Treatment of severe glenoid deficiencies in reverse shoulder arthroplasty: the Glenius Glenoid Reconstruction System experience

Philippe Debeer, MD, PhD[a],*, Bart Berghs, MD[b], Nicole Pouliart, MD, PhD[c], Gert Van den Bogaert, MD[d], Filip Verhaegen, MD[a], Stefaan Nijs, MD, PhD[e]

[a]Orthopaedics, University Hospitals Leuven, Department of Development and Regeneration, K.U. Leuven, Belgium & Institute for Orthopaedic Research and Training, Leuven, Belgium
[b]Orthopaedics, AZ Sint-Jan, Brugge, Belgium
[c]Department of Orthopaedics and Traumatology, Universitair Ziekenhuis Brussel, Vrije Universiteit Brussels, Brussels, Belgium
[d]Department of Orthopedic Surgery, AZ Elisabeth Herentals, Herentals, Belgium
[e]Traumatology, University Hospitals Leuven, Department of Development and Regeneration, K Katholieke Universiteit (K.U.), Leuven, Belgium

Background: The treatment of glenoid bone deficiencies in primary or revision total shoulder arthroplasty is challenging. This retrospective study evaluated the short-term clinical and radiologic results of a new custom-made patient-specific glenoid implant.
Methods: We treated 10 patients with severe glenoid deficiencies with the Glenius Glenoid Reconstruction System (Materialise NV, Leuven, Belgium). Outcome data included a patient-derived Constant-Murley score, a visual analog score (VAS), a satisfaction score, the 11-item version of the Disabilities of the Arm, Shoulder and Hand score, and the Simple Shoulder Test. We compared the postoperative position of the implant with the preoperative planned position on computed tomography scans.
Results: At an average follow-up period of 30.5 months, the mean patient-derived Constant-Murley score was 41.3 ± 17.5 points (range, 18-76 points) with a visual analog scale of 3.3 ± 2.5 points (range, 0-7 points). The mean 11-item version of the Disabilities of the Arm, Shoulder and Hand score was 35.8 ± 18.4 (range, 2-71), and the mean Simple Shoulder Test was $47.5\% \pm 25.3\%$ (range, 8%-92%). Eight patients reported the result as better (n = 3) or much better (n = 5). One patient had an elongation of the brachial plexus, and 1 patient had a period of instability. The average preoperative glenoid defect size was 9 ± 4 cm^3 (range, 1-14 cm^3). The mean deviation between the preoperative planned and the postoperative version and inclination was $6° \pm 4°$ (range 1°-16°) and $4° \pm 4°$ (range 0°-11°), respectively.
Conclusion: Early results of the Glenius Glenoid Reconstruction System are encouraging. Adequate pain relief, a reasonable functionality, and good patient satisfaction can be obtained in these difficult cases. Further follow-up will determine the bony ingrowth and subsequent longevity of this patient-specific glenoid component.

*Reprint requests: Philippe Debeer, MD, PhD, University Hospitals Leuven, Herestraat 49, B-3000 Leuven, Belgium.
E-mail address: philippe.debeer@uzleuven.be (P. Debeer).

Glenoid bone loss in total shoulder arthroplasty is a challenging problem. Failure to address this problem will lead to malpositioning of the glenoid component and compromise the postoperative function with associated decreased implant survival.[35] Glenoid bone defects are most frequently encountered in a revision setting but can also be present in patients with primary glenohumeral degeneration, rheumatoid arthritis, congenital deformations, and in posttraumatic cases.

Glenoid implantation can be avoided using a hemiarthroplasty, but several studies have shown inferior results compared with total shoulder arthroplasties.[17,18,21,22,24,32,35] Different techniques have been proposed to realign the axis of the glenoid and to guarantee adequate bone support for the glenoid implant. Asymmetric reaming can be used to correct the glenoid version but is not suitable for large glenoid defects and can compromise the remaining glenoid bone stock, especially that of the subchondral bone. Moreover, there is no consensus how much correction of version can safely be obtained using this technique.[4,13,27] Several studies describe the use of bone grafts; however, this is a technically demanding procedure, and bone resorption remains an issue.[16,17,20,26,29,31,33]

To overcome the problems of asymmetric reaming and bone grafts, surgeons can use augmented glenoid components to correct the glenoid version. Several authors have reported promising short-term results in both anatomic and reverse total shoulder arthroplasty.[2,11,15,19,25,30,36] The main problem with the current available augmented glenoid components is that they cannot be used in large defects.

Recently the computer-aided design and computer-aided manufacturing technology has gained popularity in the treatment of severe glenoid bone loss. This technology enables shoulder surgeons to reconstruct the damaged glenoid vault with a metallic, patient-specific glenoid component.[3,5,8,34] Here we describe the clinical and radiologic outcome of the Glenius Glenoid Reconstruction System (GGRS; Materialise NV, Leuven, Belgium), a new patient-specific custommade glenoid component, in patients with a large glenoid defect. Stoffelen et al[34] used the GGRS once in the revision of an anatomic shoulder prosthesis but Materialise currently restricts the use of this system to reverse shoulder arthroplasty.

Materials and methods

In this retrospective case study, we evaluated 10 patients with severe glenoid deficiencies from 5 different centers. We obtained informed consent from all patients.

Patient population

Since 2014, 5 different centers in Belgium have used the GGRS in 10 consecutive patients with severe glenoid defects. The indications for use of the GGRS are listed in Table I. Clinical and radiologic follow-up data were available for 8 women and 2 men. The mean patient age at time of implantation was 68.8 years (range, 61-82 years). The mean follow-up period was 30.5 months (range, 15-44 months). No patients were lost to follow-up. Six patients had undergone previous operations (range 1-12). In 3 cases, a cement spacer was present to treat an infection, and 1 other patient had a hemiarthroplasty.

Design and development of the Glenius component

All patients had a preoperative computed tomography (CT) scan as described by Eraly et al.[10] We classified all defects using the classification system of Antuna et al.[1] The dedicated commercial Mimics 14.A glenoid defects (Materialise NV) was used to create 3-dimensional (3D) surface models of the entire scapula. The 3D surface model was transferred to 3-matic 14 and 18 software (Materialise NV). A statistical shape model, based on MATLAB script (MathWorks, Natick, MA, USA), was used to quantify the amount of glenoid bone volume missing and to estimate the natural or healthy position and shape of the patient's glenoid.[9] We measured version and inclination as described by Plessers et al.[28]

Briefly, this method identifies 3 anatomic parameters: the inclination and version angle of the glenoid plane and the position of the glenoid center point. These parameter values can be computed using manually indicated landmark points. Sixteen points equally distributed along the glenoid rim are used to localize the glenoid center point and plane. The glenoid center point is defined as the center of the circle that fits the points on the inferior glenoid rim, according to De Wilde et al.[7] The glenoid plane is determined as the best-fit plane through all points on the glenoid rim. Inclination and version are measured by the orientation of the glenoid plane in the scapular coordinate system.[12]

This coordinate system is constructed by 3 points[8]: the glenoid center point, the angulus inferior (most inferior point), and the trigonum spinae (midpoint of the triangular surface on the medial border of the scapula). The line between glenoid center point and trigonum spinae defines the z-axis. The x-axis is defined perpendicular to the scapular plane formed by all 3 landmark points; the y-axis is perpendicular to the x-axis and z-axis. To measure inclination and version, the glenoid plane normal is projected, respectively, to the yz plane (scapular plane) and the xz plane of the coordinate system. Then, the angle between the projected glenoid plane normal and the z-axis is measured.

With this information, we determined the anatomic coordinate system of the scapula to create the reference axes for implant position and orientation by optimizing implant version, inclination, and offset to reconstruct the anatomic center of rotation as much as possible

Table I Description of the patient demographics, the defect classification and the components used with the GGRS

Patient ID	Sex	Age	Follow-up	Indication for GGRS	Previous surgery	Presence of implants?	Defect classification	Defect size	Humeral stem associated with GGRS	Glenosphere size associated with GGRS
		(yr)	(mo)					(cm³)		(mm)
GLEN-01	F	64	36	Congenital dysplasia	0	No	Severe combined central and posterior	8	Delta Xtend*	42
GLEN-02	M	78	44	Postinfection TSA	3	No	Severe isolated central	12	Delta Xtend*	42
GLEN-03	M	65	34	Postinfection TSA	10	Cement spacer	Severe combined central and anterior	10	Delta Xtend *	42
GLEN-04	F	67	37	Rheumatoid arthritis	0	No	Severe combined central and anterior	10	TM Reverse Shoulder System†	36
GLEN-05	F	66	40	Cuff arthropathy	0	No	Severe combined central and posterior	8	TM Reverse Shoulder System†	36
GLEN-06	F	82	28	Cuff arthropathy	0	No	Severe isolated central	13	TM Reverse Shoulder System†	40
GLEN-07	F	61	17	Postinfection TSA	6	Cement spacer	Severe isolated central	7	Delta Xtend*	42
GLEN-08	F	79	32	Charcot joint	1	No	Severe combined central and anterior	14	Delta Xtend*	42
GLEN-09	F	60	22	Failed TSA	12	Hemiarthroplasty	Severe combined central and posterior	10	Delta Xtend*	42
GLEN-10	M	66	15	Postinfection TSA	3	Cement spacer	Mild isolated central	1	Delta Xtend*	42
Mean ± SD		68.8 ± 7.5	30.5 ± 9.3					9 ± 4		

GGRS, Glenius Glenoid Reconstruction System (Materialise NV, Leuven, Belgium); *TSA*, total shoulder arthroplasty; *SD*, standard deviation.

 * DePuy Synthes, Warsaw, IN, USA.
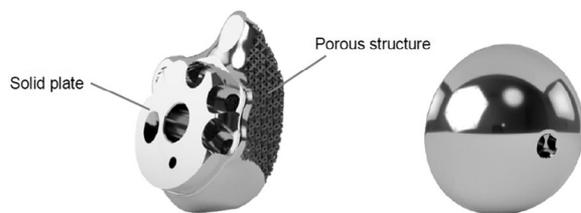 † Zimmer Biomet, Warsaw, IN, USA.

Figure 1 Custom-made titanium implant with porous coated backside that corresponds to the glenoid defect (**left**). Custom-made cobalt-chromium glenosphere (**right**).

and to avoid scapular notching. In addition, we defined optimized screw fixation trajectories for each patient to angle screws toward the best bone stock available and avoiding surrounding neurovascular structures. The Clinical Engineer prepared the preliminary screw planning, based on surgeon preferences and restricted/guided by the implant position and the remaining bone stock of the patient.

This planning was finalized through discussion with the surgeon to make sure that the screw fixation was optimized, the position of the screws did not interfere with any nerves or vessels, and the proposed insertion angles of the screws were technically feasible. An average of 5 screws were planned for implant fixation, optimizing both position and orientation to allow for cross-fixation, preferably bicortical extension, and a relatively good amount of bone stock to have good grip.

Next, the implants were designed based on the surgical plan. This implant design is patient-specific: it is made in such a way to best fit the patient's shoulder anatomy. The solid base plate is designed to cover all screw heads and to provide the female taper connection to the cobalt-chromium glenosphere. The volume between the baseplate and the host bone is then filled with a titanium trabecular augment. This structure is optimized to balance the need for sufficient contact to the bone and a relatively slim, light structure to allow easy insertion in the surgical incision. Porous structures near nerves or vessels are covered in a thin solid layer. The porous structure is intended to promote bone ongrowth and ingrowth, providing additional implant stability.

Patient-specific instruments were designed to assist the surgeon in accurate glenoid component positioning and fixation during surgery. The guide is connected to the implant, and additional supports provide unique contact surfaces fitting on the scapular bone to ensure the correct position of the implant. Drill sleeves are designed on the guide to direct the drilling of each screw hole and fixation of the bone screws according to the trajectories planned in the surgical plan.

Next to the patient-specific guide, additional plastic parts, including bone model(s) of the scapula and trial components, are provided to the surgeon to test the fit of the implant on the bone model before applying in the patients and to check the fit of the trial implant in the patient before inserting the titanium implant. The custom titanium implant (baseplate) is produced via additive manufacturing (3D printing), more specifically selective laser melting, where titanium powder particles are fused and melted layer-by-layer by a laser beam (Fig. 1). The plastic guide and models are produced via selective laser sintering, another additive manufacturing technique, where medical-grade polyamide (PA2200) powder particles are fused, but not melted, by the laser. The cobalt-chromium glenosphere is shaped from a cobalt-chromium block by computer numerically controlled milling and turning actions. Fig. 2 gives an overview of all of the components in the GGRS package. An illustrative case is shown in Fig. 3.

Figure 2 Components of the Glenius Glenoid Reconstruction System (GGRS; Materialise NV, Leuven, Belgium). The GGRS package comprises 2 plastic patient-specific guides, a plastic reconstruction of the patient's scapula, a plastic trial implant, a porous-coated titanium baseplate, a cobalt-chromium glenosphere, and several metal drill sleeves for screw insertion through the guides.

Surgical technique

All patients were operated on in the beach chair position through a deltopectoral approach. The glenohumeral joint was exposed, and any remaining prosthetic materials were identified. In 6 patients, no prosthetic material was present. We removed a cement spacer in 3 patients and an anatomic humeral component (hemiarthroplasty) in 1 other case. A circumferential release of the soft tissues around the glenoid was performed. All loose bone or cement fragments that might interfere with proper placement of the implant were removed. Care was taken not to destroy the bony anatomy of the glenoid, because any changes could alter the position of the implant.

During the débridement, special attention was paid to visualize the bone contact points for the guide. We used a plastic bone model and a trial implant as a reference for the bone contact areas of the guide and the implant. Any remaining bony prominences that might result in notching or limitation of mobility were removed after implantation of the custom-made implant. In some cases, the preoperative planning indicated that a certain amount of bone needed to be removed to allow a correct fit of the GGRS. We drilled several small holes in the remaining glenoid surface to enhance bony ingrowth, hoping to promote ingrowth of the component. To evaluate the accuracy of the débridement, the intraoperative situation of the glenoid was compared with the plastic bone model of the scapula. The plastic trial implant was fitted with the proper guide on the bone, and correct placement flush to the bone was verified.

The definitive titanium baseplate was inserted and fixed with 5 screws. The length of the screws was determined on the preoperative CT reconstructions. Next, the custom-made glenosphere was inserted and fixed. The humeral side was prepared according to the manufacturer's instructions.

Outcome rating scales

We evaluated all patients postoperatively with the Simple Shoulder Test, the 11-item version of the Disabilities of the Arm, Shoulder and Hand score, and a patient-derived Constant–Murley score.[23] Postoperative pain was evaluated using the visual analog score (VAS). Patients were asked whether they considered their postoperative
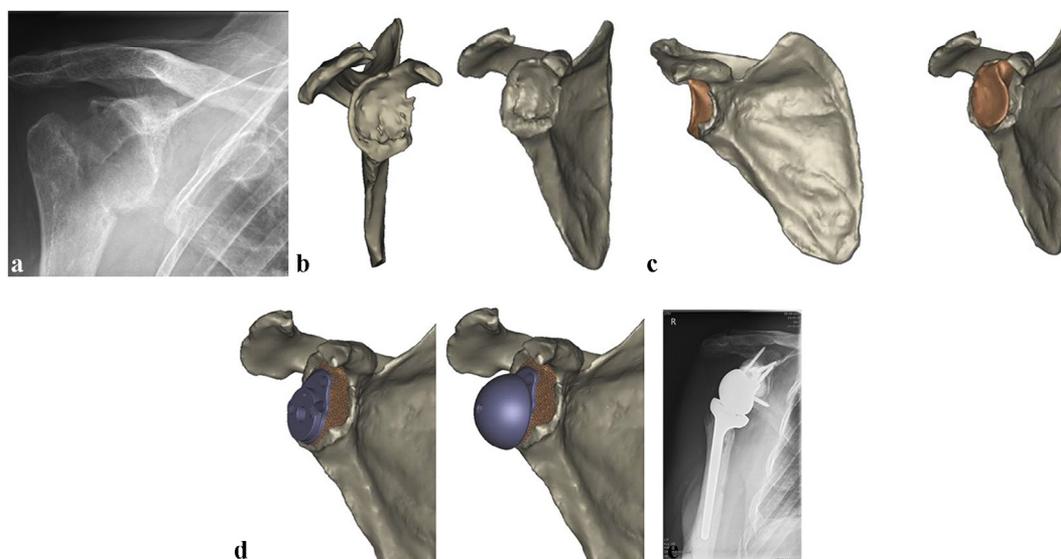
Figure 3 Resection arthroplasty with severe glenoid defect after removal of infected hemiarthroplasty (patient GLEN-02). (**a**) Standard radiographs. It is impossible to evaluate the size of the glenoid defect. (**b**) Three-dimensional computed tomography reconstruction of the scapula. The size of the defect is 12 cm^3. (**c**) Reconstruction of the original shape of the native scapula. (**d**) Virtual Glenius Glenoid Reconstruction System (Materialise NV, Leuven, Belgium) implant. Solid metal-backed baseplate with porous structure (left). The glenosphere is fixed onto the baseplate with a taper connection (right). (**e**) Postoperative radiographs show excellent implant position.

situation much better, better, the same, or worse as before surgery. Unfortunately, no preoperative data were available for all patients.

Radiographic evaluation

In all shoulders, a postoperative CT scan was obtained as described by Eraly et al.[10] We compared the position (version and inclination) of the GGRS with the preoperative planned position of the component.

Three patients (GLEN-02, GLEN-04, and GLEN-05) had a repeat CT scan more than 2 years after surgery. We measured the postoperative version and inclination, and anterior, medial, and inferior displacement of the GGRS to assess potential migration of the implant.

Results

Clinical evaluation

Results of the clinical evaluation are reported in Table II. The mean postoperative patient-derived Constant-Murley score was 41.3 ± 17.5 (range 18-76). Postoperatively the mean VAS score was 3.3 ± 2.5 points (range, 0-7 points), the mean 11-item version of the Disabilities of the Arm, Shoulder and Hand score was 35.8 ± 18.4 points (range, 2-71 points), and the mean postoperative Simple Shoulder Test was $47.5\% \pm 25.31\%$ (range, 8%-92%). Compared with before the operation, 8 patients reported a better (n = 3) or much better (n = 5) result,

Table II	Postoperative clinical outcome data					
Patient ID	VAS	CM	*Quick*DASH	SST	Satisfaction	Complications
	(points)	(points)	(points)	(%)		
GLEN-01	0	52	45.5	33.3	++	Stretch brachial plexus
GLEN-02	5	32	12.5	66.7	0	
GLEN-03	2	37	34.1	33.3	+	Instability
GLEN-04	2	29	54.5	25	++	
GLEN-05	2	67	31.8	66.7	++	
GLEN-06	2	43	29.5	75	++	
GLEN-07	6.5	27	36.4	50	0	
GLEN-08	7	18	70.5	8.3	+	
GLEN-09	6	31	40.9	25	+	
GLEN-10	0	75	2.27	91.7	++	
Mean ± (SD)	3.3 ± 2.5	41.3 ± 17.5	35.8 ± 18.4	47.5 ± 25.3		

VAS, visual analog scale for pain; *CM*, patient-derived Constant-Murley score; Quick*DASH*, 11-item version of the Disabilities of the Arm, Shoulder and Hand; *SST*, Simple Shoulder Test; *SD*, standard deviation; *++*, much better; *+*, better; *0*, same as before.

Table III   Preoperative and postoperative radiographic data

Patient	Version (°)				Inclination (°)			
	Preoperative	Planned	Postoperative	Difference*	Preoperative	Planned	Postoperative	Difference*
GLEN-01	−19	−2	2	4	−11	−4	−3	1
GLEN-02	13	−1	4	5	11	15	14	1
GLEN-03	25	2	−5	7	7	8	7	1
GLEN-04	34	−3	8	11	13	13	5	8
GLEN-05	−15	−3	−1	2	36	8	4	4
GLEN-06	11	0	6	6	28	−3	−3	0
GLEN-07	−3	0	6	6	−10	0	2	2
GLEN-08	38	−4	−7	3	5	−6	5	11
GLEN-09	−8	0	16	16	22	0	−6	6
GLEN-10	5	0	1	1	8	−3	5	8
Mean ± SD	8 ± 20	−1 ± 2	3 ± 7	6 ± 4	11 ± 15	3 ± 8	3 ± 6	4 ± 4

SD, standard deviation.

  * Difference between the preoperative planned version/inclination and the observed postoperative version/inclination.

and 2 patients rated the function of their shoulder as similar. No patients regretted having had the surgery.

Radiologic evaluation

Results of the radiologic evaluation are reported in Table III. The average preoperative glenoid defect size was 9 ± 4 cm³ (range, 1-14 cm³). Four shoulders had isolated central defects, moderate in 1 and severe in 3, and 6 shoulders had severe combined defects. The average time between the preoperative planning and surgery was 1.6 months (range, 1.1-2.0 months). The average time between the surgery and the postoperative CT scan was 3.8 months (range, 1.4-5.9 months). The mean preoperative version was $8° \pm 20°$ (range, −19° to 38°). The mean preoperative inclination was $11° \pm 15°$ (range −11° to 36°). The mean difference between the preoperative planned and the postoperative version and inclination was $6° \pm 4°$ (range, 1°-16°) and $4° \pm 4°$ (range, 0°-11°), respectively.

For 3 patients (GLEN-02, GLEN-04, and GLEN-05), we compared an immediate postoperative CT scan and a CT scan 2 years after implantation to evaluate potential migration of the component. We measured 1° difference in inclination and minimal differences (range, 0°-1°) in version. The implant position was also compared, with minimal displacements in the anterior-posterior (range, 0-1 mm), inferior-superior (range, 0-1 mm), and medial-lateral (range, 0-1 mm) directions. These measurements are of comparable magnitude of the expected measurement resolution; thus, the implants are considered stable because these postoperative data showed no migration occurred. We did not notice any clinical changes in these patients during the 2-year interval.

Complications

There were 2 postoperative complications. One patient had an elongation of the superior trunk of the brachial plexus. The patient was treated conservatively, and partial recovery was noted 3 years postoperatively. Mobility of the shoulder, however, remained limited. The second patient sustained a postoperative dislocation and was treated with a larger polyethylene insert. The shoulder remained stable after this exchange.

Discussion

The GGRS is a custom-made patient-specific implant designed to treat severe glenoid deficiencies. In this study, we note promising short-term results with respect to pain relief, clinical function, and patient satisfaction. Peer-reviewed literature on functional and radiologic outcome of patients with a patient-specific glenoid component is scarce, making it difficult to compare our results with those of other groups.[3,5,8,15,34]

Gunther and Lynch[15] reported the outcome of a custom inset polyethylene glenoid implant. At an average follow-up of 4.3 years, they noted a good clinical outcome, and radiographically, all implants were classified as "low risk" for glenoid loosening. The use of their implant, however, is limited to cases with specific defect geometries and is not suited for use in large glenoid defects.

Chammaa et al[3] used a custom-made hip-inspired implant for the treatment of severe glenoid bone loss. Their implant consists of a large acetabulum-like glenoid shell that is fixed around the scapula in contrast to the technique used in this study, where the implant is fixed into the remaining glenoid itself. At 3 years of follow-up, there was a significant improvement in pain levels and clinical outcome scores, and no evidence of glenoid loosening was observed. In 16% of the patients, however, a component revision was necessary.

We previously used a patient-specific metal-backed glenoid in a patient with loosening of the glenoid and a large glenoid defect with excellent results after 2.5 years.[34] A satisfactory outcome was also recently reported in 2 patients with a large glenoid defect treated with the Vault Reconstruction System (Zimmer Biomet, Warsaw, IN, USA).[5,8]

Radiologic analysis of our patients demonstrates a reliable correction of the preoperatively planned inclination. The

postoperative version, however, showed higher variability compared with the preoperative plan. This has several explanations: Prior operations in these patients may lead to serious stiffness of the glenohumeral joint, rendering adequate exposure of the glenoid difficult. In cases of very large defects, the GGRS implant together with the guide can be quite bulky, making a perfect fit onto the native glenoid difficult. Inadequate removal of loose bony fragments or reaming of the glenoid surface may result in an improper fit of the implant. The time between the preoperative CT scan used to create the 3D surface models and the operation may have been too long, allowing further erosion of the scapula and resulting in an improper fit of the implant.

The design of the GGRS implant requires the availability of high-quality preoperative CT scans. The presence of a glenoid component (anatomic or reversed) is a relative contraindication to use this system as a one-step procedure comprising removal of the glenoid component and reimplantation of the Glenius component. Scattering of the metal glenoid components makes delineation of the glenoid bone and the implant very difficult, rendering the CT images not useful for preoperative planning and implant design. Moreover, removal of a glenoid component has the risk that the bone structure will change and result in a suboptimal fit of the custom-made GGRS component.

A humeral hemiarthroplasty also gives artifacts on the CT scan, but adequate positioning of the patient in the CT scan gantry in such a way that there is some space between the humeral implant and the glenoid, does not impair adequate delineation of the glenoid vault. The presence of a cement spacer does not interfere with the quality of the CT images. Friction between the cement spacer and the remaining glenoid bone, however, can result in an altered shape of the glenoid vault. It is therefore advisable to keep the time between placement of the spacer and the definitive implantation of the Glenius component as short as possible.

The size of the glenoid defects varied in this series. The implant was used in 1 patient (GLEN-10) with a relatively small defect but with very poor bone quality after 3 prior operations. In this specific case, the preoperative CT planning allowed 5 fixation screws to be positioned in the best quality bone.

This study has several weaknesses. First, because this a retrospective case study in 5 different centers, we did not have preoperative clinical outcome scores for all patients. Therefore, it is difficult to assess possible improvement in functionality. However, we believe that the high patient satisfaction rate allows us to conclude that the short-term clinical outcome in these difficult to treat patients is satisfactory.

Second, although 8 of 10 patients rated their functional outcome as much better or better, we still noted 2 complications and a VAS for pain of more than 5 in 4 patients. Therefore, these results need to be interpreted with caution.

Third, in this case series, we were able to evaluate the position of the implant after a minimum of 2 years and could not demonstrate significant position changes of the implant.

Stability of a porous coated metal component largely depends on bony ingrowth, but the sequential CT scans did not allow us to prove that bony ingrowth effectively takes place. There is indeed some concern that the lack of glenoid reaming might impair bony ingrowth into the porous coating of the implant. Nevertheless, there is some evidence that selective laser-melted porous-coated scaffolds have good osseointegration characteristics. In an in vivo goat model, Demol et al[6] demonstrated increasing bone apposition and bone ingrowth of porous-coated scaffolds in unicortical defects of a tibia using micro-CT and histologic sections.

Recently, Goriainov et al[14] described a case series of 11 patients with computer-aided design and computer-aided manufacturing joint prostheses enhanced with autologous skeletal stem cells to optimize osseous integration of the implant. Using CT analysis, they were able to detect extensive new bone formation the interface of the bone and the enhanced implants. All patients had a significant improvement in the Oxford Hip Score at a mean follow-up of 19.5 months, and no surgical complications were noted.

A fourth shortcoming of this study is the lack of a control group to compare this new technique against current treatment options. This makes it difficult to determine whether this technique has superior results. We believe, however, that this study demonstrates potential advantages of this system in the treatment of severe glenoid defects.

Finally, the follow-up in this study is relatively short. Further prospective studies with sequential CT scans will be necessary to confirm the clinical results and the stability of this implant.

Conclusion

The GGRS is a new custom-made patient-specific implant designed to treat patients with severe glenoid deficiency. Short-term clinical and radiographic results of the first 10 GGRS patients are encouraging. Longer follow-up is needed to confirm the benefits of this type of implant.

Disclaimer

Philippe Debeer and Gert Van den Bogaert are consultants for Materialise NV, Leuven, Belgium. The other 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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