J Shoulder Elbow Surg (2021) 30, 1060–1067

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Short-term outcomes of reverse shoulder arthroplasty using a custom baseplate for severe glenoid deficiency

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Hypothesis and Background: Complex glenoid bone loss and deformity present a challenge for the shoulder arthroplasty surgeon. Eccentric reaming, bone grafting, augmented glenoid components, and salvage hemiarthroplasty are common strategies for managing these patients. The glenoid vault reconstruction system (VRS; Zimmer-Biomet) is a novel solution for both primary and revision arthroplasty using a custom glenoid baseplate. We hypothesized that patients undergoing reverse shoulder arthroplasty (RSA) with VRS would have acceptable short-term outcomes and complication rates.

Methods: Patients who underwent RSA with VRS for severe glenoid deformity or bone loss by one of 4 board-certified, fellowship-trained shoulder and elbow surgeons at 3 academic tertiary referral centers between September 2015 and November 2018 were eligible for inclusion. Patient data were obtained via medical record review and telephone questionnaires. The Numeric Pain Rating Scale (NPRS), Single Assessment Numeric Evaluation (SANE), American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), Penn Shoulder Scores, and range of motion (ROM) measurements were obtained pre- and postoperatively. Radiographs were reviewed at final follow-up for evidence of component loosening or hardware failure. Any complication was documented. Outcomes were compared using Wilcoxon signed-rank tests with $P < .05$ considered significant.

Results: Twelve shoulders (11 patients) were included with a mean age of 68 years; 7 were primary arthroplasties and 5 were revisions. At an average follow-up time of 30 months, median improvement in NPRS score was 7 points, SANE score 43%, ASES score 45 points, and Penn Shoulder Score 49 points. There were statistically significant improvements in median ROM measurements (forward elevation 20°, external rotation 40°, internal rotation 2 spinal levels). At final follow-up, all implants were radiographically stable without loosening. There were no complications.

Discussion and Conclusion: This study demonstrates that RSA using the custom VRS glenoid implant is a safe and effective technique addressing complex glenoid deformity or bone loss in both primary and revision settings. At short-term follow-up, all patient-reported outcomes and ROM measures improved significantly, and there were no complications. Future work should determine mid- and long-term outcomes, preferably in a prospective manner with defined patient populations.

Institutional review board approval was granted by the Georgetown-MedStar IRB System (study number: STUDY00000378).

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https://doi.org/10.1016/j.jse.2020.08.002

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

Keywords: Reverse shoulder arthroplasty; revision shoulder arthroplasty; glenoid deficiency; CAD/CAM; custom implant

Shoulder arthroplasty is an effective therapy for end-stage glenohumeral arthritis that has been demonstrated to be highly effective in relieving pain and restoring joint function in those who have failed nonoperative treatment.[25] The number of shoulder arthroplasties being performed annually is increasing and with it the number of revisions.[20] Despite the utility of shoulder arthroplasty, complex glenoid bone loss and deformity continue to present significant challenges for the shoulder arthroplasty surgeon in both primary and revision settings. These deformities may result from severe degenerative or posttraumatic changes, congenital deformities, or most commonly glenoid component failure after primary total shoulder arthroplasty (TSA). Deformities resulting in decreased surface area and bony support for implantation of the glenoid component are associated with an increased risk of early glenoid loosening and ultimately implant failure.[10]

Various techniques are used to address complex glenoid deformities and deficiencies including eccentric reaming, bone grafting, metallic baseplate augmentation with alternative centerline central screw placement and salvage hemiarthroplasty. However, clinical results of these techniques remain mixed, and the high numbers of complications including implant loosening, failure of graft incorporation, nonunion, and infection are concerning.[10,11] More recently, computer-aided design / computer-assisted manufacturing (CAD/CAM) of patient-specific glenoid components has been used to address the limitations of bone grafting and eccentric glenoid reaming in correcting more severe glenoid bone deficiencies.[4-6,10,21]

The glenoid vault reconstruction system (VRS) in conjunction with the Comprehensive Reverse Shoulder Arthroplasty System (Zimmer-Biomet, Warsaw, IN, USA) is a novel solution that uses CAD/CAM to create a custom glenoid base component to address these issues in both the primary and revision arthroplasty setting. Preoperatively, a fine-cut 2-dimensional computed tomographic scan of the patient's scapula and humerus is used to construct a 3-dimensional scapular model that is subsequently used to create a patient-specific glenoid implant made of porous plasma spray titanium (Fig. 1, *A-D*). Fixation of the implant is achieved with a 6.5-mm nonlocking central screw and a minimum of four 4.75-mm nonlocking or locking peripheral screws (Fig. 1, *E*). Screw positioning and length are chosen to place them in the best available glenoid bone. A custom boss may also be used when there is sufficient bone stock. Once the custom implant is secured and glenoid vault reconstruction is achieved, the glenosphere can be appropriately positioned and the remainder of the reverse shoulder arthroplasty (RSA) completed. A more detailed surgical technique is outlined in the Materials and Methods section.

Case reports of patients undergoing RSA using the VRS custom implant have been published and describe satisfactory short-term clinical and radiographic results.[5,6] However, improvements in standardized pain and functional outcome measures after RSA with the VRS patient-specific implant remain uncharacterized by larger studies. The purpose of this study was to report short-term functional, pain, and range of motion (ROM) outcome measures of patients with complex glenoid deformity and bone loss who underwent RSA using the VRS custom implant.

Materials and methods

Study design

This is a retrospective case series detailing the short-term outcomes of RSA with the use of a custom glenoid baseplate to address severe glenoid deficiency. Prior to data collection, institutional review board approval was obtained. Patients who underwent RSA with VRS for severe glenoid deformity or bone loss by one of 4 board-certified, fellowship-trained shoulder and elbow surgeons (A.M.M., J.A.S., D.M.L., B.B.W.) at 3 academic tertiary referral centers between September 2015 and November 2018 were eligible for inclusion. Inclusion criteria also included a minimum follow-up of 24 months and willingness to participate in the study. A retrospective chart review was performed to assess clinical outcomes measured by physical examination and shoulder questionnaires documented in patients' medical records. Telephone questionnaires were used to collect additional data when necessary. Pre- and postoperative outcome measures included (1) 10-point Numeric Pain Rating Scale (NPRS, where 0 = no pain at all, and 10 = the worst imaginable pain); (2) Single Assessment Numeric Evaluation (SANE) score (ie, patients provided a rating of their shoulder from 0% to 100%, with 100% being normal)[8]; (3) American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) score[14]; and (4) Penn Shoulder Score.[12] SANE, ASES, and Penn Shoulder Scores were chosen for this study because they have been validated for use in shoulder arthroplasty outcomes research.[8,12,14,22,23] Radiographic outcomes were assessed by comparing shoulder radiographs from patients' latest follow-up visit with previous imaging for signs of implant loosening or migration. Physical examinations were performed preoperatively and at the last follow-up visit to document shoulder active ROM for forward elevation (FE), external rotation (ER) in abduction, and internal rotation (IR) with the arm behind the back. Complications were documented by review of patient medical records, radiographs, patient interviews, and surgeon documentation.

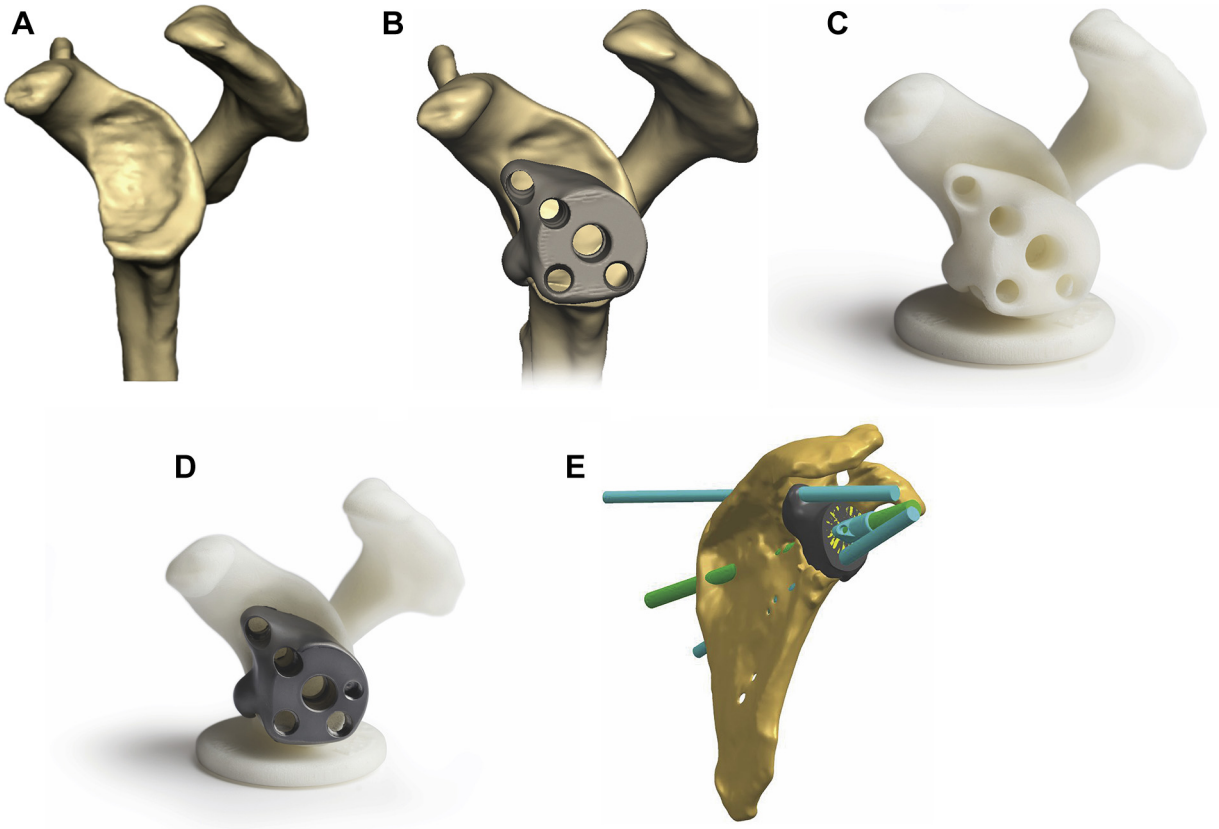

Figure 1 CAD/CAM vault reconstruction system glenoid implant (Zimmer Biomet). (**A**) 3D reconstruction produced from CT scan. (**B**) Computer-aided design used to create a proposed implant. (**C**) Prototype of implant produced. (**D**) After surgeon approval, the final implant is manufactured. (**E**) Schematic demonstrating superior peripheral screw, central compression screw, and inferior peripheral screw trajectories. Images reproduced with permission from Zimmer-Biomet. *CAD/CAM*, computer-aided design / computer-assisted manufacturing; *CT*, computed tomography.

Statistical analysis

Statistical analysis was performed using RStudio (v 0.99.902; RStudio Inc) in the R statistical environment (v 3.6.3; R Foundation for Statistical Computing). Means, ranges, counts, and percentages were provided for patient characteristics. Given the size of the sample, descriptive statistics for outcome measures were reported as median (interquartile range), and nonparametric methods were used for analysis. Differences between pre- and postoperative NPRS, SANE, ASES, Penn Shoulder Scores, and ROM measures were assessed with Wilcoxon signed-rank tests. FE and ER were both treated as continuous measurements. IR required translation to an ordinal scale for statistical analysis, as follows: no IR or to abdomen, 0; to hip/side, 1; to sacrum, 2; to L4-L5, 3; to L2-L3, 4; to T12-L1, 5; to T10-T11, 6. Comparisons of pre- and postoperative IR assessments were performed through cumulative link mixed model analysis. For all ROM analysis, patients for whom pre- or postoperative data were unavailable for a given measurement were omitted from the analysis of that measurement. The paired-sample nonparametric effect size r was calculated for NPRS, SANE, ASES, and Penn scores, with 95% confidence intervals estimated through bootstrapping with the percentile method. These were transformed to Cohen d for ease of interpretation. Between-group differences in continuous variables were assessed with Mann-Whitney U tests and Mood median test and differences in categorical variables using Fisher exact or χ^2 tests as appropriate. A P value $<.05$ was considered statistically significant.

Preoperative planning

Each patient's computed tomographic scan data, taken within 6 months of surgery, was reconstructed into a 3-dimensional model, allowing engineers to create an implant proposal. The proposal includes implant position, orientation and size, screw trajectory and size, and recommended bone removal if necessary. Surgeons can view and manipulate the plan, and prior to manufacture the proposal is accepted or modified based on surgeon input. With each custom baseplate, the surgeon receives a patient-specific bone model, implant model, implant, and if necessary, a custom boss reaming guide, all of which are sterilizable and intended as single-use disposable instruments and can also be used for plan approval.

Intraoperative approach

After induction of general endotracheal anesthesia, patients were positioned in the beach-chair position, and preoperative prophylactic antibiotics were administered. Full muscular paralysis was

induced by the anesthetist. The deltopectoral approach was undertaken and attention was directed toward glenoid exposure, with emphasis on careful release of soft tissue, removal of peripheral osteophytes on the humerus, an appropriate humeral head cut, and facile placement of retractors all while preserving as much native bone and tissue as possible. The deltoid was completely mobilized while protecting the axillary nerve, and the subacromial space was cleared of scar tissue. A slightly more aggressive humeral head cut can aid in glenoid visualization but may be performed superior to the rotator cuff insertion if the rotator cuff is still intact. Inferior capsular release was then performed on the proximal humerus with the arm adducted and externally rotated, with electrocautery placed directly on the bone with progressive external rotation of the arm. A wide retractor, such as a curved Bankart or Fukuda, was placed posteriorly and the labrum and biceps tendon were released at the 12-o'clock position. Another retractor can be placed between the labrum and the subscapularis for removal of the anterior labrum, followed immediately by placement of a spiked anterior Bankart retractor along the anterior glenoid rim, allowing for circumferential labral excision. In cases where the labrum and/or subscapularis were no longer intact, nonviable soft tissue and scar tissue was excised without violating the bone stock. Violation of native bone stock can interfere with the normal fit of patient-specific guides. In revision cases with pre-existing implants or hardware, these should be removed as necessary while preserving as much bone stock and soft tissue as possible.

Glenoid preparation

If a boss was required, as in the case where central bone was available within the glenoid vault that would otherwise interfere with the backside of the implant properly seating, the threaded glenoid guide handle was attached to the central boss reaming guide. The boss reaming guide should fit firmly on the glenoid without toggle when it is placed correctly. A Kirschner wire was inserted into the boss reaming guide, followed by a 3.2-mm Steinmann pin, ensuring that it engaged or perforated the medial cortical wall. The Kirschner wire was then removed and the cannulated central boss reamer was placed over the Steinmann pin. The glenoid was reamed until the reamer bottomed out on the guide and the etch mark on the reamer was flush with the reaming guide. The cannulated boss reamer, Steinmann pin, and boss guide were removed. Once boss reaming was completed or if boss reaming was not required, attention was turned to the bone model, which indicated whether specific areas of bone needed to be excised. Excessive bone removal should be avoided, and in the case of this series of patients, no bone grafting was performed for these combined and uncontained (complete) defects.

Glenoid baseplate trialing and placement

At this point, comparison of the in vivo glenoid to that of the bone model was made. Checking the fit of the baseplate to the bone model was performed, with the key being backside support and rotational control. Next, the inserter and threaded handle was attached to the VRS implant with a 3.5-mm hex screw. The implant was positioned on the glenoid cavity using the anterior lip to assist with orientation and positioning. With appropriate placement, the implant will fit firmly without toggle, again with the key being backside support and rotational control. Screw trajectories and the peripheral edges of the implant were checked to determine if they correlated with the bone as portrayed on the model. Impaction was avoided, but if necessary could be performed lightly to assist in implant seating. Visual confirmation of complete seating was performed by checking for gaps at the screw holes and with gentle manual testing using a small nerve hook or dental hook.

To achieve initial implant stability, 2 or more 2.7-mm drills were inserted, starting with the preassembled gold F.A.S.T. Guide (Zimmer-Biomet) inserts. Subsequently, drilling was undertaken with the 3.2-mm-diameter bit to the desired depth, as marked on the drill and as set during preoperative planning. The desired-length 6.5-mm central screw was inserted and completely tightened with the 3.5-mm hex driver, preventing any implant rotation while the screw was tightened. The screw was determined to be fully seated into the implant by attaching the inserter to the guide handle and inserting these into the reverse Morse taper of the baseplate. If the inserter sat flush without rocking or toggling, the central screw was determined to be completely and correctly seated. Soft tissue or debris may prevent complete seating. For the peripheral screws, the F.A.S.T. Guide inserts were drilled through using 2.7-mm bits. Removal of the drill guides and checking depth using the depth gauge allowed for insertion of each peripheral screw with a 3.5-mm hex driver, finishing this step with tightening each screw in an alternating fashion.

The glenosphere was then inserted and impacted, and the remainder of the humeral side portion of the procedure completed. Regarding lateralization and offset, both are extremely variable patient to patient, and engineering of the baseplate is primarily for backside fixation and support, while lateralization and offset are typically built off the sphere and humeral side.

Results

Fourteen patients were eligible for study inclusion. One patient was excluded as a result of death unrelated to surgery prior to 24-month follow-up and 2 patients were excluded because they declined study participation. Eleven patients agreed to participate in the study, with 1 having undergone bilateral surgery with the VRS patient-specific implants. Therefore, 12 shoulder arthroplasties were analyzed in total. All 12 shoulders had severe glenoid dysplasia/erosion at or medial to the base of the coracoid (Fig. 2). More specifically, all 12 glenoid defects were classified as combined and uncontained (complete) by the Antuna et al[1] and Page et al[15] classifications. No shoulder underwent impaction grafting. The patients' age at time of surgery averaged 68 $\pm$ 9 years (range, 57-78 years). Seven patients were male and 5 were female. Seven cases were primary procedures, whereas the remaining 5 were revision procedures. Average postoperative follow-up was 30 $\pm$ 9 months (range, 24-52 months). There were no complications noted at the time of most recent follow-up for any patient in the study (Table I).

The median NPRS, SANE, ASES, and Penn scores all improved in a statistically significant manner (Table II). Active FE, ER, and IR with the hand behind the back

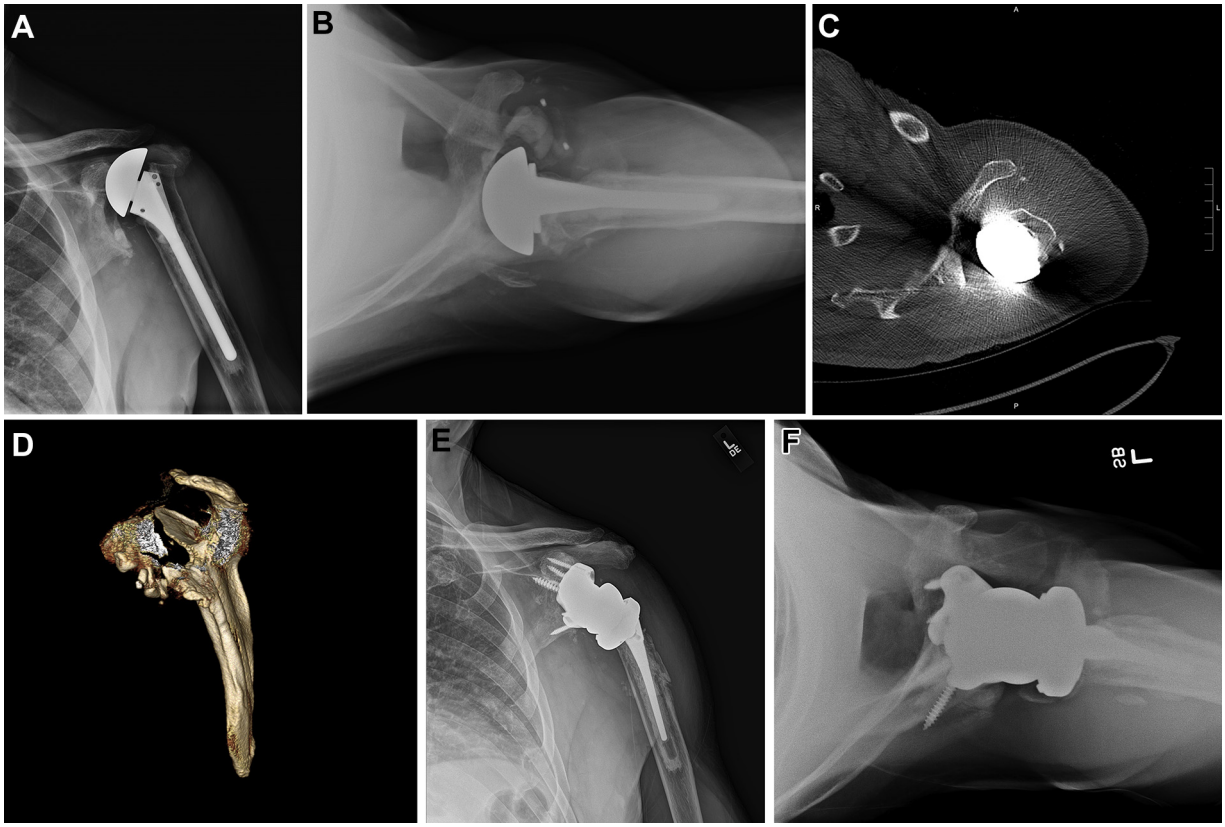

Figure 2 A 73-year-old man (patient 5) with long-standing failed TSA with destruction of glenoid, instability, and loosened glenoid component. (**A**) Anteroposterior and (**B**) axillary preoperative radiographs. (**C**, **D**) Computed tomography and 3D reconstruction shows severe glenoid vault bone loss. (**E**) Anteroposterior and (**F**) axillary radiographs shows vault reconstruction system and RSA in position. *TSA*, total shoulder arthroplasty; *RSA*, reverse shoulder arthroplasty.

improved in a statistically significant manner (Table III). Improvements in clinical outcome measures for primary RSA procedures were compared to outcomes of revision procedures. Primary procedures resulted in greater improvements in NPRS, ASES, and Penn scores; however, these differences in outcome measure improvements were not statistically significant (Table IV).

Discussion

The most important findings from this study were that patients with advanced glenoid bone loss experienced significant pain relief, improvement in both functional outcome and ROM, and no complications after RSA with a custom glenoid baseplate at short-term follow-up. These improvements in functional outcome scores were well above previously published minimal clinically important differences for each measure, and median postoperative scores were similarly higher than reported patient acceptable symptom state values.[3,8,18,22] Improvements in FE and ER were also greater than previously published minimal clinically important differences.[18] A systematic review by Puzzitiello et al[16] found that clinically significant improvements in patient-reported outcomes and objective physical examination measurements after shoulder arthroplasty could be appreciated only up to 1 year postoperatively, making our minimum follow-up time of 24 months adequate for the purposes of measuring maximum clinical improvement after RSA.

The improvements in pain and functional outcome measures seen in our patient cohort are consistent with the findings of previous studies using CAD/CAM implants to address severe glenoid bone deficiency during shoulder arthroplasty. A study by Gunther et al[9] used a custom inset glenoid implant to treat 7 patients with deficient glenoid bone and reported similar improvements in ASES scores, ROM, and pain. Similarly, Uri et al reported short-term outcomes of 21 patients with failed post-traumatic humeral head replacement associated with glenoid deficiency who underwent revision arthroplasty with a hip-inspired CAD/CAM implant. Patients in this cohort experienced similar improvements in functional outcomes and pain relief; however, ROM failed to significantly improve postoperatively. Additionally, this study reported high complication rates, with 9 of 21 patients experiencing complications, including infection, prosthetic dislocation, periprosthetic fractures, and fixation screw breakage.[24] This

Table I Patient characteristics

Patient no.	Age (at surgery)	Sex	Laterality	Primary or revision	Diagnosis	Follow-up, mo
1	57	F	L	Primary	Post-traumatic glenohumeral OA	52
2	62	F	R	Primary	Glenohumeral OA with severe glenoid dysplasia	27
3	71	F	L	Revision	Failed TSA with glenoid component loosening	30
4	78	M	L	Revision	Infected RSA	28
5	73	M	L	Revision	Failed TSA with glenoid component loosening	24
6	59	M	R	Revision	Infected TSA	24
7	50	F	L	Primary	Glenohumeral RA with severe glenoid dysplasia	32
8a	75	M	L	Primary	Glenohumeral OA with severe glenoid dysplasia	42
8b	76	M	R	Primary	Glenohumeral OA with severe glenoid dysplasia	29
9	75	M	R	Primary	Glenohumeral OA with severe glenoid dysplasia	25
10	74	F	R	Primary	Glenohumeral RA with severe glenoid dysplasia	24
11	66	M	R	Revision	Glenoid erosion after hemiarthroplasty	24

F, female; *M*, male; *L*, left; *R*, right; *OA*, osteoarthritis; *TSA*, total shoulder arthroplasty; *RSA*, reverse shoulder arthroplasty; *RA*, rheumatoid arthritis.

Table II Summary of outcome measures before and after RSA using the VRS patient-specific implant

	Preoperative	Postoperative	Δ	*P* value	*r*	95% CI	*d*	95% CI	*P* value (*d*)
NPRS	7 (7-8)	0 (0-2)	−7 (−7 to −4)	.002	−0.89	−0.90, −0.88	−3.9	−6.8, −1.0	.01
SANE	30 (20-43)	80 (58-90)	43 (18-65)	.004	0.84	0.66, 0.89	3.1	0.7, 5.5	.02
ASES	33 (21-52)	80 (67-94)	45 (20-62)	.002	0.81	0.59, 0.89	2.8	0.5, 5.0	.02
PSS	29 (17-44)	82 (62-93)	49 (20-58)	.003	0.88	0.88, 0.89	3.7	0.9, 6.5	.01

RSA, reverse shoulder arthroplasty; *VRS*, glenoid vault reconstruction system; *NPRS*, Numeric Pain Rating Scale; *SANE*, Single Assessment Numeric Evaluation; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *PSS*, Penn Shoulder Score; *CI*, confidence interval.
Values were presented as median (interquartile range).

Table III Summary of ROM measures before and after RSA using the VRS patient-specific implant

	Preoperative	Postoperative	Δ	*P* value
FE (°)	95 (80-123)	150 (140-160)	20 (13-84)	.009
ER (°)	13 (0-20)	40 (28-60)	40 (11-55)	.014
IR with hand behind back*	Sacrum	L3	2 levels	.002

ROM, range of motion; *RSA*, reverse shoulder arthroplasty; *VRS*, glenoid vault reconstruction system; *FE*, forward elevation; *ER*, external rotation; *IR*, internal rotation.
Values were presented as median (interquartile range).
* IR was rated ordinally as follows: 0, no internal rotation or positive belly press only; 1, hip/side; 2, sacrum; 3, L4-L5; 4, L2-L3; 5, T12-L1; 6, T10-T11.

Table IV Clinical outcome improvements of primary vs. revision RSA using the VRS patient-specific implant

	Primary cohort ($n = 7$)	Revision cohort ($n = 5$)	*P* value
NPRS	−7 (−9 to −7)	−4 (−5 to −4)	.408
SANE	40 (20-65)	45 (10-54)	.744
ASES	53 (39-75)	20 (18-41)	.149
PSS	53 (35-72)	20 (19-53)	.290

RSA, reverse shoulder arthroplasty; *VRS*, glenoid vault reconstruction system; *NPRS*, Numeric Pain Rating Scale; *SANE*, Single Assessment Numeric Evaluation; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *PSS*, Penn Shoulder Score.
Values were presented as median (interquartile range) and represent median improvement in outcome measures after RSA.

high complication rate was not seen using the VRS custom implant in our patient cohort.

Previous studies have reported on bone grafting and the use of augmented or custom glenoid implants in the management of glenoid bone deformity and loss to correct versions and increased stability of the glenoid component during arthroplasty; however, clinical results of these techniques have been mixed.[10] Bone grafting is another technique useful for correcting large glenoid bone deficiencies or severe posterior wear; nevertheless, it is technically demanding and clinical results remain mixed. Although some reports of bone graft use in shoulder arthroplasty have shown excellent results,[13] other studies demonstrate significant rates of unsatisfactory functional outcomes, radiographic loosening, graft subsidence, and graft resorption.[11,17] Additionally, severe glenoid deficiency, such as in the case of an uncontained defect can prevent impaction grafting from being possible.[2,11] Hemiarthroplasty with or without concentric glenoid reaming is a final option when glenoid bone stock is inadequate to support a glenoid component. However, failing to address the glenoid has been shown to result in continued glenoid bone erosion that may result in increased pain and eventual need for revision,[7] and overall pain relief and functional outcomes after hemiarthroplasty have been shown to be inferior compared with those achieved by TSA.[19]

More recently, the use of posteriorly augmented glenoid components and novel CAD/CAM implants in the management of more severe cases of glenoid deformity and deficiency have shown promising results.[4-6,9,24] These techniques have the potential to correct severe deformities, correct version, and overcome the limitations of bone grafting and eccentric reaming all while preserving bone stock. Custom implants, such as the glenoid VRS implant, are typically much more expensive than standard implant systems The list price for the VRS baseplate is US$14,940 vs. US$3700 for the standard Comprehensive Reverse baseplate. This increased cost is an important factor to consider, but may be justified in patients with severe glenoid bone deficiencies and very limited alternative surgical options. This study adds to the growing body of evidence that CAD/CAM shoulder implants offer a promising and versatile alternative to traditional techniques for managing glenoid deformity and deficiency in both primary and revision arthroplasty settings. Notably, although there were larger improvements in outcomes and pain for the patients undergoing primary arthroplasty in this study, this difference was not statistically significant, which may imply that patients undergoing both primary and revision arthroplasty have potential for significant improvements in outcomes.

Our study has a number of strengths and limitations. This is the only study to date reporting standardized pain and functional outcome measures for the VRS custom implant. Previously, publications on this implant were limited to 2 case reports; however, this case series reports patient-reported outcomes, pain, and ROM measures. Limitations include this being a retrospective case series with a small cohort and limited follow-up period. Although our minimum follow-up of 2 years was adequate to identify significant improvements in patient-reported outcomes, a longer follow-up period could improve the reliability of these results and identify any potential complications that may occur several years out from surgery. Longer follow-up is also required to determine the longevity of these implants. Finally, the surgical indications in this cohort were relatively heterogeneous. However, we would expect that these indications would be similar to those seen by most shoulder surgeons using the VRS custom baseplate.

Conclusion

At short-term follow-up, RSA using a VRS custom baseplate is a safe and effective technique in patients with complex glenoid bone loss deformity in both primary and revision settings. In this study, all patient-reported outcomes were found to be improved postoperatively, ROM was satisfactory, there were no signs of loosening or radiographic failure, and there were no complications. This custom-designed implant is a promising option for severe glenoid bone loss that would prevent traditional arthroplasty techniques. Future work should determine mid- and long-term outcomes, preferably in a prospective manner with defined patient populations.

Disclaimer

The authors, their immediate families, and any research foundations 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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