
Peer Review File

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Reviewer A

Abstract:

Comment 1: hypothesis is missing

Reply 1: We added our hypothesis.

Comment 2: please add more databases.

Reply 2: We include two of the largest databases, which are recommended for studies in clinical research. The combination of MEDLINE, EMBASE, and Cochrane will capture 97% of all relevant studies in Orthopedic Surgery (<https://www.arthroscopyjournal.org/content/authorinfo>). Our search using Pubmed and EMBASE yielded 2058 results (many duplicates) which we believe that was broad enough to find all relevant studies and that a new database would not change the results.

Comment 3: were prisma guidelines followed for the review?

Reply 3: Yes. The guidelines were strictly followed. This is indicated in the first paragraph of material and methods “The systematic review of the literature was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement”

Comment 4: there is no statistical analysis

Reply 4: Statistical analysis was not possible since there were only 6 comparative studies and, in some cases, only one harm of the study was included. This does not meet the minimum standard for a meta-analysis. Also, we opted to not consider arthroplasty as one single group and to differentiate the type of implant. These comparative studies compare different things (arthrodesis to total joint replacement or total joint replacement to hemiarthroplasty) making the samples even smaller. A meta-analysis of only 6 studies from 2019 cited in the article was possible but all arthroplasties were considered as one single group and inclusion criteria were much wider than ours. As shown in the results different implant types have very different outcomes, that is the reason why we chose to analyse them separately. We opted to report the range of outcomes from included studies. Pooled weighted means were not presented for the outcomes to prevent the effect of potential heterogeneity (especially due to different implants) that may arise when combining the studies and also due to selection bias (no randomization and concealment of patient enrolment).

Comment 5: without a statistical analysis conclusions are not coherent

Reply 5: Statistical analysis if possible would unquestionably provide stronger evidence to support the conclusions. Unfortunately, due to the reasons provided in reply 4, a meta-analysis was not possible. Given the available literature this systematic review compiles an extensive number of studies analyzed, that suggest our conclusions. Without statistical analysis we cannot state the superiority of one treatment modality over the other, and only infer by directly comparing the results from different studies. To account for lack of statistical analysis, we added the following sentence: “Future research should focus on comparing these approaches in high-power randomized controlled trials to allow stronger and more definitive recommendations.”

Introduction

Comment 6: introduction is very long. please short

Reply 6: Introduction has been shortened. Introduction has now 330 words.

Comment 7: prisma must be reported in methods not introduction

Reply 7: This is a demand present in submission checklist for authors.

Comment 8: hypothesis is missing

Reply 8: We added our hypothesis.

Methods

Comment 9: database and key terms should be improved

Reply 9: As exposed in reply 2 this systematic review already includes two of the largest medical literature databases. The key terms were chosen in order to maximize the results and not to narrow down the number of records. A more focused search strategy could exclude some viable results.

Comment 10: all steps should be performed by two authors in order to avoid bias

Reply 10: We recognise an independent selection by two authors would reduce bias. Although all titles and abstracts were screened by one author, the studies that elicited doubts were discussed with a second author for a shared decision, as well as the same second author reviewed all full-texts for inclusion. This was not clear at the manuscript, and we corrected that issue.

Comment 11: statistical analysis is missing

Reply 11: The reason is explained in reply 4

Results

Comment 12: these results are only a resume of the current literature and don't add anything

Reply 12: These results compile the most comprehensive overview of clinical outcomes, complications and survivor rates of surgical treatment of advanced hallux rigidus and provide the outcomes separated by type of implant. We believe that such a broad summary of outcomes in this theme is not available, specially subgrouping the results by hemi and total arthrodesis, as well as by different types of implants. This systematic review will help orthopaedic surgeons to consult a summarized report of available studies regarding hallux rigidus surgical treatment and achieve a more well informed decision making process based on unbiased contemporary literature.

Discussion

Comment 13: discussion is not so interesting

what are the controversies about the topic? and future perspective?

Reply 13: The main controversy is that as stated in the article “Arthrodesis has been traditionally considered as surgical standard for advanced hallux rigidus due to the superior functional outcomes and decreased pain.” In recent years we have seen an increased enthusiasm of the industry multiplying arthroplasty implants. This enthusiasm has been seen also in orthopaedic community with increased use of these implants and a proliferation of papers reporting results of these implants.

Whether the arthroplasty (either hemi or total) provides superior outcomes to the traditionally used option of arthrodesis remains elusive. Anyhow literature comparing results between these two strategies is still poor and no definitive conclusion could be made to support either surgical option. However, from the results of all included studies we can see that both strategies provide comparably satisfactory outcomes. Within discussion section, we tried to discuss this controversy while presenting the outcomes for arthrodesis/arthroplasty and for different implant types from available studies to provide readers a focused summary of outcomes for each surgical technique and implant type (in case opting to perform an arthrodesis) and help them make a more informed decision. Future directions are discussed at the end (just before limitations).

Conclusions

Comment 14: not coherent

Reply 14: We revised the conclusion statements.

Reviewer B

Comment 1: This is an interesting article on a common foot and ankle pathology. It was enjoyable to read as it is well-written, and a well-conducted review in accordance with the recommended guidance.

Reply 1: We thank you for your kind comments.

Comment 2: Page 2, Line 15; should be written as 'comprising of'.....

Reply 2: corrected

Comment 3: Page 4, Line 42: consists mainly of (instead of 'in')

Reply 3: corrected

Comment 4: Page 8, Line 138: did not make (instead of 'made')

Reply 4: corrected

Comment 5: Page 8, Line 145: there 'was' no.... (instead of 'were')

Reply 5: corrected

Comment 6: Page 15, Line 317: 'Although largely abandoned since 1995, 318 some silicone implants persist in the market....'

The above statement is misleading, as the silastic implants are not abandoned, and are still fairly commonly used. There are more recent reports available in literature to support their effective use, as listed below:

- Silastic replacement of the first metatarsophalangeal joint: historical evolution, modern concepts and a systematic review of the literature, H Majeed, EFORT Open Rev 2019;4:77-84.
- Morgan S, Ng A, Clough T. The long-term outcome of silastic implant arthroplasty of the first metatarsophalangeal joint: a retrospective analysis of one hundred and eight feet. Int Orthop 2012;36:1865–1869.

- Silastic First Metatarsophalangeal Joint Arthroplasty for the Treatment of End-Stage Hallux Rigidus, Timothy M Clough, Joseph Ring, Bone Joint J. 2020;102-B (2):220-226.

The above are just some of the articles in support of using Silastic implants. The authors of the current systematic review seem to have disqualified their use, which is a misleading statement for the readers. I would suggest to revise their view on silastic replacements by including the findings from the above studies.

Reply 6: We agree the above-mentioned phrase can be misleading since these implants still have a place in market and still have some enthusiasts with some evidence still supporting their use. Most literature indeed do not favor these implants but we considered all implant types including silastic, although only one study fulfilled all requirements for inclusion. The above articles, although very interesting, do not meet our inclusion criteria. We agree with your very valid point and corrected the phrase to avoid misleading readers: “Although it’s popularity significantly decreased since 1995, some silicone implants persist in the market and are still fairly commonly used.”

Comment 7: Page 25: In PRISMA flow diagram, there is a slight discrepancy in the numbers. The ‘Records Screened’ were 1271 and ‘Records Excluded’ were 1161, that should give 110 articles for full text assessments; however the authors state this number to be 109. Please clarify.

Reply 7: Thank you for noticing. This was a mistake in the number of excluded records which were 1162. We submitted a corrected version of the figure.

Comment 8: Page 28, Line 569: the correct word is MOXFQ not MIXFQ. The same word requires correction on Page 37, line 585.

Reply 8: Corrected