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

Renato Aroca Aroca Zan [iD],[1] Rafael Fuchs Lazarini,[2] Fabio Teruo Matsunaga,[1] Nicola Archetti Netto,[1] João Carlos Belloti,[1,3] Marcel Jun Sugawara Tamaoki[1]

[1]Orthopedics and Traumatology—Division of Hand surgery and Upper Limb, Universidade Federal de São Paulo, São Paulo, São Paulo, Brazil
[2]Department of Orthopaedics and Traumatology, Hospital Felicio Rocho, Belo Horizonte, Minas Gerais, Brazil
[3]Universidade Federal de Sao Paulo Escola Paulista de Medicina, São Paulo, Brazil

Correspondence to
Dr Renato Aroca Aroca Zan;
re_zan@hotmail.com

ABSTRACT

Introduction Anatomical total shoulder arthroplasty (TSA) is an effective treatment adopted for patients with glenohumeral osteoarthritis (OA). 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 OA. 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 1 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.

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 (OA).

► 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 OA.

► 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.

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.

PROSPERO registration number CRD42018079537.

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% and 400% for the last two decades (1990–2010), varying from 13 000 to 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 (MB) glenoid component's thickness is approximately 7 mm (4 mm for the polyethylene (PE) insert and 3 mm for the metal tray); two screws provided initial stability, and a porous back surface provided bone ingrowth[6]; in contrast, PE component 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.[8–11] 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 Preferred Reporting Items for Systematic Review and Meta-Analysis 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 <5 participants will not be eligible. We expect difficulty in finding trials with adequate sample size.

Ethics and dissemination
The 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). Systematic review registration PROSPERO, CRD 42018079537.

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[16–19] 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 (ie, use of bone graft).

Primary outcomes (critical)
Shoulder function will be assessed with 6, 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 1 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-PE components.[8 23] This outcome will be assessed as early or late, according to the postoperative follow-up of less than or greater than 1 year.

Search methods and strategy
The electronic search will be performed in February 2021 using MEDLINE (PubMed), Cochrane Central Register of Controlled Trials,[24 25] EMBASE, Web of Science, International Clinical Trials Registry Platform, ClinicalTrials.gov and Literatura Latino-Americana e do Caribe em Ciências da Saúde (for randomised or quasi-randomised controlled trials). The grey literature will also be searched using Google Scholar, OpenGrey and GreyNet.[26] 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 online supplemental appendix 1.

Data collection and analysis
Two independent reviewers will access the selected studies and the extracted data from these studies using EndNote V.X9 (Clarivate Analytics, Boston, Massachusetts, USA), 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 and (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,[27 28] 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 V.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.[28 29]

The extracted data will be further classified according to the time of follow-up as early and late, establishing 1 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 The Grading of Recommendations Assessment, Development and Evaluation (GRADE) (www.gradepro. org)[30] for assessing limitations in study design and execution, similar to a modified version of the Cochrane Bone Joint and Muscle Trauma Group tool form.[31] 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 judgement 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.[32 33] Disagreements will be solved by the analysis of a third reviewer after further analysis.[30 31]

Measures of treatment effect

The resulting dichotomous data will be analysed with a relative risk and 95% CI. When appropriate, the estimated effects will be expressed as numbers that need treatment 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), OR will be transformed into standard MD (SMD) and effect size. The Cochrane Review Manager (computer program, V.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 'file-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 (HR).[33–36]

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 (SD or SE) or number of events. An analysis will be performed independently of the lost data according to the worst-case and best-case scenarios.[34]

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.[34] 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 I² 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, subpopulations, different prediagnoses 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.[34]

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[37–39] 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.[33]

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.[40] 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.[41] There is some evidences that cemented all-PE glenoid implant has a better loosening rate than the MB design, but in terms of radiolucency, this statement is reversed.[6 42–44]

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 non-randomised and case series.[45] 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.

ORCID iD
Renato Aroca Aroca Zan http://orcid.org/0000-0001-9289-7983

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