**ABSTRACT**

**Background**

Outcomes of Reverse Total Shoulder Arthroplasty (RTSA) have typically been assessed using the same instruments as anatomical shoulder arthroplasties. However, to date there has been a lack of investigation with respect to the correlation of such scores and patient satisfaction in the RTSA population.

**Method**

The Oxford Shoulder Score (OSS) and Quick DASH (QD) were prospectively collected in 38 RTSA patients (41 shoulders) postoperatively. Scores were then evaluated to establish whether or not they correlated with patient satisfaction at a minimum of 1 year postoperatively.

**Results**

The correlation coefficient for the OSS and patient satisfaction was found to be 0.313 (p-value 0.011) and the correlation coefficient for the QD and patient satisfaction was -0.292 (p-value 0.017), showing a statistically significant, but moderately weak, relationship between the OSS and QD scores with patient satisfaction (P<0.05).

**Conclusion**

This study showed no strongly significant relationship between PROM scores and patient satisfaction following elective RTSA. These findings emphasise the need to question the appropriateness of standard PROM scores for the assessment of outcome and success following elective RTSA.

**INTRODUCTION**

The treatment of degenerative and traumatic shoulder arthritis in the presence of a functional rotator cuff (RC) has been successfully addressed with the use of anatomical joint replacement1. In the absence of a functional RC, as in rotator cuff tear arthropathy (RCTA), there is insufficient soft tissue constraint to counteract the subluxing effect of the deltoid muscle to allow satisfactory shoulder function2,3.Reversed Total Shoulder Arthroplasty (RTSA) aims to re-centre the arc of rotation of the gleno-humeral joint. Modern lateralised designs restore the glenoid-humeral relationship and the deltoid pulley improving stability and functional outcome but avoiding scapula notching that was problematic in the early prostheses1-4. Clinical studies evaluating the outcome of Reverse Total Shoulder Arthroplasty (RTSA) indicate that it has lived up to the biomechanical concept, with consistent successful restoration of range of movement (ROM) above ninety degrees of elevation and significant pain relief. External and internal rotations do however remain limited, resulting in continued difficulty with some functional activities2,4.

The aging population6, coupled with increasing indications for RTSA have meant that the procedure now accounts for a large proportion of all shoulder replacements performed in Europe and the United States of America (USA)5,7,8. Irrespective of the indication for surgery the primary goal of RTSA is usually pain relief, and in many cases on-going functional limitation is both expected and accepted23. Despite the significant differences in surgical procedure, prosthesis implant and expectation of outcome, RTSA is currently assessed in the same way as patients undergoing other types of shoulder arthroplasty surgery. Accordingly, questions have been raised regarding the suitability of this approach for this patient group.

 Most national joint registries (NJR’s) report the outcomes of arthroplasty surgery in terms of revision rates or formal survival analyses, and performance is based on revision as the end point23. Revision rate alone has however been demonstrated not to accurately reflect the success of surgery23,24. Methods to define a successful outcome following shoulder arthroplasty are subject to a degree of contention25 and increasing emphasis on the patient’s perspective has meant that they have had to evolve to encompass a broader definition of a satisfactory result23 ,26.

Patient reported Outcome measures (PROMs), are now commonly used in many health care settings27, and are often a stipulated requirement for healthcare commissioners. In the case of shoulder surgery region specific PROMs such as the Oxford shoulder Score and Quick-DASH score are commonly used alongside generic measures of satisfaction and health status. The degree to which subjective PROMs reflect objective findings and how well subjective and objective measures reflect patient satisfaction is yet to be established23, 25,28.

 PROMs questionnaires do not ask about a patient’s satisfaction with healthcare or seek their opinions about how successful their treatment was29. Some patients may continue to have functional limitations following surgery, which is reflected in a “poor” PROM score. However a patient’s expectation and acceptance of chronic functional limitations might mean that they are satisfied with the outcome and their surgery has been more successful than the PROM scores would suggest23. Patient satisfaction can provide the ultimate end-point to healthcare quality and is thus an essential part of quality assessment30,31,32.

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**AIMS OF THE STUDY**

The aim of this study was to evaluate the relationship between patient reported outcome measure scores and patient reported satisfaction following elective reverse total shoulder arthroplasty.

Null Hypothesis: there will be no positive relationship between PROM scores and patient reported satisfaction scores in patients following elective RTSA.

**METHOD OF INVESTIGATION**

 In order to address the study aims a non-experimental fixed design was used to measure the relationship between the variables OSS, QD and patient satisfaction scores (measured on a numerical rating scale (NRS)). In order to explore the relationship between the variables, data routinely collected at patients’ annual follow-up appointments was reviewed and then subjected to correlational statistics. The study evaluated outcomes of an existing service, without a reference standard and analysed data regarding an established intervention33.

The study used a sample of convenience, taking data from a consecutive patient cohort who all underwent RTSA surgery. When completing PROM scores patients were asked to complete a consent statement.

 Using National Research Ethics Service (NRES) guidance31 it was established that the study would be a service review and NRES approval was therefore not necessary. The study was registered with, and approved by, the local audit office, and permission was gained to go ahead.

 Data was routinely collected from consecutive patients who had shoulder arthroplasty surgery. Patients of four senior orthopaedic surgeons using the same, Exactech Equinoxe, prosthesis system (Exactech UK Ltd) were included. These patients were routinely reviewed annually in a dedicated shoulder arthroplasty review clinic, around the anniversary of their procedure, and standardised outcome scores were completed (OSS, QD and patient satisfaction NRS).

Patients were included if they had had a primary elective RTSR with greater than twelve months follow-up, and were over 65 years of age at the time of surgery. Patients who had revision procedures, were under 65, had not consented for their data to be used, or were not capable of proving consent, were excluded from the study, along with those who had procedures for acute trauma.

In order to ascertain the final data set for the study all of the existing data from the RTSA patient cohort, which had been collected from the commencement of the shoulder arthroplasty review clinic in February 2012 until February 2016, was reviewed. Individual patient data-sets that satisfied all of the inclusion criteria and also included a complete set of the required outcome measures at a single point in time were extracted from the database. 23, 35,36.

**STATISTICAL ANALYSIS**

The data was subjected to statistical analysis in order to establish if a significant correlational relationship existed between either of the absolute post-operative PROM scores (OSS or QD) and patient satisfaction score.

Statistical analysis of the data, to establish the strength and direction of any correlation between the variables, was completed with the guidance of a statistician from the University of Liverpool. The normality of numeric distribution of the three scores (satisfaction, OSS and QD) was examined via histograms. The scores were all found not to be normally distributed and were therefore subjected to various transformations, such as log and square root (QD) and quadratic and cube (OSS and patient satisfaction), to determine whether normality could be established35,37. Normality could not be established in any of the scores despite the transformations, therefore it was not possible to use the standard Pearson’s correlation coefficient for parametric data. Kendall’s tau-b correlation coefficient, which does not assume normal distribution of the data, was calculated to examine the relationships between OS and patient satisfaction and between QD and patient satisfaction. Kendall’s tau-b was chosen in preference to the more standard Spearman’s rank correlation coefficient due to the large number of tied ranks38.

In the case of all coefficients, a p-value was also calculated to determine statistical significance, P<0.05 was set as the guideline level to be considered statistically significant and disprove the null hypothesis. This level was selected because in the small sample this is likely to represent a significant change34,39.

**RESULTS**

 67 patients were identified who were more than 12 months post elective RTSA. Twelve patients were not eligible for the study because they’d had their surgery to revise a previous arthroplasty procedure and a further 7 were excluded because they were under 65 years of age at the time of surgery. Of the remaining 48 patients, 1 had refused to attend for post-operative follow-up, 3 had deceased prior to 12 month assessment and 1 had not yet attended for follow up. Five patients did not have a complete set of outcome scores. Of the remaining 38 patients 3 underwent bilateral RTSA. As each shoulder was assessed and scored separately both sets of data for these patients were included in the study. Complete data sets were available for 85% (41/48) of all eligible procedures.

 The indications for surgery according to diagnosis, of the included patients, are shown in Table 1.

 The age range for patients at the time of surgery was from 65 to 87 years (mean 74 years, median 73). 16 procedures (39%) were undertaken on males and 25 (61%) on females. The timescale for the post-operative review assessment ranged from 12 -37 months post-op (mean 24 months).

The OSS ranged from 16 to 48 (mean 36.63, standard deviation (SD) 9.8). The QD score ranged from 0 to 70.55 (mean 29.66, SD 20.84). The patient satisfaction scores ranged from 6 to 10 (mean 9.02, SD 1.172) (Figure 5). Patient satisfaction was scored on a numerical rating scale (NRS) with 0 representing completely unsatisfied and 10 representing completely satisfied.

 Using the Kendall-Tau B the correlation coefficient for the OSS and patient satisfaction was found to be 0.313 (p-value 0.011) and the correlation coefficient for the QD and patient satisfaction was -0.292 (p-value 0.017). There is a statistically significant relationship between the OSS (P<0.05) and patient satisfaction which is moderately weak in the positive direction. The relationship between the QD and patient satisfaction is also statistically significant (P<0.05), but moderately weak in the negative direction.

**LIMITATIONS AND STRENGTHS**

This study included a sample of convenience, nonetheless the employment of robust inclusion and exclusion criteria assured a clearly defined cohort. As such the study findings are applicable to this group and relevant to the local population, however, because of the sample selection method, they cannot be assumed to more widely represent outcomes for other patients following RTSA38.

The inclusion of patients with variable indications for surgery and comorbidities could confound the clarity of the findings. The small sample size may affect the accuracy of the study findings and preclude comparison to the broader population. The relatively short-term mean follow-up timescale also limits interpretation of the results in relation to long-term outcomes. Limiting the study to one treatment centre and one type of prosthesis has ensured a degree of consistency within the group, on the other hand this could be considered to be a further confounding factor when extrapolating findings to the wider patient population and we do not know how this particular prosthesis compares to others.

The NRS, used to measure patient satisfaction in this study, has been validated for reporting outcome of patients with various shoulder disorders as part of the Penn Shoulder Score; it was also found to have sufficient reliability and validity to be used in isolation40. Commonly used in clinical practice and research settings, the NRS is easily understood and quick to complete, resulting in high response rates. However the NRS has been criticised for being too simplistic to be able to accurately reflect the multifaceted nature of satisfaction41. It must be considered therefore that the limited relationship demonstrated between the PROM and satisfaction scores in this study could in part be due to an erroneous estimation of satisfaction based on an imperfect scoring system.

Standardised pre-op data was not available for this entire patient cohort, it was therefore not possible to compare change in the scores with satisfaction. The addition of a general health score such as the Euroqol or SF12 may also have added strength to the evaluation of patient outcome.

**DISCUSSION**

 The aim of this study was to evaluate the relationship between commonly used PROM scores and patient reported satisfaction following elective RTSA, with a view to increasing understanding of how these assessment methods reflect patient perceived outcome.

Currently there is no published data regarding the expected range for outcome scores such as the OSS and QD following RTSA. The mean OSS for the study cohort was 36.63; falling notably short when compared to the mean OSS (45.2) of an asymptomatic population over 65 years of age 43. Similarly the mean QD of 29.66 appears to be considerably inferior to that demonstrated in the general population over 60 years of age (mean 18.9) 44. Interpreting the mean PROM scores found in this study, by comparison to the general population reference, could infer that patient perceived outcome was poor. However, when considering the mean satisfaction score of the study population (9.02/10) an entirely contrasting and superior impression of success is deduced. This suggests that the PROM scores do not accurately reflect the success of the procedure as perceived by the patient.

The apparent disparity between PROM scores and satisfaction is reinforced by the results of correlation analysis. Although statistically significant, the correlations between both OSS and QD and patient satisfaction were only moderately weak. These results suggest that the patient’s perception of outcome represented by their own judgement of satisfaction does not closely align with that represented by the PROM scores. The implication of these findings is that these commonly used PROM scores may not be an appropriate method of outcome evaluation for this particular patient cohort. This highlights the need for further investigation into the most appropriate methods for assessing surgical success for RTSA.

The OSS and QD scores, both frequently used to assess RTSA outcomes, ask questions about general functional activities including tasks that are often impossible for patients with the pain and weakness associated with severe degenerative shoulder joint disease. Regardless of improvement in pain and ROM following RTSA these tasks may continue to be impossible or only possible with some degree of difficulty, as the amount of strength and movement required may not achievable. Comorbidities, which are not addressed by the surgical procedure, would also potentially continue to exert the same limitations on functional ability post-operatively as they did pre-operatively. In the presence of on-going functional difficulties a patient would still not necessarily achieve a “good” final outcome score, and possibly not have a great improvement in a score too, despite this they may still have what they consider to be a very satisfactory outcome. The PROM scores in this situation would fail to provide accurate information regarding the patient’s interpretation of the surgical outcome. These functional factors may account for the lack of correlation between PROMs and patient satisfaction. Future investigation of the correlation between change in PROMs (from pre to post-op) and satisfaction may add valuable insight to these considerations.

As concerns regarding the limitations in the application of PROM scores are raised it is also important to question the use of other outcome measures, such as patient satisfaction scores, which may well be disadvantaged by their own inadequacies25. Although it is has been argued that patient satisfaction is the ultimate objective of all healthcare intervention28, 45 there is little consensus on the best method for measuring it. To date there is a dearth of evidence for measuring satisfaction with orthopaedic intervention and no evidence to support any one method for measuring satisfaction in relation to shoulder arthroplasty surgery specifically. Nonetheless it could be argued that the NRS currently represents the most effective method for assessing satisfaction ( but not overall outcome) with shoulder surgery and was the best available option for this study. The NRS has been employed in recent literature examining the relationships between the various outcomes of shoulder arthroplasty25,42, reinforcing its relevance for utilisation in the current study. More recently Van Berckel et al (2017)46 have also found a similarly weak correlation between the QD and an NRS score of patient satisfaction.( Their study differed from this however in that the NRS was used to evaluate patient satisfaction with overall management rather than outcome as in the current study)46.

The findings of this study, which suggest a limited relationship between PROM scores and patient satisfaction, open a debate regarding the relevance of existing scores to RTSA. This is the first study to provide specific data examining the correlation between PROMs and patient satisfaction in the RTSA population. Due to the limitations of the study it is unable to answer all of the pertinent questions, but highlights issues for consideration. Further studies of this kind are required to firmly establish if existing outcome measures adequately reflect the patient’s perception and satisfaction with surgery. Prospective studies including larger patient cohorts, longer term follow-up, different age groups and indications for surgery would facilitate further clarification of the argument regarding the appropriateness of PROM scores for the assessment of RTSA.

In the current clinical and research contexts this study highlights the need to take great care when interpreting clinical scores and when planning studies of treatment effects. The routine use of PROMS in healthcare settings must be considered carefully if meaningful information is to be disseminated to patients and clinicians. There is an important risk with some patient groups, such as those undergoing RTSA, that outcomes data are liable to misinterpretation, resulting in misinformation, if the full context of expectations and outcomes are not properly understood.

**CONCLUSION**

The results of the study demonstrate that there is not a strong and significant relationship between PROM scores and patient satisfaction in a cohort of patients following RTSA. These findings suggest that in future PROM scores used for evaluating RTSA should be interpreted with caution. Further investigation is required to establish the methods of assessment that most accurately reflect the patient experience and offer a true representation of value and outcome.

**ACKNOWLEDGEMENTS**

The authors would like to acknowledge and thank the Consultant Orthopaedic Surgeons who operated on patients included in this study; Mr Matthew Smith, Mr Matthew Kent, Mr Inigo Guisasola and Mr Peter Brownson.

**DECLARATION OF CONFLICTS OF INTEREST**

The physiotherapy research fellowship held by Mrs Daw is financially supported by Exactech UK Ltd.

**FUNDING**

This work was supported by Exactech UK ltd: and Arthritis UK.

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