

BMJ Open The efficacy of the Cook-Swartz implantable Doppler in the detection of free-flap compromise: a systematic review protocol

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ABSTRACT

Introduction: The Cook-Swartz implantable Doppler monitors venous or arterial blood flow from free flaps and can detect free-flap compromise. Previous studies have shown that the use of this Doppler can improve detection and salvage rates as it provides an earlier warning than the current method of clinical assessment. Such studies assert that the implantable Doppler is of great value in monitoring free flaps in current microsurgical units. This systematic review aims to compare the efficacy of the Cook-Swartz implantable Doppler in monitoring free-flap compromise against conventional clinical free-flap monitoring techniques.

Methods and analysis: Various electronic databases will be systematically searched for studies that compare the use of Cook-Swartz implantable Doppler with clinical assessment. The selected studies will then have their titles and abstracts screened by two authors. Articles selected after title and abstract screen will have full text downloaded and the complete article will be assessed for suitability. Once the articles have been selected for inclusion, data extraction will take place. For data analysis, the outcomes of the studies will be tabulated, with descriptive statistics performed as appropriate and the detection rate of the Doppler and clinical assessment will be compared and synthesised where possible.

Ethics and dissemination: The authors hope to disseminate the findings as widely as possible. This systematic review will be published in a peer-reviewed journal and include a number of recommendations as its conclusion based on the evidence contained within. Given the wide range of specialties now utilising flaps, it will be presented at a wide range of national and international conferences.

Protocol Registration in PROSPERO: CRD42013005818 The literature search and data extraction went on until 28 January 2014. These steps were revised in line with peer review comments.

BACKGROUND

Free-flap reconstruction

Free-flap reconstruction for large tissue defects is increasingly common and plays an

important role in the field of plastic and reconstructive surgery.¹ Such surgery necessitates a microsurgical anastomosis from the harvested flap to the recipient using minute sutures. Data suggests that the commonest cause of failure is a problem with the venous anastomosis occurring within the first 24–48 h postoperatively.^{2–4} This problem affects up to 20% of all free-flap reconstructions, depending on their location and entails significant physical, psychological and emotional morbidity for patients.^{5–7}

Flap failure often necessitates further general anaesthetics and operations. Owing to the time critical nature of flap failure, reoperation may occur out of hours, which provides further logistical and practical challenges.⁷ Initially, an attempt is made to salvage the flap, if this fails, then the flap is removed and an alternative reconstructive approach may be required. In some cases, venous congestion may require blood drainage; for example, by use of medicinal leeches,⁸ which is potentially highly unpleasant for patients and predisposes them to infection and anaemia.⁹ Patients, therefore, require careful wound inspection, surveillance of haemoglobin and prophylactic antibiotics to protect them from further complications.^{8 10}

Monitoring of free flaps

Early recognition of flap compromise is the primary aim of every microsurgical unit. Prompt intervention and rescue is critical for ensuring flap survival. However, the complexities of free-flap microcirculation are often difficult to assess, and there are a wide array of possible monitoring modalities.¹¹ The commonest method of monitoring is carried out clinically and is based on subjective clinical observations. These tests are carried out

on an island of skin or 'skin paddle'—an area of skin considered to be indicative of the whole flap's arterial perfusion and venous drainage.¹² Such tests may include the colour, capillary refill or blanching time, skin temperature, turgor and degree of bleeding in response to pin-prick and use of a handheld Doppler device.¹³

Unlike solid organ transplantation, there is no objective assessment—such as decreased urine output in renal transplantation. Similarly, there are currently no suitable imaging modalities for assessing microvascular flow and specifically slow venous flow problems, though there are reports in the literature on the use of nuclear medicine techniques in successful monitoring.¹⁴ A number of small studies have highlighted the use of single-positron emission CT in the determination of free-flap compromise.¹⁵ However, large comparative studies are required with standardised techniques to further define the role of this modality in the assessment of free-flap compromise. Early compromise, which entails the large majority of flap failure, is often asymptomatic. Pain, bleeding and skin changes can take a while to develop, potentially increasing ischaemic times and reducing the possibility of successful salvage.¹⁶

Some free flaps are very challenging to monitor adequately, such as vascularised bone and muscle flaps; especially those that have been covered with a skin graft and cutaneous flaps in non-Caucasian skin. Some flaps, such as buried flaps within the head and neck are impossible to monitor by clinical assessment and in such circumstances, attempts have been made to enhance clinical monitoring using microdialysis.^{11 17} However, this can take up to 30 min to get a reading, necessitates specific training to obtain and analyse results, does not directly measure flow and costs almost \$52 000 per monitor plus additional costs of up to \$570 per flap.¹¹

The Cook-Swartz implantable Doppler

The Cook-Swartz implantable Doppler monitors the venous flow from free flaps and obtained its CE mark in 2006.¹⁸ Since then it has been distributed widely in both Europe and the rest of the world.¹⁸ It is the only device currently on the market that allows this monitoring and is protected by patent. It consists of a 20 MHz ultrasonic Doppler crystal, a silicone cuff and a monitor unit.^{19 20} This cuff secures the Doppler to the flap's vein at the time of the operation and is placed downstream of the microvascular anastomosis.²⁰ The Doppler provides monitoring for 5–10 days postoperatively and is removed by simple traction.¹⁸ A number of studies have shown that the use of this device increases success and salvage rates as it provides an earlier warning than the current method of clinical monitoring.^{12 21 22}

The potential of the Cook-Swartz Doppler

The use of the Cook-Swartz Doppler in the assessment of such flaps has demonstrated improved detection times.^{2 12 22 23} This technology is needed now more

than ever as the indications for, and therefore absolute number of, free flaps have increased. Indications for flaps include following resection of breast tumours, head and neck cancers, skin cancers, major burns and infections. Often these may be 'cross-specialty' flaps, for example, with orthopaedics to cover exposed metal work in lower limb fractures. Changes to working practices mean that these patients may be returned to an orthopaedic or general surgical ward where monitoring is performed by non-specialist nurses who may not be used to monitoring flaps, let alone over night and in challenging settings such as low light.

Why is a systematic review of this required?

To our knowledge, there has been only one systematic review involving the Cook-Swartz implantable Doppler. Poder and Fortier²⁴ investigated the efficacy and cost effectiveness of the implantable Doppler. However, we aim to investigate and further clarify the role of the Doppler as a monitoring technique by comparing it to clinical assessment. Clinical assessment is the most widely used technique and as such the standard against which the Doppler should be compared. Further clarifying the role and possible benefit of the Cook-Swartz Doppler in the detection of free-flap compromise would allow modification of practice and guidelines in line with the best evidence. We realise that previous reviews were limited by the quality of evidence available, but a number of studies have been published since the last review and, therefore, an updated review is required.

OBJECTIVES

Our objective was to perform a comprehensive systematic review of the implantable Doppler in the detection of free-flap compromise.

Primary objective

To compare the efficacy of the Cook-Swartz implantable Doppler versus clinical assessment in the detection of free-flap compromise and flap salvage.

Secondary objectives

To determine the absolute indications for use of the Doppler (if any). Quantify the sensitivity, specificity, positive and negative predictive values of the Doppler. To describe complications associated with Doppler use.

METHODS

This systematic review will be conducted according to the recommendations outlined in the Cochrane Handbook for reviews and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.²⁵

Criteria for selecting studies

The following search criteria were specifically devised to locate studies specifically pertaining to the use of the

Cook-Swartz Doppler and to provide evidence for the objectives previously stated.

Types of studies

Any study comparing the use of Cook-Swartz implantable Doppler with clinical assessment in detecting the failure of free flaps will be included. Articles must describe the use of the implantable Doppler specifically and may be of any grade of evidence (1–5 as defined by the Oxford Centre for Evidence-Based Medicine).²⁶

Any article in which data are duplicated will be excluded, as will articles not describing original data; such as editorials, letters regarding other articles and discussion pieces. Unpublished reports will be included if the methodology and results are accessible in written form.

Types of participants

Participants of any age who have undergone free-flap surgery. There will be no limitation on location of the flap or technique used.

Types of interventions

Any article describing the use of the Cook-Swartz Doppler in the detection of free-flap compromise will be considered, and articles would not be excluded based on type of flap. Articles will only be considered if they include a group monitored by clinical detection for comparison with the Cook-Swartz Doppler.

Types of comparator

Cook-Swartz implantable Doppler used on the venous or arterial pedicle of a free flap attached by any means and used to monitor free flaps postoperatively. Clinical assessment of free flaps including, but not limited to; skin colour, turgor, surface temperature, capillary refill time or handheld Doppler.

Types of outcome measures

Primary outcome

Flap failure rate, defined as the number of free flaps lost divided by the total number of flaps. This outcome will be calculated for both Doppler and clinically monitored flaps.

Secondary outcomes

Sensitivity, specificity, positive predictive value and negative predictive value.

Time to detection will be reported where possible and compared between clinically monitored and Doppler-monitored flaps.

Any complications associated with flap use will be described.

Search methods for identification of studies

Electronic searches

The following electronic databases will be searched to 24 September 2013: MEDLINE, EMBASE, PsycINFO, Ebsco,

Cochrane Database of Systematic Reviews, CINAHL, SCOPUS, SciELO, National Health Service (NHS) evidence, www.uptodate.com, <http://clinicaltrials.gov/>, <http://www.who.int/ictrp/en/>, <http://www.controlled-trials.com/>.

Search terms and keywords

The search strategy has been developed to locate papers related specifically to the Cook-Swartz implantable Doppler. This search will use the English language keywords combined with Boolean logical operators. Therefore, the following terms will be used: 'implantable Doppler' OR 'Cook-Swartz implantable Doppler' OR 'Cook-Swartz implantable Doppler'.

The search will not be limited by language. Any non-English articles identified will proceed to title and abstract screening and the full text obtained if required. If full text is not available, then the authors will be contacted to obtain an English language copy of the full text. Failing this, colleagues speaking the language will be contacted to translate. Google Translate will be used as a last resort.

Other resources

A hand search of the references of articles located by the search strategy will be used to identify any relevant citations within the grey literature. Active researchers will be contacted to identify any other published or unpublished work. An active researcher is defined as one who has published more than three articles in the field in the past 5 years, or one in the last two.

Identification and selection of articles

Studies identified by the electronic and manual search strategy will be listed. Results including citation, title and abstracts will be populated into EndNote (Thomson Reuters, New York, USA) and duplicates removed. Titles and abstracts will be screened by two authors (BG and AJF), any conflicts not resolvable between the two will be referred to the lead author (RAA) for resolution. Articles selected after title and abstract screen will have full text downloaded and a further assessment made. Once articles have been selected for inclusion, data extraction will take place.

Data extraction and management

Data will be extracted independently by two authors (BG and AJF) utilising a standard extraction form in which all data for each study will be collated. Any conflict of extraction will be resolved by discussion; where this is not possible, the lead author (RAA) will make a final decision. This data will then be entered into a Microsoft Excel 2011 database (Microsoft, Redmond, Washington, USA). Data collected will constitute three main areas:

1. Article information
 - ▶ Title
 - ▶ Authors

- ▶ Year of publication
 - ▶ Journal
2. Characteristics
 - ▶ Setting and location of the study
 - ▶ Number of patients
 - ▶ Range of patient age
 - ▶ Flap types included
 - ▶ Clinical method of assessment
 - ▶ Doppler method of assessment (arterial vs venous)
 3. Results (divided clinical and Doppler)
 - ▶ Number of patients per group
 - ▶ Specific flaps in groups (where applicable)
 - ▶ Detected
 - ▶ Flap salvage
 - ▶ Needless theatre return
 - ▶ Complications
 - ▶ Lost flaps without any signs
 - ▶ Flaps correctly monitored

Assessment of study quality and bias in included studies

Quality of evidence can be assessed based on a number of criteria; we will be specifically utilising the Grading of Recommendation Assessment, Development and Evaluation (GRADE) system as proposed by Balshem *et al.*²⁷ This will allow us to determine the quality of the evidence that is being used in the data analysis of this topic.

If we locate any randomised controlled trials (RCTs) we will use the Cochrane risk of bias tool and compare outcomes to published trial protocols. Any information missing from studies will be documented and assessed to ascertain the risk of incomplete statistical sets.

Assessment of publication bias

To ascertain whether studies with negative outcomes are not being published ('publication bias'), we will visually assess funnel plot asymmetry.^{28 29} Where both positive and negative results are published, the plot should resemble a symmetrical, inverted funnel. The precision of the estimated intervention effect will increase as the size of the sample included in the study increases. Smaller studies will, therefore, scatter widely at the bottom, with larger, more powerful studies grouping more narrowly at the top. The asymmetrical distribution of SE on analysis of the funnel plot would indicate publication bias.

Assessment of heterogeneity

Heterogeneity between studies will be assessed using Higgins²⁸ and Thompson's I^2 , which measures the percentage variability in result attributable to heterogeneity between studies rather than sampling error. Variability in the intervention effects in studies will be tested for statistical heterogeneity utilising Tau-squared (T^2), I^2 and χ^2 with corresponding p values calculated; the Cochrane tests.

The value of χ^2 statistics in the forest plot presents the assessment of whether the differences in results are compatible with chance alone. A large value of χ^2 test

relative to its degree of freedom or a low p value indicates statistical variation (heterogeneity) beyond chance. The I^2 percentage will be interpreted as follows:

- ▶ 0–30% may not be important.
- ▶ 30–60% may represent moderate heterogeneity*
- ▶ 50–90% may represent substantial heterogeneity*
- ▶ 75–100% represents considerable heterogeneity*
(*the importance of the observed I^2 value depends on; magnitude and direction of effects and strength of evidence for heterogeneity such as p value from χ^2 or a CI for I^2).²⁸

Generation of statistical heterogeneity can be a consequence of clinical (participants, interventions and outcomes) and/or methodological (study design and risk of bias) diversity or due to random error (chance) alone. T^2 represents the estimated SD of underlying effects across studies. The exact model used for meta-analysis will be based on the level of heterogeneity within our data; with a random effects model used if it is high and a fixed-effects analysis if moderate.

Data synthesis and statistical analysis

Outcomes will be tabulated, with descriptive statistics performed as appropriate. Similarly, the detection rate of each modality will be compared and synthesised where possible. Synthesis will be performed utilising Review Manager (RevMan 5.2.6) and an assessment of heterogeneity will be made. Based on this, meta-analysis will be carried out comparing Cook-Swartz Doppler to clinical monitoring; ideally utilising RCTs, but good-quality observational studies will also be considered.

Rate of flap salvage will be compared between modalities of monitoring to establish any correlation. The false positive and negative rates of the Cook-Swartz implantable Doppler will be calculated. If possible, the efficacy of the Cook-Swartz implantable Doppler in different flap types and locations will be established.

Subgroup analysis

Subgroup analyses will be undertaken of the following groups where available:

- ▶ Different flap type (if >3 studies describing specific flap types);
- ▶ Venous vs arterial Doppler probe placement;
- ▶ Different anatomic locations (if >3 studies describe the same anatomic locations).

Dissemination

The number of free flaps that are compromised per year mean that improvements need to be made to monitoring protocols. It is possible that the Cook-Swartz Doppler may well represent a useful tool for such improvement. As such, the authors hope to disseminate the findings as widely as possible, irrespective of results as they add to wider corpora of information. The systematic review will be published in a peer-reviewed journal and include a number of recommendations as its conclusion based on the evidence contained within. Given

the wide range of specialties now utilising flaps, it will be presented at a wide range of national and international conferences. Updates of the review could be conducted as more information becomes available to guide best practice and further maintain the quality of evidence.

Contributors RAA contributed in concept, initial drafting, critical revision, approval of manuscript to be submitted; BG and AJF contributed in drafting, critical revision, approval of manuscript to be submitted; TWHB and DPO contributed in concept, critical revision, approval of manuscript to be submitted.

Competing interests AJF receives bursaries from the AAGBI and the Wolfson Institute.

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