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Influence of the compliance of a patient's body on the head taper fixation strength of modular hip implants

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ABSTRACT

Background: The strength of the modular fixation between head and stem taper of total hip replacement implants should be sufficient to minimise relative motion and prevent corrosion at the interface. Intraoperatively the components are assembled by impaction with a hammer. It is unclear whether the effective compliance of the patient's body modifies the strength of the taper interface under impaction assembly. The purpose of this study was to assess the influence of the compliance of the patient's body on the taper fixation strength.
Methods: Cobalt-chrome and ceramic femoral heads were assembled with titanium alloy stem tapers in the laboratory under impaction. Impaction forces were applied with a constant energy, defined by the drop height of the impactor, according to standard experimental procedure. The compliance of the patient was simulated in the laboratory by varying the stiffness of springs mounted below the stem taper. Pull-off forces between head and neck were measured to determine fixation strength.
Findings: Decreasing spring stiffness had no effect on the applied peak impaction forces during assembly or on the pull-off forces. Pull-off forces showed no difference between metal and ceramic head materials.
Interpretation: Pull-off forces and impaction forces were independent of the spring stiffness below the stem taper, indicating that the compliance of the patient has no effect on the taper fixation strength. Impaction testing in the laboratory can therefore be performed under rigid fixation, without accounting for the compliance of the patient.

1. Introduction

Modular connections in hip replacement components allow biomechanical adjustment at primary surgery, and enable replacement of the femoral head at revision (Donaldson et al., 2014). Despite these clinical advantages, attention has recently focused on fretting and crevice corrosion at the taper interfaces between components, due to the observed biological reactions to metallic debris or even component fractures (Collier et al., 1992; Cooper et al., 2012; Cooper et al., 2013; Gilbert et al., 1993). Tapered modular connections function by generating a radial press fit, providing friction resistance to relative motion (Jauch et al., 2013). The taper geometry, materials and intraoperative assembly technique influence the stability of the interface. In particular, fixation strength is directly related to the assembly force (McGrory and McKenney, 2016; Osman et al., 2016).

The modular head is assembled intraoperatively by application of hammer blows to the head via a hand-held impactor tool. The stem is anchored in the femur, which is separated from the surgical table by the soft tissues. The proportion of the force applied to seat the head on the stem may be reduced if the implant-leg mass accelerates easily in the direction of the applied force, providing reduced reaction to the applied force. A more compliant patient could thereby reduce the effective seating force during head assembly.

The representation of the intraoperative assembly process in the laboratory has not been clearly established. Assembly in the laboratory has mostly involved rigidly fixed stem components (English et al., 2016; Frisch et al., 2016; Heiney et al., 2009; Rehmer et al., 2012). This might be a distortion of the clinical situation and result in a non-representative fixation strength. Although the ASTM-standard acknowledges this possibility, no provision for any particular representation of the compliance of the patient's body is prescribed (American Association for Testing and Materials; ASTM F2009, 2011). Impaction is prescribed by dropping a 907 g mass from 254 mm height, resulting in an impaction kinetic energy of 2.26 J (ASTM F2009, 2011).

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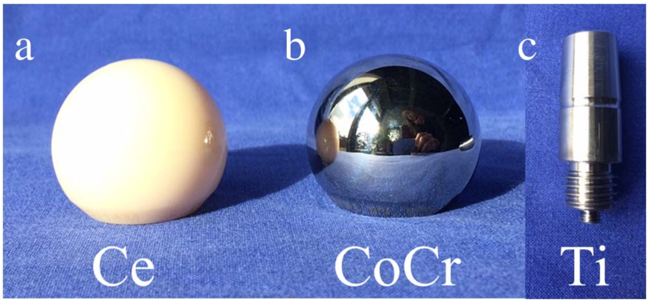

Fig. 1. Components used in laboratory testing: a) Ø 32 mm femoral head, BIOLOX®forte ceramic, CeramTec GmbH, Germany; b) Ø 32 mm femoral head, ISODUR®-F cobalt-chrome, Aesculap AG, Germany; c) 12/14 replica stem taper, Metha®, titanium, Aesculap AG, Germany.

The purpose of this study was to investigate the influence of the compliance of a patient's body on the taper fixation strength for ceramic and metal heads assembled by impaction to test the hypothesis that a more compliant body will reduce the taper fixation strength for a given impaction.

2. Methods

Ceramic femoral heads (BIOLOX®forte, Al_2O_3 'Ce', diameter 32 mm, 12/14 taper, Ceramtec GmbH, Plochingen, Germany; 20 pieces) and cobalt-chrome femoral heads (Isodur®-F, CoCr29Mo 'CoCr', diameter 32 mm, 12/14 taper, size M, Aesculap AG, Tuttlingen, Germany; 20 pieces) were implanted onto pristine titanium alloy stem tapers (Aesculap Metha®, Ti_6Al_4V 'Ti', 12/14 taper, Aesculap AG, Tuttlingen, Germany; 40 pieces). For better anchorage one end of the taper was threaded (Fig. 1).

The compliance of the patient's body was represented by springs with varying stiffness mounted below the stem taper. The mass of the movable (sprung) components was approximately 500 g (this was the lowest mass practically possible, with the aim of minimizing the effective patient inertia and thus maximizing the potential influence of the base plate stiffness). Three support stiffnesses were tested under impaction for each head material: 'soft' (0.5 N/mm, $n = 5$), 'hard' (5.0 N/mm, $n = 5$) and 'rigid' (metal tubes, $n = 5$) (Fig. 2).

Components were assembled by dropping a surgical metal mallet (Model 225010000, DePuy Synthes, England), (1 kg) on a lever arm (1 m) from a defined height onto a surgical impactor shaft (Fig. 2 a). The lower end of the impactor was instrumented with a piezoelectric impulse sensor (capacity 22 kN, Model 208C05, PCB Piezotronic Inc., Depew, NY, USA), located directly adjacent to the 15 mm thick plastic tip with a shallow concave face locating on the head. A low friction polyethylene bearing allowed the impactor shaft to rest vertically on the femoral head without manual support (Fig. 2 a).

Assembly was performed by application of a single impact to the head via the impactor, with a hammer energy of 2.26 J, resulting in a peak assembly force of approximately 4 kN, which was measured with the impulse sensor in the impactor tip. This assembly force was similar to magnitudes measured intraoperatively and applied in laboratory studies (Heiney et al., 2009; Lavernia et al., 2009; Nassutt et al., 2006; Rehmer et al., 2012).

Directly prior to assembly, the stem and head taper surfaces were wiped with acetone and allowed to dry. Prior to impaction the head was placed lightly onto the stem taper and rotated clockwise by 360°.

The axial disassembly force was measured by quasi-statically pulling off the head from the stem taper using a material testing machine (capacity 10 kN, Zwick/Roell Z010, Zwick GmbH & Co. KG, Ulm, Germany), at a rate of 0.008 mm/s, according to ISO 7206-10 and ASTM F2009, 2011. A custom grip was employed, with two hooks engaging on the flat face of the head, and an x-y table to ensure axial loading (Fig. 2 b). The peak disassembly force was recorded.

The influence of different stiffness conditions on the relation between assembly and pull-off force was analyzed using the quotient POAF (Pull-off force divided by assembly force).

Assembly forces and pull-off forces were compared statistically between groups using parametric analysis (two-way-analysis of variance) or non-parametric analysis (Kruskal-Wallis) with the probability of a Type I error set to $\alpha = 0.05$ (SPSS Statistics 21, IBM Corporation, Armonk, NY, USA). Group sample size was $n = 5$. Power analyses were performed to determine the probability of a type II error. All results are reported as mean (standard deviation (SD)).

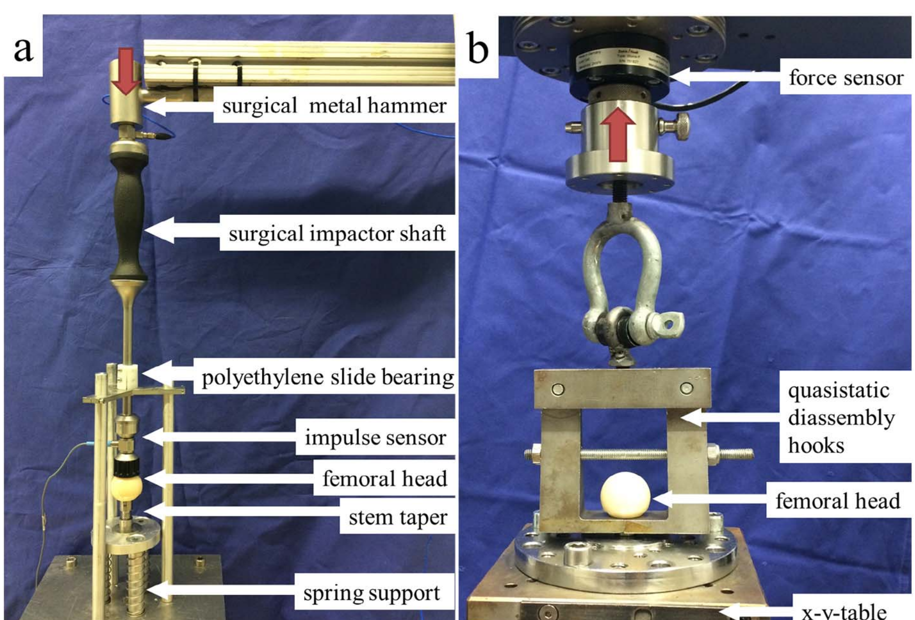

Fig. 2. a) Impaction assembly setup in the laboratory with the drop hammer and the impulse sensor incorporated into the impactor shaft. Note that the impulse sensor on the hammer was not used in the current study; b) Setup for quasi-static disassembly of the femoral head from the stem taper, according to ISO 7206-10 and ASTM F2009, 2011.