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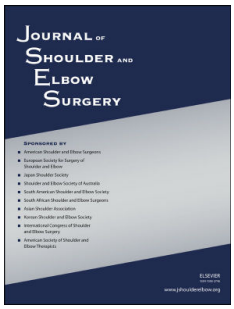

Patient Satisfaction and Clinical Outcomes of Reverse Shoulder Arthroplasty: A Minimum of 10 Years Follow-Up

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has received IP royalties/work as a consultant for Wright Medical Technology, Inc. He also works as a paid consultant, presenter, or speaker for DJ Orthopedics and Smith and Nephew and receives royalties from DJ Orthopedics. None of the commercial entities were involved in any aspect of the study. The other authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

The Texas Orthopedic Hospital's institutional review board approved this study (TOH145).

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Abstract

Background: Reverse shoulder arthroplasty (RSA) has been shown to reliably improve pain and functional outcomes for multiple pathologies. Despite its increasing utilization in the United States since its introduction in 2004, few studies have investigated long-term outcomes of this procedure. This information is vital in many ways, including durability of functional outcomes, complication profiles and implant survivorship.

Methods: Our prospectively collected shoulder arthroplasty registry included 471 patients who had undergone RSA prior to December 31, 2010 by a single surgeon at a high-volume shoulder arthroplasty center. The study sample included 94 patients with a minimum of 10 years follow-up, and we evaluated the indications for RSA, complications, pain, Single Assessment Numeric Evaluation (SANE), and patient satisfaction on these patients at baseline, 2-5 years, and 10 or more years of follow-up. Prosthesis survivorship was determined by Kaplan-Meier survival analysis performed with revision for any reason as the end point for all 471 patients in the study period regardless of follow-up interval.

Results: The 94 patients with at least 10 years of follow-up were 63% female (60) and 37% male (34), with an average age of 66±10 years at time of RSA. There were 71 (75%) primary RSAs and 23 (25%) revision RSAs. Patient-reported outcome measures at 10-years or more included a current pain rating averaging 2±3 on a 0 to 10 scale and Single Assessment Numeric Evaluation (SANE) of 73±28. There was no deterioration in function or pain from mid-term to long-term follow-up, as the SANE and pain score changed by less than the MCID or improved in 87 and 90% of patients, respectively. Overall, patients were satisfied with the RSA procedure with 52 (56%) very satisfied, 24 (26%) satisfied, 13 (14%) dissatisfied, and 4 (4%) very dissatisfied. For the subset of 68 patients that were contacted for follow-up, 64 (94%) would have the procedure again and 4 (6%) would not. Kaplan-Meier prosthesis survival rate for all 471 RSA patients was 88% (95% CI: 84-92%) at 5-years and 81% (95% CI: 74-86%) at 10-years.

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Conclusions: This study presents the largest American cohort of Grammont design RSA at a minimum 10-year follow-up. While RSA provided clinically significant and durable improvements in pain and function, the complication and revision rates were higher than prior reports. Despite this, the vast majority of patients were satisfied and would have the procedure again.

Level of evidence: Level IV; Case Series; Treatment Study
Keywords: reverse total shoulder arthroplasty; Clinical Outcomes; clinical decision; patient-reported outcome measures; patient satisfaction

Reverse shoulder arthroplasty was approved in the United States in 2004 for the treatment of cuff tear arthropathy (CTA). Since its introduction, RSA has been shown to reliably improve pain and functional outcomes for CTA and other shoulder pathologies.[1,5,7,8,10,18] Despite its increasing utilization,[11] few studies have investigated long-term clinical outcomes. To our knowledge, only two contemporary studies have published minimum 10-year results of RSA.[1,5] Long-term follow-up studies provide information vital to clinical decision making, including survivorship, complication profiles, and patient function.

The purpose of this study was to report patient-reported outcomes, satisfaction, complications, revisions, and prosthesis survivorship of RSA performed by a single, high-volume shoulder arthroplasty surgeon at a minimum of 10 years using a Grammont-design prosthesis.

Methods

Inclusion criteria

Patients were consented and enrolled in our prospective single-surgeon shoulder arthroplasty registry beginning in 2004. A retrospective review of the registry was performed to identify all patients who had undergone RSA for any diagnosis prior to December 31, 2010. A total of 472 patients were

identified in the registry and one patient was excluded because of a primary diagnosis of sarcoma necessitating resection and complex reconstruction with RSA.

Surgical technique and Postoperative Rehabilitation

The Aequalis Legacy and Legacy Long reverse shoulder arthroplasty systems were utilized (Tornier, Wright Medical, Memphis, TN, USA). These systems consist of a Grammont-design prosthesis with a medialized center of rotation and a 155^{o} neck-shaft angle. Our surgical techniques and postoperative rehabilitation protocols have been previously well described.[6]

Patient-reported outcome measures

Patients undergoing shoulder arthroplasty at our institution are asked to follow-up at yearly intervals. Patient-reported outcome measures, including the Single Assessment Numeric Evaluation (SANE), the Visual Analog Scale (VAS), and subjective patient satisfaction, are completed preoperatively and at each yearly clinic visit. In our sample of 471 patients, only 25 had completed the 10-year follow-up in the clinic. Prior to contacting patients, we searched national, state, and local mortality indexes and identified 225 patients as deceased, resulting in 221 patients needing follow-up. Contact information for the 221 patients needing follow-up was extracted from clinical and hospital medical records and each patient was called at their last known phone number. Since this follow-up was at least 10 years after RSA, many patients had moved or changed contact information since their last clinical visit. We used local and state databases to try and locate patients for follow-up when the contact information was incorrect. At least 3 attempts were made to contact each patient before they were considered lost to follow-up.

Upon successful contact with a patient, the patient was asked if they could return to the clinic. A standardized phone questionnaire was administered if the patient was unable to return to clinic. The standardized phone questionnaire consisted of a subset of 7 questions relating to shoulder pain and function following RSA (Table 1). Patients that returned to the clinic answered the subset of phone

questions within the standard registry questionnaires except question #6 as it was only administered to the phone group "If you had to go back and do the same surgery again, would you have the surgery?".

Statistical analysis

For patients with 10 years of follow-up or more, preoperative patient characteristics such as age at surgery, gender, and indication for RSA were evaluated and reported as mean, standard deviation, and range or counts and percentages as appropriate. Patient-reported outcome measures were compared at preoperative, early to mid-term (2-5 years), and final follow-up (>10 years) time points with linear mixed models; this analysis was performed for individual patients rather than using batched means at each time point. Prosthesis survivorship was determined by Kaplan-Meier survival analysis performed with revision (defined as removal or replacement of metal components) for any reason as the end point for all patients in the study period regardless of follow-up interval. All revisions after the initial procedure were included in the survivorship analysis for the first model and a second model excluded revisions due to trauma (i.e., fall or motor vehicle accident). Isolated polyethylene exchanges were not considered revisions. Patients with less than 10 years follow-up were censored according to their last clinic follow-up date; in other words, only the number of patients with documented implant survival to a date were included in the denominator of calculating survival. Analyses were completed with Stata release 15 (StataCorp LP, College Station, Texas) and statistical significance was defined as $P<.05$. Clinical significance was achieved when patient-reported outcome measures changed more than the published minimal clinically important difference (MCID).

Results

Ninety-four patients completed clinical or phone follow-up after RSA at an average of 11.4 years with a range of 10.0-15.7 years (Table 2). The study population was 63% female (59) and 37% male (34) with an average age of 66.4±9.6 years at time of RSA. RSA was the primary arthroplasty procedure for 70 (75%) patients and a revision procedure for 23 (25%). The most common indication for primary RSA

was cuff tear arthropathy (77%) followed by proximal humerus fracture (13%) (Table 3). The 23 revision patients had undergone anatomic TSA (7), hemiarthroplasty or bipolar hemiarthroplasty (11), or RSA (5) previously. There were no significant differences between primary and revision cases for age, gender, body mass index (BMI), and years of follow-up (all P>.05). However, a higher percentage of patients had primary RSA on the dominant shoulder, (66%) while only 35% of patients had revision RSA on the dominant shoulder (P=.009).

Patient-reported outcome measures

Patient-reported outcome measures significantly improved from preoperative, early to mid-term (2-5 years), and final follow-up (Figure 1). Pain, as measured by visual analog scale (VAS), decreased from 5.8±3.0 preoperatively, to 1.3±2.1 at 2-5 years (P<.001) and 2.0±2.7 at final follow-up (P<.001). The Single Assessment Numeric Evaluation (SANE) showed similar improvement with scores changing from 22.5±24.5 preoperatively, to 63.9±32.9 at 2-5 years follow-up (P<.001) and 73.3±28.2 at final follow-up (P<.001). When stratifying the sample by primary and revision cases, both patient groups were significantly improved at 2-5 years and final follow-up (all P<.001). Revision patients did not improve as much as primary patients, but this difference was small and non-significant for both pain and SANE (all P>.05).

All patients exceeded the minimal clinically important difference (MCID) score of 29 for SANE[9] and 1.4 for pain[17] when evaluating preoperative to final follow-up scores. MCID changes in outcome measures between the 2-5 year and 10-year follow-up periods occurred in a minority of patients as 64% changed less than the MCID between follow-up time points. For SANE, 23% of patients improved at or above the MCID between follow-up time periods and 13% reported deteriorating results while 26% of patients reported more pain (VAS) and 10% less pain (VAS) at the 10-year follow-up.

Patient satisfaction overall was high. Fifty-two (56%) patients were very satisfied, 24 (26%) satisfied, 13 (14%) dissatisfied, and 4 (4%) very dissatisfied. There were nine patients (10%) who were either very satisfied or satisfied at 2-5 years follow-up, and then later became dissatisfied or very

dissatisfied at 10-year follow-up. Of these patients, two patients were revised after 10 years (PJI and periprosthetic fracture), six had increased pain and one was unsatisfied with motion.

In the subset of 68 patients that were contacted by phone for follow-up, 64 (94%) would have the procedure again and 4 (6%) would not. The most frequent complaint at final follow-up was a lack of motion of their shoulder after the procedure.

Complications, Revisions and Prosthesis Survival

In this sample of primary and revision RSA patients, there were 64 complications in 60 patients after at least 10-years of follow-up (complication rate of 64%), and 48 patients (51%) required either a reoperation or component revision. Figure 2 illustrates the most common complications by postoperative time period.

In the primary RSA group, 41 of 71 patients (58%) had postoperative complications; 4 patients had multiple complications. They were, in order of frequency, dislocation (11), PJI (11), periprosthetic fracture (7), acromial stress fracture/reaction (5), aseptic baseplate loosening (4), subjective instability (defined as patients who felt that their shoulder was "clicking" or "near dislocating," and whose symptoms improved after a polyethylene exchange) (2), traumatic glenoid loosening (1), early superficial wound infection (1), hematoma (1), symptomatic intra-articular loose body (1), and axillary nerve palsy (resolved at 6 months) (1). The percentage of patients who experienced complications that occurred during the 0-6 month, 6 month to 2 year, 2-5 year, 5-10 year and after 10 year timepoints for primary RSA were 24%, 16%, 21%, 32%, and 8%, respectively.

There were 18 component revisions after primary RSA (25%). To treat PJI, 4 patients underwent two-stage revision and 6 patients underwent resection arthroplasty. Four periprosthetic fractures required open reduction and internal fixation (ORIF) and revision to a long stem prosthesis. Three cases of aseptic baseplate loosening underwent revision of the glenoid component with iliac crest autograft, and one patient refused further revision. The case of traumatic glenoid loosening required baseplate revision. In addition to revisions, there were 10 closed reductions and polyethylene/glenosphere exchanges after

dislocations, 2 polyethylene exchanges for subjective instability, 1 removal of an intra-articular loose body and 1 bearing exchange for the wound infection.

In the revision RSA group, 19 of 23 (83%) patients had postoperative complications. These included PJI (6), dislocations (5), dislocations followed by diagnosis of PJI (3), periprosthetic humerus fracture (2), aseptic baseplate loosening (2), and aseptic humeral loosening (1). Twelve (53%) patients in the revision RSA group required revision. Of the 9 patients with PJI, 6 underwent resection arthroplasty, 1 underwent two-stage revision and 2 were planned to undergo 2-stage revision but later elected to live with a spacer. The two cases of aseptic baseplate loosening underwent baseplate revision with iliac crest autograft, and the one case of aseptic humeral loosening underwent revision with a proximal humerus replacement prosthesis. In addition, there were 7 reoperations: 5 polyethylene exchanges for dislocation and 2 ORIF with stem revision of periprosthetic humeral shaft fractures. The percentage of patients who experienced complications that occurred during the 0–6-month, 6 month to 2 year, 2-5 year, and 5-10 year periods after revision RSA were 47%, 32%, 11%, and 11%, respectively.

Among the 30 patients (32%) who required a revision or reoperation, 14 patients (47%) required another operation during our follow-up period. In the primary and revision RSA groups, multiple reoperations or revisions were required in 8 (11%) and 6 (26%) of patients, respectively.

A Kaplan-Meier survival curve was used to analyze prosthesis survival, defined as retention of the originally implanted metal components (Fig 3). All patients regardless of follow-up time were included in the survivorship analysis and were censored at their last clinic follow-up date. The overall 5- and 10-year prosthesis survival rate was 88% (95% CI: 84-92%) and 81% (95% CI: 74-86%), respectively. In addition, Kaplan-Meier survival curve analysis was performed separately for revision RSA and excluding revisions due to trauma (Fig 3). After excluding revisions due to trauma, the 5- and 10-year prosthesis survival rate was 89% (95% CI: 84-93%) and 82% (95% CI: 75-87%), respectively.

Discussion

This study reported a minimum of 10-year follow-up results of 93 RSA (71 primary, 23 revision) for multiple indications performed by a single, high volume shoulder arthroplasty surgeon using the Tornier Aequalis Legacy and Legacy Long prostheses and Grammont style RSA. To our knowledge, this is the largest American cohort of RSA results at long term follow-up.

Functional outcomes and satisfaction after RSA at 10 year follow-up were favorable in this study, and almost all patients would have undergone the procedure again. These results are consistent with prior reports with a minimum of 8 or 10 year follow-up (Table 4).[1,5,13]

There were high complication and revision rates seen in both the primary and revision groups in our study. Many of the complications led to multiple operations after RSA, which is consistent with prior reports that complications of RSA can spiral into multiple revision procedures.[4] There are numerous factors to consider when interpreting these findings. First, only 94 of 471 RSAs performed during the study period met inclusion criteria (i.e., completed outcomes survey with at least 10-year follow-up), which may introduce a bias towards patients who required longer follow-up for complications. This is partially supported by the 81% survival rate by Kaplan-Meier analysis which included those patients in whom implant survival could be confirmed at a clinic visit but did not complete survey follow-up. Second, the indications for RSA were narrower during the study period, and, in our practice, included more salvage scenarios than present day; this is largely anecdotal but is somewhat reflected in that 63% of patients who had a complication after RSA underwent one or more prior shoulder surgeries. Moreover, the senior surgeon was earlier on the RSA learning curve than present. Third, some complications that were included may not directly judge RSA performance, such as traumatic complications remote from the time of RSA, early wound infection and a retained intra-articular loose body. However, even after excluding these events, the complication rate in the primary group was still 46% and in the revision group 74%. Regardless of factors that may have contributed to the high complication rates, this finding warrants continued study into long-term RSA outcomes.

The complication profile at 10 year follow-up is similar to prior studies, with the most common postoperative complications being dislocations, PJI and acromial stress fractures.[2,3] While the rate of

dislocations (15% for primary cases) and acromial stress fractures (7% in primary cases) is consistent with previous reports,[2,3] the 14% rate of PJI for primary arthroplasty was high compared to prior database or institutional registry reports around 1%.[14,15] This disparity may in part be related to this study's bias towards identifying patients who followed up for longer periods of time, and that database studies may underestimate the true incidence of PJI.[19] One new finding in this study is the high number of periprosthetic fractures (10% overall). While these may be chance events that could happen in any elderly population, they are notable given that the majority of fractures required a revision procedure.

This study adds to our understanding of long-term mechanical failures. The rate of aseptic glenoid failures (6% overall and in primary cases only) was somewhat higher than previous reports. Cuff et al[5] reported no cases and Bacle et al[1] had 4 cases, all of which were either custom implants with acromial fixation or felt to be technical error. Revision to BIO-RSA using iliac crest autograft provided good function and pain relief for all the patients in our study, and none have required subsequent revisions since then. We were unfortunately unable to obtain 10-year radiographs to comment on scapular notching and whether this progressed to aseptic loosening. Prior studies have found the prevalence of high grade notching (stage 3 or 4) ranges from 17-62%,[1,7,10,12,16] increases over time,[12,16] and is associated with deteriorating clinical outcomes.[7] No long-term series to date has found progression to glenoid loosening. There was only one case of humeral loosening in this study, and it was in a revision RSA case with poor bone quality, which is consistent with previously reported rates of about 2%. A prior radiographic study by Melis et al found that 52% of patients had lucencies greater than 2 mm around the humeral component and 6% had stem subsidence at 9.6 year follow-up;[12] however, there were no revisions for humeral loosening during their study period.[13] Overall, despite high all cause revision rates, long-term studies demonstrate low rates of aseptic glenoid and humeral loosening, and the significance of radiographic findings remains unclear.

The lack of deterioration in function between mid- and long-term follow-up is in slight contrast to previous studies suggesting more durable functional results with lateralized compared to Grammont design RSA[1,5]. While the results of these studies are a commonly cited reason to favor lateralized designs,

both studies showed significant reductions in range of motion over time, and the loss of active forward elevation was slightly greater in the lateralized design study than Grammont. Our study using a Grammont design did not show functional deterioration over time and we are not able to comment on changes in active motion. In short, there is evidence to support durable functional outcomes with both lateralized and Grammont designs.

This study has multiple limitations. As mentioned, the retrospective design and long-term follow-up may have biased our data towards patients who experienced complications. In addition, there may have been changes in surgical techniques and postoperative management over the study period. More detailed functional scores would add to our understanding of the factors contributing to patients who were dissatisfied or reported a low SANE score. For example, Bacle et al discussed the strength and active elevation of the Constant score as the drivers of low total Constant, which may suggest deltoid impairment as the cause of a poor result. In addition, we were unable to obtain radiographic follow-up for most patients. We are therefore unable to comment on the presence or significant of scapular notching and radiolucencies around components. Moreover, along with other 10-year studies, we analyzed how RSA performed for various indications. Prior studies have identified different results for RSA based on indication,[18] and therefore grouping them together may not be the ideal way to understand results on the individual level despite higher sample sizes. Lastly, these results come from a single, high-volume shoulder arthroplasty surgeon, and therefore may not be generalizable to other practice settings. Larger, multi-surgeon or registry studies may better represent the long-term results of RSA.

Conclusion

This study presents the largest American cohort of Grammont design RSA at a minimum 10-year follow-up. While RSA provided clinically significant and durable improvements in pain and function, the complication and revision rates were higher than prior reports. Despite this, the vast majority of patients were satisfied and would have the procedure again.

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Figure captions

Figure 1. Patient-reported outcome measures preoperatively and at 2-5 years and final follow-up. Pain and SANE measures were significantly improved at 2-5 years and 10+ years as compared to preoperative for all three patient groups (P<.001).

Figure 2. Timeline for complications and revisions over 10-years following reverse shoulder arthroplasty.

Figure 3. Prosthesis survival for all patients (N=471) regardless of clinical follow-up time who underwent reverse shoulder arthroplasty during the study period.

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Table 1. Standardized phone questionnaire for patients unable to return to the clinic for 10-year follow-up.

Phone question	Possible answers
1. Have you had any shoulder surgeries since Dr. [redacted] performed your shoulder replacement? If yes, do you recall the date and reason for the surgery?	Yes/no Free text
2. Using a 0-10 scale, how would you rate your pain level in your shoulder? 0 would be no pain and 10 would be the worst pain imaginable.	0-10
3. How satisfied are you with your shoulder?	Very dissatisfied, Dissatisfied, Satisfied or Very satisfied
4. How would you rate your shoulder today as a percentage of normal from 0 to 100%? 100% represents perfectly normal.	0-100%
5. Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider your current state satisfactory?	Yes/no
6. If you had to go back and do the same surgery again, would you have the surgery?	Yes/No
7. Anything else about your shoulder you would like to share?	Free text

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Table 2. Preoperative subject characteristics for primary and revision patients. Data is expressed as mean (± standard deviation or range) or number (percentage) as appropriate.

	Primary RSA N=71	Revision RSA N=23	P
Age (years)	67.4 (±9.3)	63.3 (±9.9)	.074
Female gender	45 (64%)	14 (61%)	.768
BMI	30.2 (±7.4)	28.3 (±5.0)	.261
Dominant Shoulder	46 (66%)	8 (35%)	.009
Follow-up (years)	11.4 (10-15.7)	11.6 (10-14.2)	.581

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Table 3. Indications for primary RSA

Indication	Number (%)
Cuff tear arthropathy	54 (77%)
Proximal humerus fracture	9 (13%)
Instability or fixed dislocation	4 (6%)
Infection after rotator cuff repair	2 (3%)
Severe biconcave deformity	1 (1%)

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Table 4. Comparison of studies reported in the literature with about 10 years follow-up.

	Melis et al	Bacle et al	Cuff et al	Present series
Study period	1993-2000	1995-2003	2004-2005	2004-2010
Cohort size (# of RSA)	68	87	42	93
Mean follow up (years)	9.6	12.5	11.0	11.4
Indications	CTA (48) Revision (11) Massive RCT (9)	CTA (27) Revision (21) Massive RCT (20) PTA (10) Primary OA (9)	RC deficiency (19) Failed prior RC surgery (13) Revision (10)	CTA (54) Revision (25) PHF (9) Instability or fixed dislocation (4) Post infection (2) Biconcave deformity (1)
Implant Design	Grammont	Grammont	Lateralized COR	Grammont
Survivorship at 10 years	-	93%	-	80.5%
Complication rate	14%	29%	-	64%
Revision rate	19%	12%	9%	43%
Functional outcome scores (mean)	CS (A): 60	CS (A): 55 CS (R): 86	ASES: 74 SST: 7 No ASES deterioration from mid to long term follow up.	SANE: 73 Pain: 2.0
Satisfaction	84% VS or S	-	-	82% VS or S
Mean active elevation (degrees)	132	131	126 Slight deterioration from mid to long term follow up.	-

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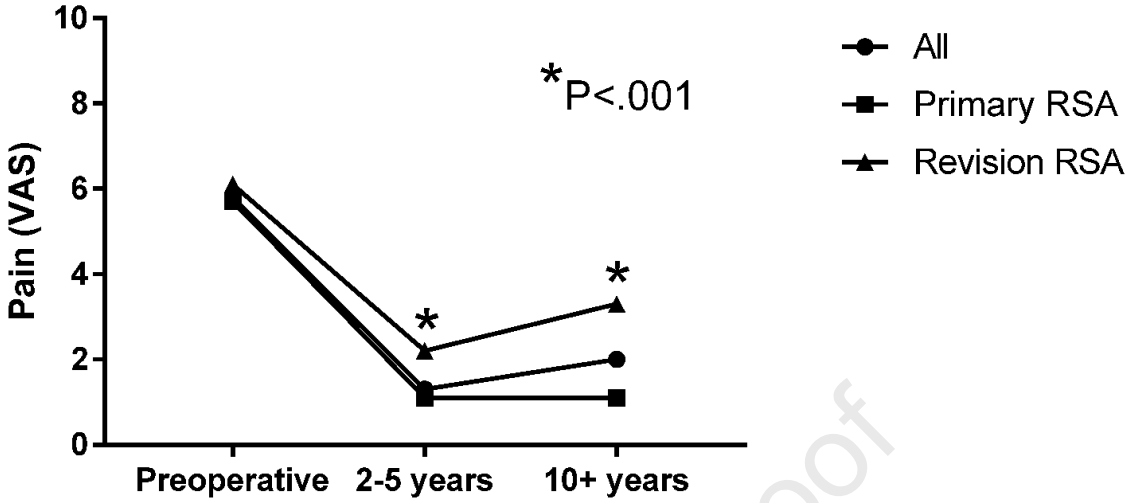

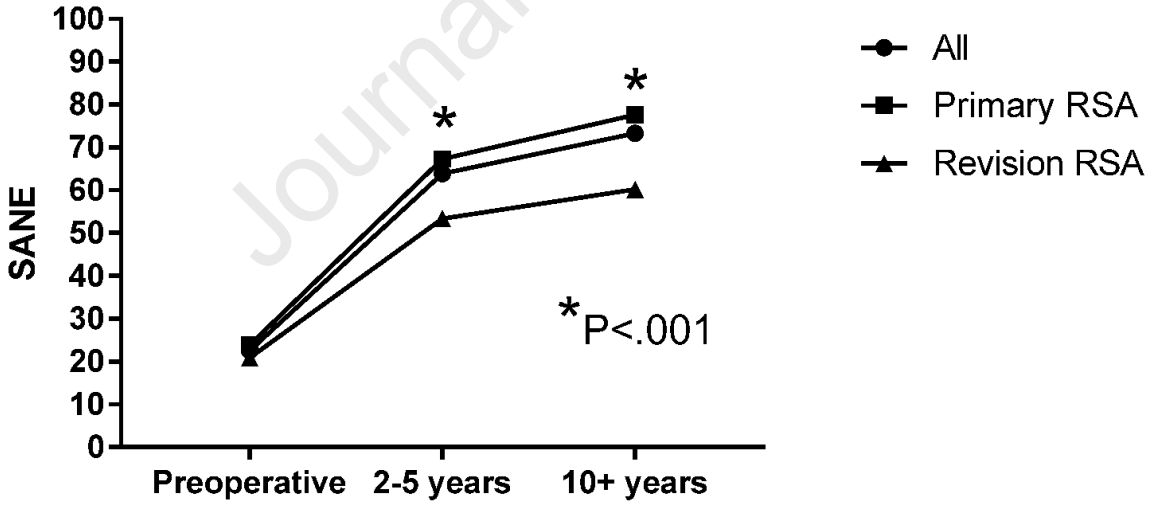

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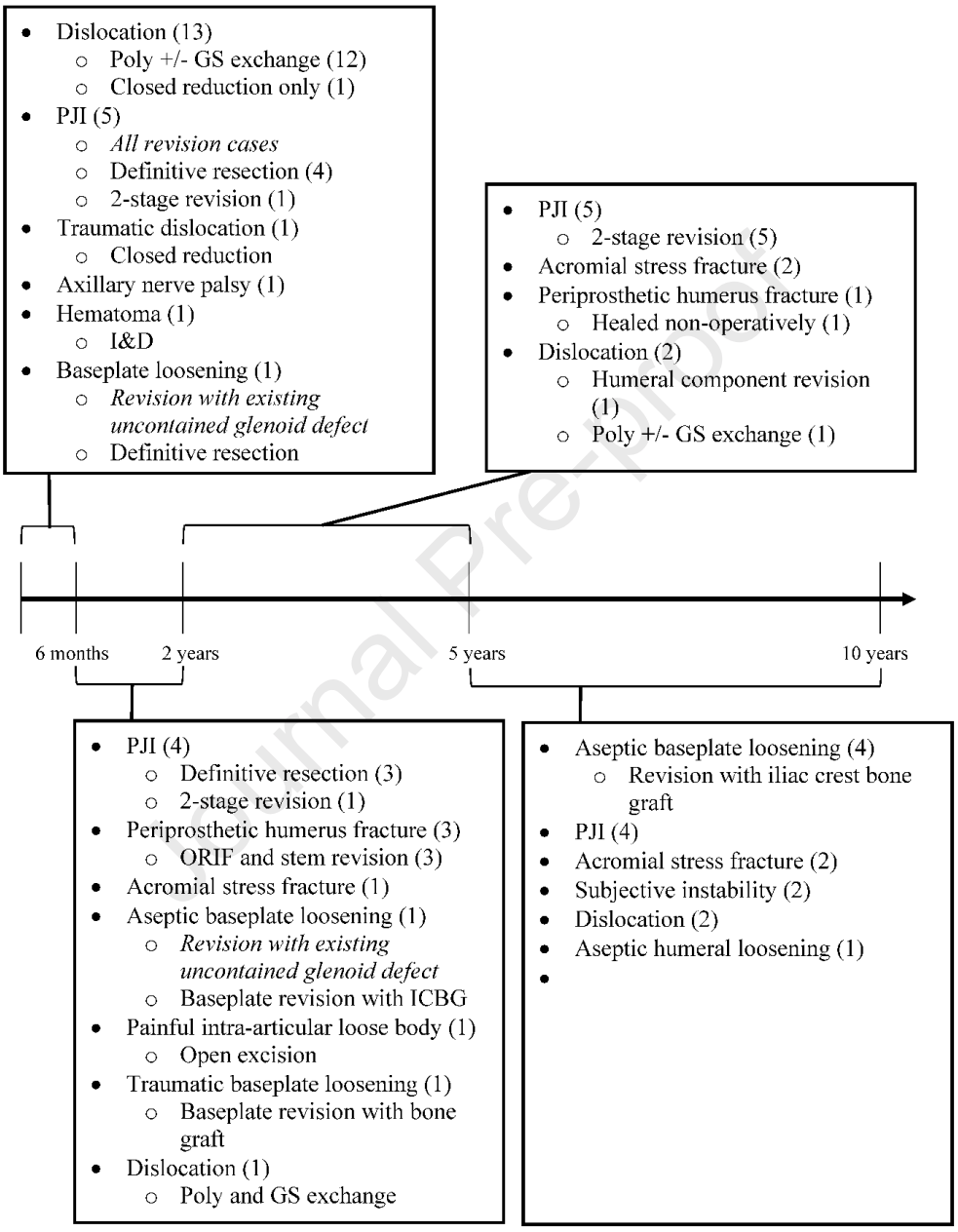
Dislocation (13)
Poly +/- GS exchange (12)
Closed reduction only (1)
PJI (5)
All revision cases
Definitive resection (4)
2-stage revision (1)
Traumatic dislocation (1)
Closed reduction
Axillary nerve palsy (1)
Hematoma (1)
I&D
Baseplate loosening (1)
Revision with existing uncontained glenoid defect
Definitive resection
PJI (5)
2-stage revision (5)
Acromial stress fracture (2)
Periprosthetic humerus fracture (1)
Healed non-operatively (1)
Dislocation (2)
Humeral component revision (1)
Poly +/- GS exchange (1)
6 months
2 years
5 years
10 years
PJI (4)
Definitive resection (3)
2-stage revision (1)
Periprosthetic humerus fracture (3)
ORIF and stem revision (3)
Acromial stress fracture (1)
Aseptic baseplate loosening (1)
Revision with existing uncontained glenoid defect
Baseplate revision with ICBG
Painful intra-articular loose body (1)
Open excision
Traumatic baseplate loosening (1)
Baseplate revision with bone graft
Dislocation (1)
Poly and GS exchange
Aseptic baseplate loosening (4)
Revision with iliac crest bone graft
PJI (4)
Acromial stress fracture (2)
Subjective instability (2)
Dislocation (2)
Aseptic humeral loosening (1)

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