Does the Surface Finish, the Taper Angle Difference and the Assembly Force Effect the Taper Strength Between Stem and Ball Head of a Modular Hip Implant?

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Introduction: Modular hip prostheses are commonly used in total hip replacement operations. The taper connection between stem and ball head gives surgeons the ability to intraoperatorically adapt the prosthesis to the patient’s hip joint anatomy. Despite a multitude of advantages modular assemblies bear the risk of micromotions between the adjacent components that may lead to fretting, wear and corrosion and can limit the lifetime of hip implants as observed in clinical applications. This issue seems to be more relevant for large diameter metal - on - metal bearings since the negative effects might be enhanced due to the higher frictional moments in the interface especially in the case of low lubrication [1]. Although clinical problems are documented, no explicit instruction guidelines to assemble the implant components are currently available. In addition to specific assembly parameters, design specific ones can also influence the local contact situation in taper interfaces. The purpose of this study was to identify the effect of the assembly force, the surface finish and the angular taper difference on the taper junction strength between stem and ball head of a modular hip implant.

Methods: Ten titanium custom - made trunnions (Corin Group PLC, Cirencester, UK) with a 12/14 conical taper connection were assembled with 28 mm cobalt - chromium ball heads (size L) by impaction using a drop - rig. Half of the stem tapers offered a smooth surface finish (Rₐ = 2.92 µm) and the others a grooved one (Rₐ = 3.77 µm). Prior to assembly, the taper interface of the ball heads and the stem tapers were helically scanned with a coordinate measuring machine (Incise, Renishaw, Gloucestershire, UK). Based on the scans, the taper angle difference, defined as the angle of the head subtracted by the angle of the stem taper, was calculated. The implant components were consecutively assembled with different peak forces ranging from 2 kN to 6 kN (F₁ = 2 kN, F₂ = 2 kN, F₃ = 4 kN, F₄ = 2 kN, F₅ = 6 kN, F₆ = 2 kN). After each assembly process they were disassembled with a materials testing machine (Series 3300, Instron, Norwood, MA, USA) to detect the pull - off force as an indicator for the taper strength. According to ISO 7206 - 10: 2003 the pull - off tests were performed at a stroke rate of 0.008 mm/ s. In order to ensure that the pull - off forces were not influenced by the consecutive test protocol, the results of all of the 2 kN tests were statistically compared. The average pull - off force for each sample at a load level of 2 kN (F₁, F₂, F₃, F₄) was calculated and then used for the following analyses to keep the sample size for the assembly load levels constant (n = 10). For statistical analyses non - parametric and parametric tests with a type - I - error probability of α = 0.05 were performed (SPSS Statistics 20, Munich, Germany).

Results: Consecutive testing of the implant components did not influence the pull - off forces at the stem - head interface (smooth: 602.7 ± 104.2 N, p = 0.829, grooved: 496.7 ± 78.8 N, p = 0.216, Kruskal - Wallis - Test). For both surface modifications, the pull - off force increased with rising peak assembly force (2 kN: 549.6 ± 84.6 N vs. 4 kN: 954.0 ± 101.4 N vs. 6 kN: 1,435.6 ± 144.7 N, p < 0.001, Twoway - ANOVA, Fig. 1). For assembly forces of 4 kN or less, stem tapers with a smooth surface finish offered significantly higher pull - off forces compared to those with a grooved surface (820.2 ± 238.6 N vs. 683.5 ± 202.4 N, p < 0.001, Twoway - ANOVA, Fig. 1). Following a 6 kN impaction, no influence of the surface finish on the pull - off force was detected (p = 0.426, Oneway - ANOVA, Fig. 1). The taper angles of the stems were on average 5.2 ± 1.7 % smaller than those of the ball heads. Both, for low and high assembly forces no correlation between the taper angle difference and the pull - off force could be found (0.143 ≤ p ≤ 0.695, ANCOVA).

Discussion: This study showed a positive correlation between assembly force and taper strength. This implies that higher assembly forces may decrease the micromotions in the interface and ultimately the probability of postoperative complications due to fretting and wear. In the case of small assembly forces (≤ 4 kN) prostheses of the tested design with a grooved surface finish exhibited a lower taper strength than smooth ones. Higher forces might initiate small local plastic deformations of the grooves at the rougher tapers leading to an improved contact situation compared to lower assembly forces. The taper angle differences indicate that the deadlock is located by a small stripe on the circumference at the closed end of the taper.
connection. However, the effect of the location of the press-fit is currently not clearly understood. Based on the results of this study, it could be speculated that smooth tapers are more appropriate to use in taper connections of modular hip implants with metal heads in the future. They seem to offer a higher taper strength than grooved ones with most likely a reduced risk of fretting related complications of the implant especially in the most common range of intraoperative assembly forces (90% below 6 kN [2]).

**Significance:** The presented study identifies important parameters affecting the taper strength at the stem-head interface of modular hip implants. The taper strength may be directly correlated to micromotions at the interface, which can initiate, in a worst-case scenario, fretting-induced postoperative complications as observed clinically.

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[2] Nassutt R et al., Relevance of the insertion force for the taper lock reliability of a hip stem and a ceramic femoral head,