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Long-term results of the Delta Xtend reverse shoulder prosthesis

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Background: Reverse shoulder arthroplasty has become the standard treatment for cuff tear arthropathy and complex fractures of the proximal humerus. The Delta Xtend prosthesis (DePuy Synthes, Warsaw, IN, USA) was launched in 2006 and has shown good short-term results. Longer-term results are not yet available.

Methods: There were 126 primary Delta Xtend prostheses implanted in our center by 1 surgeon from October 2006 until December 2009. Of these, 38 patients died, 12 were lost to follow-up, and 2 needed early revision of the prosthesis. Follow-up of at least 8 years was available for 74 patients. At preoperative and postoperative visits, shoulder function and pain were evaluated using the age- and sex-adjusted Constant-Murley score (aCS). The satisfaction rate was evaluated on a visual analog scale (VAS).

Results: The mean follow-up in our population was 113.1 months. The mean aCS was 44.6% (standard deviation [SD], 19.2) preoperatively. It increased significantly ($P < .001$) after surgery to 75.8% (SD, 12.5) at 3 months and 91.1% (SD, 11.8) at 5 years. At the latest follow-up, the mean aCS was only 79.9% (SD, 17.7), which was significantly lower ($P = .002$) than the aCS at 5 years postoperatively. An overall survival rate of more than 97% was seen at 8 years of follow-up.

Conclusion: This study confirms that the promising short-term results of the Delta Xtend prosthesis can be extended in the longer-term. However, further follow-up will be necessary to check whether the statistically significant decrease in the Constant-Murley score at latest follow-up, which was driven by a decrease in range of motion and power, continues or not.

Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Shoulder; reverse arthroplasty; cuff tear arthropathy; Delta Xtend; long-term results; cuff tear arthropathy

Cuff tear arthropathy is a common pathology in an aging population. Patients typically present with pain, loss of shoulder function, and eventually, loss of independence. Reverse total shoulder arthroplasty has become a reliable method for treating these patients and thus restoring shoulder function.[3,14,30,36] In recent decades, indications for reverse shoulder arthroplasty have been extended to fractures and revision surgery.[1,6,16,29]

The Universitair Ziekenhuis (UZ) Ghent Commissie voor Medische Ethiek (Ethics Committee) approved this study (Registration No.: EC/2018/0058).

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Short-term and midterm results of reverse shoulder arthroplasty are frequently reported, with satisfying results.[2,4,28,32,34] This explains the global increase in use of this prosthetic design over the last decades. However, only a few long-term results have been described. These studies documented a decrease in clinical results between 5 and 10 years postoperatively without radiographic evidence of prosthetic failure.[10,12,18]

The purpose of this single-center study was to describe our clinical results of the Delta Xtend reverse prosthesis (DePuy Synthes, Warsaw, IN, USA), which was introduced in 2006, with a minimum follow-up of 8 years. Favaro et al[13] and Gruber et al[17] previously described excellent midterm results and a low rate of major complications with this type of prosthesis, but long-term results are not well known until now.

Materials and methods

A retrospective clinical analysis was performed of all patients who received a Delta Xtend reverse total shoulder prosthesis in our center from October 2006 until December 2009. The patients provided informed consent. Revision cases of a total or reverse shoulder arthroplasty were excluded. The indication for reverse arthroplasty varied from cuff tear arthropathy in most of patients over proximal humeral fractures, malunions of fractures, and avascular necrosis of the humeral head. Chronic dislocation of the glenohumeral joint and destruction of the joint after septic arthritis were the indication for surgery in a few patients.

All patients were examined in the outpatient clinic preoperatively and postoperatively at fixed times. Postoperative visits were scheduled 6 weeks, 3 months, 6 months, 1 year, 2 years, 5 years, and at the latest follow-up. During these visits, shoulder function and pain were evaluated by the treating surgeon or a resident using the Constant-Murley score (CS).[7] Range of motion was measured using a goniometer, and strength measurements were made using a handheld dynamometer (IDO, Reading, Berkshire, UK). Patients who missed their latest follow-up were contacted by telephone, and a patient-based questionnaire was obtained. As described by Levy et al,[24] these results can be used interchangeably with the clinician-based CS. The total score was adjusted to age and sex using the normative values described by Katolik et al.[21]

Design of the Delta Xtend reverse shoulder system

The Delta Xtend reverse shoulder system offers a cemented cobalt-chromium monobloc stem or a hydroxyapatite (HA)-coated titanium modular uncemented stem for the humeral component. It has a non-anatomic neck-shaft angle of 155° to improve joint stability.[5] The glenoid component consists of a HA-coated baseplate with 4 screw holes. Two variable-angle locking screws and 2 compression screws in combination with a central peg, available in 3 sizes, provide a solid primary fixation. The HA coating allows for bony ingrowth and thus secondary fixation. The center of rotation is positioned on the glenoid-bone surface to diminish the shear stresses that contribute to loosening of the baseplate. The articulation between both components consists of a polyethylene cup available in different sizes and depths. An important difference between the previous Delta III system and the Delta Xtend, its current successor, is the baseplate, which has 4 screw holes and a smaller central peg, minimizing glenoid bone loss. In addition, it offers the possibility of an eccentric glenosphere, which can reduce scapular notching without further distalizing the metaglene.[17]

Surgical technique

Surgery was performed by 1 surgeon (L.D.W.) with patients under general anesthesia in the beach chair position. A deltopectoral approach was used in 41 patients, and an anterolateral approach was used in 33. The subscapularis tendon was spared by using a superior approach in 37 patients. Doing this, no tenotomy of this tendon was necessary. In the remaining 37 patients, the subscapularis tendon was already torn or a tenotomy was performed.

After release of the deltoid muscle and resection of the remnants of the supraspinatus tendon together with the coracoacromial ligament, the humeral head is dislocated. The humeral shaft is reamed and an osteotomy of the humeral head is made in 10° to 30° of retroversion.[20]

Subsequently, an extended 360° release of the glenoid is performed with resection of the labrum, the anterior and posterior joint capsule, and a complete osseous release of the long head of the triceps tendon. A Kirschner wire is drilled in the center of the inferior circle of the glenoid, perforating the anterior scapular cortex at Matsen's point. The correct position of this Kirschner wire is very important because we aim to create some inferior overhang of the glenosphere, thus preventing scapular notching.[27,31]

The convex reamer is moved over the pin, and the glenoid surface is reamed. Special attention is paid to ensure that the subchondral plate is left unharmed. After the central peg is drilled, the metaglene is placed in a slight varus position. To obtain additional rotational stability of the metaglene 2 (1 superior and 1 inferior) angular stable screws are placed. After this, the glenosphere is engaged with interposition of gentamicin-impregnated collagen and tightened by screwing in the central screw. Further impaction of the Morse taper is obtained by gently hammering the glenosphere. Thereafter, the central screw is tightened again. This process is repeated until further screw tightening is no longer possible.

After the metaphysis is reamed, the trial prosthesis is put in place, and the joint is reduced. The shoulder is tested throughout the entire range of motion, and if there is no impingement or signs of instability, the definitive components are placed.

Most of the prostheses were implanted cementless. Only in cases where no primary rotational stability could be achieved was the humeral stem was implanted with cement. For further evaluation in this study, no distinction was made between cemented or uncemented humeral stems because Wiater et al[37] showed that equivalent clinical and radiographic results were achieved in both cemented and uncemented humeral stems.

Postoperatively, immediate unrestricted active mobilization was permitted.

Statistical analysis

The results were processed using SPSS software (IBM, Armonk, NY, USA). Normality of variables was assessed by a Shapiro-Wilk test. To compare the clinical results at different times in follow-up, we used the paired samples *t* test. The independent samples *t* test was used to compare 1 variable in 2 groups of patients. Cor-

relation between the CS and age was determined by calculation of the Pearson correlation coefficient. Correlation between nominal variables (sex, indication for surgery) was calculated by the Spearman correlation coefficient. The null hypothesis tested was that there would be no significant difference between the CSs at different times. Statistical significance was set at $P < .05$.

Results

There were 149 reverse shoulder arthroplasties performed between October 2006 and December 2009 in our center. We excluded 23 because these were revision cases of a shoulder arthroplasty. One surgeon implanted 126 primary Delta Xtend prostheses in this period. During follow-up, 38 of these patients died of causes unrelated to the shoulder arthroplasty. These patients were not included in the study, even though there were no arguments to assume that there had been a problem with the prosthesis. Twelve patients were lost to follow-up. Of the remaining 76 patients, 2 needed early revision for infection or dislocation of the primary prosthesis. No other complications requiring new surgery were seen in this group. This means that 74 patients were monitored in our center for at least 8 years after primary reverse shoulder arthroplasty. Of these 74 patients, 34 were seen in the outpatient clinic at least 8 years after surgery (Fig. 1). The other 40 patients were contacted by telephone, and a patient-based score was obtained. A comparison of the clinician-based scores with the patient-based scores did not show a significant difference.

There were 21 men and 53 women with a mean age of 69.4 years (range, 31.6-83.8 years) at the time of surgery. The mean follow-up in this study was 113.1 months (range, 97-135 months).

The indication for surgery varied from cuff tear arthropathy in 78% (58 of 74 patients), proximal humeral fractures in 4% (3 patients), malunions of fractures in 7% (5 patients), to avascular necrosis of the humeral head in 4% (3 patients) and chronic dislocations of the shoulder in which no anatomic reconstruction was thought to be feasible anymore in 4% (3 patients). Destruction of the joint after septic arthritis was the indication for surgery in 3% (2 of 74) of all patients.

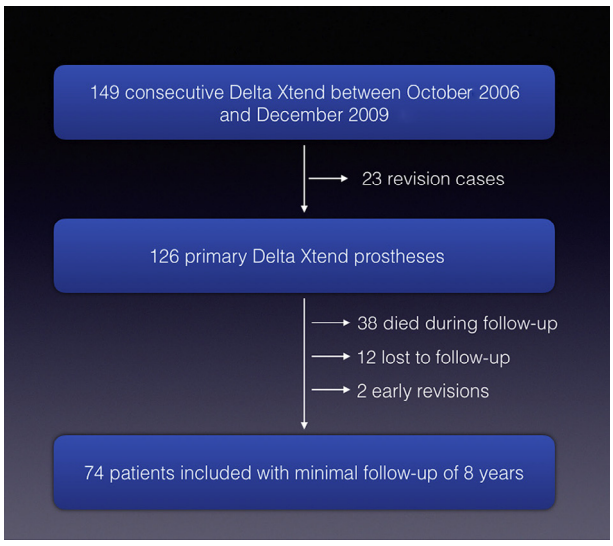

Figure 1 Patient selection.

A deltopectoral approach was used in 41 patients, and 33 were operated on using an anterolateral approach. The choice of the approach was determined by the expected state of the subscapularis tendon. In case of a presumed intact subscapularis tendon, an anterolateral approach was chosen.

Previous operations in 18 patients (24%) before the operation on the ipsilateral shoulder, consisted of cuff repair in 8 patients, an arthroscopic biceps tenotomy in 4, and a fracture osteosynthesis or a tendon transfer each in 3.

The mean preoperative CS was 37.8 (standard deviation [SD], 16.1). This score immediately increased 3 months postoperatively to 63.9 (SD, 9.9), which was a significant difference ($P < .001$). The CS further increased to 73.0 (SD 10.3) at 1 year and 76.7 (SD 9.5) at 5 years after surgery. Therefore, the null hypothesis, which claimed that there would be no statistically significant difference between preoperative and postoperative CS scores was rejected. At the latest follow-up, however, we found a mean CS of 66.6 (SD, 14.8), which was a significant decrease compared with the score after 5 years ($P < .05$).

After adjusting these values for age and sex, as described by Katolik et al,[21] the conclusion remained the same. The mean age- and sex-adjusted CS (aCS) was 44.6% (SD, 19.2%) preoperatively. At 3 months after surgery, the mean aCS was 75.8% (SD, 12.5%), which was a significant ($P < .001$) improvement. The mean aCS further increased until 5 years postoperatively (91.1%; SD, 11.8%). At the latest follow-up, the mean aCS was 79.9% (SD, 17.7%), which was significantly higher ($P < .001$) than the preoperative adjusted CS score but also significantly lower ($P = .002$) than the aCS at 5 years after surgery. All values are listed in Table I.

Because of the large difference in follow-up duration at the latest check-up (range, 97-135 months), we split the group according to the number of years of follow-up for further analysis. We created a first group, consisting of 28 patients, with a total follow-up between 8 and 9 years. The mean CS score at latest follow-up in this group was 70.1 (SD, 15.2), and the aCS was 83.8% (SD, 18.7%). A second group consisted of 24 patients with a follow-up of between 9 and 10 years. In this group, we found a mean CS at latest follow-up of 65.0 (SD, 15.4) with a mean aCS of 77.9% (SD, 18.0%). The remaining 22 patients had a follow-up of more than 10 years and were assigned to a third group. The mean CS at latest follow-up in this group was 64.1 (SD, 13.6), and the mean aCS was 77.1% (SD, 15.9%).

As previously mentioned , we found a significant decrease in CS and aCS at the latest follow-up compared with the scores at 5 years. We repeated this analysis for these 3 subgroups separately. In the first group with a follow-up between 8 and 9 years, we no longer found a significant decrease between the CS and aCS at 5 years and at the latest

Table I Summary of all scores

Constant-Murley scores	Minimum	Maximum	Mean	SD
Preoperative				
CS	3.0	63.0	37.8	16.1
aCS	3.6	77.8	44.6	19.2
3 months				
CS	46.0	90.0	63.9	9.9
aCS	56.6	108.4	75.8	12.5
6 months				
CS	45.6	96.0	71.6	11.3
aCS	51.1	107.2	85.0	12.8
1 year				
CS	48.0	89.4	73.0	10.3
aCS	51.1	107.9	86.7	12.6
2 years				
CS	38.0	92.0	75.2	10.0
aCS	45.2	104.9	89.1	12.0
5 years				
CS	39.0	92.0	76.7	9.5
aCS	46.4	104.5	91.1	11.8
At latest follow-up				
CS	20.0	88.4	66.6	14.8
aCS	23.8	109.1	79.9	17.7

SD, standard deviation; *CS*, Constant-Murley score; *aCS*, age- and sex-adjusted Constant-Murley score.

follow-up. However, in the group with a follow-up of 9 to 10 years, this decrease in CS and aCS was statistically significant ($P = .029$ and $P = .03$, respectively). Also, in the last group (follow-up of more than 10 years), this decrease between CS and aCS at 5 years and at the latest follow-up was statistically significant ($P = .022$ for CS; $P = .016$ for aCS).

No significant difference was found when the mean CS and mean aCS at latest follow-up were compared between these 3 groups.

When focusing on the subscores of the CS score, we found a significant improvement for all categories (pain, activities of daily living, range of motion, and power) 3 months after surgery ($P < .001$). The values of all subgroups were still significantly higher at the latest follow-up compared with the preoperative values ($P < .001$). As already mentioned, a significant decrease was seen in the CS between 5 years postoperatively and at the latest follow-up. A closer look at this fact shows a particularly a significant reduction in range of motion ($P = .011$) and power ($P = .025$) at the latest follow-up. The other subgroup scores (pain and activities of daily living) were not significantly lower at the latest follow-up compared with the scores at 5 years after surgery (Fig. 2).

We found no significant differences in preoperative and postoperative CS and aCS at different moments in follow-up between the patients who had already undergone operations on the ipsilateral shoulder and the patients for whom this was the first procedure.

No correlation was found between preoperative aCS and postoperative aCS on the short-term or on the longer-term.

Table II Subgroup analysis by diagnosis

Diagnosis	aCS at latest follow-up Mean (SD)
Cuff tear arthropathy	80.6 (18.5)
Avascular necrosis/malunion	74.5 (21.0)
Proximal humeral fracture	79.0 (10.5)
Chronic glenohumeral dislocation	75.2 (22.7)
Previous septic arthritis	76.7 (23.1)

aCS, age- and sex-adjusted Constant-Murley score; *SD* standard deviation.

We did find a significant positive correlation between age at time of surgery and the total aCS at 1 year after surgery ($P = .036$), but this significant correlation disappeared during further follow-up.

Indication for surgery and sex of the patient did not significantly correlate with outcome in the short-term or in the longer-term.

We also performed a subgroup analysis by diagnosis. No significant difference in aCS at the latest follow-up was found between the 5 subgroups, listed in Table II.

In the patient-based questionnaire, we asked for patient satisfaction on a VAS between 0 and 10. The mean patient satisfaction rate at latest follow-up was 8.4 (SD, 1.6; range, 2-10). There was a significant positive correlation between the patient satisfaction rating and both CS and aCS at the latest follow-up ($P < .001$).

Discussion

Long-term results of reverse shoulder arthroplasty are rarely reported, and most of these studies mention no specific type of prosthesis. We were able to describe the functional results of one specific type of reverse shoulder prosthesis, the Delta Xtend reverse shoulder system, with a minimum follow-up of more than 8 years. We found 2 studies that describe the short-term and midterm results of the Delta Xtend prosthesis.[13,17] They both showed good clinical results without major complications, comparable to the results of other reverse shoulder prostheses. However, results on the longer-term are not yet available for the Delta Xtend prosthesis.

In our population, we found a rate of revision surgery of 2.6% due to major complications such as dislocation and infection. This was comparable to the results of Sirveaux et al[32] and Favard et al,[12] but clearly lower than the revision rates reported by Guery et al[18] and Melis et al.[26] These complications occurred within a relatively short period after placement of the prosthesis. Thus, the survival rate of the Delta Xtend prosthesis in our population was 97.4% after 8 years.

After surgery, patients had a manifest improvement of shoulder function with less pain. This difference was significant, already at the first follow-up 3 months postoperatively. The clinical scores kept improving until 5 years after surgery. From that moment, we found a slight decrease in function during further follow-up. The mean improvement of aCS was

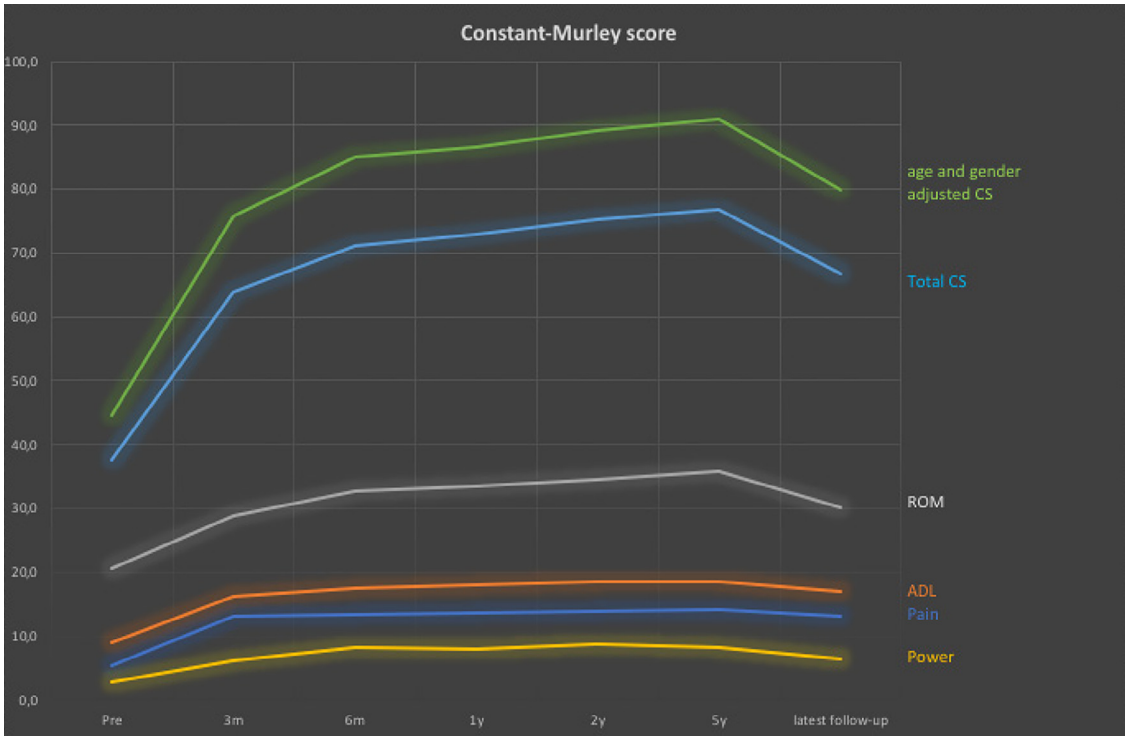

Figure 2 Evolution of mean Constant-Murley score (*CS*) during follow-up. *ROM*, range of motion; *ADL*, activities of daily living.

35.3% at the latest follow-up, which is comparable to the results in other studies.[4,10,38]

The preoperative CSs in our study were higher than those found in other studies. We found a mean preoperative CS of 37.8 compared with 23 in studies of Gerber et al[15] and Bacle et al[2] and 24.4 in the study of Favard et al.[12] However, the range of results, 3 to 63, is comparable to the range of results of 0 to 68 in this latter study. The mean CS in our population at least 8 years after surgery was 66.6, which is also slightly higher than the results in other studies.

But more important than these individual values is the tendency that is seen in all long-term studies. Shoulder function and pain seem to improve until 5 years after surgery. From that moment, all studies describe a slight decrease of the clinical scores.[2,9,11,12,15,18] As shown in our study, this decrease is likely to be attributed to a reduction in both range of motion and power. In the study of Cuff et al,[9] the reason of this decrease in the CS was only a significant loss of range of motion. The reason for this finding is unknown. Favard et al[12] found that aging of the patient population is not the cause of this decrease, because we also saw drop in the aCS.

On one hand, some authors suggested occult loosening of the prosthesis due to notching as an explanation for this deterioration.[12,18] On the other hand, Bacle et al[2] found that the decrease in the CS after 5 years was especially attributable to a loss of strength and power, suggesting an impairment of deltoid function. This impaired deltoid function could be due to the nonphysiological biomechanical requirements in reverse arthroplasty. We found in our population a combination of a decrease in both range of motion and strength as a cause for this deterioration of shoulder function after more than 5 years.

Nevertheless, despite this decrease in the CS after more than 5 years, most patients remained very satisfied with their prosthesis. We found a mean VAS score for patient satisfaction in our population of 8.4 (SD, 1.6). This is comparable to the VAS scores found by other authors.[8,19,23] This VAS score for patient satisfaction correlated positively with the CS and aCS at the latest follow-up.

Because of the relatively large difference in duration of total follow-up in our population, we split our population in 3 subgroups according to the number of years of follow-up. One could conclude from the analysis of these subgroups that the decrease in shoulder function starts after 9 years, because we could not find any significant decrease in the CSs at the latest follow-up in the subgroup with a follow-up of between 8 and 9 years. In the 2 remaining subgroups with a follow-up of more than 9 years, this decrease in the CS was significant again. However, this finding can be biased due to the small number of patients in each subgroup. When the mean CS and aCS were compared between the 3 subgroups at the latest follow-up, no significant differences were found. There was also no significant correlation between duration of follow-up and aCS at the final follow-up. This means that we cannot conclude that shoulder function is better 8 years postoperatively than it is more than 9 years postoperatively.

Previous surgery on the ipsilateral shoulder did not seem to influence the outcome of reverse arthroplasty in our population. This does not match the findings of Matsen et al,[25] who found significantly better patient-reported outcomes of

reverse shoulder arthroplasty in patients with no prior surgery on the shoulder.

No significant correlation was found between indication for surgery, sex of the patient, and outcome in the short-term or in the long-term. This differs from the findings of Werner et al,[35] who described a correlation between male sex and poor postoperative improvement. However, their results were similar to ours in the absence of any significant correlation between indication for surgery and postoperative outcome.[35]

A significant positive correlation was found in our population between age at time of surgery and total aCS at 1 year after surgery ($P = .036$). During further follow-up, this significant correlation disappeared. This corresponds to the findings of Leathers et al,[23] who found similar patient-reported outcomes both in younger and older patient groups. However, younger patients achieved increased postoperative range of motion in their study, which could not be confirmed by our results.

When the outcome of an intervention is assessed using clinical scores, determining the minimal clinically important difference (MCID) is important, because not every statistical difference is clinically meaningful to the patient. MCID was recently determined by Simovitch et al[30] for both anatomic and reverse shoulder arthroplasty. They found an improvement of 5.7 (SD, 1.9) points in the total CS was necessary to be a clinically important improvement. This value was slightly lower than the MCID of 8 described by Torrens et al.[33] All patients in our study had achieved an improvement of more than 5.7 points on total CS at the 1-year follow-up. Their improvement can therefore be considered as a clinically significant improvement. Nevertheless, we mention that the decrease in CS at 5 years of follow-up (76.7) and at latest follow-up (66.6) is also higher than the MCID, which makes this decrease clinically significant too.

One of the main strengths of this study is that this is a single-center study, in which all the shoulder arthroplasties were performed by or under the direct supervision of the same experienced surgeon with 1 prosthetic design, the Delta Xtend reverse shoulder prosthesis. This prevents a possible bias occurring due to the surgical technique or the prosthetic design. All included patients were operated on using a standardized surgical technique, and the same prosthesis was implanted in every case. The fact that 2 different surgical approaches were used was not taken into account because Lädermann et al[22] found no significant differences in clinical outcome between the deltopectoral and anterolateral approaches.

Because this was a retrospective study, it also has some limitations. Only 74 of 126 consecutive patients could be included in the study. During at least 8 years of follow-up, 38 patients (30.2%) died and 12 (9.5%) were lost to follow-up.

Another weakness of this study is the lack of radiographic results at the latest follow-up in a large number of patients. This lack of radiographic results makes it impossible to draw important conclusions about the radiographic outcomes more than 8 years postoperatively. Therefore, a possible correlation between radiographic and clinical outcome parameters cannot be demonstrated with certainty on the basis of our data.

Conclusion

We can confirm the good long-term clinical results of reverse shoulder arthroplasty. More specifically, this study has proven the same good postoperative results with the Delta Xtend reverse shoulder prosthesis as previous studies showed with other types of prostheses. With a survival rate of more than 97% after 8 years, this makes the Delta Xtend prosthesis a reliable option for reverse shoulder arthroplasty in rotator cuff–deficient shoulders. The trend of a decrease in functional outcome of reverse shoulder arthroplasty after more than 5 years, as already mentioned by other authors, was also seen in our study. With our results, we were not able to explain this finding, but we showed that it was driven by a decrease in range of motion and power. Further prospective follow-up will be useful to see whether this downward trend continues.

Disclaimer

Alexander Van Tongel has a consultancy agreement with DePuy Synthes. Lieven De Wilde received royalties from and has a consultancy agreement with DePuy Synthes. 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.

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