

Critically Appraised Topic

Skin Stretching for Burn Scar Excision – A Critically Appraised Topic

Riaz A. Agha BSc (Hons), MBBS, MRCSEng/ED, FHEA^a, Maliha Agha BSc (Hons), MSc, MPH^b

^aDepartment of Plastic Surgery, Queen Victoria Hospital, East Grinstead, West Sussex, UK; ^bDepartment of Public Health, King's College London, London, UK

Correspondence to: Riaz A. Agha, Department of Plastic Surgery, Queen Victoria Hospital NHS Foundation Trust, East Grinstead, West Sussex RH19 3DZ. UK; Tel.: +44(0) 207 754 5402; Email: ragha@nhs.net

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Abstract

Adults with burn scars are a clinical challenge, and the long term sequelae of burns can have a significant impact on the patient. Scar excision is thought to be the best treatment at present, as it results in a smaller scar. Scar stretching has shown promise in a previous study, as it may allow the surgeon to excise more burn scar. The goal of this study was to determine if good evidence exists for the use of burn scar stretching, in routine clinical practice, through the format of a critically appraised topic.

A question was formulated using the Patient Intervention Comparator Outcome (PICO) method:

- Patient – Adult burn victims
- Intervention – Scar excision + skin stretching
- Comparator – Scar excision
- Outcome – Total remaining scar

The PICO question was used to develop a search query: “*stretch* burn scar*” (where “*” represents a wildcard function). A search was then conducted using PubMed, SCOPUS, the Cochrane Library, and Trip Database. One paper was selected for critical appraisal following identification, screening, and eligibility evaluation.

The paper was critically appraised using accepted methodology outlined by Straus et al. and reporting quality was assessed using the CONSORT statement for non-pharmacological trials. Areas of methodological or reporting weakness were highlighted.

Burn scar stretching, using the device or technique in question, requires much further research before widespread usage in burns patients.

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Introduction

“Evidence-based medicine (EBM) requires the integration of the best research evidence with our clinical expertise and our patient’s unique values and circumstances.”¹

Clinical Context

A burn is an acute traumatic injury to the skin by means of exposure to heat, cold, electrical, chemical, or radiation energy.² Data from the United Kingdom (UK) National Burn Care Review (2001) estimates 250,000 cases of burn injuries annually, of which 90% are preventable. Of these, 175,000 present to Accident and Emergency departments with 13,000 requiring hospital admission, and 300 deaths.³

Most burns are relatively minor and can be safely treated in the community.⁴ Over the last 25 years, the chances of survival from significant burn injury have been steadily increasing owing to advances in critical care, nutrition, surgical protocols, and infection control.³ This situation requires a renewed focus regarding the control or rectification of chronic burn sequelae which can be detrimental to rehabilitation. The ultimate, or ideal, treatment goal is to return the individual to their pre-injury state, and allow them to retake their place in society with unaltered potential.³ The scarring process that ensues following

a burn can have devastating long-term functional and cosmetic outcomes. Pruritis, pain, and psychological morbidity are common and debilitating for the individuals involved.⁵

A multitude of reconstructive techniques have been described to improve burn scars, including: scar excision, tissue expansion, and various scar release techniques.⁶ Scar excision, followed by direct wound closure, gives the best outcome as it results in a smaller scar.⁷ However, large defect closure after burn scar excision can be challenging owing to high skin tension. Hence, it is often done as a multi-step procedure for larger burn scars.⁵ Mechanical skin stretching is a relatively new technique that is gaining increasing scrutiny, especially in the field of wound healing.⁸

The objective of this study was to determine if skin stretching is a useful intervention for burn scars by using a critically appraised topic method.

Method

Defining the research question

In order to conduct an evidence-based search, a Patient Intervention comparator Outcome (PICO) question was defined.^{9,10} This has been formulated below:

Table 1 6S system sequential results

6S System	Sources Searched	Result
Systems: computerised decision support systems	No such system currently exists for burns	N/A
Summaries	– NICE Guidelines – UpToDate – British Medical Journal Clinical Evidence	No results
Synopses of Syntheses	– DARE – UK DUETs	No results
Syntheses: Systematic reviews	– Cochrane library – Trip database	52 results
Synopses of studies: evidence-based abstraction journals	– ACP Journal Club – Centre for Reviews and Dissemination	No results
Studies: original articles published in journals	– PubMed – Scopus	88 results

- Patient – Adult burn victims
- Intervention – Scar excision + skin stretching
- Comparator – Scar excision
- Outcome – Total remaining scar

Search Strategy

From the PICO question a search phrase was developed: *stretch * burn scar*. The Boolean operator “and” is assumed. The use of the asterisk results in alternate spellings for stretch at the point that the asterisk appears i.e. stretched, stretching, etc.

The search for evidence was rationalised using the 6S system to search for pre-appraised evidence (see Table 1).¹¹ It should be noted that the American College of Surgeons (ACS) Surgery platform was not functioning at the time.

Inclusion Criteria

The search was restricted to the English language. Only study designs such as systematic reviews and randomised controlled trials (RCTs) were considered. They are the criterion standard for minimising bias when evaluating healthcare interventions when properly designed, conducted, and reported.¹² A preliminary search had already shown that one non-randomised study existed in the literature.¹³ In 2006, Melis et al. reported a prospective study documenting seven-year follow-up results, for scar width and patient satisfaction, following closure of various large tissue defects using a skin-stretching device.¹³ This study showed promising results, but there was no control group. As such, no comparison was made to the standard technique of serial scar excision and wound closure without skin stretching. This underscored the need to examine only RCTs and Systematic Reviews.

Exclusion Criteria

Non-English language and non-randomised studies were excluded. No date restrictions were imposed; the research and literature base for surgical burns management is known to be relatively small (PubMed and Scopus were searched back to 1948). Where an interim and final study existed for the same research, the interim study was excluded. Animal studies and purely cost-effectiveness studies were excluded.

Table 2 Summary table describing the Verhaegen et al. paper

PICO Item	Details from the study
Patients	30 patients with burn scars
Intervention	Scar excision + stretching (SS group)
Comparator	Scar excision alone (SE group)
Outcomes (at 12 months)	<p>Objective</p> <ul style="list-style-type: none"> – Scar surface area measurements – using planimetry of sterile tracing sheets. – Scar colour – using Derma Spectrometer. <p>Subjective</p> <ul style="list-style-type: none"> – Patient and observer scar assessment scale (POSAS). – Scar hypertrophy.

Databases

The databases used to conduct the search included: PubMed, SCOPUS, the Cochrane Library, and the Trip Database. It was believed that these databases would provide all the relevant evidence in this area with collective access to over 40 million records. EMBASE and Medline were not searched as SCOPUS indexes over 18,000 journals and includes the journals that these databases cover.

Results

The search results are shown through a flow diagram (Figure 1).

The Study Selected – Verhaegen et al. 2011 – *Sustainable effect of skin stretching for burn scar excision: long-term results of a multicenter randomized controlled trial*. A PICO table has been constructed to help summarise the paper (Table 2).

Critical Appraisal

In order to determine whether this treatment can be used with burns patients, first the validity, clinical relevance, and applicability of the results need to be assessed.

Is the research question an important and clearly focussed one?

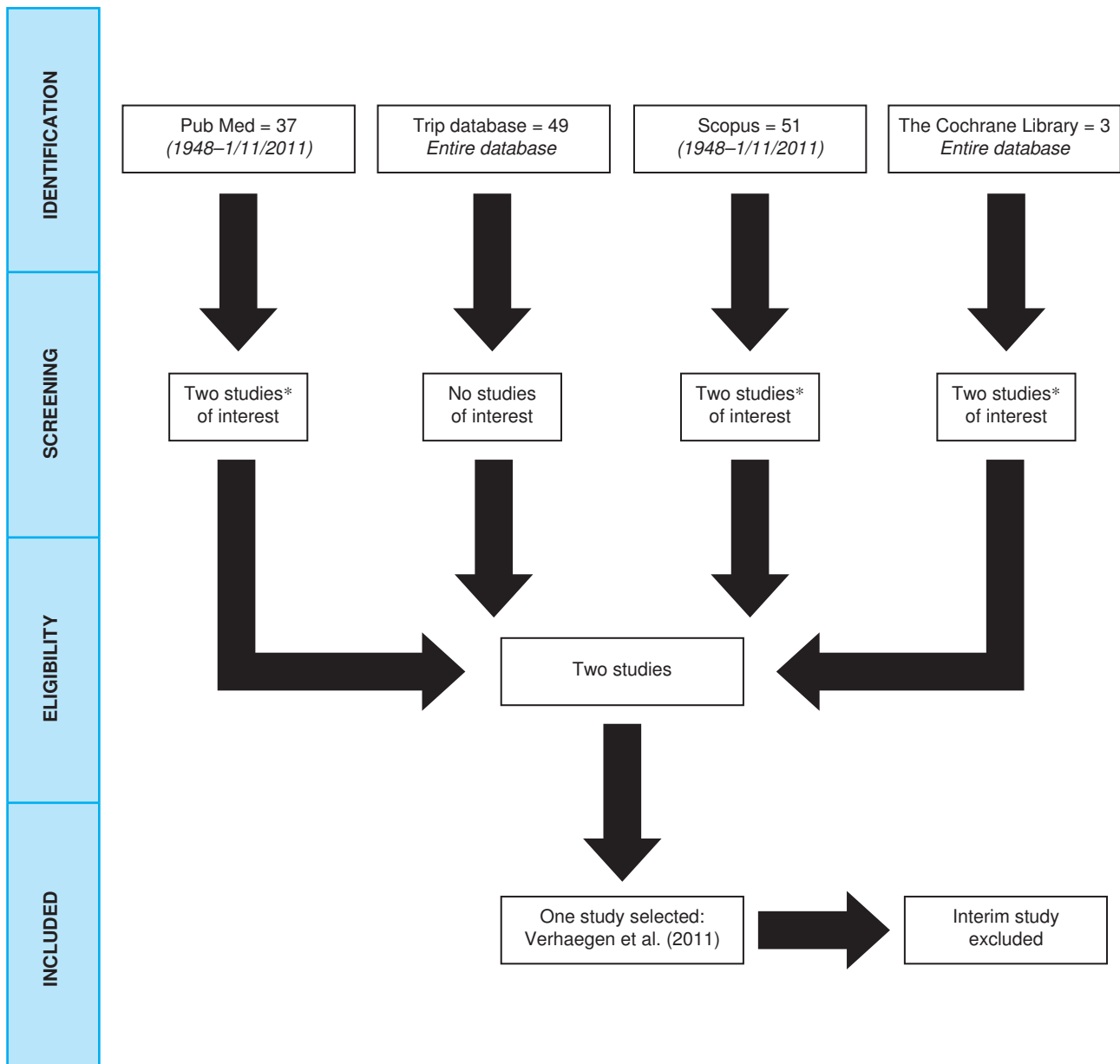
Determining whether skin stretching could help burns patients is an important question and needs to be answered. This study does add to the literature as the first RCT to examine the potential for skin stretching for burn scar management.

Methodological Quality

To assess methodological quality, guidance provided by Straus et al. was used.¹

Are the study participants representative of the target population?

From February 2008 until March 2010 thirty patients with burn scars were included (a pre-trial sample size and power calculation was either not performed or not reported). Details about the nature, context, and who performed the recruitment were not provided. Selection bias and regression to the mean effects could potentially be introduced by the study attracting



* the same two studies were found in PubMed, Scopus and the Cochrane Library.

Fig 1 PRISMA Flow diagram illustrating the search results.

those most desperate for a solution and thus willing to try new treatments. This would affect compliance and motivation and could result in Hawthorne effects in the patients under study.¹⁴ Indeed, Kirkley et al. showed how powerful Hawthorne effects can occur in surgical RCTs.¹⁵ The process of achieving informed consent for the participants is not detailed. Indeed, it would be important to understand how many potential participants rejected the new treatment option during the informed consent process.

Regarding the population specifically, the paper provides averages but not the ranges, medians, or standard deviations for patient age and scar age. The sex, ethnic group, social status, and co-morbidities of the patients recruited to the trial are not provided. Comorbidities such as depression are common in burn victims and this could represent an important confounder for the subjective outcomes.¹⁶ No mention is made of

what previous procedures the patients have had to the same site, possibly to address the same problem(s). No mention is made of the anatomical sites involved, which areas of the body were burned, or the depth of burn. Also, the inclusion and exclusion criteria applied during the recruitment phase are not specified. Potential co-interventions standardised across the five trial centres is not made clear.

Was the assignment of patients to treatments randomised?

Whilst the paper has identified itself as an RCT at several points (title, introduction and method sections), there was no mention of how the randomisation process was actually performed (i.e. the method used to generate the allocation sequence, the type of randomisation, and whether blocking was used). Furthermore, there was no mention of the

Table 3 Primary outcomes and results at 12 months

Outcome Category	Measurement Made	Results at 12 months		
		SS Group	SE Group (control)	p-value
Scar surface area measurements	Total remaining scar area	26% (n = 13)	43% (n = 14)	0.026
		95% CI not provided	95% CI not provided	
Scar hypertrophy	Linear scarring	21% (n = 13)	25% (n = 14)	0.607
		95% CI not provided	95% CI not provided	
Scar Colour	Erythema	5.70 (n = 14)	6.68 (n = not stated)	0.513
		95% CI 0.50–10.13	95% CI 1.03–12.17	
	Melanin	4.93 (n = 14)	4.56 (n = not stated)	0.727
		95% CI 0.20–23.20	95% CI 0.10–15.10	
Mean POSAS Score	Patient	3.9 (n = 14)	3.9 (n = not stated)	0.760
		95% CI 1.5–6.5	95% CI 1.5–7.7	
	Clinician	3.6 (n = 14)	3.5 (n = not stated)	0.462
		95% CI 2.4–7.0	95% CI 1.8–5.5	

individuals who generated the random allocation sequence, enrolled participants, and assigned them to interventions.

Was the randomisation concealed?

Any steps taken to conceal the allocation sequence were not stated. Allocation concealment is a key marker of methodological quality in RCTs.¹⁷

Were the baseline characteristics for both groups similar at the start of the trial?

The process of randomisation should result in two balanced groups with an equivalent share of known and unknown confounders. It is, therefore, important to ensure that both groups are similar, in all ways important to prognosis, at the start of the trial. With proper randomisation baseline differences would be due to chance. If, by chance, the groups are not similar, then the need to adjustment for potentially important prognostic factors should be determined. The paper provides no table comparing both groups at the start of the trial. However, average ages and average scar ages were provided and the differences were not statistically significant.

Was the follow-up of patients sufficiently long and complete?

Patients were followed up at three and 12 months which is sufficiently long to determine outcomes. Twenty-nine out of 30 patients completed the 12 month follow-up period. However, one patient refused follow-up measurements at 12 months but no indication was given as to why. Thus, the loss to follow-up was relatively low at 3.33%. This is below the 5% threshold of the '5 and 20 rule' i.e. less than 5% loss to follow-up leads to minimal bias and threat to validity.¹⁸

It is, however, not clear how many patients are in each group following randomisation. Whilst the paper mentions that only one patient was lost to follow-up, their results tables have n = 14 or n = 13 for each group, giving a sample size of 27 or 28 depending on the specific outcome (see Table 3). This conflict is not rationalised in the text.

Were all patients analysed in the groups to which they were randomised?

No mention is made of whether an intention-to-treat or protocol-based analysis was performed. Such analysis preserves

the value and fidelity of randomisation. In addition, no mention of the degree of cross-over between treatment and control arms is mentioned. No worst-case or sensitivity analysis was performed, but given the loss to follow-up of just 3.33%, there is unlikely to be a large impact on the results. However, all patients were accounted for at the trial's conclusion. An indication of the compliance of the patients is not detailed.

Were patients, clinicians and study personnel kept blind to treatment?

There was no mention of blinding for three of the four outcomes measures. Scar hypertrophy was scored from pictures by a plastic surgeon experienced in burn reconstructions, who was not involved in this study and 'blinded' to prevent bias. Many of the measurements are subjective and hence lack of blinding could have introduced differential measurement error and measurement bias.¹⁹ The 'objective' outcome of scar surface area measurements involved tracing around the scar with sterile tracing sheets at 12 months. The individual doing this could have been blinded to the patient's allocation in the trial – although this was not mentioned. The person doing this at the 12-month follow-up need not have been a member of the same team. Greater use of blinding for assessors, patients, and indeed surgeons would have helped ensure greater reliability for the study.

Were groups treated equally, apart from the experimental therapy?

This is not well detailed within the trial report. This is a multicentre trial and it's unclear how the treatment was standardised across the five centres involved. The level of expertise of the people involved and where they are on the relevant learning curve for delivering this novel treatment is unknown. Did any issues of therapeutic equipoise come into play – especially for those assigned to perform the standard treatment and who were not blinded? There is no detail or pre-published protocol on whether any co-treatments were involved and how they were standardised across all the centres (e.g. psychological, anaesthetic, analgesic and nutritional support or regimes which could have an impact on the subjective outcomes). Little information was provided on background on the institutes involved. How many, and what type of burns patients they treat per year, and what facilities are available? Who performed the treatment and who did the aftercare?

This also affects the external validity of the work as other units would not be able to gauge if they could deliver this as part of their burns service. Furthermore, with only 30 patients in total, each centre contributed a relatively small number of patients making their individual results prone to type II error.

Was there an appropriate measurement of outcomes?

The POSAS score used in the study, is a composite score from the surgeon and the patient. Such composite outcomes must be assessed cautiously.²⁰ Greenhalgh argues that measuring pain and other symptomatic effects is fraught with problems and outcome measures must be objectively validated.²¹ The POSAS score was validated in 2005 when 100 linear surgical scars were assessed by three independent observers with good inter- and intra-observer reliability.²²

Whilst the study does present mean values for the primary outcomes it would have been more appropriate to provide median values which would have been more robust against extreme values, especially since no evidence to suggest a normal distribution within the study population is presented.

What is the magnitude of the treatment effect and how precise was it?

The main outcomes and results for the study are shown below together with p-values and 95% confidence intervals (95% CI).

Table 3 shows that the only statistically significant outcome was total remaining scar percentage; 26% in the SS group against 43% in the SE group ($p = 0.026$). However, no 95% CIs for the individual groups were provided. The authors do provide a 95% CI of 2–31 but this figure seems to be used for the group as a whole (both SS and SE groups) and doesn't allow us to estimate the precision of the treatment effect for each group. 95% CI were not provided for the linear scarring outcome. In addition, the number of participants in some of the groups was not provided.

Reporting Quality

The Consolidated Statement on the reporting of non-pharmacological trials (CONSORT NPT) published in 2008 was used to determine the reporting quality of the paper.²³ The paper scored 13 out of 23 mandatory reporting items (Table 4 in supplementary data online, a completed CONSORT NPT checklist taken directly from paper by Boutron et al. 2008²³).

Importantly, the paper was non-compliant in the areas of:

- Randomisation details
- Allocation concealment
- Blinding
- Flow diagram of participants

These areas have been found to be lacking in a previous study of the reporting quality of 160 RCTs in Surgery,²⁴ and is now increasingly recognised as a problem within the surgical literature.^{25,26,27}

Other Reporting Concerns

The paper does mention that there were no conflicts of interest and that they received funding from the Dutch Burns Foundation. No mention is made of ethical approval for the study and the relevant ethical committee's judgement reference, or whether methodology and handling of participants

was in line with the Declaration of Helsinki. With the aim of increasing the transparency in research, the International Committee of Medical Journal Editors (ICMJE) made it mandatory for every RCT to be registered prior to outset;²⁸ however, no such registration number was provided.

The implications for the patient with burns – clinical relevance and applicability

Defining the appropriate population, and the injury patterns, where this treatment would be superior are key to determining clinical applicability. All clinically important outcomes were not considered, e.g. quality of life 12 months post-procedure would have been very useful (using validated instruments like the Hamilton method or EQ-5D).^{28,29} It would be important to understand how much of a biological, or clinical, impact the skin-stretching device provides versus the control. Statistical significance may not reliably translate to biological significance or patient satisfaction.

Assessing the applicability of the burn stretching treatment for burns patients in the English National Health Service also requires an understanding of whether the potential benefits are worth the harms and costs. With respect to harms, the study details a section on complications which included re-operations for scar releases (one patient in SE group) and dog ear corrections (one patient in SS group). However, no mention is made of how much the new treatment and the control compare in terms of cost. In addition, there was no mention of how operating times or length-of-stay differed, or how easy it was to obtain the relevant stretching devices.

Limitations

The limitations of this CAT include restriction to English language only studies, and the exclusion of non-randomised studies.

Conclusion

One of the values of an RCT is its potential to be incorporated into systematic reviews once a critical mass of studies has been reached. However, accurate replication necessitates that comprehensive information has been provided in research studies.³⁰ RCTs in surgery are difficult to initiate and conduct well.³¹ To use Paul Glasziou's analogy, it is difficult to determine whether this RCT had a fair start, fair race, and fair finish.¹ So how does the EBM practitioner reconcile the promise of such a new treatment (if only in the area of total remaining scar %). The sensible strategy, at this point in time, is to call for more research, stimulate debate and discussion in the field, and to thank the authors for their contribution.

Ethical approval

No ethical approval required for this study.

Conflict of interest

No conflicts of interest have been declared by the author.

Author contribution

Single author manuscript.

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