How long does a shoulder replacement last? A systematic review and meta-analysis of case-series and national registry reports with more than 10 years of follow-up

Jonathan P Evans MD[1,2], Jonathan T Evans MD[3], Richard S Craig FRCS (T&O)[4,5], Hasan R Mohammad MRes[4,5], Adrian Sayers MSc[3], Prof Ashley W Blom PhD[3,6], Michael R Whitehouse PhD[3,6], Prof Jonathan L Rees MD[4,5]

1. Health & Policy Research Group, University of Exeter, Exeter, EX1 2LU, UK
2. National Institute for Health Research Applied Research Collaboration South West Peninsula, University of Exeter, Exeter, EX1 2LU, UK
3. Musculoskeletal Research Unit, Translational Health Sciences, Bristol Medical School, 1st Floor Learning & Research Building, Southmead Hospital, Bristol, BS10 5NB, UK
4. Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Botnar Research Centre, Oxford, OX3 7LD, UK
5. National Institute for Health Research Oxford Biomedical Research Centre, Oxford, OX3 7LD, UK
6. National Institute for Health Research Bristol Biomedical Research Centre, University Hospitals Bristol NHS Foundation Trust and University of Bristol, Bristol, BS10 5NB, UK

Correspondence to:

Mr Jonathan Peter Evans

Health & Policy Research Group, University of Exeter, Exeter, EX1 2LU, UK

j.p.evans2@exeter.ac.uk

Panel: Research in context

Evidence before this study

Survival of shoulder replacements has often been reported in small case-series, with some follow-up extending beyond 20 years, however individual case-series are prone to bias and reporting has been highly heterogeneous. We searched MEDLINE and Embase for systematic reviews and meta-analyses of shoulder replacement series that were published in English. Of the 37 systematic reviews we identified, no articles reported combined survival estimates or patient reported outcome measures with more than 10 years follow-up. A previous analysis of the UK Hospital Episode Statistics (HES) dataset, published in 2019, combined all types of shoulder implants and found overall survival to be 90·0% (95% CI 89·6% to 90·3%) at 10 years. No study to date has attempted to provide pooled survival estimates and pooled patient reported outcomes for shoulder replacements more than 10 years after surgery.

Added value of this study

To our knowledge, we provide the first pooled survival estimate, drawn from multiple sources, for shoulder replacements at 10 years. We have also shown that shoulder replacements have a sustained positive impact on patients' lives to 10 years after surgery. Our findings showed that approximately 92% of total shoulder replacements, 91% of shoulder humeral hemiarthroplasties and 94% of reverse total shoulder replacements last for 10 years.

Implications of all the available evidence

Our findings provide valuable and overdue information for patients and clinicians considering shoulder replacement surgery. It is the first study to provide a simple and generalizable answer to two very important questions: "How long does a shoulder replacement last?" and "Will my shoulder be better in the long-term after surgery?" The data will also be useful for those commissioning healthcare services.

Abstract

Background

Shoulder replacement is an increasingly common treatment for end-stage degenerative shoulder conditions. Some shoulder replacements will fail and further operations may be required. It is important for patients and clinicians to know how long shoulder replacements last and how effectively they improve pain and function. This study aims to determine the longevity and long-term efficacy of shoulder replacements.

Methods

In this systematic review and meta-analysis, we searched MEDLINE and Embase for articles reporting 10-year or greater survival of Total Shoulder Replacements (TSR), Humeral Hemiarthroplasties (HA) and Reverse Total Shoulder Replacements (RTSR). Survival, implant and Patient Reported Outcome Measures (PROMs) data were extracted. National joint replacement registries were reviewed and analysed separately. We weighted each series and calculated a pooled survival estimate at 10, 15 and 20 years. For PROMs we pooled the Standardised Mean Difference (SMD) at 10 years.

Findings

We identified 10 series reporting all-cause survival of 529 TSRs and 420 HA, no series for RTSR met our inclusion criteria. The estimated 10-year survival for TSR was 95·6% (95% CI 93·6, 97·6) and HA 90·4% (95% CI 87·0, 94·0). A single registry contributed 7941 TSRs, 3495 HAs and 8049 RTSRs. The pooled registry 10-year survival for TSR was 92·0% (95% CI 91·0, 93·0), HA 90·5% (95% CI 81·8, 95·1) and RTSR 94·4% (95% CI 93·1, 95·7) for osteoarthritis and 93·6% (95% CI 91·0, 95·4) for rotator cuff arthropathy. Pooled 10-year PROMs revealed a substantial improvement from baseline scores (SMD 2·13 95% CI 1·93, 2·34).

Interpretation

Over 90% of shoulder replacements last more than 10 years and patient reported benefits are sustained. This long overdue information will be of use to patients and health-care providers.

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Introduction

Patients with severe pain and disability from degenerative shoulder conditions want to know whether they will benefit from shoulder replacement surgery, which type of replacement may be best and what they can expect in the long-term following surgery.[1] A review of seven national arthroplasty registers in 2017 suggested there has been a secular increase in the number of shoulder replacements performed for patients with both osteoarthritis and rotator cuff tear arthropathy. Overall the annual incidence rate has increased 2.8 fold in the last decade, but significant variation exists between countries.[2] There is a paucity of high quality outcome data to aid joint decision making by patients and clinicians, and to assist both commissioners and providers in understanding the utility and likely revision burden associated with undertaking these procedures.

Available randomised controlled trials (RCTs) are particularly limited, by size and design, in their ability to evaluate the longer-term outcomes and risks of primary shoulder arthroplasty, in particular the requirement for revision surgery.[3] To better understand the long-term benefits and risks of shoulder replacement surgery for these patients, a formal appraisal and synthesis of the more frequently available non-randomised study data is needed.

Ideally, clinicians and surgeons should be able to provide patients with contemporary condition-, age- and implant-specific outcome data for any proposed procedure and available alternatives. While implant manufacturers do facilitate the collection of implant-level data in order to gain relevant benchmark accreditation,[4] detailed and reliable data are not yet available for shoulders. Until such granular brand-level information is available, clinicians and patients need accurate information on classes of available implants. Hip and knee replacement have shown that although there is variation between brands, classes of implants behave in broadly similar fashion.[5,6] The three main constructs or classes available and referred to in this study are conventional total shoulder replacement (TSR), humeral hemiarthroplasty (HA), and reverse total shoulder replacement (RTSR). There is likely to be heterogeneity between indications for surgery, mechanisms of failure and overall revision rates between these different constructs.[7]

In this study we sought to answer a simple but important question posed by all patients: How long does a shoulder replacement last? We aimed to provide the best quality pooled estimates of implant survival at a minimum 10 years' follow-up. The decision to revise a poorly performing shoulder replacement is multifactorial that may be sensitive to both patient and surgeon preferences. Therefore, we also aimed to make a pooled estimate of the likely patient reported outcome at long-term follow-up, in essence to answer the question: Will my shoulder be better 10 years after surgery?

Methods

Search strategy and selection criteria

We conducted a systematic review and meta-analysis assessing the survival of shoulder replacements in case-series and national joint registries following a predefined protocol registered with PROSPERO (CRD42019140221) and complying with PRISMA guidelines.[8]

A search strategy using keywords and MeSH terms relating to shoulder replacement and survival (appendix 1) was used in the databases MEDLINE and Embase accessed through OVID Silver Platter. The databases were searched from their commencement to 24th September 2019. The strategy development was guided by previously published search strategies exploring the survival of hip and knee replacements.[9,10] Manual screening of the bibliographies of the full-text articles and systematic reviews was also undertaken.

Studies were included if they assessed patients who had undergone any type of shoulder replacement (a total shoulder replacement (TSR), humeral hemiarthroplasty (HA) or reverse total shoulder replacement (RTSR)). Humeral components (stemmed, stemless or resurfacing) were all considered as TSR or HA dependent on whether the glenoid (shoulder socket) was replaced or not and not sub-classified. The indication (reason) for surgery had to be predominantly osteoarthritis (OA) or rotator cuff arthropathy (RTCA). For inclusion, the case-series or published registry report had to report the survival of a specific brand of implant with a mean or median follow-up of greater than 10 years. It is widely accepted that survival of hip arthroplasties varies by the brand of implant.[5] Although this has not specifically been assessed in shoulder replacements, the technique of treating each brand as its own series was utilised as variation in survival by brand exists in hip and knee replacements, therefore the assumption would seem sensible for shoulder replacements as well. Weighting of implants in the meta-analysis would therefore provide the most robust survival estimates. This allows us to treat each series as an individual study and weight the meta-analysis of survival results according to the standard error of each series. Aggregate data from multiple implant brands would not allow this granularity and thus hide the potential variability in performance between implant brands. A cut-off of minimum mean or median follow-up of 10 years was chosen as the subject of interest of this study was "long-term" survival, where there is a current paucity of information. We accept this definition may vary subjectively but 10 years allowed inclusion of sufficient studies to make analyses robust and represents a time period that is relatable to patients and clinicians.

Studies were excluded if they reported the outcome of revision surgery, as this is often more complex surgery and carries different survivorship. Conference abstracts were excluded due to the limited data available from these reports. Systematic reviews were assessed for their citations but did not include their pooled data to avoid duplication.

The reports from all available national joint registers that collect and publish the individual implant-specific survivorship for shoulder replacements with at least 10-years of follow-up were assessed. Reports were identified through the systematic search if published or accessed through their websites.

Article screening and data extraction

Screening was undertaken in a stepwise manner using the web application Rayyan.[11] Journal article titles and abstracts were screened by two reviewers (JTE and HM) with arbitration of conflict undertaken by JPE. Full-text review and data extraction were undertaken by two reviewers independently (JPE and JTE). Data extracted were: publication date, baseline population demographics, number of patients (n), surgical indication proportion (% OA and/or % RCTA), follow-up duration (>10 years), implant name and construct type (TSA, HA or RTSA), loss to follow-up, survival estimates (including CIs) and all available Patient Reported Outcome Measure (PROM) (e.g. Visual Analogue Scales (VAS), Constant score, Disabilities of the Arm, Shoulder and Hand (DASH)), data (outcome measure used baseline mean score (SD), follow-up duration in 5 year increments, follow-up mean score (SD)). Data were not extracted from figures (e.g. Kaplan Meier plots) to avoid potential transcription inaccuracy. Discrepancy in extracted data was discussed by the authors, following which there were no cases of disagreement.

Statistical Analysis

For the assessment of the published case-series our primary exposure was the shoulder replacement implant and our primary outcome was all-cause revision, of any part of this construct, as guided by our patient group.[12] Statistical analysis was performed with Stata 15 (*Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC). Survival estimates, assuming that survivorship approximated revision risk, were pooled by meta-analysis. Each series was weighted according to its standard error (calculated from published confidence intervals). The effect size (Standardised Mean Difference (SMD)) of the primary PROMs reported in each study was pooled with meta-analysis with weighting according to sample size and analysed using a random effects model as a more conservative estimate of treatment effect. Effect size was considered small if it was less than ≥0·2, moderate if ≥0·5 and large if ≥0·8.[13]

Quality assessment

Study quality was assessed using the non-summative four-point system (consecutive cases, multi-centre, under 20% loss to follow-up and use of multivariable analysis) developed by Wylde et al.[14] This was selected in preference to the summative MINORS score due to the high loss to follow-up in joint replacement case-series and because some of the scoring criteria in MINORS were not relevant to joint replacement.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. All authors had access to the raw data. The corresponding author had full access to all of the data and the final responsibility to submit for publication

Results

The search of published case-series produced 1,376 articles. Of these, 449 duplicates were removed, leaving 927 articles for screening (figure 1). After screening, 36 full-text articles were reviewed. Additional citation searches through previously published systematic review references yielded four further full-text reviews, none of which met the inclusion criteria. Following review of full-text articles, nine articles reporting 10 individual implant specific series were included in the survival analysis, six articles that reported both survival analysis and PROMs were included in the PROMs analysis. A summary of study level characteristics is provided in Table 1. The proportion of OA as the primary surgical indication was 59% for TSR and 48% for HA. The reporting of indication was variable and was interpretable in only seven articles.

Quality assessment revealed that six (60%) of the 10 series were consecutive, two (20%) were multicenter, nine (90%) had >80% follow-up (with mean loss to follow up of 8.4%, ranging from 0% to 23.7%),and none undertook multivariable analysis. These proportions are in keeping with the fact that the quality of published case-series is low.

Case-series

Six unique series, published between 1998 – 2015, reported survival of 529 total shoulder replacements (TSR) at 13 time points with follow-up ranging from 10 to 21 years (Appendix 2).[15–21] Four reported survival at exactly 10 years (466 TSRs), three reported survival at 15 years (427 TSRs) and one reported survival at 20 years (19 TSRs). Pooled survival from those studies reporting at exactly 10 years was 95·6% (95% CI 93·6, 97·6) at 15 years 88·5% (95% CI 83·4, 94·1) and at 20 years 83·2% (95% CI 70·5, 97·8) (figure 2). When studies reported survival estimates at between 10 and 15 years, these results were rounded down to 10 years as a sensitivity analysis. This resulted in a pooled survival of six series (529 TSRs) of 90·0% (95% CI 88·3, 91·7) (figure 3).

Four unique series, published between 1998 – 2017, reported survival of 364 shoulder humeral hemiarthroplasties (HAs) at 10 time points with follow-up ranging from 10 to 21 years (Appendix 2).[16,18,21–23] Three reported survival at exactly 10 years (327 HAs), two at 15 years (151 HAs) and one at 20 years

(56 HAs). Pooled survival at exactly 10 years was 90·4% (95% CI 87·0, 94·0), at 15 years 90·6% (95% CI 84·1, 97·1), and at 20 years 75·6% (95% CI 65·9, 86·5) (figure 2). Rounding down of reported survival from those series closest to >10 but <15 years resulted in a pooled survival of four series (364 HAs) of 92·5% (95% CI 89·6, 95·3) (figure 3).

No unique single implant series with a mean follow-up of at least 10 years were found for reverse total shoulder replacements (RTSA).

Registry data

The reports of implant-level data at 10 years were only available from a single registry, the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) 2019 annual report.[24] This report yielded 10-year survival of eight series of TSRs (7,941 arthroplasties), eight series of HAs (3,495 arthroplasties) and five series of RTSRs (8,049 arthroplasties). Pooled survival estimates from registry data for TSRs at 10 years were 92·0% (95% CI 91·0, 93·0); for HAs 90.5% (95% 81·8, 95·1) and for RTSR were 94·4% (95% CI 93·1, 95·7) for a primary diagnosis of OA, and 93·6% (95% CI 91·0, 95·4) for a diagnosis of RTCA (single implant reported) (figure 4).

Patient Reported Outcome Measures

Of the 14 studies reporting survival analysis, six reported the implant level PROMs of 617 shoulder replacements for inclusion in the PROMs meta-analysis; this included two studies not included in the survival meta-analysis, excluded as they did not report confidence intervals.[17,19,20,23,25,26] Four studies reported PROMs on TSR, one on RTSR and one on HA. All reported the outcome of shoulder-specific PROMs, without the addition of generic quality of life measures. Five studies reported the Constant score, one the simple shoulder test (SST) and one a four-point linear pain scale previously described by Neer.[27] Pooled PROMs data showed a large effect of improved outcome from baseline (SMD 2·13 95% CI 1·93, 2·34) (figure 5). Subgroup analysis of PROMs exclusively from TSRs reduced the effect size marginally (SMD 2·02 95% CI 1·86, 2·19). Implant-level 10-year PROMs were not published in any registry reports. The New Zealand registry report 10-year PROMs, which were categorised by construct only (TSR, HA, RTSR, Partial resurfacing of head). Although no baseline PROMs are available for comparison, at 10-years the Oxford Shoulder Score (OSS) mean for all implants was 39.1/48 (95% CI 38.4, 39.8), for TSA (n=335) 41.0/48 (40.0, 42.0), HA (n=104) 39.4/48 (37.7, 41.1), RTSR (n=104) 39.4 (37.7, 41.1).

Discussion

We found that 90% of shoulder replacements last for at least 10 years and that patients can expect a large and sustained improvement in their patient reported outcome measures.

The methodology used is one that has been previously applied successfully to hip and knee replacement,[9,10] with the production of simple and generalisable results. The application of this process to shoulder replacement proved more complex due to sparsity and heterogeneity of data and highlights why the study question has not previously been answered. However, despite these limitations, the data from both registries and case-series independently estimate the same results. This is encouraging and suggests that these case-series are not subject to selection and publication bias.

The methods applied in this study use an individual estimate for each implant series, which is then synthesised to provide single pooled construct estimate weighted according to the standard error. The implant has been shown to be fundamental to the survival outcome of hip and knee replacement and is likely to be just as important in shoulder replacement and each individual series should be considered as a different patient cohort.[5] We have used the individual estimates for each implant to synthesise a single pooled estimate, weighting the estimates according to standard error. This type of analysis, deriving an overall estimate according to how frequently each implant has been used, is unique to our study. This analysis is dependent upon case-series, and registries' reporting of implant level data, as the only method where the patterns of implant failure can be accounted for. .

Implant survival at more than 10 years was greater than 90% for both TSR and HA in the case-series data, and also in the Australian registry data. This finding is concordant with the limited number of extended survival reports using multi-implant cohorts, including the assessment of Hospital Episode Statistics (HES) data in England [28] of 90% (95%CI 89·6 - 90·3) in a combined arthroplasty cohort, and Mayo clinic registry data [29,30] of 90·2% (95% CI 88·7, 91·7) for TSR and 90·0% (95% CI 88·0, 92·0) for HA. This study found very limited extended case-series 20-year data, all from the Mayo group, with survival for TSRs of 83·2% and HAs 75·6%, which are lower than the HES report of 87·8% (95% CI 87·2, 88·4) at 18 years but comparable to the full Mayo Clinic registry of 81·4% (95% CI 78·4, 84·5) for TSR, but worse than the HA survival of 85·0% (95% CI 81·8, 88·4) at a 20 years, notably there is a younger age cohort in their HA case-series. It is notable that the demographic characteristics from the case-series and registry data are similar for the TSR group, and concordantly their survival rates are also comparable. For the HA group, the case-series data contain a more male dominated and younger population. All but one of the case-series report an average age of <60yrs, therefore the survival findings from case-series may lack generalisability.

For RTSR, there was an absence of any implant level data from case-series at more than 10 years. This is concerning as it is currently utilized in over 50% of shoulder replacements in the UK, Norway, Australia and New Zealand. [24,31–33] It is surprising that this change in practice has occurred so rapidly with such paucity of long-term outcome evidence, particularly after the well documented problems with the widespread adoption of unproven technology in joint replacement.[6] It is therefore reassuring that we have been able to assess survival of RTSR at 10 years using data synthesised from the Australian registry data which reveals a survival of 94·0% (95% CI 93·1, 95·7) for OA and 93·6% (95% CI 91·0, 95·4) for RTCA.

Of the studies that reported survival of shoulder replacements at a mean of >10 years, five did not include confidence intervals and could not be added to the meta-analysis, six reported the composite survival of cohorts that included multiple different implants. Addition of these data would have resulted in the inclusion of 1,482 arthroplasties, increasing the analysis cohort by >150%. Failure of individual components of the construct (e.g. the glenoid or humeral component in isolation) was also reported in a large series that was excluded from the meta-analysis owing to the absence of an all-cause construct survival estimate.[34] Although component-failure data are of interest, we would regard this as best reported as a secondary endpoint, with the all-cause 1-Kaplan Meier estimate as the most appropriate method of reporting survivorship, which should always include the number of shoulder replacements at risk at the time of reporting.[35]

As shoulder replacement registries may not provide long-term survival for some time to come, we remain somewhat reliant on case-series data. If these series are to reliably inform the surgical community of implants at risk, they must be transparently reported according to current guidance on the reporting of healthcare data.[36] As novel implants and techniques are developed, we will also continue to be reliant upon case-series to highlight potential improvements in survivorship and function.

This study has identified that at over 10 years from the primary intervention a large improvement (SMD 2·13) in PROMs scores was maintained. A linear transformation, making all scores interpretable from the Constant score scale, also demonstrates a mean change score of 40·4, which exceeds the minimal clinically reported difference (MCID) of 12·8 ± 2·5 points for TSR.[37] The authors recognise the concern regarding the validity of the Constant score, and suggest that future studies report PROMs with proven validity and responsiveness. The New Zealand registry provided the only published comparator of construct-level, but not implant level, PROMs data. At 10 years this was limited to 674 replacements. Their high OSS at 10 years (80% of total score) does suggest a sustained benefit of shoulder replacements. As the New Zealand registry does not provide baseline pre-operative scores, comparison of SMD could not be undertaken.

We echo the calls for consensus in outcome choice to facilitate synthesis of data. Initiatives that promote the use of core outcome sets include the Core Outcome Measures in Effectiveness Trials (COMET), Outcome Measures in Rheumatology (OMERACT) and the International Consortium for Health Outcome Measurement (ICHOM).[38–40] Furthermore, the inclusion of PROMs in registry data has the potential to dramatically improve the assessment of patient-focused outcomes. Currently, clear associations between survival of a shoulder implant and the patient-focused domains of pain, function and quality of life cannot be ascertained.

There are limitations of this work. The data did not allow stratification or adjustment for patient factors that may have affected outcomes in the pooled analysis. The analysis could not account for differing thresholds for revision between surgeons. It is notable that many of the historic series are derived from single-surgeon series and therefore surgeon preferences may alter the resultant weighted synthesis of survivorship. We also recognise that emergent techniques and implants may demonstrate superior (or inferior) survivorship and function that is yet to be demonstrated with long-term follow-up. The impact of historic series that have utilised implants subsequently recognised as having worse outcomes can affect a synthesis of long-term outcomes. The series from Levy et al [16] which included metal-backed glenoid components had a large weighting that reduced the overall survival estimate. Reporting early failure of certain implants is important and for the best available overall estimates should continue to be included. As not all failure results in revision, we reported patient-reported outcomes to better define the overall value of shoulder replacement. Our pooled registry results are drawn exclusively from the Australian register. As the available follow-up in other registries increases, a wealth of data will soon become available, and we would encourage implant level reporting by brand and product line. We also assumed that survival estimates are equivalent to risks for generating pooled estimates, and although the assumption that no censoring occurs (patients dying with a shoulder in situ) is violated, it provides a useful method of aggregation in the absence of individual patient data. The aggregated estimates of survival are however the largest possible sample and this is the largest report of this type and length of follow-up.

The strengths of this study include an inclusive and comprehensive design and realistic interpretation of survivorship that accounts for all revisions and not a limited or biased subset, as well as a patient outcome focus. From a patient perspective, all revision surgery carries risk and therefore all-cause revision should be considered.

Conclusion

By pooling survival from case-series and registry data, we have been able to provide a reliable estimate of 10-year survival rate of shoulder replacements. We found that over 90% of shoulder replacements last for at least 10 years. Patients experienced sustained and marked benefit to 10 years. This information should be reassuring for patients, health professionals and commissioners of health services.

Contributions

JPE and JTE were responsible for study concept, design, screening, data extraction, data analysis, and writing of this manuscript.

HM completed the primary screening of abstracts and review of the manuscript.

JR, AB, MRW, RC and AS were responsible for study concept, design, and writing of the manuscript.

Declaration of interests

We declare no competing interests.

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