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TITLE

What is the evidence for efficacy and effectiveness of surgical interventions for plantar fasciopathy? Protocol for a systematic review.

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ABSTRACT

Introduction Plantar fasciopathy (PF) is a degenerative condition of the plantar fascia, secondary to repetitive overloading. For the majority, PF is self-limiting with greater than 80% of those affected gaining complete resolution within one year. However, persistent symptoms develop in approximately 10% of cases. Clinical practice guidelines for first-line treatment of PF recommend conservative management. For people with persistent symptoms that not resolved following a 6-12 month trial of conservative management, surgery may be offered. However, to date there are no systematic reviews of the effectiveness of the various surgical procedures for PF.We aim to systematically review qualitative studies assessing the effectiveness of surgical interventions in the management of plantar fasciopathy.

Methods and analysis We will search for all published and unpublished randomised controlled trials evaluating surgical interventions in the management of plantar fasciopathy. Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library, MEDLINE (OVID), EMBASE (OVID), Web of Science (ISI), and Google scholar will be searched without restrictions on date or language of publication. The primary outcomes are changes in pain severity/intensity for first step pain, and incidence and nature of adverse events. Secondary outcomes include foot and ankle related disability/function, health related quality of life, cost effectiveness, changes in other reported measures of pain e.g.: overall pain, and medication use. All data extraction will be performed by at least two independent reviewers on the basis of a priori developed extraction form. Where adequate data are found Meta-analysis will be used to combine the results of studies for all core comparisons and outcomes using random effects models.

Ethics and dissemination This systematic review does not require ethical approval as primary data will not be collected. The results of the study will be published in a peer-reviewed journal and presented at appropriate conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- To the best of our knowledge, this study will be the first systematic review that comprehensively explores and compares the effectiveness of various surgical interventions in people with plantar fasciopathy.
- This review focuses only on RCTs as these designs offer the most robust estimates of effectiveness. No language limitations have been set, ensuring that the review is as comprehensive as possible.
- The findings from this study may provide guidance to healthcare providers to select appropriate management options for patients with persistent plantar fasciopathy, which may ultimately lead to a reduction in healthcare costs and improved patient outcomes.
- We recognise that only including RCTs limits the ability of our review to fully evaluate safety and adverse events.

INTRODUCTION

Plantar fasciopathy (PF) is a degenerative condition of the plantar fascia, secondary to repetitive overloading. PF is characterized by symptoms of pain during weight bearing activities, confined to the insertion of the plantar fascia at the antero-medial aspect of the calcaneum.[1] Diagnosis of PF is typically made through clinical examination, with common features including pain on first few steps on waking or after prolonged sitting; pain on palpation of the medial plantar aspect of the calcaneus or proximal plantar fascia; plantar heel pain on passive dorsiflexion of the ankle and/or toes; and pain that worsens as the day progresses.[2]

PF affects approximately 10% of adults during their lifetime [3] with peak incidence of PF occurring between the ages of 45 and 64 years.[4] There is a paucity of high quality evidence to support most proposed risk factors for PF.[5] Populations at risk, supported by strong evidence, include people who are overweight or obese,[4,6] or have calf tightness.[7] Risk factors, supported by a weak evidence, include pes planus [8-9] or pes cavus feet,[10] long-distance runners,[5] and people with occupations requiring prolonged standing.[3-11]

For the majority, PF is self-limiting with greater than 80% of those affected gaining complete resolution within one year.[12-13] However, persistent symptoms develop in approximately 10% of cases with detrimental effects on health related quality of life.[14] Difficulty walking may affect a person's ability to maintain a healthy weight, exercise, work and has been linked to anxiety, stress and depression.[15] Hence, determining effective treatment approaches for persistent PF are essential.

Clinical practice guidelines for first-line treatment of PF recommend conservative management.[2] Although multiple conservative treatment options are available, such as gel heel pads, exercise and extracorporeal shock wave therapy,[16-17] long-term effectiveness for many is uncertain or minimal. Surgical procedures, such as plantar fasciotomy [18] or gastrocnemius release,[19] may be offered to people with persistent PF who's symptoms have not resolved following a 6-12 month trial of conservative management.[17,20] However, to date there are no systematic reviews of the effectiveness of these various surgical procedures for PF.

Objectives

The primary aim of this systematic review is to determine the effectiveness and safety of surgical interventions in adults with plantar fasciopathy.

METHODS AND ANALYSIS

The following criteria will be used for selecting studies for this review:

Types of studies

Randomised clinical trials published in any language will be included. Studies published in a language other than English will be translated. Studies in which participants were not randomised to intervention groups will be excluded.

Types of participants

Studies involving adults, aged 18 years or older, diagnosed by clinical examination with plantar fasciopathy, or with an alternative diagnostic label for this condition e.g. plantar fasciitis, plantar heel pain, plantar fasciosis, will be included. Studies will be included regardless of whether radiological diagnostic imaging has been employed and regardless of symptom duration.

Types of interventions

Any surgical procedure delivered as either a stand-alone treatment compared with placebo, no treatment, usual care or another intervention, or varying surgical procedures compared with each other will be included. Trials of surgery combined with another intervention will only be included if the comparisons allows for the specific evaluation of the effect of the surgery (for example surgery and rehabilitation versus rehabilitation only).

Types of outcome measures

Primary outcomes:

The following primary outcome measures will be analysed where such data is available:

1) Changes in pain severity/intensity for first step pain. Examples of outcomes for pain include: visual analogue scale (VAS), numerical rating scale (NRS), verbal rating scale or Likert scale. Pain intensity will be presented and analysed as change on a continuous scale or in a dichotomised format as the proportion of participants in each group who attained a predetermined threshold of improvement. For example, cut-points from which to interpret the likely clinical

importance of (pooled) effect sizes will be judged according to criteria proposed in the IMMPACT consensus statement.[21] Specifically, reductions in pain intensity compared with baseline will be judged as follows:

- < 15% - no important change;
- ≥ 15% - minimally important change;
- ≥ 30% -moderately important change;
- ≥ 50% - substantially important change.

2) The incidence and nature of adverse events such as injury, infection, rupture of the plantar fascia, worsening of symptoms, repeat procedures.

Secondary outcomes:

The following secondary outcome measures will be analysed where such data is available:

1) Foot and ankle related disability or function as measured by validated clinician-report and self-report questionnaires/scales. Examples of outcomes for disability/function include: the American Orthopaedic Foot and Ankle Society Score (AOFAS); the Foot Functional index (FFI), the Manchester-Oxford Foot Questionnaire (MOxFQ), the Foot Health Status Questionnaire (FHSQ).
2) Changes in health related quality of life (HRQoL) using any validated tool. Examples of outcomes for HRQoL include the Short Form- 36 (SF-36) health survey, EuroQol EQ-5D.
3) Cost effectiveness
4) Changes in other reported measures of pain eg: overall pain
5) Medication use

Timing of assessment of outcomes

Primary and secondary outcomes were classified as: (i) short term (≤ 3 months post-intervention), (ii) medium term (>3months - ≤ 6 months post-intervention) or (iii) long term (>6 months - ≤2 years post-treatment). For all outcomes, the latest outcome data within each time category was used for analysis. For example, if a study reported 3 week and 6 week pain outcomes, only the 6 week data will be used.

Search methods for identification of studies

Electronic searches

The following electronic databases will be searched from their inception using a combination of controlled vocabulary, i.e. medical subject headings (MeSH) and free-text terms to identify published articles:

Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library;

MEDLINE (OVID);

EMBASE (OVID);

Web of Science (ISI);

Google scholar.

There will be no language restrictions. All database searches will be based on this strategy but adapted to individual databases as necessary. The search strategy for MEDLINE is summarised in the online Supplementary File Appendix 1.

Searching other resources.

We will search clinicaltrials.gov (www.clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) (http://apps.who.int/trialsearch/) for ongoing trials. In addition, reference lists of retrieved articles will be checked for additional studies. The list of included studies will be sent to content experts to help identify any additional relevant studies.

Data collection and analysis

Selection of studies

The titles and abstracts of potential trials identified by the search strategy will be independently assessed by two review authors (SM and NOC) for their eligibility. If the eligibility of a study is unclear from the title and abstract, the full paper will be assessed. Studies that do not match the inclusion criteria will be excluded. Disagreements between review authors regarding a study's inclusion will be resolved by discussion. A third reviewer (AR) will assess relevant studies if resolution and agreement cannot be reached and a majority decision will be made. Studies will not be anonymised prior to assessment.

Data extraction and management

Two reviewers (NOC and SM) will independently extract data from all included studies using a standardised and piloted data extraction form. Discrepancies and disagreements will be resolved by consensus. In cases where consensus cannot be achieved, the trial will be assessed by a third reviewer (AR) for arbitration and a majority decision will be made.

We will extract the following data from each study included in the review:

- country of origin;
- study design;
- study population (including diagnosis, diagnostic criteria used, symptom duration, age range, gender split);
- details of concomitant treatments that may affect outcome: (medication, procedures etc. What was permitted in the protocol and data on what was used)
- sample size - active and control/comparator groups;
- Attrition rates by group for each follow up point.
- intervention(s) (including surgery type, type of surgeon e.g. podiatric surgeon, orthopaedic consultant or registrar, surgical approach, method of anaesthesia);
- Rehabilitation post surgery: including post-surgical care, rehabilitation programme received.
- type and details of comparator intervention including content, delivery, duration and dose where appropriate;
- outcomes (primary and secondary) and time points assessed (only for the comparisons of interest to this review);
- adverse effects, incidence and nature at all timepoints;
- industry or other financial sponsorship; author conflict of interest statements.

Assessment of risk of bias in included studies

Two authors [SM and NOC] will independently assess risk of bias for each study, using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions [22] with any disagreements resolved by discussion. In cases where consensus cannot be achieved, the trial will be assessed by a third reviewer (AR) for arbitration and a majority decision will be made.

We will assess the following for each study:

Random sequence generation (checking for possible selection bias). We will assess the method used to generate the allocation sequence as: low risk of bias (any truly random process, e.g. random number table; computer random number generator); unclear risk of bias (method used to generate sequence not clearly stated); high risk of bias (studies using a non-random process (e.g. odd or even date of birth; hospital or clinic record number).

Allocation concealment (checking for possible selection bias). The method used to conceal allocation to group prior to assignment determines whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We will assess the methods as: low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes); unclear risk of bias (method not clearly stated); high risk of bias (studies that do not conceal allocation (e.g. open list)).

Blinding of participants: low risk of bias (participants blinded to allocated intervention; and unlikely that blinding broken); unclear risk of bias (insufficient information to permit judgement of low/high risk of bias); high risk of bias (patients not blinded to allocated intervention OR patients blinded to allocated intervention but it is likely that blinding may have been broken (and a given outcome is likely to be influenced by lack of blinding).

Blinding of care providers: low risk of bias (care provider blinded to allocated intervention; and unlikely that blinding broken OR no/incomplete blinding but judged that a given outcome unlikely to be influenced by lack of blinding); unclear risk of bias (insufficient information to permit judgement of low/high risk of bias); high risk of bias (care provider not blinded to allocated intervention and the two interventions clearly identifiable to the care provider as experimental and control OR care provider blinded to allocated intervention but likely that blinding may have been broken (and a given outcome is likely to be influenced by lack of blinding)).

Blinding of assessor: low risk of bias (outcome assessor (including patients with respect to self-report outcomes) blinded to patients allocated intervention; and unlikely that blinding broken, or no/incomplete blinding but judged that a given outcome unlikely to be influenced by lack of blinding); unclear risk of bias (insufficient information to permit judgement of low/high risk of bias); high risk of bias (outcome assessor (including patients with respect to self-report outcomes) un-blinded to patients allocated intervention OR outcome assessor blinded to allocated intervention but likely that

blinding may have been broken (and a given outcome is likely to be influenced by lack of blinding).

Incomplete outcome data (drop outs). We will first check for possible attrition bias by considering if participant drop-out rate is appropriately described and acceptable. Low: if less than 20% drop out and appears to be missing at random. Numbers given per group and reasons for drop out described. Unclear: if less than 20% but reasons not described and numbers per group not given. Unclear that data is missing at random. High: if over 20% even if imputed appropriately.

Incomplete outcome data (protocol violations). We will separately consider if participants were analysed in the group to which they were allocated. Low: if analysed data in group to which originally assigned (be that with appropriately imputed data or an available case analysis) Unclear: insufficient information provided to determine if analysis was per protocol or intention to treat. High: if per protocol analysis used. Where available data is not analysed or participant's data is included in group they were not originally assigned to.

Selective reporting. We will assess whether studies are free of the suggestion of selective outcome reporting. Methods will be assessed as: low risk of bias (study protocol available and all pre-specified outcomes of interest adequately reported. Study protocol not available but all expected outcomes of interest adequately reported. All primary outcomes numerically reported with point estimates and measures of variance for all time points); high risk of bias (incomplete reporting of pre-specified outcomes. One or more primary outcomes is reported using measurements, analysis methods or subsets of data that were not pre-specified. One or more reported primary outcomes were not pre-specified. One or more outcomes of interest reported incompletely and cannot be entered into a meta-analysis. Results for a key outcome expected to have been reported excluded).

Other sources of bias. We will consider other risk factors such as whether trials were stopped early, differences between groups at baseline, timing of outcome assessment, control of co-interventions and author source of funding declarations.

Measures of treatment effect

The size of treatment effect on pain intensity, as measured with a VAS or NRS, will be expressed using the mean difference (MD) (where all studies utilised the same

measurement scale) or the standardised mean difference (SMD) (where studies used different scales). Where we pool data from different scales for which the direction of interpretation varies we will normalise the direction of the scales to a common direction. In order to aid interpretation of the pooled effect size the SMD will be back-transformed to a 0- to 100-mm VAS format on the basis of the median standard deviation from trials using a 0 to 100 mm VAS where possible.

Risk Ratio (RR) and Risk Difference (RD) with 95% confidence intervals will be calculated for dichotomised outcome measures. The number needed to treat to benefit (NNTB) and harm (NNTH) will be calculated as an absolute measure of treatment effect wherever possible.

Unit of analysis issues

Where an included trial compares multiple treatment arms to the same control and those arms are included in the same meta-analysis, the number of participants in control treatment arm will be split between those treatment arms.

Dealing with missing data

Where insufficient data are presented in the study report to enter into a meta-analysis, we will contact study authors to request access to the missing data.

Assessment of heterogeneity

We will not combine studies that compared surgery to no treatment/ usual care with studies that compared surgery to sham/ placebo in the same analysis. We will assess heterogeneity using the Chi ^{2} test to investigate the statistical significance of such heterogeneity, and the I^2 statistic to estimate the amount of heterogeneity. Where significant heterogeneity (p value < 0.1) is present, we will explore subgroup analyses.

Pre-planned comparisons are described in the section “Subgroup analysis and investigation of heterogeneity.”

Assessment of reporting biases

We plan to use funnel plots to visually explore the likelihood of reporting biases when there are at least 10 studies in a meta-analysis and included studies differ in size, and we will use Egger's test to detect possible small study bias.

Data synthesis

Pooling of results will be performed where adequate data exist using Review Manager (RevMan 5.3, 2014). Meta-analyses of outcome data will be undertaken only from suitably homogeneous studies using a random-effects model.

We will perform separate meta-analysis for the following classes of surgery: plantar fasciotomy, gastrocnemius release at the following time points: short term (≤ 3 months post-intervention), medium term (>3months - ≤ 6 months post-intervention) or long term (>6 months - ≤2 years post-treatment). For each broad class of surgery we will conduct the following comparisons where adequate data are available:

Surgery versus sham surgery

Surgery versus minimal care/ waiting list/ no treatment

Surgery versus non surgical treatment

For all analyses, the outcome of the risk of bias assessments for included studies will be explicitly and clearly presented in the reporting. Where inadequate data are found to support statistical pooling, narrative synthesis of the evidence will be conducted.

Certainty of the evidence

We will assess the overall certainty of the evidence for each outcome using the GRADE approach, as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions*.[22] Two review authors (SM and NOC) will independently rate the quality of the evidence for each planned comparison.

Factors that may decrease the certainty of the evidence are:

- study design and risk of bias (downgraded if more than 25% of the participants are from studies with a high risk of bias);
- inconsistency of results (downgraded if significant heterogeneity is present by visual inspection or if the I^2 value was greater than 50%);

- indirectness (generalisability of the findings; downgraded if more than 50% of the participants are outside the target group);
- imprecision (downgraded if fewer than 400 participants are included in the comparison for continuous data or there are fewer than 300 events for dichotomous data [23] and other factors (e.g. reporting bias, publication bias)).

We will consider single studies with fewer than 400 participants for continuous or dichotomous outcomes inconsistent and imprecise, providing "low certainty-evidence', which could be downgraded to "very low-certainty evidence" if there are further limitations on the certainty of evidence. We will downgrade the certainty of the evidence for a specific outcome by a level, according to the performance of the studies against these five factors and we will describe them as follows. If there are multiple serious limitations for one domain we will consider downgrading the certainty of evidence by two levels.

The GRADE system uses the following criteria for assigning grade of evidence:

- High-certainty: we are very confident that the true effect lies close to that of the estimate of the effect;
- Moderate-certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different;
- Low-certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect;
- Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

Subgroup analysis and investigation of heterogeneity

Where substantial heterogeneity is found (I^2>50%, p<0.10) we will conduct subgroup analysis investigating the possible impact of the type of surgical intervention (e.g. fasciotomy versus gastrocnemius release) or surgical approach (open vs endoscopic).

Sensitivity analysis

Where sufficient data are available we will conduct sensitivity analysis on risk of bias (investigating the effect of including/ excluding studies rated at high risk of bias (on one or more criteria other than blinding of patients or care providers) from the analysis and the choice of meta-analysis model (investigating the impact of applying a fixed effects instead of a random effects model.)

Protocol Amendments

If any amendments are deemed necessary to this protocol, they will be documented in PROSPERO and amendments will be clearly stated in the final published systematic review manuscript.

Patient and public involvement

Patients and the public were not involved in the design and development of this protocol. The findings of the review will be available to healthcare professionals, policy-makers and the public.

Ethics and dissemination

Ethical approval is not required for this study. The findings of this study may assist clinicians and guideline developers in providing recommendation to improve outcomes for people with persistent plantar fasciopathy. The procedures and findings of the study will be conducted in accordance with the PRISMA-compliant guidelines. We aim to disseminate the findings of our systematic review through publication in a peer-reviewed journal and presentation at appropriate conferences.

DISCUSSION

This review will summarise the qualitative evidence available regarding the effectiveness of surgical procedures in the management of plantar fasciopathy. The findings will help better inform clinicians regarding best practice surgical treatment approaches for patients with persistent plantar fasciopathy.

Authors' contributions: After conceptualising and designing of the study, SM and NO'C registered the protocol on the PROSPERO database. All authors critically revised the protocol and contributed to the drafting of the final manuscript. SM, NO'C, TS and AR will perform the data collection and analyses. All authors read and approved the final manuscript.

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Competing interests statement: None declared

Word count: 3421

Key Words: Plantar fasciopathy, plantar heel pain, surgery, systematic review

PROSPERO registration number: *(submitted and awaiting registration number)*

References

1 Orchard J. Plantar Fasciitis. *BMJ* 2012;356:e6603

2 Martin R, Davenport T, Reischl S, et al. Heel Pain – Plantar Fasciitis: Revision 2014 Clinical Practice Guidelines linked to the international Classification of Functioning, Disability, and Health from the Orthopaedic Section of the American Physical Therapy Association. *J Orthop Sports Phys Ther* 2014;44(11)A1-A23.

3 Riddle DL, Pulisic M, Pidcoe P, et al. Risk factors for Plantar fasciitis: a matched case-control study. *J Bone Joint Surg Am* 2003;85-A:872-877.

4 Riddle DL, Schappert SM. Volume of ambulatory care visits and patterns of care for patients diagnosed with plantar fasciitis: a national study of medical doctors. *Foot Ankle Int* 2004;25:303-31.

5 Buchbinder R. Plantar Fasciitis. *N Engl J Med* 2004;350:2159-2166

6 van Leeuwen KD, Rogers J, Winzenberg T, et al. Higher body mass index is associated with plantar fasciopathy/'plantar fasciitis': systematic review and meta-analysis of various clinical and imaging risk factors. *Br J Sports Med* 2016;50:972-981.

7 Dyck DD Jr, Boyajian-O'Neill LA. Plantar fasciitis. *Clin J Sport Med* 2004;14:305-309.

8 Irving DB, Cook JL, Young MA, et al. Obesity and pronated foot type may increase the risk of chronic plantar heel pain: a matched case-control study. *BMC Musculoskelet Disord* 2007;8:41.

9 Lee SY, Hertal J, Lee SC. Rearfoot eversion has direct effects on plantar facia tension by changing the amount of ach collapse. *Foot* 2010;20:64–70.

10 La Porta GA, La Fata PC. Pathologic conditions of the plantar fascia. *Clin Podiatr Med Surg* 2005;22:1-9.

11 Irving DB, Cook JL, Menz HB. Factors associated with chronic plantar heel pain: a systematic review. *J Sci Med Sport* 2006;9:11-22

12 Martin RL, Irrgang JJ, Conti SF. Outcome study of subjects with insertional plantar fasciitis. *Foot Ankle Int* 1998;19: 803-11.

13 Wolgin M, Cook C, Graham C, et al. Conservative treatment of plantar heel pain: long-term follow-up. *Foot Ankle Int* 1994;15:97-102.

14 Irving D, Cook J, Young M, et al. Impact of chronic plantar heel pain on health-related quality of life. *J Am Podiatr Med Assoc* 2008;98:283-289.

15 Craft L, Perna F. The Benefits of Exercise for the Clinically Depressed. *Prim Care Companion J Clin Psychiatry* 2004;6:104-111.

16 Landorf K, Menz H. Plantar heel pain and fasciitis *BMJ Clin Evid* 2008;2008:1111.

17 NICE. Plantar fasciitis: Clinical Knowledge Summaries 2015. Available at https://cks.nice.org.uk/plantar-fasciitis (accessed 5 April 2019).

18 Bazaz R, Ferkel RD. Results of endoscopic plantar fascia release. *Foot Ankle Int* 2007;28:549-56.

19 Abbassian A, Kohls-Gatzoulis J, Solan M. Proximal medial gastrocnemius release in the treatment of recalcitrant plantar fasciitis. *Foot Ankle Int* 2012;33:14-9

20 Neufeld S, Cerrato R. Plantar Fasciitis: Evaluation and Treatment. *J Am Acad Orthop Surg* 2008;16;338-346.

21 Dworkin R, Turk D, Wyrwich K, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT Recommendations. *J Pain* 2008;9:105-121.

22 Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. *The Cochrane Collaboration* 2011. Available from http://handbook.cochrane.org.

23 Mueller PS, Montori VM, Bassler D, et al. Ethical issues in stopping randomized trials early because of apparent benefit. *Ann Intern Med* 2007;146:878–881.

ONLINE APPENDIX 1: SUPPLEMENTARY FILE: Medline Search Strategy

(Plantar fasci* OR heel pain OR policeman* heel OR heel spur OR painful heel syndrome OR baxter* neuropath* OR plantar neuropath* OR calcaneal neuropath* OR nerve entrapment OR Calcaneodynia)

AND

(Plantar fascia release OR Endoscopic OR gastrocnemius release OR gastrocnemius recession OR PMGR OR spur removal OR drilling OR release OR microfasciotomy OR Surg* OR Fasciotomy OR fasciectomy OR Operat* OR Minimally Invasive OR MIS OR debridement OR microdebride* OR radiofrequency)

We will use the filter for RCTs where available in each database. Where unavailable we will use the following search terms to identify RCTs: (randomi*ed controlled trial OR controlled clinical trial OR randomi*ed OR placebo OR randomly OR trial OR groups).

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item (See items in RED font)
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review (See Title Page)
Update	1b	If the protocol is for an update of a previous systematic review, identify as such N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number see Abstract
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author provided
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review see 'Authors Contributions' subtitle
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments See "Protocol Amendments" subheading
Support:		
Sources	5a	Indicate sources of financial or other support for the review see 'Funding statement' subtitle
Sponsor	5b	Provide name for the review funder and/or sponsor N/A
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol N/A
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known See 'Introduction' subtitle
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) See 'Objectives' subtitle
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review See first 3 paragraphs of 'Methods and analysis' subtitle'
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage See '**Search methods for identification of studies'** subtitle.
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be

		repeated See Appendix 1/Online Supplementary file.
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications All included within 'Methods and Analysis' subtitle.
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale See 'Types of outcome measures' subtitle
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis See 'Assessment of risk of bias in included studies' subtitle
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned For all see 'Measures of treatment effect' to 'Data Synthesis' subtitles inclusive
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) See 'Quality of the evidence' subtitle

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

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What is the evidence for efficacy, effectiveness and safety of surgical interventions for plantar fasciopathy? Protocol for a systematic review.

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TITLE

What is the evidence for efficacy, effectiveness and safety of surgical interventions for plantar fasciopathy? Protocol for a systematic review.

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ABSTRACT

Introduction Plantar fasciopathy (PF) is a degenerative condition of the plantar fascia, secondary to repetitive overloading. For the majority, PF is self-limiting with greater than 80% of those affected gaining complete resolution within one year. However, persistent symptoms develop in approximately 10% of cases. Clinical practice guidelines for first-line treatment of PF recommend conservative management. For people with persistent symptoms that not resolved following a 6-12 month trial of conservative management, surgery may be offered. However, to date there are no systematic reviews of the effectiveness of the various surgical procedures for PF.We aim to systematically review quantitative studies assessing the effectiveness of surgical interventions in the management of plantar fasciopathy.

Methods and analysis We will search for all published and unpublished randomised clinical trials evaluating surgical interventions in the management of plantar fasciopathy. Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library, MEDLINE (OVID), EMBASE (OVID), Web of Science (ISI), and Google scholar will be searched without restrictions on date or language of publication. Inclusion criteria will include people over 18 years, diagnosed by clinical examination with plantar fasciopathy, or with an alternative diagnostic label e.g. plantar fasciitis, plantar heel pain, plantar fasciosis. The primary outcomes are changes in pain severity/intensity for first step pain, and incidence and nature of adverse events. Secondary outcomes include foot and ankle related disability/function, health related quality of life, cost effectiveness, changes in other reported measures of pain e.g.: overall pain, and medication use. Outcomes will be assessed i) short term (≤ 3 months post-intervention), (ii) medium term (>3months - ≤ 6 months post-intervention) or (iii) long term (>6 months - ≤2 years post-treatment). All data extraction will be performed by at least two independent reviewers on the basis of a priori developed extraction form. Where adequate data are found Meta-analysis will be used to combine the results of studies for all core comparisons and outcomes using random effects models. Overall certainty of the evidence for each outcome will be assessed using the GRADE approach.

Ethics and dissemination This systematic review does not require ethical approval as primary data will not be collected. The results of the study will be published in a peer-reviewed journal and presented at appropriate conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- To the best of our knowledge, this study will be the first systematic review that comprehensively explores and compares the effectiveness of various surgical interventions in people with plantar fasciopathy.
- This review focuses only on RCTs as these designs offer the most robust estimates of effectiveness. No language limitations have been set, ensuring that the review is as comprehensive as possible.
- The findings from this study may provide guidance to healthcare providers to select appropriate management options for patients with persistent plantar fasciopathy, which may ultimately lead to a reduction in healthcare costs and improved patient outcomes.
- We recognise that only including RCTs limits the ability of our review to fully evaluate safety and adverse events.
- Our ability to draw strong conclusions may be restricted by the volume and quality of the identified studies

INTRODUCTION

Plantar fasciopathy (PF) is a degenerative condition of the plantar fascia, secondary to repetitive overloading. PF is characterized by symptoms of pain during weight bearing activities, confined to the insertion of the plantar fascia at the antero-medial aspect of the calcaneum.[1] Diagnosis of PF is typically made through clinical examination, with common features including pain on first few steps on waking or after prolonged sitting; pain on palpation of the medial plantar aspect of the calcaneus or proximal plantar fascia; plantar heel pain on passive dorsiflexion of the ankle and/or toes; and pain that worsens as the day progresses.[2]

PF affects approximately 10% of adults during their lifetime [3] with peak incidence of PF occurring between the ages of 45 and 64 years.[4] There is a paucity of high quality evidence to support most proposed risk factors for PF.[5] Populations at risk, supported by strong evidence, include people who are overweight or obese,[4,6] or have calf tightness.[7] Risk factors, supported by a weak evidence, include pes planus [8-9] or pes cavus feet,[10] long-distance runners,[5] and people with occupations requiring prolonged standing.[3-11]

For the majority, PF is self-limiting with greater than 80% of those affected gaining complete resolution within one year.[12-13] However, persistent symptoms develop in approximately 10% of cases with detrimental effects on health related quality of life.[14] Difficulty walking may affect a person's ability to maintain a healthy weight, exercise, work and has been linked to anxiety, stress and depression.[15] Hence, determining effective treatment approaches for persistent PF is essential.

Clinical practice guidelines for first-line treatment of PF recommend conservative management.[2] Although multiple conservative treatment options are available, such as gel heel pads, exercise and extracorporeal shock wave therapy,[16-17] long-term effectiveness for many is uncertain or minimal. Surgical procedures, such as plantar fasciotomy [18] or gastrocnemius release,[19] may be offered to people with persistent PF who's symptoms have not resolved following a 6-12 month trial of conservative management.[17,20] However, to date there are no systematic reviews of the effectiveness of these various surgical procedures for PF.

Objectives

The primary aim of this systematic review is to determine the effectiveness and safety of surgical interventions in adults with plantar fasciopathy.

METHODS AND ANALYSIS

The following criteria will be used for selecting studies for this review:

Types of studies

Randomised clinical trials published in any language will be included. Studies published in a language other than English will be translated. Studies in which participants were not randomised to intervention groups will be excluded.

Types of participants

Studies involving adults, aged 18 years or older, diagnosed with plantar fasciopathy, or with an alternative diagnostic label for this condition e.g. plantar fasciitis, plantar heel pain, plantar fasciosis, will be included. Studies will be included regardless of whether radiological diagnostic imaging has been employed and regardless of symptom duration.

Types of interventions

Any surgical procedure delivered as either a stand-alone treatment compared with placebo, no treatment, usual care or another intervention, or varying surgical procedures compared with each other will be included. Trials of surgery combined with another intervention will only be included if the comparisons allows for the specific evaluation of the effect of the surgery (for example surgery and rehabilitation versus rehabilitation only).

Types of outcome measures

Primary outcomes:

The following primary outcome measures will be analysed where such data is available:

1) Changes in pain severity/intensity for first step pain. Examples of outcomes for pain include: visual analogue scale (VAS), numerical rating scale (NRS), verbal rating scale or Likert scale. Pain intensity will be presented and analysed as change on a continuous scale or in a dichotomised format as the proportion of participants in each group who attained a predetermined threshold of improvement. For example, cut-points from which to interpret the likely clinical importance of (pooled) effect sizes will be judged according to criteria proposed

in the IMMPACT consensus statement.[21] Specifically, reductions in pain intensity compared with baseline will be judged as follows:

- < 15% - no important change;
- ≥ 15% - minimally important change;
- ≥ 30% -moderately important change;
- ≥ 50% - substantially important change.

2) The incidence and nature of adverse events such as injury, infection, rupture of the plantar fascia, worsening of symptoms, repeat procedures.

Secondary outcomes:

The following secondary outcome measures will be analysed where such data is available:

1) Foot and ankle related disability or function as measured by validated clinician-report and self-report questionnaires/scales. Examples of outcomes for disability/function include: the American Orthopaedic Foot and Ankle Society Score (AOFAS); the Foot Functional index (FFI), the Manchester-Oxford Foot Questionnaire (MOxFQ), the Foot Health Status Questionnaire (FHSQ).
2) Changes in health related quality of life (HRQoL) using any validated tool. Examples of outcomes for HRQoL include the Short Form- 36 (SF-36) health survey, EuroQol EQ-5D.
3) Cost effectiveness
4) Changes in other reported measures of pain eg: overall pain
5) Medication use

Timing of assessment of outcomes

Primary and secondary outcomes were classified as: (i) short term (≤ 3 months post-intervention), (ii) medium term (>3months - ≤ 6 months post-intervention) or (iii) long term (>6 months - ≤2 years post-treatment). For all outcomes, the latest outcome data within each time category was used for analysis. For example, if a study reported 3 week and 6 week pain outcomes, only the 6 week data will be used.

Search methods for identification of studies

Electronic searches

The following electronic databases were searched on 28th June 2019 from their inception using a combination of controlled vocabulary, i.e. medical subject headings (MeSH) and free-text terms to identify published articles:

Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library;

MEDLINE (OVID);

EMBASE (OVID);

Web of Science (ISI);

Google scholar.

There will be no language restrictions. All database searches will be based on this strategy but adapted to individual databases as necessary. The search strategy for MEDLINE is summarised in the online Supplementary File Appendix 1.

Searching other resources.

We will search clinicaltrials.gov (www.clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) (http://apps.who.int/trialsearch/) for ongoing trials. In addition, reference lists of retrieved articles will be checked for additional studies. The list of included studies will be sent to content experts to help identify any additional relevant studies.

Data collection and analysis

Selection of studies

The titles and abstracts of potential trials identified by the search strategy will be independently assessed by two review authors (SM and NOC) for their eligibility. If the eligibility of a study is unclear from the title and abstract, the full paper will be assessed. Studies that do not match the inclusion criteria will be excluded. Disagreements between review authors regarding a study's inclusion will be resolved by discussion. A third reviewer (AR) will assess relevant studies if resolution and agreement cannot be reached and a majority decision will be made. Studies will not be anonymised prior to assessment.

Data extraction and management

Two reviewers (NOC and SM) will independently extract data from all included studies using a standardised and piloted data extraction form. Discrepancies and disagreements will be resolved by consensus. In cases where consensus cannot be achieved, the trial will be assessed by a third reviewer (AR) for arbitration and a majority decision will be made.

We will extract the following data from each study included in the review:

- country of origin;
- study design;
- study population (including diagnosis, diagnostic criteria used, symptom duration, age range, gender split);
- details of concomitant treatments that may affect outcome: (medication, procedures etc. What was permitted in the protocol and data on what was used)
- sample size - active and control/comparator groups;
- Attrition rates by group for each follow up point.
- intervention(s) (including surgery type, type of surgeon e.g. podiatric surgeon, orthopaedic consultant or registrar, surgical approach, method of anaesthesia);
- Rehabilitation post surgery: including post-surgical care, rehabilitation programme received.
- type and details of comparator intervention including content, delivery, duration and dose where appropriate;
- outcomes (primary and secondary) and time points assessed (only for the comparisons of interest to this review);
- adverse effects, incidence and nature at all timepoints;
- industry or other financial sponsorship; author conflict of interest statements.

Assessment of risk of bias in included studies

Two authors [SM and NOC] will independently assess risk of bias for each study, using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions [22] with any disagreements resolved by discussion. In cases where consensus cannot be achieved, the trial will be assessed by a third reviewer (AR) for arbitration and a majority decision will be made.

We will assess the following for each study:

Random sequence generation (checking for possible selection bias). We will assess the method used to generate the allocation sequence as: low risk of bias (any truly random process, e.g. random number table; computer random number generator); unclear risk of bias (method used to generate sequence not clearly stated); high risk of bias (studies using a non-random process (e.g. odd or even date of birth; hospital or clinic record number).

Allocation concealment (checking for possible selection bias). The method used to conceal allocation to group prior to assignment determines whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We will assess the methods as: low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes); unclear risk of bias (method not clearly stated); high risk of bias (studies that do not conceal allocation (e.g. open list)).

Blinding of participants: low risk of bias (participants blinded to allocated intervention; and unlikely that blinding broken); unclear risk of bias (insufficient information to permit judgement of low/high risk of bias); high risk of bias (patients not blinded to allocated intervention OR patients blinded to allocated intervention but it is likely that blinding may have been broken (and a given outcome is likely to be influenced by lack of blinding).

Blinding of care providers: low risk of bias (care provider blinded to allocated intervention; and unlikely that blinding broken OR no/incomplete blinding but judged that a given outcome unlikely to be influenced by lack of blinding); unclear risk of bias (insufficient information to permit judgement of low/high risk of bias); high risk of bias (care provider not blinded to allocated intervention and the two interventions clearly identifiable to the care provider as experimental and control OR care provider blinded to allocated intervention but likely that blinding may have been broken (and a given outcome is likely to be influenced by lack of blinding)).

Blinding of assessor: low risk of bias (outcome assessor (including patients with respect to self-report outcomes) blinded to patients allocated intervention; and unlikely that blinding broken, or no/incomplete blinding but judged that a given outcome unlikely to be influenced by lack of blinding); unclear risk of bias (insufficient information to permit judgement of low/high risk of bias); high risk of bias (outcome assessor (including patients with respect to self-report outcomes) un-blinded to patients allocated intervention OR outcome assessor blinded to allocated intervention but likely that

blinding may have been broken (and a given outcome is likely to be influenced by lack of blinding).

Incomplete outcome data (drop outs). We will first check for possible attrition bias by considering if participant drop-out rate is appropriately described and acceptable. Low: if less than 20% drop out and appears to be missing at random. Numbers given per group and reasons for drop out described. Unclear: if less than 20% but reasons not described and numbers per group not given. Unclear that data is missing at random. High: if over 20% even if imputed appropriately.

Incomplete outcome data (protocol violations). We will separately consider if participants were analysed in the group to which they were allocated. Low: if analysed data in group to which originally assigned (be that with appropriately imputed data or an available case analysis) Unclear: insufficient information provided to determine if analysis was per protocol or intention to treat. High: if per protocol analysis used. Where available data is not analysed or participant's data is included in group they were not originally assigned to.

Selective reporting. We will assess whether studies are free of the suggestion of selective outcome reporting. Methods will be assessed as: low risk of bias (study protocol available and all pre-specified outcomes of interest adequately reported. Study protocol not available but all expected outcomes of interest adequately reported. All primary outcomes numerically reported with point estimates and measures of variance for all time points); high risk of bias (incomplete reporting of pre-specified outcomes. One or more primary outcomes is reported using measurements, analysis methods or subsets of data that were not pre-specified. One or more reported primary outcomes were not pre-specified. One or more outcomes of interest reported incompletely and cannot be entered into a meta-analysis. Results for a key outcome expected to have been reported excluded).

Other sources of bias. We will consider other risk factors such as whether trials were stopped early, differences between groups at baseline, timing of outcome assessment, control of co-interventions and author source of funding declarations.

Measures of treatment effect

The size of treatment effect on pain intensity, as measured with a VAS or NRS, will be expressed using the mean difference (MD) (where all studies utilised the same

measurement scale) or the standardised mean difference (SMD) (where studies used different scales). Where we pool data from different scales for which the direction of interpretation varies we will normalise the direction of the scales to a common direction. In order to aid interpretation of the pooled effect size the SMD will be back-transformed to a 0- to 100-mm VAS format on the basis of the median standard deviation from trials using a 0 to 100 mm VAS where possible.

Risk Ratio (RR) and Risk Difference (RD) with 95% confidence intervals will be calculated for dichotomised outcome measures. The number needed to treat to benefit (NNTB) and harm (NNTH) will be calculated as an absolute measure of treatment effect wherever possible.

Unit of analysis issues

Where an included trial compares multiple treatment arms to the same control and those arms are included in the same meta-analysis, the number of participants in control treatment arm will be split between those treatment arms.

Dealing with missing data

Where insufficient data are presented in the study report to enter into a meta-analysis, we will contact study authors to request access to the missing data. Waiting time for authors' to respond has been set a priori to one month, with a reminder email sent at two weeks.

Assessment of heterogeneity

We will not combine studies that compared surgery to no treatment/ usual care with studies that compared surgery to sham/ placebo in the same analysis. We will assess heterogeneity using the Chi ^{2} test to investigate the statistical significance of such heterogeneity, and the I^2 statistic to estimate the amount of heterogeneity. Where significant heterogeneity (p value < 0.1) is present, we will explore subgroup analyses.

Pre-planned comparisons are described in the section "Subgroup analysis and investigation of heterogeneity."

Assessment of reporting biases

We plan to use funnel plots to visually explore the likelihood of reporting biases when there are at least 10 studies in a meta-analysis and included studies differ in size, and we will use Egger's test to detect possible small study bias.

Data synthesis

Pooling of results will be performed where adequate data exist using Review Manager (RevMan 5.3, 2014). Meta-analyses of outcome data will be undertaken only from suitably homogeneous studies using a random-effects model.

We will perform separate meta-analysis for the following classes of surgery: plantar fasciotomy, gastrocnemius release at the following time points: short term (≤ 3 months post-intervention), medium term (>3months - ≤ 6 months post-intervention) or long term (>6 months - ≤2 years post-treatment). For each broad class of surgery we will conduct the following comparisons where adequate data are available:

Surgery versus sham surgery

Surgery versus minimal care/ waiting list/ no treatment

Surgery versus non surgical treatment

For all analyses, the outcome of the risk of bias assessments for included studies will be explicitly and clearly presented in the reporting. Where inadequate data are found to support statistical pooling, narrative synthesis of the evidence will be conducted.

Certainty of the evidence

We will assess the overall certainty of the evidence for each outcome using the GRADE approach, as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions*.[22] Two review authors (SM and NOC) will independently rate the quality of the evidence for each planned comparison.

Factors that may decrease the certainty of the evidence are:

- study design and risk of bias (downgraded if more than 25% of the participants are from studies with a high risk of bias);
- inconsistency of results (downgraded if significant heterogeneity is present by visual inspection or if the I^2 value was greater than 50%);

- indirectness (generalisability of the findings; downgraded if more than 50% of the participants are outside the target group);
- imprecision (downgraded if fewer than 400 participants are included in the comparison for continuous data or there are fewer than 300 events for dichotomous data [23] and other factors (e.g. reporting bias, publication bias)).

We will consider single studies with fewer than 400 participants for continuous or dichotomous outcomes inconsistent and imprecise, providing "low certainty-evidence', which could be downgraded to "very low-certainty evidence" if there are further limitations on the certainty of evidence. We will downgrade the certainty of the evidence for a specific outcome by a level, according to the performance of the studies against these five factors and we will describe them as follows. If there are multiple serious limitations for one domain we will consider downgrading the certainty of evidence by two levels.

The GRADE system uses the following criteria for assigning grade of evidence:

- High-certainty: we are very confident that the true effect lies close to that of the estimate of the effect;
- Moderate-certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different;
- Low-certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect;
- Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

Subgroup analysis and investigation of heterogeneity

Where substantial heterogeneity is found (I^2>50%, p<0.10) we will conduct subgroup analysis investigating the possible impact of the type of surgical intervention (e.g. fasciotomy versus gastrocnemius release) or surgical approach (open vs endoscopic).

Sensitivity analysis

Where sufficient data are available we will conduct sensitivity analysis on risk of bias (investigating the effect of including/ excluding studies rated at high risk of bias (on one or more criteria other than blinding of patients or care providers) from the analysis and the choice of meta-analysis model (investigating the impact of applying a fixed effects instead of a random effects model.)

Protocol Amendments

If any amendments are deemed necessary to this protocol, they will be documented in PROSPERO and amendments will be clearly stated in the final published systematic review manuscript.

Patient and public involvement

Patients and the public were not involved in the design and development of this protocol. The findings of the review will be available to healthcare professionals, policy-makers and the public.

Ethics and dissemination

Ethical approval is not required for this study. The findings of this study may assist clinicians and guideline developers in providing recommendation to improve outcomes for people with persistent plantar fasciopathy. The procedures and findings of the study will be conducted in accordance with the PRISMA-compliant guidelines. The anticipated end date for the study is June 2020. We aim to disseminate the findings of our systematic review through publication in a peer-reviewed journal and presentation at appropriate conferences.

DISCUSSION

This review will summarise the quantitative evidence available regarding the effectiveness of surgical procedures in the management of plantar fasciopathy. The findings will help better inform clinicians regarding best practice surgical treatment approaches for patients with persistent plantar fasciopathy.

Authors' contributions: After conceptualising and designing of the study, SM and NO'C registered the protocol on the PROSPERO database. All authors critically revised the protocol and contributed to the drafting of the final manuscript. SM, NO'C, TS and AR will perform the data collection and analyses. All authors read and approved the final manuscript.

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Competing interests statement: None declared

Word count: 3421

Key Words: Plantar fasciopathy, plantar heel pain, surgery, systematic review

PROSPERO registration number: CRD42019133563

References

1 Orchard J. Plantar Fasciitis. *BMJ* 2012;356:e6603

2 Martin R, Davenport T, Reischl S, et al. Heel Pain – Plantar Fasciitis: Revision 2014 Clinical Practice Guidelines linked to the international Classification of Functioning, Disability, and Health from the Orthopaedic Section of the American Physical Therapy Association. *J Orthop Sports Phys Ther* 2014;44(11)A1-A23.

3 Riddle DL, Pulisic M, Pidcoe P, et al. Risk factors for Plantar fasciitis: a matched case-control study. *J Bone Joint Surg Am* 2003;85-A:872-877.

4 Riddle DL, Schappert SM. Volume of ambulatory care visits and patterns of care for patients diagnosed with plantar fasciitis: a national study of medical doctors. *Foot Ankle Int* 2004;25:303-31.

5 Buchbinder R. Plantar Fasciitis. *N Engl J Med* 2004;350:2159-2166

6 van Leeuwen KD, Rogers J, Winzenberg T, et al. Higher body mass index is associated with plantar fasciopathy/'plantar fasciitis': systematic review and meta-analysis of various clinical and imaging risk factors. *Br J Sports Med* 2016;50:972-981.

7 Dyck DD Jr, Boyajian-O'Neill LA. Plantar fasciitis. *Clin J Sport Med* 2004;14:305-309.

8 Irving DB, Cook JL, Young MA, et al. Obesity and pronated foot type may increase the risk of chronic plantar heel pain: a matched case-control study. *BMC Musculoskelet Disord* 2007;8:41.

9 Lee SY, Hertal J, Lee SC. Rearfoot eversion has direct effects on plantar facia tension by changing the amount of ach collapse. *Foot* 2010;20:64–70.

10 La Porta GA, La Fata PC. Pathologic conditions of the plantar fascia. *Clin Podiatr Med Surg* 2005;22:1-9.

11 Irving DB, Cook JL, Menz HB. Factors associated with chronic plantar heel pain: a systematic review. *J Sci Med Sport* 2006;9:11-22

12 Martin RL, Irrgang JJ, Conti SF. Outcome study of subjects with insertional plantar fasciitis. *Foot Ankle Int* 1998;19: 803-11.

13 Wolgin M, Cook C, Graham C, et al. Conservative treatment of plantar heel pain: long-term follow-up. *Foot Ankle Int* 1994;15:97-102.

14 Irving D, Cook J, Young M, et al. Impact of chronic plantar heel pain on health-related quality of life. *J Am Podiatr Med Assoc* 2008;98:283-289.

15 Craft L, Perna F. The Benefits of Exercise for the Clinically Depressed. *Prim Care Companion J Clin Psychiatry* 2004;6:104-111.

16 Landorf K, Menz H. Plantar heel pain and fasciitis *BMJ Clin Evid* 2008;2008:1111.

17 NICE. Plantar fasciitis: Clinical Knowledge Summaries 2015. Available at https://cks.nice.org.uk/plantar-fasciitis (accessed 5 April 2019).

18 Bazaz R, Ferkel RD. Results of endoscopic plantar fascia release. *Foot Ankle Int* 2007;28:549-56.

19 Abbassian A, Kohls-Gatzoulis J, Solan M. Proximal medial gastrocnemius release in the treatment of recalcitrant plantar fasciitis. *Foot Ankle Int* 2012;33:14-9

20 Neufeld S, Cerrato R. Plantar Fasciitis: Evaluation and Treatment. *J Am Acad Orthop Surg* 2008;16;338-346.

21 Dworkin R, Turk D, Wyrwich K, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT Recommendations. *J Pain* 2008;9:105-121.

22 Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. *The Cochrane Collaboration* 2011. Available from http://handbook.cochrane.org.

23 Mueller PS, Montori VM, Bassler D, et al. Ethical issues in stopping randomized trials early because of apparent benefit. *Ann Intern Med* 2007;146:878–881.

ONLINE APPENDIX 1: SUPPLEMENTARY FILE: Medline Search Strategy

(Plantar fasci* OR heel pain OR policeman* heel OR heel spur OR painful heel syndrome OR baxter* neuropath* OR plantar neuropath* OR calcaneal neuropath* OR nerve entrapment OR Calcaneodynia)

AND

(Plantar fascia release OR Endoscopic OR gastrocnemius release OR gastrocnemius recession OR PMGR OR spur removal OR drilling OR release OR microfasciotomy OR Surg* OR Fasciotomy OR fasciectomy OR Operat* OR Minimally Invasive OR MIS OR debridement OR microdebride* OR radiofrequency)

We will use the filter for RCTs where available in each database. Where unavailable we will use the following search terms to identify RCTs: (randomi*ed controlled trial OR controlled clinical trial OR randomi*ed OR placebo OR randomly OR trial OR groups).

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item (See items in REDform)
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review See Title Page p1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number p15
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author p1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review see 'Authors Contributions' subtitle p15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments See "Protocol Amendments" subheading p14
Support:		
Sources	5a	Indicate sources of financial or other support for the review see 'Funding statement' subtitle p15
Sponsor	5b	Provide name for the review funder and/or sponsor N/A
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol N/A
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known See 'Introduction' subtitle p4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) See 'Objectives' subtitle p4/5
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review See first 3 paragraphs of 'Methods and analysis' subtitle' p5
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage See '**Search methods for identification of studies**' subtitle. P6/7
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be

		repeated See Appendix 1/Online Supplementary file. Also referenced p7
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review p7/8
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) p7/8
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators p8
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications p8
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale See 'Types of outcome measures' subtitle p5/6
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis See 'Assessment of risk of bias in included studies' subtitle p8/9/10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised p10/11
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ) p11
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) p12
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned see 'Data Synthesis' subtitle p12
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) p12/13
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) See 'Certainty of the evidence' subtitle p12/13

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (Ale when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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