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# The impact of the underlying pathology and previous surgery on the long-term functional outcomes of the Delta Xtend reverse total shoulder arthroplasty: a prospective cohort study with a minimum follow-up of 11 years

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**Background:** Reverse total shoulder arthroplasty (rTSA) is a successful treatment option for rotator cuff tear arthropathy (CTA). Since its introduction, the range of indications has been expanded while implant designs have been enhanced. The purpose of this study is to evaluate the long-term clinical, radiographic, and patient-reported outcomes of the Delta Xtend rTSA.

**Materials and methods:** In this prospective cohort study, 108 consecutive patients who underwent implantation of rTSA using the DePuy Delta Xtend in 2008 were included. Patients were divided into 4 indication groups: CTA (60%), revision shoulder arthroplasty (15%), fracture sequelae (19%), and postinfectious arthropathy (6%). Clinical examination and radiographic follow-up were performed after 5 years and at long term with a minimum follow-up of 11 years.

**Results:** Forty three patients were eligible for follow-up with a median follow-up period of 12.5 years (range: 11.5-12.6 years, response rate 79%). The preoperative Constant score (CS) was 19 (9-24), and the CS at follow-up was 56 (41-64) with a significant increase between implantation and latest follow-up ($P < .001$). No significant difference of the CS at follow-up was reported between the 4 groups. Between the mid-term follow-up and the latest follow-up, a significant decrease of the CS of 10 (2-14) was observed ($P = .004$); however, no significant difference in the age-correlated and sex-correlated CS was reported ($P = .13$). Patients who underwent previous surgery before the index arthroplasty (51 [35-62]) had a significantly lower CS than patients without previous surgery (63 [58-66], $P = .032$). Patients with revision arthroplasty had a significantly lower range of motion at long-term follow-up than patients with CTA ($P = .013$). Implant survival was 95.3% after 11 years. Patients with fracture sequelae had a significantly higher risk for revision than patients with CTA ($P = .04$). Implant survival without revision for any complication was 89.7%; the overall complication rate was 12.5%.

This study was approved by the institutional review committee of the Technical University of Munich, Germany (Ref.: 184/18 S).

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**Conclusion:** This study demonstrated favorable long-term outcomes of rTSA and a satisfactory survival rate using the Delta Xtend system. However, a significant decline of the functional outcome was observed since the mid-term follow-up. For indications other than CTA, the functional results are inferior, and the risk for revision is higher. Previous shoulder surgery prior to the index arthroplasty leads to a worse functional outcome and a higher risk of reoperation due to any complication.
**Level of evidence:** Level IV; Case Series; Treatment Study


**Keywords:** Reverse shoulder arthroplasty; long-term; revision; survival; patient-reported outcomes; range of motion; radiographic outcomes; scapular notching

In an increasingly aging population, rotator cuff tear arthropathy (CTA) has emerged as a leading shoulder pathology.[31] In this context, reverse total shoulder arthroplasty (rTSA) has proven to be a reliable and increasingly popular treatment option for restoring shoulder function in these patients.[5,6,25,44,45] Since its development, the indications for rTSA have expanded to include the treatment of acute and chronic proximal humeral fractures as well as revision surgery.[22,45,48,52,53]

The initial Grammont design featured a medialized 155° neck-shaft angle (NSA) as well as a medialized humeral stem, which is still reflected in the Delta Xtend system (DePuy International Ltd., Leeds, UK).[6,13] Since its conception, there has been a shift to more lateralized design concepts, such as a reduced NSA, a lateralized onlay humeral system, or lateralized glenoid designs.[7,12,45,46] These changes in prosthesis design have the potential to affect stability, range of motion (ROM), and scapular notching.[33,39,46,47]

Recent studies have reported favorable mid-term to long-term results using the classic Grammont design prosthesis; however, clinical outcomes seem to be inferior for other indications than CTA.[10,11,22] Furthermore, a notable decrease of the functional results has been reported between mid-term and long-term assessments.[26,29] However, there is still a paucity of data regarding the long-term functional outcomes of newer Grammont style implant designs. Few studies have evaluated this prosthesis design with at least 10 years of follow-up, with most studies reporting only mid-term results with a minimum follow-up of 5 years.[3,5,30,32,38]

The purpose of this study was to evaluate the long-term functional and radiographic outcomes of the Delta Xtend rTSA system in context with the underlying indication for surgery. It was hypothesized that surgical indications other than CTA or massive rotator cuff tears would result in a worse functional outcome and shorter implant survival. It was further hypothesized that previous surgery would result in a worse functional outcome of the replaced shoulder.

## Materials and methods

This prospective cohort study was approved by the institutional review committee of the Technical University of Munich (Ref.: 184/18 S) and conducted according to the Declaration of Helsinki. One hundred and eight consecutive patients were included who underwent Delta Xtend reverse shoulder prosthesis implantation by the senior author (L. S.) and his team at Munich Bogenhausen Municipal Hospital's Center for Orthopaedics, Trauma Surgery, and Sports Medicine between April and December 2008. Participants were categorized into 4 groups based on indication (Table I): 64 (59%) patients with CTA/mass rotator cuff tears (group 1), 16 (15%) who underwent prosthesis revision (group 2), 21 (20%) patients with fracture sequelae (group 3), and 7 (6%) patients receiving joint replacement due to postinfectious arthropathy (group 4).

### Surgical technique

Implantation of rTSA was performed in general anesthesia in beach chair position. A deltopectoral approach was performed in case of revision surgery, previous open reduction and internal fixation (ORIF), or when removal of osteophytes required an inferior extension of the incision. A superolateral approach was performed in all other cases. The subscapularis tendon was released using the peel-off technique.[16] Cementation of the stem was performed in cases of low bone density. A 42-mm glenosphere was generally implanted, unless a small glenoid size required the use of an 38-mm glenosphere. If possible, refixation of the subscapularis tendon was performed after implantation (Table I).

### Outcome measurements

The primary endpoint of the study was defined as the necessity for revision surgery with exchange of fixed components (ie, excluding the liner). Evaluation of clinical and radiographic outcome was performed preoperatively, 6-12 weeks postoperatively, after a minimum follow-up of 5 years, and after a minimum follow-up of 11 years. Patients were considered eligible for the latest follow-up if they could be contacted at 11 years and the absence of revision could be confirmed, irrespective of the completeness of outcome parameters.

Clinical evaluation was performed in a standardized manner by investigators other than the operating surgeon and included measurement of active and passive ROM and patient-reported outcome measures, including the Constant score (CS) and visual analog scale for pain. Scores were obtained as absolute values and in relation to standard values according to age and sex.[21,61] Additionally, patient satisfaction and questions regarding activities of daily life were recorded. Abduction strength was measured using an electronic goniometer.

**Table I** Study cohort characteristics

| Study cohort characteristics | |
|---|---|
| Female, n (%) | 76 (70) |
| Age at surgery, mean yr ± SD | 73.9 ± 8.2 |
| Diagnosis | |
| CTA (group 1), n (%) | 64 (60) |
| Revision (group 2), n (%) | 16 (15) |
| Fracture sequelae (group 3), n (%) | 21 (20) |
| Postinfectious arthropathy (group 4), n (%) | 7 (6) |
| Previous surgery of the shoulder, n (%) | 56 (52) |
| Dominant side, n (%) | 69 (64) |
| Approach | |
| Deltopectoral, n (%) | 71 (66) |
| Anterosuperior, n (%) | 37 (34) |
| Glenosphere size | |
| 42 mm, n (%) | 91 (84) |
| 38 mm, n (%) | 17 (16) |
| Cemented humeral component, n (%) | 45 (42) |

*SD*, standard deviation; *CTA*, cuff tear arthropathy.

Radiographic assessment was performed using standardized true anteroposterior, Y-view, and axillary lateral radiographs. Outcome measures were defined as scapular notching, radiolucent lines, and glenoid or humeral loosening. Inferior scapular notching was graded according to the classification of Sirveaux et al.[57] Two authors (C. S. and R. R.) assessed all radiographs independently.

## Statistical analysis

Normality was assessed using the Shapiro-Wilk test and the use of histograms. Comparison of scores at different time points was performed using a paired *t*-test for normal distribution and the Wilcoxon signed rank test for non-normal distribution. Subgroup analysis was performed using the Kruskal-Wallis, unpaired *t*-test and Mann-Whitney *U* test. Holm-Bonferroni correction was used to adjust for multiple testing. Categorical variables were analyzed using the Fisher's exact test. Linear regression analysis was performed for the CS and logistic regression analysis for prosthesis revision. Prosthesis survival was assessed using the Kaplan-Meier estimator, and implant survival was compared between groups by means of the Cox regression model. The significance level was set at 0.05, and all *P* values were 2-tailed. Statistical analysis was performed using RStudio (RStudio Public Benefit Corporation, Boston, MA, USA) and R version 4.2.1 (R Foundation for Statistical Computing, Vienna, Austria).

# Results

## Demographics and indication groups

Of the initially included 108 subjects, 4 patients underwent a revision. Nonfollow-up reasons included 54 deceased patients (50%), whereas 7 patients were untraceable (6%). Forty three patients (35% male, 70.7 ± 8.2 years at surgery) were included for the long-term follow-up (response rate: 86%). The median follow-up was of 12.5 years (range: 11.5-12.6 years). The follow-up cohort of 43 patients comprised 27 (63%) from group 1 (CTA/mass rupture), 9 (21%) from group 2 (revision), 6 (14%) from group 3 (postfracture), and 1 (2%) from group 4 (postinfectious arthropathy). Fifteen (35%) of the 43 patients had undergone shoulder surgery prior to the index arthroplasty, including 2 subacromial decompressions, 9 rotator cuff reconstructions, 3 comprehensive arthroscopic management procedures, and 3 osteosyntheses. The previous joint replacements in group 2 consisted of 4 hemiprostheses and 5 anatomical shoulder arthroplasties. The group of patients with fracture sequelae (group 3) consisted of 3 individuals who underwent ORIF with a plate, while the remaining 2 were treated conservatively.

## Revisions and implant survival

In this study, we observed implant failure for any reason in a total of 4 cases (3.7%, Table II) after a median of 3.9 (2.9-5.0) years, including 1 patient from group 1 (CTA) and 3 from group 3 (fracture sequelae). Implant survival was 95.3% (95% confidence interval [CI]: 90.8-100) after 11 years (Fig. 1). After 5 years, implant survival was 96.7% (95% CI: 93.2-100). Patients who had undergone previous shoulder surgery (93.3% [95% CI: 86.2-100]) showed a lower survival probability than patients without previous surgery (97.1% [95% CI: 91.8-100]). However, this difference was not significant ($P = .051$). Logistic regression showed a significantly higher risk for revision in the fracture sequelae group than in the CTA group (odds ratio: 11.1, $P = .04$). Implant survival without reoperation for any complication was 88.2% (95% CI: 81.9-95.1) after 11 years (Fig. 1). Patients who had undergone previous shoulder surgery (80.1% [95% CI: 69.8-92.1]) showed a significantly lower survival rate compared to patients who had no prior surgery (97% [95% CI: 91.8-100]) with a hazard rate of 7.9 (95% CI: 1.1-61.1, $P = .049$).

## Complications

Including implant failure, we observed 4 complications (6.3%) in the CTA group, 2 complications (12.5%) in the revision arthroplasty group, 4 complications (28.6%) in the fracture sequelae group, and no complication in the postinfectious arthropathy group (Table III). The overall complication rate including revision was 12.5%. No significant difference was observed between the indication groups regarding complication rates ($P = .3$). One patient (male, aged 85 years) exhibited acromial pseudarthrosis due to a neglected traumatic refracture following previous ORIF with plate to treat an acromial stress fracture (Fig. 2).

**Table II** Implant failures and surgical management according to each indication group

| Group | Age, gender | Time (mo) | Reason for revison | Surgical management |
|---|---|---|---|---|
| 1 | 68, m | 40 | Chronic instability | Exchange of glenosphere and liner |
| 3 | 66, f | 29 | Aseptic loosening of humeral component | Exchange of humeral component |
| 3 | 63, f | 42 | Low-grade infection | Septic exchange |
| 3 | 84, f | 78 | Low-grade infection | Septic exchange |

*f*, female; *m*, male; *mo*, months.

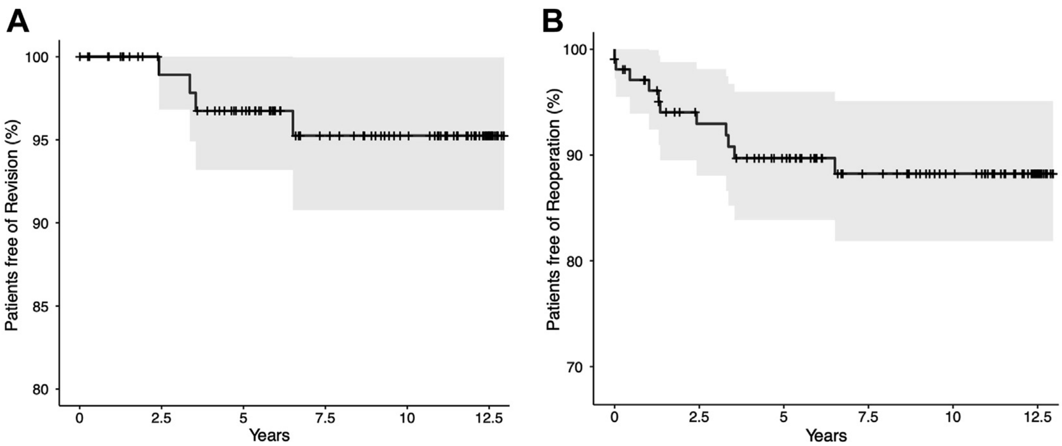


**Figure 1** Kaplan-Meier survival analysis. (**A**) Survival with exchange of components excluding the liner as the end point was 95.3% at 11 years. (**B**) Survival free or reoperation for any complication was 89.7% at 11 years.

**Table III** List of complications without revision

| Group | Age, gender | Time (mo) | Complication type | Treatment | FU (mo) |
|---|---|---|---|---|---|
| 1 | 78, m | 12 | Stress fracture of acromion | ORIF (K-wires) | 149 |
| 1 | 72, m | 15 | *Stress fracture of acromion | ORIF (plate) | 150 |
| 1 | 73, m | 23 | *Pseudarthrosis of the acromion after traumatic refracture | Conservative management due to non-compliant patient | 150 |
| 1 | 72, f | 39 | Arthrofibrosis | Arthrolysis, liner exchange | 143 |
| 2 | 79, f | 6 | Traumatic fracture of scapular spine | ORIF (plate) | 57 |
| 2 | 75, f | 16 | Dislocation | Liner exchange | 16 |
| 3 | 83, f | 0 | Postoperative hematoma | Lavage | 91 |
| 3 | 75, m | 0 | Postoperative hematoma | Lavage | 70 |
| 3 | 85, f | 0 | Dislocation | Closed reduction | 3 |

*FU*, follow-up; *mo*, months; *f*, female; *m*, male; *ORIF*, open reduction and internal fixation.
* Same patient.

## Clinical and functional outcome

Patient-reported outcome was recorded in 33 patients (77%). The median CS at follow-up was 56 (41-64) points (Table IV). No significant difference regarding the CS at follow-up was observed between the 4 groups. The increase of the CS between implantation and latest follow-up of 34 (23-44) points was significant ($P < .001$). Between the mid-term follow-up and the latest follow-up, a significant decrease of the CS of 10 (1.6-14) points was observed ($P = .004$). This decrease was caused by significantly lower ROM (decrease of 6 points, $P < .001$) and strength (decrease of 1 point, $P = .01$) at the latest follow-up compared to the mid-term assessment (Fig. 3, Fig. 4). In contrast, there was no significant difference in age-correlated and sex-correlated CS between the mid-term and long-term follow-up ($P = .13$).

Patients in the revision arthroplasty group (15 [12-18] points) had a significantly lower ROM compared to those in the CTA group (24 [20-28] points) after 11 years

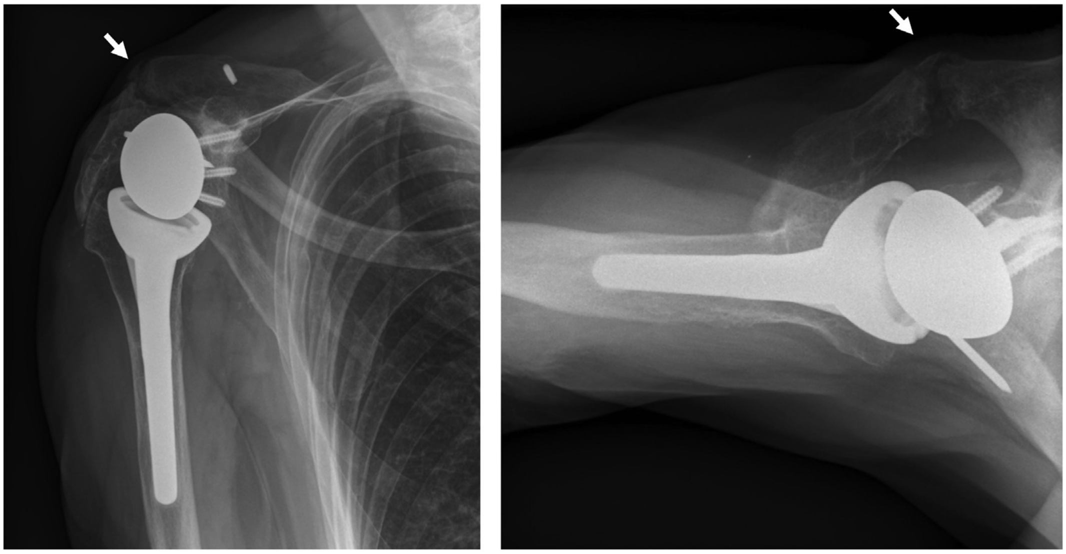

**Figure 2** Acromial pseudarthrosis (*arrows*) after neglected traumatic refracture and prior open reduction and internal fixation with plate for acromial stress fracture.

**Table IV** Clinical and radiographic outcome measurements

| | Preoperative (n = 108) | At 5 yr (n = 80) | At 11 yr (n = 43) | *P* value (preoperative vs. 11 yr) | *P* value (5 yr vs. 11 yr) |
|---|---|---|---|---|---|
| Female, n (%) | 76 (70) | 52 (65) | 28 (65) | | |
| Age, mean yr ± SD | 73.9 ± 8.2 | 79.3 ± 8.0 | 81.5 ± 8.3 | | |
| Constant score | | | | | |
| Absolute, points [IQR] | 19 [9-24] | 61 [49-73] | 56 [41-64] | **<.001** | **.004** |
| Age-correlated/sex-correlated, % [IQR] | 26 [13-33] | 92 [91-105] | 83 [62-97] | **<.001** | **.13** |
| Pain, points [IQR] | 5 [0-10] | 15 [10-15] | 15 [10-15] | **<.001** | .98 |
| ADL, points [IQR] | 6 [4.5-8] | 17 [14-20] | 18 [12-18] | **<.001** | .36 |
| ROM, points [IQR] | 6 [0-10] | 28 [20-32] | 22 [16-26] | **<.001** | **<.001** |
| Flexion, ° [IQR] | 40 [25-70] | 150 [98-150] | 110 [80-125] | **<.001** | **<.001** |
| Abduction, ° [IQR] | 30 [25-50] | 120 [90-150] | 95 [70-120] | **<.001** | **<.001** |
| Strength, kg [IQR] | 0 [0-0] | 6,0 [4.0-8.0] | 1 [0.5-5] | **<.001** | **.02** |
| Satisfaction (%) | 0 [0-30] | 85 [70-90] | 90 [80-90] | **<.001** | .72 |
| No. of patients with radiographic follow-up | | 24 | 18 | | |
| Notching | | | | | |
| No notching, n (%) | | 12 (50%) | 4 (22%) | | |
| Grade 1, n (%) | | 6 (25%) | 11 (61%) | | |
| Grade 2, n (%) | | 2 (8%) | 3 (17%) | | |
| Grade 3, n (%) | | 4 (17%) | 0 | | |
| Grade 4, n (%) | | 0 | 0 | | |

*SD*, standard deviation; *IQR*, interquartile range; *ADL*, activities of daily living; *ROM*, range of motion.
Significant *P* values are bolded.

($P$ = .013). Additionally, patients who underwent previous surgery before the index arthroplasty (51 [35-62] points) had a significantly worse CS than patients without previous surgery (63 [58-65] points, $P$ = .032). Multivariate linear regression identified the preoperative CS and previous shoulder surgery as significant predictors of the 11-year CS. Each 1-point increase of the preoperative CS was associated with a 0.38-point increase of the 11-year CS ($P$ = .038), while preoperative surgery was associated with a 10.6-point decrease of the CS at 11 years ($P$ = .049).

## Radiologic outcome

Radiologic follow-up was performed in 18 patients (55%). Eleven patients (61%) exhibited grade 1 notching and 3

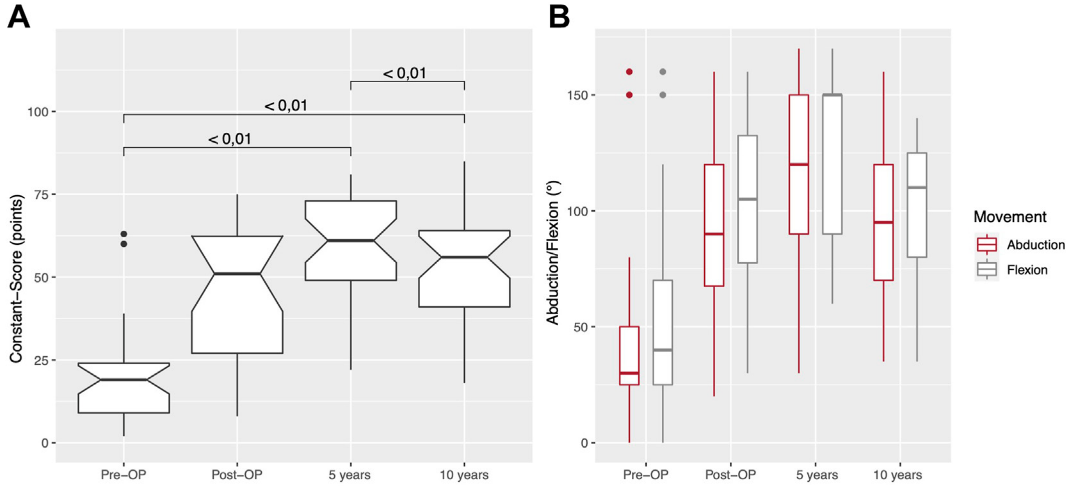


**Figure 3** Longitudinal evolution of (**A**) Constant score and (**B**) abduction and flexion during follow-up. *Pre-OP*, preoperative; *Post-OP*, postoperative.

patients (17%) had grade 2 notching on radiographic evaluation. Four patients (22%) had no notching (grade 0). No significant difference in CS was observed between patients with no notching (61.5 [51.1-67.1] points) and patients with notching grade 1 or higher (55.3 [44.9-57.2] points, $P = .43$). No radiograph showed definitive signs of loosening.

## Discussion

The most important findings of the present study indicate that rTSA with an inlay humeral design and a 155° NSA provides a significant improvement of the clinical and functional outcome and an excellent prosthesis survival in the long term. However, a decline in functional outcome was observed between 5 and 11 years. Furthermore, patients with fracture sequelae had a significantly higher risk of revision compared to patients with CTA. Patients who had undergone previous shoulder surgery had a significantly lower CS and a higher risk of reoperation due to any complication.

### Prosthesis survival

This study reported an implant survival rate of 95.3% (95% CI: 90.8-100) after 11 years. Several authors have assessed the survivorship of rTSA with a minimum of 10 years, reporting comparable survival rates of 82%-93%.[2,15,29,44,54] However, only few studies have assessed long-term results of the Delta Xtend prosthesis model. Most recently, Lafosse et al[38] reported a similar prosthesis survival of 94% after a minimum follow-up of 10 years. In contrast, Bassens et al[5] reported a lower revision rate of 2.7%. Notably, only patients with primary implantation were included, which may explain the higher survival rate of this patient cohort. To our knowledge, this study reports the longest follow-up of this prosthesis design and type. Notably, the survival rates observed in this study are higher than the reported long-term survival of the predecessor Delta III model, ranging between 79% and 93%.[4,32,44,65] In this context, registry analyses have demonstrated a 2.7-fold higher risk for revision for the Delta III model compared to the Delta Xtend prosthesis,[4,32] which may indicate an advancement in prosthesis design.

Due to the low number of revisions recorded in this cohort (4), their further statistical analysis is limited. However, it is noteworthy that 3 of the 4 observed revisions were in patients with fracture sequelae (group 3). Furthermore, regression analysis indicated that patients in this group had a significantly higher risk of revision compared to patients with CTA, confirming one of the hypotheses of the present study. These findings are consistent with the current literature, as patients with fracture sequelae have been reported to have higher complication and revision rates as well as high rates of periprosthetic infection.[22,35,41,52,53,63,67] A recent systematic review observed a cumulative incidence of periprosthetic infection of 3.7% for patients with fracture sequelae compared to 2.4% for patients with CTA or irreparable rotator cuff tears.[52] While the overall rate of infections observed in this study (2 patients, 1.9%) is lower than the rates commonly reported in the literature,[9,52,67] it is notable that both infections occurred in the fracture sequelae group. Although the reasons for these observations are not fully understood, low-grade infections of pre-existing metallic fixation systems have been discussed as a possible cause.[36]

In the present study, 1 of the 4 observed revisions was due to postoperative instability, a frequently reported complication in rTSA.[53,67] Finally, 1 revision was performed due to aseptic loosening of the humeral stem. In contrast to the other reported reasons for revision of our

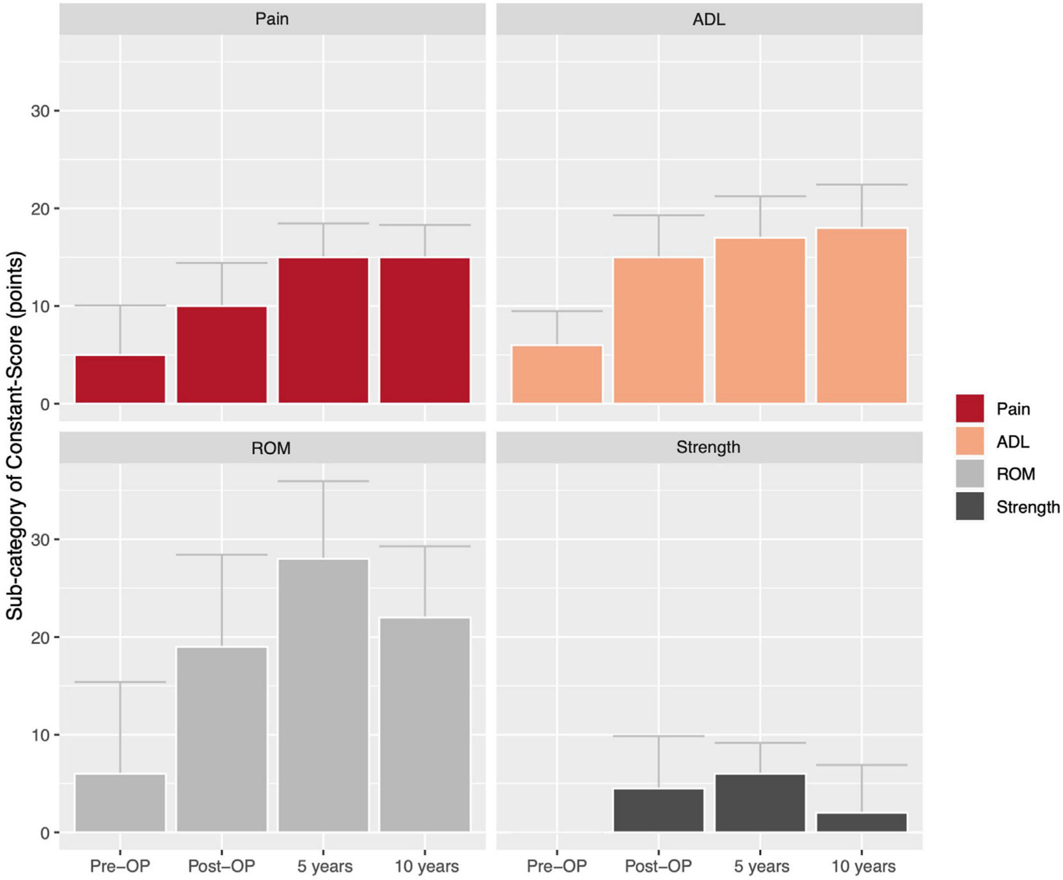


**Figure 4** Longitudinal evolution of subcategories of the Constant score. *ADL*, activities of daily living; *ROM*, range of motion; *Pre-OP*, preoperative; *Post-OP*, postoperative.

cohort, aseptic mechanical complications such as humeral loosening are less common than glenoid component loosening.[52,67] It is noteworthy that the majority of the complications occurred in the short and mid term with no complications or revisions reported in the long term after 7 years; however, a selection bias cannot be fully ruled out.

## Complications

In this study, the complication rate including revisions was 12.5%. Previous studies have reported complication rates ranging from a rate of 4% for primary implantation to as high as 45% for revision rTSA.[1,5,38,42,64] However, earlier studies reported less favorable results, suggesting an advancement in surgical technique and implant designs.[13,62,63,65] In this study, no significant difference in complication rates was observed between the indication groups. In contrast, recent studies have reported significantly higher complication and revision rates for indications other than CTA.[22,52,53,62,63] It is probable that due to the limited number of complications in our cohort, the statistical analysis between subgroups in this study was underpowered.

## Radiological outcome

In our patient cohort, we observed a high rate of scapular notching (78%); however, none of these patients showed glenoid loosening. Several authors have reported a high rate of scapular notching ranging between 68% and 94%.[2,14,58] In this context, several aspects of implant design have been observed to influence the incidence of scapular notching. Medialized glenoid systems as well as designs with a higher NSA are associated with high scapular notching rates,[18,40,46,47,65] whereas lateralized prosthesis designs and a lower NSA have been observed to result in lower scapular notching rates.[8,17,40,43,46,50,52] As the implant system used in the present study features a medialized glenoid design and a NSA of 155°, the high rates of scapular notching observed in this study may be explained. Conversely, Lafosse et al observed a lower notching rate of 40% using the same prosthesis model.[38] This difference in notching rates may be attributed to different surgical choices, as previous studies have shown that a large glenoid size and an inferior overhang may reduce the incidence of notching.[19,20,27,60] While implantation in the present cohort was performed with a focus on these 2 parameters, it is possible that differences in implant placement may have contributed to the observed variation in notching rates. However, the lack of systematic postoperative radiographic measurements of these parameters limits the comparison.

## Clinical and functional outcome

This study reported a favorable functional outcome 11 years after the implantation with a CS of 56 (41-64) points, with a long-term improvement since implantation exceeding the minimal clinically important difference (MCID).[66] This finding is consistent with the current literature reporting a long-term CS ranging from 55 to 67 points.[2,5,29,38,44] Notably, a significant decrease in the CS was observed between the mid-term and long-term follow-up in our study, caused by significant decreases in ROM and strength. However, this difference did not exceed the MCID.[66] Several authors have reported a decline in shoulder function after 5 years.[2,23,26,29] For the Delta Xtend prosthesis, Bassens et al[5] reported a significant decline in shoulder function between the mid-term and long-term follow-up, exceeding the MCID. As the observed difference between mid-term and long-term follow-up in age-correlated and sex-correlated CS was not significant, physiological changes with increasing age may explain these observations.[51] A further explanation may be provided by the concept of deltoid fatigue. Earlier studies suggested an acute loss of overhead ROM and functional outcome parameters at 6-8 years after surgery,[2,26,56] while recent studies reported a steady decline with an early onset after implantation.[51] Although the underlying causes remain unclear, overtensioning the deltoid has been suggested to lead to nonphysiological muscle fiber recruitment.[2,29,49] Structural changes in the deltoid, including reduced perfusion kinetics[28] and histologic changes,[37] have been demonstrated in the early postoperative period, possibly contributing to functional decline. As the Delta Xtend prosthesis model represents the classic Grammont design, a higher distalization of the humerus may exacerbate this effect. However, although axillary nerve injury has been reported with excessive distalisation,[34] the relationship between distalization and long-term deltoid function remains unclear.

## Impact of previous surgery on clinical and functional outcome

The patients included in this study who had undergone previous surgery of the shoulder showed a significantly worse CS and a significantly higher risk of reoperation because of any complication, confirming one of the hypotheses of this study. Similarly, an analysis of the Danish Shoulder Registry[4] reported a significantly worse functional outcome for patients with previous shoulder surgery, but did not observe a higher risk for revision. Less favorable outcomes were also demonstrated for patients who previously underwent ORIF of proximal humerus fractures[24,30] and previous rotator cuff repair.[59] Formation of scar tissue, iatrogenic damage to the rotator cuff, or undetected low-grade infections have been stated as possible reasons.[4,55] In our patient cohort, the limited size of the subgroup with previous shoulder surgery did not allow for statistical analysis or further subgrouping.

## Limitations

This study has several limitations. First, because of its prospective nature, only 31% of the initially included patients were examined at follow-up, which opens this cohort to selection bias. However, considering that 56% of the patients were deceased or medically unfit to be examined, only 9% of the patients were effectively lost to follow-up. Notwithstanding, the revision rate may be underestimated because patients lost to follow-up or deceased may have undergone revision at another institution. Second, the patients included in the pilot study represent a heterogeneous cohort in terms of indications for surgery, surgical procedure, and age. Third, the limited size of the cohort of patients available for follow-up limits the power of subgroup analysis. Moreover, no statistical power analysis was performed prior to the study to plan the study size. Fourth, given the single-center, single-surgeon, and single-implant design of this study, its external applicability may be limited. Additionally, potential bias may be introduced by the affiliations of the senior author with the implant manufacturer, including financial interests such as royalties.

The follow-up examinations were not performed by a single examiner, so that the influence of different observers cannot be ruled out. Finally, the lack of radiographic results at the latest follow-up in a large number of patients is another limitation of this study, which reduces the significance of the radiographic analysis and the correlation between radiographic and functional outcome parameters at 11 years postoperatively.

## Conclusion

This study was able to demonstrate a favorable long-term functional improvement after rTSA with a very satisfactory implant survival rate of 95.3% after 11 years. However, a significant decline of the functional outcome after the mid-term follow-up was observed. For indications other than CTA, such as the treatment of fracture sequelae, the functional results are inferior and the risk for revision is higher. Previous shoulder surgery prior to the index arthroplasty leads to a worse shoulder function and a higher risk of reoperation due to any complication. Although a high rate of scapular notching was shown, no influence on the functional outcome was evident. In conclusion, rTSA using the Delta Xtend system has been shown to provide satisfactory long-term results.

## Disclaimers:

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