Clinical Biomechanics 32 (2016) 113–117

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

In vitro initial stability of a stemless humeral implant

Philippe Favre *, Jörn Seebeck, Paul A.E. Thistlethwaite, Marc Obrist, Jason G. Steffens, Andrew R. Hopkins, Paul A. Hulme

Zimmer Biomet, Sulzerallee 8, CH-8404 Winterthur, Switzerland

ARTICLE INFO

Article history:
Received 9 July 2015
Accepted 1 December 2015

Keywords:
Stemless
Humerus
Primary stability
Micromotion
Image analysis

ABSTRACT

Background: Stemless humeral prostheses have been recently introduced. We measured for the first time their in vitro primary stability and analyzed the influence of three clinically important parameters (bone quality, implant size and post-operative loading) on micromotion. We also assessed if displacement sensors are appropriate to measure implant micromotion.

Methods: A stemless humeral implant (Sidus® Stem-Free Shoulder, Zimmer GmbH, Winterthur, Switzerland) was implanted in 18 cadaveric humeri. Three-dimensional motion of the implant was measured under dynamic loading at three load magnitudes with displacement sensors. Additionally, the relative motion at the bone–implant interface was measured with an optical system in four specimens.

Results: Micromotion values derived from the displacement sensors were significantly higher than those measured by the optical system ($P < 0.005$). Analysis of variance (ANOVA) indicated that bone density ($P < 0.0005$) and load ($P < 0.0001$) had a significant effect on implant micromotion, however the effect of implant size was not statistically significant ($P = 0.123$).

Interpretation: Micromotion of this stemless design was shown to be significantly dependent on cancellous bone density. Patients must therefore have adequate bone quality for this procedure. The influence of load magnitude on micromotion emphasizes the need for controlled post-operative rehabilitation. Measurements with displacement sensors overestimate true interface micromotion by up to 50% and correction by an optical system is strongly recommended.

1. Introduction

Recently introduced stemless humeral prostheses facilitate an anatomic reconstruction of the humeral head, minimize intraoperative humeral fractures and preserve bone stock (Berth and Pap, 2013).

While most complications in total shoulder arthroplasty involve the glenoid component, loosening of humeral stems has also been reported (Cil et al., 2009; Matsen et al., 2003; Roper et al., 1990; Sanchez-Sotelo et al., 2001; Torchia et al., 1997). Stemless humeral implants rely on a surface coating and press-fit with the cancellous bone for their stability and may have a different response to loading than stems that have cancellous and cortical bone contact. Initial clinical studies suggest that stemless shoulder implants achieve good fixation (Berth and Pap, 2013; Huguet et al., 2010; Kadum et al., 2011), but knowledge on how some of the key clinical parameters affect initial stability is missing. The first aim of this study was to determine the influence of bone quality, implant size and post-operative loading on micromotion.

In vitro measurement of reverse glenoid baseplates displacement can include elastic system deformation resulting in a large overestimation of interface micromotion (Favre et al., 2011; Hopkins et al., 2008). The second objective of the study was to assess if the use of the established displacement sensor method (Harman et al., 2005; Harris et al., 2000; Kwon et al., 2010; Peppers et al., 1998; Poon et al., 2010; Virani et al., 2008) is nevertheless appropriate for micromotion testing of a stemless humeral implant where comparatively more interface micromotion than elastic system deformation might occur, or if recent image-based solutions (Codsi and Iannotti, 2008; Favre et al., 2011) would yield more accurate results.

2. Methods

2.1. Specimens

Eighteen cadaveric stripped humeri (five bilateral female, three bilateral male shoulders and two unilateral male shoulders, average age 60 SD 10 years) were used. The specimens were cut to keep approximately 10 cm of the proximal humerus. Bone density was assessed from CT scans of the proximal humerus. Three cylindrical areas were

* Corresponding author.
E-mail addresses: philippe.favre@zimmerbiomet.com (P. Favre), joern.seebeck@zimmerbiomet.com (J. Seebeck), paul.thistlethwaite@zimmerbiomet.com (P.A.E. Thistlethwaite), marc.obrist@zimmerbiomet.com (M. Obrist), jason.steffens@zimmerbiomet.com (J.G. Steffens), andrew.hopkins@zimmerbiomet.com (A.R. Hopkins), phulme123@gmail.com (P.A. Hulme).

http://dx.doi.org/10.1016/j.clinbiomech.2015.12.004
0268-0033/

analyzed corresponding to the cancellous bone volumes surrounding the three different implant sizes (small, medium and large). Hounsfield values calibrated with respect to a density phantom (Gammex 467, Gammex Inc, Middleton, WI, USA) were converted into apparent density using a linear relationship (Esses et al., 1989).

2.2. Implantation

Sidus® Stem-Free Shoulder implants (Zimmer GmbH, Winterthur, Switzerland) were tested in this study. These implants are indicated for cementless use in hemi or total shoulder arthroplasty. They are approved and were launched in Europe in 2012. They are not approved for sale and distribution in the US market but are the subject of an ongoing clinical study to support a premarket approval. The system comprises a rough blasted titanium alloy anchor and polished cobalt chromium humeral head (Fig. 1).

The anchors were implanted into the humeri according to the surgical technique. A small size anchor was implanted in bones for which a medium size anchor may have been more suitable. This was done to ensure we had an appropriate number of small size implants for statistical analysis. The humerus was cemented (Osteobond® Copolymer Bone Cement, Zimmer, Warsaw, IN, USA) in the specimen holder while ensuring that the anchor baseplate was aligned with the specimen holder. The humeral head with a fixed measurement stage was impacted onto the taper of the implant.

2.3. Primary stability measurements

Four differential variable reluctance transducer (DVRT) displacement sensors (SG-DVRT-8, 2 μm resolution, Lord Microstrain, Cary, NC, USA) were used to measure the motion of the implant (data acquisition system: Spider 8-30 TF 600 Hz HBM; software: Catman, HBM, Darmstadt, Germany). The sensors were positioned to measure the inferior–superior tilt around the anterior–posterior axis and the inferior–superior, medial–lateral and anterior–posterior displacements during loading (Fig. 2). Attaching the sensors to the specimen holder ensured that the orientation of the sensors was kept the same for all specimens. From the DVRT output, the implant motion was calculated relative to a central point on the implant using Matlab (MathWorks Inc., Natick, MA, USA) and took into account the influence of implant tilting. To determine maximum implant motion, the resultant motion of six points on the implant periphery (Fig. 1) was calculated from translations and rotations of the central point using rigid body transformations. Similarly, for the direct comparison of the DVRT and camera based systems, implant micromotion was calculated for the same region that was imaged using the camera system. Fourteen specimens were analysed using only the DVRT system and four specimens with varying bone quality were analysed using both the DVRT and camera systems.

A factor that corrected for the elastic motion of the cancellous bone included in the DVRT measurements was derived by comparing interface micromotion using a more accurate, previously published optical method (Fig. 3) (Favre et al., 2011). An approximately 1 × 1 cm cutout was made on the side of the bone to gain visible access to the cancellous bone–implant interface. Images of the interface were taken with a high-resolution camera system (Prosilica GX1920, AVT, Stadtroda, Germany) equipped with a telecentric lens (S5LPJ4425, Sill Optics GmbH & Co, Wendelstein, Germany). The imaging axis of the lens was kept perpendicular to the analyzed plane. Pre-load (50 N) and full load images were compared using a Matlab script that called the image analysis software Fiji (Schindelin et al., 2012) as a subroutine (Favre et al., 2011). This script aligned the two images to remove any rotation and translation of the system or the camera, identified landmarks common to both images and evaluated the relative implant-bone motion during loading (see Fig. 3 bottom image). Micromotion for all landmarks within the region of interest was averaged.

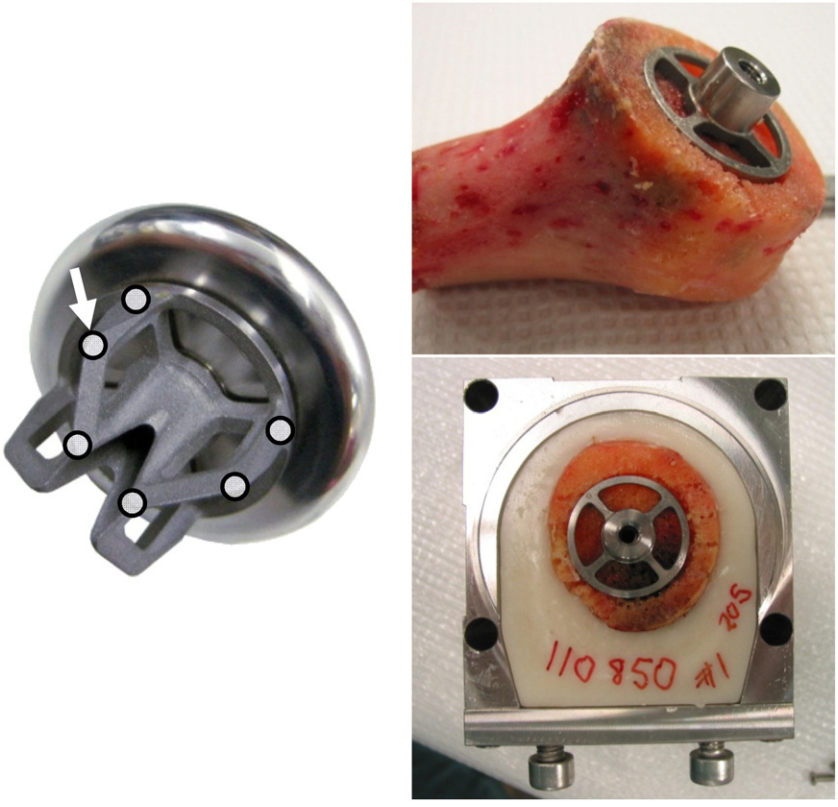

Fig. 1. Sidus® Stem-Free Shoulder (left) with locations analyzed for micromotion (the point marked with an arrow indicates the location of peak micromotion), implanted Sidus® Anchor (upper right), cemented construct (lower right).