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Midterm clinical outcomes of reverse shoulder arthroplasty in Japanese patients with rheumatoid arthritis using patient-reported outcome measures (Shoulder36)

Yuichi Nagase, MD, PhD [a,*], Masashi Naito, MD, PhD [a], Gen Momoyama, MD [b], Yoshio Uchida, MD [c], Takuji Nishikawa, MD [c], Kenta Makabe, MD [d], Sakae Tanaka, MD, PhD [d], Kazuya Tamai, MD, PhD [e]

[a] *Tokyo Metropolitan Tama Medical Center, Department of Rheumatic Surgery, Fuchu-city, Tokyo, Japan*
[b] *Itakura Hospital, Department of Orthopaedics, Funabashi-city, Chiba Prefecture, Japan*
[c] *Tokyo Metropolitan Bokutoh Hospital, Department of Rheumatology, Sumida-ku, Tokyo, Japan*
[d] *The University of Tokyo Hospital, Department of Orthopaedic Surgery, Bunkyo-ku, Tokyo, Japan*
[e] *Tohto Bunkyo Hospital, Department of Orthopaedics, Bunkyo-ku, Tokyo, Japan*

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Background: Reverse shoulder arthroplasty normally has adequate functional outcomes in patients with cuff tear arthropathy. The present study aimed to investigate the midterm clinical outcomes of reverse shoulder arthroplasty in Japanese patients with rheumatoid arthritis.
Methods: Between July 2014 and May 2016, reverse shoulder arthroplasty was performed in 14 rheumatic shoulders with joint destruction and rotator cuff tears. The range of motion, Constant score, and Shoulder36, which is a patient-reported outcome measure, were compared preoperatively and postoperatively. The prevalence of subscapular notching, subscapular osteophytes, postoperative fractures, and stress shielding of the humeral stem were evaluated by X-ray.
Results: Range of motion significantly improved from 77 to 122 degrees in flexion and from 67 to 111 degrees in abduction at four years. The Constant score significantly improved from 27 to 62, and each domain of Shoulder36 also significantly increased at four years. There was no dislocation, infection, or loosening of the prosthesis. Three shoulders presented scapular notching, and three cemented humeral stems showed stress shielding in the proximal humeral cortical bone.
Conclusion: Reverse shoulder arthroplasty performed in Japanese patients with rheumatoid arthritis not only decreased the pain and improved the function of the shoulder joint but also significantly improved patients' health and activity of daily living in midterm results.

Rheumatoid arthritis (RA), a systemic inflammatory disease due to genetic and environmental factors, leads to autoimmune dysfunction and multiple joint destruction. Recent advances in RA treatment using methotrexate and biological disease-modifying antirheumatic drugs (bDMARDs) have remarkably changed the goal of treatment from care to tight control of the disease.[26] Nevertheless, some patients still suffer from arthralgia and joint destruction as a result of either nonresponse to medication or lack of medical access due to economic reasons. Surprisingly, the impact of shoulder pain was the same as that of knee and elbow pain in patients with RA.[29] Furthermore, bilateral shoulder pain led to greater physical impairment than pain in other large joints.[20]

The importance of managing shoulder pain and its associated disorders in patients with RA is gaining recognition. Patients with RA often have a rotator cuff deficiency or dysfunction. Rozing reported that 75% of patients with RA who needed arthroplasty also had rotator cuff tears.[24] A thinned, dysfunctional rotator cuff in patients with RA is caused by the invasion of synovitis and osteoclasts into a bare area, which has no cartilage or articular capsule. Lehtinen showed that 86% of bone erosion occurred in the rotator cuff footprint.[15] Following from bone erosion and a rotator cuff

The present study was performed with the approval of the IRB and the relevant ethics committee of Tokyo Metropolitan Tama Medical Center (approval no.30-52).

* Corresponding author: Yuchi Nagase, MD, PhD, Tokyo Metropolitan Tama Medical Center, Department of Rheumatic surgery, 2-8-29, Musashidai, Fuchu city, Tokyo 183-8524, Japan.
E-mail address: nagaseyuichi17@gmail.com (Y. Nagase).

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Table I
Basic characteristics at surgery

Numbers of RSA	14
Age (yrs)	74 ± 3.8
PSL dose (mg)	2.4 ± 1.8
MTX dose (mg/week)	4.1 ± 4.0
bDMARDs usage (%)	35.7%
DAS28 (ESR)	3.9 ± 0.6
mHAQ	1.38 ± 0.7
Body height (cm)	150 ± 10.5
Body weight (Kg)	51.7 ± 12.2

RSA, reverse shoulder arthroplasty; *PSL*, prednisolone; *MTX*, methotrexate; *bDMARDs*, biological disease-modifying antirheumatic drugs; *DAS28*, Disease Activity Score 28; *mHAQ*, modified Health Assessment Questionnaire.
The mean ± standard deviation.

disorder, the rheumatic shoulder progresses to severe glenoid erosion, superior migration of the humeral head, and thinning of the acromion, called acetabulization. Moreover, patients with RA usually suffer from bone and soft tissue fragility and immune disorders, which render surgical intervention difficult. Nonetheless, pain relief and restoration of shoulder function are necessary to maintain patients' quality of life.

Unconstrained anatomic total shoulder arthroplasty (TSA) has been an option for patients with RA for several decades and reportedly has good outcomes in terms of pain relief and shoulder functionality if the patients' rotator cuff is intact.[28] On the other hand, improvement in the range of motion (ROM) and functionality were less satisfactory when cuff integrity was compromised.[30] To make matters worse, secondary rotator cuff failure leading to proximal humeral migration was frequently observed after TSA in patients with RA. Betts reported that all 14 shoulders with RA showed proximal humeral migration after TSA in the long-term follow-up (mean: 19.8 years) regardless of cuff integrity at the time of the operation.[3] Moreover, loosening of the glenoid component was associated with proximal humeral migration and bone fragility of the glenoid due to the rocking horse effect.[27]

The reverse shoulder arthroplasty (RSA) was designed by Paul Grammont[7] to enable patients with cuff tear arthropathy (CTA) to recover use of the deltoid muscle through the medialization of the center of rotation and lengthening of the deltoid muscle. In the West, RSA has been performed in CTA for several decades, and the mid- to long-term results of this procedure have been well documented.[2] On the other hand, there are only several reports of RSA in patients with RA.[4,5,9,10,12,16,21,22,31,33] For a decade, surgeons did not consider the procedure to be a satisfactory solution for patients with RA due to the potential for early loosening of the glenoid component and fragility of bone and soft tissue. Especially, there is not that kind of report in Japanese patients with RA so far. RSA has been available in Japan as a treatment option since 2014 and was performed by the author for elderly Japanese patients with RA with shoulder destruction and rotator cuff tears.

Recent clinical research has recognized the utility of patient-reported outcome measures.[23] The reliability and validity of Shoulder36 (version 1.3), made by the Japan Shoulder Society in 2011, were confirmed by an English article.[13] Kawakami reported that the correlation coefficient in each domain between Shoulder36 and the Constant score was 0.62-0.74 in 230 patients with rotator cuff tears, revealing a significant association between the two scoring systems.

The purpose of the present study was to investigate the midterm (four years) clinical and radiological outcomes of RSA in Japanese patients with RA using Constant score and the patient-reported outcome measure (Shoulder36).

Materials and methods

Between July 2014 and May 2016, RSA was performed in 14 RA shoulders with joint destruction and rotator cuff tears at Tokyo Metropolitan Bokutoh Hospital and Tokyo Metropolitan Tama Medical Center. All RSAs were performed by a single surgeon (first author) and all the patients were Japanese. The mean age at surgery was 74 ± 3.8 years. The mean follow-up duration was 57.9 ± 8.7 months. Only one patient (two shoulders) was male. One male and one female patient received bilateral RSA. All RSAs were primary cases. The mean prednisolone dose was 2.4 ± 1.8 mg, and the mean methotrexate dose was 4.1 ± 4 mg/week. The bDMARDs use rate was 35.7% and comparable with that of infliximab (one shoulder), etanercept (two shoulders), and abatacept (two shoulders). The mean disease activity score (DAS)28 (ESR) was 3.9 ± 0.6, and the mean Modified Health Assessment Questionnaire was 1.38 ± 0.7. The mean height was 150 ± 10.5 cm, and the mean weight was 51.7 ± 12.2 kg (Table I).

Preoperative and postoperative ROM were taken, and preoperative passive flexion less than 100 degrees was classified as a contracted shoulder in accordance with Itoi's report.[11] Internal rotation was ranked in accordance with the Constant score (T7: 10 points, T12: 8 points, L3: 6 points, Lumbosacral joint: 4 points, Buttock 2 points, Lateral thigh: 0 points). Preoperative and postoperative clinical and functional outcomes were assessed using Constant score and Shoulder36. Constant score is a 100-point, validated scoring system mainly used by clinicians to assess pain, function, ROM, and strength. Shoulder36 is a patient-reported outcome measure created by the Japan Shoulder Society in 2011 and contains 36 questions in six domains (pain, ROM, muscle strength, general health, activity of daily living (ADL), and sports) (Supplementary Appendix S1). The patients were asked to answer each of the 36 questions using the following scoring system; 0: cannot do it at all, 1: major difficulties and require help from someone, 2: some difficulties but manage on my own, 3: minor difficulties, and 4: no difficulties. The domain scores are calculated by taking the average for each domain. Data from the sports category were not used because patients with RA usually do not play sports. Preoperative X-ray, computed tomography (CT), and magnetic resonance imaging were performed as well. The Larsen grade for plain X-rays was used to assess the morphology of joint destruction[14] (grade 0: normal, grade 1: periarticular soft tissue swelling, osteoporosis or slight joint space narrowing, grade 2: definite early abnormality, grade 3: medium joint-destructive abnormality, grade 4: severe joint-destructive abnormality, grade 5: mutilating abnormality in which the bone outlines of the joint have disappeared). One shoulder was Larsen grade 3, seven shoulders were grade 4, and six shoulders were grade 5. In addition, preoperative rotator cuff integrity was assessed by magnetic resonance imaging and confirmed during surgery. A tear in the supraspinatus tendon alone was seen in two shoulders. Tearing or thinning of the supraspinatus and infraspinatus tendons was seen in three shoulders. Tearing or thinning of the supraspinatus, infraspinatus, and subscapularis tendons was seen in seven shoulders. Tearing or thinning in the entire rotator cuff was seen in two shoulders. There were nine contracted shoulders, five with a Larsen grade 4 and four with a Larsen grade 5. RSA (Aequalis Reversed; Tornier Inc./Wright Medical, Edina, MN, USA) was used for all 14 shoulders.

In the operative procedure, the patients were placed in the beach chair position under general anesthesia supplemented with interscalene block. The deltopectoral approach was used in all the cases. The subscapularis tendon was cut from its attachment to the lesser tuberosity and sutured to the humeral bone with No. 2 strong braid after RSA implantation. Whole periglenoid capsular release was performed in most of the cases, especially those with

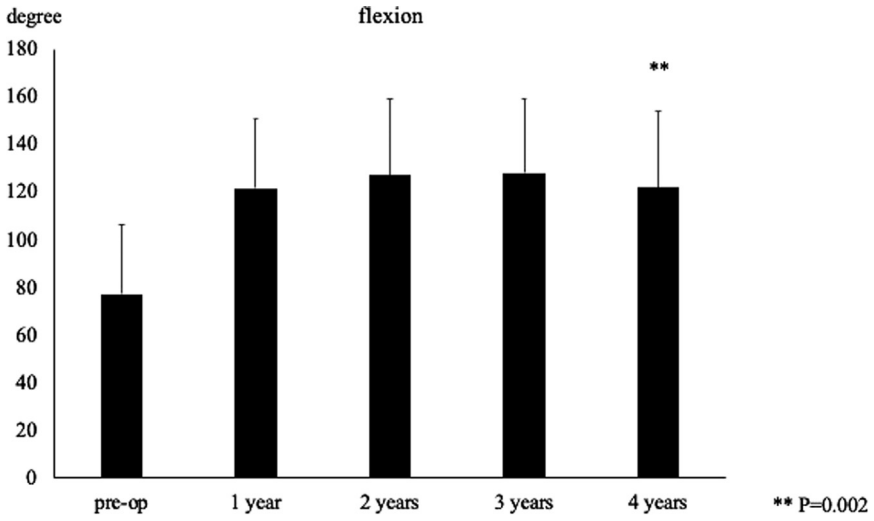

Figure 1 Changes in preoperative and postoperative flexion. Error bars represent standard deviation.

contracted shoulders. Glenoid reaming was performed manually and gently, and the firm subchondral host bone was left because good primary stability of the glenoid base plate is needed for those osteoporotic patients. A 36-mm diameter glenosphere was implanted as inferiorly as possible. A thinly (2-3 mm) sliced autobone graft was used in ten shoulders for the eroded glenoid, which is often seen in patients with RA. The humeral stems were implanted at 20 degrees of retroversion in all the cases. A cemented stem was used in 12 shoulders, and a cementless stem was used in 2 shoulders.

The arm was placed in a sling postoperatively to immobilize the shoulder joint for six weeks. Circumduction and pendulum exercises were begun on day 1, passive-assisted flexion exercises were begun on day 14, and active ROM exercises were begun at postoperative six weeks.

Postoperative clinical data and X-rays were taken every year. The prevalence of scapular notching, subscapular osteophytes, heterotopic ossification, postoperative fractures, loosening of the prosthesis, and stress shielding of the humeral stem were evaluated by postoperative X-ray. Scapular notching was classified using the grading system described previously by Sirveaux.[25]

Statistical analyses were performed using the Statistical Package for Social Sciences v.21 (IBM Corp., Armonk, NY, USA). The paired t-test was used to compare the preoperative and postoperative ROM, Constant score, and each domain of Shoulder36. The threshold for significance was $P < .05$. Descriptive data were expressed as the mean ± standard deviation.

This study was performed with the approval of the relevant ethics committees at Tokyo Metropolitan Tama Medical Center (approval no. 30-52).

Results

The ROM significantly improved from 77 ± 28 to 122 ± 32 degrees in flexion at postoperative four years ($P = .002$) (Fig. 1). Abduction also significantly improved from 67 ± 24 to 111 ± 34 degrees at four years ($P < .001$) (Fig. 2). External rotation with the arm at the side significantly decreased from 26 ± 22 to 7 ± 19 degrees at four years ($P = .026$) (Fig. 3). The preoperative internal rotation of the lumbosacral joint was the same at one-four years postoperatively ($P = .257$) (Fig. 4). The Constant score significantly improved from 27.3 ± 9.4 to 61.6 ± 18.7 at four years ($P < .001$). Furthermore, subgroup analysis of the Constant score showed significant improvement in the following domains at postoperative four years, respectively: pain, 4.6 ± 1.3 to 13.6 ± 3.1 ($P < .001$); activity, 1.3 ± 1.0 to 5.6 ± 4.2 ($P < .001$); arm position, 4.7 ± 1.5 to 8.0 ± 2.1 ($P < .001$); strength of abduction, 2.0 ± 0 to 13.8 ± 6.7 ($P < .001$); and ROM, 14.9 ± 6.8 to 20.7 ± 7.4 ($P = .041$) (Table II). Each of the domains of the patient-reported outcome measures (Shoulder36) were improved from preoperative to postoperative scores at four years, respectively: pain score, 1.3 ± 0.7 to 3.0 ± 0.8 ($P < .001$); ROM score,1.4 ± 0.8 to 2.4 ± 1.0 ($P < .001$); muscle strength score, 1.2 ± 1.4 to 2.2 ± 1.0 ($P = .015$); general health score, 2.4 ± 0.8 to 3.0 ± 0.5 ($P = .003$); and ADL score, 1.4 ± 0.8 to 2.4 ± 1.0 ($P = .003$) (Table III). No neural palsy, dislocation, or infection was observed.

Radiological examination showed no loosening of the prosthesis or heterotopic ossification. There were two cases of scapular osteophytes and three cases of scapular notching, two of which were grade 1, and one of which was grade 3. There were three cases (21.4%) of stress shielding of the humeral cemented stems, which showed thinning of the cortical bone at the proximal humerus (Fig. 5). However, the stress shielding did not progress to loosening of the humeral component so far, and no revision or late fractures, such as acromion and scapular spine, were observed in this series.

Discussion

The present study is the first to report the midterm clinical and radiological results of RSA in Japanese patients with RA. In addition, this is the first report demonstrating clinical outcomes of RSA in those patients using Shoulder36, which is a patient-reported outcome measure for the shoulder joints created by the Japanese Orthopaedic Association and the Japan Shoulder Society. RSA in patients with RA not only achieved satisfactory pain relief and restoration of shoulder functionality but also significantly improved the patients' health and ADL even at midterm assessment. Elderly patients with RA gradually decrease their ADL year by year due to general complications (eg, interstitial lung pneumonia, other joint destruction) during the follow-up period. Nevertheless, our data demonstrated that the patients' health and ADL significantly improved after RSA at four years. These data implied the impacts of the shoulder joint on the health and ADL of patients with RA.

The patients in our study achieved almost the same active forward flexion and abduction at four years as those in previous studies.[10] However, active external rotation with the arm at the side

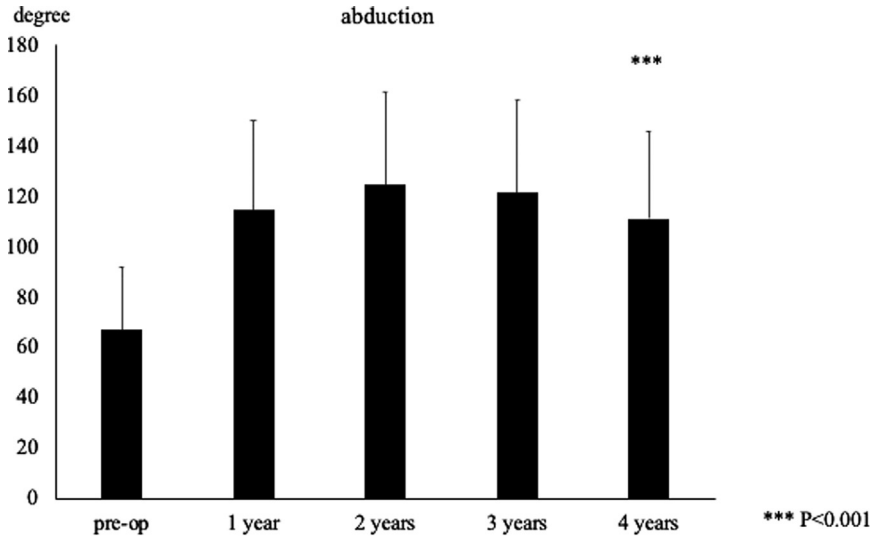

Figure 2 Changes in preoperative and postoperative abduction.

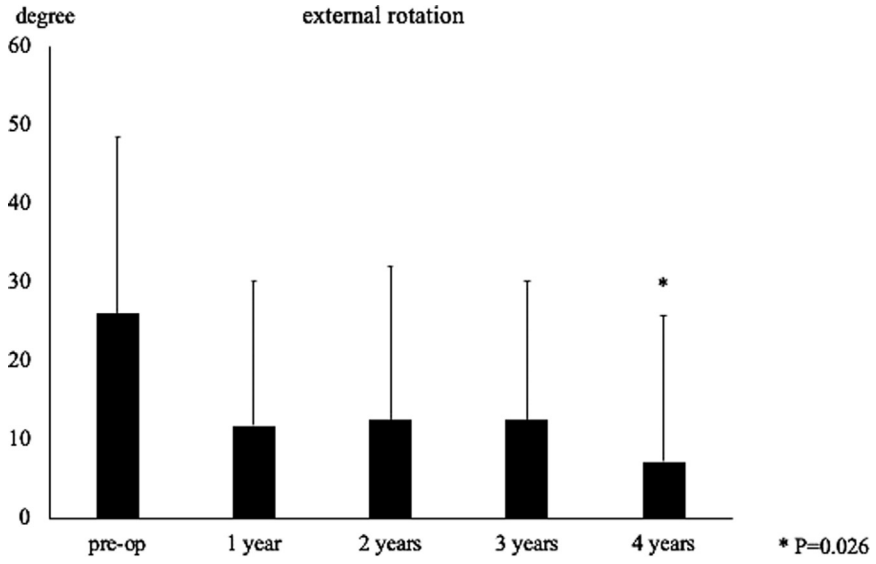

Figure 3 Changes in preoperative and postoperative external rotation.

significantly decreased at four years compared with the preoperative ROM, showing a poorer outcome than reported in previous studies.[33] One possible reason is that most of the patients in the present study had contracted shoulders (9/14 shoulders) and required a more extended humeral osteotomy than the patients with CTA to create a gap, which might have caused detachment of the teres minor at its insertion. Another reason may be the design of the Aequalis Reversed humeral stem, which was designed as an inlay stem and the diameter of metaphysis part was too large for our patients, who were mostly small Asian women with osteoporosis. Consequently, the infraspinatus or teres minor tendons might have become detached from their insertion during surgery. In addition, the Grammont design of the prosthesis may have caused medialization of the center of rotation and limited the lateral offset of the humeral stem, thus leading to decreased rotational strength. Previously, the neck-shaft angle of the humeral stem was highly inclined to avoid early dislocation. However, it is now designed to have a lower inclination to maintain teres minor insertion and to lateralize the humerus to achieve tension generated by the coupling force of the rotator cuff. Therefore, a future study examining the effect of different stem designs may help improve external and internal rotation in smaller Asian patients after RSA.

Many previous studies have reported scapular notching after Grammont-type RSA.[26] Factors associated with scapular notching include prosthetic design, glenosphere position, and humeral neck-shaft angle. Kowalsky reported a higher prevalence and severity of notching were observed with Grammont-type RSA compared with RSA designed with a small humeral neck-shaft angle stem.[18] Li reported that the prevalence of scapular notching decreased with use of an eccentric glenosphere with an inferior offset.[32] In accordance with Erickson's systematic review, the prevalence of scapular notching was 2.8% for a 135-degree neck-shaft angle in the humeral component. However, this significantly increased to 16.8% for a 155-degree neck-shaft angle.[6] Our radiological examination revealed that three of 14 shoulders (21.4%) had scapular notching, one of which had grade 3 scapular notching due to less inferior

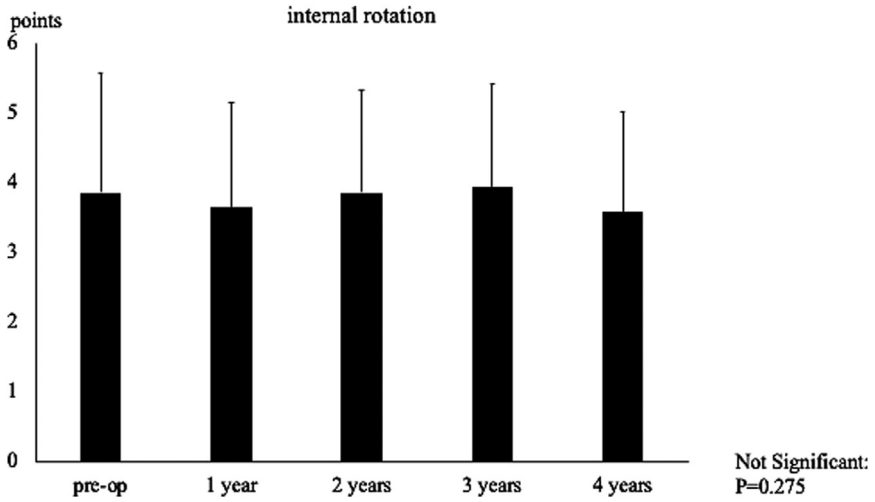

Figure 4 Changes in preoperative and postoperative internal rotation. Internal rotation was ranked in accordance with the Constant score (T7: 10 points, T12: 8 points, L3: 6 points, lumbosacral joint: 4 points, buttock: 2 points, lateral thigh: 0 points).

Table II
Changes of Constant score

Domain of Constant score	Pre-op	1 y	2 y	3 y	4 y	*P* value
Pain	4.6 ± 1.3	12.9 ± 3.2	13.6 ± 3.1	13.6 ± 3.1	13.6 ± 3.1***	***<.001
Activity	1.3 ± 1.0	7.4 ± 3.4	8.0 ± 3.0	7.7 ± 3.8	5.6 ± 4.2***	***<.001
Arm position	4.7 ± 1.5	7.9 ± 2.1	8.7 ± 1.7	8.6 ± 2.0	8.0 ± 2.1***	***<.001
Strength of abduction	2.0 ± 0	7.6 ± 3.7	9.9 ± 3.2	12.5 ± 5.4	13.8 ± 6.7***	***<.001
Range of motion	14.9 ± 6.8	20.9 ± 8.5	22.4 ± 7.5	23.1 ± 6.5	20.7 ± 7.4*	*.041
Total	27.3 ± 9.4	56.6 ± 15.5	62.6 ± 12.5	65.5 ± 12.9	61.6 ± 18.7***	***<.001

*$P < .05$, **$P < .01$, ***$P < .001$.

Table III
Changes of Shoulder36

Domain of Shoulder36	Pre-op	1 y	2 y	3 y	4 y	*P* value
Pain	1.3 ± 0.7	3.0 ± 0.8	3.0 ± 0.7	3.3 ± 0.6	3.0 ± 0.8***	***<.001
Range of motion	1.4 ± 0.8	2.5 ± 0.9	2.5 ± 1.0	2.6 ± 1.0	2.4 ± 1.0***	***<.001
Muscle strength	1.2 ± 1.4	2.4 ± 1.1	2.2 ± 1.1	2.4 ± 1.0	2.2 ± 1.0*	*.015
General health	2.4 ± 0.8	3.1 ± 0.6	3.0 ± 0.6	3.1 ± 0.6	3.0 ± 0.5**	**.003
ADL	1.4 ± 0.8	2.6 ± 0.9	2.5 ± 1.0	2.7 ± 1.1	2.4 ± 1.0**	**.003

ADL, activity of daily living.
*$P < .05$, **$P < .01$, ***$P < .001$.

offset in the glenoid base plate. The present data reflected the prosthetic design of the large humeral neck-shaft angle stem and glenosphere position.

Stress shielding of the humeral stem (cortical bone thinning with osteopenia) after RSA was recently discussed during the past decade. Al-Hadithy reported that stress shielding in cementless humeral stems was observed in 10% of cases[1] while Melis reported an incidence of 5.9% in cemented stems and 47% in cementless stems in Grammont-type RSA.[17] Nagels reported that cementless humeral stems, which occupy a large intramedullary space, led to stress shielding in the proximal lateral cortical bone in a series of 70 humeral head replacements because mechanical forces did not reach this area. The report also described that osteoporotic bone might increase the prevalence of stress shielding; in fact, 49 of the shoulders in the study had RA.[19] In the present study, three cases of stress shielding of the humeral cemented stems were observed (21.4%). However, the stress shielding has so far not progressed to loosening of the humeral component. Surgeons need to be careful to the prevalence of stress shielding after RSA in patients with RA because these patients tend to have osteoporosis.

In the past decade, RSA in patients with RA seemed to have high rates of complications, including fractures and deep infection.[8] Young recommended that the surgeon pay attention to bone and soft tissue fragility and superior glenoid erosion, which may lead to the malposition of the glenoid base plate and suggested using a cemented stem.[33] However, the authors of the present study recently used the cementless humeral stem in cases where it was able to be fixed well to the humeral cortical bone. A recent review of RSA involving 87 RA shoulders showed that outcomes in patients with RA were similar to those in patients with CTA. The author reported that the Constant score after RSA in patients with RA improved by 42 points and that the active elevation and abduction increased by 51 and 58 degrees, respectively, compared with the preoperative ROM. The adverse event rate was 31%. However, most of the adverse events consisted of minor complications; eight consisted of revision surgeries, and four consisted of infection. The

Figure 5 X-ray at postoperative 3.5 years after right RSA. Stress shielding of the proximal humerus and a subscapular osteophyte were observed.

study concluded that RSA in patients with RA apparently produced similar results to those obtained with RSA for CTA.[21]

The limitations of the present study were that 1) it was not a randomized control study, that is, there was no control group; anatomical TSA for RA shoulders with cuff tears might serve as the control group in this study, but a past report already showed that these data did not improve ROM[30]; 2) the outcomes were midterm. Bacle recently reported long-term results (minimum ten years) for the Grammont-type RSA (67 prostheses for CTA) and long-term Constant score decreased below the mid-term value.[2] Therefore, long-term follow-up is necessary in the present study as well. However, Ekelund described short-term and midterm results in 27 cases of RSA in RA shoulders for a minimum follow-up of 18 months (mean, 56 months; range, 18-143 months) and demonstrated a decrease in pain and an increase in the Constant score.[5] Moreover, our new data demonstrated that RSA in Japanese patients with RA improved their general health and ADL even at midterm assessment with the patient-reported outcome measures (Shoulder36); 3) the subject pool was small. We focused on outcomes and complications of the Grammont-type RSA (Aequalis Reversed) in Japanese patients with RA. Further studies with a larger cohort of patients comparing Aequalis Reversed with other devices are necessary.

Conclusion

RSA performed in Japanese patients with RA not only improved the pain and functionality of the shoulder joints but also significantly improved the patients' health and ADL at the midterm assessment. RSA was found to be an effective treatment method as long as bone and soft tissue fragility was duly considered in elderly Japanese patients with RA.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jseint.2020.09.016.

Disclaimer

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