, meaning the diameter of the SIEV can be relatively large, but the deep venous system is still large enough to drain the complete flap.[25]

The advantage of the technique described in this article is that it offers direct information about the venous pressure in the superficial system and thus if the SIEV should be anastomosed or not. If the pressure is increased, the preparation for the second anastomosis can be made together with the preparation of the donor site, thus potentially saving operative time. Also, the results of this study indicate that the pressure in the SIEV rises before clinical signs of congestion are observed. This means that a possible complication can be acted on in an earlier phase, making the chance on severe complications smaller.

Because this is a pilot study, the results of this study need to be confirmed in a larger population, especially taking into consideration that in the current population venous congestion was observed only once. Apart from confirming our findings in a larger population, this pilot study also raises some questions among others about the redistribution of flow in a flap after harvest on the perforator vessels, for example, how the pressure will change after flap transfer and microsurgery and if the pressure will come back to the baseline after surgery. Also, the pressure in the contralateral SIEV could be of interest; in a unilateral reconstruction, for example, this might give an indication of the amount of flap that can be safely taken beyond the midline.

Compared with new monitoring techniques, the advantage of the described technique is that it is simple, inexpensive, and easy to use. The materials used to measure the venous pressure are commonly used by anesthesiologists and are therefore at hand. And because these materials are disposable, they do not need to be sterilized afterward or bagged before use.

Conclusion

Although the results of this report are preliminary, it indicates that the pressure in the superficial vein of DIEP flaps might be of predictive value for venous congestion. A study with a larger population needs to be performed to confirm the expectations this study brings forth.

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Chapter 5

Advancements in free flap monitoring in the last decade: a critical review

J.M. Smit, MD, C.J. Zeebregts, MD, PhD, R. Acosta, MD,
P.M.N. Werker, MD, PhD

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Summary

Introduction: The authors conducted a review of the recent literature on the monitoring of free flaps to create an overview of the current monitoring devices and their potential as an ideal monitoring method.

Materials and methods: A literature-based study was conducted using the PubMed and Cochrane databases. The following search terms were used: "flap" and "monitoring." All monitoring methods found between January of 1999 and January of 2009 were evaluated. Monitoring methods that were described in five or more clinical reports were further investigated.

Results: The advantages and disadvantages of conventional monitoring methods, the implantable Doppler system, color duplex sonography, near-infrared spectroscopy, microdialysis, and laser Doppler flowmetry are presented. Furthermore, an overview is given of their potential as ideal monitoring method.

Conclusion: The implantable Doppler system, near-infrared spectroscopy, and laser Doppler flowmetry appear to be the best monitoring devices currently available. As most of the publications on monitoring have focused on the reliability of the systems, future research should also address their cost efficiency.

Introduction

Since its introduction in the late 1950's[1] the free flap has evolved to the method of choice as a means to reconstruct or close large defects. In the last decade, success rates of 95 percent and higher have been reported.[2-4] Despite these improving success rates, microvascular failure remains a costly disaster. As salvage rates have been reported to be inversely related to the time interval between the onset of ischemia and its clinical recognition,[5] the monitoring of free flaps remains of major importance. In 1975, Creech and Miller[6] described what the ideal monitoring device should be like. It should be harmless to patient and flap, rapidly responsive, accurate, reliable, and applicable to all types of flap. Furthermore, it should be equipped with a simple display so that even relatively inexperienced personnel can alert the development of circulatory impairments. Despite the introduction of various new and improved techniques, none of these techniques has succeeded to meet all these so-called ideal criteria. We conducted a review of the recent literature on free flap monitoring to create an overview of the current monitoring devices and to define the ideal monitoring method.

Materials and methods

A literature-based study was conducted using the PubMed and Cochrane databases. The following search terms were used: "flap" and "monitoring." All monitoring methods found between January of 1999 and January of 2009 were evaluated. Monitoring methods that were described in five or more clinical reports were further investigated. Only studies written in the English language were included. For historical and technical backgrounds, reports older than 1999 were used whenever considered necessary.

The number of hits per monitoring method and the properties of the different publications are described in *Table 1*. No head-to-head comparison of monitoring methods was found. In selecting data about the reliability of the system, obviously prospective trials with a large population were preferred over others.

Data analysis

Data are presented as positive predictive value (chance that the flap is indeed compromised when a change of signal occurs) and negative predictive value (chance that the flap is not compromised when a normal signal remains). Cases in which the signal changed (whatever the reason) while the flap was not compromised were rated as false positive. Cases in which the signal did not change while the flap was compromised were rated as false negative. If the monitoring device gave a change in signal in a compromised flap, but this compromise was not noticed otherwise by the medical staff, it was rated as true positive.

	Conventional methods	Implantable Doppler system	Color duplex sonography	Near infrared spectroscopy	Microdialysis	Laser Doppler flowmetry
Number of hits	19	10	10	8	6	6
Number of trials	5	7	8	6	4	5
Number prospective trails	3	0	5	6	3	3
Mean population per trial	33 (range 8-67)	91 (range 5-369)	21 (range 5-54)	29 (range 11-41)	34 (range 14-78)	87 (range 11-232)
Type of reconstructions reported in trials	H&N: - Breast: - Extrem: - Buried: 4* Comb: 1	H&N: 3 Breast: 1 Extrem: 1 Buried: 1 Comb: 1	H&N: 2 Breast: 1 Extrem: 1 Burried: 4 Comb: -	H&N: 1 Breast: 4 Extrem: 1 Buried: - Comb: -	H&N: 1 Breast: 1 Extrem: - Buried: 1 Comb: 1	H&N: 1 Breast: 1 Extrem: - Buried: - Comb: 3

Table 1; Number of hits per monitoring method and characteristics of these publications. Comb; reconstructions at different anatomical locations.
** Although these reports describe monitoring buried flaps, they do this by adding an external component, making them not completely buried flaps.*

Results

Conventional methods
Conventional monitoring methods include clinical assessment of skin color, turgor (especially in replants) and temperature of the flap, and capillary refill. Handheld Doppler may also be regarded as a conventional technique.[7,8]
Current technologic advances in media and the Internet inspired some authors to use regular digital images to monitor color. It can help detect changes in time more quickly. Another advantage is that images can be transmitted via the Internet to the consulted surgeon at home. In dynamic processes, a video recording can be made as well.[9,10] To monitor color, buried flaps can be given an external component (either skin[11] or a vessel stump[12]). These can be removed later during a secondary procedure. Nevertheless, monitoring the color of muscle flaps covered by a skin graft remains cumbersome and not infrequently vascular problems are not signaled in time to allow for successful reintervention.

The temperature can be monitored using touch, temperature probes,[13] temperature-sensitive tape[14] (*Figure 1*), and a handheld non-contact thermometer.[15] Surface temperature monitoring is regarded by some authors to be of value only in monitoring replantations and small free flap reconstruction because of its inability to detect changes before flap failure or reoperation in deep inferior epigastric perforator flaps.[16]
To aid postoperative localization of the vessels by Doppler, the anasto-

motic sites are often marked on the skin by ink. A transparent film dressing can be used to protect the mark from fading during the patient's inpatient stay.[17]

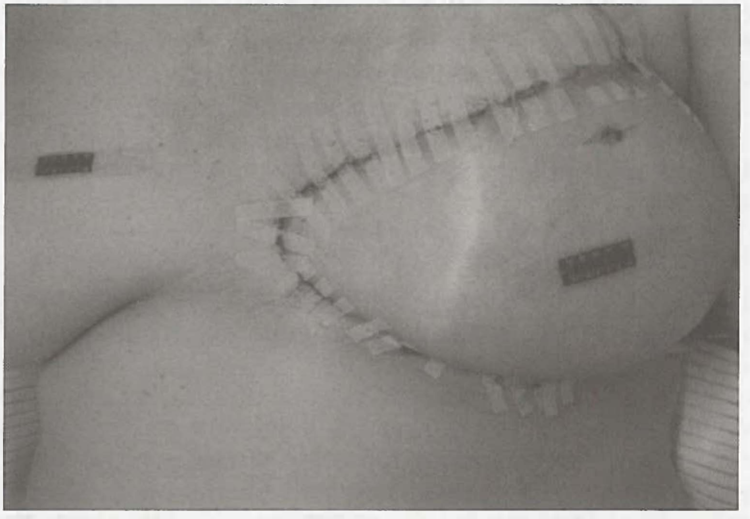

Figure 1; Temperature strip monitoring (Sharn Anesthesia, Inc., Tampa, Fla.) on a deep inferior epigastric perforator flap used for microsurgical breast reconstruction. One strip shows the temperature of the flap, while the other strip registers the temperature of the contralateral breast.

Figure 2; The implantable Doppler system (Cook Medical, Cook Ireland Ltd., Limerick, Ireland) showing the silicone cuff around the vein before skin closure. The Doppler crystal (which is attached to the cuff) is connected to a thin wire through which it exits the wound.

Implantable Doppler system
The implantable Doppler system is an invasive technique that allows direct and continuous monitoring. The technique was introduced in 1988 by Swartz et al.[18] in microsurgical reconstructions. The system consists of an implantable 20-MHz ultrasonic probe that is mounted on a silicone cuff that can be wrapped around the venous pedicle[19] and a battery-operated portable monitor. Different methods have been described to attach the cuff around the vein, including microclips,[20] sutures,[21] and fibrin sealant,[22] all with good results. Postoperatively, the surgeon, nursing staff, and the patient are able to hear the audible venous signal. The ultrasonic Doppler crystal is connected to a thin wire through which it exits the wound. The wire is plugged into the monitor at the patient's bedside. The electrode slides free from the cuff when pulled externally at 5 to 10 days postoperatively, depending on the length of monitoring required. The electrode is designed to separate from the cuff when a tension of 50 g is applied[18,19] (*Figure 2*).

The system has been praised for its ease of use, value in buried flaps, and the information it offers during the inset of the flap.[23-27] Difficulty in the interpretation of back and forth motion of blood in the internal mammary vein, however, may occur. This can be tested by listening if the signal stops after clamping the vein. If the signal does not, the system is of less use.[28] The negative predictive value of the implantable Doppler system is reported to be 100 percent.[21,25,26,29] In one reported case, the signal remained while the pedicle was kinked. In this case, the cuff was, however, wrapped around a vein in which two perforators drained, which explains the remaining signal.[30] The positive predictive value in a study including 369 head and neck cases was 81 percent.[24] Another study on 121 breast reconstructions described a positive predictive value of 93 percent.[25] In reports in which the system is used not exclusively for the vein but for monitoring either artery or vein, this number has been reported as low as 18 percent.[26,29] The costs of the system consist of $3100 for the monitoring box and $412 for each disposable probe.[31]

Color duplex sonography
Color duplex sonography is a noninvasive monitoring technique that combines the recording of blood flow velocity with the recording of blood flow direction. Combined color flow and spectral Doppler imaging within both flap and recipient vessels enables accurate assessment of anastomotic patency (*Figure 3*).

Color duplex sonography is often used in buried flaps and head and neck reconstructions, because in these circumstances, flaps cannot possibly be monitored with conventional methods.[32-37] Its strength is the precise and quantitative characterization of inflow and outflow,[38] and it has been reported to prevent unnecessary revisions.[35] The technique, however, requires experience with the device, as well as detailed knowledge of the recipient site and flap. This means that in some cases the radiologist and microsurgeon both have to be available when assessing the flap.[33] This explains why in several reports the system is often used no more than once a day.[34,35,37,38] Color duplex sonography has also been used as complementary test in studies addressing near-infrared spectroscopy[39,40] or the implantable Doppler system.[29] Two studies, with a combined population of 65 cases of head and neck reconstructions and buried flaps, reported the positive and negative predictive values of 100 percent.[33,38] The cost of the color duplex system may vary from $30,000 to $225,000, depending on its specifications.[41]

Figure 3; Color duplex sonography showing the monitoring of a buried gracilis flap.

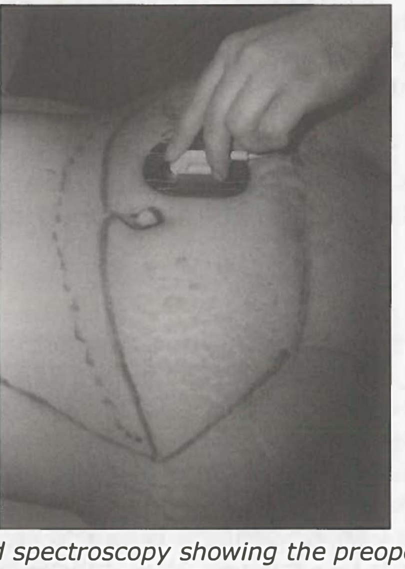

Figure 4; Near-infrared spectroscopy showing the preoperative calibration of the device in a deep inferior epigastric perforator flap reconstruction.

Near-infrared spectroscopy
Near-infrared spectroscopy is a noninvasive technique, which allows continuous monitoring of flap tissue oxygenation and perfusion. It was first described by Jöbsis[42] in 1977 in the exposed heart and brain, and was first reported in a plastic surgical journal in 1995 to monitor flaps and limbs in rabbits.[43]

Near-infrared spectroscopy employs the principles of optical spectrometry to measure haemoglobin content and oxygenation in local tissues. The system delivers selected and calibrated wavelengths of near-infrared light via a probe attached to the skin to tissues. Because of the applied technique, the monitoring is not influenced by movements of the probe, like for example in laser Doppler flowmetry.[44] Selective light absorption by oxygen-dependent tissue chromophores, primarily hemoglobin, results in the reduction of light intensity. The attenuated optical signal exiting the tissue is analyzed using spectrophotometric principles that relate light absorption to the tissue concentration of the chromophore.[45]

Characteristic absorption spectra of oxygenated and deoxygenated hemoglobin permit the system to calculate concentration of both haemoglobin forms.[46] The tissue penetration depth of near-infrared light can be up to 20 mm[44] (*Figure 4*).

Near-infrared spectroscopy is reported to allow objective and early detection of flow failure. It can accurately identify early signs of arterial and venous thrombosis before clinical signs of flap failure.[44,47] In the first few postoperative hours, however, there can also be a slight physiological decrease in oxygen saturation, which should not be misunderstood as a vascular complication. After 12 hours, the oxygen saturation returns to normal levels.[40,47] While some authors prefer nearinfrared spectroscopy for flaps with a cutaneous component,[44] others also advocate its use in buried flaps.[47] Three studies, with a combined population of 98 patients, reported both positive and negative predictive values of 100 percent.[44,47,48]
The cases reported in these studies included head and neck and breast, as well as buried flaps. The costs for a near-infrared spectroscopy monitoring system are $16,500 for the monitoring box and $150 for the disposable sensor.[49]

Microdialysis
Microdialysis is an invasive, intermittent, indirect monitoring technique. It was first described by Delgado et al.[50] in 1972 for detecting neurotransmitters and ischemia in monkeys. In 1998, Röjdmark et al.[51] reported its use for monitoring myocutaneous flaps.

Microdialysis is a sampling technique that studies the biochemistry of organs or tissues. A double-lumen microdialysis catheter or probe similar in size to an 18-gauge venous cannula is placed (using an open needle) under direct vision into the tissues. It is connected to a small pump, which infuses physiologic fluid through the catheter. Across a dialysis membrane, this fluid equilibrates with the interstitial fluid surrounding the catheter, and therefore aliquots of the perfusate can be analyzed on the tissue content of glucose, lactate, pyruvate, and glycerol metabolite concentrations. A falling glucose and rising lactateto-pyruvate ratio indicates anaerobic metabolism and thus indicates an arterial compromise.[52] A rising glycerol level reflects cell membrane damage and is seen in both venous congestion and arterial compromise[53] (*Figure 5*).

Microdialysis is capable of detecting vascular complications before clinical signs of vascular compromise.[54] A learning curve, however, is required to optimize the use of the system.[54] Besides, it takes 30 minutes to get a reading (20 minutes to fill the microvial and 10 minutes to analyze the fluid).[55] Microdialysis can be of extra value in buried and intraoral flaps.[55–57] The reported positive predictive value of microdialysis varies. In a study containing 78 consecutive flaps located at different anatomical locations, a positive predictive value of 90 percent was noted.[54] In another study of 25 head and neck reconstructions, however, the positive predictive value was reported to be 22 percent.[57] Although this percentage is low, it could have been caused by the learning curve of the system.[57] Both studies reported a negative predictive value of 100 percent.[54,57] The cost for the analyzer/ monitor itself is almost $52,000; the additional costs including catheters, reagents, and consumables are $570 per flap.[58]

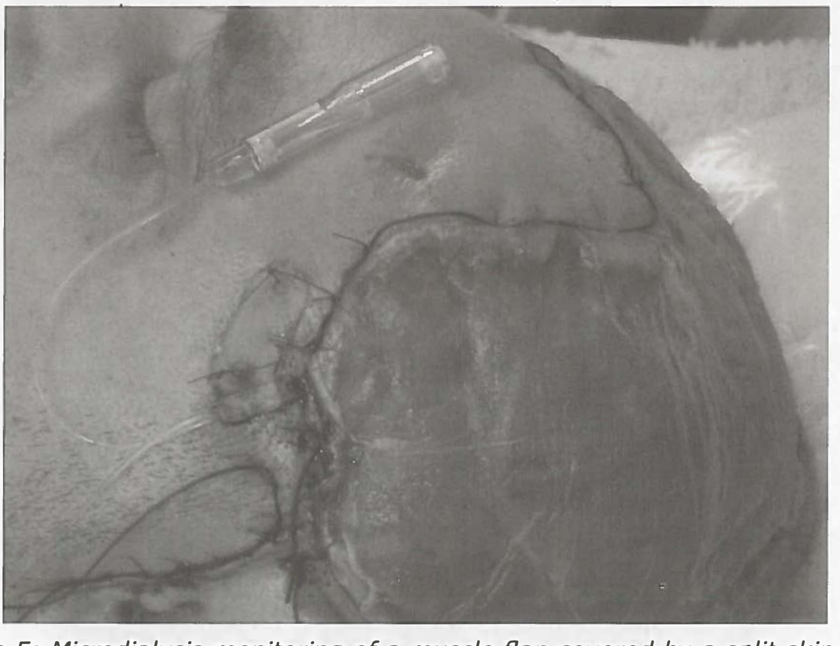

Figure 5; Microdialysis monitoring of a muscle flap covered by a split skin graft. The catheter is inserted into the flap and secured by sutures. A microvial is connected to the catheter to collect the fluid. An advantage of microdialysis, shown here, is that the catheter can be inserted next to the flap and tunneled to it subcutaneously, preventing interference between monitoring and wound dressings.

Laser Doppler flowmetry

Laser Doppler flowmetry provides a noninvasive continuous means of determining tissue perfusion. One of the first reports on laser Doppler flowmetry was an experimental animal study by Riva et al.[59] in 1972 to measure the blood flow in the retinal artery of albino rabbits. In 1977, it was reported by Stern et al.[60] in the assessment of blood flow in human skin.

In laser Doppler flowmetry, tissue is illuminated with coherent laser light through a fiberoptic cable. Backscattered light is collected by the same probe, and a frequency shift is extracted by the heterodyne light beating technique. The power-spectral density of shifted light is a linear function of the average velocity of moving cells within the tissue. Depending on the probe geometry, a detection of blood flow and flow velocity up to 8-mm depth is possible.[61] The probe can be attached to the skin by using double-sided adhesive rings; sutures can also be used when a firmer attachment is required[62] (*Figure 6*).

It is more important to observe trends in laser Doppler flowmetry readings rather than the absolute value, particularly in cases of venous occlusion, in which there is typically a less abrupt decline in flow values.[63,64] The system can be sensitive to vibration, motion of the probe, or tissue. If the flowmeter indicates an abnormal blood flow, just repositioning of the probe can improve the flow readings.[62] To better evaluate the microcirculation of the flap, laser Doppler flowmetry has been used with light guide reflectance spectrophotometry.[26] To more effectively differentiate between arterial occlusion and venous congestion, it has been used in combination with tissue spectrometry with good results.[61] Two large studies, with of a combined population of 326 cases, showed a

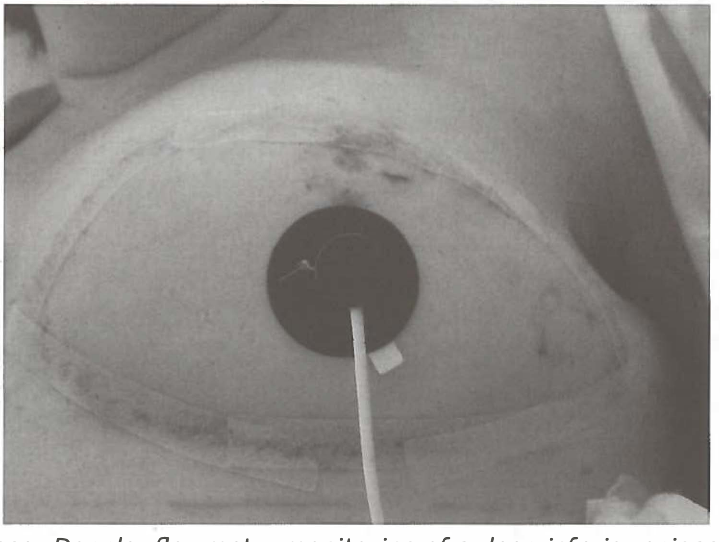

Figure 6; Laser Doppler flowmetry monitoring of a deep inferior epigastric perforator flap reconstruction.

negative predictive value of 100 percent and positive predictive value between 94 and 100 percent.[62,63] The cases in which the probe had to be repositioned are, however, not included in these numbers.[62,63]

The price of the laser Doppler flowmeter ranges upward from $5460, and the price of the probe ranges upwards from $1015. The probe can be used far at least 10 cases or half a year before it needs to be replaced. The current generation of laser Doppler flowmetry devices have integrated temperature sensors to aid monitoring.[65]

Monitoring technique	Positive predictive value	Negative predictive value	Conti-nuous	Inva-sive	Direct	Easy to interpret	Simple technique	Appli-able to all types of flaps	Costs
Conventional methods			-	-	+/-	-	+	-	
Implantable Doppler system	81% - 93%[24,25]	100%[24,25]	+	+	+	+	+	+	$3,100 (monitoring box), $412 (disposable probe)[31]
Color duplex sonography	100%[33,38]	100%[33,38]	-	-	+	-	-	+	$30,000 to $225,000[41]
NIRS	100%[44,47,48]	100%[44,47,46]	+	-	+	+	+/-	-	$16,500 (monitoring box), $150 (disposable sensor)[49]
Microdialysis	90%[54]	100%[54,57]	-	+	-	-	-	+	$52,000 (analyzer), $570 (Catheters, reagents, and consumables)[58]
Laser Doppler flowmetry	94%-100%*[62,63]	100%[62,63]	+	-	+	+/-	+/-	-	$5,460 (laser Doppler flowmeter), $1,015 (probe, per 10 cases)[66], **

*Table 2; Different monitoring methods compared with criteria of Creech and Miller; * The cases in which the probe had to be repositioned are, however, not included in these numbers.** The system also includes a temperature probe.*

Discussion

Until today, the most commonly applied monitoring methods have been conventional techniques. In only approximately 10 percent of reported cases are other methods used, and in most of those cases the method used is laser Doppler flowmetry.[66,67] This study was undertaken to create an overview of methods of free flap monitoring in the recent literature to define which monitoring method is currently the best. It remains difficult to compare trials of different monitoring methods. Methods of investigation and definitions differ widely per study. Furthermore, it is important to realize that each study is being performed in a different setting in which technical skills, type of reconstructions, and experience in free flap monitoring may differ.

Although conventional monitoring methods are cheap, the results of this study do not favor the sole use of these methods when taking into account the response time of the method. The implantable Doppler system, near-infrared spectroscopy, microdialysis, and laser Doppler flowmetry have all been reported to detect a vascular complication earlier compared with conventional methods. A rapid response can often be achieved by a continuous monitoring method, such as the implantable Doppler system, near-infrared spectroscopy, and laser Doppler flowmetry. Microdialysis is not continuous; a microvial has to be inserted to collect a sample, and this sample has to be analyzed. Furthermore, taking into account that the costs of microdialysis are the highest and the output is more difficult to interpret, we do not think it is the best monitoring method available at this moment.

Most research protocols used color duplex sonography only once a day to monitor flaps and used it primarily as a method of control, when in doubt or for buried flaps.[29,33–35,39,40] We believe that these are the best indications for the use color Doppler sonography. It is, however, more time consuming compared with most other methods, and trained personnel are needed to interpret the data correctly.[33,35] If, however, a vascular compromise is found, especially in buried flaps, the chances for a successful reintervention may be limited, due to an extended ischemic interval.

When comparing near-infrared spectroscopy, the implantable Doppler system, and laser Doppler flowmetry, near-infrared spectroscopy probably has the most potential in becoming the ideal monitoring method. The system is reliable; all reports state a 100 percent positive and negative predictive value,[44,47,48] and it also gives information on the exact type of complication. Furthermore, near-infrared spectroscopy is noninvasive and is reported to monitor tissue up to 20mmin depth,[44] making it applicable to most flaps.

The implantable Doppler system is the cheapest of the newer monitoring methods. Two other important advantages are that it can be used in all types of flaps and that its reading is easy to interpret, because the flow of the vein is reflected as an all or none phenomenon. Therefore, the system may be especially useful for less-trained personnel. What makes the system less ideal is the fact that it is an invasive system and that a component (the silicone cuff) remains behind after removal of the lead and Doppler crystal. Besides, the placement of the system is critical, resulting in the lower positive predictive value.[24,25]

Laser Doppler flowmetry is a system with similarities to near-infrared spectroscopy but with some differences as well. The penetration depth is reported up to 8 mm,[61] compared with 20mm with near-infrared spectroscopy.[44] In addition, instead of looking at an absolute value, one follows trends with laser Doppler flowmetry,[63,64] as flow and not oxygenation is monitored. This is also why near-infrared spectroscopy is more reliable if the external probe temporarily detaches, because the oxygenation is more equally divided over the flap compared with flow. An advantage laser Doppler flowmetry has over near-infrared spectroscopy is its cost, being less than half of the price of the near-infrared spectroscopy system (*Table 2*).

As most of the publications on monitoring have focused on the reliability of the systems, future research should address "head-to-head" comparisons of the different monitoring methods as well as the cost efficiency of the systems, especially as it becomes more important to further reduce the costs of healthcare. The cost effectiveness can, for example, be calculated by investigating how the success rate of the free flaps, and in particular the success rate of the revision, changes by the introduction of a monitoring system.

Conclusion

The results of this study do not favor the sole use of conventional monitoring methods when taking into account the time of response of the method. The implantable Doppler system, near-infrared spectroscopy, and laser Doppler flowmetry appear to be the best monitoring devices currently available. As most of the publications on monitoring have focused on the reliability of the systems, future research should also address their cost efficiency.

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Note
The prices named in this article for the different monitoring devices only serve as an indication. It is important to realize that they might vary per country and in time.

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Chapter **6**

Post operative monitoring of microvascular breast reconstructions using the implantable Cook–Swartz Doppler system: A study of 145 probes & technical discussion

J.M. Smit, MD, I.S. Whitaker, B.A. (Hons), M.A. Cantab, MBBChir, M.R.C.S, A.G. Liss, MD, PhD, T Audolfsson, MD, M. Kildal, MD, PhD, R. Acosta, MD

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Summary

Introduction: Accurate post operative assessment of free tissue transfers is challenging despite all the subjective and objective techniques available today. In our continual search to optimise patient outcomes, we introduced the Cook-Swartz probe into our clinical practice in May 2006.

Materials and methods: We present our single centre experience in 103 patients undergoing 121 microvascular breast reconstructions and monitored using implantable Cook-Swartz venous Dopplers between May 2006 and January 2008.

Results: In total, we used 145 probes on 121 microvascular breast reconstructions (DIEP=102, SIEA=15, SGAP=4) in 103 female patients. The mean operative time was 4 h and 55min (μ=295; range 117-630; $\sigma \pm$ 101 min) and we suffered 2 complete flap losses. A problem with the audible signal was noted in 15 patients (4 intra-operatively). We revised 14 of the 15. All fourteen had compromised anastomoses. In the remaining case, the patient was not returned to theatre as the primary surgeon was confident there were no other signs of vascular compromise. Overall, when using the venous Doppler probe we found a false positive rate of 6.7% and 0% false negatives.

Conclusion: We advocate the use of a Cook-Swartz probe which has been well received by both surgeons, nursing staff and patients, as an adjunct to traditional clinical monitoring techniques. We also include a comprehensive experience based technical discussion concerning its application, attachment, use and post-operative removal.

Introduction

Accurate assessment of the perfusion of free tissue transfers has always been a challenge for surgeons undertaking microvascular reconstructive procedures, and there are a range of contemporary techniques in clinical use, and currently in development.[1] Routine monitoring of free flaps is increasingly being undertaken by nursing staff on the ward, and often junior medical staff covering the ward have little experience of such monitoring and are not assigned specifically to the operating surgeons team. It is well recognised that surgical experience is an important predictor for flap survival[2] and recent advances in technology and improvements in surgical technique have led to reported success rates between 95 and 98%.[2] This success has been achieved in conjunction with improved monitoring of flap circulation post-operatively. Considering free tissue transfers are time consuming and complex procedures with inherent risks, we are always looking for devices that have the potential to minimise patient morbidity.

In our continual search to optimise patient outcomes, we introduced the Cook-Swartz probe (Cook Medical®, Cook Ireland Ltd, Limerick, Ireland) into our clinical practice in May 2006. The Cook-Swartz venous Doppler system is a technique for monitoring venous flow in free tissue transfer consisting of an implantable 20 MHz ultrasonic probe around the venous pedicle and a battery operated portable monitor. Although it was developed in the USA some time ago, and has been available for clinical use in the USA for several years,[3-5] it has only gained the CE mark and been distributed in Europe since 2006. Only a handful of small preliminary reports have been described in Europe and Australasia over the last 2 years,[6,7] with promising results. We present our experiences, on 103 patients with the device and advocate the use of a Cook-Swartz probe as an adjunct to traditional clinical monitoring techniques. We also include an experience based technical discussion concerning its application, attachment, use and post-operative removal.

The Cook-Swartz Doppler monitoring system

The Cook-Swartz venous Doppler monitoring system is a technique for monitoring blood flow following free tissue transfer. It consists of an implantable probe with a removable, 20 MHz ultrasonic Doppler crystal and a silicone cuff to secure it around the vessel adventitia of the venous pedicle, and a battery operated or line powered portable monitor. The cuff consists of a small 8 x 5 mm^2 thin silicone sheet which is wrapped around the vessel and the overlying ends secured. The probe's proximal end exits as a thin wire through the wound and is connected to an intermediate extension cable that is attached to the patient through the use of specially designed retention tabs. The intermediate cable plugs into a transportable monitor at the patient bedside, which is battery or mains operated. The intermediate cable allows detachment of the probe whilst the patient mobilises post-operatively. The electrode slides free from the cuff when pulled externally at 5-10 days postoperatively depending on the length of monitoring required. The electrode is designed to separate from the cuff, when a tension of 50 grammes is applied. By 5 days the cuff is sufficiently adherent to the vessel and the vessel adherent to the surrounding tissue, allowing safe traction and removal of the electrode. The probe allows direct vessel monitoring of a microvascular anastomosis at a specific site along a designated vessel. It is possible to listen to the signal in the donor vessels whilst selecting a vessel for anastomosis. It is possible to use multiple probes if several venous anastomoses are carried out. Post-operatively, the surgeon, nursing staff and the patient are able to hear the audible venous signal. It potentially gives an early warning to flaps with compromised pedicles before clinical signs are apparent, allowing an earlier return to theatre (*Figure 1*).

Materials and methods

The patients details of 103 patients undergoing 121 microvascular breast reconstructions (DIEP=102 , SIEA=15, SGAP=4) and monitored using 145 implantable Cook-Swartz venous Dopplers between May 2006 and January 2008 were retrieved. All patients were operated on in a single centre, with three senior plastic and reconstructive surgeons performing the operations. The age, sex, indication for surgery, type of flap, type of anastomosis, recipient vessels, ischemia time, anastomotic time, revisions and surgical outcomes were reviewed from our comprehensive database.

Figure 1; The Cook-Swartz venous Doppler monitoring system. The blue and green wires connect the probe with the white monitoring box.

Results

Our study group included 121 microvascular breast reconstructions on 103 female patients with an age range of 22 to 67 years (μ=50; σ ± 9.5) All breast reconstructions were for oncological reasons; with 29 immediate breast reconstructions and 92 delayed reconstructions. The DIEP flap was the most often used flap (n=102 breasts). SIEA (n=15) and SGAP (n=4) flaps were used less commonly. The internal mammary artery was the recipient site in the majority of cases (n=113). The circumflex scapular artery was the recipient vessel in seven cases (n=7) and the Thoracodorsal artery once (n=1). 117 (97%) of arterial anastomosis were end to end. The respective vein was used for the venous anastomosis. In 51 flaps, a second venous anastomosis was performed as the flap subjectively appeared engorged following successful primary venous anastomosis. The cephalic vein was most commonly used as the recipient vessel for the secondary anastomosis (n=36). The internal mammary (n=8), circumflex scapula (n=4) and Thoracodorsal (n=3) were also used. 170 (99%) of venous anastomoses were performed in an end to end fashion, the rest were preformed end to side.

The mean ischemia time was one hour (μ=60; range 20-155; σ ± 24 min). The mean anastomotic time was 14 min (μ=14; range 4-38; σ ± 5 min) and 9 min (μ=9; 1-35; σ ± 6 min) for the artery and vein, respectively. The mean operative time was 4 h and 55 min (μ=295; range 117-630; σ± 101 min). There were 2 complete flap losses and one case of partial necrosis (overall success rate 98%). Overall we used 145 implantable probes in 121 cases.

A problem with the audible signal was noted in 15 patients. A poor audible flow signifying flap compromise was picked up intra-operatively in four cases. There were problems with the artery in three cases (two arterial thrombosis, one arterial spasm), and one problem with the vein (one venous pedicle was kinked). In 10 of the remaining 11 cases, a salvage procedure was performed.

The mean time to re-operation was 35 h and 52 min (μ=35h52; range 1h01-80h00; σ ± 29h07). The most common intra-operative finding were an arterial thrombosis (n=4) and a venous thrombosis (n=4). A haematoma causing venous compression was seen in two cases. In the remaining case, the patient was not returned to theatre as the primary surgeon was confident there were no other signs of vascular compromise. The two flap failures were due to 1 arterial, and 1 venous thrombosis (*Table 1*). Overall, when using the venous Doppler probe we found a false positive rate of 6.7% and 0% false negatives.

Case	Age	Risc factors	Flap used	Immediate vs delayed recostruction	Receptor vessels	Type of arterial anastomosis	Arterial anastomosis material	Type of venous anastomosis	Venous anastomosis material	Change in signal	Time to reoperation (hours)	Intraoperative findings	Flap outcome
1	45	DM[a]	DIEP[c]	Delayed	internal mammary	end to end	suture	End to end	Clips	Stop	Iorf	Arterial thrombosis	Success
2	52		SIEA[d]	Delayed	internal mammary	end to end	suture	End to end	Clips	Stop	Ior	Arterial thrombosis	Failure
3	56		DIEP	Delayed	internal mammary	end to end	suture	End to end	Unilink®	Pulsating	Ior	Arterial spams	Success
4	57		DIEP	Delayed	internal mammary	end to end	suture	End to end	Suture	Weak signal	Ior	Venous insufficience	Success
5	59		DIEP	Delayed	internal mammary	end to end	suture	end to end	Clips	Stop	1	Hematoma	Success
6	59	HT[b]	DIEP	Immediate	internal mammary	end to end	suture	End to end	Suture	Stop	4	Venous thrombosis	Success
7	35		SGAP[e]	Immediate	internal mammary	end to end	suture	End to end	Clips	Stop	11	Hematoma	Success
8	53	HT	SGAP	Delayed	internal mammary	end to end	suture	End to end	Clips	Decrease	14	Venous thrombosis	Success
9	39		SGAP	Immediate	internal mammary	end to end	clips	End to end	Unilink®	Stop	22	Arterial thrombosis	Success
10	39		DIEP	Delayed	internal mammary	end to end	suture	End to end	Unilink®	Stop	51	Arterial thrombosis	Success
11	43		DIEP	Delayed	internal mammary	end to end	suture	End to end	Clips	Stop	51	Arterial thrombosis	Success
12	38		DIEP	Delayed	internal mammary	end to end	suture	End to end	Unilink®	Stop	54	Arterial thrombosis	Partial necrosis
13	58		DIEP	Delayed	internal mammary	end to end	suture	End to end	Unilink®	Decrease	74	Venous thrombosis	Failure
14	34		DIEP	Immediate	internal mammary	end to end	suture	End to end	Unilink®	Stop	80	Venous thrombosis	Success
15	60		DIEP	Immediate	internal mammary	end to end	suture	End to end	Clips	Stop	No surgery performed	No surgery performed	Success

Table 1; Cases in which the medical staff were alerted to poor audible Doppler flow.
DM; diabetis melitus, HT; hypertension, DIEP; deep inferior epigastric perforator, SIEA; superficial inferior epigastric artery, SGAP; superior glutal artery perforator, Ior; intra operative revision.

Discussion

In many cases, the complexities of flap microcirculation are difficult to assess despite all the subjective and objective examination techniques available today.[1,2,8-15] Efficacious post-operative monitoring of free tissue transfers in mandatory in order to detect vascular occlusion at an early enough stage to allow re-exploration and ultimately improve the chances of flap salvage.[16,17] Of the techniques currently available to monitor free flaps post-operatively, clinical assessment is the most commonly used,[11,18] however there is a need for experienced interpretation and such tests are often unreliable.[11,19] Clinical changes may be subtle initially and by the time they are clinically apparent, salvage of the flap may be impossible due to irreversible tissue damage. Notwithstanding this, some authors still believe clinical observation to be the 'gold standard'.[20] It is clear there is a wide variation in the post-operative monitoring of free tissue transfers, in the UK at least.[10,18,21] Flap perfusion has been investigated using a myriad of techniques using: sodium fluorescein,22-26 indocyancine green,[27-30] radioactive isotopes (technitium 99 m,[31,32] xenon 133,[33] sodium 22[34]), hydrogen gas clearance,[35,36] microdialysis,[37-39] tissue pH,[40-43] pO2,[44-54] surface temperature,[55,56] near infra-red spectroscopy,[57-61] hand held Doppler,[62] laser Doppler[57,63-66] and photoplethysmography.[67-69]

It is an indictment of all the techniques available that most surgeons still rely on their own clinical observation. However, with the routine monitoring of free flaps on the ward often being undertaken by junior ward nurses, and inexperienced junior doctors on rotation, it is incumbent on us as senior medical practitioners to strive to optimize patients outcomes following microsurgery and lead us towards the ideal method of monitoring flap viability proposed by Creech and Miller (1975).[70] Over time, flap salvage rates decline significantly and the ideal time to detect a flap with inflow or outflow compromise is before the patient leaves the operating theatre.

Implantable probes such as the Cook-Swartz Doppler system offer this exciting opportunity. Initial experimental work with the implantable Doppler probes showed that there were un-necessary re-explorations (false positives 3%) and venous thrombosis that were not detected (false negative 5%) when the probe was placed only on the arterial pedicle. Significant delay of up to 5 h was found between a problem with venous outflow to loss of the arterial signal in large muscle flaps.[3] These findings were corroborated by Swartz[4,5] when he found that arterial probes immediately detected an arterial occlusion but continued to record pulsation for up to 6 h after venous occlusion. Venous probes detected a venous problem immediately and an arterial problem on average 6 min after arterial occlusion. A recent small study (n=24) in the United States has described promising results for the implantable venous Doppler in head and neck surgery[71] with increased success and operative salvage rates.

Two other recent studies, one in the UK7 (n=24) and one in New Zealand6 (n=4) have also advocated the probe's use. This device has only recently become available for general use in the UK and mainland Europe, and we have been using it since the release date.

Since May 2006, we have performed 121 microvascular breast reconstructions (29 immediate and 92 delayed) on 103 female patients. The majority of our cases were DIEP flaps using the internal mammary vessels as the recipient site. We performed a second venous anastomosis to augment venous outflow in 51 flaps, most commonly using the cephalic vein as the recipient vessel.

Overall, our success rate of 98% is comparable with other published studies.[72-74] From the 145 implantable probes used in 121 cases, a problem with the audible signal was noted in 15 patients. A poor audible flow signifying flap compromise was picked up intra-operatively in four cases. There were problems with the artery in two cases (one arterial thrombosis, one arterial spasm), and two problems with the vein (one venous thrombosis and one venous pedicle was kinked). In the remaining 11 cases the change in signal was picked up on the ward and in 10 a salvage procedure was performed. The mean time to re-operation was 35 h and 52 min (μ=35h52; range 1h01-80h00; σ = 29h07). Eight of the ten flaps returned to theatre were salvaged successfully. It is of note that in one case, even though there was a change in Doppler signal, the decision was made not to return the patient to theatre. Upon complete clinical examination of the patient and flap, there was no indication that flap viability was threatened. Overall, when using the venous Doppler probe we found a false positive rate of 6.7% and a false negative rate of 0%. We routinely remove the probe at seven days post-operatively.

As a surgical team, we have very positive experiences with the application and use of the Doppler probe and would advocate its use as an adjunct to clinical monitoring techniques. Since introduction into our clinical practice, the Cook-Swartz probe has changed the way we monitor free flaps. Whereas previously we relied on the regular use of handheld Doppler probes and clinical tests, we now only use these methods if there is a clear change in audible Doppler output. This makes the monitoring less labour intensive and cause less patient disruption, as we can often turn the monitor on quietly at night without waking the patient.

The Cook implantable probe - technical aspects

Application and attachment

We manipulate the silicone cuff bi-manually with fine non-toothed forceps. One side of the cuff is gently wrapped around the vein (distal to the anastomosis) and then the other side. Both ends of the cuff are gently gripped by the forceps, and micro-clips are used to secure the cuff in situ (*Figure 2*). It is important to get the tension correct as the Doppler probe in the cuff must be securely in contact with the vein. If the cuff is too tightly secured, the potential for venous outflow obstruction exists. If the probe is not well approximated either no signal is produced, or it may rotate and induce vasospasm in the arterial wall if adjacent. Other possible methods to secure the cuff include fibrin glue[75] and sutures.[7] We prefer using microclips as we believe very accurate placement may be achieved, and adjustment is easy due to the atraumatic 'sliding' nature of application and removal. In our experience the use of this system adds less than five minutes to the procedure. Whilst with any procedure there is a learning curve, we have found it straightforward to use from the first case. It has been used by three surgeons in our unit during this study without technical difficulties with its application or use. The Cook-Swartz system can be used in conjunction with other monitoring techniques and the probe allows direct vessel monitoring of microvascular anastomoses at a specific site along a designated vessel. If two venous anastomoses are needed to augment high flow flaps, multiple Doppler probes can be used as the monitor has two channels that can be used simultaneously.

Post-operative removal

In our clinic the probes are removed the seventh day post surgery. The probes are removed by the responsible consultant. They are removed by using minimal traction on the wire where it exits the flap. Manufacturers specifications state that a force of only 50 grams needs to be applied. After removal the probe, we routinely perform a final check with the hand held Doppler to ascertain anastomotic integrity. Of the 145 probes we have removed so far, we have encountered no complications.

Figure 2; Attachment of the silicone cuff using micro-clips.

Cost
Each disposable probe costs £270 and the monitoring box £1750. Considering the cost of return to theatre and revision, morbidity of flap loss and consequences for the patient, we believe that venous Doppler monitoring can be justified.

Conclusion

In our experience with 145 probes, we found a false positive rate of 6.7% and a false negative rate of 0%. We advocate the use of a Cook-Swartz probe which has been well received by both surgeons, nursing staff and patients, as an adjunct to traditional clinical monitoring techniques.

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Chapter 7

The introduction of the implantable Doppler system did not lead to an increased salvage rate of ompromised flaps, a multivariate analysis

J.M. Smit, MD, P.M.N. Werker, MD, PhD, A.G. Liss, MD, PhD, M. Enajat, G.H. de Bock, PhD, T. Audolfsson, MD, R. Acosta, MD

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Summary

Introduction: The Cook-Swartz implantable Doppler system was introduced at the Uppsala University Hospital to ease free flap monitoring and improve salvage rates by an earlier detection of vascular compromise. The aim of the current analysis was to investigate whether the system indeed improved the salvage rate of revisions.

Materials and methods: All cases that needed revision among a consecutive series of patients being monitored with the implantable Doppler system between June of 2006 and January of 2009 were compared with a similar set of patients operated on before the introduction of the implantable Doppler system over an equal time span monitored with conventional methods. Data were extracted from the medical files of the patients. Logistic regression was used to identify factors associated with the outcome of the revision. Values of $p < 0.05$ were considered statistically significant.

Results: A total of 327 flaps were monitored with the implantable Doppler system, of which 35 needed revision. In the control group, 303 flaps were included, of which 40 needed revision. The revision was successful in 69 percent of the cases in the implantable Doppler system group; in the group monitored by only conventional methods, this rate was 60 percent. Univariate analysis showed no statistical difference between these success rates ($p = 0.441$; odds ratio, 1.455; 95 percent confidence interval, 0.560 to 3.775). Multivariate analysis did not show a statistical difference either ($p = 0.799$; odds ratio, 1.143; 95 percent confidence interval, 0.410 to 3.182).

Conclusion: The introduction of the implantable Doppler system did not lead to a significant increase in the salvage rate of revised flaps.

Introduction

Since its introduction in the late 1950's,[1] the free flap has evolved into the method of choice as a means of reconstructing large defects. Over the past decade, success rates of 95 percent and higher have been reported.[2–5] Despite these high success rates, complications do occur. They can be divided into general and specific complications. General complications include infection, hematoma, and systemic complications such as pulmonary and cardiac problems. Specific complications are caused by arterial and/or venous occlusion or insufficiency. When such a specific complication occurs and is not acted on fast enough, it will cause necrosis of the flap, either partially or totally.[6,7] To spot these problems in time, flaps are routinely carefully monitored during the early postoperative period to enable reintervention and salvage of the flap.

Conventional monitoring techniques, which are still most commonly used today, include inspection, palpation, capillary refill, handheld Doppler ultrasonography, surface temperature probes, and pinprick tests.[8,9] Adjunctive techniques used to monitor flaps postoperatively include the implantable Doppler system designed by Swartz et al.,[10] near-infrared spectroscopy,[11–13] microdialysis,[14–16] laser Doppler flowmetry[17,18] in some cases combined with tissue spectrophotometry,[19] and modified oxygen microelectrode combined with laser-Doppler flowmetry.[20]

The Cook-Swartz implantable Doppler system was introduced at the Department of Plastic and Reconstructive Surgery of the Uppsala University Hospital in June of 2006 to facilitate free flap monitoring. The goal of its introduction was to ease free flap monitoring and improve salvage rates by an earlier detection of complications. The aim of the current analysis was to investigate whether the system indeed improved the salvage rate of revisions.

Patients and methods

Setting

The Section of Microsurgery of the Uppsala University Hospital, Sweden, consists of three plastic surgeons and a rotating resident. Since 2000, the number of free flaps performed has been approximately 100 per year.

Study design

All cases among a consecutive series of patients that needed revision being monitored with the implantable Doppler system between June of 2006 and January of 2009 were compared with a similar set of patients (control group) operated on before the introduction of the implantable Doppler system over an equal time span monitored with conventional methods. The groups were compared for the success rate of the revisions.

Patients
In the analysis of revision outcome, only the revised cases were included in which vascular compromise was found during surgery (true-positive readings). Patients undergoing revision but in which no vascular compromise was found during surgery (false-positive readings) were excluded from the analysis. The failed cases in which no revision was undertaken were also included. This was done to prevent bias and the suggestion that we chose to perform fewer revisions in potentially less successful cases to increase our salvage rate.

Monitoring protocol
All patients went to the intensive care unit directly after surgery. The flap was monitored by trained nursing personnel who were in close contact with the microsurgeon and the anaesthesiologist involved. During the first 4 hours after surgery, the flap was checked every 15 minutes. Between 4 and 8 hours after surgery, measurements took place every 30 minutes. After 8 hours, measurements were performed every hour. After the first day, the patient was returned to the ward. On the second day, measurements were taken every 2 hours; on the third day, every 3 hours; and from day 4 until day 7, every 4 hours.

Implantable Doppler system
The Cook-Swartz Doppler Flow Monitoring System (Cook Medical, Cook Ireland Ltd, Limerick, Ireland) consists of an implantable, removable, 20-MHz ultrasonic probe mounted on a silicone cuff that is used to secure the probe around the adventitia of the venous pedicle (*Figure 1*). The probe is attached to a wire that exits the body through the incision, where it becomes an external wire attached to the skin by silicone tabs placed around the wire. The external wire can be connected through an extension cable to a portable monitor that provides audible real-time monitoring of venous blood flow. The wire and probe are designed to detach from the silicone cuff with minimal tension, once postoperative vascular monitoring is terminated. Because the flap can often be seen during the monitoring with the implantable Doppler probe, the color of the flap can be used as an adjuvant monitoring method. The system can be of extra value in flaps that are difficult to monitor with conventional methods (e.g., buried or muscle flaps).

Conventional methods
Conventional monitoring methods used were temperature, color, capillary refill, turgor, and handheld Doppler device. The skin temperature was measured continuously. A difference of more than 2°C from the surrounding tissue was considered abnormal. The surrounding tissue of the flap and donor site served as a guideline for the color and turgor. With a handheld Doppler device, the flow was checked. To make the monitoring of buried flaps more reliable, a small skin pedicle was left attached when possible. Intraoral flaps were monitored by only color, turgor, and handheld Doppler assessment.

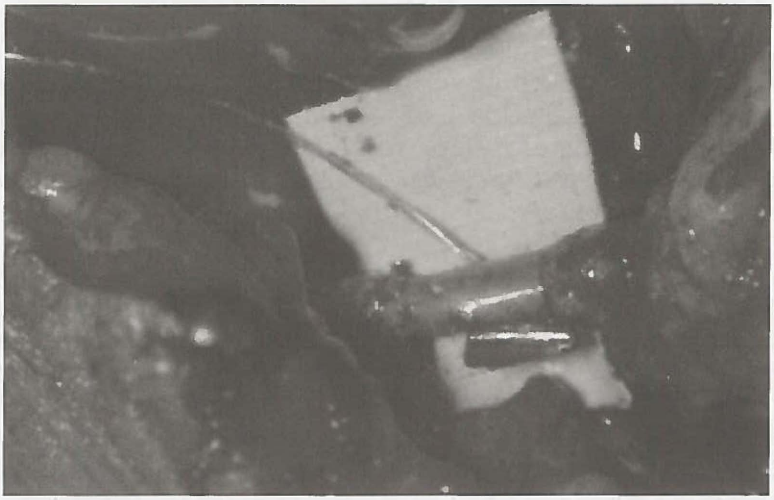

Figure 1; The silicone cuff with the Doppler crystal wrapped around the vein. The cuff is positioned distal to the anastomoses. The Doppler signal leaves the body through the wire attached to the cuff; this wire can be removed 5 to 10 days after surgery by applying a tension of 50 g. (Courtesy of Cook Medical, Cook Ireland Ltd., Limerick, Ireland).

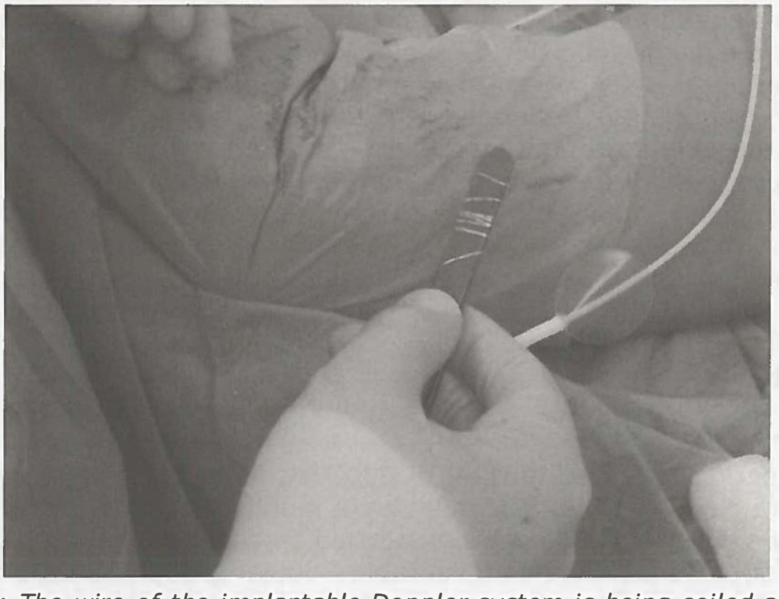

Figure 2; The wire of the implantable Doppler system is being coiled around a forceps to ensure that, after inset of the flap, tension on the external wire is not being transferred directly to the junction between the wire and the silicone cuff.

Data
The following data were collected by reviewing patient files: age, sex, indication for surgery, date of surgery, American Society of Anesthesiologists classification, nicotine use, administration of radiotherapy, location of the defect, type of flap, surgeon, recipient vessels, ischemia time, complications, need for revision, revision indication, and surgical outcome of all patients.

Definitions
Surgical outcome was defined as either success or failure. A successful case was defined as a case in which flap survival was either complete or partial. Failure was defined as complete flap failure. This definition was chosen because the group of partial necroses was too small to use for separate statistical analysis, and it is our vision that partial necrosis is more often attributable to poor flap design than to late detection of a compromised pedicle.

Statistical analysis
Statistical analysis was performed using SPSS version 16.01 (SPSS, Inc., Chicago, Ill.). The chi-square test and the t-test were used to compare the characteristics of the implantable Doppler device group with the control group. Logistic regression was used to identify factors associated with the outcome of the revision. The association with each factor was first determined using univariate logistic regression. A value of $p < 0.05$ was considered statistically significant. Apart from the monitoring method used, the following variables were analyzed for their effect on the salvage rate: sex, age, American Society of Anesthesiologists classification, nicotine use, radiotherapy before surgery, location defect, type of flap, surgeon, recipient vessels, and ischemia time. To make sure the subgroups were large enough for a proper analysis (expected value per cell >5), small subgroups were merged. The type of monitoring, and factors with a value of $p < 0.05$, were entered into a multivariate logistic regression model.

Results

Population
In the period reviewed, a total of 630 free microvascular reconstructions were performed; 323 of them were monitored with the implantable Doppler system and 307 were monitored by conventional methods. The overall success rate in the implantable Doppler group was 96.6 percent. In the group monitored by conventional methods, this rate was 94.8 percent (*Table 1*).

Of flaps that were monitored with the implantable Doppler system, an alteration in the Doppler signal was observed in 38 cases (11.6 percent). In four cases, no further action was undertaken. Of these cases, two were compromised flaps in which the decision was made not to perform any further actions because the chances of success were regarded as minimal on taking the patient characteristics in consideration (these cases are included in the analysis); in one case, there were no other clinical signs of a compromised flap; and in the other case, the patient himself had accidentally removed the wire. A total of 34 cases (10.4 percent) were reoperated on. In one case, the anastomoses were found patent during surgery. This case was excluded from further analysis. The findings during revision were arterial and venous thrombosis (n = 4), arterial thrombosis (n = 12), arterial inflow insufficiency (n = 1), venous thrombosis (n = 9), venous congestion (n = 3), and a hematoma compromising the anastomosis (n = 4). In all cases, the alteration in the Doppler signal was either before or at the same time as any clinical signs of flap compromise.

In the group monitored by conventional methods, 39 cases (12.9 percent) were taken back to the operating room because of suspicion of vascular compromise. The findings during revision were arterial and venous thrombosis (n = 5), arterial thrombosis (n = 15), arterial spasm (n = 1), venous thrombosis (n = 15), venous congestion (n = 1), and a hematoma compromising the anastomosis (n = 2). In one case, no revision was undertaken for a failing flap, because the compromise was found in a relatively late phase. This case was included in the analysis as well (*Table 2*).

	Patients monitored with implantable Doppler system (n = 323)	**Patients monitored by conventional methods (n = 307)**
Location defect		
Breast area	251	197
Head and neck area	39	52
Extremities	33	58
Type of flap		
Cutaneous/ fasciocutaneous	283	258
Musculocutaneous	32	33
Osteocutaneous	6	13
Revision rate	10.4%	12.9%
Success rate	96.6%	94.8%

Table 1; Characteristics of reviewed groups.

	Patients monitored with implantable Doppler system	Patients monitored by conventional methods
Arterial and venous thrombosis	4	5
Arterial thrombosis	12	15
Arterial insufficiency	1	-
Arterial spams	-	1
Venous thrombosis	9	15
Venous congestion	3	1
Hematoma	4	2
Failed flap, no revision undertaken	2	1
Total	35	40

Table 2; Cases included in analysis

Characteristics of the patients under study
In the revised group that was monitored by the implantable Doppler system, the mean age was 49.1 ± 12.5 years (range, 26 to 85 years). The mean American Society of Anesthesiologists classification was 1.7 (four patients were treated for hypertension and two had diabetes). The reconstructions performed were breast reconstructions, flaps to extremities, and head and neck cases in 69, 17, and 14 percent, respectively. In the revised group that was monitored with conventional methods, the mean age was 46.8 ± 14.3 years (range, 8 to 80 years). The mean American Society of Anesthesiologists classification was 1.9 (two patients were treated for hypertension, two had diabetes, and one used corticosteroids). The reconstructions carried out were breast reconstructions, flaps to extremities, and head and neck cases in 58, 27, and 15 percent, respectively (Tables 3 and 4).

Statistical comparison of the groups only revealed significant differences on the items "senior surgeon" and "use of nicotine." More cases in the group monitored by the implantable Doppler system were operated on by the senior author (R.A.), and significantly more patients smoked at the time of admission in the conventional monitoring methods group.

Success rate revisions for each monitoring method
The revision was successful in 69 percent of the cases in the implantable Doppler system group. Thirty-one percent of the flaps failed. In the group that was monitored by only conventional methods, 60 percent of the flaps could be salvaged with the help of a revision, and 40 percent of them failed. Univariate analysis showed no statistical difference between these success rates (p=0.441; odds ratio, 1.455; 95 percent confidence interval, 0.560 to 3.775).

Multivariate analysis

The variables "location defect" and "radiotherapy before surgery" showed a statistically significant difference (*Table 5*) and were put in the multivariate analysis together with "the monitoring method used." The multivariate analysis showed no statistical differences between the groups (*Table 6*). A strong tendency was shown between the salvage rate and location of the defect, meaning revisions in the breast reconstructions were more likely to be successful compared with reconstructions elsewhere.

Value	Patients monitored with implantable Doppler system (n=35)	Patients monitored by conventional methods (n=40)	p-value
Sex			
Male	9	7	0.386
Female	26	33	
Age (mean)	49.1	46.8	0.456
ASA classification			
I	14	12	0.364
II or more	21	28	
Nicotine use			
Yes	1	11	0.004
No	34	29	
Radiotherapy prior to surgery			
Yes	17	12	0.099
No	18	28	
Location defect			
Head and neck	5	6	0.534
Breast	24	23	
Extremiteiten	6	11	
Type of flap			
Fasciocutane	31	32	0.312
Other (musculocutane, osteocutane)	4	8	
Surgeon			
R. Acosta	26	24	0.003
Other	9	16	
Recipient vessel			
Internal mammary artery	23	18	0.072
Other	12	22	
Ischema time (mean)	74.2	87.9	0.095

Table 3; Characteristics of revised cases for each monitoring method.
ASA; American society of anesthesiologists.

Origin of flap	Patients monitored with implantable Doppler system (n = 35)	Patients monitored by conventional methods (n = 40)
DIEP[a]	14	17
S-GAP[b]	5	6
SIEA[c]	5	-
Antero lateral thigh	4	2
Radialis	2	2
Lateral arm	-	5
Latissimus dorsi	3	3
Fibula	1	3
Other (scapular, gracillis, serratus)	1	2

Table 4; Flaps used for each monitoring group.
DIEP; deep inferior epigastric perforator, S-GAP; superior gluteal artery perforator, SIEA; superficial inferior epigastric artery.

Discussion

A total of 36 flaps were included in the implantable Doppler group, whereas in the group monitored with conventional methods, 40 were included. We found that the success rate of the revised flaps increased from 60 percent to 69 percent after the introduction of the implantable Doppler system. However, this difference is not significant. The multivariate analysis in both groups showed a strong association between the location of the defect and the outcome of the revision: the chance of a successful revision is larger in a breast reconstruction as compared with a head and neck or extremity case.

A number of previous reports have also addressed the value of the implantable Doppler system.[21–26] In the report by Kind et al.,[23] their experience with the implantable Doppler system was analyzed in 147 cases. After the introduction of the probe, the success rate of revisions increased from 71 percent to 100 percent, and they claimed this increase in successful salvage rates to be significant. However, this was not substantiated by statistical tests. In the other reports, the authors only share their experience with the probe and its reliability, without discussing how it affected the salvage rate of their compromised flaps. Although all reports are positive about the ability of the implantable Doppler system to detect a compromised flap,[22–26] an important downside of some reports is the high rate of false-positive readings[21,24,25] of the system of up to 88 percent. If false-positive readings are not recognized at an early stage, this could lead to an unnecessary revision and an increase in costs.

The results of our study surprised us to some extent, because we anticipated a beneficial effect of the new monitor device. Inflow or outflow disturbance initiates a cascade of events that sooner or later leads to changes in the outer aspect of the flap (color, temperature, refill), which are the subject of conventional monitoring methods. Therefore, we expected that with the introduction of the implantable Doppler system the signaling would improve, leading to earlier intervention with more favorable outcomes. A possible explanation for this is that our monitoring with conventional methods was already of good quality and therefore the introduction of the implantable Doppler system led to only a marginal improvement. In units that experience more problems with conventional monitoring, the introduction of the implantable Doppler system may have a larger effect. To answer this, a multicenter, randomized, controlled study has to be performed, including centers with different levels of experience in monitoring. This study can include all type of flaps or only a specific group. In our center, the greatest advantage of the implantable Doppler system was experienced in the head and neck cases.

In this study, a failure rate of salvages of 31 and 40 percent was reported. In a post hoc power analysis, 450 patients per group would be needed to achieve 80 percent power to detect this 9 percent difference given a significance level of 5 percent. It can be questioned whether a statistical difference given these numbers might be clinically different.
When introducing a new system into clinical practice, a learning curve always needs to be respected. In our case, the learning curve was relatively uneventful. This may be attributable to a thorough introduction of the system for medical and nursing staff. An important aspect when working with the system is how to place the wire in the wound. Because the Doppler crystal can be easily dislodged from the silicone cuff (only a tension of 50 g is required), we make sure that the wire is absolutely slack inside the wound. We achieve this by coiling the wire around a forceps (*Figure 2*), to give it a spiral shape. In this way, any tension on the wire is not transferred directly to the junction between the wire and the silicone cuff. This safety measure may explain our relatively low false-positive rate of 8 percent.

The case in the implantable Doppler system group in which an unnecessary revision was performed was a bilateral deep inferior epigastric perforator breast reconstruction in which the signal did not stop but altered in one flap. Because there were also some clinical signs suggesting anastomotic problems, the patient was taken back to the operating room. Inspection during revision, however, did not show an anastomotic problem, and no further problems occurred with the flap.
Although in this case the threshold was low to take the patient back to the operating room, in recent years, we have become more critical about attempting to perform revision in the first place. In some, already during the initial reconstruction, it may be impossible to achieve or maintain good circulation through the flap. In such cases, we now have adopted the strategy of aborting the reconstruction and removing the flap instead

of performing two or three unsuccessful salvage procedures. These flaps in our series have nevertheless been scored as failures; however, this was not related to the time point of reintervention.

When comparing the implantable Doppler system with the conventional monitoring methods group, criticisms include the fact that the group monitored with just conventional methods contains more smokers and that there is a statistical difference attributable to the senior surgeon operating on the case. The difference in nicotine use is related to the difference in study populations. The group monitored with conventional methods includes relatively more head and neck and extremities cases, which are operated on more acutely, making it impossible to select patients with regard to their smoking habits. If possible, we want our patients to stop smoking at least 2 months before surgery, because it has been shown that smoking can decrease the chances of a successful reconstruction.[27] The difference in surgeon can be explained by a change in our team: in 2006, one of the senior surgeons left our department. Although these variables differ between the groups, our analysis did not show that one of these variables had a significant influence on the salvage rate of the revised cases.

When comparing newer monitoring methods, such as the implantable Doppler system, with conventional methods, one of the issues is the cost. Ideally, a new monitoring system should offer a return on investment by saving a higher number of flaps, cost an insignificant amount compared with the total expenditure, or offer nonfinancial benefits. The cost of a free flap at Uppsala University Hospital is €25,000, whereas each disposable probe costs €330 and the monitoring box costs €2650, which is a one-time investment, and costs less than €10 in each case in this series. This is a 1.4 percent increase in costs compared with conventional methods. As far as the nonfinancial benefits are concerned, although not strictly investigated, it can be said that the system has been very well perceived by medical and nursing staff. Compared with conventional monitoring methods, it has been found to be easier to interpret, especially for those not so familiar with free flap monitoring. In addition, the system offers more patient comfort. Monitoring can be accomplished without waking up the patient at night. Finally, because of its direct and continuous monitoring, it offers valuable information during the early reperfusion phase intraoperatively and during the positioning of the patient postoperatively.

Based on these findings, we still find the extra investment of the implantable Doppler system worthwhile. We have planned a prospective study to further explore the ease-of-use aspects of the system.

Variable	Successful revision (n=48)	Unsuccessful revision (n=27)	P-value	Odds ratio	Confidence interval (CI: 95%)
Monitoring method					
Implantable Doppler system	24	11	0.441	1.455	0.560
Conventional methods	24	16			– 3.775
Sex					
Male	10	6	0.888	0.921	0.293
Female	38	21			– 2.891
Age (mean)	46.6 years	50.2 years	0.278	0.980	0.946 – 1.016
ASA classification					
I	20	6	0.094	2.500	0.855
II of more	28	21			– 7.314
Radiotherapy prior to surgery	23	6			
Yes	25	21	0.032	3.220	1.105
No					– 9.383
Nicotine use					
Yes	5	7	0.088	0.332	0.094
No	43	20			– 1.176
Location					
Breast	35	15	0.016	3.365	1.250
Other (head and neck, extremities)	13	12			– 9.063
Type of flap					
Fasciocutane	42	21	0.276	2.000	0.575
Other (musculocutane, osteocutane)	6	6			– 6.959
Surgeon					
R. Acosta	27	15	0.954	1.029	0.398
Other	21	12			– 2.658
Recipient vessel					
Internal mammary artery	30	11	0.072	2.424	0.982
Other	18	16			– 6.362
Ischemia time (mean)	79.1 min	88.9 min	0.314	0.994	0.982 – 1.006

Table 5; Univariate analysis of potential factors associated with success rate of the revisions. ASA; American society of anesthesiologists.

Variable	P-value	Odds ratio	Confidence interval (CI: 95%)
Monitoring by implantable Doppler system	0.799	1.143	0.410 – 3.182
Defect located at breast area	0.056	2.721	0.973 – 7.612
Received radiotherapy prior to surgery	0.112	2.487	0.808 – 7.657

Table 6; Multivariate analysis of potential factors associated with success rate of the revisions.

Conclusion

After introduction of the implantable Doppler system, the salvage rate of our flaps did not improve statistically significantly. Despite this, its addition to the care of our patients was judged as a positive innovation in free flap monitoring by medical and nursing staff and by patients because of its ease of use and the information it offers.

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Chapter 8

Less confidence in free flap monitoring with the implantable Doppler system: a pilot randomized controlled clinical trial

J.M. Smit, MD, S. Klein, MD, E.H. de Jong, G.H. de Bock, MD, PhD, P.M.N. Werker, MD, PhD

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Summary

Introduction: The implantable Doppler system was introduced at our clinic to make the monitoring of free flaps more convenient. In order to test this system, we measured the level of confidence the system gave during monitoring, in comparison with conventional monitoring methods.

Materials and methods: Patients undergoing free flap reconstruction at the Department of Plastic Surgery at the University Medical Center Groningen were asked to participate in a pilot randomized clinical trial. Prior to each monitoring assessment, randomization was used to determine whether the flap was to be monitored by the implantable Doppler system, or by conventional methods. Surgeons and nurses were asked to score their confidence in their findings on a scale from one to ten. A univariate logistic regression was used to investigate factors potentially associated with confidence in monitoring.

Results: After six months, the study was terminated prematurely due to technical difficulties with the implantable Doppler system. By then, 22 flaps in 20 patients and 1,099 monitoring assessments had been included in the study. The implantable Doppler system provided significantly less confidence compared to conventional monitoring methods (OR: 0.6, CI 95%: 0.5 – 0.8). Personal experience in flap monitoring resulted in a higher level of confidence when stating the certainty of the monitoring reading (from <10 flaps to 10-50 flaps (OR: 2.4, CI 95%: 1.7 - 3.3), and from 10-50 flaps to >50 flaps (OR: 10.3, CI 95%: 6.4 – 16.5)).

Conclusion: Although these are initial results, they indicate that the implantable Doppler system offers less confidence in flap monitoring, compared to conventional monitoring methods. This suggests that the implantable Doppler system does not offer more certainty concerning monitoring outcome, compared to conventional monitoring methods.

Introduction

Microsurgical free tissue transfer has become the standard for reconstruction of large tissue defects. In the last decades, success rates of 95-99% have been reported.[1-4] Despite these high success rates, complications (especially flap loss) cause major distress for both patients and medical professionals. Considering that free flaps are time-consuming, complex procedures with inherent risks and psychological ramifications for the patient, it is crucial to optimize chances of a successful outcome. One of the means of improving these odds is by accurate assessment of the blood circulation of free tissue transfers from the moment the vascular anastomoses are created, until the period of greatest risk of vascular compromise has passed. To help surgeons and nursing staff in this assessment, there is a range of contemporary techniques in clinical use, and currently under development.[5] Clinical tests to monitor free flaps, such as inspection (to assess color), palpation (to assess temperature) and capillary refill of the flap, are still most commonly used. The hand-held Doppler is also often used in addition to the clinical tests, but this method is not always 100% reliable.[6,7]

Other techniques used to monitor flaps postoperatively include the Cook-Swartz implantable Doppler system,[8-11] near infrared spectroscopy,[12-14] indocyanine-green fluorescence video angiography,[15] simultaneous non-invasive laser Doppler flowmetry and tissue spectrophotometry,[16] and modified oxygen microelectrode combined with laser-Doppler flowmetry.[17]

In our ongoing efforts to optimize patient outcome, we introduced the Cook-Swartz implantable Doppler system (Cook Medical®, Cook Ireland Ltd, Limerick, Ireland) at our clinical practice in 2007. The system, introduced in Europe in 2006, consists of an implantable 20 MHz ultrasonic probe mounted on a silicone sleeve that can be placed around the vein. A battery operated device is used to monitor the venous outflow of a free tissue transplant.[8,9] In two previous studies, we investigated the reliability of the system as a primary monitoring device,[10] and the effect the system had on our success rate.[18] A suggested advantage of the system is that it makes monitoring the blood flow in a flap easier, and more objective[10]. This however, has not yet been fully investigated. This study was commenced in order to examine whether the implantable Doppler system is indeed easier to use as a primary monitoring device than conventional monitoring methods. Our hypothesis was that if a device is easier to use, this should result in more certainty in the interpretation of readings in the medical and nursing staff. Therefore, the aim of this study was to investigate which method, the implantable Doppler system or the conventional monitoring methods, gave medical and nursing staff most confidence when monitoring free flaps.

Materials and methods

Population

All patients of at least eighteen years of age undergoing a free flap reconstruction at the Department of Plastic Surgery at the University Medical Center Groningen were asked to participate in this study. Inclusion started in January, 2010. Patients were included prior to surgery, after informed consent had been obtained. Patients receiving flaps that could not be monitored by conventional monitoring methods were excluded from the study.

Study protocol

An implantable Doppler probe was placed in each included patient during surgery. After surgery, flaps were monitored using our standard protocol (every hour during the first day post surgery, every two hours during the second day, and every four hours during following days, until the fifth day post surgery or discharge). Prior to each monitoring moment, randomization was used to determine whether the flap would be monitored by the implantable Doppler system or by conventional methods. Randomisation took place by the throw of a die.

After evaluation of the flap, nursing and medical staff were asked to score their findings (normal blood flow or not), as well as their confidence in their findings (on a scale from one to ten). The levels of confidence in monitoring were consequently divided into the following categories: very uncertain (1-2), uncertain (3-4), indifferent (5-6), certain (7-8), and very certain (9-10). Each monitoring participant was asked to state their function, the date and time, and their personal experience in monitoring free flaps on the same form. The participant was also asked to fill in the number of times the concerned flap had been monitored before.
In cases where there was doubt concerning the blood flow of a flap, the monitoring person alarmed the next person in line, so that the flap could be re-evaluated. If the doubt was considered justified by our medical staff, the patient was taken to the operating room for exploration of the vascular anastomoses.

The Medical Ethical Committee of the University Medical Center Groningen granted approval for this study.

Cook-Swartz probe implantation, operation and removal

A Cook-Swartz implantable 20 MHz ultrasonic Doppler crystal mounted on a silicone cuff was implanted in all patients during the free flap procedure, and was fixed around the draining vein of the pedicle using Ligaclips. If two flap veins were connected, two probes were installed. The probe was placed around the vein, since the work of Swartz et al.9 has indicated that this increases the sensitivity of the device, particularly to venous obstruction, compared to probes monitoring arterial flow. The probe wires were coiled inside the surgical wound, and left the body through the surgical incision. The system's accuracy was checked by temporarily blocking the vein by gently compressing it using microforceps. If the system functioned properly, the sound would immediately stop, simultaneous with venous compression. If this was the case, the operation was completed. If not, additional measures were taken to ensure that the probe was properly placed, and the monitor produced a reliable sound. Extra care was taken to fix the probe wire in such a way that it could not be removed inadversely in the early postoperative period.

After ten days, the probe was removed by gentle traction on the wire. The silicone cuff was left behind.

Details of conventional monitoring

Color assessment:

If the flap had a skin component, its color had to match the color of the skin from where the flap was harvested. If the flap became pale or blue, this indicated a possible patency problem with one or more anastomoses.

Temperature assessment:

The surface temperature of the flap was measured using special band-aids. Slightly lower or higher temperatures than the surrounding skin were accepted, though the temperature difference between the skin flap and the surrounding skin had to remain stable. This method was only applicable in flaps with a skin component.

Capillary refill:

Normal refill time was between two and three seconds. If the refill time increased or decreased, this was a sign of a potential patency problem with the anastomoses.

Hand held Doppler probe:

If the signal ceased to be repetitive at equal intervals, or stopped completely, this was interpreted as possible problem with the patency of the anastomoses.

Objectives and outcomes

This study served as a pilot study in order to perform a power analysis for a larger study, and our aim was to include 30 flaps. Our primary objective was to investigate whether the implantable Doppler system, or the conventional monitoring methods, gave medical and nursing staff most confidence when monitoring free flaps. Secondary objectives were to investigate if there were differences in the confidence scores between day and night time, between medical and nursing staff, and between people with different levels of experience in free flap monitoring. A potential relationship between confidence scores and the number of days post surgery was also examined.

Data collection and definitions

The patients' age, sex, indication for surgery, date of surgery, ASA-classification, nicotine use, radiotherapy treatment, location of the defect, type of flap, surgical team, types of anastomoses, recipient vessels, surgery time, ischemia time, anastomotic time, complications, and surgical outcome were recorded on a form specially designed for this study.

Surgery time was defined as the time between the first incision, and the application of a dressing. Ischemia time was defined as the time between the division of the pedicle, and reconstitution of circulation over both anastomoses. The anastomotic time was the time between the first and the last manipulation of the vessels with suture material. Complications were classified as hematoma, infection, superficial necrosis, seroma, anastomotic failure, or combinations of these complications. The surgical outcome was scored as successful survival, partial necrosis (>10%), or total necrosis.

Data analysis
A Chi-square test was used to compare the monitoring characteristics of the different monitoring methods used. A univariate logistic regression was used to investigate a potential association between the monitoring methods used, and confidence in monitoring. Other variables which may have had an effect on the confidence in monitoring were also analyzed using a univariate logistic regression. To avoid low numbers per group, (≤ 5 patients per category), small subgroups were merged. Data is presented as odds ratio (OR), 95% confidence interval (CI:95%), and p-value. A p-value less than 0.05 was considered to be statistically significant. The type of monitoring, as well as variables with a p-value less than 0.05 were entered into a multivariate logistic regression model. Statistical analysis was performed using SPSS 16.01 (SPSS Inc, Chicago, Illinois, USA).

Results

Population
Although our aim was to include 30 flaps, the study was terminated prematurely, because in two cases the Doppler crystal attached to the silicone cuff did not release when the wire was retracted. In these cases, the wire separated from the crystal, leaving the crystal behind. This system malfunction, combined with the fact that sufficient data had been collected, led to the decision to discontinue use of the device, and termination of the study.

During the six months this study ran, 19 patients were included that underwent 23 free flap reconstructions. (Four patients underwent a bilateral Deep Inferior Epigastric Perforator (DIEP) breast reconstructions.) One flap was excluded, because the implantable Doppler system did not function properly. The error was observed directly after application, and since no obvious explanation could be discovered, this flap was excluded from the study. Therefore, in total, 22 flaps in 18 patients were included. In the study, 12 females and 6 males were included with a mean age of 51 years (mean 50.6; SD 13.0; min-max 35-74). The most common indications for surgery were breast reconstructions (n=13), followed by reconstructions of the head and neck (n= 8), and reconstruction of the extremities (n= 1). The types of flaps used were the DIEP, free fibula flap, anterolateral thigh (ALT) flap, radial forearm flap, and superficial inferior epigastric artery (SIEA) flap. Of these flaps, three were revised post surgery due to vascular compromise. Two DIEP flaps were returned to the operating room: one due to arterial and venous thrombosis, and the other due to a hematoma causing compression of the pedicle. An ALT flap was also surgically revised due to venous congestion. Although flow was restored in the DIEP flap with arterial and venous thrombosis during the initial revision, the flap became compromised again and eventually failed despite a second salvage procedure. The other DIEP flap was salvaged after evacuation of the hematoma. During exploration of the ALT flap, it became clear that the congestion was caused by the silicone cuff of the implantable Doppler system. The cuff was slightly twisted, compromising the venous return. The ALT was salvaged after surgery, resulting in a total of 21 successful cases. (*Table 1*)

Sex (n=18)	
male	6 (33%)
female	12 (67%)
Mean age (n=18)	51
ASA classification (n=18)	
I Healthy patient, no medical problems	7 (39%)
II Mild systemic disease	7 (39%)
III Severe systemic disease, but not incapacitating	4 (22%)
Nicotine use	
yes	7 (32%)
no	15 (68%)
Radiotherapy prior to surgery	
yes	5 (23%)
no	17 (77%)
Location defect	
head/neck	8 (36%)
breast	13 (59%)
extremities	1 (5%)

Table 1; Patient, flap, and surgical characteristics

Value	Implantable Doppler group (n=594)	Conventional methods group (n=505)	p-value
Days post surgery			
first day	309 (52%)	266 (53%)	0.829
day two or more	285 (48%)	239 (47%)	
Time of day			
day	296 (50%)	256 (51%)	0.776
night	298 (50%)	249 (49%)	
Function			
medical staff	18 (3%)	18 (4%)	0.620
nursing staff	576 (97%)	487 (96%)	
Experience in monitoring			
<10 flaps	143 (25%)	117 (24%)	0.468
10-50 flaps	235 (41%)	181 (38%)	
>50 flaps	202 (35%)	185 (38%)	
Times monitored concerned flap			
1-5	364 (62%)	308 (62%)	0.933
>5	221 (38%)	189 (38%)	

Table 2; Monitoring characteristics per monitoring method.

Monitoring characteristics
In total, 1,099 monitoring moments were registered during the six month period, 594 of which were with the implantable Doppler system, and 505 of which were with conventional methods (*Table 2*). No significant differences were observed between the implantable Doppler group, and the conventional methods group. Monitoring was predominantly performed by the nursing staff (97%), most of which (75%) had experience in free flap monitoring in 10 or more flaps. No large differences were observed in the frequency between day and night time monitoring or the experience of monitoring of the concerned flap. (*Table 2*)

Confidence in monitoring
Over 75% of the staff that scored in the implantable Doppler group was very certain of their scores, compared to 83% in the conventional methods group (*Table 3*). When these two groups are compared, a significant difference is observed (OR: 0.6, CI 95%: 0.5 – 0.8; p =0.002).

Confidence	Implantable Doppler group n = 594 (%)	Conventional methods group n = 505 (%)
Very uncertain	4 (1%)	6 (1%)
Uncertain	7 (1%)	1 (0%)
Indifferent	13 (2%)	4 (1%)
Certain	124 (21%)	75 (15%)
Very certain	446 (75%)	419 (83%)

Table 3; Confidence scores in monitoring: the implantable Doppler, and conventional methods group.

Value	Very uncertain-certain (n=134)	Very certain (n=865)	OR	CI: 95%	p-value
Monitoring method					
conventional methods	86 (37%)	419 (48%)	1		
implantable Doppler	148 (63%)	446 (52%)	0.6	0.5-0.8	0.002
Location defect					
head/neck/extremities	101 (43%)	341 (39%)	1		
breast	133 (57%)	524 (61%)	1.1	0.9-1,6	0.301
Composition flap					
other	66 (28%)	220 (25%)	1		
fasciocutanous	168 (72%)	645 (75%)	1.2	0.8-1.6	0.392
Revised flap					
no	212 (91%)	773 (89%)	1		
yes	22 (9%)	92 (11%)	1.1	0.7-1.9	0.583
Days post surgery					
first day	134 (51%)	441 (51%)	1		
day two or more	100 (49%)	424 (49%)	1.3	1.0-1.7	0.088
Time of day					
day	119 (57%)	433 (50%)	1		
night	115 (43%)	432 (50%)	1.0	0.8-1.4	0.829
Function					
nursing staff	231 (99%)	832 (96%)	1		
medical staff	3 (1%)	33 (4%)	3.1	0.9-10.0	0.066
Experience in monitoring					
<10 flaps	108 (47%)	152 (18%)	1		<0.001
10-50 flaps	96 (42%)	320 (38%)	2.4	1.7-3.3	<0.001
>50 flaps	25 (11%)	362 (43%)	10.3	6.4-16.5	<0.001
Times monitored					
concerned flap	144 (63%)	528 (62%)	1		
1-5	86 (37%)	324 (38%)	1.0	0.8-1.4	0.860
>5					

Table 4; Univariate logistic regression of factors potentially associated with confidence in monitoring: odds ratios and 95% CI for the presence of very certainty scores (9-10).

Value	OR	CI: 95%	p-value
Monitoring method			
conventional methods	1		
implantable Doppler	0.6	0.5-0.9	0.004
Experience in monitoring			
<10 flaps	1		<0.001
10-50 flaps	2.4	1.7-3.4	<0.001
>50 flaps	10.3	6.4-16.7	<0.001

Table 5; Multivariate logistic regression of factors associated with confidence in monitoring.

If other variables are studied (medical vs. nursing staff, experience in flap monitoring, experience in monitoring this flap, time of day, and the number of days post surgery), a significant difference is only observed between the confidence in monitoring, and the experience in monitoring. The confidence in monitoring increases as the experience increases (from <10 flaps to 10-50 flaps (OR: 2.4, CI 95%: 1.7 - 3.3; p <0.001) and from 10-50 flaps to >50 flaps (OR: 10.3, CI 95%: 6.4 – 16.5; p <0.001)).

The variables 'monitoring method used' and 'experience in flap monitoring' resulted in statistically significant differences, and both were therefore used in the multivariate analysis. In the multivariate analysis, the difference remained significant in both variables. The confidence level remains higher in the conventional methods group, and increases as experience with flap monitoring increases (*Table 5*). The confidence scores per monitoring method used were independent from the personal experience in flap monitoring. This implies that the fact that conventional methods resulted in higher confidence scores than the implantable Doppler method, was unrelated to the amount of experience in flap monitoring (*Table 5*).

Scores indicating compromise

In five flaps, scores indicating comprise had been given. In three cases, surgical revision was indicated and undertaken. The other two flaps concerned false positive readings. Both false positive readings were obtained using the implantable Doppler system in DIEP flaps. In these cases, the resident on call was consulted, and concluded that there was in fact no vascular compromise.

Interestingly enough, the first indication for revision of the failed DIEP flap was not picked up on by either monitoring method. Initially, the flap was monitored using conventional methods, and later by the implantable Doppler system. In both cases, nursing staff indicated that they were very uncertain of their reading, but that they thought the flap was not compromised. The second time the flap was compromised it was detected with the implantable Doppler system as well as with conventional methods.

The compromise in the other two flaps was detected once using the implantable Doppler system, and the other time by conventional monitoring methods. After further inspection of both flaps by medical staff, it was concluded that the flaps were indeed compromised, and were returned to the operating room.

Discussion

The most important quality of a monitoring device is its reliability, and after that, it is the effect it has on the success rate of free flap reconstructions. Reliability is however, a function of the certainty with which users interpret their readings. The aim of this study was therefore to investigate which method, the implantable Doppler system or the conventional monitoring methods, gave medical and nursing staff most confidence when monitoring free flaps. Contrary to what we expected, the confidence in monitoring decreased with the use of the implantable Doppler system (OR: 0.6, CI 95%: 0.5 – 0.8; p =0.002).

Previous reports have also addressed the added value of the implantable Doppler system in free flap monitoring.[18-24] Most reports share their experience with the probe and its reliability. There are reports that are positive about its value and the additional information it can provide, while others are more sceptical about the system. One of the limitations that has been thoroughly discussed, is its vulnerability. The crystal may for example detach form the cuff, resulting in false positive readings.

Although the system was already introduced at our clinical practice in 2007, we discovered more problems with it as we started to use the system on a daily basis. The most prominent problem we encountered during this study, was that in one case the silicone cuff compromised the venous return of the flap. The cuff was slightly twisted in relation to the vein, and therefore exerted pressure on the vein. This ultimately required surgical intervention to solve the problem. The possibility exists that the twisting of the cuff occurred due to incorrect surgical attachment. In our opinion however, if the instructions for cuff placement are followed, the monitor device should not potentially be able to compromise a flap.

Apart from the surgical revision that was necessary due to the system itself, we also encountered several technical problems with the system. In two cases that have been described earlier, the crystal did not release from the cuff when the wire was retracted, but the wire separated from the crystal. The crystal was therefore left behind in the body. In another case, the system malfunctioned directly after placement. The monitoring box did not give an audible signal, despite the presence of venous flow. After reassessing that everything was connected correctly and the crystal was still attached to the cuff, still no signal was heard. Another monitoring box device was tested in this specific case, but also did not produce a signal.

A number of studies compare the results of flaps monitored with the implantable Doppler to those monitored with conventional monitoring methods, yielding conflicting results. Schmulder et al.[19] reported a significant increase in their success rates after the introduction of the implantable Doppler system. On the other hand, in a previous study, we did not find the introduction of the system to affect our salvage rates.18. In this previous study, although not specifically tested, the implantable system was presented as a positive innovation, due to its convenient use and the information it provides. In this prospective study, we could not confirm this. There are no previous studies that have objectively assessed how the implantable Doppler system influences the confidence in monitoring.

The general consensus in available literature is that in flaps that are difficult to monitor with conventional methods, e.g. head and neck cases and buried flaps, the system can be of greatest value.[11,18,19,22] Although we did not specifically investigate the indication for the implantable Doppler system, the system has predominantly been used at our clinic for buried flaps in which conventional methods are of little value. During this period, prior to this study, the system was subjectively perceived as a positive aid in free flap monitoring.

In most reports, it is recognized that a learning curve applies when starting to use the system. This means there are certain consequences, varying from an incorrect reading[21] to vascular compromise caused by the system.[20]

During the implementation of the research protocol, we encountered certain problems at the beginning of the research. The nursing staff from other wards than the Plastic Surgery ward were less familiar with the monitoring of free flaps. We tried to overcome this with several presentations prior to the start of the project, as well as providing informative flyers. A thorough explanation of the study and the monitoring methods used, was also included in the scoring book that accompanied each patient. Despite these efforts, we noticed that some nurses were less familiar with monitoring, and less confident with the implantable Doppler system. This may have caused the implantable Doppler system to score slightly lower compared to the conventional monitoring methods. The level of confidence in monitoring did not change significantly over time however, nor were the confidence scores per monitoring method dependent on personal experience in flap monitoring. These observations indicate that it is unlikely that the scores in the implantable Doppler group would have been significantly higher, if these nurses had been equally familiar with both monitoring methods.

One important positive aspect of this study compared to other studies, is that this is a randomized controlled trial. Each flap was monitored with the implantable Doppler system as well with conventional monitoring methods, meaning that each flap served as its own control. This enabled us to collect a large number of measurements in a relatively small number of flaps.

A limitation of this study is that we did not validate whether the confidence in a monitoring method is a correct measurement for the ease of use of a monitoring device. The outcome that the confidence in monitoring increases with the experience in free flap monitoring does however strengthen our belief that the confidence in monitoring is a representative scale for the ease of use.

Another limitation is the randomization method, which was the roll of a die. This can easily be manipulated by the person monitoring. There is no indication, however, that this occurred during the study. A die was chosen as randomization method, because it is a convenient method for frequent randomization. If we had for example, selected phone calls as a method for randomization, this would have meant that over 1,000 phone calls had to be made during the study period. We decided against this, because we were afraid that the extra work load of making a phone call each monitoring moment would reduce the compliance of medical and nursing staff.

Conclusion

Although these are initial results, they indicate that the implantable Doppler system offers less confidence, compared to conventional monitoring methods. It can therefore be suggested that the implantable Doppler system is not more convenient to use.

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Chapter 9

Summary and general discussion

Summary and general discussion

The aim of this thesis was to investigate if innovations around free flap surgery are able to improve the outcome of free flap reconstructions. In line with the recent developments, the focus of this thesis was the role of preoperative investigations of the vasculature of the flap and the post operative monitoring.

The *first chapter* discusses the three different phases that are of importance in free flap reconstruction; the preoperative planning of the flap, the surgery itself and the post operative care. When each phase is optimized, the reconstruction becomes safer, faster and easier to perform. As previous research has predominantly focused on intraoperative innovations, the focus of this thesis is the role of preoperative investigations of the vasculature of the flap and the postoperative monitoring.

The *second chapter* describes the various methods for vascular mapping of flaps together with their advantages and disadvantages. Computed tomography angiography (CTA) and magnetic resonance angiography (MRA) are currently the best methods available to map the vasculature of donor sites of perforator flaps with variable anatomy such as Anterolateral Thigh and Deep Inferior Epigastric Perforator (DIEP). Both methods can produce 3D image of the vasculature and their surrounding structures. In flaps with standard anatomy and superficial vasculature hand held Doppler remains the method of choice.

The *third chapter* reports on how the introduction of CTA as part of the diagnostic work-up in perforator flap reconstructions resulted in a reduction in surgery time. Compared to flaps that were worked up with only hand held Doppler a reduction in surgery time was achieved of 91 minutes ($p<0.001$). There was a tendency for fewer complications in the CTA group compared to the hand held Doppler group.

Chapter four is a pilot study measuring the pressure in the superficial venous system before and after flap dissection in DIEP flaps. The aim was to investigate if there was a change in pressure and if this was correlated to venous congestion. The mean increase in pressure after flap dissection was 10.6 mmHg (mean = 10,6; range -1 - 31; SD± 7.0 mmHg). Clinical signs of venous congestion were observed in one case. In this case the increase in venous pressure was with 31 mmHg also the highest. So although the results are preliminary, they indicate that the pressure in the superficial vein of DIEP flaps might be of predictive value for venous congestion.

Chapter five is a review about the current devices to monitor free flaps and their potential as ideal monitoring method. The results of this study do not favour the sole use of conventional monitoring methods when taken into account the time of response of the method and their unreliability, especially in muscle flaps. The implantable Doppler system, near infrared spectroscopy and laser Doppler flowmetry appear to be the best monitoring devices currently available. When interpreting these data one should realize however that most of the publications on monitoring have focussed solely on the reliability of a single system. The efficiency and the costs of the systems as well as their comparison in randomized multicenter studies should be focus of future research.

The *sixth chapter* presents a single center's experience in 121 microvascular breast reconstructions monitored with the implantable Doppler system. A change in the audible signal was noted in 15 patients (4 intra-operatively). Fourteen of these flaps were revised and all were found to have compromised anastomoses. In the remaining case, the patient was not returned to theatre as the surgeon was confident that there were no other signs of vascular compromise. Overall, when using the implantable Doppler system a false positive rate of 6.7% and 0% false negatives were found. In this center the implantable Doppler system was well received by surgeons, nursing staff and patients, as an adjunct to conventional monitoring methods.

If the introduction of the implantable Doppler system leads to improved salvage rate of revised flaps was investigated in *chapter seven*. A total of 327 flaps were monitored with the implantable Doppler system of which 35 needed a revision. In the control group 303 flaps were included of which 40 needed a revision. Revisions were successful in 69% of the cases in the implantable Doppler system group, in the group monitored by only conventional methods this was 60%. A univariate analysis showed no statistical difference between these success rates (p=0.441; OR; 1.5; CI 95%: 0.6 – 3.8). The multivariate analysis, did not show a statistical difference either (p=0.799; OR 1.1; CI 95%: 0.4 – 3.2). This led to the conclusion that the introduction of the implantable Doppler system did not lead to significant increase in the salvage rate of revised flaps.

In the *eighth chapter*, nursing and medical staff were asked to score in a pilot study how certain they were of their monitoring measurement. The scores of the implantable Doppler system were compared to those of conventional monitoring methods. This study was stopped due to technical difficulties with the implantable Doppler system. In the implantable Doppler system group, participants were significantly less certain compared to conventional monitoring methods in an univariate model as well as in a multivariate model, (OR: 0.6, CI 95%: 0.5 – 0.8, p = 0.002) and (OR: 0.6, CI 95%: 0.5 – 0.9, p = 0.004) respectively. This suggests that the implantable Doppler system is not easier in use compared to conventional monitoring methods as it offers less confidence.

Evaluation of thesis

In 2009 a series of papers were published about surgical innovation and evaluation.[1-3] In this series suggestions were made how surgical science can be improved and progress in surgical care and interventions become safer, more efficient, and better. A five-stage paradigm was suggested to describe the development of innovative surgical procedures (*Table 1*). Obstacles related to the study design of randomised controlled trials and non-randomised studies assessing surgical interventions were discussed as well as the issues related to the nature of surgical procedures, such as their complexity, surgeon-related factors and the range of outcomes. The widespread use of prospective databases and registries was encouraged and randomised trials are advocated whenever possible to investigate efficacy and to allow power calculations adequate pre-trial data.

The studies in this thesis are representing different stages of the development of surgical innovations. The report on CTA in the planning of perforator flaps can be labelled as a stage 2a study. During the time of study the Department of Plastic Surgery of the Uppsala University Hospital was one of the first who used CTA as a routine workup in the planning of perforator flaps. The pilot study about the pressure in the SIEV is a good example of a stage 1 study, in which safety and proof of the concept were the main goals. The studies about the implantable Doppler system are stage 2b studies in which experience with the system is described and its potential advantages and limitations are explored.

With regards to methodology of the studies in the thesis there are positive aspects but limitations as well. The pilot study about the confidence the implantable Doppler system offers compared to conventional monitoring methods had the highest methodological quality. It was a randomized controlled trial, with the aim to provide data for a power analysis to perform a large series. Due to the inadvertent events during this study, it was however decided not to perform such a larger trial.

The study about the effect of CTA in perforator flaps as well as the study about the effect of the implantable Doppler system on the salvage rate of compromised flaps were both retrospective historically controlled trails. Ideally these would have been prospectively controlled trials, however due to practical reasons this was not possible. These studies were performed in other clinics then the primary researcher was working, making it difficult to start a prospective study.

The pilot study about the venous pressure in the SIEV was set up to test the safety of the procedure and proof of the concept could work. In both these goals we succeeded. With the help of this study a larger prospective trial can be performed.

Stage	Description
0 (innovation)	The initial pre-human work and development.
1 (innovation)	The first time it is used in human beings.
2 a (development)	The technical details of the operation and the equipment have improved but the details have not been completely worked out.
2 b (early dispersion and exploration)	The individual learning curves are progressing quickly, especially among the original innovators. Indeed, many technical details of the operation have now been perfected.
3 (assessment)	The procedure is now part of many surgeons' practices. The innovation is quickly becoming the standard of care, and soon only a few surgeons will not have adopted the new technique.
4 (long-term implementation and monitoring)	This stage relates to how the procedure is doing in routine practice, and the perspective is one of long-term monitoring.

Table 1; Stages of surgical innovation as described by Barkun et al..[1]

Future research

Based on our finding during this research, we have several suggestions for future research in the field of free flap monitoring.

1) The introduction of CTA in the planning of DIEP flaps by Masia et al.[4] caused a revelation in the planning of perforator flaps. In the beginning CTA generated two dimensional pictures only (*Figure 1a*) in three planes and provided the sizes and locations of the perforators relative to a reference point. With the introduction of new software packages it became possible to make 3D reconstruction of the abdominal vasculature (*Figure 1b*) in multiple planes.[5] Although CTA has many advantages, there are some an important disadvantages; the radiation dose it inflicts on the patient[4,6] and the necessity to use iodinate contrast medium which may cause vascular or renal damage as well as allergic reactions.[7]

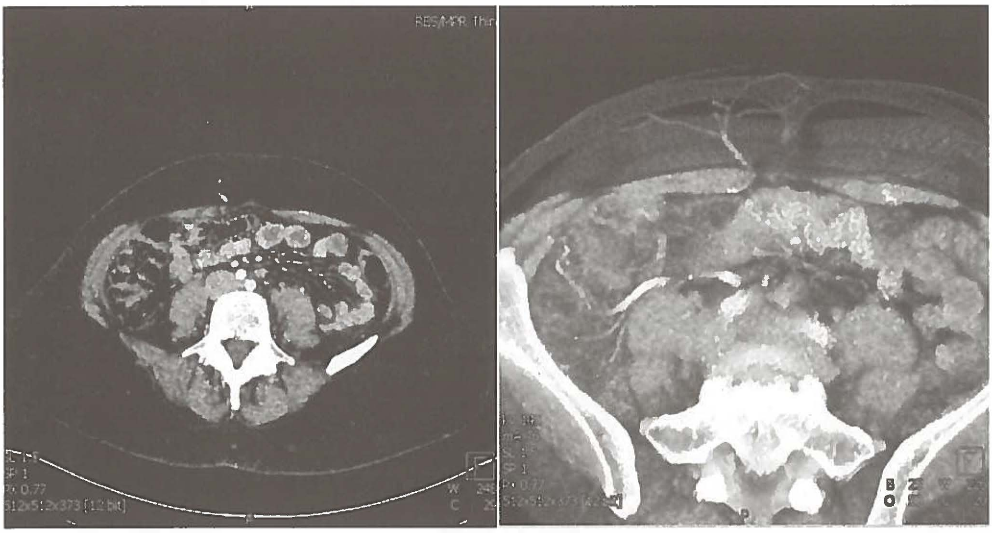

Figure 1; Two CTA images of the same patient. The direction of viewing is from caudal to cranial. a) A 2D reconstruction, which was initially used. Two parts of the perforator can be seen in the subcutanous tissue just above the right rectus muscle. The reconstruction can be viewed in three planes. b) A 3D reconstruction at a slightly lower level. The perforator and its branching pattern can be seen. In this case there is a branch to the contra lateral side as well. The reconstruction can be viewed from every direction.

In contrast to CTA, MRA is performed without radiation and there is no need for iodinate contrast medium, which makes it less harmful for patients. Although MRA is not able yet to scan as small a diameter of vessels as CTA, future developments will probably make this possible. It can however be discussed of how much clinical relevance the scanning of small calibre vessels (<0.5mm) is.[8] All of this leads us to believe that MRA will be the new standard in the planning of perforator flaps in the near future. Prospective studies are however needed to fully investigate the full potential of MRA, ideally in a direct comparison to CTA.

2) We hypothesized actual hemodynamics in the flap after dissection than measuring its diameter, and indeed, we found that the venous pressure in the SIEV after flap dissection is of predictive value for venous congestion. Although the results of our pilot study are promising, a larger study needs to be performed to validate this. It may remain difficult to really pinpoint when to perform an anastomosis of the SIEV for several reasons. First of all, due to the relatively low incidence of venous congestion in DIEP flaps[9]; one out of 20 flaps gets congested to some extent. In large centers often no more than 100 DIEP breast reconstructions a year are performed, which means there are five cases each year to include in the venous congestion group. This makes the number of years a study needs to run to get enough power for a validate conclusion excessively long. This can however be overcome by a multicenter study design. There are nevertheless ethical difficulties as well, if the chance on venous congestion is investigated properly, an anastomosis of the SIEV should not be performed in at least some cases in which venous congestion is expected to occur. This is ethically however difficult if not impossible to perform.

3) We are of opinion that in the design of future monitoring devices one should strive for more independence of the interpretation of medical or nursing staff of its reading. Instead the devices should be programmed in such a way that they are able to interpret the data generated during monitoring and alarm when the incoming data differ from baseline so much, that it is likely that a flap is compromised. This would require a monitoring method to deliver data continuously and the ability to set alarm margins to make the monitoring outcome less dependent on monitoring personnel for interpretation.

A monitoring method that is able to collect data continuously, detects compromise potentially earlier and therefore increases the chances on a successful revision. A second advantage would be that the monitoring is less operator dependent, making it more predictable and hopefully accurate. Finally, as the monitoring is completely taken over by a device it becomes less labour intensive for the nursing and medical staff. We believe that the principle of a device that monitors blood flow, such as the implantable Doppler flow device, offers a good starting point a future monitoring system. Only the reading (at present an audible signal) needs to be converted into a more easy to interpret signal. The design of future studies should be prospective, in which each included patient will be monitored by conventional methods as well as by the new method which is able to interpret its own data. With this design each patients serves as it own control, making the two groups identical in patient characteristics.

4) Another field of future research may be what type of monitoring is effective in what kind of setting, as there are big differences between clinics performing free flap reconstructions. In highly specialised centres where revision rates are as low as one or two percent, the added value of monitoring compared to its costs might not be in balance. Monitoring is labour intensive and it might only safe one out of 100 or 200 flaps in these centres. On the other end of the spectrum, there are centres that are less experienced and successful in free flap surgery, with revisions rates of up to 30 percent.[10,11] Although in the first place it can be questioned if it advisable to persist in free flap surgery with these revision rates, it might ultimately be advantageous for these centres to use other monitoring methods in addition to conventional methods.

For these less experienced centres a multicenter study may be of interest. Of each centre the number of flaps, the success rate, the revision and salvage rate should be registered. Also the monitoring protocols should be noted and the costs involved. With such a design an estimate can be made on the role of the monitoring systems, on how many flaps are salvaged per centre and on the costs for monitoring this brings. This can be compared to the costs for a free flap. Based on these outcomes a suggestion can be made per centre whether the monitoring at the moment is efficient, needs more attention or might not be necessary. Following these suggestions prospective studies can be started in which the suggested alterations in the monitoring are compared the old monitoring protocols. Ultimately this may lead to an increase of success in all centres where free flap surgery is performed.

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Chapter 10

Summary and general discussion (Dutch)

Summary and general discussion (Dutch)

In de reconstructieve chirurgie worden zogenaamde vrije lappen toegepast. Dit zijn transplantaten die meestal bestaan uit verschillende weefselsoorten in verschillende samenstelling. Hun overeenkomst is hun wijze van bloedvoorziening: ze hebben allemaal in ieder geval één aanvoerende slagader en één of twee afvoerende aders.

Als een patient een reconstructie met een vrije lap ondergaat, zijn er binnen het zorgtraject drie onderdelen te onderscheiden: de voorbereidings fase op de ingreep of preoperatieve planning, de ingreep zelf en de postoperatieve fase. Iedere verbetering binnen deze stadia zal het doorlopen van het zorgtraject veiliger, sneller en gemakkelijker maken. Lange tijd zijn onderzoekers met name bezig geweest met het verbeteren van de chirurgische procedure zelf.

Het doel van dit proefschrift is te onderzoeken of innovaties in de andere fasen van het traject van de vrije lap chirurgie de vlotte doorloop en het resultaat kunnen verbeteren. De nadruk van het proefschrift ligt op de rol van preoperatieve onderzoeken van het bloedvatstelsel van de lap en het postoperatieve monitoren van de doorbloeding. Verbetering van deze twee stadia van vrije lap reconstructie, zou uiteindelijk tot een optimaler resultaat voor de patiënt en een voordeligere procedure voor het ziekenhuis moeten leiden.

Het *eerste hoofdstuk* bespreekt de drie verschillende stadia die van belang in vrije lapreconstructie zijn. Daarbij wordt een globaal overzicht geschetst van de huidige stand van zaken.

In *hoofdstuk twee* passeren de diverse methoden om de vaatvoorziening van lappen in beeld te brengen de revue. Computer tomografie angiografie (CTA) en magnetische resonantie angiografie (MRA) zijn momenteel de beste methoden om de vasculatuur van de plaats waar het weefsel geoogst wordt in kaart te brengen als de anatomie minder voorspelbaar is, zoals bij de antero-laterale dijlap en de DIEP-lap, afkorting voor deep inferior epigastric perforator. Beide methoden kunnen 3D beelden van de bloedvaten en hun omringende weefsels creëren. Bij lappen met voorspelbare anatomie of een oppervlakkige vaatsteel, blijven de hand Doppler of zelfs geen aanvullend onderzoek de voorkeur houden.

Het *derde hoofdstuk* beschrijft dat de introductie van CTA als onderdeel van de work-up van de perforatorlap borstreconstructies een significante vermindering van de operatietijd opleverde. Vergeleken met lappen die met enkel de hand-held Doppler in kaart werden gebracht, werd een reductie in operatietijd bereikt van 91 minuten ($p<0.001$). Tevens was er een tendens voor minder complicaties in de CTA groep in vergelijking met de hand-held Doppler groep.

Hoofdstuk vier is een pilot-studie waarin de druk in het oppervlakkige veneuze systeem voor en na het vrijleggen in DIEP lappen werd gemeten. Het doel was om te onderzoeken of er een verandering in druk optrad en of dit gecorreleerd was met veneuze stuwing. De gemiddelde toename van de druk na de dissectie van de lap was 10,6 mmHg (gemiddelde = 10,6; bereik -1 tot 31; SD ± 7,0 mmHg). Klinische tekenen van veneuze stuwing werden eenmaal waargenomen. In deze casus was de toename van de veneuze druk ook de hoogste, namelijk 31 mmHg. Hoewel de resultaten van deze studie voorlopig zijn, indiceren ze dat de druk in de oppervlakkige vene van DIEP lappen van voorspellende waarde is voor veneuze stuwing.

Hoofdstuk vijf is een overzichtsartikel over de huidige methoden om de bloedvoorziening van vrije lappen te monitoren en het potentieel van deze methoden als ideale monitor methode. De resultaten van deze studie spreken het gebruik van enkel conventionele monitor methoden tegen in verband met de langere reactietijd en een verminderde betrouwbaarheid, met name in spierlappen. Het implanteerbare Doppler systeem, near infrared spectroscopy en laser Doppler flowmetry lijken de beste monitor methoden die op dit moment beschikbaar zijn. Bij de interpretatie van deze data moet echter wel gerealiseerd worden dat het merendeel van de publicaties enkel over de betrouwbaarheid van één methode gaat. Een rechtstreekse vergelijking tussen monitor methoden, waarbij de efficiëntie en de kosten van de systemen aan bod komt, zal in de toekomst moeten plaatsvinden.

Het *zesde hoofdstuk* presenteert de ervaring die is opgedaan met het implanteerbare Doppler systeem in 121 microvasculaire borstreconstructies. Een probleem met het geluidssignaal werd opgemerkt bij 15 patiënten (4 intra-operatief). Veertien van deze lappen werden herzien, in alle gevallen bleek de bloedvoorziening gecompromitteerd. Eenmaal werd niet terug gegaan naar de operatiekamers omdat er geen andere tekenen van een gestoorde vascularisatie waren en de chirurg ervan overtuigd was dat een revisie niet nodig was. Voor het implanteerbare Doppler systeem werd een vals-positief percentage van 6,7% en een vals-negatief percentage van 0% gevonden. Het implanteerbare Doppler systeem werd goed ontvangen door chirurgen, verpleegkundigen en patiënten, als een aanvulling op de conventionele monitor methoden.

Of de invoering van het implanteerbare Doppler systeem heeft geleid tot een verbetering van het succes percentage van gereviseerde lappen is onderzocht in *hoofdstuk zeven*. De revisie van gecompromitteerde lappen was succesvol in 69% van de gevallen in de groep waarbij het implanteerbare Doppler systeem gebruikt werd. In de groep, gemonitord met behulp van conventionele methoden, was dit 60%. Een univariate analyse toonde geen statistisch verschil tussen deze slagingspercentages (p = 0,441; OR; 1,5; 95% CI: 0,6 - 3,8). De multivariate analyse, toonde ook geen statistisch verschil (p = 0,799; OR; 1.1; 95% CI: 0,4 - 3,2). Dit leidde tot de conclusie dat de invoering van het implanteerbare Doppler systeem niet heeft geleid tot een significante toename in het succes percentage van gereviseerde lappen.

In het *achtste hoofdstuk* zijn in een pilot studie verplegend en medisch personeel gevraagd om te scoren hoe zeker ze waren over hun meting bij het monitoren van vrije lappen. De scores van het implanteerbare Doppler systeem werden vergeleken met die van conventionele monitor methoden. Deze studie werd gestopt vanwege technische problemen met het implanteerbare Doppler systeem. In de groep van het implanteerbare Doppler systeem, waren de deelnemers significant minder zeker in vergelijking tot de deelnemers in de conventionele monitor methoden groep. Dit was zowel in een univariaat model als in een multivariaat model, (OR: 0,6, 95% CI: 0,5 - 0,8, p = 0,002) en (of: 0,6, 95% CI: 0,5 - 0,9, p = 0,004), respectievelijk. Dit suggereert dat het implanteerbare Doppler systeem niet gemakkelijker is in gebruik in vergelijking met conventionele monitor methoden.

Belangrijkste conclusies

- Uit de literatuur blijkt dat CTA en MRA momenteel de beste methoden zijn om de vasculatuur van de plaats waar het weefsel geoogst wordt in kaart te brengen als de anatomie minder voorspelbaar is. Bij lappen met voorspelbare anatomie of een oppervlakkige vaatsteel, blijven de hand Doppler of zelfs geen aanvullend onderzoek de voorkeur houden.
- De introductie van CTA als onderdeel van de work-up van de perforatorlap borstreconstructies in plaats van enkel de hand Doppler kan een significante vermindering van de operatietijd opleveren.
- Er zijn concrete aanwijzingen dat de druk in de oppervlakkige vene van DIEP lappen van voorspellende waarde is voor veneuze stuwing.
- In de literatuur wordt het gebruik van enkel conventionele monitor methoden niet aangeraden in verband de langere reactietijd en een verminderde betrouwbaarheid. Het implanteerbare Doppler systeem, near infrared spectroscopy en laser Doppler flowmetry lijken de beste monitor methoden die op dit moment beschikbaar zijn.
- Voor het implanteerbare Doppler systeem werd een vals-positief percentage van 6,7% en een vals-negatief percentage van 0% gevonden.
- De invoering van het implanteerbare Doppler systeem leidt niet tot een significante toename in het succes percentage van gereviseerde lappen.
- Het lijkt er op dat het implanteerbare Doppler systeem niet gemakkelijker is in gebruik in vergelijking met conventionele monitor methoden.

Chapter 11

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Chapter 12

Curriculum vitae

Curriculum vitae

Jeroen Smit was born in Breda, The Netherlands, on July 18th, 1981. After completing preparatory scientific education at the Onze-Lieve-Vrouwe Lyceum in Breda, he started his medical training at the Radboud University in 2000.

As a student he became interested in plastic surgery and became involved in research from the third year of his studies. Initially under the supervision of dr. C.G. Bauland, later under supervision of dr. E.H.M. Hartman. Before obtaining his medical degree in 2006, he went to Uppsala, Sweden for five months to do research under supervision of dr R. Acosta. This is where the idea for his PhD started to rise and later further developed under the guidance of dr. C.J. Zeebregts. Apart from his medical studies he was involved in the Nijmeegse Student Rugby Association Obelix and later became an active mountainbiker, competing in a variety of national and international competitions.

After completing his medical degree he worked as a SHO in general surgery in the Sint Franciscus Guesthouse in Rotterdam. After five months, he transferred to the Catharina Hospital in Eindhoven where he became a SHO in plastic surgery. During this period he came in contact with prof. dr. P.M.N. Werker and with his guidance and help, the plans for a PhD became definitive. In 2009 he moved to Barcelona where he worked on his PhD for one year. During that year he was brought in contact with prof, dr. G.H. de Bock, who was of great help during the last part of his PhD. In 2010 he started his plastic training in the Catharina Hospital in Eindhoven (head: dr J.H.A. van Rappard). For his training he is currently working at the general surgery department of the Catharina Hospital (head: G.A.P. Nieuwenhuijzen) for two years.

Chapter 13

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List of publications

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