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Lack of Consensus on the Definition of Aseptic Loosening in Total Ankle Replacement: A Scoping Review Protocol

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ADMINISTRATIVE INFORMATION

Support - Melbourne Orthopaedic Group.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 June 2023 and was last updated on 14 June 2023.

INTRODUCTION

Review question / Objective Objectives: 1. to identify and evaluate the definitions of aseptic loosening reported in the literature related to total ankle replacement (TAR). 2. to assess the variations and discrepancies in the definitions of aseptic loosening among the eligible studies. 3. to explore the potential implications of the lack of consensus on the definition of aseptic loosening in total ankle replacement, including diagnostic criteria, clinical outcomes, and research comparability. 4. if the data allows, to propose recommendations for a standardized definition of aseptic loosening in total ankle replacement based on the findings of the review

Research questions

1. What are the various definitions of aseptic loosening used in studies reporting on TAR outcome?
2. What are the discrepancies in the definitions of aseptic loosening among the eligible studies?
3. What is the significance of the lack of consensus on the definition of aseptic loosening in TAR?
4. What recommendations can be made to establish a standardised definition of aseptic loosening in TAR?

Background Total ankle replacement (TAR) is a surgical procedure that has been increasingly utilised as a treatment option for end-stage ankle arthritis, offering pain relief and improved joint function. However, aseptic loosening remains a significant concern and one of the most common complications associated with TAR. Aseptic loosening is characterised by the dissociation of the implant-bone interface in the absence of infection, leading to instability, pain, and functional impairment. It can necessitate revision surgery and adversely affect the long-term outcomes of TAR.

To effectively diagnose, monitor, and manage aseptic loosening in TAR, it is crucial to establish a clear and consistent definition of this complication. However, the current literature reveals a lack of consensus among researchers and clinicians regarding the specific definition of aseptic loosening in the context of total ankle replacement. This lack of consensus raises concerns about

diagnostic accuracy and outcome reporting. It hampers accurate comparison of results between studies, impedes the development of universally accepted diagnostic criteria, and hinders advancements in treatment strategies.

The variability in the definition of aseptic loosening among studies investigating TAR is multifactorial. Factors contributing to this lack of consensus may include variations in the clinical and radiological criteria used to identify loosening, differences in the assessment methods employed, and variations in the follow-up duration.

A standardized definition of aseptic loosening in total ankle replacement would provide clarity, facilitate accurate diagnosis, enable meaningful comparisons between studies, and enhance the overall quality of research and patient care.

The purpose of this narrative systematic review protocol is to comprehensively analyse the available literature to identify the variations and discrepancies in the definitions used, examine the potential implications of the lack of consensus on the definition of aseptic loosening in total ankle replacement. By synthesizing the available evidence and highlighting the divergent definitions and approaches currently utilized, this systematic review seeks to provide valuable insights into the challenges posed by the lack of consensus on the definition of aseptic loosening in TAR. The findings of this review will contribute to a better understanding of the current state of knowledge in this area and lay the foundation for the development of a standardized definition, ultimately enhancing the clinical management and research of aseptic loosening in total ankle replacement.

The aim of this protocol study is to present a transparent and objective methodology for conducting a narrative systematic review focused on increasing our understanding of the lack of consensus regarding the definition of aseptic loosening in total ankle replacement.

Rationale Total ankle replacement (TAR) is a popular surgical option for end-stage ankle arthritis, but aseptic loosening remains a significant concern leading to pain, instability, and functional impairment. The lack of consensus among researchers and clinicians regarding its definition hampers diagnosis, outcome reporting, and treatment advancements. Variability in definitions arises from differences in criteria, assessment methods, and follow-up duration. Establishing a standardized definition would enhance clarity, diagnosis, comparisons, and research quality. This systematic review aims to identify variations and implications of the lack of consensus, offering insights and laying the foundation for a standardized definition, improving patient care and research on aseptic loosening in TAR.

METHODS

Strategy of data synthesis We will employ a combination of text words, synonyms, and variations, along with database-specific subject headings, to conduct the search. The electronic databases Embase via embase.com, Medline ALL via Ovid, and the Cochrane Library will be searched. The retrieved references will be exported to Mendeley citation manager, and any duplicates will be removed. In addition to electronic database searches, we will screen the bibliographic references of all included articles and citations of articles to identify any additional relevant studies that may have been missed. An initial search will be conducted on the 1st of July, 2023. The detailed search strategy can be found in the online supplementary file. The search results will be presented using a PRISMA diagram.

The following search strategy will be used:

Database: Ovid MEDLINE(R) ALL

((exp Arthroplasty, Replacement, Ankle/ OR (ankle* adj3 (arthroplast* or replace*)).ti,ab,kw.) AND (exp Prosthesis Failure/ OR exp Equipment Failure Analysis/ OR (aseptic adj3 loose*).ti,ab,kw. OR (prosthe* adj3 (fail* or loose*)).ti,ab,kw. OR (exp Radiography/ AND exp Treatment Outcome/) OR (radiograph* adj3 (result* or outcome* or assess*)).ti,ab,kw.)) NOT (comment OR letter OR "systematic review").pt.

Further limits: Past 10 years, English language

Database: Embase

((exp ankle arthroplasty/ OR exp ankle replacement/ OR exp ankle prosthesis/ OR (ankle* adj3 (arthroplast* OR replace*)).ti,ab,kw.) AND (exp prosthesis complication/ OR exp device failure analysis/ OR exp prosthesis loosening/ OR (aseptic adj3 loose*).ti,ab,kw. OR (prosthe* adj3 (fail* or loose*)).ti,ab,kw. OR ((exp radiography/ OR exp ankle radiography/) AND (exp treatment outcome/ OR exp clinical outcome/)) OR (radiograph* adj3 (result* or outcome* or assess*)).ti,ab,kw.)) NOT (conference abstract/ or "systematic review"/ or letter/ or (conference-abstract or letter).pt.)

Further limits: Past 10 years, English language

Cochrane Library

https://www.cochranelibrary.com/advanced-search/search-manager

([mh "Arthroplasty, Replacement, Ankle"] OR ((ankle*) NEAR/3 (arthroplast* or replace*)):ti,ab,kw) AND ([mh "Prosthesis Failure"] OR [mh "Equipment Failure Analysis"] OR ((aseptic) NEAR/3 (loose*)):ti,ab,kw OR ((prosthe*) NEAR/3 (fail* or loose*)):ti,ab,kw OR ([mh "Radiography"] AND [mh

"Treatment Outcome"]) OR ((radiograph*) NEAR/3 (result* or outcome* or assess*)):ti,ab,kw).

Eligibility Inclusion criteria: Studies that report on aseptic loosening in the context of total ankle replacement. Studies involving human participants. Studies published in peer-reviewed journals. No restriction on study design, applied surgical technique, implant design, baseline characteristics of the cohort. Studies published in the last decade will be considered for inclusion.
Exclusion criteria:
Animal studies, conference abstracts, technical notes, system design descriptions, letters to the editor and non-english language studies will not be considered for inclusion. Studies published prior to 2013 will be excluded from our study.
Methodological considerations:
Studies using reference of other studies for the definition of aseptic loosening of TAR will be included in our study, however these studies will be noted separately in our PRISMA flowchart diagram.

Source of evidence screening and selection Two reviewers (PK and TS) will conduct the initial screening of references based on their titles and abstracts to identify studies that potentially meet the inclusion criteria. Any references deemed potentially relevant will be obtained in full text and independently assessed by the same two reviewers (PK and TS). In case of any disagreements regarding study eligibility, a consensus will be reached through discussion. If needed, a third reviewer (DS) will provide a final decision.

Data management The data from the full-text articles will be extracted and entered into a standardized form and summarized in a narrative synthesis. The definitions of aseptic loosening reported in the included studies will be analysed to identify variations and discrepancies. The specific information to be extracted can be found in Table 2 and Table 3.
Table 2 includes the following:
Nr. Description
1. Authors and year of publication
2. Country of study
3. Study design and methodology
4. Publishing journal
5. Study population and sample size
6. Applied TAR implant design
7. Precise description of aseptic loosening of TAR
8. Follow-up time
9. Reference used for defining aseptic loosening of TAR
10. Applied imaging modality (x-ray, computed tomography, magnetic resonance imaging, etc.)
11. Outcome measures related to aseptic loosening
Table 3. includes the number of papers using each definition
Definition of aseptic loosening of TAR / Nr.of papers.

Reporting results / Analysis of the evidence After extraction, a comprehensive review of the data will be conducted by the authors. The data will be presented in the above mentioned tabular format and in a narrative form. Furthermore, depending on the availability of sufficient information, we will analyse the change of applied definition of aseptic loosening of TAR in a chronological fashion throughout the published articles, in order to identify possible tendencies and advancements.

Presentation of the results The results will be presented in a tabular format summarising the main findings regarding the applied definition of aseptic loosening of TAR. The tabular presentation will be completed by a scoping analysis. In addition, a narrative description of the results and observed discrepancies of the applied definitions will be provided.

Language restriction Only studies written in english language will be considered.

Country(ies) involved Australia.

Keywords Total Ankle Replacement, Aseptic Loosening, Definition, Consensus, Lack.

Dissemination plans The findings of this study will be shared through peer-reviewed publications and conference presentations. All relevant data pertaining to the study are either included in the article itself or provided as supplementary information.

Contributions of each author
Author 1 - Peter Kvarda.
- conceived and designed the analysis.
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