

# Glenoid Bone Grafting Procedures in the Treatment of Anterior Shoulder Instability With Bone Defect: When to Indicate? Protocol for a Systematic Review

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## Protocol

**Keywords:** Shoulder instability, Systematic review, Protocol, Glenoid defect, Bone block procedures

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# Abstract

**Background:** Chronic traumatic anterior instability of the shoulder is a frequent event, especially in young athletes. Several management techniques have been proposed for this condition. The objectives of these procedures are to re-establish a stable and functional shoulder and to prevent the development of osteoarthritis. It is well known in the literature that a bone loss greater than 20% to 25% leads to a higher rate of recurrence and worse prognosis regarding the evolution of anterior shoulder instability, often requiring glenoid bone grafting procedures. Previous studies evaluated the recurrence and complications associated with these procedures; however, there are various clinical and radiological indications, and no study systematically evaluated these indications, which are associated with better clinical outcomes and lower rates of complications. This paper outlines the protocol for a systematic review intended to summarise the best available clinical evidence and will indicate what further research requires.

**Methods:** An electronic search will be conducted on MEDLINE, EMBASE, Web of Science, CINAHL, Cochrane, and EBSCO databases. Clinical studies of glenoid bone grafting procedures have been indicated for the treatment of anterior shoulder instability, evaluating which indications are related to a better functional result for the patient. Risk of bias will be assessed using the Downs and Black checklist for observational studies and the Cochrane Collaboration tool for randomised controlled trials.

**Discussion:** This systematic review will summarise the clinical and radiological indications for glenoid bone grafting procedures, revealing those related to better outcomes. The findings from this review will establish the quality of currently available evidence, thereby determining the need for further studies to establish the best indications for these procedures.

**Systematic review registration:** PROSPERO CRD42020210462

## Background

Chronic traumatic anterior instability of the shoulder is a frequent event, especially in young patients [1,2]. Several management techniques have been proposed for this condition. The objectives of these procedures are to re-establish a stable and functional shoulder and to prevent the development of osteoarthritis.

Bankart surgery is the most commonly used procedure in these cases [3]. It involves soft tissue tensioning and is usually performed by arthroscopy [4]. The Latarjet and Bristow techniques are the most common among the glenoid bone grafting procedures and consist of a transfer from the coracoid to the glenoid [5] and are indicated in the cases of high risk of recurrence and the presence of associated bone lesions [6].

It is well known in the literature that a bone loss greater than 20% to 25% leads to a higher rate of recurrence and worse prognosis regarding the evolution of anterior shoulder instability, often requiring glenoid bone grafting procedures [7,8]. The Bristow and Latarjet techniques showed good results in

patients with bone defects [9,10]. Previous studies evaluated the recurrence and complications associated with these procedures [11,12]; however, there are various clinical and radiological indications, and no study systematically evaluated these indications, which are associated with better clinical outcomes and lower rate of complications. This paper outlines the protocol for a systematic review intended to summarise the best available clinical evidence and will indicate what further research requires.

## **Method/design**

### **Protocol development and registration**

This systematic review is registered in the International Prospective Register of Systematic Reviews (PROSPERO) (CRD42020210462). Literature search methods, inclusion and exclusion criteria, outcome measures, and statistical analysis will be defined according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines (PRISMA-P provided as a separate file). We received ethical approval from our institution (9738310820).

### **Types of intervention/comparators**

All studies in which at least one treatment arm includes the glenoid bone grafting procedure in patients older than 18 years will be included. Studies may have a single intervention group or two or more intervention groups. There is no restriction regarding any comparison group.

### **Types of outcome measures**

There will be no exclusions based on the outcomes reported in the identified studies. All outcomes at all time points, regardless of follow-up, will be of interest to this review.

The primary outcomes of interest include, but are not limited to:

(i) Shoulder-specific function and pain scores.

Measured using a validated scale such as Oxford Shoulder Score (OSS), American Shoulder and Elbow Surgeon Score (ASES), Disabilities of the Arm Shoulder and Hand (DASH) questionnaire, Constant scale, PENN shoulder score, Shoulder Pain and Disability Index (SPADI), Simple Shoulder Test (SST), and the University of California at Los Angeles scale (UCLA).

(ii) Shoulder pain outcomes

Single-item shoulder pain measures to be assessed by validated assessment tools such as the visual analogue scale (VAS), Likert pain scale, and other validated or non-validated dichotomous, categorical, or ordinal assessments or patient-reported outcomes (PROs).

(iii) Health-related quality of life

Including but not limited to overall health-related quality of life (HRQoL) as assessed by EuroQoL-5D (EQ-5D), Short Form-36 (SF36), and Health Utilities Index (HUI).

Other secondary outcomes include:

Recurrence of shoulder instability, complications related to synthesis material, and the development of arthritis

## **Types of studies**

This review will consider all relevant randomised controlled trials (RCTs) and non-randomised studies (comparative and single intervention groups). Retrospective studies will be excluded in addition to review articles, editorials, and single case studies. Only studies published in English will be included. Only published studies will be included.

## **Electronic search**

The following databases will be searched: (a) MEDLINE (1946 until October week 2, 2020) via OvidSP, last search on 13 October 2020; (b) MEDLINE in-process and other non-indexed citations (latest issue) via OvidSP, last search on 13 October 2020; (c) Ovid EMBASE (1974 to latest issue), last search on 13 October 2020; (d) Web of Science (latest issue); last search on 13 October 2020; (e) CINAHL Complete (latest issue), last search on 13 October 2020; Cochrane Central Register of Controlled Trials (October 2020), last search on 13 October 2020; (f) EBSCO (latest issues); last search on 13 October 2020. Search terms will use two strings linked by an AND modifier. The first string will include Latarjet OR Bristow OR Eden-Hybinette OR Bone block procedures; the second string: shoulder instability. Truncated search terms utilising the wildcard character and the “related articles” function will be used to broaden the search. Additionally, the references of included articles will be hand-searched to identify any additional studies.

## **Study selection**

Two researchers (PHSL and PSB) will independently screen all titles and abstracts identified from the search strategy. Full reports will be obtained if the initial screening indicates that the identified studies are potentially relevant. Full reports that meet the inclusion criteria will be included in the review. Reasons for exclusion will be recorded at each stage and detailed in a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. A third independent reviewer (LMR) will help resolve any discrepancies or disagreements if they arise.

## **Risk of bias and quality assessment**

The risk of bias assessment will be performed at both the study and outcome levels if the latter is possible. The risk of bias of the included studies will be appraised using the Downs and Black checklist for observational studies and the Cochrane Collaboration tool for randomised controlled trials (RCTs) [13,14]. At the outcome level, the risk of bias assessment will be conducted using a funnel plot to

measure publication bias. The information obtained will be used in data synthesis to assess the quality of reported data. The kappa ( $\kappa$ ) statistic will be used to evaluate inter-reviewer agreement at all screening stages. The agreement will be classified as follows:  $\kappa$  of 0.81-0.99 will be considered nearly perfect agreement;  $\kappa$  of 0.61-0.80 will be substantial agreement;  $\kappa$  of 0.41-0.60 will be moderate agreement; 0.21–0.40 fair agreement and a  $\kappa$  value of 0.20 or less will be considered slight agreement. To verify the presence of reporting bias, we will determine whether the RCT protocol was published before the recruitment of patients or when the study had started. For studies published after 01 July 2005, we will screen the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organisation (<http://apps.who.int/trialssearch>). We will evaluate whether selective reporting of outcomes is present (outcome reporting bias). We will compare the fixed effect estimate against the random effect model to assess the possible presence of small sample bias in the published literature (i.e., in which the intervention effect is more beneficial in smaller studies). In the presence of a small sample bias, the random effect estimate of the intervention is more beneficial than the fixed effect estimates. The potential for reporting bias will be further explored by funnel plots if  $\geq 10$  studies are available.

### **Data extraction**

The following data items will be extracted: the year of publication, study design, sample size, country of study, type of patients, patient characteristics, inclusion and exclusion criteria for surgery indication, outcome measures, and conclusions. The corresponding authors of the original publications will be contacted via email in the event of insufficient data. Data will be entered into Review Manager 5.3 (Cochrane Collaboration, Oxford, UK). References will be managed using the reference management software EndNote X7 (Clarivate Analytics).

### **Data synthesis and analysis**

Statistical analysis will be performed using IBM SPSS Statistics (Armonk, NY, USA). Descriptive statistics will be calculated for variables of interest. Continuous measures will be summarised with the use of means and standard deviations, while categorical data will be summarised with the use of counts and percentages. Quantitative analysis including a meta-analysis and sensitivity analysis of subgroups will be performed if the data is sufficiently homogenous. In addition to an overall analysis, further analyses will be performed according to the study design if a sufficient number of RCTs and observational studies are identified. A standard mean difference with 95% confidence intervals will be used in the analysis. Both the fixed-effects and random-effects models will be considered in the analysis of data and the most appropriate will be used. Statistical heterogeneity will be quantified using  $I^2$  and  $\tau$  statistics [15] and reasons explored as able. Small study biases will be explored using funnel plots if there are sufficient studies (10 or more) [15].

If a meta-analysis of randomised comparative studies is possible, we will use the random effect method in Stata version 14.0 using the metan command. Sensitivity analyses will assess differences associated with study design and patient population where feasible. Data will be analysed to treat basis without

imputation of missing data where possible. Given the nature of the comparison, no cluster randomised or cross-over trials are anticipated.

The quality of evidence for all outcomes will be judged using the Grading of Recommendations Assessment, Development, and Evaluation working group methodology. The quality of evidence will be assessed across the domains of risk of bias, consistency, directness, precision, and publication bias. Additional domains may be considered where appropriate. Quality will be adjudicated as high (further research is very unlikely to change our confidence in the estimate of effect), moderate (further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate), low (further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate), or very low (very uncertain about the estimate of effect).

It is unlikely that a meta-analysis can be performed given the anticipated relatively low number of comparative studies and differences in methodology. In this circumstance, the methods and results of the systematic review will be written qualitatively. A narrative summary of the evidence will be produced and where appropriate tables will report the study design, patient population, intervention details, and outcomes for each patient identified in the review.

## **Discussion**

There is a pressing need to define the best indications for glenoid bone graft procedures that have been frequently used in recent times, especially in patients with bone defects. Although there are many clinical and radiological indications, there is still a lack of evidence to demonstrate when these procedures are indicated. The present systematic review will enable us to conclude on the indications for glenoid bone graft procedures, which are related to better functional results and lower rates of complications. Conducting a systematic review of the literature will provide a summary of the existing findings on this topic and critical appraisal of the risk of bias and methodological quality of the currently available evidence. These will be essential in designing future studies to establish the best indications for these procedures.

## **Abbreviations**

PROSPERO: International Prospective Register of Systematic Review; PRISMA: Preferred items for reporting systematic review and meta-analysis; OSS: Oxford Shoulder Score; ASES: American Shoulder and Elbow Surgeon Score; DASH: Disabilities of the Arm Shoulder and Hand questionnaire; SPADI: Shoulder Pain and Disability Index; SST: Simple Shoulder Test; UCLA: University of California at Los Angeles scale; VAS: visual analog scale (VAS); PROs: patient-reported outcomes (PROs).

## **Declarations**

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Not applicable

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## Author's contributions

PHSL contributed to the conception and design of the study, development of data extraction forms, search strategy, manuscript writing and final review of the manuscript. LMR contributed to the methodological design, critical revision and final review of the manuscript. ACP contributed to the search strategy, critical revision and final review of the manuscript. CVA contributed to the search strategy, critical revision and final review of the manuscript. PSB contributed to the methodological design, critical revision and final review of the manuscript. BE contributed to the methodological design, critical revision and final review of the manuscript. All authors read and approved the final manuscript. PHSL is the guarantor of the review.

## Ethics approval

Ethics approval of the Federal University of São Paulo (9738310820).

## Consent for publication

Not applicable

## Competing interests

The authors declare that they have no competing interests

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