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Effect of trunnion roughness and length on the modular taper junction strength under typical intraoperative assembly forces

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ABSTRACT

Modular hip implants are at risk of fretting-induced postoperative complications most likely initiated by micromotion between adjacent implant components. A stable fixation between ball head and stem-neck taper is critical to avoid excessive interface motions. Therefore, the aim of this study was to identify the effect of trunnion roughness and length on the modular taper strength under typical intraoperative assembly forces.

Custom-made Titanium trunnions (standard/mini taper, smooth/grooved surface finish) were assembled with modular Cobalt-chromium heads by impaction with peak forces ranging from 2 kN to 6 kN. After each assembly process these were disassembled with a materials testing machine to detect the pull-off force as a measure for the taper strength.

As expected, the pull-off forces increased with rising peak assembly force ($p < 0.001$). For low and moderate assembly forces, smooth standard tapers offered higher pull-off forces compared to grooved tapers ($p < 0.038$). In the case of an assembly force of 2 kN, mini tapers showed a higher taper strength than standard ones ($p = 0.037$).

The results of this study showed that smooth tapers provided a higher strength for taper junctions. This higher taper strength may reduce the risk of fretting-related complications especially in the most common range of intraoperative assembly forces.

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1. Introduction

Modular hip prostheses are commonly used in operation routines of total hip replacements and offer at least one conical taper junction connecting the femoral stem-neck with the ball head. This concept was established in the 1970s to allow surgeons more flexibility in the choice of head material and diameters, and head-stem offsets for a more individualised anatomical reconstruction of the patient's hip joint [1] while retaining the femoral stem and to substantially reduce the inventory [2]. It was assumed that due to an optimized positioning of the artificial joint the revision rates could be decreased. However, the latest clinical data do not reflect the desired positive effects [3–6] with revision rates of up to 86% for a double-tapered modular hip prosthesis after a follow-up time of less than five years [4]. In recent years concerns have arisen regarding fretting [7,8], wear [9,10] and corrosion at modular taper junctions [8,9,11–15] further increasing the number of revision surgeries [5,8,9,12,16]. The resulting postoperative complications include, but are not limited to, pain [7,13,17], soft tissue damage [7,11], the formation of pseudotumours [7,15,18,19] and osteolysis [20,21] and are frequently associated with high metal ion levels in the blood and/ or urine [15,22–24]. Despite the fact that the precise failure mechanism at taper interfaces is not yet completely elucidated, it is undisputed that micromotion between the adjacent implant components plays a role for this clinical concern [9,25–28]. Previous experimental [28–33] and numerical studies [34,35] have evaluated micromotion at taper interfaces: the documented values report a large range from a few microns to more than 40 µm indicating that several factors such as, the prosthesis geometry, manufacturing tolerances of the taper, the location of the taper connection (head-stem or stem-neck), taper surface topography and the assembly conditions may influence the micromotion levels [28–32,35]. These may be linked to changes in the location and size of the taper contact area [36] and the assembly force. Taper junctions are exposed to high bending and torsional loads during daily activities supporting the occurrence of micromotion. These can provoke mechanical, as well as electrochemical initiated, processes in the fluid environment of the hip joint leading firstly, to fretting [27,37,38] and mechanically assisted crevice

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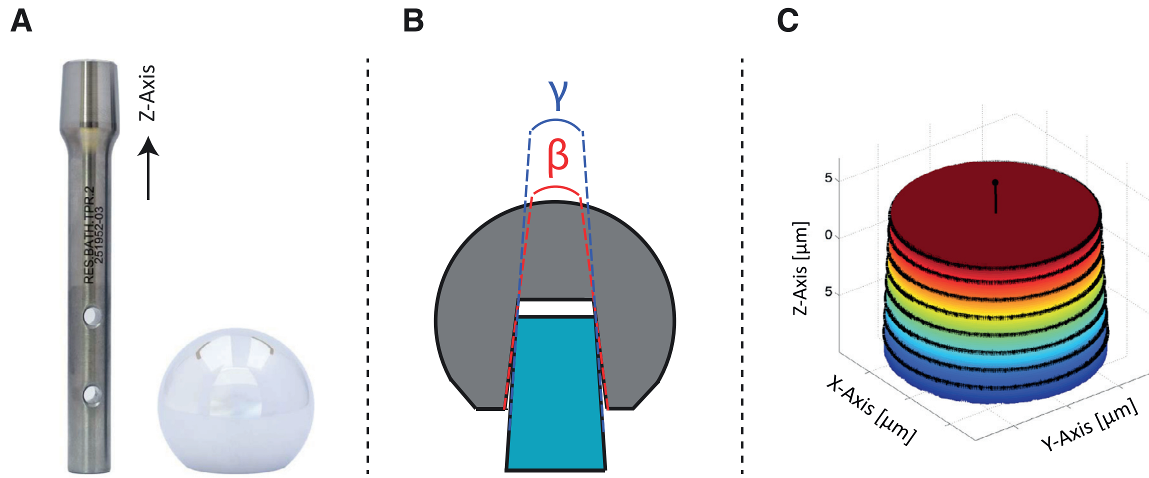

Fig. 1. Custom-made trunnion with a 12/14 taper connection and a 28 mm cobalt-chromium ball head (A); Stem-head taper interface indicating the taper angle of the trunnion (γ) and the ball head (β, B); 3D plot of the stem taper surface based on the measurement with the coordinate measuring machine (C).

corrosion [9,14,16,39] and secondly, to a cascade of adverse local tissue responses [5,13,40] in the form of pseudotumours [18,19,39,15], allergic reactions and middle to high grade tissue damage [11,15]. The material susceptibility to fretting and corrosion seems to be an important factor in the failure mechanism as well. However, no consistent consensus currently exists either for similar or for mixed material couplings [16,25,27,37,38]. Fretting-induced postoperative complications were first reported in significant numbers for large diameter metal-on-metal hip joint articulations [11,41–43] and these device designs appear to negatively enhance taper issues due to higher friction moments at the interface especially in case of low lubrication [44]. Besides fretting-induced complications, an insufficient taper strength caused, for example, by an inadequate intraoperative assembly, may also provoke a loosening of the taper connection [11]. Cases of disassembly of the ball head after dislocation [45,46] or during closed reduction of a dislocated femoral component [47,48] have also been observed in clinical applications.

The current state-of-the-art implies that a firm and permanent fixation of the implant components is critical to minimize postoperative issues [10,16,25,49,50]. Although this fact is well known, explicit guidelines to assemble the implant components are currently rarely available in manufacturer's operative procedure guidelines [51–53]. Moreover, those handling instructions, for example, describing the procedure to assemble a ball head onto a stem taper, are kept very vague [51–53]. It is hypothesised that design-, implantation- and surgeon specific parameters may influence the risk of excessive interface motions and subsequently fretting and corrosion due to inadequate assembly and fixation of these modular implants.

Therefore, the aim of this study was to determine the effect of taper surface roughness and length on the stem-head taper junction strength under typical intraoperative assembly forces.

2. Materials and methods

2.1. Materials, profilometry and assembly

Three groups of titanium custom-made trunnions (Fig. 1A, Ti6Al4V alloy, ASTM F136, in total n = 15, Corin Group PLC, Cirencester, UK) with a 12/14 conical taper connection, different taper lengths and surface finishes were used for mechanical testing (Table 1): smooth, standard tapers (Group 1) vs. grooved, standard tapers (Group 2) vs. grooved, mini tapers (Group 3). The taper length of the mini tapers was approximately 6.5 mm shorter compared to the standard tapers (14.5 mm) while retaining the taper size (maximum cone diameter 14 mm). Prior to the assembly, the taper surfaces were cleaned with ethanol to remove any potential surface contamination and the profile of the stem tapers' outer surface was scanned with a contactless, high-resolution, three-dimensional measurement instrument (ProScan2000 Surface Profilometer, Scantron Industrial Products Ltd, Taunton, UK). Two different surface areas were scanned per test sample with a scan area of 1 mm^2 and a step size of 0.002 mm in both directions each. Based on the scans, the average roughness values Rz and Ra were determined for each trunnion. Additionally, the taper interface of the ball heads and trunnions were helically scanned with a coordinate measuring machine using a ruby stylus for digitisation of the geometry (Incise, Renishaw, Gloucestershire, UK, Fig. 1B and C). The surface profiling was primarily used to determine the taper angles and to estimate the location of the press-fit and the contact area (Fig. 1B and C). The data sets were analyzed using a custom script (MATLAB R2011b; MathWorks, Natick, MA, USA). The centre of mass for each helix was determined allowing the identification of the taper axis that was used as a basis for a subsequent best-fit algorithm. Due to a very robust algorithm, the proximal plane of the trunnions' and the ball heads' plane at the open end, respectively, did not have to be aligned absolutely horizontally during scanning, an angle deviation of up to 3° was acceptable. Based on the outcome of this analysis, the taper angle difference, defined as the angle of the head subtracted by the angle of the trunnion, was calculated (Fig. 1B). The components were then assembled at ambient environmental conditions with a 28 mm cobalt-chromium ball head (LC−CoCr29Mo alloy, ASTM F1537, size L) by an impaction using a previously described custom-made drop-rig [54] to mimic the intraoperative procedure. The drop tower consisted of two vertical sliders guiding a horizontal beam with a drop weight attached (total mass 2.4 kg). The drop weight was capped with a nylon disc to reduce the risk of multiple impactions due to a rebound effect. The drop rig was pre-calibrated in order to identify the relationship between drop height and peak assembly force. Based on the simulated peak assembly force the drop height ranged between 22 mm and around 60 mm. Each trunnion-head pair was consecutively assembled along the taper axis with different peak forces ranging from 2 kN to 6 kN (sequence of assembly: $F_1 = 2$ kN, $F_2 = 2$ kN, $F_3 = 4$ kN, $F_4 = 2$ kN, $F_5 = 6$ kN, $F_6 = 2$ kN, Table 1). The assembly forces were chosen in alignment with typical intraoperative forces [55,56].

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