



Clinical and radiological outcomes of a stemless reverse shoulder implant: a two-year follow-up in 56 patients

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Background: Since the introduction of stemless anatomic shoulder arthroplasty, many studies have been published on anatomic implants. For reverse stemless implants, however, there are only a few clinical follow-up studies available. The current clinical case series aims to present clinical and radiological outcomes of a new stemless reverse prosthesis system (Lima Shoulder Modular Replacement stemless).

Methods: We prospectively evaluated the outcome of 56 stemless total shoulder arthroplasties in 56 patients with a mean age of 61.2 years (46–76 years) at the time of implantation at a minimum follow-up of 24 months (range 24–41 months). All patients were physically and radiologically examined. Clinical outcomes were evaluated by using the Constant–Murley Score and the Subjective Shoulder Value.

Results: The mean Subjective Shoulder Value was 84.27% at the latest follow-up. Significant improvements from preoperative to latest follow-up were documented for Constant–Murley Score (34.9 pts to 74.43 pts, $P < .001$) and active range of motion (abduction 72° to 130°, flexion 36° to 138°, and external rotation 16° to 28°). There was one complete loosening of the humeral component without reoperation. Radiolucency lines were observed in anteroposterior or axial radiographs at the humeral component in 23% of the cases, most of them in anteroposterior view at the calcar region. Radiolucency line findings did not affect clinical outcomes. Major complications or revisions did not occur so far.

Conclusion: At short-term follow-up, stemless reverse shoulder systems show comparable clinical and radiological outcomes compared to stemmed reverse implants in the literature.

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Reverse shoulder arthroplasty (RSA) is an effective tool in the portfolio of the shoulder surgeon treating massive rotator cuff tears, cuff tear arthropathy, and primary osteoarthritis of the shoulder with severe eccentric glenoid wear (B2/3 glenoid according to Walch) or in older patients with osteoarthritis and a “cuff at risk.”^{1,15,20} The main complaints of these patients are pain and loss of shoulder function (range of motion [ROM] and strength). The number of RSA implantation is rapidly increasing, along with a 5-fold increase in the US market within the past 10 years.¹⁹

From the classical stemmed “Grammont”-style prosthesis up to now, there was a significant change in design, especially at the glenoid side, but also on the humeral side. In 2004, the stemless anatomic implants emerged on the market. One of the rare stemless reverse implants currently available on the European market is

the Lima Shoulder Modular Replacement (SMR) stemless reverse prosthesis (Lima Corporate, Villanova, San Daniele del Friuli, Italy). The theoretical advantages of stemless reverse implants are equivalent to the postulated benefits of the stemless anatomical designs: preservation of the humeral bone stock, reduced peri-prosthetic fracture risk, higher adaptability during implantation, easier implantation in cases of altered anatomy such as post-traumatic malunion, as well as less complex revision surgery in case of failure of the stemless device.^{4,5,8,19} Since introducing the stemless reverse designs, there have been only a few studies reporting on short- and mid-term outcomes.^{7,9,10,13,17}

The first stemless implant, which was introduced in 2004, was the Total Evolutive Shoulder System (TESS; Biomet, Warsaw, IN, USA) which used a stemless “corola” design as a metaphyseal anchor.

Despite promising clinical and radiological results of this reverse system, the TESS was followed by the Zimmer Biomet Nano comprehensive. The Nano reverse system was withdrawn from the market by Zimmer. In 2015, Lima (Lima Corporate, Villanova, San Daniele del Friuli, Italy) released its SMR stemless shoulder system. This is a convertible system that contains two humeral-sided parts

This study was approved by the local ethics committee of St. Vinzenz-Klinik Pfronten (SVP-2012-01).

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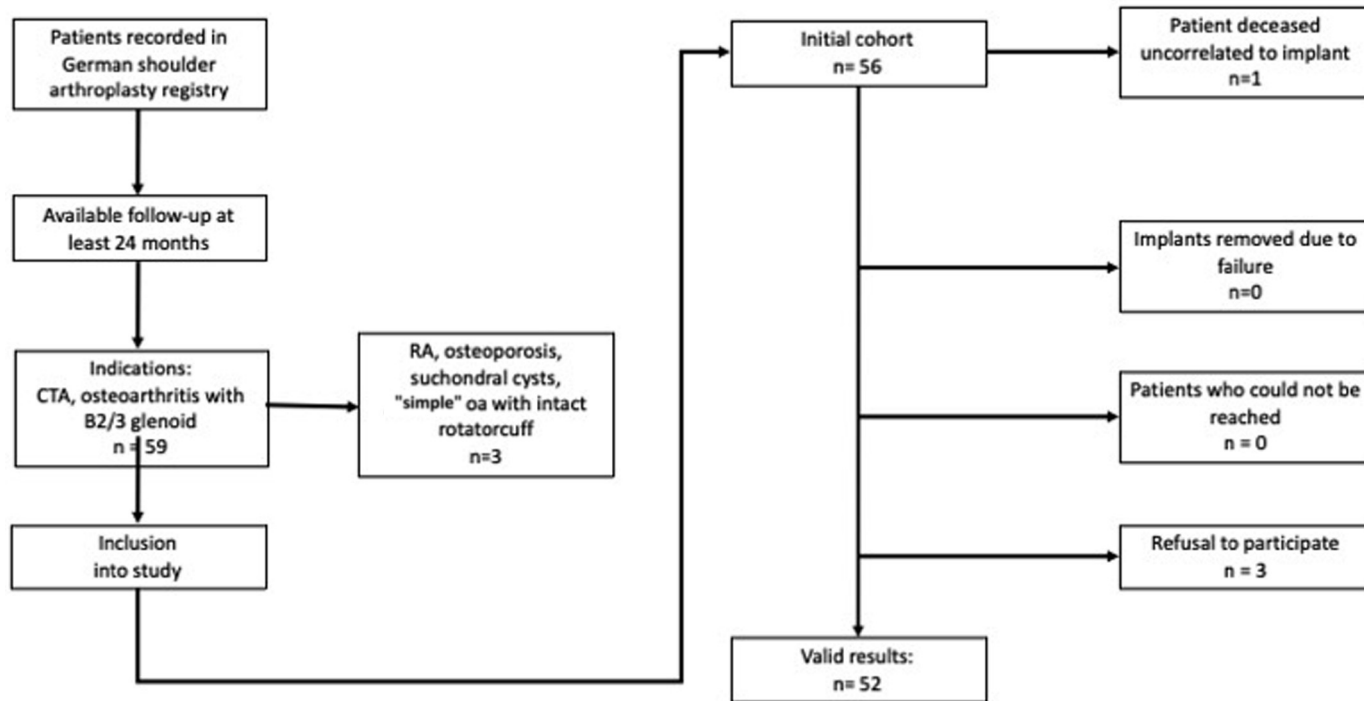


Figure 1 Inclusion/exclusion flowchart.

for reverse configuration (humeral core component and reverse liner). The humeral core component is built of trabecular titanium, which is expected to improve ingrowth. When used in reverse configuration, a metallic reverse liner is impacted into the humeral core component. This metallic liner, manufactured out of Cobalt-Chrome-Molybdenum alloy, then articulates with an all polyethylene glenosphere. The SMR stemless is usable in Europe; within the United States, the Food and Drug Administration (FDA) approval is pending. To the best of our knowledge, no clinical results on the Lima SMR stemless implant, neither anatomic nor reverse, have been published so far.

The following study aimed to evaluate clinical and radiological results of the Lima SMR stemless reverse implant at short-term follow-up.

Materials and methods

Ethical approval for this study protocol was granted by our local ethics committee board. Consent of each patient was obtained. All patient data were anonymized before analysis.

Study population

From January 2016 to November 2018, 59 stemless reverse total shoulder arthroplasties in 59 patients (23 women and 36 men) were planned. Of these prospectively included 59 patients, 56 ended up with a stemless implant. Fifty-two of the initial 56 patients could be followed up with a minimum duration of 24 months (range 24-47).

The following indications for RSA were included: not repairable rotator cuff tears, cuff tear arthropathy, posttraumatic arthrosis of the glenohumeral joint, B2/3 glenoid according to Walch classification, and osteoarthritis with a “cuff at risk” (Table I). Patients with rheumatoid arthritis, severe osteoporosis, or large subchondral cysts at the metaphysis were excluded

Table 1
Indications for implantation.

Primary osteoarthritis with B2/3 glenoid	8
Primary osteoarthritis with R.C. at risk	13
Cuff tear arthropathy	29
Secondary osteoarthritis (posttraumatic, instability)	6

from our study. For the first cohort in our clinic, we decided to operate only on patients younger than 70 years because of the expected good bone quality. For osteoporosis and cysts, there was no specific screening except the plain x-ray which was taken for preoperative planning. Three patients were, therefore, not operated with a stemless implant. During the study period, all patients fitting the inclusion criteria were operated with a stemless implant. Three patients refused to take part in the follow-up and were seen as dropouts. One patient died in a car accident, unrelated to the implant. So, in conclusion, we managed to follow up 52 out of 56 patients for at least 2 years (Fig. 1).

The indications for reverse shoulder implantation in the study population are presented in Table I.

Surgical technique and rehabilitation

C.S. performed all surgeries with the patient under general anesthesia combined with an interscalene catheter and single-shot antibiotics in beach chair position, using a deltopectoral approach.

Arthrotomy was performed by resecting the upper third of the subscapularis tendon, and the lower part of the subscapularis tendon was preserved. Teres minor and as much infraspinatus as possible were spared. The intramedullary resection guide was used, and the level of resection was defined by the anatomical neck, thus

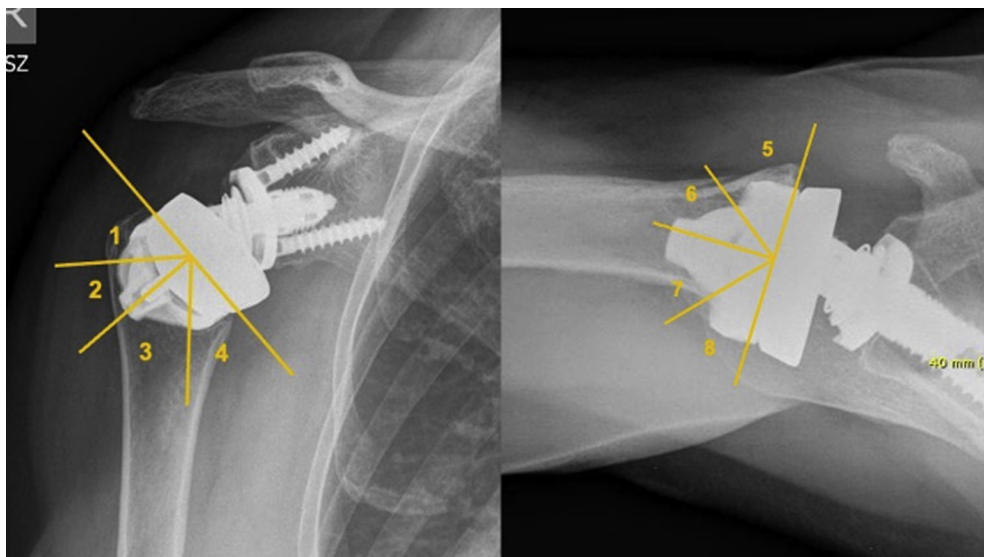


Figure 2 For the assessment of radiolucencies, the humerus was divided into four periprosthetic zones (each 45°, base 190° to the central “peg” of the core) on the anteroposterior radiographs as well as on the axillary radiographs.

resulting in a 142° resection. The baseplate and glenosphere were implanted in a standardized fashion.

The size (width and depth) of the core at the glenoid side was determined using the sizing tool (XS, S, M, L). The reamer was used under strict control to preserve the cortical ring. Cancellous bone from the resected humeral head was used for impaction grafting before implanting the core implant into the cortical ring. Trial inlays were used to assess a sufficient tension of the deltoid muscle. After reduction, there was no need for further refixation of the subscapularis tendon.

Within the first 4 weeks after surgery a 15° abduction pillow (SAS comfort, Medi, Bayreuth, Germany) was used for pain-dependent immobilization and during sleep. From the second week on, active ROM was explicitly trained. Combined adduction and internal rotation as well as weightbearing with more than 5 kg were not allowed for 6 weeks.

Clinical assessment

The clinical results were assessed by an independent board-certified orthopedic surgeon prospectively before the operation and at 12 months and with a minimum of 24 months follow-up using the absolute Constant-Murley Score (CMS) as well as the age- and gender-corrected CMS and the Subjective Shoulder Value (SSV).^{6,12} For strength measurements in abduction, we used the digital force gauge IsoForceControl V1.1 (MDS Medical Device Solutions AG, Oberburg, Switzerland) at the wrist in 90° of shoulder abduction.

ROM was measured by using a goniometer.

Radiological assessment

For radiologic follow-up, we analyzed true anteroposterior and axillary view radiographs taken at the latest follow-up. Post-operative radiographs were available for comparison. Radiolucency was assessed at the humeral side according to the classification of Moroder et al.¹⁶ Here, the humeral component is divided into four zones on anteroposterior and axillary views, with each zone corresponding to a 45° angle. In total, eight zones were defined (Fig. 2).

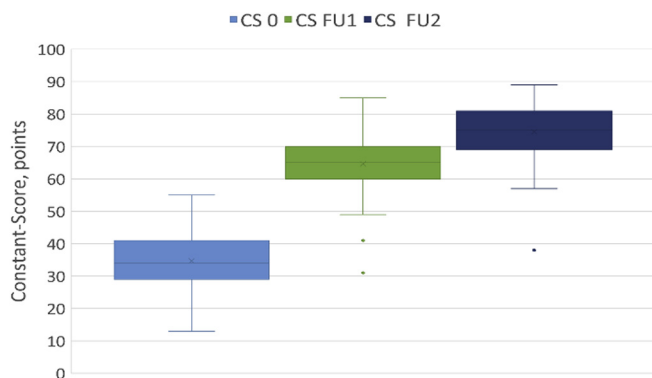


Figure 3 Overall results before operation to follow-up 1 (one year) and follow-up 2 (last follow-up).

Table 2 Graduation of radiolucency.

Radiolucency grade	Seen on x-ray
0	No sclerosis
1	Sclerosis and less than 1 mm space
2	Sclerosis with more than 1 mm space
3	radiologic loosening of the implant

The latest radiographs were rated by three independent observers. Radiolucency was defined as a loss of the bone adjacent to the implant and graded from 0 to 3, as shown in Table II.

The glenoid component was not evaluated for this study as it is a standard component used in the stemmed and the stemless implant.

Statistical analysis

Data were gathered and sorted using MS-Excel 16/365 (Microsoft, Seattle, WA, USA), while SPSS 24.0 (IBM, Armonk, NY, USA) was used for statistical analysis. The Shapiro-Wilk test was used to test for normal distribution. Parametric data were analyzed using the t-test. For nonparametric data, we performed either the

Table III
Overall results before operation to follow-up 1 (one year) and follow-up 2 (last follow-up).

	Follow-up 1		Follow-up 2		P value 1 vs. 0	Mean	SD	P value 2 vs. 1
	Mean	SD	Mean	SD				
Flexion, °	87	24.5	127	20.3	<.000	138	25.3	<.000
Abduction, °	72	22.7	111	19.0	<.000	130	18.3	<.000
External rotation, °	15	16.57	25	11.82	<.000	28	9.51	.062
Pain	5.27	2.36	12.24	2.08	<.000	13.6	1.3	<.000
Strength	3.58	4.45	12.42	3.93	<.000	15.67	3.37	<.000
ADL	8.95	2.76	14.15	2.1	<.000	15.05	2.17	<.000
ROM	17.1	5.06	25.84	3.91	<.000	29.51	4.46	<.000
CMS, absolute	34.9	9.82	64.6	9.34	<.000	72.44	8.69	<.000
CMS, relative	37.9	10.54	70.28	10.05	<.000	80.98	9.31	<.000
SSV	35.00	15.06	74.0	11.52	<.000	84.27	10.02	<.000

SD, standard deviation; ADL, activities of daily living; ROM, range of motion; CMS, Constant-Murley Score; SSV, Subjective Shoulder Value.

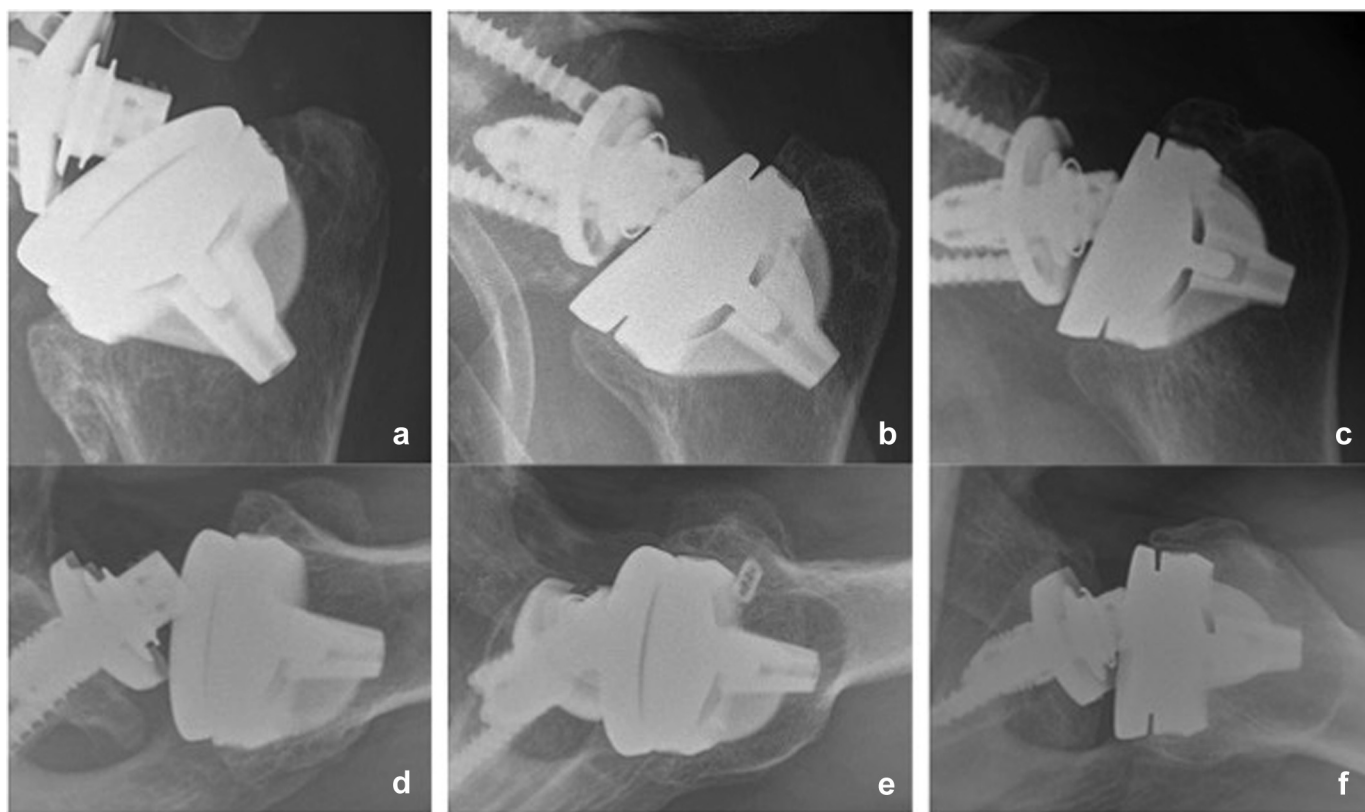


Figure 4 Examples for radiological outcomes. (a) No RLL. (b) Grade 1 ap: in zone 1 and 4; axillary view in zone 5. (c) Grade 2 ap: in zone 1; axillary view in zone 5, grade 1 zone 6.

Wilcoxon signed-rank test for comparing preoperative to post-operative data or the Mann-Whitney U test for analyses between groups. The level of significance was set at $P < .05$.

Fleiss' Kappa was calculated for interobserver reliability in the radiographic evaluation.

Results

Study population

In 56 of the scheduled 59 patients, a stemless reverse system was implanted. In three patients planned for a stemless implant, a good primary fixation of the implant was not achievable because of a too-small metaphysis; therefore, a stemmed implant was used instead, and the cases were excluded from the study. Thus, 56 cases were available for evaluation (Fig. 2).

The mean age of the included patients was 61.2 years (range 46-76 years) at the time of surgery (male 62%/ female 38%). The average follow-up duration was 29.3 ± 6.2 (range 24-47) months. One patient died because of a car accident and was lost to follow-up. Three patients were not willing to continue follow-up, one due to the distance to our clinic and two because of the COVID-19 pandemic, resulting in a follow-up rate of 93% (n = 52).

One gross loosening was seen on the x-ray. Interestingly the patient did quite well and wanted no revision. No other complications led to revision surgery.

Functional results

Our survey revealed statistically significant improvements for SSV and the absolute and corrected CMS as well as all its subcategories: pain, activities of daily living, ROM, and strength

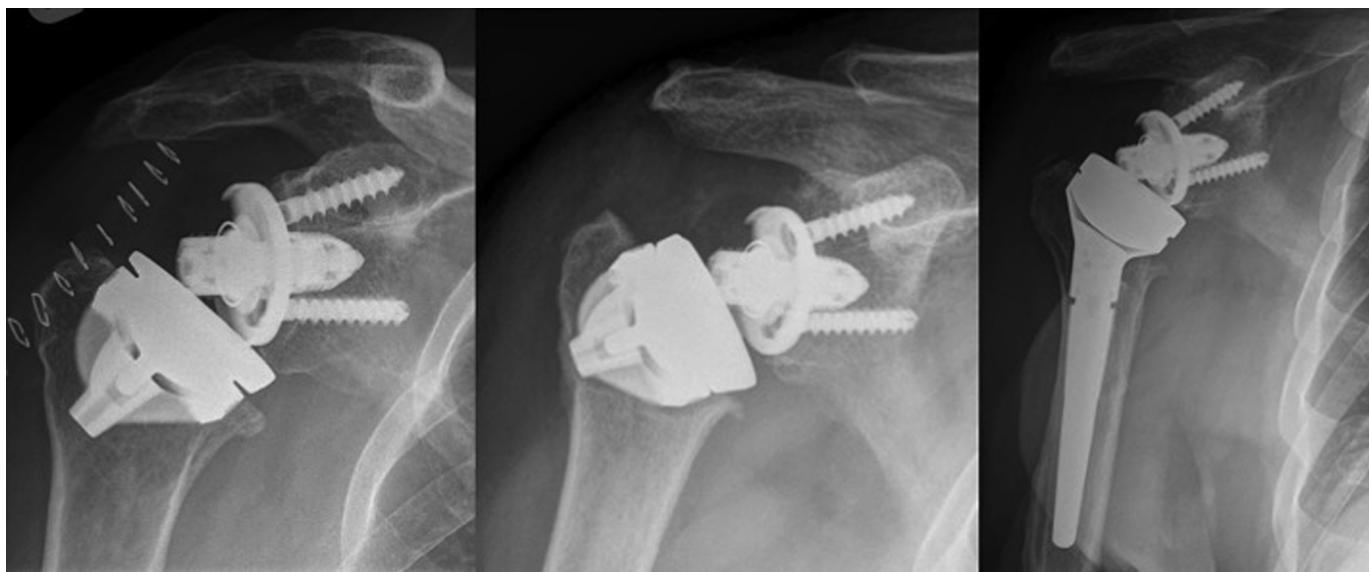


Figure 5 Periprosthetic fracture. (a) Direct postoperative; (b) after fall; (c) revision with stem.



Figure 6 Aseptic loosening. (a) Primary implantation not deep enough; (b) loosened implant; (c) integrated but tilted implant.

(each $P < .001$). Gains in active and passive ROM were seen in all planes of motion (each $P < .001$). These results were consistent from the first follow-up after 1 year to the second follow-up with further significant improvement in all categories ($P < .001$) but external rotation (Table III, Fig. 3).

Radiological results

Complete x-ray imaging was available for all 52 patients. The analysis showed no periprosthetic fracture or dislocation. We observed one gross loosening of the humeral component, which consolidated in a stable situation but at a different humeral inclination angle (120°). Analyzing the x-rays, we saw the fault on our implantation, the core does not have the necessary depth of seating

in the implantation. All other implants did not show signs of movement of the core.

Overall, we observed radiolucency lines (RLLs) in 12 patients (23.1%). Most lucencies appeared in zone 1 (11 patients), zone 5 (9 patients), zone 4 (6 patients), and zone 3 (2). Patients with radiolucencies did not differ regarding age, follow-up, CMS, or functional results compared to patients without radiolucent lines. RLLs < 1 mm were seen in 10 arthroplasties (19.2%). RLLs > 1 mm (grade 2) were observed in 2 cases (3.8%).

Radiological stress shielding was not observed. Figure 4 shows examples for the different radiological outcome options.

Interrater reliability for the radiological analysis was assessed between observers C.S., M.D., and L.A. The Fleiss-Kappa was determined at $k = 0.82$ (almost perfect agreement).

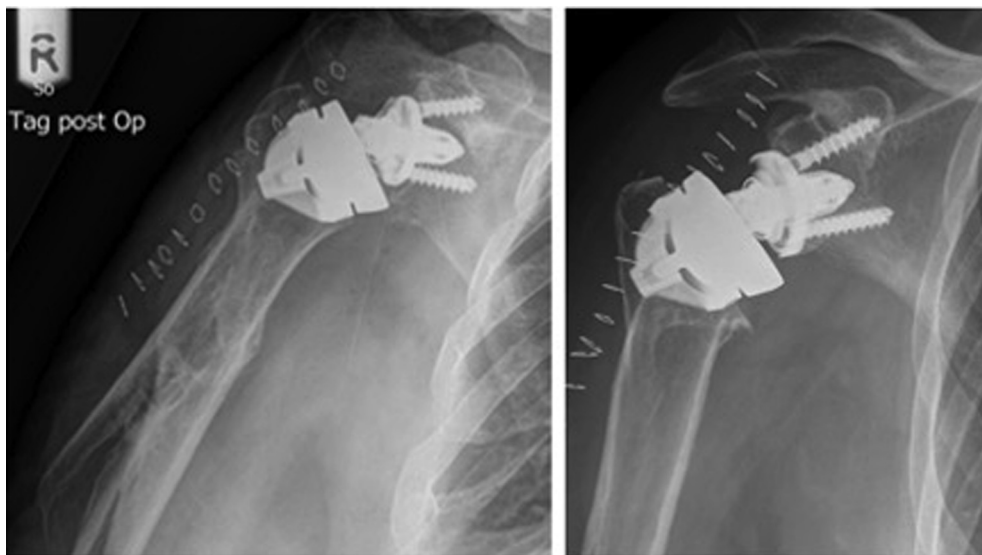


Figure 7 Example of stemless reverse in fracture sequelae.

Complications

No patient had to be revised up to now due to implant-related complications. One patient was revised because of a deep infection leaving the implant in situ. Another patient was revised to a stemmed revision implant for a periprosthetic fracture after a fall down 12 stairs (Fig. 5).

One implant did move significantly during rehabilitation but showed stable consolidation at a 120° angle after 10 weeks instead of 4 weeks of immobilization (Fig. 6).

Discussion

The aim of this study was to evaluate the Lima SMR reverse stemless prosthesis in functional outcomes and radiological results of the humeral component.

To our knowledge, this is the first short-term follow-up series of the Lima SMR reverse stemless system.

We were able to demonstrate significant improvements in ROM. Abduction increased from 72° to 130°, flexion from 86° to 138°, and external rotation from 16° to 28°.

For the TESS system, Kadum et al¹¹ showed an increase in abduction from 30° to 110° and in flexion from 50° to 110° in a cohort of 16 patients with a mean follow-up duration of 39 months. Teissier et al¹⁸ demonstrated a raise in flexion from 96° to 143° and in external rotation from 26° to 39° in 91 RSAs with a mean follow-up duration of 41 months.^{11,18} Ballas and Béguin published regarding the TESS in a cohort of 56 patients and with a minimum follow-up duration of 58 months a gain in flexion from 79° to 140° and in external rotation from 13° to 45°.² According to the literature, the Lima SMR Reverse in our study reaches similar results in ROM with even higher levels in abduction.

Significant improvements from preoperative to latest follow-up were documented in CMS from 34.9 pts to 74.4 pts, $P < .001$. The sex- and age-related CMS raised from 37.8 pts to 81 pts and the SSV from 35% to 84.3% after 2 years of follow-up.

For the “stemless” Verso prosthesis, Levy et al¹⁴ published their results with a follow-up of 2 to 7 years. There was an increase in the SSV from 8% preoperatively to 85% postoperatively and in the CMS from 14 pts to 59 pts. The age- and sex-related CMS improved from 21 pts to 86 pts.¹⁴

Moroder et al¹⁶ showed in their matched control in which they compared 29 patients with stemless TESS vs. 24 patients with stemmed RSA with a mean follow-up duration of 34.2 months, a CMS with 65.4 pt and an SSV with 86.6%.

Ballas and Béguin² published an increase in the CMS in a mid-term follow-up of 58 months from 29 pts to 62 pts.

The average age in our cohort was 61.2 years, which seems to be lower than that in the existing literature, where the average age is reported to be over 70 years.^{14,18}

The radiological results are comparable to other implants. There was one complete loosening of the humeral component due to failure in implantation and, additionally, not following the initial rehabilitation protocol (patient started with weightlifting in the third week). Interestingly, the prosthesis gained clinical stability at 120° and still is not revised.

Radiolucencies were observed in anteroposterior or axial radiographs at the humeral component in 23.1% of the cases and most often occurred in zone 1 and 5. We believe that this happens because of an intraoperative effect of the most cranial and most caudal points of reaming, thus maybe a bit of eccentric reaming because we could see the “lucencies” in zone 1 and 5 in the direct postoperative x-rays as well as in the follow-up x-rays in all these cases. The lucencies in zone 3 and 4 appeared in the later follow-up (24 months, plus). So, the latter eight patients seem to have “real” lucency lines, which results in 14% overall.

However, we could not show any impact of the RLLs on the clinical outcome.

We see comparable results (23%) in the shorter follow-up compared to the literature about radiolucencies appearing in stemless implants. Beck et al³ published for the TESS prosthesis 38.8% of humeral RLL in 8 years of follow-up in 48 RSAs without functional impairment.

In discussing complications, a stemless reverse implant seems to be a safe procedure (Fig. 7).

Kadum et al¹¹ showed in a 35-month follow-up of 49 patients with the TESS no implant loosening and a reduction of the VAS at rest from 30 down to 10 and from 65 down to 10 during activity.

Ballas and Béguin² reported various complications such as one humeral bone fracture without consequences, five incidences of scapular notching, and one instability that lead to revision but no loosening at the humeral side.

The biggest patient group was published by Teissier et al¹⁸ in 2015, again using the TESS.

Ninety-one stemless cases with a minimum follow-up duration of 24 months. No loosening was reported, but there was 19% scapular notching. Three complications appeared. One persistent instability with recurrent dislocations needed a revision surgery with a higher polyethylene implant. One patient suffered a spine fracture, and one patient had a traumatic clavicle fracture after a fall.

Limitations

This study has some limitations. The study design is a prospective clinical nonrandomized outcome study. There is underlying bias due to the inclusion criteria of age below 70 years which implies good bone quality. The cohort in our study is compared to that of younger age in other studies. The reason is that the indication for a new stemless implant, in our opinion, was younger patients with a good bone stock and lack of osteoporosis, for good ingrowth and stable fixation. We did not start implanting in older patients because of the fear of lower bone quality. Now, as we see no severe loosening, the indication for stemless use might be expanded. Since, to our knowledge, this is the first study about the Lima SMR stemless, we could only compare our results to studies that used different implants.

Conclusion

The Lima SMR stemless reverse shows promising short-term results in clinical, functional, and radiologic outcomes. The results are comparable to those of other reverse arthroplasties. Mid- to long-term results need to be provided in further studies.

Disclaimers:

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Conflicts of interest: The 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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