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Title: Assessment of head displacement and disassembly force with increasing assembly load at the head/trunnion junction of a total hip replacement prosthesis

Abstract

Background

Most femoral components used now for total hip arthroplasty are modular, requiring a strong connection at assembly. The aim of this study was to assess the effect of assembly force on the strength of head-trunnion interface and to measure the initial displacement of the head on the trunnion with different assembly forces.

Methods

Three assembly load levels were assessed (A:2kN,B:4kN,C:6kN) with 4 implants in each group. The stems were mounted in a custom rig and the respective assembly loads were applied to the head at a constant rate of 0.05kN/s (ISO7260-10:2003). Load levels were recorded during assembly. Head displacement was measured with a laser sensor. The disassembly force was determined by a standard pull-off test.

Results

The maximum head displacement on the trunnion was significantly different between the 2kN group and the other two groups (4kN, 6kN, p=0.029), but not between the 4kN and 6kN groups (p=0.89). The disassembly forces between the three groups were significantly different (mean ± SD, A:1316±223kN;B:2224±151kN; C:3965±344kN;**p= 0.007**), with increasing assembly load leading to a higher pull-off force. For the 4kN and 6kN groups, a first peak of approximately 2.5kN was observed on the load recordings during assembly before the required assembly load was eventually reached corresponding to sudden increase in head displacement to approximately 150μm.

Conclusions

An assembly force of 2kN may be too low to overcome the frictional forces needed to engage the head and achieve maximum displacement on the trunnion and thus an assembly load of greater than 2.5kN is recommended.

Keywords

Assembly force; Biomechanical testing; Head-taper connection; Modular hip prosthesis; Pull-off force

Introduction

Modular femoral stems have become the standard of care for total hip replacement, and whilst outcome and survival has been excellent [1], recent issues of trunnion related wear have raised awareness of the importance of assembly [2]. Most modern modular stems use a taper interface with the modular head which requires intraoperative assembly. This interlock gives considerable resistance to any rotational or distracting forces at this junction [3]. The strength of this connection is dependent on the exact taper design [4, 5], the force used to impact the taper [3, 4] and the condition of the taper surface [6]. A strong connection is required at this interface to reduce unintended disassembly after implantation [7-9] and micromotion at the interface resulting in interface corrosion and fretting [10-14], loosening and generation of wear debris [14]. Manufacturer instructions vary from a light tap to several sharp hammer blows [15-17]. Impaction forces and techniques including number of hammer blows, also vary between surgeons [18]. Previous studies have looked at disassembly forces at this junction following impaction forces from 2 kN to 4 kN, which is the range taken to represent a surgeon's 'light hammer blow' and 'firm hammer blow' [18-20]. These studies demonstrated that the pull-off strength increased with impaction force with some suggesting that only a single impact was required for stable assembly [21].

To our knowledge, there are no studies in the literature that investigate the displacement of the head on the trunnion after impaction with different assembly forces. The aim of this study was to assess the effect of different assembly forces on the initial displacement of the femoral head on the trunnion and on the strength of the femoral head-trunnion junction.

Materials and Methods

Twelve JRI^{TM} Furlong HAC collared femoral stems with 28 mm cobalt-chromium heads (JRI, Sheffield, UK) were used in this study (four per test group). The trunnions were size 12/14 and grooved. Prior to testing, the trunnion and femoral head were cleaned with acetone and examined to ensure that there were no obvious debris or visible damage.

The stem was mounted on a custom rig and a ring with a laser target was placed around its trunnion. The femoral head was then placed onto the trunnion using a standardised technique of one twist, and clamped into a custom Instron adaptor using the ring previously placed around the trunnion. A pre-calibrated laser sensor (optoNCDT 1302-20, Micro-Epsilon, Ortenburg, Germany) was used to measure the femoral head displacement during assembly (Figure 1). A custom LabView program (LabView version 7.1, National Instruments^{TM}, Austin, USA) was used to record the displacement. Finally, the rig was aligned and rigidly attached to a materials test machine (Model 3367 with 30 kN load cell, Bluehill^{TM} software version 2.21, Instron, Norwood, MA, USA) for testing. A synchronisation pulse from the Instron was used to register the assembly force and laser displacement measurements. The data collected was then combined and analysed using a custom Matlab routine (MATLAB R2011b; MathWorks, Natick, USA).

The heads were assembled on the stems with the Instron at a constant rate of 0.05 kN/s (ISO 7206-10:2003 [22]) to a pre-defined peak assembly load, and the head displacement was measured using the laser sensor (Figure 2). Three assembly loads were assessed: 2 kN, 4 kN and 6 kN, with four implants per assembly load group.

A pull-off test was then carried out using the Instron at a constant rate of 0.008 mm/s (ISO 7206-10:2003 [22]) and the peak disassembly force of the head-trunnion junction was recorded (Figure 2).

For all statistical analyses, non-parametric tests with α = 0.05 were used. All statistical analyses were carried out with SPSS (version 21, IBM, New York, USA).

Results

During assembly of the 2 kN assembly load group, almost no displacement was seen until a sudden change in displacement occurred just before the load reached 2 kN (Figure 3). There was a similar initial trend with the 4 kN and 6 kN assembly load groups, where a sudden change in displacement of about 150 µm corresponding to a spike of 2.5 kN in the loading profile was observed. This was followed by a more gradual change in displacement up to the pre-defined peak assembly force. There were no significant difference in the initial first peak load spike value between the 4 kN and 6 kN groups (load: 2.48 ± 0.23 kN for 4 kN vs. 2.55 ± 0.52 kN for 6 kN; $p = 1$ Mann-Whitney U test).

The mean maximum head displacement on the trunnion tended to increase with increasing assembly load: 53.18 ± 26.43 µm for 2 kN vs. 150.48 ± 70.35 µm for 4 kN vs. 150.08 ± 60.48 µm for 6 kN. The Kruskal Wallis test indicated a significant difference between the different assembly load groups ($p = 0.039$). Further analysis using the Mann-Whitney U test showed a nearly significant difference between the 2 kN and 4 kN groups, and a significant difference between the 2 kN and 6 kN groups (Figure 4). However, there was no significant difference in maximum head displacement between the 4 kN and 6 kN assembly load groups ($p = 0.89$).

The pull-off force increased significantly with assembly load: 1.32 ± 0.22 kN for 2 kN vs. 2.22 ± 0.15 kN for 4 kN vs. 3.97 ± 0.34 kN for 6 kN (Kruskal Wallis: $p = 0.007$; Mann-Whitney U: Figure 5). Further analysis of the data showed that there was a strong linear correlation between the assembly force and the pull-off force (Spearman’s correlation coefficient, $r_s = 0.946$ and $p < 0.001$).

Discussion

The results of this study demonstrated that the displacement of the head on the trunnion was significantly greater with a 6 kN assembly force, compared with a 2kN force. A 4 kN assembly force also showed greater displacement of the head compared to the 2 kN force, which approached significance. There was no significant difference between the 4 kN and 6 kN groups.

Additionally, it was noted that there was a peak in the loading force profile at 2.5 kN associated with a sudden rapid increase in displacement of the head on the trunnion to near its maximum displacement for that assembly load. This suggests an assembly force of at least 2.5 kN is required to reliably seat the head on the trunnion. Above 2.5 kN further head displacement was small and occurred at a significantly slower rate.

To our knowledge, no previous study in the literature has looked at head displacement on the trunnion with varying assembly loads. Previous studies looking at impaction force from surgeons’ hammer blows have indicated 2 kN to correspond to a ‘light’ hammer blow and 4 kN to correspond to a firm hammer blow [18, 19, 21, 23]. Studies have also shown that it is not the number of impactions but the single strongest impaction that determined the junctional strength at the head/trunnion interface [3]. Rehmer et al [21] recommended a 4 kN assembly force for all bearing conditions. Based on the results seen with head displacement on the trunnion, this study suggests that an assembly force of at least 2.5 kN is required to engage the head/trunnion junction and hence a surgeon’s ‘light’ hammer blow may not be adequate when assembling the junction in vivo. Additionally, in terms of head displacement only, a force greater than this may not be necessary as there is no significant change in head displacement. Indeed, Nganbe et al [24] demonstrated that with increasing compression force of the head on the trunnion, plastic deformation of the neck itself can occur so caution with excessive force must be observed.

From this study, it was observed that a force of at least 2.5 kN was required to overcome the initial friction at the head/trunnion interface and allow the head to ‘slip’ onto the trunnion. This is thought to be due to the ‘stick-slip’ phenomenon [25]. Normally the static friction coefficient between two surfaces is larger than the dynamic friction coefficient but if an applied force is large enough to overcome the static friction, then the reduction in this ratio can cause a sudden increase in rate of the movement of one surface over the other. Thus, an assembly loading force of 2 kN in these prostheses was too small to fully engage the head/trunnion interface. Once this phenomenon had occurred, there was no significant further increase in the displacement of the head on the trunnion in either the 4 or 6 kN groups and indeed, no significant difference in maximum displacement between these groups supporting that the displacement during this phenomenon was likely to represent adequate engagement at this junction.

There is much debate as to the ideal magnitude and method of delivering the assembly force by surgeons. This varies from hand-assembly, where mean forces are approximately 200 N [19], to the greatest possible impact with a hammer where mean forces can vary between 4 kN up to 12 kN [3, 19, 2]. Those studies that recommend hand-assembly [20] argue that early mobilisation will allow forces of up to 250% of BW (which for an average 70 kg person would be approximately 1750N) to act on the junction. However, this joint force does not act directly along the taper axis; hence the axial force is reduced and may not itself be of sufficient magnitude anyway to achieve adequate interlock at the head/trunnion junction as demonstrated in this study. Mroczkowski et al [26] demonstrated that when the modular head/trunnion interface was hand-assembled (i.e. minimal assembly load), the onset of fretting corrosion occurred a lower cyclic loads (200-500 N) compared to when an a higher assembly load (6.7 – 8 kN) was used. In the latter, no changes in onset of fretting corrosion were observed until the cyclic load reached approximately 2500 N. For the hand-assembly group, they noticed that with increasing cyclic load, the head seated further on the taper until further increases did not increase micromotion (and fretting corrosion) until a second load threshold of approximately 2500 N was reached, similar to the higher load assembly group. Hence they concluded that a higher assembly force to ensure proper seating of the head on the taper was necessary to create the most stable interface and reduce the extent of initial fretting corrosion. This study corroborates this, and suggests that a minimum impaction force of 2.5 kN is required. The concern with recommending the greatest possible impaction with a hammer as the assembly load is that of generating excessive forces. Nassut el al [19] reported that forces of up to 12 kN could be generated which could damage the femoral head itself or the surrounding bone.

The greater the assembly load, the greater the pull-off force required to disassemble the head trunnion junction. This difference was significant between each group. Our results are similar to those seen in previous studies [3]. Pennock et al [3] and

Rehmer et al [21] demonstrated a linear relationship between the assembly force and pull-off force. In our study, despite no further significant increase in head displacement between the 4 and 6 kN groups, the mean pull-off force increased significantly. This may be explained by ‘cold-welding’ between the head and trunnion induced by the higher assembly force. Heiney et al [18] suggested that inadequate impaction lead to an incomplete cold-weld and this could potentially lead to a difference in wear and micromotion at the junction of the components.

This study had some limitations. The test samples used were of a specific prosthesis (JRI^{TM} Furlong HAC uncemented collared stems) with a grooved trunnion with size 12/14 and size 28 mm metal heads. Hence the results of this study are only directly applicable to this prosthesis with components of this size. This is however, the commonest size trunnion used in most modern total hip arthroplasty stems [2]. The trunnions of these stems were a titanium alloy (Ti-6Al-4V) and the heads in this study were composed of cobalt-chromium (Co-Cr) alloy. Rehmer et al [21] demonstrated that different material combinations of the components influenced the pull off forces but the observed trend of increasing pull-off force with increasing assembly force was similar.

Another limitation was the small sample groups used. Though small, the study was still able to show significant differences between the groups and the numbers of samples were comparable to previous studies in the literature.

Quasistatic loading and not dynamic impaction was used to apply the assembly load to the head in this study which may not be as representative of the technique for in vivo assembly. Static loading was chosen for this study in order to deliver the intended forces accurately given that with hammer impaction, there is potential for slightly varying forces with each blow, even with custom designed jigs. Additionally Rehmer et al [21], by using both techniques, determined that the head-neck stability depended on the peak force applied and not impulse magnitude or rate. They found no significant differences in pull-off forces between this method of loading and impaction loading. Chen et al [27] and Nganbe et al [24] also used quasistatic loading in their studies. For this study, this loading was in compliance with the ISO standards 7206-10:2003 for testing total hip replacement implants. This study can serve as a baseline study which can be further expanded to investigate the effects of impact loading. Pull-off testing was used to assess the strength of the head/trunnion junction in this study. However, in vivo, some studies suggest the most likely mode of failure of this junction would be rotational overload around the taper axis [21] and hence testing turn-off moments may have been a better way to assess this interlock. This would be technically more difficult to achieve and Rehmer et al [21] demonstrated that this was linearly related to the assembly load and hence to the pull-off strength. Though the results of this study suggest no further significant increase in displacement of the head on the trunnion with greater than 2.5 kN assembly load, the maximum load tested was 6 kN and it is possible that greater loads may cause further displacement.

Conclusion

The results of this study suggest that for this prosthesis, an assembly load of > 2.5 kN is recommended to ensure that the head and trunnion are engaged at this junction with higher assembly loads increasing the strength of this junction. According to previous studies which looked at forces generated by surgeons' hammer impacts [18], this would correspond to at least a 'medium' or 'firm' hammer blow for most surgeons.

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