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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 baseplate (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 μm for the 2-peg design and 43 μm for the 1-peg design), i.e. both were below the borderline for secure Osseointegration of 150 μm. 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.

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 (±6° range), as well as a superior, polyaxial locking screw (±15° 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 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 inversed 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 μm) were laser welded to the superior and inferior rim of the base plate (Fig. 3B).

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