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Design parameters and the material coupling are decisive for the micromotion magnitude at the stem–neck interface of bi-modular hip implants

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ABSTRACT

Several bi-modular hip prostheses exhibit an elevated number of fretting-related postoperative complications most probably caused by excessive micromotions at taper connections. This study investigated micromotions at the stem–neck interface of two different designs: one design (Metha, Aesculap AG) has demonstrated a substantial number of in vivo neck fractures for Ti–Ti couplings, but there are no documented fractures for Ti–CoCr couplings. Conversely, for a comparable design (H-Max M, Limacorporate) with a Ti–Ti coupling only one clinical failure has been reported. Prostheses were mechanically tested and the micromotions were recorded using a contactless measurement system.

For Ti–Ti couplings, the Metha prosthesis showed a trend towards higher micromotions compared to the H-Max M (6.5 ± 1.6 μm vs. 3.6 ± 1.5 μm, $p = 0.08$). Independent of the design, prostheses with Ti neck adapter caused significantly higher interface micromotions than those with CoCr ones (5.1 ± 2.1 μm vs. 0.8 ± 1.6 μm, $p = 0.001$). No differences in micromotions between the Metha prosthesis with CoCr neck and the H-Max M with Ti neck were observed (2.6 ± 2.0 μm, $p = 0.25$).

The material coupling and the design are both crucial for the micromotions magnitude. The extent of micromotions seems to correspond to the number of clinically observed fractures and confirm the relationship between those and the occurrence of fretting corrosion.

1. Introduction

Bi-modular hip prostheses were introduced to allow surgeons an individual reconstruction of the hip joint anatomy in total hip arthroplasty (THA). An adaptation of the prosthesis to the anatomical situation of the patient after implantation of the stem can be realized by choosing suitable neck adapters differing in length, offset, caput collum diaphysis (CCD) angle and anteversion [1–4]. Despite these advantages, in clinics the use of bi-modular hip systems led to an increased rate of postoperative problems [5–8], resulting in increased revision rates up to approximately 11% ten years after implantation [9]. The Australian Joint Registry 2012 reported a more than twice as high cumulative revision rate of bi-modular hip implants (10.6%) in comparison to modular systems with fixed neck adapters (4.3%) ten years postoperatively [9]. The main revision reasons are aseptic loosening, prosthesis dislocation and infection [9].

Forces and moments are transferred from the upper body to the leg across the hip joint loading the femoral neck in bending. In bi-modular hip systems, the taper connection between stem and neck adapter is situated in the part of the neck, where high moments act as a result of the large lever arm between joint friction and the force vector of the joint force. Consequently, the taper junction of such bi-modular implants is challenged heavily a hazard area for fretting, corrosion and fractures [10,11]. As a consequence, Stryker recalled voluntarily Rejuvenate and ABG II Modular-Neck Stems in July 2012 [12]. The potential for fretting and corrosion at taper interfaces explains why an increased number of fretting-induced neck fractures of various bi-modular hip systems has been observed clinically within the last few years [2,13–20]. The mean in vivo lifetime to the occurrence of fretting-induced fractures is about 24 months (range: 8–48 months) [2]. Some bi-modular hip prosthesis designs are more often affected by fretting-induced neck fractures rather independent of material coupling. Revision rates range between 5.9% and 12.8% after 5 years implantation time [9]. The different clinical outcome implies the hypothesis that design

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parameters such as dimensioning and stiffness difference of the adjacent components, or discrepancies in geometric parameters (such as taper angle difference), are crucial factors.

Fretting-induced surface damages at taper connections has been predominantly observed for titanium alloys [2,10,11,14] and seems to be the result of the limited oxide layer abrasion resistance of these alloys [21]. Fractures often occurred slightly below the proximal end of the stem taper in a mechanical highly stressed region with high bending loads [1,2]. Previous studies have indicated that critical micromotions between adjacent components at taper interfaces might be responsible for initiating the failure mechanism, which ultimately can lead to fretting-induced fatigue. The threshold for critical micromotions leading to fretting is not yet known. It is hypothesized that if these motions exceed a critical value, a removal of the passivation layer occurs, causing the ongoing repassivation process and produce an increase in layer thicknesses in the affected area. Surface damages caused by small micromotions between adjacent surfaces, known as fretting, involve fretting and crevice corrosion and produce metal debris in the form of ions [7,22,23] and in the form of particles [3,24–26] remaining within the periprosthetic tissue or migrating in other regions with yet not fully known consequences. Wear debris stimulates a cascade of tissue reaction with an activation of osteoclasts and an inhibition of osteoblasts, which may implicate degradation of bone around the prosthesis [25,27–31]. An accelerate progressive deterioration of the adjacent metal surfaces might be enforced by the fluid environment surrounding the prosthesis in vivo leading subsequently to severe corrosion [1,2,4] and the initiation of cracks [32]. In a worst-case scenario, the propagation of these cracks might result in fatigue fracture of the neck adapter especially during an overload event [2,15].

After market launch in the year 2004, an elevated number of neck fractures at the taper junction of the Metha Short Hip System (Aesculap AG, Tuttlingen, Germany) occurred. Neck fractures were almost exclusively observed for the combination of a titanium neck adapter with the titanium stem and small or medium CCD angles [2]. As soon as this problem was observed in 2006, the system was temporarily taken off the market and re-introduced at the beginning of the year 2007 with cobalt-chromium neck adapters. Other bi-modular designs like the H-Max M design (Limacorporate, Villanova di San Daniele (UD), Italy) just have sporadic documented neck failures and are still used with Ti-Ti material couplings. However, CoCr necks for the H-Max M prosthesis were introduced on the market in October 2010 and are currently used in clinical application. Presently, it is unclear why one design works in a Ti–CoCr material coupling and the other in a Ti–Ti coupling, respectively, and which design parameters are responsible for the diverse clinical outcome of the different designs.

Studies have shown that relative movements at taper connections [2,33–36] are influenced by several factors. Finite element analyses and experimental studies have shown that the applied load [34,35], the conical mismatch [34], the neck offset [35], the initial assembly force [34], the taper material coupling [2,33], the head diameter [37], taper surface structure [38] and the assembly condition (contamination) [2,33] influence the relative motion of the taper. However, in most of the cited studies, the interface micromotion is superimposed by the elastic deformation of the taper parts (relative motions), so that the pure micromotion was only estimated (if at all) [2,34,35]. Over all designs and experimental test conditions, the reported motions ranged between 3 μm and 41 μm [2,33–35]. However, neither for similar nor for mixed material combinations a general statement exists relating to their fretting behaviour [20,26,39–46].

In order to get a better understanding of the main influencing factors, it is necessary to compare clinically successful to non-successful bi-modular stem designs with regard to the probably main factor for initiation of fretting induced problems – the micromotion at the taper interface.

This study investigated the influence of different material couplings for two bi-modular prosthesis designs with different clinical outcome on micromotions in the stem–neck interface.

The focus in this study is putting on the comparison of the micromotion magnitude of the clinically successful Metha prosthesis (Ti stem) with CoCr neck adapter and those of the also successful H-Max M prosthesis (Ti stem) with a Ti neck in comparison to the clinically failed Metha prosthesis with Ti neck adapter. In order to differentiate between the influence of the design (geometry) and the effect of the material coupling, Ti stems from both designs were combined with neck adapters made from Ti and CoCr. In case of H-Max M prostheses CoCr neck adapters were produced especially for this study since they were not available on the market at the time.

2. Materials and methods

2.1. Experimental set-up

Six bi-modular hip prostheses of each of the two different designs (Metha, Aesculap AG, Tuttlingen, Germany; H-Max M, Limacorporate, Villanova di San Daniele (UD), Italy, Fig. 1) were mechanically tested. For the Metha prosthesis, a size 4 and for the H-Max M prosthesis the size no. 9 were chosen based on a given patient anatomy. The tested H-Max M neck adapters were used with the longest available neck length simulating a worst-case scenario with maximal bending load in the interface. Only one length of Metha neck was available. Both tested prosthesis designs had a CCD – angle of 130° and a neutral anteversion. Half of the Ti6Al4V alloy (Ti) stems were assembled with Ti neck adapters, half with CoCr29Mo necks (CoCr). CoCr neck adapters for the H-Max M prosthesis were specially manufactured by Limacorporate since these were not marketed at the time of performing this experimental study. A CoCr alloy ball head was used for all measurements (Ø 32 mm, size L). Aligning the neck axis of the two design results in an angle of 10° between the proximal stem planes (σ, Fig. 1). The endplanes of the Metha neck adapter exhibit an angle of 10° (ψ, Fig. 1) whereas these planes of the H-Max M prosthesis are parallel. Differences were also existent in stem ($\Delta s \approx 34.5$ mm) and neck length ($\Delta d \approx 8.3$ mm).

Prior to mechanical testing, the surfaces of the conical taper junctions of the clinically relevant components (Metha: Ti stems & CoCr necks; H-Max M: Ti stems & necks) were scanned using a coordinate measuring machine (Mitutoyo BHN 305, Mitutoyo Deutschland GmbH, Germany) to determine the taper angles of the stems and the neck adapters. The taper angle difference at the stem–neck taper interface was defined as the taper angle of the neck minus the taper angle of the stem. A positive taper angle difference corresponds to the first contact between stem and neck adapter tapers occurring at the open end of the stem taper.

For mechanical testing, the stems were embedded in PMMA (polymethylmethacrylate, Technovit 4004, Heraeus Kulzer GmbH, Wehrheim Ts., Germany) in accordance to ISO 7206-4 in 10° adduction and 9° flexion (Fig. 2). Axial load during assembly and dynamic testing was applied at the top of the CoCr ball head. The implant components were quasi-statically assembled with a velocity of 0.5 kN/s (force-controlled) up to a load of 2.0 kN using a servohydraulic testing machine (MiniBionix II, MTS, Eden Prairie, MN, USA, Fig. 2). An axial force-controlled sinusoidal load between 0.23 kN and 4.30 kN, corresponding to the hip contact force during walking upstairs [47], was then applied at a frequency of 1 Hz for 10,000 cycles.

For the recording of the relative motions at the stem–neck interface, four eddy current sensors were used (Type U05 (78),