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Glenoid Failure after Total Shoulder Arthroplasty, cemented all-polyethylene versus metal-backed: A Systematic Review Protocol

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Glenoid Failure after Total Shoulder Arthroplasty, cemented all-polyethylene versus metal-backed: A Systematic Review Protocol

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Abstract

Introduction

Anatomical Total Shoulder Arthroplasty (TSA) is an effective treatment adopted in patients with glenohumeral osteoarthritis. The glenoid component failure is the main risk that occurs in this therapeutic choice; however, doubts remain, regarding the selection of the best implant in order to avoid such complication.

Methods and analysis

A systematic review of randomised clinical trials (RCTs) or quasi-randomised trials will be carried out, applying the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) protocols,

comparing polyethylene (keeled and pegged) versus metal back implants in adult patients with glenohumeral osteoarthritis.

Our search strategy will be carried out in the MEDLINE, PubMed, Cochrane Central Register of Controlled Trials, EMBASE, Web of Science. Data management and extraction will be performed using a data withdrawal form and by analysing study method characteristics, participant characteristics, intervention characteristics, results, methodological domains.

The summaries of research evidence will be accessed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE). Shoulder function through functional scores such as Constant-Murley (CM) and American Shoulder and Elbow Surgeons (ASES), pain (Visual Analogue Scale), infection, procedure failure, radiograph radiolucency and loosening, are the selected outcomes. Another analysis such as subgroup, heterogeneity, sensitivity and statistical are going to be performed whenever possible.

Discussion

This systematic review aims to analyse how glenoidal implants behave in Total Shoulder Arthroplasties and therefore provide evidence concerning the best clinical practice in order to avoid complications.

Ethics and dissemination:

This study has been approved by the IRB of Universidade Federal de São Paulo (protocols 0725/2017, 2.157.415 and 70473017.5.0000.5505) and findings will be disseminated through peer-reviewed publication and conference presentations.

Systematic review registration

PROSPERO, CRD 42018079537.

Keywords

Shoulder, arthroplasty, glenoid, loosening, keel, peg, metal back, osteoarthritis, replacement.

Strengths and limitations of this study

- This systematic review is a response to priority setting conducted in collaboration with policy-makers who recognised a gap in available synthesised evidence regarding approaches for hypertension screening (mass, opportunities or targeted screening strategies).
- This review will include randomised and non-randomised controlled studies to capture all relevant evidence regarding programmes of hypertension screening.
- We will conduct a comprehensive search across several databases without restricting for language or publication status.

- We plan to meta-analyse outcome data; however, included studies may vary in terms of study design and the outcomes reported, and therefore we may present narrative evidence syntheses.
- The review authors have complementary expertise in systematic review methods and content which will ensure a review that is relevant for policy and practice.

Introduction

Osteoarthritis (OA) of the glenohumeral joint is a common clinical condition that affects adult population [1]., mainly in patients between 60 and 80 years old [2].

Total Shoulder Arthroplasty has been proved to be effective to treat this condition [3]. There has been an increase rate in these procedures between 300% to 400% for the last two decades (1990-2010), varying from 13.000 to 42.000 approximately, with an annual variation in the order of 10.6% [4,5]. It was also observed that approximately 24% of complications of this surgery were related to glenoid implant and 28.5% of those required surgical revision due to loosening. Loosening of the glenoid implant is the main cause of failure, followed by pain and decrease in range of motion after a TSA [6,7,8,9]. This important complication compromises the function of the joint and can even lead need of reoperation.

This systematic review aims to evaluate the glenoid component by comparing the effectiveness of different types of implants, either with metal back or those exclusive in polyethylene (keeled or pegged), considering function of the shoulder and complications (persistence or worsening of pain, infection and failure of the surgery regarding glenoidal implants loosening in the glenohumeral joint).

Methods and analysis

Types of Studies and inclusion criteria:

This systematic review will follow recommendations proposed by the Cochrane Handbook of Interventions Reviews [10,11] and PRISMA protocols [12,13]. Our study will include only randomised or quasi-randomised controlled clinical trials, comparing metal-backed glenoid designs and polyethylene (keeled or pegged) design in Total Shoulder Arthroplasties.

Ethics Approval and dissemination:

This study has been approved by the Institutional Review Board (IRB) of Universidade Federal de São Paulo (protocol 0725/2017, 2.157.415 and 70473017.5.0000.5505) (document attached).

Types of participants (inclusion and exclusion criteria):

The inclusion eligibility studies that assessed adults that underwent TSA due to idiopathic and inflammatory OA [14,15,16,17]. The following exclusion criteria were adopted: Patients with previous surgery,

neurological diseases (Charcot's Arthropathy, Parkinson's disease), Revision surgeries of arthroplasty and Reverse Total Arthroplasty.

Primary Outcomes:

Functional results, complications and failure represented by new surgical intervention, will be our main outcomes. We will consider the Constant-Murley (CM) [18], American Shoulder and Elbow Surgeons (ASES) [19] and University of California at Los Angeles (UCLA) [20] to measure function as a validated score. Complications like deep infection affecting prosthesis components, persistence or worsening of pain (Visual Analogue Scale - VAS) [21], loosening or breakage of implanted materials, dislocation, surgical revision.

Secondary Outcomes:

Clinical and radiographic outcomes will be assessed by range of motion (forward flexion, lateral and internal rotation) and indirect radiographic signs that evidence the loosening of the glenoid implant. The Lazarus classification for keeled components and Franklin classification for pegged components were the systems selected to assess radiolucency concerning those all-polyethylene components [22,23].

Quality of life analysis validated short form scores 36 [24], will also be assessed.

Search methods and strategy:

The electronic search will be carried out in the MEDLINE (PubMed), Cochrane Central Register of Controlled Trials [25,26], EMBASE, Web of Science, International Clinical Trials Registry Platform, ClinicalTrials.gov and Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS for randomised or quasi-randomised RCTs). The grey literature will also be searched through Google Scholar, OpenGrey and GreyNet [27].

We are going to use the following terms in different combinations and combinations for our search: “total shoulder arthroplasty”, “glenoid”, “keeled”, “pegged”, “loosening”, “metal-backed” and “radiolucency”. No restriction on language or publication status.

Data collection and analysis:

Two independent reviewers will access the selected studies, as well as the data extracted from these studies using EndNote X9, in order to facilitate collaboration among them during the selection process.

Two authors will select independently and analyse the eligible studies for this systematic review through the title and abstract. The selected studies will be entirely reviewed. Any disagreement will be resolved through discussion and, when necessary, will be judged by a third author in an attempt to resolve a possible conflict.

Data Extraction and Handling:

Data extraction will be performed by two reviewers will extract the data using an appropriate extraction form based on methodological characteristics, including design and duration, whether the protocol was published prior the recruitment of the patients, possible funding sources and study registration; characteristics of the participants including location, number of recruits, their evaluation, inclusion and exclusion criteria, age and classification relevant to the disease addressed; characteristics of the intervention like duration, surgery type and complications; results through time and loss of follow-up; methodological domains and risk of bias. The extracted data will be also classified according to the time of follow-up into early and late, establishing 1 year as the cut off for this division.

Access to risk of bias:

Two authors will independently evaluate various aspects of methodological quality of the included studies using a modified version of the Cochrane Bone Joint and Muscle Trauma Group tool form [28]. Some items will be considered: random sequence generation, allocation concealment, participant blinding, outcome assessment blinding, selective reporting and potential influence of incomplete outcome data, in each trial, will also be carried out. After judgment and classification, these criteria will produce three levels of bias: low, high or unclear. Disagreements will be solved by the analysis of a third reviewer [29,30].

Measures of treatment effect:

The resulting dichotomous data will be analysed with relative risk (RR) with a 95% confidence interval. When appropriate, we will express the estimated effects as numbers that need treatment (NNTs). Data on continuous outcomes will be expressed as an average difference of 95% in the confidence interval (CI). We intend to group the results with the mean difference (MD) if two or more trials reveal results from the same valid instrument of evolution (with the same units of measurement). If primary studies measure the same variables using different instruments (as well as different units of measurement), Cochrane Review Manager on its 5.3 version will be used for the statistical analyse.

Dealing with Missing Data:

We will perform an intention-to-treat analysis in order to include all randomised participants of any intervention. Insufficient information according to the estimated effects, as well as the number of participants, mean, uncertainty measurement (standard deviation or error) or number of events; we will contact the authors of the selected trials.

An analysis will be carried out independently of the lost data, submitting them to the worst and best scenarios.

Heterogeneity Analysis:

The heterogeneity of the estimated effects between the included studies will be evaluated through visual inspection of the forest plots and the statistical I^2 test (significant > 50%).

Data Synthesis:

The results of comparable tests will be grouped using the fixed-effect model and a 95% CI. However, the variable model will be used when there is a diversity in clinical or methodological characteristics.

Subgroup Analysis and Heterogeneity Investigation:

Where appropriate, subgroups will be analysed in order to explore the difference in side effect related to the type of glenoid selected.

Confidence in Cumulative Evidence:

We will apply GRADE (www.gradepro.org) in order to describe and rate the quality of evidence and the strength of the recommendations, classifying them as *high, moderate, low* and *very low* [31,32,33].

Results:

Following this protocol publication, electronic searches will be carried out and the selected trials will be analysed. By the time we get the final results, we are going to send this paper for publication. Our intention is to have it ready by the end of 2021.

Discussion:

We observe an increasing rate of TSA in the adult population and, therefore, complications also assume an increasingly important role in this particular treatment. The glenoid component is the main site of these complications in terms of pain, limiting range of motion, but also in

worsening quality of life. These findings are correlated with loosening or even implant breakage [34]. There are some evidences that cemented all-polyethylene glenoid implant has a better loosening rate compared to the metal-backed design, but in terms of radiolucency, this statement is reversed [35,36,37,38].

Nowadays we have several types of glenoid implants in both polyethylene and metal-backed designs, however searching the literature, there is a lack of systematic reviews. In fact, we found only one study including trials with low level of evidence such as nonrandomised and case series [39]. Further evaluation on this subject with better methodological quality should be carried out covering functional, clinical, and radiographic outcomes as well as complications.

We expect difficulty to find trials with adequate sample size, standardization in the functional scores, follow-up pattern and also methods of the results, promoting a possible limitation in our revision. The aim of this study is to provide support and scientific evidence for decision making in orthopaedic clinical practice regarding the glenoid implant selection on TSA, serving as a guide for future trials with better methodological quality.

List of abbreviations:

(ASES) American Shoulder and Elbow Surgeons

(CI) Confidence Interval

(CM) Constant-Murley

(GRADE) Grading of Recommendations Assessment, Development and Evaluation

(LILACS) Literatura Latino-Americana e do Caribe em Ciências da Saúde

(MD) Mean Difference

(NNTs) Numbers that Need Treatment

(OA) Osteoarthritis

(PRISMA) Preferred Reporting Items for Systematic Review and Meta-Analysis

(RCTs) Randomised Clinical Trials

(RR) Relative Risk

(SMD) Standard Mean Difference

(TSA) Total Shoulder Arthroplasty

(UCLA) University of California at Los Angeles

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Consent for publication

Not applicable.

Availability of data and materials

The datasets that will be used and/or analysed during the current study will be available from the corresponding author on reasonable request.

Competing interests

The author(s) declare(s) that they have no competing interests.

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Rafael Fuchs Lazarini.

Contributions

RAZ is the guarantor of the review and drafted the manuscript. RAZ, FTM, JCB and MJST conceptualized the methods. RAZ and RFL contributed for the development of the eligibility criteria, and the data extraction items. RAZ, FTM and MJST designed the work. NAN helped with the electronic search and translation. All authors reviewed several drafts of the manuscript for critical content and also approved the final protocol.

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Glenoid component in anatomic total shoulder arthroplasty

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Citation

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Review question

Total shoulder arthroplasty patients above 18 years old, due to osteoarthritis, comparing glenoid components, shoulder function, complications.

Searches

"arthroplasty, replacement, shoulder", keeled OR pegged OR metal back [MeSH Terms], from 2006 to 2017.

Our search will be carried in the Cochrane Library, PubMed, Excerpta Medica Database (EMBASE), and Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS).

In addition, ongoing and recently completed clinical trial protocols will be searched in the ISRCTN Registry (www.isrctn.com), International Clinical Trials Registry Platform, ClinicalTrials.gov, Cochrane Central Register of Controlled Trials, LILACS , and Plataforma Brasil.

There will be no restrictions to language or publication status.

Types of study to be included

Clinical randomized trials or quasi randomized.

Condition or domain being studied

Total shoulder arthroplasty due to arthritis, fracture sequelae, inflammatory, analyzing the glenoid component (keeled, pegged, metal back), which one is better?

Participants/population

Adults above 18 years old.

Intervention(s), exposure(s)

Total shoulder arthroplasty with metal back glenoid component.

Comparator(s)/control

Total shoulder arthroplasty with polyethylene glenoid component, keeled or pegged.

Context

Main outcome(s)

Shoulder function and complications.

Timing and effect measures

6 months and 1 year follow up.

Additional outcome(s)

X-rays and quality of life.

Timing and effect measures

6 months and 1 year follow up.

Data extraction (selection and coding)

Eletronic search from PubMed, Google Academic, Embase and MEDLINE. 2 researchers, discrepancies will

be resolved by a third researcher.

Risk of bias (quality) assessment
2 researchers will access independently, without masking of the source or authorship of trial reports, discrepancies will be resolved by a third researcher.

Strategy for data synthesis
Pool results of comparable groups of trials using the fixed-effect model and 95% confidence intervals.

Analysis of subgroups or subsets
Perform subgroup analyses in order to explore effect size differences in relation to the glenoid type.

Contact details for further information
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Organisational affiliation of the review
Unifesp
www.unifesp.br

Review team members and their organisational affiliations
Dr Marcel Jun Tamaoki. Unifesp
Dr Fábio Matsunaga. Unifesp

Anticipated or actual start date
07 November 2016

Anticipated completion date
03 June 2019

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Unifesp

Conflicts of interest

Language
(there is not an English language summary)

Country
Brazil

Stage of review
Review_Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Arthroplasty, Replacement, Shoulder; Humans; Scapula; Shoulder

Date of registration in PROSPERO
11 January 2018

Date of publication of this version
11 January 2018

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

PROSPERO
International prospective register of systematic reviews

National Institute for Health Research

Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	Yes	No
Risk of bias (quality) assessment	Yes	No
Data analysis	Yes	No

Versions

11 January 2018

Glenoid Failure after Total Shoulder Arthroplasty, cemented all-polyethylene versus metal-backed: A Systematic Review Protocol

Databases:

- Medline
- EMBASE

Date range:

• All dates included.

Renato Aroca Zan, Rafael Fuchs Lazarini, Fábio Teruo Matsunaga, Nicola Archetti Netto, João Carlos Belloti & Marcel Jun Sugawara Tamaoki.

Full Search Strategy

Languages:• All languages included (where applicable, attempts at translation will be conducted).

Population:• All populations included (to be specified in inclusion/exclusion criteria during screening).

Study Type:• All study types included (to be specified in inclusion/exclusion criteria during screening).

Medline (Ovid) Legend:

((((((("arthroplasty, replacement, shoulder"[MeSH Terms] OR ("arthroplasty"[All Fields] AND "replacement"[All Fields] AND "shoulder"[All Fields]) OR "shoulder replacement arthroplasty"[All Fields] OR ("total"[All Fields] AND "shoulder"[All Fields] AND "arthroplasty"[All Fields]) OR "total shoulder arthroplasty"[All Fields]) AND glenoide[All Fields]) AND loosening[All Fields]) OR keeled[All Fields]) OR pegged[All Fields]) OR metal-backed[All Fields]) AND radiolucency[All Fields]AND

EMBASE (Ovid) Legend:

#1('total shoulder arthroplasty':ti,ab,kw AND 'glenoid cavity':ti,ab,kw AND 'prosthesis loosening':ti,ab,kw OR 'glenoid baseplate' OR 'glenoid component of shoulder prosthesis' OR polyethylene) AND radiolucency glenoid loosening2020-04-272020-04-27105

Sources
MEDLINE
Embase
Search ('total shoulder arthroplasty': ti,ab,kw AND 'glenoid cavity':ti,ab,kw AND 'prosthesis loosening':ti,ab,kw OR 'glenoid baseplate' OR 'glenoid component of shoulder prosthesis' OR polyethylene) AND radiolucency
In Fields total shoulder arthroplasty in Title total shoulder arthroplasty in Abstract total shoulder arthroplasty in Author keyword glenoid cavity in Title glenoid cavity in

Abstract glenoid cavity in Author keyword prosthesis loosening in Title prosthesis loosening in Abstract prosthesis loosening in Author keyword

PRISMA-P 2015 Checklist

This checklist has been adapted for use with systematic review protocol submissions to BioMed Central journals from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

An Editorial from the Editors-in-Chief of *Systematic Reviews* details why this checklist was adapted – **Moher D, Stewart L & Shekelle P:** Implementing PRISMA-P: recommendations for prospective authors. *Systematic Reviews* 2016 **5**:15

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	1-3
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 (e.g., PROSPERO) and registration number in the Abstract	☒	☐	46
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	4-8, 408-414
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	416-421
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	☐	☒	n/a
Support					
Sources	5a	Indicate sources of financial or other support for the review	☐	☒	n/a
Sponsor	5b	Provide name for the review funder and/or sponsor	☐	☒	n/a
Role of sponsor/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	☒	☐	67-85
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to	☒	☐	80-85

Section/topic	#	Checklist item	Information reported Yes	Information reported No	Line number(s)
		participants, interventions, comparators, and outcomes (PICO)			
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	88-93, 99-103
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	123-129
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	☒	☐	130-133
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	135-137
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	138-142
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	135-154
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☒	☐	144-154
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☒	☐	104-121
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	☒	☐	155-164
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☒	☐	185-187
	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 (e.g., I^2, Kendall's tau)	☒	☐	166-172
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☒	☐	193-194
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	189-198
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☒	☐	189-194

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	195-198

BMJ Open

Glenoid failure after total shoulder arthroplasty with cemented all-polyethylene versus metal-backed implants: a systematic review protocol

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Glenoid failure after total shoulder arthroplasty with cemented all-polyethylene versus metal-backed implants: a systematic review protocol

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Abstract

Introduction

Anatomical Total Shoulder Arthroplasty (TSA) is an effective treatment adopted for patients with glenohumeral osteoarthritis. The glenoid component failure is the main risk that occurs in this therapeutic choice; however, doubts remain regarding the selection of the best implant for avoiding complication. This systematic review aims to

evaluate the glenoid component in TSA by comparing the complications of different types of implants.

Methods and analysis

A systematic review of randomised clinical trials or quasi-randomised trials will be performed by applying the Preferred Reporting Items for Systematic Review and Meta-Analysis protocols and comparing polyethylene (keeled and pegged) versus metal-backed implants in adult patients with glenohumeral osteoarthritis. Our search strategy will be performed using MEDLINE, PubMed, Cochrane Central Register of Controlled Trials, EMBASE, and Web of Science. Data management and extraction will be performed using a data withdrawal form and by analysing study method characteristics, participant characteristics, intervention characteristics, results, and methodological domains. The database search will be performed by February 2021. The Grading of Recommendations Assessment, Development and Evaluation will be used for assessing the quality of evidence of each study selected; however, some critical and important outcomes were determined such as the shoulder function through functional scores (Constant-Murley and American Shoulder and Elbow Surgeons), complications represented by pain (visual analogue scale), surgical revision, radiograph radiolucency, and loosening. The confidence in estimated effects for these outcomes will be applied as the overall confidence. The outcomes will be defined as early or late, according to the postoperative follow-up of less than or greater than one year, respectively, for complications and radiographs. For the shoulder function, follow-ups will be divided into 6, 12, and 24 months. Heterogeneity is expected in systematic reviews; therefore, the selection of outcomes, as well as the sample size, and specific statistical analysis can lead to meta-analysis; however, if it fails, narrative evidence synthesis will be conducted. Other analyses such as descriptive, subgroup, and sensitivity analyses will

be performed whenever possible. This systematic review will, therefore, provide evidence concerning the best clinical practice for avoiding complications.

Ethics and dissemination

This study has been approved by the institutional review board of Universidade Federal de São Paulo (protocols 0725/2017, 2.157.415, and 70473017.5.0000.5505), and the findings will be disseminated through peer-reviewed publication and conference presentations.

Systematic review registration

PROSPERO, CRD 42018079537.

Strengths and limitations of this study

- This systematic review will be conducted in response to a gap in the evidence regarding an increasing number of shoulder surgical procedures performed for treating shoulder osteoarthritis.
- This review will include only randomised and non-randomised controlled trials for assessing all relevant available evidence regarding the types of glenoid implants for total shoulder arthroplasties for shoulder osteoarthritis.
- A comprehensive search will be performed across several databases with no restrictions for language, date, and status of publication.
- We expect difficulty in finding trials with adequate sample size, standardisation of the functional scores, follow-up pattern, and methods of the results, indicating a possible limitation in our revision.
- All authors of this review have expertise in methodology in systematic reviews as well as experience in orthopaedic surgical procedures that will ensure relevance to applicability and practice.

Introduction

Osteoarthritis (OA) of the glenohumeral joint is a common clinical condition that affects adult population between 60 and 80 years old.[1, 2] Total Shoulder Arthroplasty (TSA) has been proven to be effective for treating this condition.[3] Utilisation of TSA increased between 300%–400% for the last two decades (1990–2010), varying from 13,000–42,000 approximately, with an annual variation of 10.6%.[4, 5] Approximately 24% of complications of TSA were related to glenoid implant, and 28.5% of those required surgical revision owing to loosening of the implant. Metal-backed glenoid component (MB) thickness is approximately 7 mm (4 mm for the polyethylene insert and 3 mm for the metal tray); two screws provided initial stability, and a porous back surface provided bone ingrowth; [6] in contrast, polyethylene component (PE) thickness is approximately 3–4 mm; [7] it is fixed across the glenoid surface through pegs or keel requiring cement and its elasticity modulus is 0.5 GPa, which is closest to cancellous (0.4 GPa) and cortical (2.0 GPa) bones and far from metal (cobalt/chrome (200 GPa) and titanium (112 GPa)).[7] Loosening of the glenoid implant is the main cause of failure, followed by pain and decrease in the range of motion after a TSA. [8, 9, 10, 11] This complication compromises the function of the joint and reoperation might be needed.

This systematic review aims to evaluate the glenoid component in TSA by comparing the complications of different types of implants, either with MB or PE components (keeled or pegged), considering the function of the shoulder, complications (persistence or worsening of pain and failure of the surgery with regard to the implant loosening in the glenohumeral joint leading to a revision surgery), and radiograph radiolucency.

Methods and analysis

Types of studies and inclusion criteria:

This systematic review will follow the recommendations proposed by the Cochrane Handbook of Interventions Reviews[12, 13] and PRISMA protocols[14, 15]. Our study will include only randomised or quasi-randomised controlled clinical trials, comparing MB glenoid designs and PE designs (keeled or pegged) for TSA; other studies such as experimental, cadaveric, cohort, observational, case report, and case control will be excluded. Small samples of <five participants will not be eligible. We expect difficulty in finding trials with adequate sample size.

Ethics approval and dissemination:

The study has been approved by the institutional review board of Universidade Federal de São Paulo (protocol 0725/2017, 2.157.415, and 70473017.5.0000.5505) (document attached).

Types of participants (inclusion and exclusion criteria)

Eligible articles with adults patients (>18 years old) who underwent TSA, with cemented pegs or keel PE or MB, owing to idiopathic or inflammatory OA[16, 17, 18, 19] will be included in this study. The following exclusion criteria will be adopted: Patients with previous surgery, neurological diseases (Charcot's arthropathy, Parkinson's disease, etc.), revision surgeries of arthroplasty, reverse total arthroplasty, and studies assessing other types of glenoid implants or even mixed arthroplasties (i.e., use of bone graft).

Primary outcomes (critical)

Shoulder function will be assessed with six, 12, and 24 months of postoperative follow-ups, with two validated scores, Constant-Murley (CM)[20] and American Shoulder and Elbow Surgeons (ASES)[21]; the analysis is made on the following aspects: activity level, range of motion, arm positioning, usage of pain killers, and work. Complications such as persistence or worsening of pain (visual analogue scale (VAS))[22] and

loosening or breakage of implanted materials can lead to a surgical revision. These outcomes will be assessed as early or late, according to the postoperative follow-up of less than or greater than one year.

Secondary outcomes (important)

Radiolucency will be assessed by the occurrence of radiographic lines between the glenoid implant/cement and the native bone, indicating the loosening of the implant. Lazarus classification for keeled components and Franklin classification for pegged components will be used for assessing radiolucency concerning all-polyethylene components.[23, 24] This outcome will be assessed as early or late, according to the postoperative follow-up of less than or greater than one year.

Search methods and strategy

The electronic search will be performed in February 2021 using MEDLINE (PubMed), Cochrane Central Register of Controlled Trials,[25, 26] EMBASE, Web of Science, International Clinical Trials Registry Platform, ClinicalTrials.gov, and Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS for randomised or quasi-randomised controlled trials). The grey literature will also be searched using Google Scholar, OpenGrey, and GreyNet.[27] A medical librarian expert and a discussion group, will conduct effective search strategy.

The following terms will be used in different combinations and combinations for our search: ((((((("arthroplasty, replacement, shoulder"[MeSH Terms] OR ("arthroplasty"[All Fields] AND "replacement"[All Fields] AND "shoulder"[All Fields]) OR "shoulder replacement arthroplasty"[All Fields] OR ("total"[All Fields] AND "shoulder"[All Fields] AND "arthroplasty"[All Fields]) OR "total shoulder arthroplasty"[All Fields]) AND glenoid[All Fields]) AND loosening[All Fields]) OR keeled[All Fields]) OR pegged[All Fields]) OR metal-backed[All Fields]) AND

radiolucency[All Fields]. There will be no restriction on language or publication status. Full search strategies for the main databases are provided in appendix 1.

Data collection and analysis

Two independent reviewers will access the selected studies and the extracted data from these studies using EndNote X9 (Copyright Clarivate Analytics, 22 Thomson Place, 36T3 Boston, MA 02210, U.S.), to facilitate collaboration among them during the selection process.

Two authors will independently select and analyse the eligible studies for this systematic review through the title and abstract using the following criteria: 1) randomised clinical trials or quasi-randomised trials, 2) TSA with cemented glenoid PE or MB, 3) TSA loosening after PE or MB. Selected studies will be entirely reviewed for determining their eligibility, and any disagreement will be solved through discussion and, when necessary, will be judged by a third author in an attempt to resolve a possible conflict.

Based on the population, intervention, comparisons, and outcomes,[28, 29] the results will be established for each outcome, the magnitude of the effects, and the assessment of the quality of evidence (QE), besides the five reasons (risk of bias, imprecision, inconsistency, indirectness, and risk of publication bias) that can lower the confidence in those estimated effects, downgrading the QE.

Data extraction and handling

Data extraction will be performed by two reviewers; data will be extracted using an appropriate customised extraction form (Microsoft Access/Excel, Excel Version 16.34. 2020), based on 1) methodological characteristics, including design and duration, whether the protocol was published prior to the recruitment of the patients, possible funding sources, and study registration; 2) characteristics of the participants including

location, number of recruits, their evaluation, inclusion and exclusion criteria, age, and classification relevant to the disease addressed; 3) characteristics of the intervention such as duration, surgery type, and complications; 4) results through time and loss of follow-up; and 5) methodological domains and risk of bias.[29, 30]

The extracted data will be further classified according to the time of follow-up as early and late, establishing one year as the cut off for this division.

Assessment of risk of bias

Two authors will independently evaluate various aspects of the methodological quality of the included studies using GRADE (www.gradepro.org)[31] for assessing limitations in study design and execution, similar to a modified version of the Cochrane Bone Joint and Muscle Trauma Group tool form.[32] Some items will be considered: random sequence generation, allocation concealment, participant blinding, intention-to-treat analysis properly applied, loss of follow-up, outcome assessment blinding, quality criteria such as trials that stopped early for benefit and when there are cross-over designs, selective reporting, and potential influence of incomplete outcome data for each trial, will also be performed. After judgment and classification, the QE for each outcome will generate three levels of risk of bias: high, uncertain, and low, and it can be rated by the GRADE approach depending on the "seriousness" of bias.[33, 34] Disagreements will be solved by the analysis of a third reviewer after further analysis.[31, 32]

Measures of treatment effect

The resulting dichotomous data will be analysed with a relative risk (RR) and 95% confidence interval (CI). When appropriate, the estimated effects will be expressed as numbers that need treatment (NNTs) measuring the complications of the two types of

glenoid implants in the population of TSA. Data on continuous outcomes will be expressed as an average difference of 95% (CI). The results will be grouped with the mean difference (MD) if two or more trials reveal results from the same valid instrument of evolution (with the same units of measurement). If primary studies measure the same outcomes such as shoulder function through validated scores, complications, or radiograph using different instruments (as well as different units of measurement), odds ratio will be transformed into standard mean difference (SMD) and effect size. The Cochrane Review Manager (Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) will be used for statistical analyses, combining SMD using inverse variance method. Selective publication of studies can lead to a false estimated effect known as "fill drawer problem". Small numbers of patients and studies funded by industry are also factors that negatively influence publication bias, which can be evaluated using funnel plots; less publications bias was detected when studies were distributed around the best estimate of effect (hazard ratio).[34, 35, 36, 37]

Missing data

An intention-to-treat analysis will be performed to include all randomised participants of any intervention. Authors of the selected trials will be contacted regarding insufficient information according to the estimated effects as well as the number of participants, uncertainty in measurements (standard deviation or error), or number of events. An analysis will be performed independently of the lost data according to the worst-case and best-case scenarios.[35]

Descriptive analysis

All studies will be described in detail with a valid tool because of heterogeneous information, varied objectives, inclusion criteria, data collection methods, as well as participants demographic characteristics, and each outcome.

Subgroup analysis and heterogeneity investigation and analysis

Subgroups will be analysed to explore the difference in the side effect related to the type of glenoid implant selected.[35] The heterogeneity of estimated effects between the included studies will be evaluated using the following topics:

1) Split subgroups for allowing comparisons (PE × MB, keel PE × peg PE) if trials are similar,
2) Separate factors that introduce heterogeneity using summary plot,
3) Determine relative effects,
4) Visual inspection using Florestal plot and statistical Higgins I^2 test (significant > 50%).

Data synthesis

The results of comparative tests will be grouped using the random-effect model and a 95% CI because of different true estimated effects between the selected studies, diversity in population, or methodological characteristics. Despite study similarities, studies cannot be assumed to be identical. However, the variable model will be used when there is a diversity in clinical or methodological characteristics.

Sensitivity analysis

The effects of concealment allocation, studies at risk of bias, missing data, time bias, sub-populations, different pre-diagnoses, and other kind of implants or surgical techniques will be investigated. Such articles will be excluded so that the quality of our primary analysis is not compromised.[35]

Confidence in cumulative evidence

GRADE (www.gradepro.org) will be applied to describe and rate the QE and the strength of recommendations, classifying them as *high, moderate, low*, and *very low*[38, 39, 40] according to the study design, ranging from the randomised trials (high QE) to observational studies (low QE). The five categories mentioned before (risk of bias, inconsistency, indirectness, imprecision, and publication bias) can lower the GRADE approach; however, large effects, dose-response relationship, and all plausible residual confounders or biases (would reduce a demonstrated effect or suggest a spurious effect if no effect was observed) can upgrade the QE.[34]

Some critical and important outcomes for the GRADE approach were determined: shoulder function through functional scores (CM and ASES), complications represented by pain (VAS), surgical revision, radiograph radiolucency, and loosening.[41] These outcomes will be assessed individually, and individual recommendation will be provided.

Following this protocol publication, electronic search will be performed and the selected trials will be analysed. Once we get the results, we intend to publish this manuscript. Our intention is to have the manuscript ready by the end of 2021. We expect to observe an increasing rate of TSA in the adult population; therefore, complications also assume an increasingly important role in this particular treatment. The glenoid component is the main site of these complications in terms of pain, limiting the range of motion and worsening the quality of life. These findings are correlated with loosening or even implant breakage.[42] There is some evidences that cemented all-PE glenoid implant has a better loosening rate than the metal-backed design, but in terms of radiolucency, this statement is reversed.[6, 43, 44, 45]

Currently, there are several types of glenoid implants in both PE and MB designs; however, there is a lack of systematic reviews based on a literature search. Particularly,

only one study was found, including trials with a low level of evidence such as nonrandomised and case series.[46] Further evaluation on this subject with better methodological quality should be performed for covering functional, clinical, and radiographic outcomes as well as complications.

We expect difficulty in finding trials with adequate sample size, standardisation of the functional scores, follow-up pattern, and methods of the results, indicating a possible limitation in our revision. Our study will serve as a guide for future trials with better methodological quality.

Ethics approval and dissemination

This study has been approved by the institutional review board of Universidade Federal de São Paulo (protocol 0725/2017, 2.157.415, and 70473017.5.0000.5505) (document attached).

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Patient and public involvement

No patient was involved. It is a secondary study.

Consent for publication

Not applicable.

Availability of data and materials

The datasets that will be used and/or analysed during the current study will be available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Contributions

RAZ is the guarantor of the review and drafted the manuscript. RAZ, FTM, JCB, and MJST conceptualized the methods. RAZ and RFL contributed to the development of the eligibility criteria and data extraction items. RAZ, FTM, and

MJST designed the work. NAN helped with the electronic search and translation. All authors reviewed several drafts of the manuscript for critical content and approved the final protocol.

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Not applicable.

Glenoid failure after total shoulder arthroplasty with cemented all-polyethylene versus metal-backed implants: a systematic review protocol

Databases:

- Medline
- EMBASE

Date range:

• All dates included.

Renato Aroca Zan, Rafael Fuchs Lazarini, Fábio Teruo Matsunaga, Nicola Archetti Netto, João Carlos Belloti & Marcel Jun Sugawara Tamaoki.

Full Search Strategy

Languages:• All languages included (where applicable, attempts at translation will be conducted).

Population:• All populations included (to be specified in inclusion/exclusion criteria during screening).

Study Type:• All study types included (to be specified in inclusion/exclusion criteria during screening).

Medline (Ovid) Legend:

((((((("arthroplasty, replacement, shoulder"[MeSH Terms] OR ("arthroplasty"[All Fields] AND "replacement"[All Fields] AND "shoulder"[All Fields]) OR "shoulder replacement arthroplasty"[All Fields] OR ("total"[All Fields] AND "shoulder"[All Fields] AND "arthroplasty"[All Fields]) OR "total shoulder arthroplasty"[All Fields]) AND glenoide[All Fields]) AND loosening[All Fields]) OR keeled[All Fields]) OR pegged[All Fields]) OR metal-backed[All Fields]) AND radiolucency[All Fields]AND

EMBASE (Ovid) Legend:

#1('total shoulder arthroplasty':ti,ab,kw AND 'glenoid cavity':ti,ab,kw AND 'prosthesis loosening':ti,ab,kw OR 'glenoid baseplate' OR 'glenoid component of shoulder prosthesis' OR polyethylene) AND radiolucency glenoid loosening2020-04-272020-04-27105

Sources
MEDLINE
Embase
Search ('total shoulder arthroplasty': ti,ab,kw AND 'glenoid cavity':ti,ab,kw AND 'prosthesis loosening':ti,ab,kw OR 'glenoid baseplate' OR 'glenoid component of shoulder prosthesis' OR polyethylene) AND radiolucency
In Fields total shoulder arthroplasty in Title total shoulder arthroplasty in Abstract total shoulder arthroplasty in Author keyword glenoid cavity in Title glenoid cavity in

Abstract glenoid cavity in Author keyword prosthesis loosening in Title prosthesis loosening in Abstract prosthesis loosening in Author keyword

PRISMA-P 2015 Checklist

This checklist has been adapted for use with systematic review protocol submissions to BioMed Central journals from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

An Editorial from the Editors-in-Chief of *Systematic Reviews* details why this checklist was adapted – **Moher D, Stewart L & Shekelle P:** Implementing PRISMA-P: recommendations for prospective authors. *Systematic Reviews* 2016 **5**:15

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	1-3
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 (e.g., PROSPERO) and registration number in the Abstract	☒	☐	46
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	4-8, 408-414
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	416-421
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	☐	☒	n/a
Support					
Sources	5a	Indicate sources of financial or other support for the review	☐	☒	n/a
Sponsor	5b	Provide name for the review funder and/or sponsor	☐	☒	n/a
Role of sponsor/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	☒	☐	67-85
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to	☒	☐	80-85

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		participants, interventions, comparators, and outcomes (PICO)			
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	88-93, 99-103
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	123-129
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	☒	☐	130-133
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	135-137
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	138-142
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	135-154
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☒	☐	144-154
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☒	☐	104-121
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	☒	☐	155-164
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☒	☐	185-187
	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 (e.g., I^2, Kendall's tau)	☒	☐	166-172
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☒	☐	193-194
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	189-198
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☒	☐	189-194

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	195-198