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Influence of Assembly Force and Distraction on the Femoral Head-Taper Junction

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ABSTRACT

Background: This study investigates if the placement of femoral heads (trials and actual implants) using varying impaction forces causes physical compromise to the trunnion.
Methods: Trunnion and head taper wear patterns were evaluated after impaction and removal of new femoral stem trunnions and ceramic heads at various impaction loads (2 kN, 4 kN, or 6 kN, n = 6/group). In addition, trunnion wear patterns were measured after plastic trials were hand-placed on new trunnions and underwent range of motion testing in a Hip Simulator (n = 5).
Results: There was no significant difference in trunnion or head surface deviation, taper angle, or surface roughness in any groups preimpaction and postimpaction and removal. There was no significant surface trunnion damage from assembly and range of motion testing of the plastic femoral head trial.
Conclusions: The use of femoral head trials and the concurrent impaction and removal of a new femoral head were not associated with significant trunnion surface damage for the impaction loads observed in this study.

Modular femoral components are the standard in modern total hip arthroplasty (THA). Modularity allows benefits to the surgeon in fine-tuning of limb length, offset, and in some cases, femoral anteversion. However, modularity has also introduced new clinical problems and mechanical complications. A number of clinical retrieval studies and clinical case series have identified an unexpected level of corrosion at the taper-trunnion junction [1–5]. This corrosion can lead to clinically significant adverse local tissue reactions (ALTRs), which can result in pain and instability, leading to revision surgery [5–7].

There are a number of variables that affect corrosion, stress, and ultimate wear of the femoral head-taper junction. Large-diameter femoral heads, certain trunnion geometry, flexural rigidity of the neck, longer neck lengths, increased head offset, and inadequate mating have all been associated with tribocorrosion in the literature [1,2,8,9]. In addition, there are theoretical risks that damage to the trunnion can cause mechanically assisted crevice corrosion and increase the likelihood for an ALTR. Owing to this potential increased risk of tribocorrosion with trunnion damage, surgeons take certain steps to ensure a clean head-neck interface. Indeed, a titanium taper sleeve is often used in the setting of placing a new ceramic head on a used trunnion surface to avoid this tribocorrosion risk, as well as the risk of head fracture [10–12].

In THA, the femoral head is impacted onto the femoral stem during surgery and in certain scenarios, may need to be removed from the trunnion and replaced. The effect of these forces of impaction and distraction on the trunnion is not known. In addition, before final implant head placement, a trial head is placed on the trunnion and tested through a range of motion of the hip. The effect of femoral head trialing, impaction, and removal on the trunnion is not well understood, and it is not clear whether similar precautions, such as the taper sleeve, should be utilized [4].

The purpose of this biomechanical study is to investigate the potential physical changes in the trunnion caused by the placement

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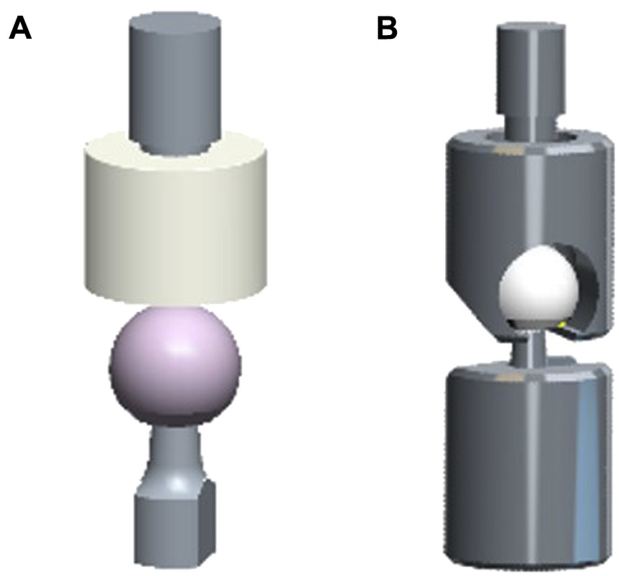

Fig. 1. Images showing the impaction (A) and distraction (B) set ups. Impaction was performed using an MTS Bionix 858 Servo Hydraulic Test Frame, and distraction was performed using an Instron 5582.

and removal of femoral head trials and actual implants using varying impaction forces.

Materials and Methods

In the first stage of testing, 5 femoral head trials and 5 new trunnions (Stryker 5 deg 40 sec Ti6Al4V) were obtained. The femoral head trials were placed by hand onto the trunnions to simulate the clinical scenario. The paired heads and trunnions were then assembled on a hip simulator (MTS Hip Simulator, MN) according to anatomical positioning, where testing was conducted with the acetabular liner stationary and mounted in a superior position oriented at 0°. The entire assembly was then placed on a 23° incline block to provide flexion-extension, abduction-adduction, and rotational motion. The load was held constant at 20 lbs for 2 rotations at a frequency of 0.5 Hz (30 rpm), and femoral heads were then removed by hand. Load and rotation were intended to replicate in vivo head trialing.

In the second stage of testing, 18 new ceramic femoral heads (Stryker Biolox Delta, 32 mm) and 18 new trunnions (Stryker Ti6Al4V) were obtained. The implants were divided into 3 groups, based on varying impaction load of 2 kN, 4 kN, and 6 kN (n = 6 samples per impaction load). These impaction loads are consistent with previously described loads, with literature reporting 2 kN as a "light blow," and 4 kN as a "firm blow" [13–17]. The 6 kN condition, therefore, represents a degree of force beyond those usually seen in clinical scenarios. Impaction of the femoral heads was performed using a hydraulic test frame (MTS Bionix 858 Serve Hydraulic Test Frame) at the desired impaction loads (Fig. 1A). Following impaction, distraction of the femoral heads was performed in accordance with ISO 7206-10, and the resultant forces were measured (Instron 5582) (Fig. 1B). Each femoral head was impacted and distracted once, and no implants were reused for further testing.

The female taper of the ceramic femoral heads and the stem trunnions were inspected using a coordinate measurement machine (CMM, Wenzel LH87 CMM) to calculate taper angle and surface deviation. The surface deviation was calculated as the deviation from the average cone shape. The trunnion surfaces were also analyzed using white-light interferometry (Zygo NewView 6000 3D Optical Profiling System), to measure average surface roughness. Three points were taken from each quadrant of the male taper (12 points total), and a 20× objective magnification lens with cylindrical surface removal was utilized for characterization of the surfaces. In addition, analysis of the trunnion surface form deviation, and thus the greatest deviation of the actual surface from the nominal surface (a perfect cone) was performed using Geomagic Qualify 2012.

Initial power analysis demonstrated that a minimum of 3 samples per group would provide adequate power to identify a difference in femoral head pull-off force, using a $\beta = 0.8$ and $P < .05$, similar to protocols in prior studies [18,19]. To maximize study power, we utilized 6 samples per group. Post hoc analysis revealed that this sample size had 95% power to detect a difference in taper angle of 0.01° and difference in surface deviation of 0.005 mm, below the 0.02° and 0.0.1 mm described as clinically relevant in previous studies [20,21]. Statistical calculations were performed using a Student's t test with statistical significance set at $P < .05$.

Results

Average Distraction Force per Assembly Condition (kN)

Distraction force increased with impaction load. The distraction forces necessary to extract the heads significantly increased in a progressive manner among the 2 kN (1.5 kN extraction force), 4 kN, (2.7 kN) and 6 kN (3.7 kN) groups ($P < .05$).

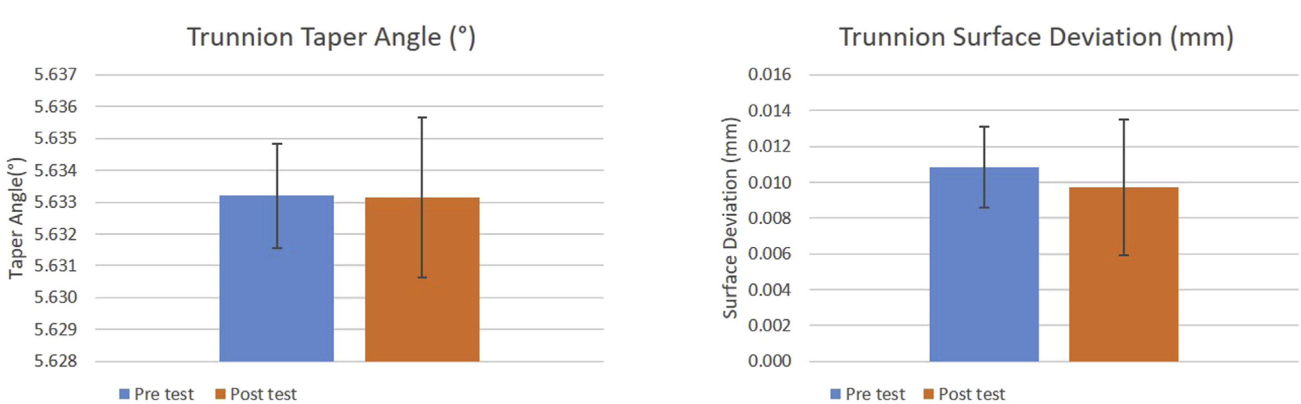

Fig. 2. Effect of femoral head trialing on trunnion taper angle and surface deviation. There was no significant difference in either category before and after testing.