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Short-term safety, function, and quality of life in patients treated with Univers Revers prosthesis: a multicenter 2-year follow-up case series

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Background: The use of reverse total shoulder arthroplasty (RTSA) has dramatically increased in recent years with the advent of new prosthesis designs regularly entering the market. We define the rate of local complications during the first 2 years after RTSA with the Univers Revers prosthesis and describe the changes in radiologic outcomes, as well as function, pain, satisfaction, and quality of life.
Methods: This multicenter, prospective case series included rotator cuff tear arthropathy patients who underwent RTSA with the Univers Revers. Incidence percentages of complications and pathologic radiographic changes were documented. Mixed-model linear regression was used to examine changes in range of motion, shoulder function (Constant score, Shoulder Pain and Disability Index, Subjective Shoulder Value), and quality of life (EQ-5D-5L [European Quality of Life 5 Dimensions 5 Level] and EQ-VAS [EuroQol Visual Analog Scale]).
Results: Of 187 patients, 59.4% were women, and the mean age was 75.3 years (range, 56-91 years). Twenty-five percent of patients had a postoperative complication; 5 complications were severe (2.7%, 5 of 187), whereby 2 were implant related (1.1%; 95% confidence interval [CI], 0.1%-3.8%). The incidence of scapular notching was 10.6% (95% CI, 6.5%-16%). After 2 years, abduction, flexion, and abduction strength improved by 54° (95% CI, 50°-58°), 57° (95% CI, 53°-60°), and 5 kg (95% CI, 4-5 kg), respectively ($P < .001$), whereas external rotation at 0° (1°; 95% CI, –1° to 3°) did not improve ($P = .4$). The Constant score improved by 39 (95% CI, 38-41); Shoulder Pain and Disability Index, by 50 (95% CI, 47-52); and Subjective Shoulder Value, by 43 (95% CI, 41-45) ($P < .001$).

Institutional review board/ethics committee approval was granted by the Cantonal Ethics Committee of Zürich (KEK-ZH-Nr. 2013-0185).

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Furthermore, the EQ-5D-5L index value improved by 0.31 (95% CI, 0.30-0.33), and the EQ-VAS score improved by 16 (95% CI, 14-18) ($P < .001$).

Conclusion: Our case series showed a low complication rate with a consistent clinically relevant and statistically significant improvement across most clinical and patient-reported outcomes for the Univers Revers. Long-term safety requires further investigation.

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

Keywords: Shoulder; arthroplasty; reverse shoulder replacement; complications; Constant score; adverse events; quality of life

Rotator cuff tear arthropathy is associated with rotator cuff insufficiency, degenerative changes of the glenohumeral joint, and superior migration of the humeral head.[25] These pathologic changes often lead to chronic pain, impaired range of motion, substantial functional limitation, and decreased quality of life.[17]

Reverse total shoulder arthroplasty (RTSA) is the treatment of choice for glenohumeral arthritis with irreparable rotator cuff tears,[10,15] which has proved effective in reducing pain and restoring function in older adults,[33] who usually reach maximum functional improvement 1 year after surgery.[8] Despite these good clinical outcomes, the complication rate of primary RTSA is estimated at approximately 15%,[5] with some reports documenting rates as high as 68%.[34] The most prevalent complications include dislocation, infection, scapular notching, loosening, nerve injury, acromial and scapular spine fractures, intraoperative fractures, and component disengagement.[5]

Most of the current RTSA prostheses are constructed using the same general principle of reversing the ball and socket.[22] Nevertheless, substantial variations in implant design and component positioning influence the location of the joint center of rotation and, therefore, overall joint mobility and stability.[1] One notable aspect is the lack of consensus on the optimal humeral component inclination angle (135° vs. 155°); many RTSA devices are only available with either the lower-angle option or its higher-angle counterpart.[12] Since 2012, the Univers Revers system (Arthrex, Naples, FL, USA) has been on the market. From the wide range of stem, cup, spacer, inlay, or glenosphere components available, various configurations and biomechanical properties offer contrasting effects on motion restoration in different planes.[32] Although the Univers Revers is widely used to treat rotator cuff arthropathy, there are still no prospective data characterizing the complication rate and functional outcomes of this inverse shoulder prosthesis.

To address this gap, we aimed to define the rate of local complications during the first 2 years after RTSA with the Univers Revers and describe the changes in radiologic outcome, as well as function, pain, satisfaction, and quality of life.

Materials and methods

Study design and population

This prospective, multicenter case-series study was performed in 1 Swiss clinic and 4 clinics in Germany. Between November 2013 and December 2016, we enrolled adult patients with a diagnosis of primary degenerative shoulder osteoarthritis or secondary osteoarthritis, either of which was associated with insufficiency in the centering function of the rotator cuff or a massive rotator cuff tear, or diagnosis of primary osteoarthritis with a severe glenoid defect and posterior humeral head subluxation. The main exclusion criteria were previous arthroplasty of the ipsilateral shoulder, acute shoulder trauma, post-traumatic secondary osteoarthritis, rheumatoid arthritis, or any form of malignancy.

Study intervention

All patients underwent RTSA with the Univers Revers shoulder prosthesis (Fig. 1).[23] Preoperative planning was based on radiographic imaging. The Univers Revers set of template transparencies was used for glenoid and humeral component sizing. For patients with large glenoid bone defects, computed tomography with 3-dimensional images of the glenoid were additionally used to minimize the risk of glenoid component malposition. Intraoperatively, glenosphere size and offset, as well as the size and necessity of the spacer, were adjusted with trial reductions ensuring appropriate deltoid tension, stability, and range of motion. The choice of neck-shaft angle was made preoperatively and not standardized. When possible, the subscapularis tendon was repaired.

After surgery, the treated arm was immobilized with an abduction pillow for up to 4 weeks while patients followed a standardized physical therapy program involving passive, active-assisted, and active mobilization for 3 months.

Follow-up

Clinical and functional examinations, assessment of adverse events (AEs), radiologic evaluation, and patient self-assessments were performed before surgery (baseline) and at 6 weeks (only AEs and quality of life), 6 months, 1 year, and 2 years after surgery.

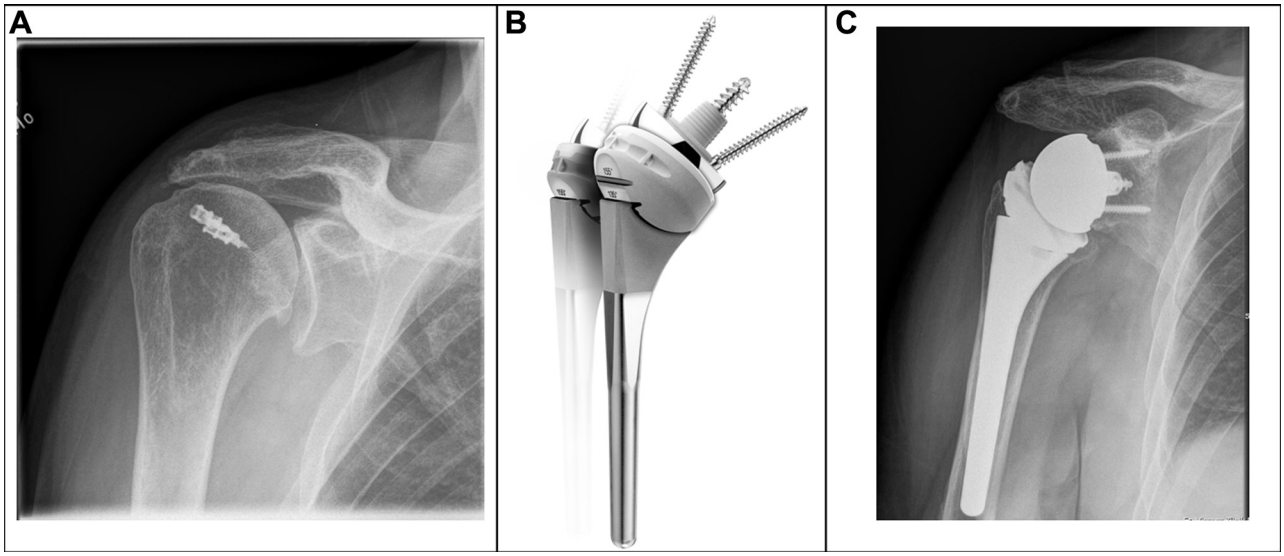

Figure 1 (**A**) Preoperative radiograph. (**B**) Univers Revers shoulder prosthesis system. (**C**) Radiograph of same patient 24 months after reverse total shoulder arthroplasty.

Complications: AEs and serious adverse device effects

To determine the complication rates, all local (operated site) AEs were documented during follow-up. AEs were defined in line with the International Organization for Standardization (ISO) 14155 standard as "any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device" and classified as previously described.[4] The time frame of occurrence (intraoperative or postoperative), AE severity, possible relation to the implant, and AE treatment were documented. Serious adverse device effects (SADEs) are implant-related serious adverse events (SAEs) (eg, implant breakage).[4] Patients were encouraged to report AEs regardless of clinical visits.

Radiographic assessments

Rotator cuff integrity was evaluated by magnetic resonance imaging (or computed tomography arthrography and/or ultrasound when magnetic resonance imaging was contraindicated). The levels of tendon retraction,[28] muscle atrophy,[31] and fatty infiltration[18,20] were evaluated as previously described. At each follow-up, radiographs were screened according to international consensus.[11] Radiographic grading was performed centrally in the coordinating center by 2 shoulder surgeons with 35 and 10 years of experience; the results were determined by consensus. Heterotopic bone formation was classified according to a modification of the Brooker classification,[7] in which grade 1 indicates islands of bone within the soft tissues around the shoulder; grade 2, bone spurs from the proximal humerus or scapula with at least 1 cm of space remaining between opposing bone surfaces; grade 3, bone spurs from the proximal humerus or scapula with a reduction in the space between opposing bone surfaces to less than 1 cm; and grade 4, apparent bone ankylosis of the shoulder.

Assessment of shoulder function, quality of life, and patient satisfaction

Shoulder functional outcomes were assessed with the Constant score (CS),[9] Shoulder Pain and Disability Index,[2] and Subjective Shoulder Value (SSV).[19] Range of motion was assessed with a goniometer according to a standardized protocol. Internal rotation was assessed by the Apley scratch test. We used a spring balance (Pesola AG, Schindellegi, Switzerland) or Isobex (Cursor AG, Bern, Switzerland) dynamometer for abduction strength measurements. Quality of life was assessed with the EuroQol Visual Analog Scale (EQ-VAS) (0, worse; 100, best)[14] and European Quality of Life 5 Dimensions 5 Level (EQ-5D-5L) questionnaire.[21] In addition, patients were asked whether they would agree to undergo the same operation again and to what extent their expectations of the operation were fulfilled (0, not at all; 10, fully).

Statistical analyses

Statistical analyses were performed using Intercooled STATA (version 14; StataCorp, College Station, TX, USA) and R (version 3.6.0; R Foundation for Statistical Computing, Vienna, Austria). On the basis of the published literature, we expected that SADEs within 2 years after surgery would occur during the study at a rate of around 2%.[30] A power calculation was performed with nQuery-Advisor (version 7.0; Statistical Solutions, Cork, Ireland), which included a compensation factor for anticipated dropouts. The percentages of patients with AEs and radiographic pathologies were reported with 95% confidence intervals (CIs). Mixed-model linear regression with a random per-person intercept was used to produce age-adjusted, sex-adjusted, and baseline value–adjusted trajectories for range of motion, shoulder functional scores, and quality of life.

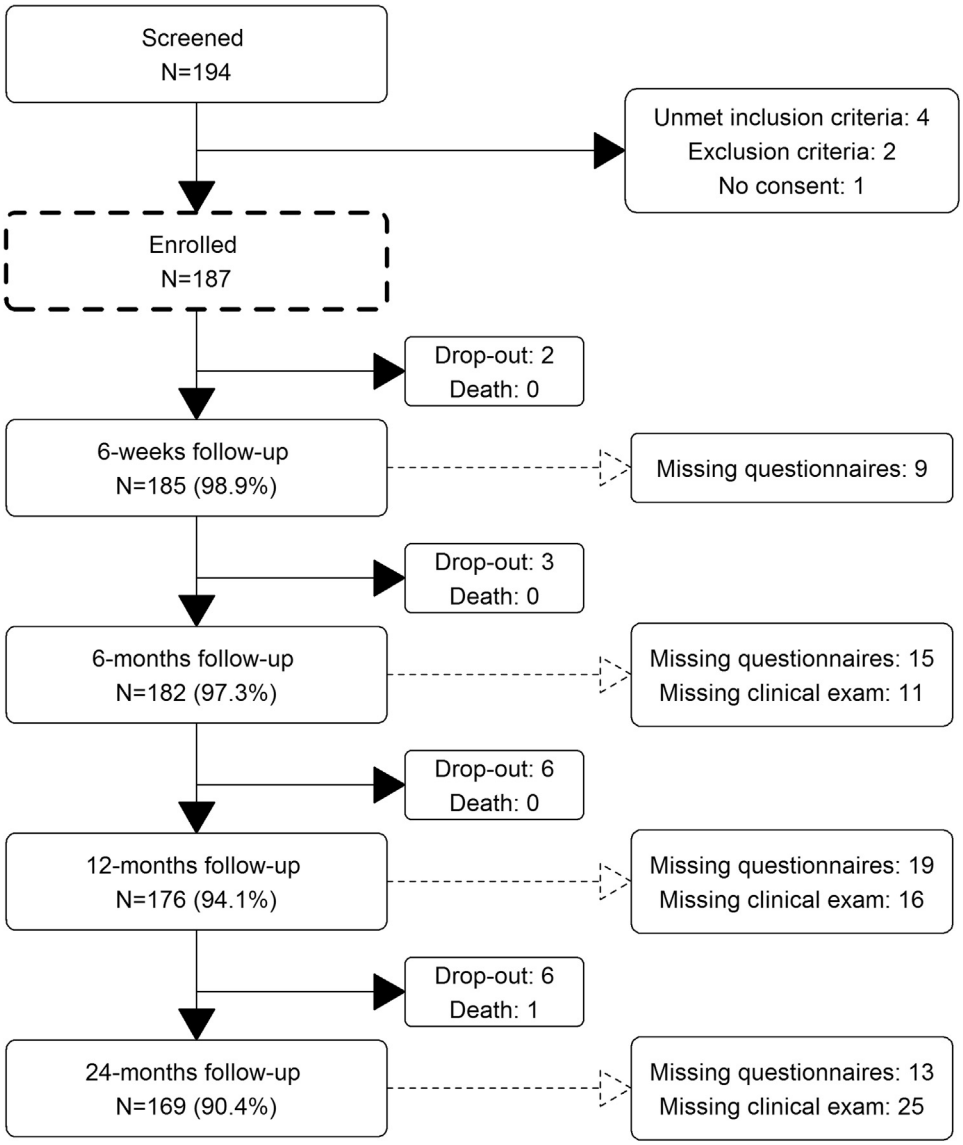

Figure 2 Study flowchart.

Results

Baseline characteristics

In total, 187 patients met the inclusion criteria and were enrolled (Fig. 2). Most were women (59%, 111 of 187), and the mean age was 75.3 years (standard deviation [SD], 6.1 years); 22% of patients (42 of 187) were older than 80 years (Table I). Only 14% of patients (26 of 187) had no comorbidities, whereas 22% (41 of 187) had 3 or more. The mean follow-up time was 23 months. At baseline, the average CS was 32 (SD, 14) and SSV 40 (SD, 18). Range-of-motion tests showed suboptimal abduction (mean, 68°; only 21% reached 90°) and flexion (mean, 76°). The level of rotator cuff lesion retraction was at least grade II in 63% of patients (Supplementary Table S1).

Neck-shaft angle and glenosphere offset and size

The deltopectoral approach was used in all patients. In the vast majority (98%, 183 of 187), the implant neck-shaft angle was 135°, whereas the remaining 4 patients received a 155° implant. Glenosphere offset was lateral (+4 mm lateral) and standard (+0 mm lateral) in 82% and 17% of patients, respectively, whereas the remaining 2 patients had an inferior offset (+2.5 mm inferior). The most frequently used glenosphere size was 39 mm (47.6%, 89 of 187 patients), followed by 36 mm (32.6%, 61 of 187) and 42 mm (19.8%, 37 of 187).

Adverse events and SADEs

Overall, 65 local AEs were documented in 51 patients (27%, 51 of 187). Five AEs occurred intraoperatively; all

Table I Baseline characteristics

	Overall	With clinical examination at 24 mo	No clinical examination at 24 mo	*P* value
n	187	144	43	
Age, mean (SD), yr	75 (6)	75 (6)	76 (7)	.299
Age category, n (%)				.909
50-60 yr	4 (2)	3 (2)	1 (2)	
61-70 yr	32 (17)	24 (17)	8 (19)	
71-80 yr	109 (58)	86 (60)	23 (53)	
>80 yr	42 (22)	31 (22)	11 (26)	
Male sex, n (%)	76 (41)	57 (40)	19 (44)	.717
BMI, mean (SD)	27 (4)	27 (5)	26 (4)	.268
Smoking: yes, n (%)	11 (6)	8 (6)	3 (7)	>.999
No. of comorbidities, n (%)				.825
0	26 (14)	19 (13)	7 (16)	
1	72 (39)	54 (38)	18 (42)	
2	48 (26)	39 (27)	9 (21)	
≥3	41 (22)	32 (22)	9 (21)	
Previous operation: yes, n (%)	49 (26)	36 (25)	13 (30)	.626
EuroQol VAS, mean (SD)	64 (20)	65 (20)	62 (21)	.295
EQ-5D-5L index value, mean (SD)	0.6 (0.26)	0.59 (0.27)	0.63 (0.25)	.339
Constant score, mean (SD)	32 (14)	32 (15)	30 (11)	.385
Shoulder Pain and Disability Index, mean (SD)	36 (18)	36 (17)	36 (18)	.960
Subjective Shoulder Value, mean (SD)	40 (18)	40 (18)	42 (20)	.489
Flexion, mean (SD), °	76 (35)	78 (36)	70 (29)	.195
Abduction, mean (SD), °	68 (30)	68 (32)	66 (23)	.763
Abduction at least 90°: yes, n (%)	39 (21)	29 (21)	10 (23)	.869
External rotation at 90°, mean (SD), °	18 (27)	18 (28)	18 (22)	.988
Internal rotation at 90°, mean (SD), °	16 (20)	13 (20)	23 (20)	.046
External rotation at 0°, mean (SD), °	28 (21)	29 (22)	22 (16)	.070
Positive drop-arm test result, n (%)	20 (53)	14 (50)	6 (60)	.861
Positive external rotation lag sign test result, n (%)	75 (60)	57 (60)	18 (58)	>.999
Abduction strength of affected arm, mean (SD), kg	1 (2)	1 (2)	1 (2)	.681
Abduction strength of unaffected arm, mean (SD), kg	5 (3)	5 (3)	5 (3)	.931
Maximal internal rotation, n (%)				.569
Lateral aspect of thigh	20 (11)	18 (13)	2 (5)	
Gluteal region	51 (28)	37 (27)	14 (33)	
Lumbosacral region	51 (28)	38 (27)	13 (30)	
L3	36 (20)	27 (19)	9 (21)	
Th12	20 (11)	15 (11)	5 (12)	
Interscapular T7	4 (2)	4 (3)	0 (0)	

SD, standard deviation; *BMI*, body mass index; *VAS*, visual analog scale; *EQ-5D-5L*, European Quality of Life 5 Dimensions 5 Level.
Active ranges of motion are presented. *P* values show the difference in baseline characteristics between patients with and patients without clinical examinations at 24 months. External rotation and internal rotation at 90° were only measured in patients who could reach 90° of passive abduction.

were local, and none were severe or had serious medical consequences (Table II). Three intraoperative AEs were possibly linked to the implant. In the first patient, the screw head broke during insertion; in the second, the screw could not be inserted at all; and in the third, a fissure fracture of the lateral greater tuberosity occurred.

There were 60 postoperative local AEs. One-quarter of the patients (46 of 187, 25% [95% CI, 19%-31%]) had at least 1 postoperative local AE (Table III). Local SAEs were reported in 5 patients (2.7%; 95% CI, 0.9%-6.1%), 2 of which (1.1% [95% CI, 0.1%-3.8%]; 2 of 187, or 0.6 [95% CI, 0.1-2.0] per 100 person-years) were SADEs, each requiring another operation, and one of which involved implant revision. Both events resulted from a fall; the baseplate and glenosphere detached in 1 patient, and a periprosthetic fracture occurred in the other patient. There were no reports of implant dislocation, infection, or loosening. An acromial fracture was reported in 3 patients (1.6%; 95% CI, 0.3%-4.6%).

Table II Intraoperative local adverse events

	Total	Fracture	Implant breakage	Other*
n/N	5/187	2/187	1/187	2/187
% (95% CI)	2.7 (0.9-6.1)	1.1 (0.1-3.8)	0.5 (0-2.9)	1.1 (0.1-3.8)
Severity†				
Mild	3	1	1	1
Moderate	2	1	0	1
Severe	0	0	0	0
Implant related	3	1	1	1

CI, confidence interval; *n*, number of patients with at least 1 event; *N*, total number of patients at risk.

* Screw insertion problem and tearing of ventral deltoid.

† Mild is defined as temporary or mild discomfort (<48 hours), for which no medical intervention or treatment is needed. Moderate is defined as a slight to moderate limitation in activity, with some support needed; no or minimal medical intervention or treatment is needed. Severe is defined as significant impairment of activity, for which the patient needs regular support; medical intervention or treatment is needed, and hospitalization is possible.

Radiographic follow-up

Seven patients did not undergo radiologic follow-up. In all other patients, there were no signs of implant migration and/or loosening or shoulder joint displacement (Table IV). Overall, 10.6% of patients (19 of 180) (95% CI, 6.5%-16%) with at least 1 follow-up radiograph had scapular notching. Most patients (79%, 15 of 19) had grade I scapular notching; 2 patients had grade II, 2 had grade III, and 0 had grade IV. Ten percent of the patients (18 of 180) (95% CI, 6%-15.3%) had heterotopic ossification, with half categorized as grade I; 5, grade II; and 4, grade III.

Change in shoulder functional outcomes

Throughout the 2-year follow-up period, large, clinically meaningful and statistically significant ($P < .001$) improvements occurred in all 3 shoulder functional outcomes (Fig. 3, *A*; Supplementary Tables S2 and S3). The Shoulder Pain and Disability Index improved by 50 (95% CI, 47-52) on average; the SSV, by 43 (95% CI, 41-45); and the CS, by 39 (95% CI, 38-41).

Change in range of motion and abduction strength

We also found large, clinically meaningful and statistically significant ($P < .001$) improvements in all range-of-motion tests over the 2-year postoperative period, except external rotation at 0° (Fig. 3, *B*). Flexion and abduction improved, on average, by 57° (95% CI, 53°-60°) and 54° (95% CI, 50°-58°), respectively. The proportion of patients reaching 90° of abduction improved from 21% to 96% ($P < .001$). For patients who achieved 90° of abduction at baseline, external rotation improved by 31° (95% CI, 25°-38°) and internal rotation, by 29° (95% CI, 25°-33°). No significant change was noted for external rotation at 0° (1° [95% CI, –1° to 3°], $P = .4$). For abduction strength, a large improvement of 5 kg (95% CI, 4-5 kg) was observed after 2 years ($P < .001$) (Fig. 3, *B*). Maximum shoulder internal rotation substantially improved with a large reduction in the percentage of patients being unable to reach at least the lumbosacral region (from 39% at baseline to only 14% at 2-year follow-up, $P < .001$) (Fig. 3, *C*).

Change in quality of life and patient satisfaction

Significant ($P < .001$) improvement was found in both quality-of-life measures over the course of follow-up; the EQ-5D-5L index value improved by 0.31 (95% CI, 0.3-0.33) (Fig. 3, *D*) and the EQ-VAS improved by 16.0 (95% CI, 14-18) after 2 years. At 24 months, 95% of the patients indicated they would agree to undergo the operation again. Furthermore, on a scale from 0 to 10, mean expectation fulfillment was rated 9.2 (interquartile range, 9.0-10.0) at 24 months.

Discussion

This prospective, multicenter study of patients with rotator cuff arthropathy evaluated the complication rate, shoulder function, and quality of life after RTSA with the Univers Revers system. We showed clinically relevant increases in most functional outcomes and in quality of life, as well as good patient satisfaction. The rate of local SAEs and implant-related complications within 2 years of follow-up was 2.7% and 1.1%, respectively, which is in line with the findings of the systematic review of Smith et al.[30]

Previous work has shown that instability, periprosthetic fracture, infection, and component loosening are the most common complications of reverse shoulder arthroplasty, accounting for 81.2% of all complications.[6] In our sample, we did not observe dislocations during the first 2 years of follow-up. Nevertheless, 2 severe complications were implant related, with 1 requiring a revision operation. Although direct comparison to other studies and prostheses

Table III Incidence percentages of postoperative local AEs, local SAEs, and SADEs

	n (% [95% CI])		
	Overall	SAE	SADE*
n	187		
Any local AE	46 (24.6 [18.6-31.4])	5 (2.7 [0.9-6.1])	2 (1.1 [0.1-3.8])
Implant problem	1 (0.5 [0-2.9])	1 (0.5 [0-2.9])	1 (0.5 [0-2.9])
Implant failure or breakage	1 (0.5 [0-2.9])	1 (0.5 [0-2.9])	1 (0.5 [0-2.9])
Implant dislocation	—	—	—
Implant loosening	—	—	—
Other implant problem	—	—	—
Bone and/or cartilage	7 (3.7 [1.5-7.6])	2 (1.1 [0.1-3.8])	1 (0.5 [0-2.9])
Periprosthetic fracture	1 (0.5 [0-2.9])	1 (0.5 [0-2.9])	1 (0.5 [0-2.9])
Scapular fracture	3 (1.6 [0.3-4.6])	1 (0.5 [0-2.9])	—
Clavicle fracture	—	—	—
Septic arthritis	—	—	—
Other bone problem†	3 (1.6 [0.3-4.6])	—	—
Musculoskeletal system and/or soft tissue	33 (17.6 [12.5-23.9])	1 (0.5 [0-2.9])	—
Hypersensitivity (allergic reaction)	—	—	—
Pain	30 (16 [11.1-22.1])	1 (0.5 [0-2.9])	—
Periarthritis (frozen shoulder)	—	—	—
Tendon rupture	—	—	—
Peripheral neuropathy	1 (0.5 [0-2.9])	—	—
Peripheral paralysis	—	—	—
Complex regional pain syndrome	—	—	—
Other‡	3 (1.6 [0.3-4.6])	—	—
Wound	12 (6.4 [3.4-10.9])	1 (0.5 [0-2.9])	—
Infection (sepsis)	1 (0.5 [0-2.9])	1 (0.5 [0-2.9])	—
Hematoma	6 (3.2 [1.2-6.9])	—	—
Thrombosis	—	—	—
Other wound and/or surrounding area problems§	6 (3.2 [1.2-6.9])	—	—

AE, adverse events; *SAE*, serious adverse event; *SADE*, serious adverse device effect; *CI*, confidence interval.

An SAE is defined as an event that causes significant impairment of activity, for which the patient needs regular support; medical intervention or treatment is needed, and hospitalization is possible. SADEs are implant (device)–related SAEs. It should be noted that 1 event can be classified into more than 1 subcategory.

* Both SADEs resulted from a fall. Regarding the implant failure, the patient had polytrauma after a fall from a great height, including a complex pelvic ring fracture, lumbar spine fracture, and traumatic brain injury. Concerning the shoulder, the entire baseplate shifted laterally, exposing the upper part of the screws. During revision, the glenosphere was loose and could be easily removed by hand. A new baseplate and glenosphere were implanted. The second SADE was a periprosthetic fracture treated by open repositioning and locking compression plate osteosynthesis.

† Symptomatic os acromiale, irritation at acromioclavicular joint, and osteoarthritis of sternoclavicular joint.

‡ Radial nerve partial deficit, shoulder bruise after a fall, and perifocal hematoma swelling with lymphedema.

§ Scapular dyskinesis; mild axillary neurapraxia with impaired deltoid function; wound scarring; shoulder bruise after a fall; intraoperative smear indicating bacterial detection, with no treatment or consequences; and perifocal hematoma swelling with lymphedema.

is difficult because of heterogeneity in designs, patient populations, sample sizes, and follow-up times, an older report presented revision rates of 8.6% and 13% for mean follow-up periods of 17 and 33 months, respectively.[22] In addition, acromial fractures occurred in 3 patients (1.6%) in our study, a finding that is in line with previous reports.[6]

Radiographic follow-up showed around a 10% incidence for both scapular notching and heterotopic ossification. For the latter, the rate overlaps with the incidence of 6.6% (95% CI, 4.4%-9.6%) previously reported for a longer mean follow-up period of 35.3 months.[29] The rate of scapular notching is substantially lower than previously reported incidences ranging from 44% to 96%.[27] This difference is unlikely to be explained by the short follow-up period of 2 years because scapular notching usually appears between 6 and 14 months postoperatively.[27] The low rate of scapular notching in our study supports previous observations suggesting that a lateralized center of rotation and lower neck-shaft angle might decrease scapular notching.[26] Longer follow-up is required to determine whether this lower rate and grading of scapular notching will further progress and/or provide any clinically meaningful benefits.[24]

An intrinsic limitation of a case-series study design is the lack of a comparison group. However, we were interested, a priori, in the overall safety of the Univers Revers system as well as the postoperative changes in function and quality of life. The reported complication rates and functional recovery trajectories provide useful clinical

Table IV Radiographic findings: incidence percentages

	Data
Scapular notching	
% (95% CI)	10.6 (6.5-16)
n	19 of 180
Heterotopic ossification	
% (95% CI)	10 (6-15.3)
n	18 of 180
Acromial fracture	
% (95% CI)	1.7 (0.3-4.8)
n	3 of 180
Other*	
% (95% CI)	0 (0-2)
n	0 of 180

CI, confidence interval.

* The core set evaluated implant migration, radiolucency and/or implant loosening, shoulder joint displacement, wear of implant articular surfaces, and implant breakage and/or disassembly.

data. In addition, we implemented a wide range of standard clinical examinations and validated instruments for the assessment of shoulder function[3] and performed radiologic evaluations using a recent international consensus set of parameters.[11] An additional limitation of our study is that approximately 23% of the enrolled patients underwent no in-person clinical examination at 2 years. Nevertheless, patients were encouraged to report AEs regardless of the visit schedule and likely would have contacted their operating clinic in case of an SADE, which is the main focus of this study.

Although our study fills a scientific gap regarding the first 2 years after surgery for this particular RTSA system, longer postoperative follow-up periods of 5 and 10 years are still essential to understand long-term implant survival, as well as patient function and well-being. On the other hand, Ernstbrunner et al[13] recently evaluated the longitudinal evolution of mid- to long-term results of RTSA in

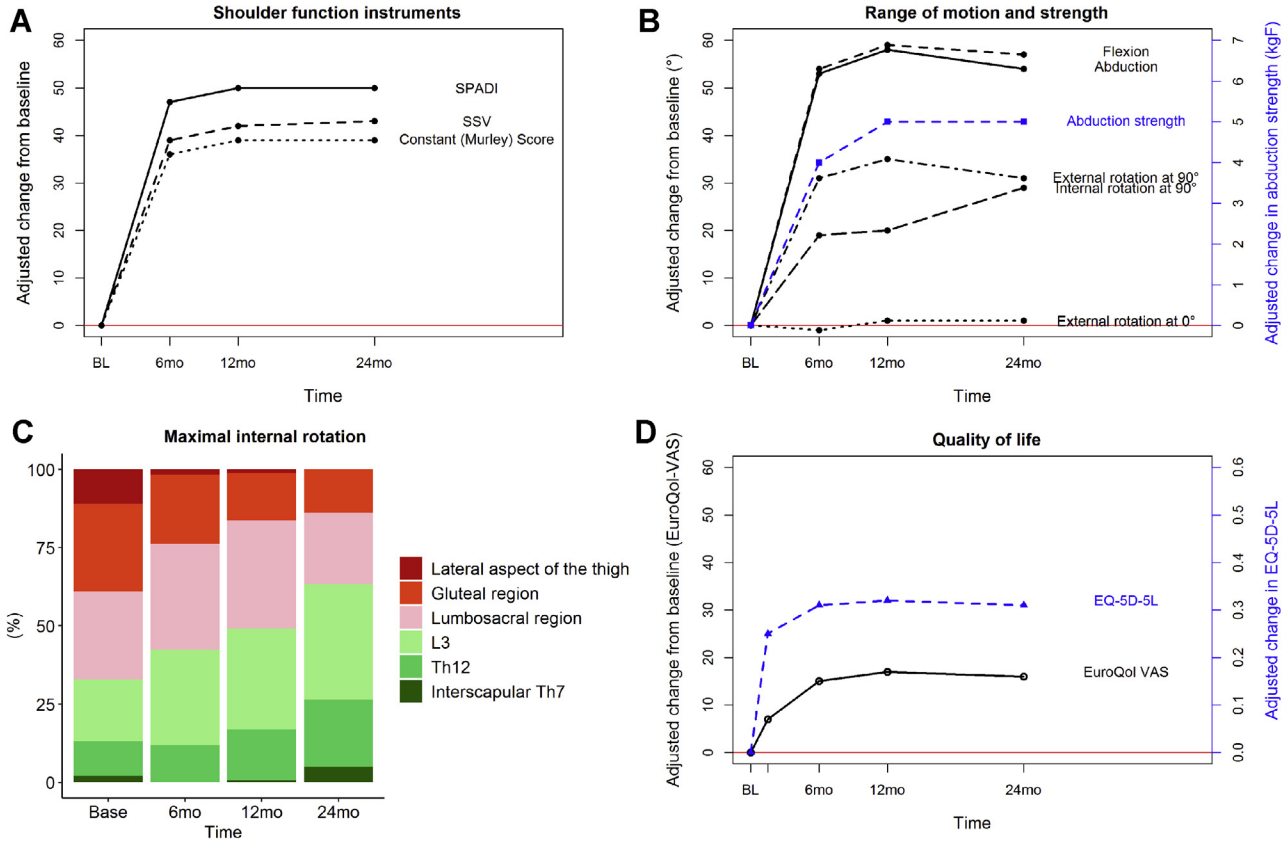

Figure 3 (**A**) Adjusted changes from baseline (*BL*) in Shoulder Pain and Disability Index (*SPADI*), Subjective Shoulder Value (*SSV*), and Constant score. Each score's theoretical range is 0-100. (**B**) Adjusted changes from baseline (*BL*) in range-of-motion tests (*left y-axis*) and abduction strength (*right y-axis, blue*). (**C**) Maximal achieved internal rotation (Apley scratch test) by follow-up time point. (**D**) Adjusted changes from baseline (*BL*) in quality-of-life instruments: EuroQol Visual Analog Scale (*VAS*) (*left y-axis*) and European Quality of Life 5 Dimensions 5 Level index value (*EQ-5D-5L*) (*right y-axis, blue*). *kgF*, kilogram-force; *Base*, baseline.

patients with massive irreparable rotator cuff tears; none of the examined clinical scores or active ranges of motion significantly deteriorated up to 20 years after surgery.

Conclusion

This prospective case series demonstrated a low failure rate and an overall good short-term safety profile of the Univers Revers shoulder prosthesis, which is associated with satisfying improvement in function and quality of life during the first 2 postoperative years. Prolonged follow-up is warranted to evaluate long-term implant stability, persistence of shoulder function, and patient satisfaction.

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Supplementary data

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