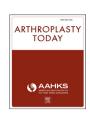
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Original research

The stability of dual-taper modular hip implants: a biomechanical analysis examining the effect of impact location on component stability

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ABSTRACT

Background: The purpose of this study was to investigate the stability of dual-taper modular implants following impaction forces delivered at varying locations as measured by the distraction forces required to disassemble the components.

Methods: Distraction of the head-neck and neck-stem (NS) tapers of dual-taper modular implants with 0° , 8° , and 15° neck angles were measured utilizing a custom-made distraction fixture attached to a servohydraulic materials test machine. Distraction was measured after hand pressing the components as well as following a simulated firm hammer blow impaction. Impacts to the 0° , 8° , 15° necks were directed axially in line with the neck, 10° anterior, and 10° proximal to the axis of the neck, respectively. Results: Impaction increased the range of NS component distraction forces when compared to hand pressed components (1125-1743 N vs 248-302 N, respectively). Off-axis impacts resulted in significantly reduced mean ($\pm95\%$ confidence interval) distraction forces (8° neck, 1125 ± 117 N; 15° neck, 1212 ± 73 N), which were up to 35% lower than the mean distraction force for axial impacts to the 0° neck (1743 ± 138 N)

Conclusions: Direction of impaction influences stability of the modular interface. The greatest stability was achieved with impaction directed in line with the longitudinal axis of the taper junction. Off-axis impaction of the 8° and 15° neck led to significantly reduced stability at the NS. Improving stability of dual-taper modular hip prostheses with appropriately directed impaction may help to minimize micromotion, component settling, fretting corrosion, and subsequent failure.

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Introduction

Modularity in total hip arthroplasty has offered many benefits including the versatility to fine tune offset, leg length, and version, while also reducing the necessary inventory and cost of the arthroplasty [1–3]. However, each additional modular interface

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introduces a source for wear particle generation with particulate quantities possibly exceeding that generated at the articular articulate surface [4-6]. While several theories exist as to etiologies of wear-particle generation and subsequent corrosion at the modular interface, research suggests that the process begins with mechanical fretting and disruption of the protective oxide layer leading to the release of metal ions at the taper interface [7,8]. Both the debris and corrosion at the modular surface can have a multitude of effects on the outcome of the prosthesis including osteolysis, adverse local tissue reactions, increased risk of neck failure or fracture, and increased distraction force requirements at revision surgery [9]. It has been postulated that the process of fretting may begin at impaction of the components at index surgery [4], thus indicating the importance of proper engagement and stability of the components to prevent micromotion and subsequent fretting corrosion.

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Proper seating of components may help reduce micromotion between the 2 components and increase the load required to initiate fretting [8]. For impacts applied in line with the head and neck taper junctions of the 0° neck, previous research has shown that the stability of the modular taper is determined by the force of impaction, which is directly proportional to the force required to distract the components in this ideal scenario [3]. However, the ability to direct an ideal impaction along the axis of the mating components is exacerbated by implant neck angulation. Prior work in our laboratory has shown significant changes in the impact forces transmitted to the taper junctions for various impact locations and neck angles [10]. Under similar impact conditions (same mass and drop height), the resultant impact force and force measured at the head neck (HN) or neck stem (NS) were affected by the configuration of impact location and neck angle.

In the context of assembling modular hip implants, prior studies have not accounted for the effects of impact location and neck angle on the stability at the modular interface [3,11]. The purpose of the present study was to investigate the effect that impact location has on subsequent stability of both the head-neck (HN) and neck-stem (NS) taper junctions. A secondary objective was to evaluate hand-assembled taper junction stability because weight-bearing taper engagement, subsequent to unimpacted hand assembly of the implant, is an optional surgical procedure.

Material and methods

Modular implants (Wright Medical Technologies, Inc., Arlington, TN) consisted of the stem, neck, and head. Size 9, 139-mm medial length stems, and 32-mm heads were used with long necks having the following 3 orientations: 0° (straight), 8° anterior (A/R), and 15° anterior. Three implants were constructed utilizing each of the 3 different neck angulations, for a total of 9 implants. Each implant was hand assembled then distracted, reassembled by hand, and distracted a second time to obtain the stability measurements (n=6) for nonimpacted implants. Next, each implant was hand assembled, underwent a predefined impact based on the neck angle (described in the following section). Implants were then distracted, reassembled, and impacted again and distracted a second time to obtain the stability measurements (n=6).

Modular hip impact and distraction experiments were conducted to determine the effect that impact location and neck angle has on taper junction stability. Impact configurations were chosen

based on previous research, which showed the impact force delivered to a 0° neck was greater than an off-axis impacted 8° neck but less than an off-axis impacted 15° neck [10]. Thus, a low to high range of impact forces were expected to provide a range of implant stabilities. Distraction experiments were conducted on both hand-assembled and impacted implants. Distraction of hand-assembled implants was performed first to establish a baseline stability. HN and NS taper junctions were both distracted to determine the stability of each.

Hand assembly consisted of inserting the neck into the stem, applying firm pressure to engage the NS taper, then seating the head on the neck, and again applying firm pressure to engage the HN taper. For the impacts, each implant was hand assembled, as mentioned previously, then loaded into a custom-built fixture secured in an impact drop tower (Fig. 1). A drop mass impactor was used to simulate a surgeon's firm mallet blow, estimated at 4000 N [11]. That impact load was calibrated to a height of 203 mm above the implant contact point of the axially aligned 0° neck, a height that was consistent across the 8° and 15° neck impacts. For all impact tests, the impactor was raised to the calibrated height, held suspended by a magnetic clamp (MagJig 60, MagSwitch Technology, Inc., Lafayette, CO), then released. The impactor body was a steel mass (700 g), which allowed attachment of a load cell (Model 1051V6, Dytran Instruments, Inc., Chatsworth, CA) to record the impact forces. A Duralon load cell housing covered the load cell, preventing sensor ringing from metal-to-metal impacts. The implants were positioned such that the 0° neck received an axial impact, the 8° neck received a 10° anteriorly off-axis impact (ie. the impact point of contact was anterior to the neck axis), and the 15° neck received a 10° proximally off-axis impact (ie, the impact point of contact was proximal to the neck axis; Fig. 2). Implant positions were adjusted to the desired impact location, clamped in place in the base fixture, and adjusted in the x-y direction to center the head under the impactor.

After hand pressing or impacting the implant, it was loaded into a custom-built distraction fixture to first distract the NS taper junction and then the HN taper junction (Fig. 3). The fixtures were connected to a servohydraulic materials test machine (Model 8501, Instron Corp., Norwood, MA) and pulled apart at a displacement rate of 0.1 mm/s. Distraction force was measured by a load cell (Catalog Number 2518-600, Instron Corp) and recorded on a personal computer. Impact and distraction forces were compared to assess taper joint stability with the ideal axially impacted 0° neck.

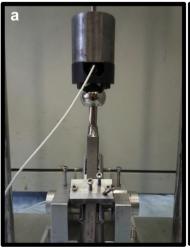






Figure 1. Implants positioned in the drop tower of the impactor. Zero degree neck (a), 8° neck (b), and 15° neck (c).

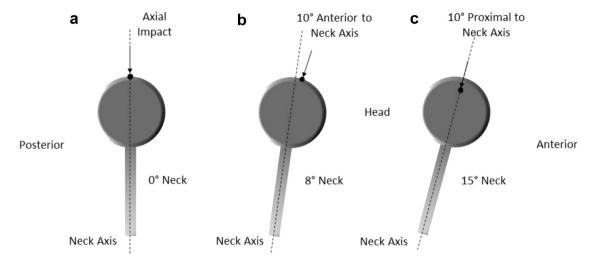


Figure 2. Schematic diagram depicting the impact locations on the implant head of the 0° (a), 8° (b), and 15° neck (c). Posterior side of the implant is to the left, anterior is to the right, and proximal is out of the plane of the page.

Both the HN and NS junction stabilities were analyzed. All comparisons used analysis of variance tests with the level of significance set to $\alpha=0.05$.

Results

Modular implants were hand pressed or impacted with distraction forces measured to determine the stability of the HN and NS taper junctions. Results for the distraction forces for the hand-assembled and impacted implants are shown in Figures 4 and 5, respectively. Hand-pressed assembly of the implants resulted in distraction forces of 95 \pm 43 N (mean \pm 95% confidence interval), 118 \pm 43 N, and 161 \pm 32 N for the HN junction of the 0°, 8°, and 15° necks, respectively (Fig. 4). The distraction forces were greater (P < .0001) in the NS junction with forces of 302 \pm 65 N, 250 \pm 78 N, and 248 \pm 65 N for the 0°, 8°,

and 15° necks, respectively. There were no differences in the distraction forces among the 3 neck angulations for either the HN (P = .0934) or NS (P = .4871) junctions.

Impacted implants had NS distraction forces that were between 3 and 5 times greater than the NS distraction forces observed in the hand-pressed assembly of implant components. Those distraction forces for the impacted implants were on the order of 1500 N while those for the hand pressed were on the order of 300 N.

Implant stability as determined by the distraction force was virtually unchanged between the HN and NS junctions for the impacted implants of the 8° and 15° necks (Fig. 5). The distraction forces for the 8° neck were 1096 ± 160 N at the HN and 1125 ± 117 N at the NS while the distraction forces for the 15° neck were 1222 ± 98 N at the HN and 1212 ± 73 N at the NS. In the 0° neck, the NS and HN distraction forces were 1743 ± 138 N and 1329 ± 226 N,

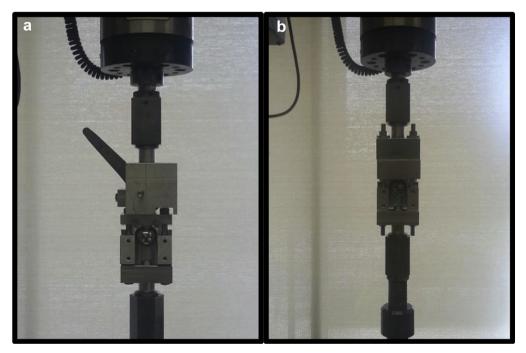


Figure 3. Distraction test setup. Neck-stem distraction (a). Head-neck distraction (b).

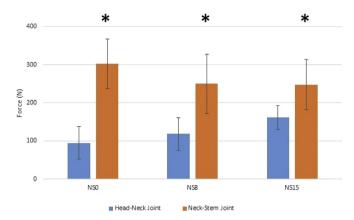


Figure 4. Hand-assembled implant mean distraction forces for the head-neck and neck-stem junctions in the 0° (N0), 8° (N8), and 15° (N15) necks. Error bars represent $\pm 95\%$ confidence intervals. *Neck-stem taper junctions significantly greater than their head-neck junction counterparts.

respectively. None of the NS forces were significantly different than the HN forces (P=.0881). No significant differences in HN distraction force were found between the 3 neck angulations (P=.1815). However, distraction force differences were found between the 3 neck angulations for the NS junction. The NS distraction force of the 0° neck was significantly greater than both the 8° (P<.0001) and 15° (P<.0001) necks. After the series of hand-assembled tests, each implant was impacted and distracted twice. From the first to second series of experiments, there were no consistent patterns of increasing or decreasing distraction force among the neck configurations. Nonsignificant (P>.05) differences of 253 N, 15 N, and 31 N were observed in the 0° , 8° , and 15° necks, respectively.

Impact forces delivered to the implants were calibrated to a height chosen to impart a firm hammer blow (4000 N) for an axially aligned impact to the 0° neck. The results of the recorded impact forces are shown in Figure 6. The results show that a firm hammer blow varies with the combination of impact location and implant neck angulation. The 0° neck mean impact force was 3553 ± 386 N. While this was not significantly higher than the impact force of 3119 ± 234 N applied to the 8° neck (P = .1660), the impact forces to these 2 neck angulations were both significantly lower than the 15° neck, with a resultant impact force of 4756 ± 296 N (P < .0001).

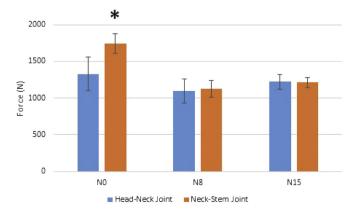


Figure 5. Impacted implant mean distraction forces for the head-neck and neck-stem junctions in the 0° (N0), 8° (N8), and 15° (N15) necks. Error bars represent $\pm 95\%$ confidence intervals. *0° neck neck-stem taper junction significantly greater than the 8° and 15° neck neck-stem junctions.

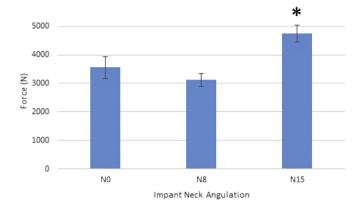


Figure 6. Impact force delivered to the head of the 0° (N0), 8° (N8), and 15° (N15) necks. *Impact force to the 15° necks was significantly greater than the 0° and 8° necks.

Discussion

The purpose of this study was to evaluate the stability of dual-taper modular hip prostheses as measured by the distraction force following impaction as well as manual insertion of components. Hand-assembled implant stabilities were not different among the neck angulations at either the NS or HN taper junction, yet the stability of the NS taper junction was greater than the HN junction. Impacted implant NS distraction forces were 3-5 times larger than the same hand-assembled junction. Unlike the hand-assembled implants, differences between the NS and HN junctions were not observed for impacted implants. Although, there was a nonsignificant increase in the NS taper junction distraction force of the 0° neck compared to its HN junction. Among the impacted implants, the distraction force at the NS junction in the 0° neck was greater than those in the 8° and 15° necks and was the only observable difference.

Stability differences between hand-assembled taper junctions can be explained by the assembly process. Necks were pressed into the stems and then compressed a second time when the heads were pressed onto the necks. This produced a 1.7 to 3.0 times increase in the NS taper junction. Impacting the implants produced a further 3-5 times increase for both HN and NS junctions, with distraction forces that ranged from $1096 \pm 160 \text{ N}$ to $1743 \pm 138 \text{ N}$.

Contrary to previous studies showing a linearly proportional relationship between the force of impaction and force required to distract components [3], the results of this study showed that this relationship is influenced by neck angle and impact location. Trigonometric decomposition of force vectors suggest that 95% of the impact force would be delivered to the 15° NS taper and 97.5% would be delivered to the 8° NS junction. However, the impact results of this and previous work have shown an increase in the impact force delivered to the 15° NS taper [10]. Based on the reported impact forces, this should result in the 15° NS taper junction having the largest distraction force, even greater than the axially impacted 0° neck.

Despite the significantly increased impact force to the 15° neck, it did not translate to a higher degree of stability measured by the distraction force. The reason for the differences in impact force results may arise from the neck configurations affecting the energywork relationship, where the force of impact is inversely proportional to deformation of the construct, the low-impact forces of the 8° neck may be caused by the degree of construct deformation from a torsional displacement of the implant components. The results of which may produce the lower impact force but still allowed engagement of the NS taper junction. In the preceding case, the

direction of the applied force was such that a moment would be produced about the long axis of the stem. On the other hand, the disparity in impact and distraction forces for the 15° neck may result from component binding, which prevented taper engagement displacements and produced a stiffer implant construct with increased resultant impact forces. In this case, the direction of the applied force would increase the moment at the NS junction.

Understanding the extent to which implant angulation and impact location can alter the stability of the implant is of significant clinical importance. When an implant is impacted off axis on an angled neck, we can see that more work is needed to better predict how distraction force will be affected. Simply impacting the implant with greater force does not translate across the spectrum of implant configurations. In these experiments, the 15° neck had a significantly increased impact force but saw a significant reduction in stability versus an axial impact to the 0° neck. These results highlight the importance of taking into consideration both the direction as well as the magnitude of the impaction force to allow proper seating of components.

While direction of impaction proved to be significant for the NS taper, the stability of the HN tapers did not differ among the varying NS configurations as it related to the direction of impaction. This can be explained by the fact that the angle of impaction used in this study was in reference to the HN interface. Thus, the magnitude of the off-axis impaction is magnified in the angled necks such that a 10° anterior impact for an 8° neck would in fact be 18° anterior to the NS interface. A 10° proximal impact of the 15° neck would result in a combined 10° proximal and 15° anterior impaction seen at the NS interface. These results may suggest that so long as the impaction is directed is within 10° of the taper axis, there is minimal clinical significance in taper stability, whereas a combined angle of impaction outside a 10° radius results in decreased stability at the modular junction.

Clinically, retrieval analysis of dual-taper implants at the time of revision revealed maximal corrosion at the medial and lateral sides of the distal NS taper [12], which correlates with the point of maximal micromotion [5]. Cyclic loading and subsequent micromotion lead to the corrosion and fretting patterns observed in this location of retrieved specimens at time of revision [12]. However, proper initial seating of components at index procedure may help minimize subsequent micromotion and fretting. In vitro corrosion experiments have shown that impaction assembly better resisted fretting than hand-assembled components [13], and impaction has been shown to increase implant stability [11,14]. Stability is therefore an influential factor in preventing micromotion and resisting corrosion. This study illustrates how stability is influenced during assembly, which may play a significant role in the subsequent development of modular interface corrosion.

Modular hip implant assembly technique has varied with respect to impacting the assembly before reduction or leaving the assembly hand pressed and allowing body weight to stabilize the implant. Several studies have shown that implant stability is increased with impaction of the implant before reduction [11,14]. Explanation of this finding might be derived from the results of the present study. The rationale for hand assembly and no impaction was predicated on the idea that patient body weight would compress and seat the modular hip implant components. Allowing the components to be compacted in vivo would be similar to a proximal off-axis impact at an angle greater than those used in this study [15]. This study showed that the NS taper joint stability is significantly reduced if the impaction force is not axially directed. This sensitivity to impact location is an important finding because the NS joint has a greater incidence of mechanically assisted crevice corrosion.

This study once again demonstrates that the ability to have consistent stable modular junctions with dual taper components is affected by the direction of the impacted force. The results of this study indicate that stability at the modular junctions of dual taper hip prosthesis is improved when impaction is in line with the longitudinal axes of each individual taper junction. Introducing an angle in the neck eliminates the ability to achieve such a goal and explains the decreased stability seen in the 8° and 15° necks in this study. Failure of dual taper implants related to complications including corrosion at the NS interface, adverse local tissue reaction, and neck fracture has led to decreased utilization and recall of these implants and negated the theoretical benefits achieved with the additional modular interface [9]. Nonetheless, revision cases of failed implants will continue to be a challenge that orthopaedic surgeons face, and understanding the mechanism by which these complications and failures occur may provide us insight for future direction in designing new implants.

Conclusions

The location of impaction has a significant effect on the stability of dual-taper modular hip implants, measured by the component distraction force. Off-axis impacts to a modular hip implant with an angulated neck significantly affected the impact force and the stability of the modular taper, especially at the NS junction. HN stability is less sensitive to the assembly impaction location. Hand-assembled implant stability is several times less than impaction. A result that may lead to stability deficits similar to off-axis impacts because body-weight compression would not be ideally applied in an axial location. Ideal modular implant assembly is axial to the taper and would require special assembly techniques for angulated necks.

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