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Cemented vs. cementless stems for reverse shoulder arthroplasty for proximal humerus fractures: a registry analysis with patient-reported outcomes from a level 1 trauma centre

Kyle Raubenheimer, MD[a], Mitchell Atkinson, MBBS[a], Matthew Yan, MB BChir, MA(Cantab)[a], Michael Perret, MBBS(Hons), FRACS[a], Stefan Bauer, MD[b,c], Dylan Harries, BSc (Hons), PhD[d], David R.J. Gill, MB ChB, FRACS, FAOrthA[e], William G. Blakeney, MBBS, MS, MSc, FRACS[a,b,*]

[a]*Royal Perth Hospital, Perth, Australia*
[b]*University of Western Australia, Perth, Australia*
[c]*Ensemble Hospitalier de la Côte, Morges, Switzerland*
[d]*South Australian Health and Medical Research Institute (SAHMRI), Adelaide, South Australia, Australia*
[e]*Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), Adelaide, South Australia, Australia*

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Background: Reverse total shoulder arthroplasty (rTSA) is being increasingly used in the treatment of comminuted or unreconstructible proximal humerus fractures. It is currently unclear if cementless rTSA have equivocal revision rates, mortality, and functional outcomes compared to cemented or cementless rTSA.

Methods: Two data sources were used for this study. All rTSA performed for proximal humerus fractures between 1 January 2010 and 1 January 2020 recorded on the Australian Orthopaedic Association National Joint Replacement Registry were used to determine revision rate and mortality between cemented and cementless rTSA. Patient-reported outcome measurements, including the American Shoulder and Elbow Surgeons score, Oxford Shoulder Score, and single assessment numerical value were obtained via telephone from Royal Perth Hospital (RPH) patients between 01 January 2010 and 10 February 2021.

Results: The study included 83 patients who underwent rTSA for proximal humerus fractures at RPH. There were 4335 rTSA procedures identified at other hospitals nationally. Of these, 54% of rTSA used cementless humeral stems. There was no significant difference in revision rate or mortality between cemented and cementless humeral stems adjusted for age and gender. For the RPH cohort, patient-reported outcome measurements scores included American Shoulder and Elbow Surgeons score of 65.9 (CI: 60.6-71.2), Oxford Shoulder Score of 34.6 (CI: 31.9-37.2), and single assessment numerical value of 68.8 (CI: 61.8-75.8).

Conclusion: Revision rates and mortality are similar between cemented and cementless humeral stems used for rTSA for proximal humerus fractures. For appropriate patients, cementless humeral stems may be an acceptable first-line treatment for proximal humerus fractures.

Reverse total shoulder arthroplasty (rTSA) is currently the second most common operative management strategy for proximal humerus fractures, and the only operative treatment that increased in prevalence between 2008 and 2017.[12] The incidence of proximal humerus fractures is rising.

Traditionally, humeral arthroplasty has been performed with implant designs that require cement for adequate fixation-in the context of poor bone stock and osteoporosis typical of most

Ethical approval was sought and obtained from the RPH Human Research Ethics Committee in Western Australia (RGS5089). The AOANJRR is approved by the Commonwealth of Australia as a Federal Quality Assurance Activity (F2022L00986) Part VC of the Health Insurance Act 1973 and Part 10 of the Health Insurance Regulations 2018. All AOANJRR studies are conducted in accordance with ethical principles of research (the Helsinki Declaration II).

*Corresponding author: William Blakeney, MBBS, MS, MSc, FRACS, Orthopaedic Department, Royal Perth Hospital, North Block, Level 5, 197 Wellington St, Perth, Western Australia 6000, Australia.

E-mail address: william.blakeney@uwa.edu.au (W.G. Blakeney).

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patients.[6] Arthroplasty using cement is associated with drawbacks, including bone cement implantation syndrome, increased surgical time, and challenges during revision.[19] Some modern rTSA designs allow for press-fitting of humeral stems, mitigating the need for bone cement, and thus eliminating the negative side effects of cementation. There is limited evidence investigating the difference in revision rates between cemented and cementless stems for rTSA.[7,10,13] Few studies have investigated revision rates and mortality for all indications of rTSA.[11,15,18] Furthermore, no studies have directly compared mortality between cemented and cementless humeral stems for rTSA, particularly for proximal humerus fractures. It is currently unclear if cementless rTSA for proximal humerus fractures have equivocal revision rates, mortality, and functional outcomes as compared to cemented rTSA.

The primary aim of this study is to compare revision rates between cemented and cementless humeral stemmed rTSA for proximal humerus fractures. Secondary aims included comparison of mortality from a national database and patient-reported outcomes from a single major trauma center. The null hypothesis is that there is no difference in revision rates between cemented and cementless humeral stems in rTSA for proximal humerus fractures.

Methods

Study design

There were 2 main components to the current project as follows: (a) a retrospective, national cross-sectional study investigating the difference in clinical outcomes between cemented and cementless humeral stems for reverse shoulder arthroplasty for primary diagnosis fracture, and (b) a retrospective cohort study investigating the patient-reported outcomes for patients receiving a reverse shoulder arthroplasty for proximal humerus fractures from a level 1 major trauma center in Western Australia. A comparison between the revision rates at the Western Australian trauma center and national rates was also conducted.

Ethical approval was sought and obtained from the Royal Perth Hospital (RPH) Human Research Ethics Committee in Western Australia (RGS5089). The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) is approved by the Commonwealth of Australia as a Federal Quality Assurance Activity (F2022L00986) part VC of the Health Insurance Act 1973 and part 10 of the Health Insurance Regulations 2018. All AOANJRR studies are conducted in accordance with ethical principles of research (the Helsinki Declaration II).

Setting: clinical outcomes for cemented vs. cementless stems for proximal humerus fractures

The AOANJRR is a national database of hip, knee, and shoulder arthroplasty procedures performed within Australia. Shoulder arthroplasty has been included since 2004 and has documented almost all shoulder arthroplasty procedures nationally since November 2007.[16] Data are externally validated against patient-level data obtained from state health departments, with missing data followed-up with relevant hospitals following a sequential, multilevel matching process. Data are matched twice a year with the Australian National Death Index to identify deaths. The comparison of cemented vs. cementless humeral stems for primary diagnosis fracture was analyzed from the AOANJRR.

Setting: patient-reported outcome measures (PROMs)for cementless stems for proximal humerus fractures

RPH is a level 1 trauma center in Western Australia and houses the Western Australian State Major Trauma Unit, which services all major trauma within the state. Data were collected using digital and written medical records, operation reports, and clinic reports from RPH.

Participants: clinical outcomes for cemented vs. cementless stems for proximal humerus fractures

In the current project, all rTSAs performed for primary diagnosis fracture between 1 January 2010 and 1 January 2020 were identified within the AOANJRR. The inclusion criteria included all patients over the age of 50 years in the AOANJRR who underwent stemmed rTSA for primary diagnosis fracture with a humeral cementless or cemented stem design. As all eligible cases recorded in the registry were included, no sample size calculation was performed a priori. The most common implants in this study were as follows: Lima modular shoulder replacement (SMR) reverse shoulder implant (shoulder modular replacement; Lima Corporate, San Daniele del Friuli, Italy), Delta Xtend (DePuy Synthes, Raynham, MA, USA), and the Aequalis Ascend Flex (Tornier SAS-Wright Medical Inc, Bloomington, MN, USA).

Participants: PROMs for cementless stems for proximal humerus fractures

To determine PROMs for patients, all rTSAs performed at RPH between 1 January 2010 and 10 February 2021 for proximal humerus fractures were screened for eligibility. All patients with proximal humerus fractures received a Lima SMR reverse shoulder implant (shoulder modular replacement, Lima Corporate, San Daniele del Friuli, Italy). A minimum follow-up period of 2 years was required. Two years has been proposed as the minimum amount of time needed to assess complications of rTSA.[17,21] Once identified, verbal consent was obtained from all patients via telephone and a study participant information sheet, and withdrawal form was sent to the participants via mail.

The inclusion criteria included a convenience sample of all patients who received an rTSA for a proximal humerus fracture at RPH between 1 January 2010 and 10 February 2021.

The exclusion criteria included inability to give informed consent (eg, dementia, cognitive decline, or mortality). Patients were classified as loss to follow-up following 5 attempts at contact via telephone on 5 separate days.

Variables: clinical outcomes for cemented vs. cementless stems for proximal humerus fractures

Data on mortality following rTSA was obtained from the AOANJRR through linkage to the Australian National Death Index. Revision outcomes following primary rTSA, including the reason for and type of revision, were determined through the registry's matching process to link primary and revision procedures. Demographic variables, including age at the time of operation, sex, American Society of Anesthesiologists's score, and body mass index, were obtained from the data collection forms provided to the registry at the time of surgery. Eligible rTSA procedures were followed-up until patient death or closure of the database on 31 December 2022.

Variables: PROMs for cementless stems for proximal humerus fractures

Data were collected from hospital medical records for patient demographics (age at time of surgery and gender), mechanism of injury, and survivorship. For patient-reported outcomes, telephone follow-up interviews were conducted, and variables collected included American Shoulder and Elbow Surgeons score (ASES),

Table I
Summary of primary total reverse shoulder replacement performed between 1 January 2010 and 1 January 2020 in patients aged >50 Years by hospital and humeral fixation (primary diagnosis fracture).

Variable	Royal Perth hospital cementless	Royal Perth hospital cemented	Other hospitals cementless	Other hospitals cemented	Total
Follow-up years					
Mean ± SD	4.7 ± 2.2	3.8 ± 3.5	5.2 ± 2.7	5.4 ± 2.7	5.2 ± 2.7
Median (IQR)	4.4 (3.5, 5.9)	3.1 (1.2, 6.5)	4.8 (3.4, 6.8)	5.1 (3.6, 7)	4.9 (3.5, 6.9)
Minimum	0.1	0.6	0	0	0
Maximum	10.2	8.5	12.9	12.9	12.9
Age					
Mean ± SD	72.9 ± 10.2	79 ± 5.2	74.5 ± 8.6	75.5 ± 8.5	74.9 ± 8.6
Median (IQR)	74 (66, 81)	80.5 (75, 83)	75 (69, 81)	75 (70, 82)	75 (69, 81)
Age group					
<55	4 (5.8%)		20 (0.9%)	10 (0.5%)	34 (0.8%)
55-64	12 (17.4%)		288 (12.4%)	189 (9.4%)	489 (11.1%)
65-74	21 (30.4%)	1 (25%)	849 (36.5%)	718 (35.8%)	1589 (36%)
≥75	32 (46.4%)	3 (75%)	1171 (50.3%)	1090 (54.3%)	2296 (52.1%)
Gender					
Male	16 (23.2%)		380 (16.3%)	289 (14.4%)	685 (15.5%)
Female	53 (76.8%)	4 (100%)	1948 (83.7%)	1718 (85.6%)	3723 (84.5%)
ASA score*					
ASA 1	1 (1.6%)		44 (2.3%)	39 (2.4%)	84 (2.3%)
ASA 2	24 (39.3%)		702 (36.7%)	598 (37.2%)	1324 (36.9%)
ASA 3	35 (57.4%)	2 (100%)	1071 (55.9%)	879 (54.7%)	1987 (55.4%)
ASA 4	1 (1.6%)		98 (5.1%)	91 (5.7%)	190 (5.3%)
BMI category†					
Underweight (<18.50)			21 (1.7%)	30 (3%)	51 (2.2%)
Normal (18.50-24.99)	15 (26.8%)		286 (22.5%)	239 (23.6%)	540 (23.1%)
Pre obese (25.00-29.99)	18 (32.1%)	1 (50%)	421 (33.1%)	321 (31.7%)	761 (32.5%)
Obese class 1 (30.00-34.99)	14 (25%)		288 (22.7%)	237 (23.4%)	539 (23%)
Obese class 2 (35.00-39.99)	4 (7.1%)		140 (11%)	106 (10.5%)	250 (10.7%)
Obese class 3 (≥40.00)	5 (8.9%)	1 (50%)	115 (9%)	79 (7.8%)	200 (8.5%)
Total	69	4	2328	2007	4408

SD, standard deviation; *IQR*, interquartile range; *ASA*, American Society of Anesthesiologists; *BMI*, Body Mass Index (kg/m^2).
*Excludes 823 procedures with unknown ASA, Score.
†Excludes 2067 procedures with unknown BMI, Category.

Oxford Shoulder Score (OSS), single assessment numeric evaluation (SANE) value, and date of final telephone follow-up for this study. This was a convenience sample and therefore no formal sample size calculations were performed.

Statistical analysis

Descriptive statistics were determined for both clinical outcome and patient-reported outcome datasets. Continuous variables were summarized using means and standard deviations (SD). Categorical variables were reported as frequencies and percentages.

The primary outcome was mortality following rTSA for primary diagnosis fracture using either cemented or cementless humeral stems. To address the fact that mortality is a patient-level outcome, only the first eligible procedure for each patient was included in the analyses of mortality. Time to death was summarized using Kaplan–Meier estimates of survivorship, with right-censoring of follow-up at closure of the database on December 31, 2022. The secondary outcome was revision for any reason following primary rTSA. Kaplan–Meier estimates were used to summarize the time to 1st revision, with censoring at the time of death and closure of the database. Pointwise 95% confidence intervals (CI) for the cumulative percent survival and cumulative percent revision were calculated using unadjusted Greenwood estimates for the standard error.

Hazard ratios (HR) comparing mortality and revision rates between cemented and cementless stems were estimated using Cox proportional hazards models, adjusting for patient age and gender at the time of the index procedure. The proportional hazards assumption was checked analytically for all models through the addition of an interaction between the fixation used (cemented or cementless) and the log of time. In all models considered, this term was not significant at the 5% level, and as a result, time-varying models were not fitted. In this study, HRs are therefore reported for the entire time period. All tests were two-tailed at 5% levels of significant, with analysis performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

For the Royal Perth cohort, differences between cemented and cementless cohorts were compared. Categorical data were compared using Fisher's exact tests due to low numbers of revisions and mortality. Statistical analyses were completed using R Statistical Package (R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 4335 rTSA procedures were included in the national, cross-sectional analysis with 54% utilizing cementless humeral stems (Table I). Cementless humeral stems were more often used in female patients than male patients; however, age groups were similar between cemented and cementless stems (Table I) There was no statistically significant difference in mortality between cemented and cementless humeral stems (Fig. 1). The Kaplane-Meier estimates for mortality at 1 year, 3 years, and 9 years for cementless humeral stems were 96.9% (CI: 96.1%-97.5%), 89.4% (CI: 88.1%-90.6%), and 58.9% (CI: 55.6%-62.1%), respectively. For cemented humeral stems, the estimates for mortality at 1 year, 3 years, and 9 years were 96.5% (CI: 95.6%-97.2%), 88.2% (CI: 86.7%-89.6%), and 56.2% (CI: 52.9%-59.4%), respectively. A total of 204 revisions occurred during the study period (Table II). While the revision rates for cemented vs. cementless humeral stems for rTSA were higher in cementless stems, this did not reach statistical

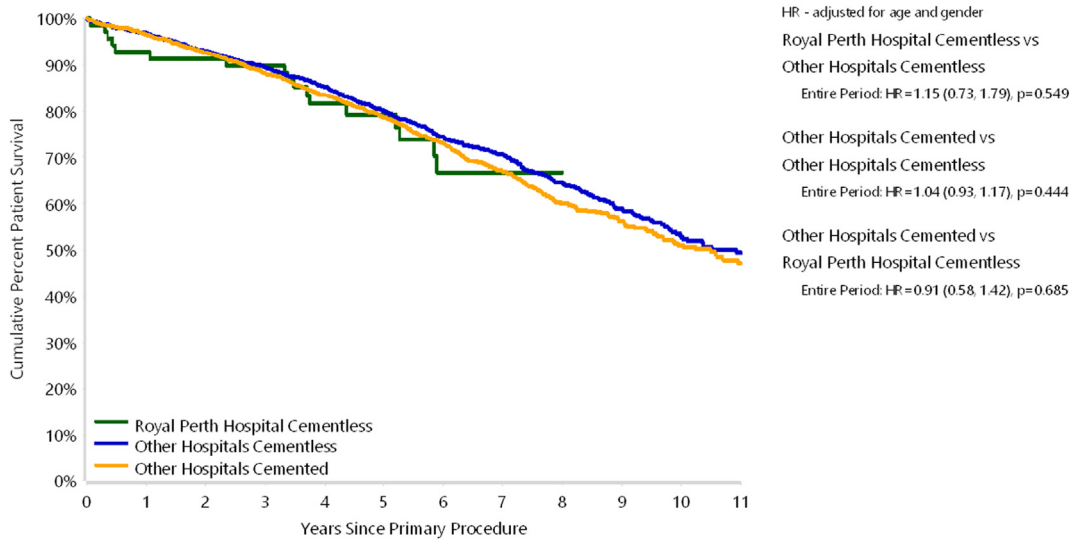

Figure 1 Cumulative percent survival of patients with primary total reverse total shoulder replacement performed between 1 January 2010 and 1 January 2020 in patients aged >50 Years by hospital and humeral fixation (primary diagnosis fracture).

Table II
Revised number of primary total reverse total shoulder replacement performed between 1 January 2010 and 1 January 2020 in patients aged >50 Years by hospital and humeral fixation (primary diagnosis fracture).

Hospital	Humeral fixation	N Revised	N Total
RPH	Cementless	2	68
	Cemented	0	4
Other hospitals	Cementless	115	2328
	Cemented	74	2005
Total		**191**	**4405**

RPH, Royal Perth Hospital.

significance ($P = .135$; Fig. 2). The top 3 reasons for revision for both cemented and cementless stems were instability or dislocation, followed by infection and then fracture (Fig. 3).

PROMs

Patient demographics for the PROMs cohort from the tertiary major trauma center are detailed in Table III and the patient recruitment flowchart detailed in Fig. 4. Between 01 January 2010 and 10 February 2021, there were 83 patients who underwent rTSA for proximal humerus fractures at RPH. Of these, 4 (4.8%) were cemented and 79 (95.2%) were cementless. Fourteen patients had died by follow-up, 26 were lost to follow-up, 5 declined participation, and 3 met the exclusion criteria (Fig. 4). The median time to follow-up was 183 weeks (interquartile range: 153-295 weeks). Two patients underwent revision for their rTSA, one of whom had a cemented stem and the other had a cementless stem. Both revisions were for infection. There was no statistical difference in revision risk ($P = .09$) or mortality ($P = .53$) between fixation types. Thirty-five patients were subsequently included in the PROMs arm of the study (Fig. 4). Overall, the PROMs cohort was younger, with a higher proportion of males than the overall national cohort (median age: 73 (interquartile range: 64-77) years vs. 75 (interquartile range: 69-81) years; proportion of males: 29% vs. 16%). Only 1 of the cemented rTSA had data collected on PROMs, and subsequently, they were excluded in the overall analysis. Exclusion of the cemented rTSA PROMs did not alter the mean scores of the total PROMs cohort. The mean scores for each functional outcome were as follows: ASES score of 65.9 (CI: 60.6-71.2), OSS of 34.6 (CI: 31.9-37.2), and SANE value of 68.8 (CI: 61.8-75.8).

Discussion

The most pertinent finding from the present project was that there is no statistically significant difference in revision rate between cemented and cementless humeral stems in rTSA for proximal humerus fractures. Furthermore, there is no statistically significant difference in mortality between cemented and cementless stems. We observed functional outcome scores comparable to those seen in previous studies for cemented and cementless stems for proximal humerus fractures.

Results from this study indicated no difference in revision rates between cemented and cementless rTSA in the national cohort. Furthermore, there was no difference between the national cohort and the RPH cohort in revision rate, despite a significant difference in the proportion of cementless vs. cemented rTSA. Only 2 patients (2.4%) in the RPH cohort underwent a revision-the indication for both revisions was infection. These observations are in keeping with the findings of a recent meta-analysis of 41 studies reporting reoperation rates by Rossi et al. who found no difference between cemented and cementless stems in proximal humerus fractures.[14] A Norwegian registry analysis for shoulder arthroplasties for all indications found no difference in revision rates for rTSA for any indication, including fractures.[5] Fixation did not influence revision rates, although it should be noted that there was a limited sample size.[5]

The data from the AOANJRR demonstrates that the choice to use cemented or cementless stems may be highly influenced by the choice of stem. The cementless SMR stem used in the present study has good diaphyseal fixation and is not reliant on metaphyseal fixation. This is important in proximal humerus fractures where metaphyseal fixation is often not possible. The AOANJRR annual report identified that SMR stems in proximal humerus fractures are ~7 times more likely to be cementless (1434 cementless vs. 217 cemented).[16] Looking at the next most used stem, Delta XTend (Depuy) shows the opposite trend (1190 cemented vs. 213 cementless). The Aequalis stem (Tornier) is ~15 times more likely to be cemented (1107 cemented vs. 60 cementless). Additionally, patient factors, such as body mass index, implant variations, including humeral fracture

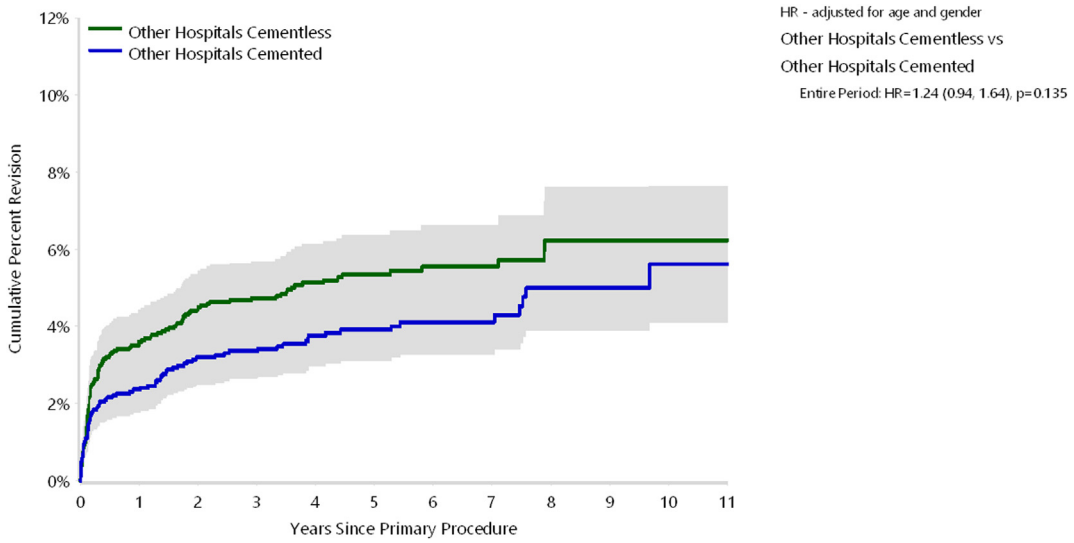

Figure 2 Cumulative percent revision of primary total reverse total shoulder replacement performed between 1 January 2010 and 1 January 2020 in patients aged >50 Years from hospitals other than Royal Perth hospital by humeral fixation (primary diagnosis fracture).

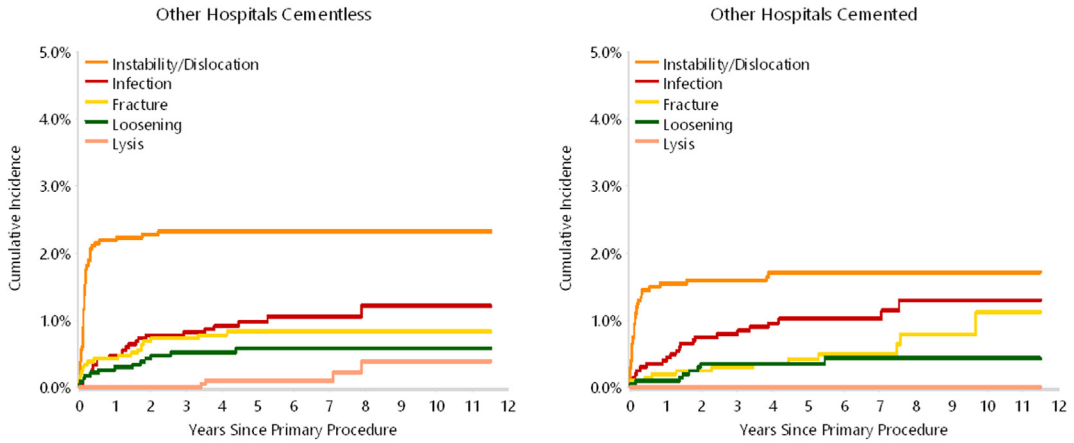

Figure 3 Reasons for revision for cemented and cementless reverse total shoulder arthroplasty performed between 1 January 2010 and 1 January 2020 in patients aged >50 Years from hospitals other than Royal Perth hospital by humeral fixation (primary diagnosis fracture).

Table III
Demographics, revision rates, mortality and patient-reported outcome measures between fixation types of patients with reverse shoulder arthroplasty from Royal Perth hospital.

Variable	Total	PROMs cohort
Age		
Median (IQR)	74 (66, 81)	73 (64, 77)
Range	47-91	47-85
Gender		
Male	23 (27%)	10 (29%)
Female	62 (73%)	25 (71%)
Revision	2 (2.4%)	0
Mortality	14 (17%)	-
ASES		
Mean (95% CI)	-	65.9 (61-70.8)
OSS		
Mean (95% CI)	-	34.6 (31.2-36.2)
SANE		
Mean (95% CI)	-	68.8 (59.1-72.6)
Total	83	35

PROMs, Patient-Reported Outcome Measures; *IQR*, Interquartile Range; *ASES*, American Shoulder and Elbow Surgeons score; *CI*, Confidence Interval; *OSS*, Oxford Shoulder Score; *SANE*, Single Assessment Numerical Evaluation.

stems, and humeral head size have been associated with the revision rate.[16] This should be considered when interpreting this study.

Surgeons may be selective about cementing, choosing to use cement in the more elderly osteoporotic bone, as is often the case in hip replacements. The importance of including the single hospital data where more than 95% of cases were cementless is to demonstrate that in proximal humerus fractures, cementless is an option for all comers. The cemented prostheses in this series were implanted by a predominantly lower limb surgeon, who may have been influenced by the trends in lower limb arthroplasty.

The current study showed no difference in mortality between cemented and cementless rTSA. Studies investigating mortality after reverse shoulder arthroplasty are limited. Amundsen et al. performed an analysis of the Danish Shoulder Arthroplasty Registry of mortality for all types of shoulder arthroplasties for all indications.[2] While fracture patients had a 6-fold higher risk of mortality within 30 days, most patients received stemmed hemiarthroplasties, and subgroup analyses were not performed.[2] Similarly, in a case series performed by Dacombe et al. in the United

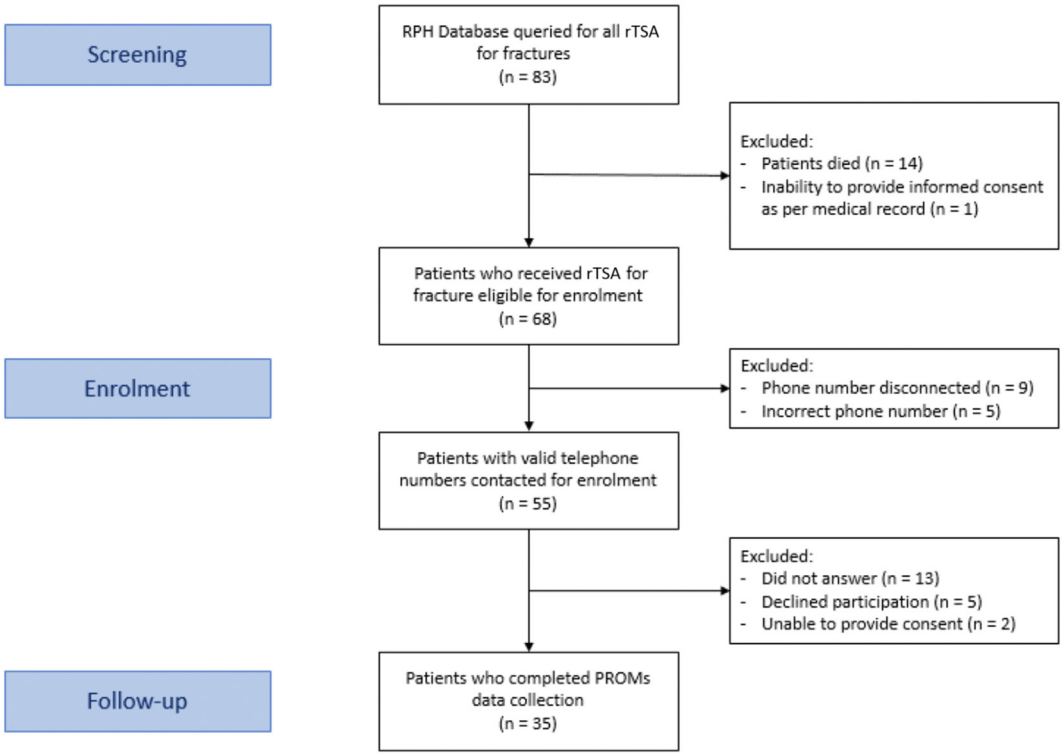

Figure 4 Flowchart of patient recruitment for patient-reported outcomes from a single level 1 major trauma center. *RPH*, Royal Perth Hospital; *PROMs*, patient-reported outcome measures; *rTSA*, reverse total shoulder arthroplasty.

Kingdom, trauma was associated with an increased hazard ratio for mortality, although only 45% of their patients received rTSA.[4] A recent American single-center study investigating survivorship for all indications conducted in the Florida, United States, observed increased odds of mortality at 1 year with the use of a cemented stem and use of a cemented stem noted to be an independent predictor of mortality.[1] The authors stated that increased mortality risk for cemented stems may have been secondary to selection bias, as cemented stems were only routinely used in frail patients with poor bone stock.[1] Taken together, the results for revision rates and mortality from the present study coupled with the existing literature suggest that cementless stems for rTSA may be a reasonable first-line option for proximal humerus fractures with adequate bone stock. Further high-powered cohort studies and randomized control trials are warranted to provide top-tier evidence of revision and mortality rates between cemented and cementless stems for rTSA.

Studies have looked at various PROMS, following rTSA for proximal humerus fracture. In a recent systematic review and meta-analysis, cemented humeral stems for rTSA for proximal humerus fractures had a mean ASES score of 73.9, while cementless humeral stems had a mean ASES score of 82.9.[14] A British cohort recorded a mean OSS of 38 for cementless rTSA for proximal humeral fractures two years postoperation.[3] Youn et al. noted a mean ASES score of 75.9 and OSS of 42.5 in a New Zealand cohort of 20 patients who received rTSA for proximal humerus fractures.[22] Lo et al. recorded postoperative ASES scores of 91 and SANE scores of 89 for 43 patients in Texas, USA.[9] In a study on 30 patients from a level 1 trauma center in Michigan, USA, ASES scores were 82.0, with a mean pain rating of 0.8 postoperatively.[20] More recently, Rossi et al. found an ASES score of 73 and a SANE score of 76 in 35 patients with cementless rTSA performed in Argentina.[13] The PROMs observed in the present study are lower than scores in other studies. Reasons for this difference in PROMs are unclear but may be related to the high comorbidity of this series with 60% American Society of Anesthesiologists's 3 or higher. Of note, our PROMs cohort only captured 1.5% of patients of the cementless rTSA national cohort and a single-cemented rTSA patient. Caution should be exercised when extending these findings to the general cementless rTSA cohort. Furthermore, more data of PROMs on the cemented rTSA cohort are required to better understand the effect of cement use on PROMs in proximal humerus fractures. The mode of administration of the PROM questionnaire may have had an effect. A pilot study investigating the PROMs in the AOANJRR cohort found no difference between electronic capture methods and telephone follow-up for total hip or total knee arthroplasty; however, for shoulder arthroplasty, electronic responders reported higher pain scores than telephone responders.[8]

We acknowledge the limitations of this study. As the first part of this study was registry-based, registry data may be biased by residual confounding and selection bias insofar as the decision for the use of bone cement may be influenced by surgeon preference, implant, or patient factors that were not captured by the registry. Therefore, caution should be exercised when interpreting these results without the full clinical context. Secondly, this paper is limited by the period during which theory regarding rTSA for proximal humerus fractures has changed. Developments in patient selection, and implant theory and design may prove to be additional confounders to the data from the national cohort used in this study. Thresholds for revision of rTSA are not well-established in the population of interest. While reasons for revision were provided, neither dataset provided granularity on the decision-making process for revisions. In the PROMs portion of the study, this study was limited by a small sample size, with significant attrition due to mortality and loss to follow-up. It also used a single-implant design, so findings may not be extended to other prostheses.

Conclusion

This study demonstrates that mortality and revision rates are similar between cemented and cementless humeral stems used for rTSA in proximal humerus fractures. Cementless humeral stems in rTSA for proximal humerus fractures may be an acceptable first-line treatment for patients with adequate bone stock.

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jseint.2024.09.023.

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