



Materialise Glenius

Glenoid Reconstruction System

Clinical Data Report

Executive summary

Glenoid defects can make reverse shoulder arthroplasty challenging. In patients with severe erosion, the clinical outcome with standard implants and additional bone grafting is unpredictable.^{1,2}

The Glenius Glenoid Reconstruction System can be used during reverse shoulder arthroplasty in patients with severe glenoid bone defects who need primary or revision surgery. The system includes a pre-operative 3D planning, a bone model, and implant trial, a personalized implant and guides.



The personalized implant is designed to retain as much as possible of the glenoid bone. The pre-operative planning and included 3D-printed bone model and trial helps to gain predictability and confidence during surgery.

From left to right: Shoulder cutting guides, trial implant, Glenius implant in titanium and 3D-printed bone model. All included in the Glenius Glenoid Reconstruction System.

The personalized guides support an accurate positioning and fixation of the glenoid component: a study in 10 cadaveric shoulders with glenoid defects showed significantly less angular deviations and shorter intraosseous screw length when the personalized guides were used to place the personalized implant.³

Published literature and post-marketing surveillance show that the Glenius Glenoid Reconstruction System leads to durable and safe reconstruction of the shoulder in patients with severe glenoid defects. Longer follow-up data are intended to confirm these results.

¹ Boileau P, Melis B, Duperron D, Moineau G, Rumian A. Revision surgery of reverse shoulder arthroplasty. J Shoulder Elbow Surgery 2013; 22: 1359-70.

² Gallusser N, Farron A. Complications of shoulder arthroplasty for osteoarthritis with posterior glenoid wear. Orthopaedics & Traumatology: Surgery & Research 2014; 100: 503-08.

³ Eraly K, Stoffelen D, Vander Sloten J, Jonkers I, Debeer P. A patient-specific guide for optimizing custom-made glenoid implantation in cases of severe glenoid defects: an in vitro study. J Shoulder Elbow Surgery 2015; 25 (5): 837-845.

1. Clinical experience

Evidence on the clinical outcome and safety of patients treated with Glenius Glenoid Reconstruction System is based on published literature and post-marketing surveillance (PMS).

Between January 2014 and May 2019 79 patients were already treated with the Glenius Glenoid Reconstruction System and the number of patients is still counting. Glenius was used in primary surgeries (36%) as well as in revision surgeries (48% revision of an anatomical or reverse glenoid component and 16% revision after hemiarthroplasty).

Most patients had a defect classified as Wallace type 2 or type 3 (Figure 1). A measurement of the missing glenoid bone volume showed that for 76% of the treated patients more than 5 cm³ of bone was missing (Figure 1).

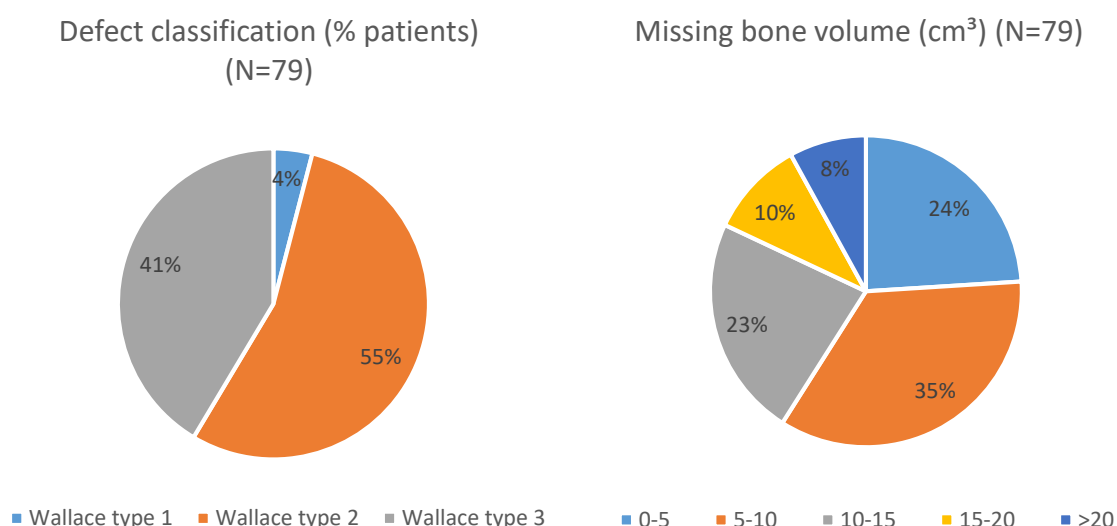


Figure 1 Defect classification and missing bone volume for patients treated with Glenius Glenoid Reconstruction System (internal data)

Wallace type 1: the most medial point of the intact glenoid articular surface is at the level of, or lateral to the base of the coracoid; Wallace type 2: the most medial point of the intact glenoid articular surface falls between the base of the coracoid and the most medial point of the spino-glenoid notch; Wallace type 3: the most medial point of the intact glenoid articular surface reaches the level of the spino-glenoid notch or is medial to it. The Wallace classification is described by Kocsis et al. 2016.⁴ The method to measure missing bone volume is described by Plessers et al. 2018.⁵

⁴ Kocsis G, Thyagarajan D, Fairbairn K, Wallace W. A new classification of glenoid bone loss to help plan the implantation of a glenoid component before revision arthroplasty of the shoulder. Bone Joint J. 2016. 98-B, pp. 374-80.

⁵ Plessers K, Vanden Berghe P, Van Dijck C, Wirix-Speetjens R, Debeer P, Jonkers I, Vander Sloten J. Virtual reconstruction of glenoid bone defects using a statistical shape model. J Shoulder Elbow Surg. 2018 Jan;27(1):160-166.

2. Peer-reviewed publication

Published literature showed there were no revisions after an average follow-up of 30.5 months (2.5 years), and no signs of migration 2 years after surgery.⁶

A retrospective analysis by Debeer *et al.* in 10 patients with severe glenoid erosion reported a stable reconstruction with no revisions after an average follow-up of 30.5 months (range 15-44 months, N=10). For three patients, an analysis of the post-operative CT scan and a CT scan two years after surgery confirmed there were no signs of migration.

Post-operative complications were reported in two patients: One patient presented an elongation of the superior trunk of the brachial plexus, and the other reported dislocation. No patient regretted having had the surgery (N=10) and 80% percent of patients (8/10) reported a better (n=3) or much better (n=5) result compared to their condition before the operation.⁵

3. Post-marketing surveillance

The Post-marketing surveillance (PMS) is based on a post-marketing survey and an internal complaints database.

A post-marketing survey was performed between July and September 2019 and asked surgeons about the number of implant-related revisions (meaning the Glenius implant is removed or replaced) and complications for patients treated with Glenius and not previously reported to the company. The response rate of the survey was 31%, meaning data gathered from 12 surgeons out of the 39 surgeons who have received the survey, showing the results of 27 patients.



The surgeons participating in the survey reported that there were no previously unreported revisions or complications for the patients treated with Glenius. The average time since surgery for the patients included in the analysis was 26.6 months (range 3-60 months, N=27). For 30% of patients, the surgery was performed more than three years ago.

⁶ Debeer P, Berghs B, Pouliart N, Van den Bogaert G, Verhaegen F, Nijs S. Treatment of severe glenoid deficiencies in reverse shoulder arthroplasty: the Glenius Glenoid Reconstruction System experience. J Shoulder Elbow Surgery 2019;28(8):1601-1608.

An internal complaints database includes post-marketing data based on voluntary reporting by the surgeon. A revision that occurred 13 months after surgery was reported for one patient (Figure 2). Additionally, nine complications for six patients were reported: four dislocations with liner revision, three infections and one acromion fracture. For five patients with complications, no revision was needed.

4. Conclusion

The results from the Debeer *et al.* are consistent with post-marketing surveillance, showing that 96% of patients (27/28) had successful treatment without revision (meaning removal or replacement of the implant). The average time since surgery was 26.6 months or 2.2 years (Figure 2).

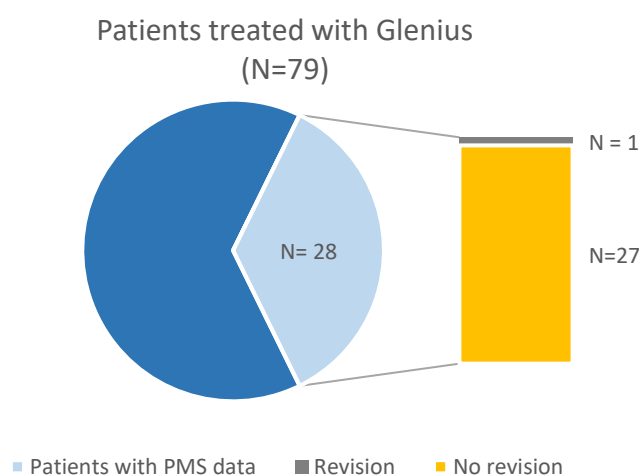


Figure 2 Clinical outcome on implant revision for patients treated with Glenius Glenoid Reconstruction System and included in post-marketing surveillance. Revision is defined as removal or replacement of the implant (*PMS = post-marketing surveillance*)



In conclusion, published literature and post-marketing surveillance show that the Glenius Glenoid Reconstruction System leads to durable and safe reconstruction of the shoulder in patients with severe glenoid defects.

Longer follow-up data are intended to confirm these results. Therefore, a prospective observational clinical trial in 25 patients started in 2019. The primary objective of this study is to assess the improvement in the clinical outcome of reverse total shoulder arthroplasty with Glenius Glenoid Reconstruction System one year after surgery.

The secondary objectives are to gather patient-reported clinical outcomes, radiological outcomes (implant position/migration, complications), implant revision rates, and safety up to 5 years after surgery. Results on an interim analysis are expected to be available in the course of 2021.

5. References

1. Eraly K, Stoffelen D, Vander Sloten J, Jonkers I, Debeer P. A patient-specific guide for optimizing custom-made glenoid implantation in cases of severe glenoid defects: an in vitro study. J Shoulder Elbow Surgery 2015; 25 (5): 837-845.
2. Stoffelen D, Eraly K, Debeer P. The use of 3D printing technology in reconstruction of a severe glenoid defect: a case report with 2.5 years of follow-up. J Shoulder Elbow Surgery 2015; 24(8):e218-22.
3. Debeer P, Berghs B, Pouliart N, Van den Bogaert G, Verhaegen F, Nijs S. Treatment of severe glenoid deficiencies in reverse shoulder arthroplasty: the Glenius Glenoid Reconstruction System experience. J Shoulder Elbow Surgery 2019;28(8):1601-1608.

6. Conference proceedings

The Glenius technology was mentioned or displayed in the following conference talks or proceedings:

- Berlin Shoulder Course 2016:
Management of glenoid bone loss in primary RSA, O. Verborght
- Orthopaedic Revision Forum 2015:
Treatment of shoulder periprosthetic joint infection, P. Debeer
Patient-specific instrumentation in reversed shoulder arthroplasty, O. Verborght
Glenoid reconstruction with allograft-autograft: a biological solution, R. Ihrman
The advantage of 3D printing in complex glenoid reconstructions, D. Stoffelen
- CORS 2013:
Achieving optimal custom-made glenoid implant position and fixation using patient-specific guides in cases of severe glenoid defects, K. Eraly
- EFFORT 2013:
Custom metal augments produced by selective laser melting for the reconstruction of severe bone defects; in vivo evaluation of bone ingrowth and biological fixation, J. Demol
- SECEC 2013:
A patient-specific guide for optimizing custom-made glenoid implant positioning in cases of severe glenoid defects, P. Debeer
- EFORT 2012:
CT-based computerized planning method for shape reconstruction of severe glenoid defects, K. Eraly



- EORS 2012:
Bone ingrowth in porous titanium bone augments in in vivo goat model: customization and functionalization, J. Demol
- CARS-ISCAS 2011:
Computer-based planning method for shape reconstruction of severely damaged glenoids, K. Eraly
- TGCS 2011:
CT-based virtual shape reconstruction for sever glenoid bone defects, K. Eraly