

The influence of Diabetes Mellitus and Obesity on upper limb arthroplasty outcomes: A systematic review protocol

Review question/objective

The objective of this review is to locate and synthesize the best available evidence investigating the impact of selected comorbidities on upper limb arthroplasty outcomes.

The review question is, are patients with Diabetes Mellitus or Obesity at increased risk of complications and/or poorer postoperative outcomes following Total Shoulder, Reverse Total Shoulder and Total Elbow Arthroplasty?

Background

Joint arthroplasty refers to the partial or total artificial replacement of a joint used to alleviate pain and physical dysfunction associated with end-stage degenerative disease, joint malformation or trauma.¹ It is an effective treatment commonly used in the medical care of the elderly population, with the median age of 70 and 74 years reported for male and female shoulder arthroplasty patients in 2015, respectively².

Obese and overweight adults are highly prevalent in the Australian population, with the conditions most commonly present in the elderly.³ In 2011-12, 75.0% of Australians aged 65-74 years were overweight or obese.³ Similarly, Diabetes Mellitus (DM) has been identified as more commonly present in older age groups, affecting 15.0% of Australians aged 65-74 years.³ As displayed, risks of developing chronic diseases such as DM or Obesity escalate with age, increasing the possibility of comorbid patients presenting for elective orthopaedic surgery. The incidence of such conditions is on the rise,⁴ and further consideration of their impact on patient outcomes following arthroplasty is imperative.

The amount of research investigating the influence of comorbidity on perioperative and long-term outcomes following lower limb arthroplasty is increasing. Pre-existing DM has been associated with an increased risk of perioperative mortality,⁵ deep vein thrombosis,⁶ deep infection and poorer long-term function,⁷ following Total Knee Arthroplasty (TKA). Similarly, DM and Obesity are prevalent morbidities of hip arthroplasty patients and have been identified as risk factors for periprosthetic joint infection.^{8, 9} Research concerning the influence of comorbidity on upper limb arthroplasty outcome is both sparse and contradictory.

Obesity

Risk associated with Total Shoulder Arthroplasty (TSA) outcomes in obese patients is the most widely studied, yet most controversial upper limb cohort, given the mixed findings reported. Morbidly obese patients (Body Mass Index (BMI) > 40 kg/m²) generally stay longer in hospital postoperatively, however, in-hospital mortality, pulmonary embolism (PE), infection and cardiac complication rates did not appear to differ from their non-obese or obese counterparts.¹⁰ More recently, Jiang et al.¹¹ considered the 30-day complication profile of 4796 patients categorized by BMI class; a greater BMI was associated with longer surgical times, however, no association between BMI class and complications after surgery, for example blood transfusions, were identified.¹¹ Conversely, Werner et al.¹² identified obesity as a patient factor associated with early revision of shoulder arthroplasty. Furthermore, an increased risk of postoperative complication has been reported in patients with a BMI > 50 kg/m².¹³ These patients were classed as "superobese" and experienced significantly higher rates of infection within 1 year, venous thromboembolism (VTE), dislocation and revision compared with, at minimum, one of the Non-obese, Obese or Morbidly Obese comparator groups.¹³ Super-obesity was not associated with periprosthetic fracture and postoperative stiffness.¹³

The influence of Obesity on mid-term outcomes following TSA has also been investigated. Linberg et al.¹⁴ followed a cohort of morbidly obese shoulder arthroplasty patients, reporting improvements in pain and function, as measured at 2-years post-surgery. A more recent, comparative study identified increases in quality-of-life, pain and fatigue scores amongst TSA patients across all BMI classes.¹⁵ Despite these improvements, authors noted that overall physical function in obese (30 kg/m²) and overweight (25- 29.9 kg/m²) patients did not significantly improve following TSA, with such patients failing to achieve improvement levels as those reached in the 'normal-weight' patient population (<25 kg/m²).¹⁵ Studies investigating the relationship between Reverse TSA (rTSA) and Obesity have also presented mixed findings. Gupta et al.¹⁶ reviewed 119 patients with a minimum 90-day follow-up, categorised by BMI. Patients with a BMI exceeding 35 kg/m² presented higher rates of overall complication, specifically blood loss and consequent blood transfusion.¹⁶ On the contrary, evidence also supports rTSA as an effective procedure for the morbidly obese,¹⁷ with no increased risk for complications such as periprosthetic infection.¹⁸

Unlike shoulder arthroplasty, research investigating the impact of Obesity on outcome following Total Elbow Arthroplasty (TEA) is limited, yet comparable. Within the 90-day postoperative period, Griffin et al.¹⁹ identified a higher rate of VTE and infection in obese and morbidly obese TEA patients. Postoperatively, one year onwards, dislocation and revision also occurred at a greater rate in the morbidity obese group.¹⁹ Similarly, Baghdadi et al.²⁰ also identified a significantly higher rate of TEA revision in severely obese patients when compared to the non-obese patient group.

Diabetes Mellitus

Diabetic patients undergoing TEA have reportedly endured significantly longer hospital length of stay and higher rates of perioperative complications than their non-diabetic counterparts.²¹ Reported complications have included increased rates of pneumonia, myocardial infarction and transfusion requirements.²¹ Further findings have also identified DM as an independent risk factor for urinary tract infection following TEA.²² The influence of DM on shoulder arthroplasty patients has also been investigated. Pounce et al.²³ identified an association between DM and in-hospital death and perioperative complications following shoulder arthroplasty.²³

The available evidence regarding the impact of comorbidities such as Obesity and DM on upper limb arthroplasty outcomes appears to be inconclusive and contradictory. An understanding of the relationship between pre-existing comorbidities and arthroplasty outcomes is essential as it may impact patient selection for different types of orthopaedic surgery. Patients must be better informed of any additional risks associated with a pre-existing chronic disease, as this may influence their decision-making process. Orthopaedic surgeons may also consider further alternate treatments or precautionary measures to ensure the safety and effectiveness of the arthroplasty procedure in patients identified at greater risk for poorer outcome.

To date, research has considered a number of perioperative, short and longer-term complications for patients with comorbid conditions in isolation. An inclusive review with consideration of perioperative, as well as mid and longer-term outcomes is now needed to develop a clear understanding of the impact of comorbidities on upper limb arthroplasty. A preliminary literature database search in PubMed, in addition to a screening of the review registry PROSPERO, indicated that this topic has not previously been assessed through systematic review methodology, nor is currently under investigation. The primary objective of this systematic review is to investigate the impact of DM or Obesity on complications and postoperative outcomes in TSA, rTSA and TEA patients.

Keywords

Comorbidity; Diabetes Mellitus; Elbow Arthroplasty; Obesity; Shoulder Arthroplasty.

Inclusion criteria

Types of participants

This review will consider studies that include adults (18 years or older) who have undergone upper limb arthroplasty, specifically primary TSA, rTSA and TEA.

Exposure

This review will consider studies that evaluate the influence of comorbidity on the arthroplasty outcomes. Comorbidities to be considered will include the presence of either:

1. Obesity

The World Health Organization uses BMI as an index of weight-for-height.²⁴ BMI is commonly used to classify levels of Obesity and is categorised under the following ranges:

- Normal Weight: $<25\text{kg/m}^2$
- Overweight: $25 - 29.9\text{ kg/m}^2$
- Obese: $30 - 39.9\text{ kg/m}^2$
- Morbidly Obese: $\geq 40\text{ kg/m}^2$

This review will categorise Obesity as a BMI $\geq 30\text{ kg/m}^2$.

2. Diabetes Mellitus

Type 1 and Type 2 DM will be considered. Given classification and diagnostic criteria for DM may change over time, we will consider patients formally diagnosed with DM using standard criteria valid at the time of the beginning of the study. Criteria should ideally be described in the article.

Types of outcomes

This review will consider studies that include the following outcome measures:

Postoperative complications and outcomes including:

- *Infection (Surgical Site Infection and Periprosthetic Infection)*
 - Diagnosed by, but not limited, to laboratory and microbiological testing.
- *Urinary Tract Infections*
 - Diagnosed by, but not limited to, laboratory testing for positive urine culture.
- *Blood Transfusion*
- *Pneumonia*
 - Diagnosed by, but not limited to, chest x-rays and blood tests.
- *Venous Thromboembolism (Deep Vein Thrombosis and Pulmonary Embolism)*
 - Diagnosed by, but not limited to Duplex Sonography, Doppler Ultrasonography or Computed Tomography Scan.
- *Acromial or Stem Fractures* (For example Periprosthetic fractures).
- *Length of Stay*
- *Operative Duration*
- *Pain:* as measured by scoring systems such as the Visual Analogue Scale for Pain.

- *Function:* as measured by Range of Motion or on scoring systems such as the Constant – Murley Shoulder Score.
- *Quality of Life:* as measured by scoring systems such as the Short Form-36.
- *Unscheduled return to theatre (For causes such as instability or dislocation).*
- *Revision* following primary Total Shoulder or Elbow arthroplasty.
- *Mortality*

Types of studies

This review will consider analytical epidemiological study designs including prospective and retrospective cohort studies and case-control studies for inclusion.

Search strategy

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of PubMed and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in English will be considered for inclusion and no limitation on publication date will be assigned.

The databases to be searched include:

- PubMed
- CINAHL
- Embase

The grey literature search, or search for unpublished studies, will include:

1. *National and international conference proceedings.*

Conferences chosen for review will be based on those listed by the Australian Orthopaedic Association (AOA) of which are relevant to the present review topic and provide electronically accessible proceedings. The conference proceedings of the most recent conference will be screened. Conferences will include:

- American Academy of Orthopaedic Surgeons Annual Meeting
- Australian Orthopaedic Association Annual Scientific Meeting
- Canadian Orthopaedic Association Annual Scientific Meeting

- British Orthopaedic Association Annual Congress
- European Federation of National Associations of Orthopaedics and Traumatology Congress

2. *Open Grey – European database of grey literature*

Initial keywords and search filters to be used will be:

1. Arthroplasty OR Replacement OR total shoulder OR total elbow
2. Comorbidity OR Obesity OR Body Mass Index OR overweight OR Diabetes Mellitus
3. Outcome OR perioperative OR midterm OR long term OR infection OR length of stay OR urinary tract infection OR mortality OR venous thrombosis OR fracture OR function OR quality of life OR pain OR revision OR complication.
4. 1 AND 2 AND 3

Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute System for the Unified Management, Assessment and Review of Information (JBI-SUMARI) (Appendix I). However, methodological quality of papers will not influence eligibility for inclusion. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flowchart will be used to report study selection and inclusion in the review.²⁵

Data collection

Data will be extracted from papers included in the review using the standardized data extraction tool from JBI-SUMARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and objective.

The following components will be extracted from each of the studies:

- Type of Arthroplasty procedure: Total Elbow, Total Shoulder or Reverse Total Shoulder.
- Demographics and characteristics of participant cohorts including age, gender, level of glycaemic control (i.e. controlled or not controlled), Type 1 or Type 2 Diabetes Mellitus, nationality or ethnicity, indication for primary arthroplasty and function.
- Arthroplasty outcomes including postoperative complications and outcomes.

Data synthesis

Quantitative data will, where possible, be pooled in statistical meta-analysis using JBI-SUMARI. All results will be subject to double data entry. Effect sizes expressed as odds ratios (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. A Random effects model will be used and heterogeneity will be assessed statistically using the standard Chi-square and I squared. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Where possible, sub-group analysis may be conducted to further explore the different levels of BMI, type of DM, differences in surgical treatment groups or level of methodological quality of included papers.

Conflicts of interest

The authors declare that there is no conflict of interest.

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275 **Appendix I: Appraisal instruments**

276 **SUMARI Appraisal instrument**

JBI Critical Appraisal Checklist for Case Control Studies

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not applicable
1. Were the groups comparable other than the presence of disease in cases or the absence of disease in controls?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were cases and controls matched appropriately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were the same criteria used for identification of cases and controls?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Was exposure measured in a standard, valid and reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Was exposure measured in the same way for cases and controls?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were confounding factors identified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were strategies to deal with confounding factors stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes assessed in a standard, valid and reliable way for cases?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was the exposure period of interest long enough to be meaningful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

JBI Critical Appraisal Checklist for Cohort Studies

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not applicable
1. Were the groups similar and recruited from the same population?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the exposures measured similarly to assign people to both exposed and unexposed groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Was the exposure measured in a valid and reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were confounding factors identified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were strategies to deal with confounding factors stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes measured in a valid and reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Was the follow up time reported and sufficient to belong enough for outcomes to occur?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was follow-up complete, and if not, were the reasons to loss to follow-up described and explored?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Were strategies to address incomplete follow-up utilized?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Was appropriate statistical analysis used?				

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Analytical Cross Sectional Studies

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not applicable
1. Were the criteria for inclusion in the sample clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the study subjects and the setting described in detail?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Was the exposure measured in a valid and reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were objective, standard criteria used for measurement of the condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were confounding factors identified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were strategies to deal with confounding factors stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes measured in a valid and reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Case Series

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not applicable
1. Were there clear criteria for inclusion in the case series?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Was the condition measured in a standard, reliable way for all participants included in the case series?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were valid methods used for identification of the condition for all participants included in the case series?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Did the case series have consecutive inclusion of participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Did the case series have complete inclusion of participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was there clear reporting of the demographics of the participants in the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Was there clear reporting of clinical information of the participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were the outcomes or follow up results of cases clearly reported?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was there clear reporting of the presenting site(s)/clinic(s) demographic information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Was statistical analysis appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

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282 **Appendix II: Data extraction instruments**

283 **SUMARI data extraction instrument**

**JBI Data Extraction Form for
Experimental / Observational Studies**

Reviewer Date

Author Year

Journal Record Number

Study Method

RCT	<input type="checkbox"/>	Quasi-RCT	<input type="checkbox"/>	Longitudinal	<input type="checkbox"/>
Retrospective	<input type="checkbox"/>	Observational	<input type="checkbox"/>	Other	<input type="checkbox"/>

Participants

Setting

Population

Sample size

Group A Group B

Interventions

Intervention A

Intervention B

Authors Conclusions:

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Reviewers Conclusions:

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Study results

Dichotomous data

Outcome	Intervention () number / total number	Intervention () number / total number

Continuous data

Outcome	Intervention () number / total number	Intervention () number / total number