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The influence of stem taper re-use upon the failure load of ceramic heads

Julian Gührs*, Annika Krull, Florian Witt, Michael M. Morlock

TUHH Hamburg University of Technology, Denickestrasse 15, 21073 Hamburg, Germany

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ABSTRACT

Ceramic components are frequently used in total hip replacement due to their good tribological properties. In revision of broken ceramic heads clinical uncertainties arise, whether the taper of the stem can be re-used with a new ceramic head, especially if the stem is well fixed. Ceramic is a brittle material. Even small damage on the male stem taper can lead to stress concentrations causing premature failure of a new ceramic head. As a consequence, manufactures strictly prohibit stem taper re-use for ceramic heads. The aim of this study was to determine the fracture strength of ceramic heads assembled to re-used male stem tapers, which were subjected to prior head fracture. Five 12/14 Ti6Al4V male tapers and 15 Al_2O_3 ceramic heads (BIOLOX forte®; ∅ 28 mm, L) were used for three consecutive fracture tests. Before and after every fracture test, all components were inspected visually and the surface geometry was analyzed. Mean fracture force (52.5 kN) did not decrease with the number of taper re-uses ($p \geq 0.77$) but the range increased significantly from initially 4.1 kN to 31.8 kN for the first and 52.6 kN for the second re-use due to some components failing at very low loads. Visual inspection was not sufficient to predict the reduced failure loads. Ceramic heads should therefore not be put on used male tapers without metal adapter sleeves.

1. Introduction

The use of ceramic heads in total hip arthroplasty is constantly increasing due to their good wear characteristics, biocompatibility and reduction of fretting corrosion risk [1,2]. They are used especially in young patients and clinical results are very good [3]. However, ceramic is a brittle material and fractures of the components can occur in unfavorable situations. The probability of these fractures is very low (0.004–0.35% for alumina heads) but they do happen [4–11]. The main reasons for head fracture are local stress concentrations caused by taper interface contamination or damage [12] or due to loosening of the head on the taper after insufficient assembly [13]. These reduce the fracture strength greatly, which can cause component fracture during high loads in the patient such as they appear for example during tripping or falling [14]. The development of third generation toughened alumina/zirconia composite ceramics (e.g. ceramys®, BIOLOX delta®) has reduced the fracture risk. A multicenter study with 264 of these new heads with a mean follow up of 31.2 month showed no case of head fracture [15]. Manufacturer data based on all reported head fractures state the fracture risk to be 0.002% [16]. This is a promising situation for the future but many pure alumina ceramic heads of the second generation have been implanted and head fracture could still occur and require revision surgery.

Hip revision is associated with blood loss and risks of infections for the patient and the surgeon tries to limit the intervention to a minimum. After fracture of the head, the fragments have to be removed and the joint space thoroughly cleaned. Some surgeons perform also a synovectomy. The stem is often well-fixed and the male taper visually appears undamaged. Exchanging a well ingrown stem causes major bone damage and blood loss for the patient, as well as a high effort for the surgeon with an elevated risk for long-term secondary revision [17,18]. Ceramic manufacturer's instructions for use (IfU) prohibit the surgeon to re-use a stem taper for a new ceramic head. In order to prevent subsequent ceramic head fracture, as they have been reported [9,19], the surgeon has to either replace the stem or use a metal adapter sleeve. In contrast, other authors find no evidence of increased fracture risk for stem re-use [20]. This makes it difficult for the surgeon to draw a clear conclusion with the available information [21].

Ceramic heads fail in a brittle manner due to their low fracture toughness and lack of ability to deform plastically. In comparison to the fracture toughness of ductile materials such as titanium alloys ($K_{IC} = 44$–66 MPa $\sqrt{m}$), alumina ceramics have about ten times lower fracture toughness ($K_{IC} = 3$–5 MPa $\sqrt{m}$) [22]. Even small damage of the male stem taper may lead to local stress concentrations, causing the loading during daily activities to generate stress which exceeds the ceramic's residual strength. The influence of various contaminants or artificially introduced damage of the taper surface on the fracture strength of ceramic heads has been widely investigated. High correlations between damage and reduced fracture strength

* Corresponding author. Tel.: +49 40428783384; fax: +49 40428782996.
E-mail addresses: j.guehrs@tuhh.de (J. Gührs), annika.krull@tuhh.de (A. Krull), witt@tuhh.de (F. Witt), morlock@tuhh.de (M.M. Morlock).

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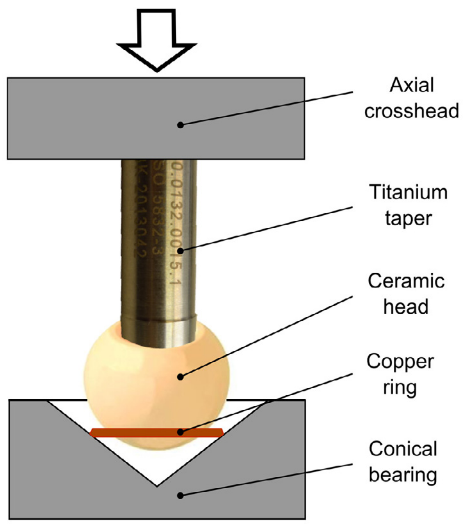

Fig. 1. Testing set-up according to ISO 7206-10. The conical bearing block is fixed and the axial crosshead is centered before testing to prevent transverse forces. The copper ring prevents local stress concentrations.

have been reported [12,23,24]. The aim of this study was to determine the in-vitro fracture load of new ceramic heads paired with re-used tapers that have been subject to prior head fracture and to evaluate related surface damage. This investigation is clinically motivated since stem taper re-usage after ceramic head fracture is still controversial and strong evidence is required.

2. Methods

Five male stem tapers with a ridge profile (12/14, Ti6Al4V, ridge height 12 μm, ridge spacing 210 μm, similar to the taper of the Aesculap Metha® prosthesis) were subjected to multiple fracture tests with Al_2O_3 ceramic heads (BIOLOX forte®; ∅ 28 mm, Neck length L, Ceramtec GmbH, Plochingen, Germany). Target angular mismatch was 0.09° with the male taper angle being greater. Tests were performed on a custom-made axial test rig based on ISO 7206-10 on a Zwick Z400 material testing machine (Zwick GmbH & Co. KG, Ulm, Germany, Fig. 1).

Before every testing, heads and tapers were thoroughly cleaned using alcohol and dried in air before assembly. This corresponds to the clinical practice, even so the step of cleaning the stem taper with alcohol is performed clinically only by very few surgeons. Most surgeons just rinse with water and dry. The heads were placed on the tapers at a marked position to ensure reproducibility of positioning. The components were assembled with an axial preload of 2 kN and afterward loaded until failure with a constant displacement rate of 0.04 mm/s according to the specifications of ISO 7206-10 to allow comparison of the results with the manufacturer's proof testing. The head is positioned centered onto a copper ring placed inside the conical bearing, which is deformed to adapt to the head during preloading to ensure homogeneous load transfer from the bearing into the head, similar as in the physiological situation by the cup. The load condition represented the head assembly condition during surgery and corresponded to the required standardized proof tests for fracture strength carried out by the manufactures. With each of the male tapers, three subsequent fracture tests were performed giving a total number of 15 fractured heads and two re-uses per male taper (Fig. 2). The maximum force at the point of fracture was evaluated. Statistical analysis was performed with a type I error probability of $\alpha = 0.05$ (IBM SPSS Statistics 21, IBM Corporation, Armonk, NY, USA).

Geometry measurements including the taper angle of the taper surfaces (male and female taper) were acquired before and after each fracture test using a tactile coordinate measuring device (BHN805, Mitutoyo Deutschland GmbH, Neuss, Germany; machine accuracy <3 μm). Scanning was performed with a 2 mm diameter ruby tip

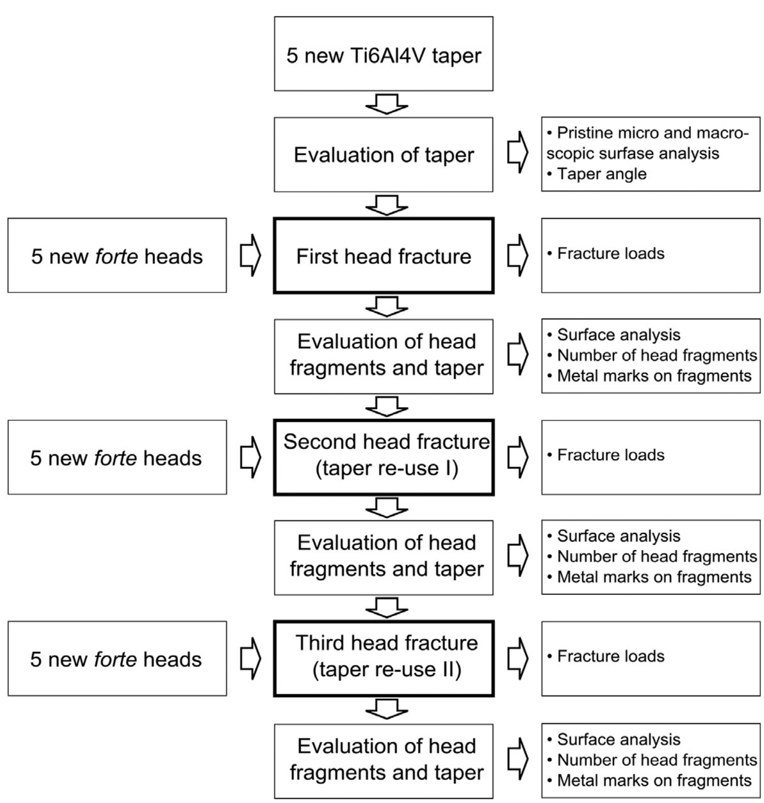

Fig. 2. Flow chart of the testing procedure.