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## Hydsurgical debridement versus conventional surgical debridement for acute partial-thickness burns (Protocol)

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[Intervention Protocol]

# Hydrosurgical debridement versus conventional surgical debridement for acute partial-thickness burns

Justin CR Wormald<sup>1</sup>, Ryckie G Wade<sup>2,3</sup>, Jonathan A Dunne<sup>4</sup>, Declan P Collins<sup>4</sup>, Abhilash Jain<sup>5,6</sup>

<sup>1</sup>Department of Plastic Surgery, Chelsea and Westminster Hospital NHS Foundation Trust, London, UK. <sup>2</sup>Department of Plastic and Reconstructive Surgery, Leeds Teaching Hospitals NHS Trust, Leeds, UK. <sup>3</sup>Faculty of Medicine and Health, University of Leeds, Leeds, UK. <sup>4</sup>Burns Unit, Chelsea and Westminster Hospital NHS Foundation Trust, London, UK. <sup>5</sup>Department of Plastic and Reconstructive Surgery, Imperial College Healthcare NHS trust, St Mary's Hospital, London, UK. <sup>6</sup>Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

Contact address: Justin CR Wormald, Department of Plastic Surgery, Chelsea and Westminster Hospital NHS Foundation Trust, Fulham Road, London, UK. [justinwormald@gmail.com](mailto:justinwormald@gmail.com), [justin.wormald@nhs.net](mailto:justin.wormald@nhs.net).

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## ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of hydrosurgical debridement and skin grafting versus conventional surgical debridement and skin grafting for the treatment of acute partial-thickness burns.

## BACKGROUND

### Description of the condition

Burn injuries are the fourth most common traumatic injury and cause an estimated 265,000 deaths worldwide (WHO 2008). In 2004, 11 million people required medical attention for burn injuries (WHO 2017).

Most burn injuries occur in low- to middle-income countries that do not have the infrastructure to reduce the incidence and severity of these injuries (CDC 2008; Peck 2011). In men, most burn injuries occur at home, outdoors, or at work with equal preponderance, whereas for women and children the injury occurs most often at home during cooking and while children are unsupervised

(Davies 1990; Hemeda 2003; Mabrouk 2003; Rossi 1998; Stewart 2016). The incidence of burn injury is significantly increased by warfare, most notably in Iraq where the incidence has tripled since 2003 (Peck 2011; Stewart 2016).

Across all demographics, flame is the most common cause of burns in adults, accounting for 35% to 42% of hospital admissions (ABA 2005). Scalds are the most common cause of hospital admissions for children in the US; however, in low- to middle-income countries, the rate of flame burn and scalds is similar (Peck 2011). Clothing ignition is a common cause of burn injury, often in countries where open fires are frequently used in the household (Barss 1983; Demamu 1991; Kalayi 1994; Peck 2011). Occupational burns account for 20% to 25% of burn injuries, most commonly flame burns and scalds and most often affecting people in the food

industry (Peck 2011; Pruitt 2007). Other less common but important causes of burn injury include chemical burns, electrical burns (including lightning) and radiation. For the purposes of this review, burns and scalds both fall under the definition of 'burns'. Burn injuries are a significant cause of morbidity and mortality for both adults and children in the UK. There is a global downward trend in burn incidence, severity, hospital stay and mortality but still, in the UK, approximately 250,000 people are burnt annually (Hettiarachy 2004; Smolle 2017). Of these, approximately 175,000 attend hospital and in 2014, 19,000 children and adults were admitted to hospital for burn injuries (Dunn 2016).

If the burn injury extends through the epidermis only it is classified as superficial (Hettiarachy 2004). If it extends into the dermis it is classified as mid-dermal and then deep dermal if it extends further (Hettiarachy 2004). If the burn extends through the dermis to the subcutaneous tissue, it is classified as full-thickness (Hettiarachy 2004). The diagnosis of burn depth is made clinically on initial assessment (Hettiarachy 2004). However, it is subject to change, and during the process of debridement a more accurate assessment can be made. A clinical assessment of the amount of burnt skin is also made and quantified as a percentage of the total body surface area (%TBSA).

The management of a burn depends on many factors beyond the scope of this review. In summary, superficial burns may be managed with dressings alone, but deeper burns, of any aetiology or those that fail to heal promptly, are usually treated surgically (Hettiarachy 2004, Smolle 2017). Accordingly, surgery for acute burn injuries is undertaken in different situations: as an emergency (to save the life or limb of a person with burns) or at a later stage to remove the unhealthy tissue and enable reconstruction (Hettiarachy 2004, Smolle 2017). For emergency burns surgery, the management depends on the depth and size of the burn, its anatomical site and the time since the burn injury. Emergency burns surgery aims to debride burnt skin until healthy tissue is reached, at which point skin grafts or temporising dressings are applied. It is important that only burnt tissue is debrided and no healthy/viable skin or tissue is unnecessarily removed as this may adversely affect the outcome (Gurfinkel 2010; Orgill 2009). In some cases, if there is evidence of viable dermis following debridement (superficial or mid-dermal burns), then the wound may not require skin grafting and may heal spontaneously with dressings alone. However, early debridement and skin grafting has been the standard of care for decades and the evidence suggests that surgical debridement within 24 to 48 hours after burn injury reduces blood loss, risk of infection, length of hospital stay and mortality, and improves subsequent split-thickness skin graft take (Rowan 2015).

## Description of the intervention

Conventional debridement of burn wounds is performed with an angled blade by tangentially shaving burned tissue until healthy,

bleeding tissue is encountered (Orgill 2009). The goal of wound debridement is to remove injured and non-viable tissue from the area of injury to prevent bacterial proliferation, reducing the risk of infection and creating the optimal wound bed for complete healing, most often by autologous split-thickness skin grafting (Eldad 1998; Robson 1973). Commonly used instruments for conventional debridement include the Brathwaite, Cobbett or Watson knife, the Humby knife, the Goulian or Weck knife, or a simple scalpel. These are all static metallic blades used free-hand by surgeons to tangentially remove layers of burnt skin until bleeding (and thus presumed healthy) tissue is encountered. In the 1970s, gas and later electric powered surgical dermatomes were developed: similar to an electric razor, with an oscillating blade that evenly removes surface layers of the skin at a defined depth. More recently still, dermabrasion techniques have been used for the debridement of deep partial thickness burns with promising effect but limited evidence (Jeffery 2007; Yontar 2017). These mechanical systems have limited value because they are technically difficult to use, and may provide an inaccurate or uncontrollable debridement. Lastly, enzymatic debridement is slowly gaining acceptance but is limited both by the %TBSA of the burn that can be treated at one time and its availability in some countries (Rosenberg 2015). Hydrosurgery system debridement is an alternative to conventional blade debridement. The principle of hydrosurgical debridement is the emission of pressurised, sterile 0.9% sodium chloride in combination with a localised vacuum system that simultaneously debrides, irrigates and removes non-viable tissue. Hydrosurgery enables surgeons to accurately debride burned tissue while preserving viable dermis in the acute setting. Conversely, if the entire dermis has sustained thermal or chemical injury, such as in full thickness burns, then the burn requires complete excision with a scalpel to achieve healing and hydrosurgery is not indicated.

## How the intervention might work

The hydrosurgery system console highly pressurises saline solution and generates a jet, emitted from the tip of the hand-held instrument. The jet travels through the nozzle of the instrument generating a Venturi effect which is an increase in the fluid's velocity and a decrease in its static pressure due to its passage through a constricted area. The high-pressure jet clears non-viable tissue from a wound, which is then collected through a vacuum generated by the Venturi effect, via an evacuator port next to the tip of the instrument and into a collection canister (NICE 2014; Sainsbury 2009). The single-use, 45 degree angled, hand-held instrument attaches to a console and is activated by the surgeon using a foot-pedal. The pressure of the fluid jet can be adjusted by the surgeon, allowing for a precise depth of debridement, and thus achieving an accurate wound debridement with complete removal of non-viable tissue and maximal preservation of healthy tissue. (Cubison 2006; Gurunluoglu 2007; Jeffery 2007; Matsumura 2012).

## Why it is important to do this review

Hydrosurgery may provide more accurate debridement, potentially increasing the amount of viable native tissue for healing after burns surgery and faster operating time, limiting the negative effects of general anaesthesia, blood loss and insensible fluid loss which may be encountered with excessive blade debridement, and hypothermia from the prolonged exposure required for other debridement techniques (Hyland 2015; NICE 2014; Rees-Lees 2008). Its proposed efficacy is based on the results of a number of clinical studies in a variety of patient populations (Cubison 2006; Kimble 2008). However, the available literature also suggests an increase in adverse events following hydrosurgery compared to control and equivalent post-operative pain (NICE 2014). Despite a number of clinical trials evaluating the use of hydrosurgery in wounds, its efficacy and risk of adverse events following surgery for burn wounds is unclear. There has been no formal evidence synthesis exercise to date to determine efficacy based on these trials, neither has there been a rigorous assessment of the quality of the evidence base. Considering its potential advantages but significant cost, an objective and thorough evaluation of its efficacy is warranted.

## OBJECTIVES

To assess the effects of hydrosurgical debridement and skin grafting versus conventional surgical debridement and skin grafting for the treatment of acute partial-thickness burns.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We will include published and unpublished randomised controlled trials (RCTs), including cluster RCTs, irrespective of language of report. Studies using quasi-randomisation will be excluded.

#### Types of participants

We will include RCTs recruiting people of any age described in the primary report as having any acute partial-thickness burn injury requiring surgical debridement and split-thickness skin grafting, managed in any care setting. As the method of defining burn injury may vary, we will accept definitions as used by the study authors. Studies recruiting participants with burn injury alongside people with other types of wounds will be included if the data for people

with burn injury are presented separately (or available from the study authors).

#### Types of interventions

The primary intervention of interest will be hydrosurgery. We will include any RCT in which the use or type of hydrosurgery during the treatment period is the only systematic difference between treatment groups.

We anticipate that likely comparisons will include hydrosurgical debridement and split-skin grafting compared with conventional surgical debridement and split-skin grafting but we will also include trials which compare different methods or protocols for hydrosurgery with each other (i.e. hydrosurgery A versus hydrosurgery B - where the type of hydrosurgery used is the only systematic difference between the studies). We will not include studies that compare debridement methods with no debridement as this will not capture the population of interest which is burns that require surgical debridement.

#### Types of outcome measures

We list primary and secondary outcomes below. If a study is otherwise eligible (i.e. correct study design, population and intervention/comparator) but does not report a listed outcome, then we will contact the study authors where possible to establish whether an outcome of interest here was measured but not reported.

We will report outcome measures at the latest time point available (assumed to be length of follow-up if not specified) and the time point specified in the methods as being of primary interest (if this is different from the latest time point available). For all outcomes, we will class assessment of outcome measures from:

- up to or equal to eight weeks as short term;
- over eight weeks to 26 weeks as medium term;
- over 26 weeks as long term.

#### Primary outcomes

- Time to complete healing after graft (defined by the original studies and based on clinical assessment).
- Postoperative infection (clinical diagnosis, as described by the original study and supported by microbiological evidence where possible).

Where all three of the outcomes above are reported, we will present all data in a summary outcome table for reference, but will focus on reporting time to healing. We will accept authors' definitions of what constituted a healed wound.

#### Secondary outcomes

- Operative efficiency as measured by the reported operative time (in minutes); this may be recorded in various formats (total

anaesthetic time, knife-to-skin to closure time, or be undefined) but we feel that this level of differentiation is not important because in the setting of a randomised trial, the only between-group difference should be in the intervention and as time is a ratio variable, differences in total operative time versus anaesthetic time etc. will be proportional and as such are equivocal.

- Scar outcome (measured using a standardised validated scar scale e.g. Vancouver, Patient Scale and an Observer Scale (POSAS). We will not include ad hoc scar outcome measures that are not likely to be validated and would not be common to multiple trials).
- Resource use (including measurements of resource use such as number of dressing changes, burn clinic appointments, length of hospital stay and re-operation/intervention).
  - Health-related quality of life
  - Other adverse outcomes (including blood transfusion volumes (per %TBSA) within the first seven postoperative days).

## Search methods for identification of studies

### Electronic searches

We will search the following electronic databases to retrieve reports of relevant RCTs:

- Cochrane Wounds Specialised Register (to present);
- the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library, latest issue);
- Ovid MEDLINE (1946 to present);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations);
- Ovid Embase (1974 to present);
- EBSCO CINAHL Plus (1937 to present).

The draft search strategy for CENTRAL can be found in [Appendix 1](#). We will adapt this strategy to search Ovid MEDLINE, Ovid Embase and EBSCO CINAHL Plus. We will combine the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying RCTs in MEDLINE: sensitivity- and precision-maximising version (2008 revision) ([Lefebvre 2011](#)). We will combine the Embase search with the Ovid Embase filter developed by the UK Cochrane Centre ([Lefebvre 2011](#)). We will combine the CINAHL Plus search with the trial filters developed by the Scottish Intercollegiate Guidelines Network ([SIGN 2017](#)). There will be no restrictions with respect to language, date of publication or study setting. We will also search the following clinical trials registries:

- [ClinicalTrials.gov](#);
- [World Health Organization \(WHO\) International Clinical Trials Registry Platform](#);
- [EU Clinical Trials Register](#).

### Searching other resources

We will contact corresponding authors and the manufacturers and distributors of Versajet hydrosurgery systems. We will try to identify other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials as well as relevant systematic reviews, meta-analyses and health technology assessment reports.

## Data collection and analysis

### Selection of studies

Two review authors will independently assess the titles and abstracts of the citations retrieved by the searches for relevance. After this initial assessment, we will obtain full-text copies of all studies considered to be potentially relevant. Two review authors will independently check the full papers for eligibility; disagreements will be resolved by discussion and, where required, the input of a third review author. Where required and possible, we will contact study authors where the eligibility of a study is unclear. We will record all reasons for exclusion of studies for which we had obtained full copies. We will complete a PRISMA flowchart to summarise this process ([Liberati 2009](#)).

Where studies have been reported in multiple publications/reports, we will obtain all publications. While the study will be included only once in the review, we will extract data from all reports to ensure maximal relevant data are obtained. The authors of such studies will be contacted by email to ensure there has been no duplication of data or double counting of participants.

### Data extraction and management

We will extract and summarise details of the eligible studies using a data extraction sheet. The data extraction sheet will be piloted on two studies by two authors independently and any issues with the form will be rectified by both authors following the pilot. Two review authors will extract data independently and will resolve disagreements by discussion, drawing on a third review author where required. Where data are missing from reports, we will attempt to contact the study authors to obtain this information. Where a study with more than two intervention arms is included, we will extract only data from intervention and control groups that meet the eligibility criteria.

We will extract the following data where possible by treatment group for the pre-specified interventions and outcomes in this review. Outcome data will be collected for relevant time points as described in [Types of outcome measures](#):

- country of origin;
- type of burn and surgery including whether the burn was grafted or not;

- unit of randomisation (per participant) - single burn or multiple burns on the same participant;
- unit of analysis;
- trial design (e.g. parallel, cluster);
- care setting;
- number of participants randomised to each trial arm;
- eligibility criteria and key baseline participant data;
- details of treatment regimen received by each group;
- number of operative procedures;
- details of any co interventions, such as wound dressings;
- primary and secondary outcome(s) (with definitions);
- outcome data for primary and secondary outcomes (by group);
- hospital stay (days);
- duration of follow-up;
- number of withdrawals (by group);
- publication status of study; and
- source of funding for trial.

### Assessment of risk of bias in included studies

Two review authors will independently assess included studies using the Cochrane tool for assessing risk of bias (Higgins 2011a). This tool addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete data, selective outcome reporting and other issues. In this review, we will record issues with unit of analysis, for example, where a cluster trial has been undertaken but analysed at the individual level in the study report (Appendix 1). We will assess blinding and completeness of outcome data for each of the review outcomes separately. We note that, since wound healing is a subjective, clinical outcome, it can be at high risk of measurement bias when outcome assessment is not blinded. We will present our assessment of risk of bias using two 'Risk of bias' summary figures; one which will be a summary of bias for each item across all studies, and a second which will show a cross-tabulation of each trial by all the 'Risk of bias' items. We will class studies with an assessment of high risk of bias for the randomisation sequence domain or the allocation concealment domain or the blinded outcome assessment domain (for specified outcome) (or a combination of these) as being at overall high risk of bias (for specified outcome). For trials using cluster randomisation or within-participant randomisation, we will also consider the risk of bias in terms of: recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with trials randomising participants (Higgins 2011b) (Appendix 2).

### Measures of treatment effect

For dichotomous outcomes, we will calculate the risk ratio (RR) with 95% confidence intervals (CI). For continuously distributed outcome data, we will use the mean difference (MD) with 95% CIs, if all trials use the same or similar assessment scale. If trials

use different assessment scales, we will use the standardised mean difference (SMD) with 95% CIs. We will only consider mean or median time to healing without survival analysis as a valid outcome if reports specify that all wounds healed (i.e. if the trial authors regarded time to healing as a continuous measure as there is no censoring). We will report time-to-event data (e.g. time-to-complete wound healing) as hazard ratios (HR) where possible in accordance with the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011). If studies reporting time-to-event data (e.g. time to healing) do not report an HR, then, where feasible, we plan to estimate this using other reported outcomes, such as the numbers of events, through the application of available statistical methods (Parmar 1998).

### Unit of analysis issues

Where studies randomise at the participant level and measure outcomes at the wound level (e.g. wound healing), we will treat the participant as the unit of analysis when the number of wounds assessed appears equal to the number of participants (e.g. one wound per person).

Particular unit of analysis issues in wound care trials can occur when studies randomise at the participant level, use the allocated treatment on multiple wounds per participant and then analyse outcomes per wound; or studies undertake multiple assessments of an outcome over time per participant. These approaches should be treated as cluster or within-participant trials, alongside more standard cluster designs (e.g. delivery of interventions at an organisational level).

Where a cluster trial has been conducted and correctly analysed, effect estimates and their standard errors may be meta-analysed using the generic inverse variance method in Review Manager 5 (RevMan 2014).

We will record where a cluster RCT has been conducted but incorrectly analysed. This will be recorded as part of the 'Risk of bias' assessment. If possible, we will approximate the correct analyses based on *Cochrane Handbook* guidance for *Systematic Reviews of Interventions* (Higgins 2011c) using information on:

- the number of clusters (or groups) randomised to each intervention group; or the mean size of each cluster;
- the outcome data ignoring the cluster design for the total number of participants (e.g. number or proportion of participants with events, or means and standard deviations); and
- an estimate of the intracluster (or intraclass) correlation coefficient (ICC).

If the study data cannot be analysed correctly, we will extract and present outcome data and but not analyse them further.

We will also note when randomisation has been undertaken within participant or at the wound level, that is, a split-site or split-body design. We will assess whether the correct analysis has been undertaken and record any issues in the 'Risk of bias' section. If an incorrect analysis has been undertaken, we will contact authors



to attempt to obtain the original data or try to approximate the correct analysis if the required data are available. If this is not possible, we will extract and present the relevant outcome data but not analyse them further or pool them.

### Dealing with missing data

It is common to have data missing from trial reports. Excluding participants post-randomisation from the analysis, or ignoring those participants who are lost to follow-up compromises the randomisation, and potentially introduces bias into the trial. Where there are missing data we think should be included in the analyses, we will contact the relevant study authors to request whether these data are available.

Where data remain missing for the 'proportion of wounds healed' outcome, for analysis we will assume that if randomised participants were not included in an analysis, their wound did not heal (i.e. they would be considered in the denominator but not the numerator).

In a time-to-healing analysis using survival analysis methods, drop-outs should be accounted for as censored data, so no action regarding missing data will be taken.

For continuous variables (e.g. length of hospital stay), and for all secondary outcomes, we will present available data from the study reports/study authors and do not plan to impute missing data. Where measures of variance are missing, we will calculate these where ever possible. If calculation is not possible, we will contact the study authors. Where these measures of variance are not available, we will exclude the study from any relevant meta-analyses that are conducted.

### Assessment of heterogeneity

Assessment of heterogeneity can be a complex, multi-faceted process. First, we will consider clinical and methodological heterogeneity: that is, the degree to which the included studies vary in terms of participant, intervention, outcome and characteristics such as length of follow-up. This assessment of clinical and methodological heterogeneity will be supplemented by information regarding statistical heterogeneity assessed using the Chi<sup>2</sup> test (a significance level of  $P < 0.10$  will be considered to indicate statistically significant heterogeneity) in conjunction with the I<sup>2</sup> measure (Higgins 2003). The I<sup>2</sup> statistic examines the percentage of total variation across RCTs that is due to heterogeneity rather than chance (Higgins 2003). In general, I<sup>2</sup> values of 25% or less may mean a low level of heterogeneity (Higgins 2003), and values of more than 75% indicate very high heterogeneity (Deeks 2011). Where there is evidence of high heterogeneity, we will attempt to explore this further: see [Data synthesis](#).

### Assessment of reporting biases

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of results. Publication bias is one of a number of possible causes of 'small-study effects,' that is, a tendency for estimates of the intervention effect to be more beneficial in smaller RCTs. Funnel plots allow a visual assessment of whether small-study effects may be present in a meta-analysis. A funnel plot is a simple scatter plot of the intervention effect estimates from individual RCTs against some measure of each trial's size or precision (Sterne 2011). We plan to present funnel plots for meta-analyses comprising 10 RCTs or more using Review Manager 5 (RevMan 2014). We will also cross-reference reports with published protocols in an attempt to assess completeness of data reporting, omissions and potential resultant bias.

### Data synthesis

We will combine details of included studies in a narrative review according to type of comparator, possibly by location/type of wound and then by outcomes by time period. Clinical and methodological heterogeneity will be considered and pooling undertaken when studies appear appropriately similar in terms of wound type, intervention type, duration of follow-up and outcome type.

In terms of meta-analytical approach, we are unable to pre-specify the amount of clinical, methodological and statistical heterogeneity in the included studies, but it might be extensive. Thus, we anticipate using a random effects approach for meta-analysis. Conducting meta-analysis with a fixed effect model in the presence of even minor heterogeneity may provide overly narrow confidence intervals. We will only use a fixed-effect approach when clinical and methodological heterogeneity is assessed to be minimal and the assumption that a single underlying treatment effect is being estimated holds. Chi-squared and I-squared will be used to quantify heterogeneity but will not be used to guide choice of model for meta-analysis. We will exercise caution when meta-analysed data are at risk of small study effects because a random effects model may be unsuitable. In this case or where there are other reasons to question the selection of a fixed effect or random effects model, we will assess the impact of the approach using sensitivity analyses to compare results from alternate models. We will report any evidence that suggests that the use of a particular model might not be robust. We may meta-analyse even when there is thought to be extensive heterogeneity. We will attempt to explore the causes behind this using meta-regression, if possible (Thompson 1999). We will present data using forest plots where possible. For dichotomous outcomes, we will present the summary estimate as an RR with 95% CI. Where continuous outcomes are measured in the same way across studies, we plan to present a pooled MD with 95% CI; we plan to pool SMDs estimates where studies measure the same outcome using different methods. For time-to-event data, we plan to plot (and, if appropriate, pool) estimates of HRs and 95% CIs as presented in the study reports using the generic inverse variance method in Review Manager 5. Where time to healing is



analysed as a continuous measure but it is not clear if all wounds healed, we will document use of the outcome in the study but will not summarise or use data in any meta-analysis. Pooled estimates of treatment effect will be obtained using Cochrane Review Manager 5 software (RevMan 2014).

### 'Summary of findings' tables and the GRADE approach

Two review authors will independently use the GRADE approach to assess the quality of the evidence for each outcome to determine confidence in the estimate of the observed effects (Schünemann 2013). These two review authors will independently rate the outcomes as high, moderate, low, or very low quality/certainty evidence. Consensus on rating will be achieved by involvement of a third review author if needed. The results for important outcomes will be presented in 'Summary of findings' tables. These tables present key information concerning the quality of the evidence, the magnitude of the effects of the interventions examined and the sum of the available data for the main outcomes (Schünemann 2011a). The quality of a body of evidence involves consideration of within-trial risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias (Schünemann 2011b).

We plan to present the following outcomes in the 'Summary of findings' tables:

- time to complete healing after graft;
- percentage of graft take post-debridement;
- postoperative infection.

### Subgroup analysis and investigation of heterogeneity

We will assess potential heterogeneity across the following areas specifically: where there is evidence of between-trial heterogeneity, we envisage subgroup analyses being conducted as follows:

- adult versus paediatric populations;
- anatomical site of burn (e.g. limbs versus face versus trunk);
- % TBSA of burn (e.g. less than 10%, 10% to 20%, greater than 20%).

### Sensitivity analysis

Where possible, we plan to perform sensitivity analyses to explore the effect of the following criteria:

- blinding (blinded studies versus non-blinded studies);
- concealment of allocation (allocation adequately concealed versus not reported or inadequate);
- presence of attrition bias;
- type of randomisation (truly randomised with adequate method of generating the randomisation sequence versus not reported);
- use of a fixed versus a random effects model.

Further sensitivity analyses may be performed in the review stage depending on the characteristics of included studies where appropriate.

Elements of this Methods section are based on the standard Cochrane Wounds protocol template.

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\* Indicates the major publication for the study

## APPENDICES

### Appendix 1. Provisional search strategy for the Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

#1 MeSH descriptor: [Burns] explode all trees  
#2 burn or burns or burned or scald\*:ti,ab,kw  
#3 thermal next injur\*:ti,ab,kw  
#4 #1 or #2 or #3  
#5 MeSH descriptor: [Debridement] explode all trees  
#6 MeSH descriptor: [Hydrotherapy] explode all trees  
#7 hydrosurg\*:ti,ab,kw  
#8 hydro-surg\*:ti,ab,kw  
#9 hydrosscalpel\*:ti,ab,kw  
#10 hydro-scalpel\*:ti,ab,kw  
#11 versajet\*:ti,ab,kw  
#12 water next jet\*:ti,ab,kw  
#13 waterjet\*:ti,ab,kw  
#14 water-jet\*:ti,ab,kw  
#15 fluid next jet\*:ti,ab,kw  
#16 fluidjet\*:ti,ab,kw  
#17 fluid-jet\*:ti,ab,kw  
#18 debrid\*:ti,ab,kw  
#19 hydro next jet\*:ti,ab,kw  
#20 hydrojet\*:ti,ab,kw  
#21 hydro-jet\*:ti,ab,kw  
#22 #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #20 or #21  
#23 #4 and #22

### Appendix 2. Risk of bias assessment (individually randomised controlled trials)

#### The Cochrane tool for assessing risk of bias

##### 1. Was the allocation sequence randomly generated?

###### Low risk of bias

The investigators described a random component in the sequence generation process such as: referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots.

###### High risk of bias

The investigators described a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example, sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

###### Unclear risk of bias

Insufficient information about the sequence generation process provided to permit a judgement of low or high risk of bias.

## **2. Was the treatment allocation adequately concealed?**

### **Low risk of bias**

Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially-numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes.

### **High risk of bias**

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: use of an open random allocation schedule (e.g. a list of random numbers); assignment envelopes without appropriate safeguards (e.g. envelopes were unsealed, non-opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

### **Unclear risk of bias**

Insufficient information provided to permit a judgement of low or high risk of bias. This is usually the case if the method of concealment was not described, or not described in sufficient detail to allow a definite judgement, for example, if the use of assignment envelopes was described, but it remained unclear whether envelopes were sequentially numbered, opaque and sealed.

## **3. Blinding - was knowledge of the allocated interventions adequately prevented during the study?**

### **Low risk of bias**

Any one of the following.

- No blinding, but the review authors judged that the outcome and the outcome measurement were not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

### **High risk of bias**

Any one of the following.

- No blinding or incomplete blinding, and the outcome or outcome measurement was likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

### **Unclear risk of bias**

Either of the following.

- Insufficient information to permit judgement of low or high risk of bias.
- The study did not address this outcome.

## **4. Were incomplete outcome data adequately addressed?**

### **Low risk of bias**

Any one of the following.

- No missing outcome data.

- Reasons for missing outcome data were unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data were balanced in numbers across intervention groups, with similar reasons for missing data across groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk was not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, a plausible effect size (difference in means or standardised difference in means) among missing outcomes was not enough to have a clinically relevant impact on the observed effect size.
- Missing data were imputed using appropriate methods.

### **High risk of bias**

Any one of the following.

- Reason for missing outcome data were likely to be related to the true outcome, with either an imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk was enough to induce clinically relevant bias in the intervention effect estimate.
- For continuous outcome data, a plausible effect size (difference in means or standardised difference in means) among missing outcomes was enough to induce a clinically relevant bias in the observed effect size.
- 'As-treated' analysis done with a substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

### **Unclear risk of bias**

Either of the following.

- Insufficient reporting of attrition/exclusions to permit a judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided).
- The study did not address this outcome.

## **5. Are reports of the study free of suggestion of selective outcome reporting?**

### **Low risk of bias**

Either of the following.

- The study protocol was available and all the study's prespecified (primary and secondary) outcomes that were of interest in the review were reported in the prespecified way.
- The study protocol was not available but it was clear that the published reports included all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon).

### **High risk of bias**

Any one of the following.

- Not all the study's prespecified primary outcomes were reported.
- One or more primary outcomes was/were reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not prespecified.
- One or more reported primary outcomes was/were not prespecified (unless clear justification for their reporting was provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review was/were reported incompletely so that they could not be entered in a meta-analysis.
- The study report failed to include results for a key outcome that would be expected to have been reported for such a study.

### Unclear risk of bias

Insufficient information provided to permit a judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

## 6. Other sources of potential bias

### Low risk of bias

The study appeared to be free of other sources of bias.

### High risk of bias

There was at least one important risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- was claimed to have been fraudulent; or
- had some other problem.

### Unclear risk of bias

There may be a risk of bias, but there was either:

- insufficient information to assess whether an important risk of bias existed; or
- insufficient rationale or evidence that an identified problem will introduce bias.

## Appendix 3. Risk of bias (cluster randomised controlled trials)

In cluster randomised trials, particular biases to consider include: recruitment bias; baseline imbalance; loss of clusters; incorrect analysis and comparability with individually randomised trials.

**Recruitment bias:** can occur when participants are recruited to the trial after the clusters have been randomised, as the knowledge of whether each cluster is an 'intervention' or 'control' cluster could affect the types of participants recruited.

**Baseline imbalance:** cluster randomised trials often randomise all clusters at once, so lack of concealment of an allocation sequence should not usually be an issue. However, because small numbers of clusters are randomised, there is a possibility of chance baseline imbalance between the randomised groups, in terms of either the clusters or the participants. Although not a form of bias as such, the risk of baseline differences can be reduced by using stratified or pair-matched randomisation of clusters. Reporting of the baseline comparability of clusters, or statistical adjustment for baseline characteristics, can help reduce concern about the effects of baseline imbalance.

**Loss of clusters:** occasionally complete clusters are lost from a trial, and have to be omitted from the analysis. Just as for missing outcome data in individually randomised trials, this may lead to bias. In addition, missing outcomes for participants within clusters may also lead to a risk of bias in cluster randomised trials.

**Incorrect analysis:** many cluster randomised trials are analysed by incorrect statistical methods, not taking the clustering into account. Such analyses create a 'unit of analysis error' and produce over-precise results (the standard error of the estimated intervention effect is too small) and P values that are too small. They do not lead to biased estimates of effect. However, if they remain uncorrected, they will receive too much weight in a meta-analysis.

**Comparability with individually randomised trials:** in a meta-analysis including both cluster and individually randomised trials, or including cluster randomised trials with different types of clusters, possible differences between the intervention effects being estimated need to be considered. For example, in a vaccine trial of infectious diseases, a vaccine applied to everyone in a community would be expected to be more effective than if the vaccine was applied to only half of the people. Another example is provided by a Cochrane Review of hip protectors (Hahn 2005). The cluster trials showed large positive effect whereas individually randomised trials did not show any clear benefit. One possibility is that there was a 'herd effect' in the cluster randomised trials (which were often performed in nursing homes, where compliance with using the protectors may have been enhanced). In general, such 'contamination' would lead to underestimates of effect. Thus, if an intervention effect is still demonstrated despite contamination in those trials that were not cluster randomised, a confident conclusion about the presence of an effect can be drawn. However, the size of the effect is likely to be underestimated. Contamination and 'herd effects' may be different for different types of cluster.



## CONTRIBUTIONS OF AUTHORS

**Justin Wormald:** conceived the review question; developed the protocol; coordinated the protocol development; produced the first draft of the protocol; contributed to writing or editing the protocol; made an intellectual contribution to the protocol; approved the final version of the protocol prior to submission; and is a guarantor of the protocol.

**Ryckie Wade:** developed the protocol; produced the first draft of the protocol; contributed to writing or editing the protocol; made an intellectual contribution to the protocol; and approved the final version of the protocol prior to submission.

**Jonathan Dunne:** developed the protocol; contributed to writing or editing the protocol; made an intellectual contribution to the protocol; and approved the final version of the protocol prior to submission.

**Declan Collins:** contributed to writing or editing the protocol; made an intellectual contribution to the protocol; advised on the protocol; and approved the final version of the protocol prior to submission.

**Abhilash Jain:** contributed to writing or editing the protocol; made an intellectual contribution to the protocol; advised on the protocol and approved the final version of the protocol prior to submission.

### Contributions of editorial base:

Kurinchi Gurusamy (Editor): edited the protocol; advised on methodology, interpretation and protocol content; approved the final protocol prior to submission.

Gill Rizzello (Managing Editor): coordinated the editorial process; advised on content; edited the protocol.

Naomi Shaw (Information Specialist): designed the search strategy and edited the search methods section.

Ursula Gonthier (Editorial Assistant): edited the reference section.

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Justin Wormald: none known.

Ryckie Wade: none known.

Jonathan Dunne: none known.

Declan Collins: I have received two grants from charities for the purchase of equipment and service development. Neither grant application is related to this work. I have performed one lecture on an unrelated topic (autologous fibrin glue use in burns patients). Payment for this lecture was not to myself but to a hospital research fund.

Abhilash Jain: none known.

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