Cemented all-polyethylene glenoid with standard or individualized backside curvature

A retrospective comparative study

Anatomic shoulder replacement is a safe and effective therapy for the treatment of primary glenohumeral osteoarthritis and other shoulder joint disorders [8, 13, 28, 33, 34]. A standard-stem prosthesis in combination with an all-polyethylene glenoid currently represents the gold standard of anatomic shoulder replacement [10, 16, 23]. Revision of standard-stem prostheses is challenging and frequently associated with relevant bone loss from the proximal humerus [1, 4]. Developments in recent years have therefore focused primarily on the humeral portion of shoulder prostheses and have resulted in the introduction of the fourth generation of shoulder prostheses with stemless and short-stem prostheses with metaphyseal anchoring [13, 29–31].

The weak link in anatomic shoulder replacement, however, is the glenoid component [14, 26, 41]. Loosening rates of 30–70% in long-term follow-up of more than 10 years are described in the literature [7, 38]. The focus of more recent developments has thus been on optimizing the design of the glenoid component with individualized adaptation to the glenoid anatomy. Raiss et al. recently published the 2-year results of an all-polyethylene glenoid with variable backside curvature adapted to the individual anatomy [27]. The authors reported that the short-term results are promising with no loosening of the glenoid component and a low rate of radiolucent lines.

The aim of the current study was to compare the clinical and radiographic results of this new all-polyethylene glenoid with variable backside curvature adapted to the individual anatomy with a standard all-polyethylene glenoid without variable curvature. The hypothesis was that the new all-polyethylene glenoid with variable backside curvature adapted to the individual anatomy has a significantly lower rate of radiolucent lines on follow-up 2–4 years postoperatively.

Materials and methods

All consecutive patients who received an anatomic shoulder replacement from the senior author (ML) from October 2010 to July 2016 were included in this retrospective comparative single-center study. Inclusion criteria were:

1. The indication of primary glenohumeral osteoarthritis
2. Anatomic shoulder replacement with a short-stem prosthesis (Ascend™, Wright Medical, Memphis, TN, USA) and a keeled all-polyethylene glenoid
3. Follow-up period of at least 24 months

The exclusion criteria were:

1. Existing damage to the rotator cuff
2. Previous infection in the affected shoulder joint

Following a review of the inclusion and exclusion criteria, 92 patients with 99 implanted shoulder prostheses were included. In the context of this study, 87 of 99 shoulder joints (follow-up rate: 88%) could be examined. Three patients refused to participate, one patient died from unrelated reasons, and eight patients were unable to participate in the follow-up because of health problems. Of the 87 shoulders, 42 (48%) underwent arthroplasty with a standard all-polyethylene glenoid (group 1; Ascend Aequalis Glenoid, Wright Medical, Memphis, TN, USA) from October 2010 to June 2013, and 45 (52%) with an all-polyethylene glenoid with variable backside curvature adapted to the individual anatomy (group 2; Ascend™ Perform Glenoid, Wright Medical) from July 2013 to July 2016.

The mean age of all patients at the time of surgery was 68 years (range, 34–84); 38 patients (44%) were male and 49 (56%) were female. In 48 cases (55%) the right shoulder was operated on and in 39 cases (45%) the left shoulder. The two groups were comparable with respect to epidemiological parameters (Table 1; p ≥ 0.251).

Operative technique

All procedures were carried out by the senior author of this study (ML) using a standardized technique. Subscapularis...
tenotomy was performed via a deltopectoral approach. Tenodesis of the long head of the biceps was undertaken as standard. Following exposure, the humeral head was resected at the level of the anatomic neck either by a free-hand technique or using a resection guide depending on the intraoperative decision of the surgeon. The glenoid was then exposed. Glenoid size was determined by means of the sizer present. Three different sizes (small, medium, large) were available in group 1 with a standard backside curvature. In group 2 an “extra-large” size was also available. Additionally, in group 2, the radius of curvature of the glenoid was determined (sizes small and medium: 30 mm, 35 mm, and 40 mm; sizes large and extra-large: 40 mm, 50 mm, and 60 mm).

Table 2 gives an overview of the glenoid components implanted in this study.

The guide wire was then placed via a central sleeve. The glenoid reamer matching the previously determined glenoid size was inserted over the wire and any cartilage still present was removed, preserving as much subchondral bone as possible. The keel for the subsequent glenoid component was then prepared, rinsed, and dried. The keel and the backside of the glenoid component were then coated with high-viscosity pressurized polymethylmethacrylate cement and the glenoid component held in place with the compactor until the cement hardened. Following insertion of the humeral component, the subscapularis tendon was repaired with four to five nonresorbable sutures. The arm was immobilized postoperatively for 4 weeks on a shoulder abduction pillow at 15° of abduction with passive exercise for 6 weeks followed by active exercise.

### Clinical follow-up

Clinical follow-up was undertaken by two blinded observers (SS, JE) in the course of follow-up. The clinical parameters determined were:
- Range of motion on abduction (Abd)
- Flexion (Flex) and external rotation (Er)
- Constant Score (CS)
- Age- and sex-adapted Constant Score (CS%)
- Subjective Shoulder Value (SSV)
- Objective satisfaction (very satisfied, satisfied, unsatisfied, very unsatisfied).

Complications and revision procedures were also recorded.

### Radiographic follow-up

Radiographs of the affected shoulder in two planes (anteroposterior and axial) were obtained for all patients preoperatively, immediately postoperatively, and in the course of follow-up. In addition, magnetic resonance imaging (MRI) was performed preoperatively on all patients. Glenoid morphology was determined according to the method of Walch [35] as modified by Bercik et al. [3], together with glenoid version, based on the axial radiographs and MRI. Centering of the humeral head (in %) was measured on axial radiographs and centering was classified according to the method of Walch [35] based on the preoperative and postoperative axial radiographs. Determination of humeral centering based on the axial radiograph taken during follow-up was not possible in five patients.

On the immediately postoperative radiographs and the anteroposterior radiographs taken in the course of follow-up, the glenoid component was analyzed for the occurrence of radiolucent lines and loosening. Radiolucent lines around the glenoid were classified according to the method of Môle [20]. The radiographic analysis was performed by two blinded observers (MS, SS) independently of one another. Agreement in respect of the assessment of radiolucent lines was analyzed statistically. In the event of discrepancies, a consensus was reached after discussion of the case.

### Statistical analysis

Statistical analysis was performed with SPSS 23.0 software (IBM Corp., Ehningen, Germany). The level of significance was set at \( p < 0.05 \). Differences between the two groups were calculated using the \( t \) test for continuous data and scores and the chi-square test (\( n \geq 5 \)) or Fisher’s exact test (\( n < 5 \)) for categorical data. Interob-
Cemented all-polyethylene glenoid with standard or individualized backside curvature. A retrospective comparative study

**Abstract**

**Background.** The clinical and radiographic results of an all-polyethylene glenoid with variable backside curvature adapted to the individual anatomy were compared with a standard all-polyethylene glenoid.

**Methods.** This retrospective study included 87 patients with primary glenohumeral osteoarthritis and anatomic shoulder replacement with a short-stem prosthesis and cemented all-polyethylene glenoid. In all, 42 patients with a mean age of 67 ± 8 years were treated with an all-polyethylene glenoid without variable curvature (group 1) and 45 patients with a mean age of 68 ± 10 years were treated with an all-polyethylene glenoid with individualized curvature (group 2).

**Results.** After a mean follow-up period of 31 months (range, 24–50) a significant improvement was observed in all clinical parameters compared to the method of Mole. The clinical outcome was determined by range of motion, Constant Score (CS) age- and sex-adjusted Constant Score (CS%) and Subjective Shoulder Value (SSV). Radiographs were analyzed for the occurrence of radiolucent lines according to the method of Mole.

**Conclusion.** The all-polyethylene glenoid with individualized curvature showed promising short-term clinical and radiographic results. Further studies with a longer follow-up are necessary to evaluate whether the new all-polyethylene glenoid is superior to the standard all-polyethylene glenoid.

**Keywords**

Radiolucent lines · Shoulder joint · Shoulder arthroplasty · Metal-backed · Shoulder replacement

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**Vergleich eines zementierten individualisierten Polyethylen-Glenoids mit einem Standard-Polyethylen-Glenoid. Eine retrospektive Vergleichsstudie**

**Zusammenfassung**

**Hintergrund.** In dieser Studie wurden die klinischen und radiologischen Ergebnisse eines neuen Polyethylen-Glenoids mit variabler, an die individuelle Anatomie angepasster Kurvatur mit einem Standard-Polyethylen-Glenoid verglichen.

**Material und Methoden.** In diese Studie wurden 87 Patienten mit primärer Oamarthrose und anatomicem Schultergelenkersatz mit einer Kurzschulterprothese und zementiertem Polyethylen-Glenoid eingeschlossen. Davon wurden 42 Patienten (Durchschnittsalter 67 ± 8 Jahre) mit einem Polyethylen-Glenoid ohne variable Kurvatur (Gruppe 1) und 45 Patienten (68 ± 10 Jahre) mit einem Polyethylen-Glenoid mit individualisierter Kurvatur (Gruppe 2) versorgt. Das klinische Ergebnis wurde anhand von Bewegungsumfang, Constant Score (CS), alters- und geschlechtsadaptiertem CS (CS%) und subjektivem Schulterwert (SSV) erfasst. Anhand der Röntgenbilder wurde der Radiolucent-Score nach der Methode von Mole bestimmt.

**Ergebnisse.** Nach einer durchschnittlichen Follow-up-Dauer von 31 Monaten (24–50 Monate) wurde in beiden Gruppen eine signifikante Verbesserung der klinischen Parameter erzielt (p < 0,001). Der Radiolucent-Score unmittelbar postoperativ betrug 0,8 ± 1,4 in Gruppe 1 und 0,7 ± 1,1 in Gruppe 2 (p = 0,713). Zum Zeitpunkt der Abschlussuntersuchung lag der Radiolucent-Score bei 1,2 ± 2,0 in Gruppe 1 und bei 0,9 ± 1,1 in Gruppe 2 (p = 0,410). Bei 5 von 42 Patienten (12%) aus Gruppe 1 und 4 von 45 Patienten aus Gruppe 2 (9%) nahm der Radiolucent-Score im Laufe der Zeit zu. Ein Patient in Gruppe 1 (2%) zeigte radiologisch eine gelenkiale Lockerung.

**Schlussfolgerung.** Das Polyethylen-Glenoid mit individualisierter Kurvatur weist gute kurzfristige klinische und radiologische Ergebnisse auf. Weitere Studien mit längerem Follow-up sind notwendig, um zu prüfen, ob das individualisierte Polyethylen-Glenoid dem Standard-Polyethylen-Glenoid überlegen ist.

**Schlüsselwörter**

Strahlendurchlässige Linien · Schultergelenk · Schulterprothese · Metallverstärkt · Schultergelenkersatz
other parameters of preoperative status (Table 3) and the clinical outcome at follow-up (Table 4) were comparable (p ≥ 0.276).

### Radiographic results

A type B1 glenoid according to Walch was found preoperatively in 44 patients (51%), in 24 patients (28%) it was classified as A2 and in 17 patients (20%) as B2 (Table 5). Preoperatively determined glenoid retroversion was 11.2°±9.8. Humeral centering was 53%±6 preoperatively, and 59 shoulders (68%) were classified as centered and 24 shoulders (28%) as posteriorly decentered. There was no difference between the two groups regarding radiographic parameters preoperatively (p ≥ 0.101).

Interobserver agreement for the determination of the radiolucent line score was almost perfect (κ = 0.890). The radiolucent line score immediately postoperatively was 0.8±1.4 in group 1 and 0.7±1.1 in group 2 (p = 0.713). At the time of follow-up, the radiolucent line score was 1.2±2.0 in group 1 and 0.9±1.1 in group 2 (p = 0.421). In five of 42 patients (12%) in group 1 and four of 45 patients in group 2 (9%) the radiolucent line score increased over time. The increase was not significant in group 1 (p = 0.344) and group 2 (p = 0.448). The radiolucent line score at the time of follow-up was more than 1 in 13 patients in group 1 (31%) and in 10 patients in group 2 (22%) (p = 0.356). Detailed analysis showed that radiolucent lines occurred most frequently in zones 3 and 4 in both groups, although in group 2 the same number or fewer radiolucent lines were present in all zones (Fig. 1).

Glenoid loosening occurred at the time of follow-up in one of 87 patients (1%) with a radiolucent line score of 10 (Fig. 2).

As the clinical outcome is still satisfactory (CS 71, SSV 75, pain 13), the patient has refused surgical revision to date. The detailed radiographic results are summarized in Table 6.

Complications occurred in two patients (2%; both group 1). In addition to the previously described glenoid loosening, one patient had to undergo revision for a postoperative hematoma.

### Discussion

Anatomic shoulder replacement is a safe and effective method of treating primary glenohumeral osteoarthritis and other shoulder joint disorders [26]. Owing to greater life expectancy combined with a high functional requirement, the number of primary and revision procedures...
The anatomy of the glenoid is highly variable, and insufficient allowance is made for this in traditional glenoid components with only one radius of curvature of the backside [36]. Because of the variable anatomy of the glenoid, (almost) complete removal of subchondral bone is required in many cases in order to adapt the anatomy of the glenoid to the existing design of the glenoid component. However, preparation of the glenoid with the removal of subchondral bone has been identified as a substantial risk factor for the development of glenoid loosening [37]. This was the rationale for the development of new glenoid implants with variable backside curvature adapted to the individual anatomy.

In this study, the clinical and radiographic results of a new all-polyethylene glenoid with variable backside curvature adapted to the individual anatomy were compared with a standard all-polyethylene glenoid.

A significant improvement in all clinical parameters was obtained in both groups with no differences between the two groups. The results from the present study are comparable to the previously published results following total shoulder arthroplasty with third- and fourth-generation prostheses.

The radiographic results of the present study are promising with a low rate of radiolucent lines in the 31-month follow-up period. The radiolucent line scores in both groups were low with no differences between the two groups. The hypothesis postulated initially must therefore be rejected. Detailed analysis shows that the new all-polyethylene glenoid with variable backside curvature adapted to the individual anatomy exhibits the same number or fewer radiolucent lines in all six zones. Furthermore, analysis showed that a smaller proportion of cases (22% vs. 33%) had more than one radiolucent line.

The results of the current study confirm those of Raiss at al., who recently published the outcomes of 118 cases with a follow-up period of 38 months using the same glenoid component [27]. They reported that the mean radiolucent line score after 38 months was 1.06 points, which is comparable to the results of the current study. Radiographic glenoid loosening was not observed in their study.

Compared with previously published studies of radiographic outcomes with a comparable or pegged design or only partially cemented components, the rate of radiolucent lines in this study is very low [10, 12, 19, 24, 40]. Kasten et al. in 2010 analyzed the radiographic outcomes of 96 cases treated with a cemented all-polyethylene glenoid with a standard backside and showed radiographically that glenoid loosening had increased from 9% after 5 years to 33% after 9 years [15]. By adapting the glenoid component to the individual anatomy...
of the shoulder, it is hoped to achieve a long-term reduction in the rate of glenoid loosening.

Alternative designs of the glenoid component include the pegged all-polyethylene glenoid and the metal-backed glenoid. The pegged all-polyethylene glenoid shows good radiographic results in the medium-term follow-up period [9, 11, 18]. One cause for concern, however, is the “ballooning” phenomenon of osteolysis around the central peg, which is described in more than 50% of cases [2, 21]. Metal-backed glenoids have the great advantage over conventional all-polyethylene glenoids of convertibility, although many metal-backed glenoids exhibit high rates of osteolysis within the first few years and should therefore be used with some degree of reservation [6, 14, 22, 39]. Watson et al. have recently published 2-year results following implantation of a trabecular metal-backed glenoid in anatomic total shoulder arthroplasty and found 25% rates of radiographic metal debris and osteolysis at a minimum 2-year follow-up in this series with one catastrophic failure [39]. The authors concluded that this implant should be used with caution, and patients must be followed up closely. As far back as 2002, Boileau et al. published the results of a prospectively randomized study comparing a cemented polyethylene component with uncemented metal-backed glenoid components. After a follow-up period of 36 months, three of 20 patients had to undergo revision because of loosening of the metal-backed glenoid. At the same time, however, the rate of radiolucent lines was significantly higher with the polyethylene glenoid than with the metal-backed glenoid (85% vs. 25%). The authors therefore concluded that efforts must continue to improve glenoid component design and fixation [5].

In summary, the best possible evidence from long-term data is currently available for the cemented keeled glenoid component. However, even with cemented keeled all-polyethylene glenoids, high loosening rates have been observed during long-term follow-up. The design of existing all-polyethylene glenoids has been adapted and now, instead of a standard backside, backsides with variable curvature adapted to the individual anatomy are promising.

The results of the new all-polyethylene glenoid with variable backside curvature adapted to the individual anatomy are promising.

At short-term follow-up, the standard all-polyethylene glenoid and the new all-polyethylene glenoid with variable backside curvature do not show significant differences.

Further studies with a longer-term follow-up are required to investigate whether the new design has a positive effect on outcome.

### Limitations

This study has several limitations. The study design is retrospective, and the study hypothesis was postulated retrospectively. Furthermore, the patients were not randomized to the surgical procedure. A further limitation is the short follow-up period. The strengths of the study lie in the standard surgical and follow-up treatment procedures, since the same surgeon treated all patients. A further strength of the study is that two highly homogeneous patient groups with respect to age, sex, and diagnosis, and differing only in the design of the glenoid component, were compared.

### Practical conclusion

#### Table 6 Comparison of the radiographic results at the time of follow-up between the two groups

|                  | Aequalis (n = 42) | Perform (n = 45) | p     |
|------------------|------------------|-----------------|-------|
| RLL score, postoperative | 0.8 ± 1.4        | 0.7 ± 1.1       | 0.713a |
| RLL score, final follow-up | 1.2 ± 2.0        | 0.9 ± 1.1       | 0.421b |
| RLL score > 1 (n; %) | 13 (31%)         | 10 (22%)        | 0.356c |
| Glenoid loosening (n; %) | 1 (2%)           | 0               | 0.483d |
| Glenoid retroversion (*) | 10.4 ± 8.5      | 9.1 ± 6.0       | 0.448e |
| Humeral centering (%) | 0.45 ± 0.06      | 0.47 ± 0.05     | 0.093f |
| Glenoid Index (Walch) (n; %) | NA               | NA              | NA    |
| Anterior         | 22 (52%)         | 14 (31%)        | 0.197g |
| Centered         | 18 (43%)         | 25 (60%)        |       |
| Posterior        | 1 (2%)           | 2 (4%)          |       |
| NA               | 1 (2%)           | 4 (9%)          |       |

NA not available, RLL radiolucent line
aChi-square test
tTest
fFisher’s exact test

### Compliance with ethical guidelines

**Conflict of interest.** M. Schnetzke, S. Sulzer, and J. Engelke, 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. M. Loew received royalties from Tornier/Wright, which is related to the subject of this work. No company had any input into the study design, protocol, testing, data analysis, or manuscript preparation.

All procedures performed in studies involving human participants were in accordance with the ethical stan-
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Original Contribution

dards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards (Ethical Committee of Heidelberg University, application number 6/16). Informed consent was obtained from all individual participants included in the study.

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