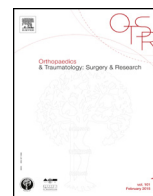




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Original article

Evaluation of a new baseplate in reverse total shoulder arthroplasty – comparison of biomechanical testing of stability with roentgenological follow up criteria



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ABSTRACT

Background and purpose: To minimize notching problem associated with reversed prostheses, inferior positioning of base plate is recommended. This reduces the risk of notching, but does not eliminate it completely. Both polyethylene/PE-induced osteolysis and implant-to-bone or implant-to-implant contact may still occur, contributing to the risk of screw-breakage and resulting long-term failure. Therefore, the stability and integration of a newly developed base plate without inferior screw and inversion of bearing materials was investigated.

Patients and methods: Biomechanical assessment of primary stability of the two types of glenoid base-plate (1- and 2-pegged) was carried out according to ASTM F-2028-02 (American Society for Testing and Materials). Patients with a follow-up period of at least 2 years were clinically ($n = 78$) and for most of them radiologically ($n = 61$) examined. The X-rays were evaluated for loosening and scapular notching.

Results: The mean values of micromotions after 100,000 cycles showed no relevant differences between the 2-peg and the 1-peg base plates ($47 \mu\text{m}$ for the 2-peg design and $43 \mu\text{m}$ for the 1-peg design), i.e. both were below the borderline for secure Osseointegration of $150 \mu\text{m}$. Radiologically, no signs of loosening or radiolucent lines/RLL were found for both base plates. The mean incidence of inferior scapular notching was 23.6% (42 mm glenoid sphere: 15.8%). Only grade 1 and grade 2 notching was observed. Additionally as result of absence of PE-induced osteolysis shape, size, borderline and location of notching differed from those observed with conventional reverse total shoulder arthroplasty bearing materials.

Conclusion: In combination with modified inferior operating technique, the newly designed implant has the potential to reduce the incidence of scapular notching and to avoid both PE-induced osteolysis and metal-screw contact. The new design did not compromise stability of the base plate in any way during the investigation period, as demonstrated both by the data from the biomechanical investigation and also by the radiological follow-up.

Level of evidence: Level III, case-control study.

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1. Introduction

Due to the principles underlying the design of inversed shoulder prostheses, various specific complications may occur, among which scapular notching is of particular interest. It results from the contact between the humeral component and the scapular neck and may lead to large osseous lesions with occasional glenoid loosening [1–3]. In addition to mechanical osseous abrasion, PE (polyethylene)-induced osteolysis play a key role, due to massive

abrasions of the humeral acetabular rim caused by contact between the humeral component and the scapular neck [4–6]. PE abrasion may then lead to a chronic inflammatory reaction of the joint capsule which in turn may cause active osteolysis [7]. Nerot and Sirveaux have classified the abrasion defects into four grades: grade 1 and 2 are a mixture between mechanical notching and PE abrasion-induced osteolyses; grade 3 and 4 are purely PE-induced osteolyses, because mechanical erosion is unlikely above the inferior lag screw [8,9].

In addition to the PE-bone contact, a metal-metal contact between the inferior lag screw of the metaglene and the humeral component may occur which may lead to metallosis and fractured screws [2,4,10].

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Thus, currently available prostheses have undergone various design modifications to reduce scapula notching combined with modified surgical technique insofar that an inferior placement of the glenoid component is now considered desirable. In the prosthesis studied by the authors, the design modifications include an eccentric glenoid base plate, a medially flattened humeral inlay, and a larger diameter of the head (glenoid sphere). In addition, the studied prosthesis shows two crucial design changes to avoid the PE-bone contact and metal-metal contact between the inferior screw and the humeral component. Firstly, the material of the gliding components was exchanged, i.e., the glenoid sphere consists of PE and the humeral component of metal. In this way, PE abrasion at the humeral component by osseous contact is no longer possible. Secondly, the design of the glenoid baseplate was modified in such a way that an inferior lag screw is no longer required for secure fixation.

We hypothesize that the implant should offer a reduced notching rate, due to design modifications and the adapted surgical technique, no signs of PE-induced osteolysis by the prevention of PE abrasion (except for the normal tribology-related abrasion), and a secure integration of the glenoid base plate despite the fact that no inferior lag screw is used.

Therefore, the aim of this prospective study is to verify biomechanical test results in accordance with clinical and radiological outcome at 2 years.

2. Methods

2.1. Implant design

The design of the investigated prosthesis (Affinis Inverse, Mathys Ltd Bettlach, Switzerland) is in line with the proven design of the Grammont prosthesis, i.e., the medialized center of rotation is located at the back of the base plate, because of the numerous advantages corresponding with it [11]. The prosthesis consists of a humeral stem for cemented or cementless implantation with modular concave medial flattened metal inlays in three thicknesses (0 mm, 3 mm, 6 mm) for each glenoid sphere diameter (Fig. 1).

The most original design feature was the inversion of the glenoid sphere and inlay material with the aim to avoid PE-abrasion by scapular contact. The PE glenoid sphere (UHMWPE) is available in different sizes (36 mm, 39 mm, 42 mm).

The standard glenoid base plate is composed of a base plate with two inline pegs, anterior and posterior lag screws ($\pm 6^\circ$ range), as well as a superior, polyaxial locking screw ($\pm 15^\circ$ range) (Fig. 2A). With no central anchoring peg limiting the distance between the anterior screw and the posterior screw, the holes for these screws were arranged closer to each other and therefore closer to the center of the base plate. The screws can be directed convergent to each other into the central glenoid bone, thus leaving more bone substance for the fixation of these lag screws (compared to conventional central 1-peg base plates). Furthermore, the convex rear surface in combination with the eccentric design of the base plate (3 mm in relation to reamer axis; i.e., the base plate is eccentric, not the glenoid sphere) allows for preserving bone stock and also shifting the glenoid sphere inferiorly. The backside surface of the base plate is coated with calcium phosphate. The depth of the humeral component as well as the humeral inclination angle were intentionally not changed compared to the Delta-III prosthesis.

For revision cases, glenoid base plate with 1 longer peg and two locking screws is available (Fig. 2B).

2.2. Biomechanical Tests

The biomechanical tests were performed in cooperation with the independent, accredited test laboratory EndoLab® Mechanical



Fig. 1. Investigated prosthesis with a stem for cementless implantation and a standard glenoid base plate.

Engineering GmbH, Rosenheim, Germany. The setup was developed in accordance with the ASTM F2028-02 (American Society for Testing and Materials) and F1829-98 guidelines and specifically adapted for inverted endoprosthesis testing [12,13] (Fig. 3A).

The base plates were fixed in blocks of artificial bone made of polyurethane foam in accordance with ASTM F1839-08 and F1839-97, each with mounted 36 mm diameter glenoid spheres [14,15]. Both base plate types were tested in three test runs. For each test run, a completely new set of implants was used.

The glenoid base plate was loaded with a constant compression force of 750 N perpendicularly to the glenoid plane and an alternating shearing force of likewise 750 N was exerted with a frequency of 1 Hz along the superior-inferior axis. Data were obtained during the entire test run (from 0 to 100,000 cycles) of all 50 cycles. Small adaptor arms to hold the high precision motion sensors (accuracy of $2 \mu\text{m}$) were laser welded to the superior and inferior rim of the base plate (Fig. 3B).

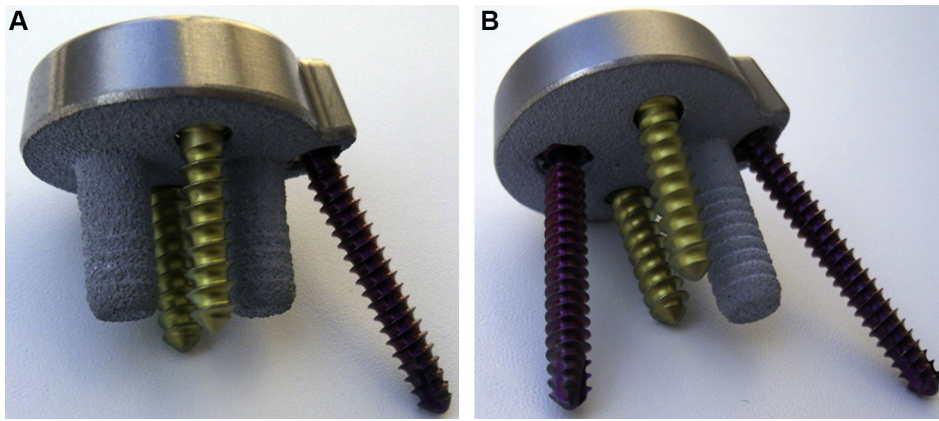


Fig. 2. A. The standard base plate is designed for cementless implantation and fixed with two pegs, one anterior and one posterior lag screw, as well as one superior polyaxial locking screw. B. The revision base plate has only one, though longer peg, as well as one superior and one inferior polyaxial locking screw.

2.3. Radiographic evaluation

In a prospective consecutive study, 85 patients with implanted inverted prostheses were followed-up (FU; all Marienstift

Arnstadt) for a minimum period of 2 years (mean FU 25.5 [±2.0] months). The average age was 71.9 years (±7.4 years). The following indications were included: rotator cuff defect arthropathy/RDA in 52 cases, fracture sequelae 15, revision of prosthesis from

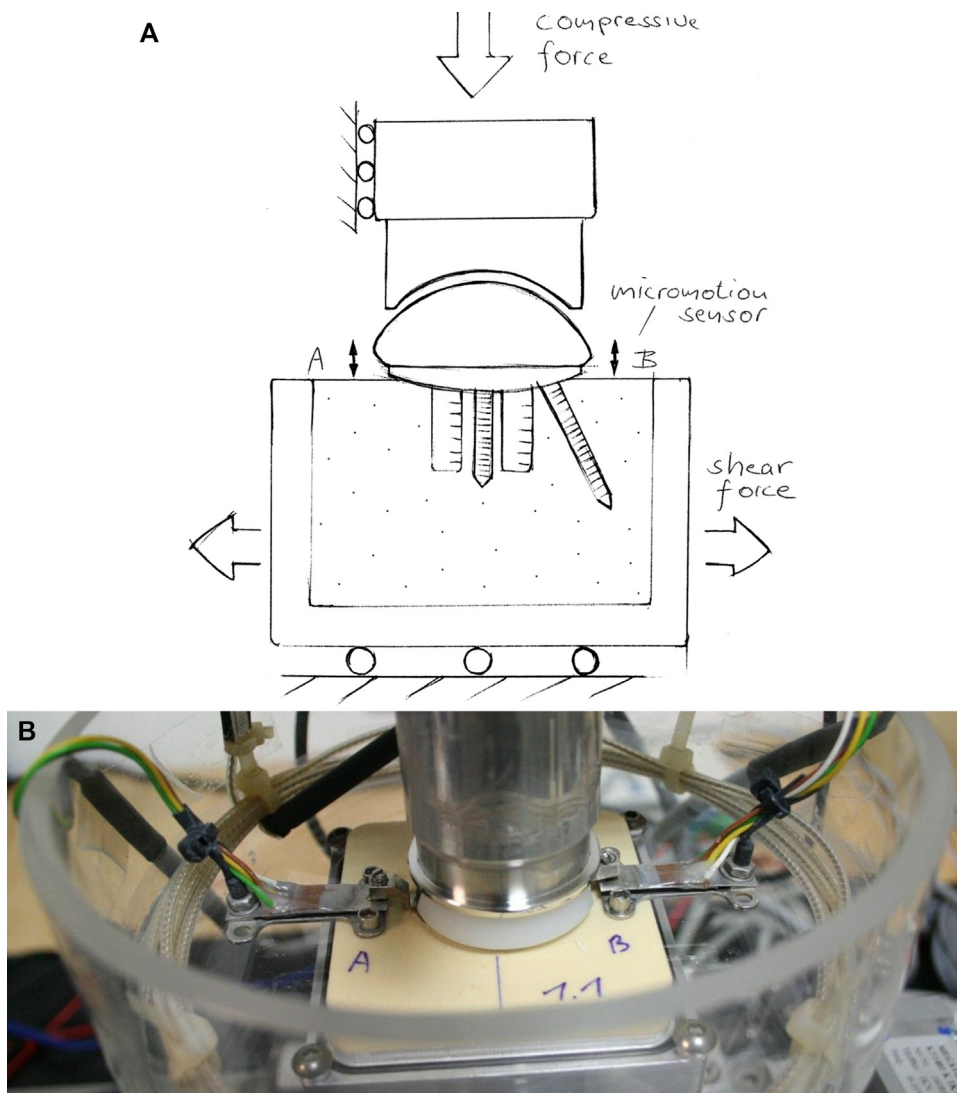


Fig. 3. A, B. Test set-up for the dynamic evaluation of glenoid loosening or dissociation modified for reversed prostheses according to ASTM F2028-02 [12].

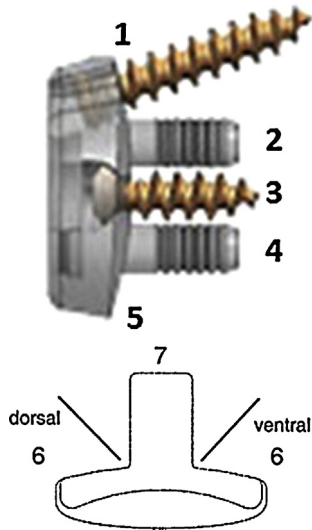


Fig. 4. Defined zones on base plate where radiolucent lines were measured: zone 1,3,5,6 under base plate, zone 2,4,7 on pegs.

anatomical to inverted shoulder prosthesis 9, primary fractures 6, and other indications 3 (1 × persistent dislocation, 2 × postinfectious arthropathy).

The patients were examined preoperatively and postoperatively, as well as after 6 weeks, and 3, 6, 12, 24, and 48 months. Out of the 85 included patients, a clinical FU was possible in 78 cases. One patient deceased and a FU was not possible in 6 cases due to bad health condition, living too far from clinic or having no time. In all 6 patients, the prosthesis was in situ. Out of the 78 patients, clinical and radiological follow-up was possible in 61 patients, in 17 patients only clinical FU were available. A total of 24 patients already had a 4-year follow-up. Of these 24 patients, 22 could be followed-up clinically.

All X-rays were taken in true a.p. projection with horizontally orientated X-ray beams, 30° abduction of the arm and in expiration. The radiography quality criteria included orthograde projection of the base plate and a freely projected scapular neck border without overlapping humeral components. Radiographs which did not meet the required standard were rejected. So, out of the 61 available X-rays, only 55 radiographs were judgable. These X-rays were evaluated after a mean FU of 25.5 (± 2.0) months.

Evaluation criteria were signs of loosening, radiolucent lines/RLL and scapular notching (Fig. 4). Due to the fact that the standard glenoid base plate featured two anchoring pegs, but no inferior lag screw, the notching classification according to Nerot [8,9] had to be modified (Fig. 5). All radiographs were evaluated by the team, until all evaluation discrepancies were resolved.

2.4. Clinical evaluation

Clinical parameters were documented using the Constant-Murley-Score (CS) and the American Shoulder and Elbow Surgeons Score (ASES). In addition, visual analogue scale (VAS) for patient satisfaction as well as all intraoperative and postoperative complications were documented.

2.5. Statistical analysis

All clinical data were entered into the web-based MEMdoc documentation system (MEM Research Center, University of Berne, Switzerland). Statistical analysis was performed using SAS software (Enterprise Guide 4.2, NC, USA). The improvement in CS and adjusted CS over time was tested with the Wilcoxon rank sum

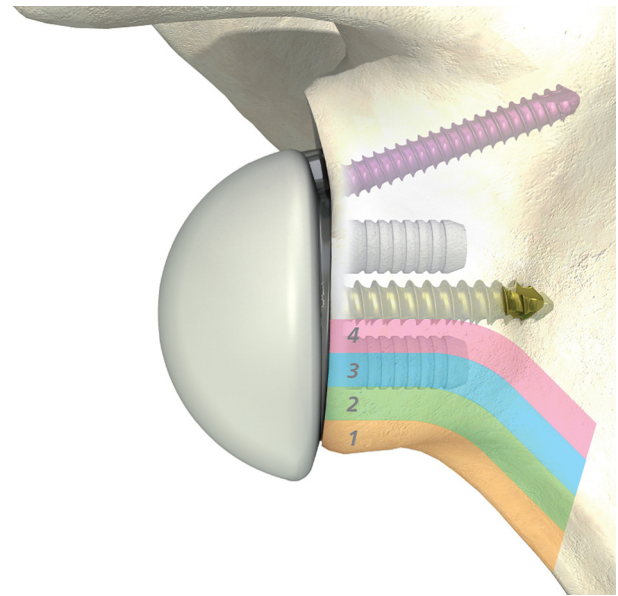


Fig. 5. The Sirveaux notching classification adapted to the new prosthesis with a standard glenoid base plate implant [9,10]. Grade 1: extends from the inferior scapular rim to the middle of the distance from the scapular rim to the inferior peg; grade 2: extends up to the inferior peg without peg contact; grade 3: extends to the middle of the inferior peg; grade 4: contact with the two lag screws.

test. The influence of the glenosphere size as well as the indication on the notching was tested with the Fisher’s exact test. In all cases, the threshold *P* value for statistical significance was defined as <0.05. Data are presented as means ± standard deviation, unless otherwise indicated.

3. Results

3.1. Biomechanical Investigation

After 100,000 cycles, almost identical, very small micromotions were measured for both glenoid components (Fig. 6). The mean values for the 2-peg design were 47 μm (range 42–50 μm) and for the 1-peg design 43 μm (range 33–58 μm), respectively, i.e. no relevant differences were found between the two tested base plates. The test results indicate an almost identical stability of the investigated base plates (2-peg design without inferior screw compared to 1-peg design with inferior screw).

3.2. Radiographic findings

Altogether 55 X-rays meeting the set quality criteria were included in the radiological analysis. No signs of loosening or radiotranslucent zones (RLL) were found in the area of the glenoid base

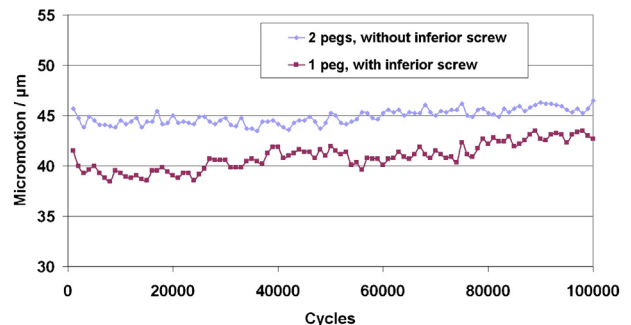


Fig. 6. Characteristic curve of micromotions between 1,000 and 100,000 (μm).



Fig. 7. Notching grade 1 of the new prosthesis with 2-peg base Plate 25 months after implantation. Notice the type and location of the notch – it represents the shape of the humeral inlay, shows a sharp sclerotic borderline and the bone defect is located away from the metaglene without any contact to it.

plate or the humeral component. Only in six cases in zone 1 and 5 of the base plate, small RLL ≤ 0.5 mm were observed. It was not to say if these were real RLL or result of incorrect reaming. No signs of scapular notching were found in 76.4% of patients. Regarding the extent of notching, only grade 1 (in 16.4%) and grade 2 (in 7.3%) cases were observed. There was no evidence of PE-induced osteolyses (Fig. 7), i.e., the notching was small, had a sharp, partly sclerosed borderline, a shape in line with the configuration of the humeral component, and a location distant from the base plate. Likewise, during the extended follow-up period of so far 4 years, the notching did not get in contact with the base plate. The notching rate was 23.7% (Table 1).

3.3. Clinical outcome

At 2 years, the average FU period for the 78 included patients was 25.5 (± 2.0) months. For the total group, the mean CS increased significantly from preoperatively 18.4 (± 7.9) points to 61.3 (± 19.4) points ($P < 0.0001$) and the adjusted CS increased significantly from 25.8% (± 11.6) to 86.4% (± 28.7) ($P < 0.0001$). After 4 years, the 22 patients included at that time achieved 64.2 (± 18.4) points for the CS and 92.1% (± 26.5) for the adjusted CS. Likewise, the individual CS values for pain improved from 3.6 (± 2.6) to 12.1 (± 3.6) points and for strength from 1.1 (± 0.6) to 12.1 (± 7.7) points. VAS

Table 1

Notching rate after a mean follow-up of 25.5 (± 2.0) months, ($n = 55$). Notching rate was 23.6%.

Notching	Frequency (n)	Percent	Notching rate (%)
Grade 0	42	76.4	0.0
Grade 1	9	16.3	16.3
Grade 2	4	7.3	7.3
Grade 3	0	0.0	0.0
Grade 4	0	0.0	0.0
Total	55	100.0	23.6

for patient satisfaction and activities of daily living (ADL) showed the same trend; they increased from preoperatively 2.0 (± 2.3) to 8.6 (± 1.9) points at the time of the follow-up and from 3.5 (± 2.5) to 15.2 (± 7.9) points, respectively. The ASES score improved from 16.6 (± 9.8) points preoperatively to 66.9 (± 20.5) points at the year 2 FU.

3.4. Complications

During the follow-up period, 6 (7.1%) implant-related complications were observed. Thereof 3 infections (all in fracture sequelae or revision group), 2 periprosthetic fractures and one fracture of the spina scapulae. In one of the infections, the gliding pair was exchanged, in the other 2 cases, the prosthesis was removed. In one of the periprosthetic fractures, the stem was revised and in the other case, an osteosynthesis without revision was done. The fracture of the spine was treated with osteosynthesis (ORIF). In total, the revision rate was 4.7%.

4. Discussion

The primary aim of this study was to evaluate the primary (by biomechanical testing) and secondary stability (by radiological FU) of a newly developed base plate of a reversed prosthesis, which has no inferior screw to avoid the risk of implant-to-implant notching between humeral and glenoid component. The secondary aim was to investigate the postulated reduced incidence of the notching phenomenon without PE-induced osteolysis as well as the documentation of characteristic clinical parameters.

Our biomechanical test results indicate an almost identical stability of the newly developed base plate with the 2-peg design without inferior screw compared to the conventional 1-peg design with inferior screw. Micromotion measurements were lower compared to published data of common reversed shoulder prosthesis [16,17]. Both were below the borderline for secure osseo-integration of 150 μm [18,19].

The importance of a medialized center of rotation of the glenoid sphere for minimal micromotions at the base plate–bone interface was shown in different investigations [11,16,17]. In consideration of these known biomechanical rules corresponding to the first rationale published by Grammont and Baulot [20], the center of rotation was kept at the rear of the base plate and we realized a curved-backed design with two pegs with macrostructure coating. In our opinion, the combined effects of these important design features resulted in the low micromotions. Thus, this metaglene design allows implantation without the inferior screw to avoid implant-screw contact.

Here, the statements of [21] are of particular interest. When examining explanted reverse prostheses, they found that even in modern, i.e., optimized, prosthesis designs, contact between the humeral component and the inferior screw cannot always be prevented. Consequently, neither PE abrasion nor screw erosion can be avoided. In our opinion, the logical consequence is to eliminate the inferior screw altogether – as one potential way to avoid this problem.

The theoretical considerations were verified by the clinical results – even without the inferior screw, complete integration of all base plates was achieved; in none of the cases RLL or loosening were observed at the pegs and only in 6 cases in zone 1 and 5 (superior and inferior rim) at the rear surface of the base plate.

The achieved clinical outcomes are very encouraging. They are at the same level as the data published for other implants [22,23]. The inversion of the articulating partners has not resulted in

any implant-specific complications during the observation period. These results confirm with primary biomechanical studies with conventional and reversed articulating materials [24].

The design changes (eccentric base plate, larger diameter of glenoid sphere and flattened medial rim of humeral component) and the modified surgical technique for inferior positioning of the glenoid implant enabled a marked reduction in the notching rate [25]. The notching rate in this study was noticeably lower compared with published data [6,23,26]. As important as the reduction of the notching rate is the fact that radiography did not reveal any signs of PE-induced osteolysis. This confirms the correctness of the theoretical concept behind the exchange of the articulating materials.

4.1. Limitations

The use of three specimens per test run meets the requirements of the standard. However, statistical conclusions were not drawn. By increasing the number of specimens, a statistical distribution could be assumed and, based on this, significance testing could be performed.

With the use of the polyurethane foam according to the ASTM standard, the question remains whether this material is suitable to simulate natural glenoid bone and whether realistic strength-related data and reproducible mechanical anchoring data can be obtained in this way.

Regarding the radiological analysis of the metaglene, it has to be noted that no fluoroscopy-guided X-ray technique was available; therefore, 6 radiographs could not be used for the analysis of the notching rate. In addition, the anterior and posterior notching was not examined.

5. Conclusion

The magnitude of micromotions of the two newly developed 2-peg base plate indicates an almost identical primary anchoring stability compared to the conventional 1-peg design. This is reflected in the radiological examination by the absence of any relevant radiolucent lines beneath the glenoid base plate. Besides the good integration of the base plate, a markedly reduced notching rate and especially no signs of PE-induced osteolyses were observed.

Thus, the design changes, i.e., the modification of the base plate and the inversion of the articulating materials, represent suitable methods to reduce the notching rate, to prevent screw erosions or fractures and to avoid PE-induced osteolyses.

Disclosure of interest

UI: this author is medical investigator and consultant from Mathys Ltd., Bettlach, Switzerland.

GK: this author is medical investigator and consultant from Mathys Ltd., Bettlach, Switzerland.

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