Journal Pre-proof

Short-term clinical and radiological outcome of the uncemented isoelastic monoblock Affinis Glenoid vitamys in stemless anatomic total shoulder arthroplasty: a multicenter study

Agnieszka Halm-Pozniak, MD, Philip Kasten, MD, Professor, Max J. Kääb, MD PhD, Marco Greis, MD, Sebastian Gros, MD, Alexander Berth, MD, Professor

PII: S2666-6383(26)00072-1

DOI: https://doi.org/10.1016/j.jseint.2026.101687

Reference: JSEINT 101687

To appear in: *JSES International*

Received Date: 10 February 2026

Accepted Date: 15 February 2026

Please cite this article as: Halm-Pozniak A, Kasten P, Kääb MJ, Greis M, Gros S, Berth A, Short-term clinical and radiological outcome of the uncemented isoelastic monoblock Affinis Glenoid vitamys in stemless anatomic total shoulder arthroplasty: a multicenter study, *JSES International* (2026), doi: https://doi.org/10.1016/j.jseint.2026.101687.

Short-term clinical and radiological outcome of the uncemented isoelastic monoblock Affinis Glenoid vitamys in stemless anatomic total shoulder arthroplasty: a multicenter study

Running title: Outcomes of Affinis Glenoid vitamys uncemented

Authors

Agnieszka Halm-Pozniak, MD [a], Philip Kasten, MD, Professor [b], Max J. Kääb, MD PhD [c d]; Marco Greis, MD [e], Sebastian Gros, MD [f], Alexander Berth, MD, Professor [a]

Affiliations

[a] Department of Orthopaedic Surgery, Otto-von-Guericke-University, Leipziger Str. 44, 39120 Magdeburg, Germany

[b] Orthopädisch Chirurgisches Centrum (OCC), Wilhelmstrasse 134, 72074 Tübingen, Germany

[c] Sporthopaedicum Straubing, Bahnhofplatz 27, 94315 Straubing, Germany

[d] University Hospital Regensburg, Clinic for Trauma Surgery, Franz-Josef-Strauss-Allee 11, 93042 Regensburg, Germany

[e] MVZ Marienstift Arnstadt, Wachsenburgallee 12, 93310 Arnstadt, Germany

[f] Helios Park-Klinikum Leipzig, Strümpellstrasse 41, 04289 Leipzig, Germany

Correspondence

Agnieszka Halm-Pozniak: agnieszka.halm-pozniak@med.ovgu.de

Postal address: Department of Orthopaedic Surgery, Otto-von-Guericke University, Leipziger Str. 44, 39120 Magdeburg, Germany

Disclaimer

The study received partial funding from Mathys Ltd. Bettlach / Enovis, Switzerland. Funds sponsored statistical analysis through an independent consultant, medical advisor contracts, and travel expenses for A. Halm-Pozniak, P. Kasten, M.J. Kääb, S. Gros, and A. Berth, as well as medical writing and editorial support from a medical writing agency. Mathys Ltd. Bettlach / Enovis was not involved in the design or execution of the study, the analysis or interpretation of the data, or the decision to submit the results.

The study received ethics committee approval from the Institutional Review Board of the Medical School of the Otto-von-Guericke University Magdeburg (IRB no.68/19), and all procedures were conducted in accordance with the Declaration of Helsinki.

Each author certifies that institutional approval of the human protocol for this study was obtained and that all investigations were conducted according to the Declaration of Helsinki.

Acknowledgements

We thank Mathys Ltd. Bettlach / Enovis for partially funding this study, and Medical Minds GmbH for providing medical writing and editorial support.

Short-term clinical and radiological outcome of the uncemented isoelastic monoblock Affinis Glenoid vitamys in stemless anatomic total shoulder arthroplasty: a multicenter study

Running title: Outcomes of uncemented Affinis Glenoid vitamys

Abstract

Background: This study evaluated the short-term clinical and radiological outcomes of an uncemented isoelastic monoblock glenoid component in stemless anatomical total shoulder arthroplasty (aTSA). We hypothesized that the implant's design and biomechanical properties would offer sufficient fixation and good functional outcomes.

Methods: In this prospective multicenter study, 75 patients received stemless aTSA for shoulder osteoarthritis using the Affinis Glenoid vitamys implant. We evaluated 64 patients at a mean follow up of 25.2 ± 2.1 months. The Constant score, Simple Shoulder Test, active range of motion, and complications were recorded. The radiological evaluation was based on the occurrence of radiolucent lines (RLLs) and periprosthetic bone adaptations using plain radiographs and scored according to Lazarus and Molé.

Results: Clinical scores and range of motion outcomes improved significantly after surgery ($P < 0.001$). The radiological evaluation revealed minor humeral periprosthetic bone adaptations without clinical consequences. RLLs on the glenoid side were detected in 31.5% of cases; most (62%) of them were < 2mm. The mean adapted Molé score was 1.08 ± 2.34. Since the majority of observed RLLs were not located around the pegs, 95% of the investigated implants were classified 0 according to Lazarus. Finally, no revision surgery was necessary due to failed fixation or loosening of the glenoid component.

Conclusion: Stemless aTSA with the uncemented isoelastic monoblock Affinis Glenoid vitamys yielded good and reliable short-term radiological and clinical results. Studies with a longer follow-up period are necessary to confirm these results.

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

Keywords: Uncemented glenoid; isoelasticity; anatomic shoulder arthroplasty; radiological outcome; clinical outcome; survival; shoulder; osteoarthritis

Numerous studies have proven, that the clinical use of anatomic total shoulder arthroplasty (aTSA) with a conventional cemented polyethylene (PE)-glenoid is a safe and effective treatment option for glenohumeral osteoarthritis (OA).[21,34,35,40,38] However, the increased risk for a revision as a result of aseptic glenoid loosening and / or rotator cuff (RC) insufficiency remains a serious concern regarding the long-term survival of aTSA with a cemented PE glenoid.[2,10,39] Therefore, aTSA is currently the subject of controversial debate, particularly in elderly patients, as a revision to a reversed TSA may be necessary due to a secondary RC failure.[40] In younger patients, however, the most common reason for revisions in aTSA is a mechanical failure of the glenoid component by loosening, PE wear, displacement and / or implant breakage.[46,48] Over the last two decades numerous innovations in prosthetic design, surgical techniques and implant materials aimed to increase the survivorship of anatomic glenoid components.[49,30,38] The modern concepts include modularity and convertibility to a reverse TSA, new fixation strategies (e.g. hybrid fixation, use of trabecular metal) to secure primary fixation and subsequently improve secondary implant stability as well as the possibility to address bone loss and deformities by augmented glenoid components.[1,32,22] These advancements have shown promising early results with lower occurrence of radiolucent lines (RLLs), as well as loosening and revision rate compared to the early glenoid components.[14,13,16]

A new concept is the use of isoelastic materials. This study evaluated the clinical and radiological results of aTSA using an uncemented, monoblock glenoid component, which has an elastic modulus similar to bone. The biomechanical characteristics of this implant were successfully used in total hip arthroplasty for many years.[44,19,43] We hypothesized that this glenoid component could provide sufficient primary implant stability and successful osseointegration. Therefore, the radiological analysis of X-rays focused on the detection of RLLs and further potential radiographic changes around the glenoid component and their clinical impact.

Materials and Methods

Patients

This prospective, multicenter, non-comparative study enrolled 75 patients from five centers in Germany treated with primary stemless aTSA using an uncemented isoelastic monoblock glenoid between January 2020 and June 2021 by primary or secondary osteoarthritis (OA) of the shoulder. The inclusion and exclusion criteria are shown in detail in Table I. The study was performed in accordance with the standards of the 1964 Declaration of Helsinki and was approved by the Institutional Review Board of the Medical School, Otto-von-Guericke University of Magdeburg (148/17). Written informed consent was obtained from all patients prior to inclusion in the study.

Surgical technique and implants

All surgeries were performed by senior shoulder surgeons with the patients in a beach chair position via a standard deltopectoral approach under general anesthesia in combination with an interscalenic block.

The patients were treated with the Affinis Short stemless shoulder arthroplasty system (Mathys Ltd. Bettlach / Enovis) (Fig. 1). The stemless humeral component was a metaphyseal fixation device made from titanium with four fins, each containing a window for bone ingrowth. The components were additionally coated with calcium phosphate. The surgeons selected the stemless prosthesis based on the preoperative subject assessment of bone quality (e.g., bone density, presence of cysts) on radiographs and MRI scans as well as the patient's activity level, age, and comorbidities. Therefore, none of them were intended to be treated with a stemmed prosthesis.

The glenoid replacement was performed with the Affinis Glenoid vitamys, which is an uncemented monoblock component made of vitamin E-enriched, highly cross-linked

polyethylene (HXLPE). It has an elastic modulus similar to bone. The backside and the pegs of the implant were coated with a thin layer of titanium particles (Fig. 1).

After exposure of the proximal humerus and removal of osteophytes, the humeral head was resected using the manufacturer's resection device. Subsequently, the cancellous bone of the metaphysis was prepared according to the manufacturer's instructions. For glenoid preparation, a circumferential release of the labrum and capsule was performed to achieve an adequate glenoid exposure. Then, a guided K-wire was placed centrally to ensure accurate positioning of the implant with regard to orientation and inclination, and for precise subsequent preparation of the glenoid. Through the K-wire, a stepwise glenoid reaming was performed to the planned size. Eccentric reaming was performed by B-type glenoids. Additional bone or osteophytes were removed if needed. Two peg holes were then drilled using a K-wired guide and the glenoid trial was inserted to confirm the correct sizing. Then, the glenoid implant was placed with an impactor. Accurate bone-implant alignment was assured. The surgeons did not use augmented glenoid components in this study. Finally, the metaphyseal fixation device was impacted almost entirely in the prepared cancellous humeral bone. The ceramic humeral head was fixed through a Morse taper by hand and the whole prosthesis was then ultimately positioned until the head is sitting flush on the resection plane.

Clinical evaluation

Primary clinical and functional outcomes included the active range of motion (ROM) measured by using a goniometer in the scapular plane (forward elevation, extension), in the neutral position of the arm at the side (external rotation), the absolute and age- and gender-adjusted Constant-Murley-Score (CS),[8] and the Simple Shoulder Test (SST).[18] Preoperative evaluations were performed 1day prior surgery. The postoperative follow-up (FU) visit was at a minimum

of 24 months postoperatively (Table II). Complications were also noted. All measurements were performed by the same person, who was one of the authors and / or surgeons.

Radiographic evaluation

Radiographic evaluation was carried out using antero-posterior and axillary views. All radiographs were taken by a certified radiologist and medical radiologic technologists, all of them experienced and specialized in musculoskeletal radiology. Special care was taken to assess the positioning of the scapula and humeral rotation when analyzing changes in component position. The RC integrity was assessed preoperatively in the MRI. The glenoid morphology was classified according to Walch et al.[47] and MRI images suitable for basic bone visualization were included in these analyses if the preoperative axial radiographs were of limited use for a proper assessment.[6,31]

The glenoid version angle was calculated using the method of Friedmann[15] and the evaluation of the posterior humeral head subluxation was carried out taking according to Walch and Domos.[47,11]

The radiographs were analysed regarding the presence of RLLs or other periprosthetic bone adaptions (bone resorption, stress shielding). The radiographic assessment was performed separately by five authors (A.H.-P., P.K., M. K., M. G., S. G., A. B.), all of them experienced orthopaedic surgeons. If RLLs were present, the width was measured in millimetres using CHILI digital radiology software system (CHILI Web software, V4.0).

The RLLs around the pegged glenoid component were graded by eight zones and measured for width according to Greiner et al.[20] (Fig. 2) and scored according to Lazarus and Molé.[36] For radiographic analysis of the stemless humeral component, 5 regions of interest (ROI) were defined around the implant according to Bell et al. (Fig. 2).[4]

The original Molé-Score only evaluates RLLs on antero-posterior X-rays of keeled glenoids. Thus, we used a modified Molé-Score which was adapted to be used for a two-pegged design and added measurements of RLLs in axillary radiographs.[20]

Statistical analysis

We performed all statistical analyses with the Statistical Analysis System (SAS), version 9.4 (SAS Institute Inc., Cary, NC, USA).

Unless otherwise specified, results are given as mean ± standard deviation. A *P* value of <0.05 was considered statistically significant. A sample size of 50 was considered to reach 95% statistical power to detect a difference between the null hypotheses with a significance level (alpha) of 0.05 using a 2-sided one-sample t-test. T Wilcoxon signed rank test was used to compare the pre- to postoperative values of the functional outcome parameters. The correlations between the RLLs versus clinical outcome and versus glenoid type were calculated with the Fisher-Exact Test. The intraclass correlation coefficient (ICC) was calculated for assessment of interobserver reliability using measurements on 30 randomly selected postoperative radiographs by five authors.

Postoperative protocol

Postoperatively, patients were instructed to wear a neutral rotation sling for six weeks. The early postoperative rehabilitation program was standardized across all centers and included passive, non-weight-bearing upper extremity exercises over the initial 6 weeks: supported pendulum exercises and isometric deltoid muscle activation as well as gentle active mobilization of the elbow, wrist, and hand. In the supine position, patients were allowed active external rotation up to 20° and forward elevation up to 90°. After six weeks, active external rotation progressively increased, and full forward elevation within pain-free limits and shoulder internal rotation gradually increased to full ROM, excluding heavy lifting. Muscle-strengthening exercises and sports activities were allowed over the following three months.

Results

Patients

The data of the 75 subjects enrolled in the present study are summarized in Table II. A total of 10 patients were lost to FU; 3 patients died unrelated to the surgery and 7 were unable to visit the hospital due to personal reasons during the pandemic, leaving 65 patients that were evaluated. In this cohort, one radiographic evaluation was not feasible due to poor image quality. Data were excluded from the evaluation, although the humerus and glenoid implants were not considered loose.

Clinical assessment

The preoperative and postoperative functional status (CS, SST, and active ROM) of the patients is presented in Table III. The functional assessment showed a significant postoperative improvement compared to preoperative results for all outcome parameters ($P < 0.001$).

Complications

There were 2 (3%) complications during the study period. One complication occurred intraoperatively during the preparation of the glenoid component. During the reaming process, the reamer was damaged. A one-size smaller reamer was therefore used and accordingly the patient was treated with a smaller glenoid component. Another patient suffered from acute shoulder pain and loss of function on the affected side four weeks after surgery that was caused by a forced abduction and external rotation during the outpatient rehabilitation program. The clinical suspicion of a subscapularis tendon lesion could not be confirmed by ultrasound or MRI, so we suspected that an overstretching/ overloading of the subscapularis tendon was responsible for the complaints. The subsequent conservative treatment was successful, pain symptoms diminished after two weeks, and radiographs during FU demonstrated proper alignment and centering of the humeral component.

Radiographic assessment

The radiological evaluation during the FU was available for 64 (85%) of the 75 shoulders. The interobserver reliability of the evaluation of the postoperative radiographs was substantial for the glenoid component (ICC 0.661; 95% confidence interval 0.442 to 0.805) and almost perfect for the humeral component (ICC 0.902; 95% confidence interval 0.824 to 0.947). The preoperative evaluation of glenoid morphology (Walch-type, retroversion) and extent of posterior humeral head subluxation are shown in Table II. In general, the radiological evaluation of the humerus and glenoid components during the FU in both groups did not present a loosening of implant nor was any component classified "at risk" for loosening.

Glenoid implant

RLLs around the glenoid implant were found in 31.5% of the cases (n = 20/64). Of these, nine patients had RLLs in one zone, five patients in two zones, three patients in three zones, two patients in four zones and one patient in five zones. The mean adapted Molé score[36] was 1.08 ± 2.34 points (range, 0 to 11). The extent and distribution of the RLLs in relation to the evaluated ROI is shown in Table IV.

Since the majority of observed RLLs were not located around the pegs, 95% (n = 61/64) of the investigated components were classified 0 according to Lazarus.[33]

The RLLs were assessed in relationship to the glenoid type according to Walch.[47] We found 60% of RLLs in type B2, 38% in type A2, and 30% in type B1 (Table V). However, no correlation was found between glenoid morphology and appearance of RLLs (P= 0.28).

Furthermore, there were no statistical differences between the CS (P = 0.12) and SST (P = 0.25) and glenoid types according to Walch.[47] Additionally, no correlation was found between the adapted Molé score[36] and postoperative CS (Spearman correlation of 0.07, P = 0.60) and SST (Spearman correlation of 0.04, P = 0.75).

Humerus implant

RLLs at the two-year FU examination were detected in 1 (1.5%) case measuring ≤1 mm and in zone 5 around the stemless humeral component according to Bell et al.[5] Comparing the anteroposterior radiographs at two-year FU with the postoperative radiographs, a decrease of bone mineral density in the area of the greater tuberosity was observed in 2 (3.1%) cases. We also detected partial exposure of the fins underneath the humeral head component in 1 (1.5%) stemless humeral implant. Finally, a minimal bone resorption in the calcar region in the FU radiographs was found in 3 (4.6%) cases. All of these periprosthetic bone reactions are signs of minimal stress shielding with no influence on the functional outcome during the short-term FU.

Discussion

This prospective multicenter study demonstrates excellent short-term clinical and radiological results of stemless aTSA at a minimum of two years FU using a novel uncemented isoelastic monoblock glenoid component (Fig. 3). In general, the findings in the present study showed significant improvements in pain assessment, functional scores, and ROM. The radiographic assessment showed only a low number of RLLs on the glenoid side suggesting a sufficient implant stability.

The glenoid implant design investigated in this study is based on the idea of the isoelastic features of RM Pressfit vitamys cup model (Mathys Ltd. Bettlach / Enovis) successfully used in total hip arthroplasty, which has led to excellent long-term clinical and radiographic outcomes.[23] It consists of HXLPE stabilized with vitamin E resulting in a higher resistance to oxidation, ageing, and abrasion than conventional PE types.[3] Interestingly, this HXLPE component shows elastic modulus equivalent to human cancellous bone.[3] The potential biomechanical benefit of the "isoelasticity" allows a force transmission from the implant to the periprosthetic bone stock that is comparable to physiological conditions.[28] This properties may diminish stress shielding, a potential risk for implant failures.[25] The primary stability of the implant used in this study relies on pressfit fixation of the two central pegs in an appropriately prepared glenoid bone bed.[17] However, in order to enable sufficient secondary and long-term stability, osseointegration of the implant into the surrounding bone tissue is crucial.[28] To support this process, the surface with contact to the periprosthetic bone as well as the anchoring pegs of the implant are coated with a layer of pure titanium particles, leaving a coarsely porous surface structure to enhance the structural connection between the bone and the implant.[41,37] Another advantage of this glenoid component and its surface is a non-modular design. This "monoblock" design may be a promising solution for glenoid implant failure modes caused by creating several interfaces in modular shoulder components.[24] Besides the beneficial aspects of

231 "modularity", various studies have shown that corrosion, fretting, PE wear or metal debris still
232 remain major concerns in modular prosthesis.[9,12]

233 The main findings of this study are the radiographic outcomes where 69% of the shoulders had
234 no RLLs around the glenoid at 24 months. Moreover, RLLs of > 2 mm were rare and confined
235 to the zones at the glenoid base (zones one, three and five) and not around the pegs (zones two,
236 four and seven). These radiological findings suggest a sufficient bony ingrowth of the two
237 central pegs, which is essential prerequisite for the stability of uncemented pegged glenoid
238 implants.[7,17] However, the RLLs rate of 31% after 2 years reported in this study may arouse
239 some concerns and requires critical analysis. First, the physiological variation of the glenoid
240 version and inclination as well as the positioning of the patient during the X-ray may influence
241 the projection of the glenoid component and also the assessment of RLLs. Despite the
242 standardized internal protocol and experienced radiologists, some deviations of a few degrees
243 from an ideal alignment cannot be ruled out. Second, design-related factors may also have
244 influenced the appearance of RLLs in this study. It can be speculated, that the thin, radiopaque
245 titanium layer on the convex PE surface facing the reamed sclerotic bone could simulate RLLs.
246 These typical appearance of the "double lines" with a gap < 1 mm are located behind the
247 baseplate on the edges of the glenoid component and can be detected directly on the
248 postoperative X-rays. These immediate minor gaps show no progression during the FU and are
249 distinct from those, that develop over time and are based on different mechanism (wear,
250 loosening). A recent experimental study of Kasten et al. support this assumption, that the tilting
251 of this novel, uncemented, titanium coated PE glenoid in relation to the X-ray could affect the
252 appearance of RLLs. [27]

253 Compared with other contemporary cemented, pegged polyethylene glenoid components
254 investigated at similar or longer FU periods,[20,29] we observed fewer and less pronounced RLLs.
255 The possible explanation are the biomechanical properties the monoblock PE component and

its isolelasticity. Moreover, there was a significant difference in FU (5 years FU by Greiner vs. 2 years FU in our study) that may also influence the occurrence of the RLLs. In contrast, a similar amount of shoulders (71.2%) as reported in this study remained free of glenoid RLLs in a recent study on aTSA using vitamin E infused all-PE cemented glenoid at a median FU of 35.3 months.[14] However, the authors of this study observed glenoid osteolysis in 5.7% of cases,[14] unlike our results where no osteolysis occurred. This may be related to the titanium coating of the implant used in the present study, which may have promoted osseointegration. The second possible explanation is the difference in the investigated PE components. The one used in our study was a double pegged high cross-linked PE, while the one evaluated by Entezari was a moderately cross-linked PE with peripheral peg. The fact that most of the RLL in this study were located at convex surface of the glenoid and not around the pegs explains the very low average Lazarus score. Additionally, the observed fraction of shoulders with a Lazarus grading of 0 (95%) was greater than that reported for cemented all-PE glenoid with a similar two-peg design at ≤ 5 years (73.3%).[20] This finding was further supported by the mean Molé score achieved in this study, which was lower than that reported with cemented PE glenoids at ≤5 years (1.1 ± 2.3 versus 2.9 ± 3.4).[20]

On the other hand, some authors found no significant differences in the rate of glenoid RLL between uncemented and cemented PE glenoids at 6 years postoperatively.[19] However, these comparisons must be interpreted with caution given the differences in PE types, overall design features, FU periods, and methodological differences in radiological evaluation potentially modifying radiographic findings.

The results of this study showed that the evaluated clinical scores and ROM values improved significantly after surgery and the appearance of RLLs did not influence the postoperative clinical outcome during the FU. No radiographic signs of glenoid component failure or loosening were observed. However, it still must be evaluated in further studies what effect the

281 radiographic changes around the glenoid component used in this study may have on mid- and
282 long-term clinical outcomes or implant survival.

283 Moreover, in the present study glenoid morphology did not have significant impact on the
284 appearance of RLLs during the two-year FU. In contrast, the study of Greiner et al. showed that
285 glenoid morphology types B2 and C predispose patients to worse radiographic results.[20]
286 Although our results could not confirm these findings, it must be noted that B2 glenoid was
287 represented only in 6 (9%) cases of the total cohort and no case had type C glenoid morphology.
288 This discrepancy may be related to differences in the FU and selection criteria regarding the
289 extent of glenoid retroversion and humeral head subluxation.

290 This study had some limitations with regard to radiological implant assessment. First, the
291 evaluation of radiological bony changes and occurrence of RLLs around the implant was only
292 performed with conventional radiographs. There is some evidence that the radiological
293 technique can affect the appearance of radiographs, particularly with respect to RLLs in
294 shoulder arthroplasty.[26,42] Considering these methodological aspects relating to the imaging
295 processing, all radiographs were obtained pre- and postoperatively according to a standardized
296 internal protocol and were performed by a board certified radiologists and technical assistants.
297 Second, a postoperative computer tomography (CT) scan would have strengthened the
298 precision in the detection of RLLs and periprosthetic bone adaptations.[45] However, regarding
299 the requirements of radiation safety and patient protection, this was not applicable in the daily
300 clinical practice as well as in the FU period. According to a recent cadaveric study, X-ray
301 evaluation of uncemented glenoid component is a reliable method to detect RLLs, but CT scans
302 can deliver greater sensitivity if bony changes occur.[7] Third, a methodological limitation of this
303 study lies in the assessment of the outcome parameters. The clinical and radiologic evaluations
304 were performed by the authors. Therefore, the potential risk of observational bias related to the
305 presented results could not be excluded by this study design. To obtain a more critical and

unbiased assessment, further data collection in this ongoing study includes independent evaluators for radiographic analysis. Moreover, it must be mentioned that the sample size was relatively small for a multicenter study. Nevertheless, it achieved the adequate statistical power to collect meaningful results. Larger as well as mid- and long-term studies should validate these findings and expand the available radiographic and clinical data on the investigated glenoid component. Finally, the study received partial funding from Mathys Ltd. Bettlach / Enovis, Switzerland. Funds sponsored statistical analysis through an independent consultant, medical advisor contracts, and travel expenses for some of the authors. Although the company was not involved in the design or execution of the study, the analysis or interpretation of the data, or the decision to submit the results, a potential bias could exist.

Conclusion

The use of the uncemented isoelastic monoblock Affinis Glenoid vitamys in stemless aTSA demonstrated good and reliable results, excellent clinical outcomes, and a low complication rate in a short-term FU. In addition, the radiological analysis showed a low number of RLLs around the glenoid implant. This may suggest that the biomechanical properties and design of this glenoid component could provide sufficient implant stability and survivorship over a mid- and long-term FU; however, this must be confirmed in further studies.

References

1. Adapa N, Rosso AJ, Cavallaro SM, Setter KJ. Glenoid fixation strategies: cemented, metal-backed, and hybrid. Semin. Arthroplast. JSES. 2024 Mar 1;34(1):266–274. doi:10.1053/j.sart.2023.07.001

2. Al-Asadi M, Rajapaksege N, Abdel Khalik H, Abesteh J, Athwal GS, Khan M. Outcomes and complications of failed anatomic shoulder arthroplasty revised with reverse arthroplasty: a systematic review. J. Shoulder Elb. Surg. 2025 Jul 1;34(7):1832–1840. doi:10.1016/j.jse.2024.10.012

3. Alexander JJ, Bell SN, Coghlan J, Lerf R, Dallmann F. The effect of vitamin E–enhanced cross-linked polyethylene on wear in shoulder arthroplasty—a wear simulator study. J. Shoulder Elb. Surg. 2019 Sep 1;28(9):1771–1778. doi:10.1016/j.jse.2019.01.014

4. Bell S, Coghlan J. Short stem shoulder replacement. Int. J. Shoulder Surg. 2014 Jul 1;8(3):72–75. doi:10.4103/0973-6042.140113,

5. Bell SN, Christmas MUSI, Coghlan JA. Proximal humeral osteolysis and glenoid radiolucent lines in an anatomic shoulder arthroplasty: a comparison of a ceramic and a metal humeral head component. J. shoulder Elb. Surg. 2020 May 1;29(5):913–923. doi:10.1016/J.JSE.2019.09.032

6. Bohonos CJ, Russell SP, Morrissey DI. CT versus MRI planning for reverse geometry total shoulder arthroplasty. J. Orthop. 2021 Nov 1;28:21–25. doi:10.1016/J.JOR.2021.10.003

7. Bülhoff M, Sonntag N, Trefzer R, Hirt B, Jäger S, Schonhoff M, et al. Bone support correlation of X-Ray and CT for a new PE-glenoid. Arch. Orthop. Trauma Surg. 2024;144(9). doi:10.1007/S00402-024-05556-3

8. Constant C, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res . 1987;214(160–4).

9. Crackau M, Märtens N, Harnisch K, Berth A, Döring J, Lohmann CH, et al. In vivo corrosion and damages in modular shoulder prostheses. J. Biomed. Mater. Res. - Part B Appl. Biomater. 2020 Jul 1;108(5):1764–1778. doi:10.1002/JBM.B.34519,

10. Dillon MT, Chan PH, Prentice HA, Burfeind WE, Yian EH, Singh A, et al. The association between glenoid component design and revision risk in anatomic total shoulder arthroplasty. 2020;doi:10.1016/j.jse.2020.02.024

11. Domos P, Checchia CS, Walch G. Walch B0 glenoid: pre-osteoarthritic posterior subluxation of the humeral head. J. Shoulder Elb. Surg. 2018 Jan 1;27(1):181–188. doi:10.1016/J.JSE.2017.08.014,

12. Eckert JA, Mueller U, Jaeger S, Panzram B, Kretzer JP. Fretting and Corrosion in Modular Shoulder Arthroplasty: A Retrieval Analysis. Biomed Res. Int. 2016;2016. doi:10.1155/2016/1695906

13. Edwards TB, Labriola JE, Stanley RJ, O'Connor DP, Elkousy HA, Gartsman GM. Radiographic comparison of pegged and keeled glenoid components using modern cementing techniques: A prospective randomized study. J. Shoulder Elb. Surg. 2010 Mar 1;19(2):251–257. doi:10.1016/J.JSE.2009.10.013

14. Entezari V, Ho JC, Sahoo S, Del Core M, Cannon D, Grewal G, et al. Early radiographic and clinical outcomes of primary short stem anatomic total shoulder arthroplasty with a peripherally enhanced fixation glenoid: a multicenter study. Semin. Arthroplast. JSES. 2024 Sep 1;34(3):533–544. doi:10.1053/J.SART.2024.01.007

15. Friedman RJ, Hawthorne KB, Genez BM. The use of computerized tomography in the

measurement of glenoid version. JBJS. 1992;74(7):1032–1037.

16. Gartsman GM, Elkousy HA, Warnock KM, Edwards TB, O'Connor DP. Radiographic comparison of pegged and keeled glenoid components. J. Shoulder Elb. Surg. 2005 May 1;14(3):252–257. doi:10.1016/J.JSE.2004.09.006

17. Geraldes DM, Hansen U, Jeffers J, Amis AA. Stability of small pegs for cementless implant fixation. J. Orthop. Res. 2017 Dec 1;35(12):2765–2772. doi:10.1002/JOR.23572,

18. Godfrey J, Hamman R, Lowenstein S, Briggs K, Kocher M. Reliability, validity, and responsiveness of the simple shoulder test: Psychometric properties by age and injury type. J. Shoulder Elb. Surg. 2007 May 1;16(3):260–267. doi:10.1016/J.JSE.2006.07.003

19. Goodloe JB, Oldenburg KS, Toner S, Rabinowitz JM, Barfield WR, Eichinger JK, et al. Comparison of press-fit versus peripherally cemented hybrid glenoid components in anatomic total shoulder arthroplasty: minimum 5-year follow-up. JSES Int. 2022 Jan 1;6(1):21–25. doi:10.1016/j.jseint.2021.09.009

20. Greiner S, Berth A, Kääb M, Irlenbusch U. Glenoid morphology affects the incidence of radiolucent lines around cemented pegged polyethylene glenoid components. Arch Orthop Trauma Surg. 2013;133:1331–1339. doi:10.1007/s00402-013-1813-7

21. Grob A, Freislederer F, Marzel A, Audigé L, Schwyzer H-K, Scheibel M, et al. Glenoid Component Loosening in Anatomic Total Shoulder Arthroplasty: Association between Radiological Predictors and Clinical Parameters—An Observational Study. J. Clin. Med. 2021, Vol. 10, Page 234. 2021 Jan 11;10(2):234. doi:10.3390/JCM10020234

22. Habermeyer P, Rapaport J, Raiss P, Magosch P. Convertible glenoid replacement in the anatomical total shoulder arthroplasty: medium-term results. Arch. Orthop. Trauma

392 Surg. 2024;144(9). doi:10.1007/S00402-024-05536-7,

393 23. Haefeli PC, Zwahlen ZM, Baumgärtner R, Link BC, Beck M. RM Pressfit vitamys: the
394 10-year follow-up. HIP Int. 2025 Mar 1;35(2):142–149.
395 doi:10.1177/11207000241304659,

396 24. Hornung AL, Hall DJ, Je M, Wright JL, Nicholson GP, Garrigues GE, et al. Do total
397 shoulder arthroplasty implants corrode? J. Shoulder Elb. Surg. 2022 Nov 1;31(11):2381–
398 2391. doi:10.1016/j.jse.2022.04.026

399 25. Hsu JE, Hackett DJ, Vo K V., Matsen FA. What can be learned from an analysis of 215
400 glenoid component failures? J. Shoulder Elb. Surg. 2018 Mar 1;27(3):478–486.
401 doi:10.1016/j.jse.2017.09.029

402 26. Hudek R, Werner B, Abdelkawi AF, Schmitt R, Gohlke F. Radiolucency in stemless
403 shoulder arthroplasty is associated with an imaging phenomenon. J. Orthop. Res. 2017
404 Sep 1;35(9):2040–2050. doi:10.1002/JOR.23478

405 27. Kasten P, Sonntag N, Trefzer R, Jäger S, Bülhoff M. Do radiolucent lines in uncemented
406 glenoid implants appear and disappear with x-ray beam tilting? A cadaveric radiographic
407 study. Clin. shoulder Elb. 2025 Sep 1;28(3):317–324. doi:10.5397/CISE.2025.00262

408 28. Khan AZ, Maxwell MJ, Parrott RM, Bowler AR, Glass EA, Miller D, et al. Effect of
409 vitamin E–enhanced highly cross-linked polyethylene on wear rate and particle debris in
410 anatomic total shoulder arthroplasty: a biomechanical comparison to ultrahigh-
411 molecular-weight polyethylene. J. Shoulder Elb. Surg. 2024 Jul 1;33(7):1465–1472.
412 doi:10.1016/j.jse.2023.11.016

413 29. Kilian CM, Press CM, Smith KM, O'Connor DP, Morris BJ, Elkousy HA, et al.
414 Radiographic and clinical comparison of pegged and keeled glenoid components using

415 modern cementing techniques: midterm results of a prospective randomized study. J.
416 Shoulder Elb. Surg. 2017 Dec 1;26(12):2078–2085. doi:10.1016/j.jse.2017.07.016

417 30. Kim DM, Alabdullatif F, Aldeghaither M, Shin MJ, Kim H, Park D, et al. Do Modern
418 Designs of Metal-Backed Glenoid Components Show Improved Clinical Results in Total
419 Shoulder Arthroplasty? A Systematic Review of the Literature. Orthop. J. Sport. Med.
420 2020;8(9):2325967120950307. doi:10.1177/2325967120950307

421 31. Kim J-H, Min Y-K. Normal Range of Humeral Head Positioning on the Glenoid on
422 Magnetic Resonance Imaging: Validation through Comparison of Computed
423 Tomography and Magnetic Resonance Imaging. Clin. Shoulder Elb. 2018 Dec
424 1;21(4):186. doi:10.5397/CISE.2018.21.4.186

425 32. Kim MS, Ahn YS, Lee SH, Jeong HJ, Kim YK, Oh JH. Can convertible metal-backed
426 glenoid components replace cemented polyethylene glenoid components in anatomical
427 total shoulder arthroplasty? BMC Surg. 2023 Dec 1;23(1):1–9. doi:10.1186/S12893-
428 023-02092-6/FIGURES/3

429 33. Lazarus MD, Jensen KL, Southworth C, Matsen FA. The radiographic evaluation of
430 keeled and pegged glenoid component insertion. J. Bone Joint Surg. Am.
431 2002;84(7):1174–1182. doi:10.2106/00004623-200207000-00013

432 34. Magosch P, Habermeyer P, Vetter P. Radiologic midterm results of cemented and
433 uncemented glenoid components in primary osteoarthritis of the shoulder: a matched pair
434 analysis. Arch. Orthop. Trauma Surg. 2023 Jan 1;143(1):225–235. doi:10.1007/s00402-
435 021-04021-9

436 35. Märtens N, Heinze M, Awiszus F, Bertrand J, Lohmann CH, Berth A. Long-term
437 survival and failure analysis of anatomical stemmed and stemless shoulder arthroplasties.
438 Bone Joint J. 2021 Jul 1;103-B(7):1292–1300. doi:10.1302/0301-620X.103B7.BJJ-

2020-0915.R3

36. Molé D, Roche O, Riand N, Lévigne C, Walch G. Cemented Glenoid Component: Results in Osteoarthritis and Rheumatoid Arthritis. Shoulder Arthroplast. 1999;163–171. doi:10.1007/978-3-642-58365-0_16

37. Nelson CG, Brolin TJ, Ford MC, Smith RA, Azar FM, Throckmorton TW. Five-year minimum clinical and radiographic outcomes of total shoulder arthroplasty using a hybrid glenoid component with a central porous titanium post. J. Shoulder Elb. Surg. 2018 Aug 1;27(8):1462–1467. doi:10.1016/J.JSE.2018.01.012

38. Page RS, Alder-Price AC, Rainbird S, Graves SE, De Steiger RN, Peng Y, et al. Reduced Revision Rates in Total Shoulder Arthroplasty With Crosslinked Polyethylene: Results From the Australian Orthopaedic Association National Joint Replacement Registry. Clin. Orthop. Relat. Res. 2022 Oct 1;480(10):1940–1949. doi:10.1097/CORR.0000000000002293,

39. Page RS, Pai V, Eng K, Bain G, Graves S, Lorimer M. Cementless versus cemented glenoid components in conventional total shoulder joint arthroplasty: analysis from the Australian Orthopaedic Association National Joint Replacement Registry. J. Shoulder Elb. Surg. 2018 Oct 1;27(10):1859–1865. doi:10.1016/j.jse.2018.03.017

40. Papadonikolakis A, Neradilek MB, Matsen FA. Failure of the glenoid component in anatomic total shoulder arthroplasty: a systematic review of the English-language literature between 2006 and 2012. J. Bone Joint Surg. Am. 2013 Dec 18;95(24):2205–2212. doi:10.2106/JBJS.L.00552

41. Raju KAK, Biswas A. Surface modifications and coatings to improve osseointegration and antimicrobial activity on titanium surfaces: A statistical review over the last decade. J. Orthop. 2025 Sep 1;67:68–87. doi:10.1016/j.jor.2025.01.002

463 42. Ricchetti ET, Jun BJ, Jin Y, Ho JC, Patterson TE, Dalton JE, et al. Relationship between
464 Glenoid Component Shift and Osteolysis after Anatomic Total Shoulder Arthroplasty:
465 Three-Dimensional Computed Tomography Analysis. J. Bone Jt. Surg. 2021 Aug
466 4;103(15):1417–1430. doi:10.2106/JBJS.20.00833

467 43. Schoch BS, Zarezadeh A, Priddy M, King JJ, Wright TW. Uncemented fixation of a
468 monoblock ingrowth polyethylene glenoid: early follow-up. J. shoulder Elb. Surg. 2020
469 May 1;29(5):968–975. doi:10.1016/J.JSE.2019.09.034

470 44. De Steiger RN, Muratoglu O, Lorimer M, Cuthbert AR, Graves SE. Lower prosthesis-
471 specific 10-year revision rate with crosslinked than with non-crosslinked polyethylene
472 in primary total knee arthroplasty. Acta Orthop. 2015 Nov 2;86(6):721–727.
473 doi:10.3109/17453674.2015.1065046,

474 45. Tang H, Huang X, Cheng X, Yang D, Huang Y, Zhou Y. Evaluation of peri-prosthetic
475 radiolucent lines surrounding the cementless femoral stem using digital tomosynthesis
476 with metal artifact reduction: A cadaveric study in comparison with radiography and
477 computed tomography. Quant. Imaging Med. Surg. 2020 Jul 1;10(9):1786–1800.
478 doi:10.21037/QIMS-19-1018,

479 46. Wagner ER, Houdek MT, Schleck CD, Harmsen WS, Sánchez-Sotelo J, Cofield R, et al.
480 The role age plays in the outcomes and complications of shoulder arthroplasty. J.
481 Shoulder Elb. Surg. 2017 Sep 1;26(9):1573–1580. doi:10.1016/j.jse.2017.01.020

482 47. Walch G, Badet R, Boulahia A, Khoury A. Morphologic study of the glenoid in primary
483 glenohumeral osteoarthritis. J. Arthroplasty. 1999;14(6):756–760. doi:10.1016/S0883-
484 5403(99)90232-2

485 48. White CA, Duey A, Zaidat B, Li T, Quinones A, Cho SK, et al. Does age at surgery
486 influence short-term outcomes and readmissions following anatomic total shoulder

arthroplasty? J. Orthop. 2023 Mar 1;37:69–74. doi:10.1016/j.jor.2023.02.007

49. Wright MA, O'Leary M, Johnston P, Murthi AM. Advances in Anatomic Total Shoulder Arthroplasty Glenoid Implant Design. J. Am. Acad. Orthop. Surg. 2025 Jan 15;33(2):56–64. doi:10.5435/JAAOS-D-23-00257,

Figure and Table Legends

Figure 1: The Affinis Short stemless prosthesis system with the Affinis Glenoid vitamys uncemented glenoid component (Mathys Ltd. Bettlach / Enovis).

Figure 2: Regions of interest of the glenoid in true ap and axillary view (A) and humerus component in true ap view (B).

Figure 3: True ap radiographs of a 66-year-old female with primary osteoarthritis of the left shoulder undergoing aTSA with the Affinis Short stemless prosthesis and an Affinis Short Bionit ceramic head combined with an Affinis Glenoid vitamys uncemented glenoid component. Radiographs taken preoperatively, immediately postoperatively, and at 24 months postoperatively; aTSA: anatomic total shoulder arthroplasty.

Table I Inclusion and exclusion criteria

Table II Baseline characteristics

Table III Clinical evaluation

Table IV Mean RLLs score by glenoid zones at 24 months postoperative

Table V Correlation between RLLs and glenoid type

Table I: Inclusion and exclusion criteria

Inclusion criteria
- primary OA of the shoulder stage III or IV according to Kellgren and Lawrence [3]
- posttraumatic OA of the shoulder / humerus fracture sequelae type 1a according to the modified Boileau classification by Kimmeyer et al. [1 4]
- secondary OA of the shoulder by synovial chondromatosis
- dislocation arthropathy stage 2 or 3 according to Buscayret [2]
- persistent pain at rest with loss of shoulder function despite conservative treatment for more than 12 months
- intact rotator cuff confirmed by preoperative MRI
- cross sectional imaging (MRI): glenoid retroversion <15 °, humeral head subluxation < 70 %
Exclusion criteria
- prior shoulder surgery to the affected shoulder
- known or suspected non-compliance (e.g. drug or alcohol abuse)
- rheumatoid arthritis
- neuromuscular or other skeletal disorders
- metabolic bone diseases and bone interacting medical-treatment

OA – osteoarthritis, MRI – magnetic resonance imaging

1. Boileau P, Trojani C, Chuinard C, Lehuec JC, Walch G. Proximal humerus fracture sequelae: Impact of a new radiographic classification on arthroplasty. Clin. Orthop. Relat. Res. 2006;442:121–130. doi:10.1097/01.BLO.0000195679.87258.6E,

2. Buscayret F, Edwards TB, Szabo I, Adeleine P, Coudane H, Walch G. Glenohumeral arthrosis in anterior instability before and after surgical treatment: Incidence and contributing factors. Am. J. Sports Med. 2004 Jul;32(5):1165–1172.

doi:10.1177/0363546503262686,

3. KELLGREN JH, LAWRENCE JS. Radiological assessment of osteo-arthrosis. Ann. Rheum. Dis. 1957;16(4):494–502. doi:10.1136/ARD.16.4.494

4. Kimmeyer M, Schmalzl J, Schmidt E, Graf A, Rentschler V, Gerhardt C, et al. Surgical treatment of fracture sequelae of the proximal humerus according to a pathology-based modification of the Boileau classification results in improved clinical outcome after shoulder arthroplasty. Eur. J. Orthop. Surg. Traumatol. 2024 Feb 1;34(2):757–769. doi:10.1007/S00590-023-03721-9,

Table II: Baseline characteristics

Characteristic	
Number of shoulders, n	75
Age at surgery, years, mean ± SD (range)	66 ± 10 (34–84)
Sex n (%)	
Male	42 (56)
Female	33 (44)
Operated side, n (%)	
Right	38 (51)
Left	37 (49)
Follow up, months, mean ± SD (range)	25.2 ± 2.1 (24.1 – 30.4)
Glenoid morphology, n (%)	
A1	37 (49)
A2	22 (29)
B1	10 (13)
B2	6 (8)
Indication for surgery, n	
Primary OA of the shoulder	68
Posttraumatic OA of the shoulder / humerus fracture sequelae	4
Secondary OA by synovial chondromatosis	1
Dislocation arthropathy	2
Glenoid size distribution, n (%)	
1	20 (28)
2	40 (53)
3	11(15)
4	4 (5)

SD- standard deviation; OA- osteoarthritis

Table III: Preoperative and postoperative values of Constant Score, Simple Shoulder Test and active range of motion.

Parameter	Preoperative	24 months postoperative	*P value*
Absolute CS (points)	27.2 ± 12.2	70 9 ± 14.4	**<0.001**
Adjusted CS (points)	36.0 ± 15.1	96.3 ± 20.9	**<0.001**
SST (points)	2.4 ± 2.4	10.1 ± 2.1	**<0.001**
Forward elevation (°)	86 ± 72	152 ± 24	**<0.001**
Extension (°)	20 ± 8.1	25 ± 11.6	**<0.001**
External rotation (°)	21 ± 14	51 ± 18	**<0.001**

CS- Constant-Murley score; SST- Simple Shoulder Test. Data given as means ± standard deviations.

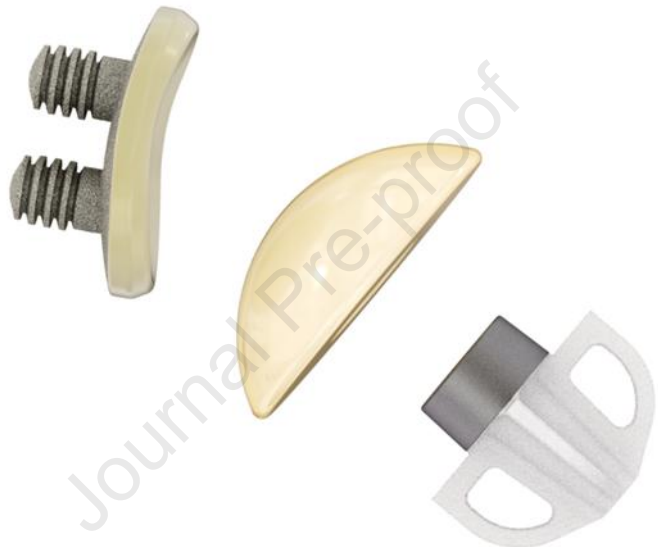
Table IV: Mean adapted RLLs score by glenoid zones

Glenoid zone (points / zone)	**n RLLs**	**<1.0 mm** (1 point)	**1–2 mm** (2 points)	**>2 mm** (3 points)	**Mean RLLs score *** (max. 24 points)
1	5 (8%)	2 (3%)	2 (3%)	1 (2%)	0.14
2	1 (2%)	0 (%)	1 (2%)	0 (0%)	0.03
3	6 (9%)	3 (5%)	2 (3%)	1 (2%)	0.16
4	2 (3%)	1 (2%)	1 (2%)	0 (0%)	0.05
5	11 (17%)	7 (11%)	2 (3%)	2 (3%)	0.27
6	7 (11%)	3 (5%)	3 (5%)	1 (2%)	0.19
7	2 (3%)	1 (2%)	1 (2%)	0 (0%)	0.05
8	9 (14%)	5 (8%)	4 (6%)	0 (0%)	0.20
Mean	43 (67 %)	22 (36 %)	16 (26 %)	5 (9 %)	1.08 ± 2.34

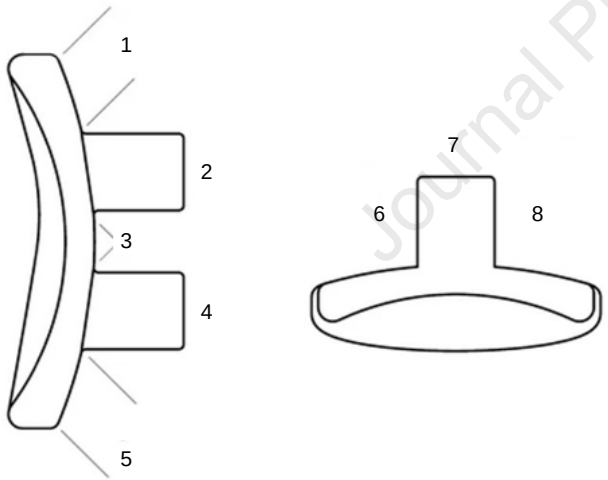
n: number of cases; RLL- radiolucent lines; Mean RLLs score *: adapted Molé-Score according to Greiner et al.

Table V: Correlation between glenoid type according to Walch and the occurrence of RLLs

Glenoid type	**none**	**any RLLs > 0 mm**	**Total**
A 1	22 (79%)	6 (21%)	28 (44 %)
A 2	13 (62%)	8 (38%)	21(77%)
B 1	7 (70%)	3 (30%)	10 (16%)
B 2	2 (40%)	3 (60%)	5 (8%)
Total	44 (69%)	20 (31%)	64 (100 %)



(A)



(B)