## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | What is the evidence for efficacy, effectiveness and safety of surgical interventions for plantar fasciopathy? Protocol for a systematic review. |
| **AUTHORS** | Macrae, Sian; Roche, Andrew; Sinnett, Timothy; O'Connell, Neil |

## VERSION 1 – REVIEW

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| **REVIEWER** | Luciane Lopes<br>Universidade de Sorocaba |
| **REVIEW RETURNED** | 29-May-2019 |

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| **GENERAL COMMENTS** | This manuscript set out to evaluate the effectiveness of the surgery in plantar fasciopathy. Although this intervention has not yet been studied the subject plantar fasciopathy appears in 13 RS recorded in Prospero.<br>After careful reading of the manuscript some concerns appeared and it would be important that the authors could improve the methodological detail. Below I point out my concerns:<br><br>1- Title - How will authors differentiate effectiveness and effectiveness? Why this differentiation in the title? Suggestion: change the title only by placing what will be evaluated and include safety because surgical interventions like any other intervention present risks and studies should always measure the balance between benefit and risk.<br><br>2- 2- Abstract - the abstract has serious problems of lack of information. The essay has problems and leaves a series of doubts that need to be better clarified in the abstract (initial reading of a manuscript). The abstract is not well described. To better describe the inclusion criteria of the patients. It is also unclear what is the minimum follow-up of patients after surgery. It is also unclear whether the sample of patients who underwent surgery is one who has not previously tried the usual measures. That is, are we dealing with patients who failed with initial therapy and then went to surgery, or are we dealing with patients who have just received the diagnosis of plantar fasciopathy? Do the authors intend to use GRADE and evaluate the quality of included studies? Important details missing in the abstract<br>3- Add the registration number in Prospero<br>4- STRENGTHS AND LIMITATIONS OF THIS STUDY - in this part the authors need to provide more details of potential methodological limitations of this SR<br>5- Text - The protocol described in Prospero is different from that described in this manuscript. Some details provided in the prosperous are not included in this manuscript. I urge the authors to be consistent with this. Here are some important doubts about the |

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| | proposed method:<br><br>A. The question (PICO) - Considering that the patient can improve after 10 months of treatment and that only 10% become refractory, it is not clear if the question of this RS is to answer if the surgical intervention would be alternative for those refractory? It does not seem right to try surgery before a less invasive treatment. If the authors are considering surgery before verifying that the patient would respond to a less invasive treatment, the rationale for this question needs to be better clarified in the introduction and method.<br>B. Inclusion criteria: To better define the population and the condition of the study. Do obese, elderly, and athletic patients enter into this analysis? Will they be patients who have just received the diagnosis? If the duration of the diagnosis is not well specified, patients with different risks will be included, since after 10 months only 10% of the patients do not improve. The criteria for inclusion of patients and types of fasciitis (plantar fasciitis, plantar fasciopathy, plantar fasciosis, painful heel syndrome or calcaneodynia) need to be better clarified. For example, patients with diabetes, athletes, etc.<br>C. Intervention: need to better describe the type of surgery and what the authors are calling usual care? Usual care can be physiotherapy or use of painkillers and rest. What will be considered? Use of analgesics may also distort the symptoms. How will this be assessed?<br>D. Outcomes: Will the authors measure gaps in benefit in surgery and permanent lesions made by surgery? Pain" is likely to be an overarching theme but there are many criteria that relate to pain (e.g. palpation pain, first step pain in the morning, mean pain over a specific time period or worst pain over a specific time period).<br>E. Type of study setting (primary, secondary or tertiary care settings) could bring hetergeneidade of the data. |

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| **REVIEWER** | Henrik Riel<br>Center for General Practice at Aalborg University, Denmark |
| **REVIEW RETURNED** | 15-Jul-2019 |

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| **GENERAL COMMENTS** | Thank you for the opportunity to review "What is the evidence for efficacy and effectiveness of surgical interventions for plantar fasciopathy? Protocol for a systematic review." The review will shed light on the role of surgical interventions in the management of plantar fasciopathy. The protocol is well-written and sufficiently described. Listed below are my few comments divided into major and minor.<br><br>Major<br>Why is first-step pain the primary outcome? Is this truly the most appropriate primary outcome among all the outcomes described? Taking into account how the condition is characterised and the associated disability, few patients would say that the first-step pain is their biggest concern. I find it a very unidimensional measure and overall pain, an average of pain during the day or during the past week would be more appropriate if 'pain' is the primary outcome. Using a questionnaire would be optimal though I do acknowledge that it would be difficult given the large heterogeneity in the questionnaires used in this condition.<br><br>Minor<br>P2, line 24: Please change "controlled" to "clinical" to be consistent throughout the manuscript. |

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| | P4, line 40: Please change "are" to "is"<br><br>P5, line 18: Who will perform the translation and how?<br><br>P5, line 24: Will studies that have only used patient history to diagnose the condition be excluded?<br><br>P8, line 8: Studies that have been using a non-random process should have been excluded by the time you are performing the RoB assessment. It might be worth mentioning that none of the studies should be able to be assessed to have a high risk of bias in this aspect.<br><br>P11, line 36: Have you apriori decided an acceptable waiting time for study authors' response? If yes, please state this.<br><br>P14, line 49: I am sure that you mean "quantitative" and not "qualitative" evidence in this sentence. |

**VERSION 1 – AUTHOR RESPONSE**

Reviewer(s)' Comments to Author:

Reviewer: 1
Reviewer Name: Luciane Lopes
Institution and Country: Universidade de Sorocaba please state any competing interests or state 'None declared': None

Please leave your comments for the authors below This manuscript set out to evaluate the effectiveness of the surgery in plantar fasciopathy. Although this intervention has not yet been studied the subject plantar fasciopathy appears in 13 RS recorded in Prospero.
After careful reading of the manuscript some concerns appeared and it would be important that the authors could improve the methodological detail. Below I point out my concerns:

1- Title - How will authors differentiate effectiveness and effectiveness? Why this differentiation in the title? Suggestion: change the title only by placing what will be evaluated and include safety because surgical interventions like any other intervention present risks and studies should always measure the balance between benefit and risk.

Thank you for your query with regard to differentiating efficacy and effectiveness. Effectiveness will be assessed by comparing surgery to usual care/ no treatment, whereas efficacy will be determined by comparing surgery to 'sham' surgery. 'Safety' has now been included within the title. While we will consider carefully all data on adverse events, the authors are aware that randomised controlled trials are not the best way to assess safety - due to their limited sample sizes they may not capture data on a harm which are unlikely to occur frequently within such a sample.

2- 2- Abstract - the abstract has serious problems of lack of information. The essay has problems and leaves a series of doubts that need to be better clarified in the abstract (initial reading of a manuscript). The abstract is not well described. To better describe the inclusion criteria of the patients. It is also unclear what is the minimum follow-up of patients after surgery. It is also unclear whether the sample of patients who underwent surgery is one who has not previously tried the usual measures. That is, are we dealing with patients who failed with initial therapy and then went to surgery, or are we dealing with patients who have just received the diagnosis of plantar fasciopathy? Do the authors intend to use GRADE and evaluate the quality of included studies? Important details missing in the abstract.

Thank you for highlighting these omissions. The following sentences have now been added to the Abstract:

“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.”

“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).”

“Overall certainty of the evidence for each outcome will be assessed using the GRADE approach.”

With regards to the reviewers comment:
“It is also unclear whether the sample of patients who underwent surgery is one who has not previously tried the usual measures. That is, are we dealing with patients who failed with initial therapy and then went to surgery, or are we dealing with patients who have just received the diagnosis of plantar fasciopathy?” We will include all studies that looked at plantar fasciopathy populations and surgical intervention. We think it likely that most studies will include people refractory to conservative treatment. We are extracting data on treatment prior to surgery, but cannot describe in further depth at this stage until after data extraction has occurred.

3- Add the registration number in Prospero

The Prospero number has now been added to the manuscript: CRD42019133563

4- STRENGTHS AND LIMITATIONS OF THIS STUDY - in this part the authors need to provide more details of potential methodological limitations of this SR

The following limitation has been added to address potential methodological limitations:

- “Our ability to draw strong conclusions may be restricted by the volume and quality of the identified studies.”

If there are any further specific limitations to our methodology, please be explicit and we will be happy to consider a further addition.

5- Text - The protocol described in Prospero is different from that described in this manuscript. Some details provided in the prosperous are not included in this manuscript. I urge the authors to be consistent with this.
Thank you for this feedback. The Prospero format contains pre-set sub-headings which have been completed by the authors – hence, the information provided on Prospero is in line with the requested subtitles on the Prospero site. The authors recognise that the Protocol submitted to BMJ Open has such content provided in greater detail. We have reviewed the content of both protocols in response to your feedback, and could not identify discrepancies/ inconsistencies in the information that is provided on both protocol locations. We would welcome any specific feedback on the exact discrepancies that the reviewer relates to.

Here are some important doubts about the proposed method:

A. The question (PICO) - Considering that the patient can improve after 10 months of treatment and that only 10% become refractory, it is not clear if the question of this RS is to answer if the surgical intervention would be alternative for those refractory? It does not seem right to try surgery before a less invasive treatment. If the authors are considering surgery before verifying that the patient would respond to a less invasive treatment, the rationale for this question needs to be better clarified in the introduction and method.
Many thanks for highlighting this point. We are planning to look at all studies that looked at plantar fasciopathy populations. We think it likely that most studies will include people refractory to

conservative treatment, but we will consider this potential issue in the interpretation of the results. However, we will possibly be limited by what we find in terms of primary studies.

B. Inclusion criteria: To better define the population and the condition of the study. Do obese, elderly, and athletic patients enter into this analysis? Will they be patients who have just received the diagnosis? If the duration of the diagnosis is not well specified, patients with different risks will be included, since after 10 months only 10% of the patients do not improve. The criteria for inclusion of patients and types of fasciitis (plantar fasciitis, plantar fasciopathy, plantar fasciosis, painful heel syndrome or calcaneodynia) need to be better clarified. For example, patients with diabetes, athletes, etc.
Thank you for raising this point. We will include all studies that looked at plantar fasciopathy populations. However, we do not anticipate that these comparisons will lend themselves to formal sub-group analysis and have not planned for any. We will, however, consider the potential influence of various sources of heterogeneity in our interpretation of the results.

C. Intervention: need to better describe the type of surgery and what the authors are calling usual care? Usual care can be physiotherapy or use of painkillers and rest. What will be considered? Use of analgesics may also distort the symptoms. How will this be assessed?
We are extracting this data but cannot describe in further depth at this stage until data extraction has occurred. With regards to 'Usual care', we are extracting full details of usual care and we will consider how it impacts any decisions to combine studies and, regardless of pooling, how it impacts our interpretation of the data.

D. Outcomes: Will the authors measure gaps in benefit in surgery and permanent lesions made by surgery? Pain" is likely to be an overarching theme but there are many criteria that relate to pain (e.g. palpation pain, first step pain in the morning, mean pain over a specific time period or worst pain over a specific time period).
We are not entirely clear on what the reviewer is referring to in this point and would welcome further clarity. However, by measuring clinical outcome and adverse events we will base our conclusions on the balance of benefits and harms.

E. Type of study setting (primary, secondary or tertiary care settings) could bring hetergeneidade of the data.
Thank you for raising this concern. We are extracting data on the setting though we anticipate the majority of settings will be within secondary care. However, we will consider the setting in our interpretation of the data extracted.

Reviewer: 2
Reviewer Name: Henrik Riel
Institution and Country: Center for General Practice at Aalborg University, Denmark Please state any competing interests or state 'None declared': None declared.

Please leave your comments for the authors below Thank you for the opportunity to review "What is the evidence for efficacy and effectiveness of surgical interventions for plantar fasciopathy? Protocol for a systematic review." The review will shed light on the role of surgical interventions in the management of plantar fasciopathy. The protocol is well-written and sufficiently described. Listed below are my few comments divided into major and minor.

Major
Why is first-step pain the primary outcome? Is this truly the most appropriate primary outcome among all the outcomes described? Taking into account how the condition is characterised and the associated disability, few patients would say that the first-step pain is their biggest concern. I find it a very unidimensional measure and overall pain, an average of pain during the day or during the past week would be more appropriate if 'pain' is the primary outcome. Using a questionnaire would be optimal though I do acknowledge that it would be difficult given the large heterogeneity in the questionnaires used in this condition.

Thanks you for raising this important point. A wide variety of subjectively reported pain measures are assessed in studies investigating plantar fasciopathy, including: first step pain; worst pain experienced

in last 24 hours; average pain over the past week/day, and non-specific pain scores with no clarification as to which specific descriptor of pain is being recorded. We note that all these pain options assess different entities. We wished to choose a specific pain definition as our primary outcome. People with PF usually report their worst pain and most aggravating factor to be 'first step pain'. First step pain is also commonly used as an outcome measure in studies investigating plantar fasciopathy.[1-3] These are the reasons for our choice of first step pain as our primary outcome. The authors recognise that first step pain on its own is limited and unidimensional, hence we have chosen to include a range of other patient centred outcomes such as functional outcomes, and alternative pain outcomes, and we will, where present, include composite multi-dimensional outcomes specific to this condition. We also plan to look at other measures of pain as secondary outcomes as described in the protocol.


1. Bishop C, Thewlis D, Hillier S. Custom foot orthoses improve first step pain in individuals with unilateral plantar fasciopathy: A pragmatic randomised controlled trial. *BMC Musculoskeletal Disorders* 2018;19: 1-11.
2. Rompe RD, Cacchio A, Weil Jr. L, et al. Plantar fascia-specific stretching versus radial shock-wave therapy as initial treatment of plantar fasciopathy. Journal of Bone and Joint Surgery 2010; 92: 2514-2522.
3. Radwan Y, Mansour A, Badawy W. Resistant plantar fasciopathy: Shock wave versus endoscopic plantar fascial release. International Orthopaedics 2012;36:2147-2156.


Minor

P2, line 24: Please change "controlled" to "clinical" to be consistent throughout the manuscript.
Thank you for highlighting this. The wording has now been changed.

P4, line 40: Please change "are" to "is"
This has been changed.

P5, line 18: Who will perform the translation and how? Thank you for your query. We will source translators as required depending on what we find. We have an engaged community of people in our institution and externally who we may need to call upon.

P5, line 24: Will studies that have only used patient history to diagnose the condition be excluded?
We appreciate the reviewers comment and recognise that by specifying the need for clinical examination as our inclusion criteria we may exclude specific studies that haven't used this terminology. On that basis we have amended our inclusion criteria in this protocol and on Prospero to include studies that report inclusion of participants with a diagnosis of plantar fasciopathy or an associated diagnostic terminology, regardless of diagnostic work up. However, we will consider and reflect on any uncertainty regarding the populations included in identified studies in our interpretation of the results of the studies.

P8, line 8: Studies that have been using a non-random process should have been excluded by the time you are performing the RoB assessment. It might be worth mentioning that none of the studies should be able to be assessed to have a high risk of bias in this aspect.
Thank you for raising this query. Studies that identify themselves as RCTs may still, on closer inspection, employ methods that cannot be considered to be true randomisation, or may be unclear on the methods. It remains possible that a study that might be at high RoB, is identified by the formal RoB assessment.

P11, line 36: Have you apriori decided an acceptable waiting time for study authors' response? If yes, please state this.

Thank you for highlighting this omission. The following text has been added:

"Waiting time for authors' to respond has been set a priori to one month, with a reminder email sent at two weeks."

P14, line 49: I am sure that you mean "quantitative" and not "qualitative" evidence in this sentence.

Thank you for highlighting this error. This has now been corrected within the text on P14 and also in the Abstract.

**VERSION 2 – REVIEW**

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| **REVIEWER** | Henrik Riel<br>Center for General Practice at Aalborg University |
| **REVIEW RETURNED** | 19-Aug-2019 |

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| **GENERAL COMMENTS** | I would like to thank the authors for responding adequately to the previous comments. |