Citation for published version:
Jauch-Matt, S, Miles, A & Gill, H 2017, 'Effect of trunnion roughness and length on the modular taper junction strength under typical intraoperative assembly forces', *Medical Engineering & Physics* , vol. 39, pp. 94-101. https://doi.org/10.1016/j.medengphy.2016.11.001

DOI:
10.1016/j.medengphy.2016.11.001

Publication date:
2017

Document Version
Peer reviewed version

Effect of trunnion roughness and length on the modular taper junction strength under typical intraoperative assembly forces

Jauch-Matt S.Y.[1], Miles A.W.[1], Gill H.S.[1]

[1] Centre for Orthopaedic Biomechanics, Department of Mechanical Engineering, University of Bath, Bath, United Kingdom

Corresponding author:
Dr. - Ing. Sabrina Y. Jauch-Matt, M.Sc.
University of Bath
Centre for Orthopaedic Biomechanics
Claverton Down
Bath, BA2 7AY
United Kingdom

Phone: +44-(0)-1225-38-5961 or -3627
Fax: +44-(0)-1225-38-6928
Email address (corresponding author): sabrina.jauch@tuhh.de
Email addresses of co-authors: a.w.miles@bath.ac.uk and r.gill@bath.ac.uk

Bath, October 14th, 2016
4431 words (without title page, ethical approval, acknowledgements and references)
Keywords: modular hip prosthesis, stem-head taper connection, fretting, taper strength, pull-off force

Abstract

Modular hip implants are at risk of fretting-induced postoperative complications most likely initiated by micromotion between adjacent implant components. A stable fixation between ball head and stem-neck taper is critical to avoid excessive interface motions. Therefore, the aim of this study was to identify the effect of trunnion roughness and length on the modular taper strength under typical intraoperative assembly forces.

Custom-made Titanium trunnions (standard/mini taper, smooth/grooved surface finish) were assembled with modular Cobalt-chromium heads by impaction with peak forces ranging from 2 kN to 6 kN. After each assembly process these were disassembled with a materials testing machine to detect the pull-off force as a measure for the taper strength.

As expected, the pull-off forces increased with rising peak assembly force ($p<0.001$). For low and moderate assembly forces, smooth standard tapers offered higher pull-off forces compared to grooved tapers ($p<0.038$). In the case of an assembly force of 2 kN, mini tapers showed a higher taper strength than standard ones ($p=0.037$).

The results of this study showed that smooth tapers provided a higher strength for taper junctions. This higher taper strength may reduce the risk of fretting-related complications especially in the most common range of intraoperative assembly forces.

199 words (max. 200 words)

1. Introduction

Modular hip prostheses are commonly used in operation routines of total hip replacements and offer at least one conical taper junction connecting the femoral stem-neck with the ball head. This concept was established in the 1970s to allow surgeons more flexibility in the choice of head material and diameters, and head-stem offsets for a more individualised anatomical reconstruction of the patient's hip joint [1] while retaining the femoral stem and to substantially reduce the inventory [2]. It was assumed that due to an optimized positioning of the artificial joint the revision rates could be decreased. However, the latest clinical data do not reflect the desired positive effects [3–6] with revision rates of up to 86 % for a double-tapered modular hip prosthesis after a follow-up time of less than five years [4]. In recent years concerns have arisen regarding fretting [7,8], wear [9,10] and corrosion at modular taper junctions [8,9,11–15] further increasing the number of revision surgeries [5,8,9,12,16]. The resulting postoperative complications include, but are not limited to, pain [7,13,17], soft tissue damage [7,11], the formation of pseudotumours [7,15,18,19] and osteolysis [20,21] and are frequently associated with high metal ion levels in the blood and/ or urine [15,22–24]. Despite the fact that the precise failure mechanism at taper interfaces is not yet completely elucidated, it is undisputed that micromotion between the adjacent implant components plays a role for this clinical concern [9,25–28]. Previous experimental [28–33] and numerical studies [34,35] have evaluated micromotion at taper interfaces: the documented values report a large range from a few microns to more than 40 μm indicating that several factors such as, the prosthesis geometry, manufacturing tolerances of the taper, the location of the taper connection (head-stem or stem-neck), taper surface topography and the assembly conditions may influence the micromotion levels [28–32,35]. These may be linked to changes in the location and size of the taper contact area [36] and the assembly force. Taper junctions are exposed to high bending and torsional loads during daily activities supporting the occurrence of micromotion. These can provoke mechanical, as well as electrochemical initiated, processes in the fluid environment of the hip joint leading firstly, to fretting [27,37,38] and mechanically assisted crevice corrosion [9,14,16,39] and secondly, to a cascade of adverse local tissue responses [5,13,40] in the form of pseudotumours [18,19,39,15], allergic reactions and middle to high grade tissue damage [11,15]. The material susceptibility to fretting and corrosion seems to be an important factor in the failure mechanism as well. However, no consistent consensus currently exists either for similar or for mixed material couplings [16,25,27,37,38]. Fretting-induced postoperative complications were first reported in significant numbers for large diameter metal-on-metal hip joint articulations [11,41–43] and these device designs appear to negatively enhance taper issues due to higher friction moments at the interface especially in case of low lubrication [44]. Besides fretting-induced complications, an insufficient taper strength caused, for example, by an inadequate intraoperative assembly, may also provoke a loosening of the taper connection [11]. Cases of disassembly of the ball head after dislocation [45,46] or during closed reduction of a dislocated femoral component [47,48] have also been observed in clinical applications.

The current state-of-the-art implies that a firm and permanent fixation of the implant components is critical to minimize postoperative issues [10,16,25,49,50]. Although this fact is well known, explicit guidelines to assemble the implant components are currently rarely available in manufacturer's operative procedure guidelines [51–53]. Moreover, those handling instructions, for example, describing the procedure to assemble a ball head onto a stem taper, are kept very vague [51–53]. It is hypothesised that design-, implantation- and surgeon specific parameters may influence the risk of excessive interface motions and subsequently fretting and corrosion due to inadequate assembly and fixation of these modular implants.

Therefore, the aim of this study was to determine the effect of taper surface roughness and length on the stem-head taper junction strength under typical intraoperative assembly forces.

2. Materials and methods

2.1. Materials, profilometry and assembly

Three groups of titanium custom-made trunnions (Figure 1A, Ti6Al4V alloy, ASTM F136, in total n = 15, Corin Group PLC, Cirencester, UK) with a 12/14 conical taper connection, different taper lengths and surface finishes were used for mechanical testing: smooth, standard tapers (Group 1) vs. grooved, standard tapers (Group 2) vs. grooved, mini tapers (Group 3). The taper length of the mini tapers was approximately 6.5 mm shorter compared to the standard tapers (14.5 mm) while retaining the taper size (maximum cone diameter 14 mm). Prior to the assembly, the taper surfaces were cleaned with ethanol to remove any potential surface contamination and the profile of the stem tapers' outer surface was scanned with a contactless, high-resolution, three-dimensional measurement instrument (ProScan2000 Surface Profilometer, Scantron Industrial Products Ltd, Taunton, UK). Two different surface areas were scanned per test sample with a scan area of 1 mm^2 and a step size of 0.002 mm in both directions each. Based on the scans, the average roughness values Rz and Ra were determined for each trunnion. Additionally, the taper interface of the ball heads and trunnions were helically scanned with a coordinate measuring machine using a ruby stylus for digitisation of the geometry (Incise, Renishaw, Gloucestershire, UK, Figure 1B and C). The surface profiling was primarily used to determine the taper angles and to estimate the location of the press-fit and the contact area (Figure 1B and C). The data sets were analysed using a custom script (MATLAB R2011b; MathWorks, Natick, MA, USA). The centre of mass for each helix was determined allowing the identification of the taper axis that was used as a basis for a subsequent best-fit algorithm. Due to a very robust algorithm, the proximal plane of the trunnions' and the ball heads' plane at the open end, respectively, did not have to be aligned absolutely horizontally during scanning, an angle deviation of up to 3° was acceptable. Based on the outcome of this analysis, the taper angle difference, defined as the angle of the head subtracted by the angle of the trunnion, was calculated (Figure 1B). The components were then assembled at ambient environmental conditions with a 28 mm cobalt-chromium ball head (LC-CoCr29Mo alloy, ASTM F1537, size L) by an impaction using a previously described custom-made drop-rig [54] to mimic the intraoperative procedure. The drop tower consisted of two vertical sliders guiding a horizontal beam with a drop weight attached (total mass 2.4 kg). The drop weight was capped with a nylon disc to reduce the risk of multiple impactions due to a rebound effect. The drop rig was pre-calibrated in order to identify the relationship between drop height and peak assembly force. Based on the simulated peak assembly force the drop height ranged between 22 mm and around 60 mm. Each trunnion-head pair was consecutively assembled along the taper axis with different peak forces ranging from 2 kN to 6 kN (sequence of assembly: $F_1 = 2$ kN, $F_2 = 2$ kN, $F_3 = 4$ kN, $F_4 = 2$ kN, $F_5 = 6$ kN, $F_6 = 2$ kN). The assembly forces were chosen in alignment with typical intraoperative forces [55,56].

2.2. Disassembly and statistics

After each assembly process the implant components were disassembled using a materials testing machine (Series 5965, Instron, Norwood, MA, USA) to measure the pull-off force as an indicator for the taper strength (Figure 2). The trunnions were rigidly attached to the testing machine base and almost the complete ball head was enclosed by a second fixture that was directly coupled to the materials testing machine's actuator and the axial load cell (Figure 2). According to ISO 7206-10: 2003 the pull-off tests were performed at a stroke rate of 0.008 mm/s with a data acquisition rate of 10 Hz. 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 (F_1, F_2, F_4, F_6) was calculated and then used for the following analyses to keep the sample size for the assembly load levels constant (n = 15).

For statistical analyses non-parametric and parametric tests with a type-I-error probability of $\alpha = 0.05$ were performed (SPSS Statistics 20, Munich, Germany). For further correlation analyses, the pull-off forces were z-standardized leading to a variable's mean of zero and a standard deviation of one. Correlations between two metric variables were assessed using linear regression.

3. Results

3.1. *Profilometry & taper angles*

The trunnion surface showed a regular shaped pattern similar to a wave profile with a groove depth of approximately 15.5 µm (grooved)/ 7.5 µm (smooth) and a groove spacing of around 300 µm (grooved) and 150 µm (smooth), respectively (Figure 3). Independent of the taper length, grooved tapers had significantly higher roughness values in terms of both Rz (16.76 ± 0.57 µm vs. 7.97 ± 1.45 µm, $p = 0.001$, Mann-Whitney U) and Ra (4.14 ± 0.54 µm vs. 2.92 ± 0.44 µm, $p = 0.003$, Mann-Whitney U) in z-axis than those with a smooth surface finish (Figure 3). The ball heads exhibited on average a taper angle of 5.67 ± 0.05° leading to a mean taper angle mismatch for standard trunnions of 0.10 ± 0.05°. Since both, the standard and the mini tapers, exhibited a 12/14 taper connection, the taper angles of the mini tapers were larger compared to the standard tapers resulting in a taper angle mismatch of approximately zero (- 0.03 ± 0.02°).

3.2. *Pull-off forces*

For all of the performed mechanical tests, the consecutive testing of the implant components did not influence the pull-off forces at the trunnion-head interface ($0.216 \leq p \leq 0.922$, Kruskal-Wallis / one way ANOVA). Overall, independent of the taper length and the surface finish, the recorded pull-off forces were on average 24.9 % (± 9.3%) of the assembly force. For both surface modifications, the pull-off force of standard tapers increased significantly with rising peak assembly force (Group 1 & 2, 2 kN: 0.549 ± 0.084 kN vs. 4 kN: 0.954 ± 0.101 kN vs. 6 kN: 1.436 ± 0.145 kN, $p < 0.001$, two way ANOVA, Figure 4). For assembly forces of 4 kN or less, standard stem tapers with a smooth surface finish had significantly higher pull-off forces compared to those with a grooved surface (Group 1 & 2, 0.820 ± 0.239 kN vs. 0.684 ± 0.202 kN, $p < 0.001$, two way ANOVA, Figure 4). Following a 6 kN impaction, no influence of the surface finish on the pull-off force was detected (Group 1 & 2, 1.435 ± 0.145 kN, $p = 0.426$, one way ANOVA, Figure 4). Similar to the standard tapers, a positive correlation between assembly and pull-off force was also determined for the mini tapers (Group 3, linear regression, adj. $R^2 = 0.804$, $p < 0.001$). Only in case of an assembly force of 2 kN, grooved mini tapers exhibited a significantly higher taper strength compared to grooved standard tapers (Group 2 & 3, 0.630 ± 0.113 kN vs. 0.497 ± 0.041 kN, $p = 0.037$). However, with rising assembly force this effect became smaller and smaller: at 4 kN still a trend was observed (Group 2 & 3, $p = 0.065$, Welch Test) whereas for the highest assembly force of 6 kN no effect could be found anymore (Group 2 & 3, $p = 0.266$, one way ANOVA, Figure 4). Independent of the assembly force, for the standard tapers a significant influence of the taper angle mismatch on the taper junction strength was not observed (Group 1 & 2, $0.403 \leq p \leq 0.990$, linear regression). In contrast, the pull-off forces of the mini tapers tended to increase with decreasing angular mismatch in the assessed range of -0.05° to -0.01° for all assembly forces (Group 3, $0.022 \leq p \leq 0.093$, linear regression). Z-standardized pull-off forces of mini tapers showed a significant negative correlation with the taper angle difference (Group 3, adj. $R^2 = 0.718$; $p < 0.001$, Figure 5).

4. Discussion

Fretting-induced postoperative complications of modular hip prostheses have become a serious problem in total hip arthroplasty [57]. Micromotion between adjacent implant components appears to be critical for this clinical concern [9,25–28]. In combination with fluid ingress into crevices resulting from angular differences of adjacent implant components or an insufficient taper fixation, this may lead to fretting and/ or corrosion [9,16,27,37–39,15], dramatically limiting the functional life of a hip replacement [3–6,28]. Additionally, misalignments and even a complete disassembly of a prosthesis component can be caused under adverse circumstances by an insufficient taper strength [45–48]. Although these clinical problems are well documented, no explicit instructional guidelines to assemble the implant components are provided for most of the implants available on the market. Since the importance of a stable, rigid connection of taper junctions has been identified [10,16,25,49], this experimental study focused on the impact of trunnion roughness and length on the taper junction's strength under typical intraoperative assembly forces.

In the presented study only one taper design with a 12/14 taper was assessed with one specific material coupling (Ti - CoCr). This fact may limit the transferability of the results to other designs and/or material combinations. Due to differences in the taper geometry of cobalt-chromium and ceramic ball heads, it is expected that the location of the press-fit, the size of the contact area and the prevalent contact pressure will be different for the two materials. The taper angle of ceramic ball heads is usually higher compared to metal heads suggesting that the press-fit area is located nearer to the closed end of the taper connection. Therefore, a general statement on the effect of the assessed influencing parameters cannot be easily drawn without any further investigations. For the assembly process a custom-made drop tower was used which utilised a plastic cap at the impactor's end. This scenario does not represent the clinical situation in which the implant components were usually assembled by one or more metal hammer blows. Due to the plastic end cap, the applied kinetic energy was reduced compared to a metal-on-metal blow as a consequence of a damping effect. This study is furthermore limited by assessing the surface topography of the trunnions only, as the profilometer measurements of the head female tapers could not be made because of the nature of the profilometer used in this study. The initial contact situation at the stem-head taper directly after assembly was evaluated, rather than the assessment of changes in taper strength due to any subsequent dynamic loading that may mimic the usual daily activity of a patient. Thus, due to this lack of dynamic loading, potential interface micromotions were not recorded.

The surface topography of the tapers used in this experimental study was comparable to threaded taper designs available on the market [17,58]; they offered a repetitive distinct surface pattern with a specific groove height and spacing between two adjacent threads. The rough tapers showed an average maximum profile height (Rz) comparable to the Profemur (Wright Medical), Synergy (Smith and Nephew), Summit and Corail (DePuy Synthes) prosthesis with values between 16.02 µm and 17.38 µm, however, their average roughness (Ra) was lower (4.14 µm vs. 2.23 - 3.35 µm) [58]. The groove depth of the clinically used threaded designs is smaller compared to the rough tapers (7.24 - 13.49 µm vs. ≈ 15.5 µm) [58]. The roughness value Ra of the smooth tapers was comparable to the clinically used ones named before as well as to the Trilock and Silent stem tapers (DePuy Synthes, 2.09 - 2.83 µm vs. 2.92 ± 0.44), whereas, Rz conformed to the Secure-fit Max threaded design (Stryker, 7.23 µm) and the non-threaded designs ABG II (Stryker), Taper-lock (Zimmer), Accolade (Stryker) and SROM (DePuy Synthes, 6.1 - 7.5 µm) [58]. It should be noted, that the test method used to determine the surface topography of the tapers deviated from the one applied by Munir et al. [58]. In the present study only 2D characteristics were assessed, whereas Munir et al. used an interference microscope and a post-processing step to determine 3D topographical surface features as well.

This experimental study clearly demonstrated that the taper length and the surface roughness can significantly influence the taper junction strength predominantly in the most common range of intraoperative assembly forces. As expected and in agreement with other studies, the pull-off forces increased significantly with rising peak assembly force [50,59–62]. A doubling of the assembly force resulted in a 1.7 times higher pull-off force whereas a tripling gave rise to a 2.6-fold increase of the taper strength. Rehmer et al., MacLeod et al. and Ihesiulor et al. found a significant higher mean pull-off force/ assembly force ratio (25% vs. 33 - 67%) compared to this study [50,61,63]: possible reasons may be differences in the topography and roughness of the taper surfaces, the taper length and head size leading to discrepancies in the location of the interlock and the contact force. Additionally, varying assembly procedures (dynamic vs. static) and rigs, disassembly test speeds as well as different material combinations may also have played a role [50,61,63]. The prosthesis design also affects the taper junction strength and its variability substantially [59]. The taper angle mismatch is suspected to be of considerable importance as well [60]. A correlation between head size and taper strength has already been found [61]: 36 mm metal heads exhibited a significantly lower pull-off force compared to 28 mm ones when impacted with peak forces of 5 kN or less. This finding has been associated with the high failures rates in large diameter hip replacements [61]. Previous studies reported an increased seating of the head on the stem taper (primary seating) for high assembly forces [33,62]. This seems to result in a more favourable taper contact situation with a high contact pressure in the stem-head interfaces associated with the observed improved taper strength [62] and a reduction in micromotion [33].

Following an impaction of 4 kN or less, smooth standard tapers exhibited a higher taper strength, most probably due to a more favourable contact situation. The spacing between two adjacent grooves and their depths is much smaller for the smooth surface finish compared to the grooved tapers. Only in case of high assembly loads, small local plastic deformations of the grooves are expected suggesting an increasing contact area comparable to smooth tapers. Witt et al. found a significant increase in the area and the number of ridges being in contact with rising assembly force [36]. In a similar manner, Fallahnezhad et al. determined in their FE-Analysis an increasing contact length and pressure with rising assembly force, whereas the contact length of CoCr/Ti couplings was always larger compared to CoCr/ CoCr junctions [60]. Furthermore, a positive correlation between assembly force and the amount of permanent plastic deformation has been reported [36]. Besides the reduced taper strength of rough tapers following a slight or moderate impaction, these tapers seem to be also more susceptible to fretting than smooth tapers [64]. Furthermore, a positive correlation between taper surface roughness (Rpk) and wear rates has been reported [17]. In an in vitro study, Panagiotidou et al. found a noticeable rupture of the oxide film during dynamic loading at a modular Ti/ CoCr junction with a rough surface profile, whereas the fretting and corrosion damage for a smooth taper was marginal [64].

Discrepancies in the taper strength between standard and mini tapers following a light hammer blow may also be traced back to differences in the contact area and contact pressure. As expected and in alignment with a FE-Analysis, the contact of standard tapers occurs proximally (closed end of taper connection) due to a positive angular mismatch [60,65], in contrast to mini tapers with a mismatch of almost zero and therefore an unpredictable location of the area being in contact (proximal, distal or across the whole taper length). This statement is in agreement with a previously published study: Witt et al. found out that the location of the damaged area is irregularly distributed along the whole taper surface in case of a small taper angle difference [36]. Cook et al. expects an influence of the angular mismatch within the stem-head taper connection on the generation of wear particle [10]. However, Kocagoz et al. could not confirm a direct correlation between angular mismatch and wear and corrosion scores [65]. But, the angular mismatch seems to be inversely correlated with the amount of interface micromotions [33].

It is speculated that the intraoperative assembly procedure has a significant influence on the initial contact situation [60] and subsequently a big influence for the clinical performance. In addition to the assembly force, impaction angle, the number of impactions and the instrumentation tool, the presence of contaminants in the interface due to an insufficient cleaning is also considered as potentially critical. An inadequate assembly associated with the impact not aligned axially may increase the presence of crevices within conical taper connections, allowing fluid ingress and ultimately the creation of corrosion. During surgery some surgeons assemble the modular components by multiple impactions and under different conditions i.e. wet or dry. It has been shown, that the impact force of the first hammer blow is the most important one with regard to the taper strength [50,59]. The assembly force sequence in case of multiple impactions [59] and the taper condition prior to the assembly (wet or dry) may also change the pull-off forces either in a positive or negative way, depending on the prosthesis design [59]. The presence of bone chips contaminating the tapers can exhibit interface micromotions more than double that compared to clean tapers [30]. Weisse et al. demonstrated, that contaminants such as bone chips, tissue or blood in the stem-head taper interface can reduce the static fracture load of ceramic ball heads by up to 90% compared to non-contaminated interfaces [66]. It should furthermore be considered that, depending on the surgical approach chosen, a dynamic assembly of the stem-head taper junction with a hammer or a head impactor can be excessively difficult or impossible. It can also be speculated that the tapers cannot be easily cleaned to remove any contaminants in the interface prior to the assembly [57]. To the authors’ knowledge there are currently no data available implying that the number of fretting complications directly correlates to a specific surgical approach. This suggests that not only the assembly force and condition (wet or dry) but rather several factors affecting the risk of fretting e.g. the taper design, angular mismatch, head diameter and the used materials. Nevertheless, for further developments of modular components this issue needs to be adequately addressed.

Although there are currently no data available confirming that a high taper strength is directly linked with a reduced risk of fretting complications, it seems to be highly probable that this hypothesis is true. Fretting can only occur if there are crevices present, which allow fluid ingress [27]. In case of a high taper strength accompanied with an extremely high contact pressure the crevices within the taper junction may be negligibly small avoiding fluid ingress and preventing the initiation of corrosion. A few experimental in vitro studies have already assessed the influence of assembly load, axial load and assembly condition (wet vs. dry), respectively, on the onset of fretting. Goldberg et al. and Mroczkowski et al. assessed the fretting corrosion behaviour using an in vitro electrochemical test set-up [27,49]. The open circuit potential (OCP) decreased with rising cyclic load whereas the fretting current increased. This can be seen as a result of a removal of the oxide film and a subsequent repassivation within the taper connection [49]. The force threshold to initiate taper fretting is significantly higher for implants assembled with a strong impaction (6.7 - 8.0 kN) in air (onset at a load of ≈ 2.5 kN [49]) than those pressed only by hand (for wet and dry condition, onset at a load less than 0.5 kN [49]) or statically assembled with 2.0 kN (onset at a load less than 1.3 kN [27]). However, during daily living activities, modular taper connections are not only exposed to pure axial loads but rather to a combination of axial and rotational loads. In addition, a positive correlation between assembly force and the minimum torque required to initiate fretting processes in the interface has already been reported [54]. The determined values for load and torque at the onset of fretting can easily be reached during daily living activities [27,54]. Baxmann et al. showed with an in-vitro fretting test system that fretting wear with indications of particle detachment can occur in case of a low contact pressure (normal load ≤ 50N) combined with high interface motions (≥ 25N) [67]. Chu et al. found out in their FE Analysis that a separation of contact in the taper connection can cause wear and corrosion [68]. Based on the current knowledge, a correlation between taper strength and fretting damage seems possible but cannot be directly deduced.

As already mentioned by MacLeod et al., the initial contact situation directly after the assembly procedure does not permit direct conclusions on the long-term performance [61]. Nevertheless, the taper strength may be one of several contributors to estimate the risk of fretting.

5. Conclusions

This study has demonstrated that trunnion-specific parameters as well as the assembly force have a significant impact on the stem-head taper strength. High assembly forces gave rise to a greater pull-off force; this may decrease the interface micromotions and ultimately the risk of fretting and wear. Nevertheless, it should be considered that an excessively high hammer blow may provoke damage to the bony structure and/or the surrounding tissue during surgical assembly. Therefore, an assembly force of around 4 kN appears to be a reasonable compromise in agreement with the previous recommendation made by Rehmer et al. [50] and Haschke et al. [33].

An important finding is that smooth tapers are more appropriate to use in taper connections with modular metal heads in the future since these tapers offer a higher taper strength, especially, in the most common range of intraoperative assembly forces. It is furthermore suspected, that rough tapers are more susceptible to fretting than smooth ones [64]. The results also indicate that mini tapers can exhibit comparable taper strength to those of standard tapers even if they offer an overall smaller taper surface area. There is thus evidence that it is not the overall taper surface area that is essential, but rather the actual taper contact area, which is affected by, but not limited to the surface topography, taper angle mismatch and the assembly force.

Ethical approval

Not required.

Acknowledgements

The authors gratefully acknowledge the cooperation and support of Corin Group PLC.

Conflict of interest statement

All authors do not have any conflicts of interest that are related to this study, to disclose.

References

[1] Srinivasan A, Jung E, Levine BR. Modularity of the femoral component in total hip arthroplasty. J Am Acad Orthop Surg 2012;20:214–22. doi:10.5435/JAAOS-20-04-214.

[2] Barrack R. Modularity of Prosthetic Implants. J Am Acad Orthop Surg 1994;2:16–25.

[3] Silverton CD, Jacobs JJ, Devitt JW, Cooper HJ. Midterm results of a femoral stem with a modular neck design: Clinical outcomes and metal ion analysis. J Arthroplasty 2014;29:1768–73. doi:10.1016/j.arth.2014.04.039.

[4] Bernstein DT, Meftah M, Paranilam J, Incavo SJ. Eighty-six Percent Failure Rate of a Modular-Neck Femoral Stem Design at 3 to 5 Years. J Bone &amp; Jt Surg 2016;98:e49.

[5] De Martino I, Assini JB, Elpers ME, Wright TM, Westrich GH. Corrosion and Fretting of a Modular Hip System: A Retrieval Analysis of 60 Rejuvenate Stems. J Arthroplasty 2015;30:1470–5. doi:10.1016/j.arth.2015.03.010.

[6] Meftah M, Haleem AM, Burn MB, Smith KM, Incavo SJ. Early corrosion-related failure of the rejuvenate modular total hip replacement. J Bone Joint Surg Am 2014;96:481–7. doi:10.2106/JBJS.M.00979.

[7] Molloy DO, Munir S, Jack CM, Cross MB, Walter WL, Walter WK. Fretting and corrosion in modular-neck total hip arthroplasty femoral stems. J Bone Joint Surg Am 2014;96:488–93. doi:10.2106/JBJS.L.01625.

[8] Higgs GB, Hanzlik JA, MacDonald DW, Gilbert JL, Rimnac CM, Kurtz SM. Is Increased Modularity Associated With Increased Fretting and Corrosion Damage in Metal-On-Metal Total Hip Arthroplasty Devices? J Arthroplasty 2013;28:2–6. doi:10.1016/j.arth.2013.05.040.

[9] Gilbert JL, Buckley C a., Jacobs JJ. In vivo corrosion of modular hip prosthesis components in mixed and similar metal combinations. The effect of crevice, stress, motion, and alloy coupling. J Biomed Mater Res 1993;27:1533–44. doi:10.1002/jbm.820271210.

[10] Cook SD, Barrack RL, Baffes GC, Clemow a J, Serekian P, Dong N, et al. Wear and corrosion of modular interfaces in total hip replacements. Clin Orthop Relat Res 1994:80–8. doi:10.1097/00003086-199401000-00013.

[11] Meyer H, Mueller T, Goldau G, Chamaon K, Ruetschi M, Lohmann CH. Corrosion at the cone/taper interface leads to failure of large-diameter metal-on-metal total hip arthroplasties. Clin Orthop Relat Res 2012;470:3101–8. doi:10.1007/s11999-012-2502-5.

[12] McKellop H a., Sarmiento a., Brien W, Sang Hyun Park. Interface corrosion of a modular head total hip prosthesis. J Arthroplasty 1992;7:291–4. doi:10.1016/0883-5403(92)90051-Q.

[13] Fricka KB, Ho H, Peace WJ, Engh CA. Metal-on-metal local tissue reaction is associated with corrosion of the head taper junction. J Arthroplasty 2012;27:26–31.e1. doi:10.1016/j.arth.2012.03.019.

[14] Whittaker RK, Hothi HS, Meswania JM, Berber R, Blunn GW, Skinner JA, et al. The effect of using components from different manufacturers on the rate of wear and corrosion of the head-stem taper junction of metal-on-metal hip arthroplasties. Bone Joint J 2016;98-B:917–24. doi:10.1302/0301-620X.98B7.36554.

[15] Sassoon AA, Barrack RL. Pseudotumour formation and subsequent resolution in metal-on-metal total hip arthroplasty following revision: Instructional review and an illustrative case report with revision using a dual mobility design. Bone Jt J 2016;98-B:736–40. doi:10.1302/0301-620X.98B6.36908.

[16] Goldberg JR, Gilbert JL, Jacobs JJ, Bauer TW, Paprosky W, Leurgans S. A multicenter retrieval study of the taper interfaces of modular hip prostheses. Clin Orthop Relat Res 2002:149–61.

[17] Whittaker RK, Hothi HS, Eskelinen A, Blunn GW, Skinner JA, Hart AJ. The variation in taper surface roughness for a single design effects the wear rate in total hip arthroplasty. J Orthop Res 2016. doi:10.1002/jor.23456.

[18] Chana R, Esposito C, Campbell P a., Walter WK, Walter WL. Mixing and matching causing taper wear: Corrosion associated with pseudotumour formation. J Bone Jt Surg - Br Vol 2012;94-B:281–6. doi:10.1302/0301-620X.94B2.27247.

[19] Cook RB, Bolland BJRF, Wharton J a., Tilley S, Latham JM, Wood RJK. Pseudotumour formation due to tribocorrosion at the taper interface of large diameter metal on polymer modular total hip replacements. J Arthroplasty 2013;28:1430–6. doi:10.1016/j.arth.2013.02.009.

[20] Lee SH, Brennan FR, Jacobs JJ, Urban RM, Ragasa DR, Glant TT. Human monocyte/macrophage response to cobalt-chromium corrosion products and titanium particles in patients with total joint replacements. J Orthop Res 1997;15:40–9. doi:10.1002/jor.1100150107.

[21] Jacobs JJ, Urban RM, Gilbert JL, Skipor a K, Black J, Jasty M, et al. Local and distant products from modularity. Clin Orthop Relat Res 1995:94–105.

[22] Jacobs JJ, Skipor a K, Patterson LM, Hallab NJ, Paprosky WG, Black J, et al. Metal release in patients who have had a primary total hip arthroplasty. A prospective, controlled, longitudinal study. J Bone Joint Surg Am 1998;80:1447–58.

[23] Savarino L, Granchi D, Ciapetti G, Cenni E, Nardi Pantoli A, Rotini R, et al. Ion release in patients with metal-on-metal hip bearings in total joint replacement: A comparison with metal-on-polyethylene bearings. J Biomed Mater Res 2002;63:467–74. doi:10.1002/jbm.10299.

[24] Savarino L, Granchi D, Ciapetti G, Cenni E, Greco M, Rotini R, et al. Ion release in stable hip arthroplasties using metal-on-metal articulating surfaces: a comparison between short- and medium-term results. J Biomed Mater Res A 2003;66:450–6. doi:10.1002/jbm.a.10595.

[25] Lieberman JR, Rimnac CM, Garvin KL, Klein RW, Salvati E a. An analysis of the head-neck taper interface in retrieved hip prostheses. Clin Orthop Relat Res 1994:162–7. doi:10.1097/00003086-199403000-00021.

[26] Tan SC, Teeter MG, Del Balso C, Howard JL, Lanting B a. Effect of Taper Design on Trunnionosis in Metal on Polyethylene Total Hip Arthroplasty. J Arthroplasty 2015;30:1269–72. doi:10.1016/j.arth.2015.02.031.

[27] Goldberg JR, Gilbert JL. In vitro corrosion testing of modular hip tapers. J Biomed Mater Res B Appl Biomater 2003;64:78–93. doi:10.1002/jbm.b.10526.

[28] Grupp TM, Weik T, Bloemer W, Knaebel H-P. Modular titanium alloy neck adapter failures in hip replacement--failure mode analysis and influence of implant material. BMC Musculoskelet Disord 2010;11:3. doi:10.1186/1471-2474-11-3.

[29] Jauch SY, Huber G, Haschke H, Sellenschloh K, Morlock MM. Design parameters and the material coupling are decisive for the micromotion magnitude at the stem-neck interface of bi-modular hip implants. Med Eng Phys 2014;36:300–7. doi:10.1016/j.medengphy.2013.11.009.

[30] Jauch SY, Huber G, Hoenig E, Baxmann M, Grupp TM, Morlock MM. Influence of material coupling and assembly condition on the magnitude of micromotion at the stem-neck interface of a modular hip endoprosthesis. J Biomech 2011;44:1747–51. doi:10.1016/j.jbiomech.2011.04.007.

[31] Jauch SY, Huber G, Sellenschloh K, Haschke H, Baxmann M, Grupp TM, et al.

Micromotions at the Taper Interface Between Stem and Neck Adapter of a Bimodular Hip Prosthesis During Activities of Daily Living. J Orthop Res 2013;31:1165–71. doi:10.1002/jor.22354.

[32] Gilbert JL, Mehta M, Pinder B. Fretting crevice corrosion of stainless steel stem-CoCr femoral head connections: Comparisons of materials, initial moisture, and offset length. J Biomed Mater Res Part B Appl Biomater 2009;88B:162–73. doi:10.1002/jbm.b.31164.

[33] Haschke H, Jauch-Matt SY, Sellenschloh K, Huber G, Morlock MM. Assembly force and taper angle difference influence the relative motion at the stem–neck interface of bi-modular hip prostheses. J Eng Med 2016;230:690–9. doi:10.1177/0954411916648717.

[34] Shareef N, Levine D. Effect of manufacturing tolerances on the micromotion at the Morse taper interface in modular hip implants using the finite element technique. Biomaterials 1996;17:623–30. doi:10.1016/0142-9612(96)88713-8.

[35] Abdullah K. Study of factors affecting taper joint failures in modular hip implant using finite element modelling. Model. Simul. Optim. - Focus Appl., InTech, Rijeka; 2010, p. 121–34.

[36] Witt F, Gührs J, Morlock MM, Bishop NE. Quantification of the Contact Area at the Head-Stem Taper Interface of Modular Hip Prostheses. PLoS One 2015;10:e0135517. doi:10.1371/journal.pone.0135517.

[37] Urban R, Gilbert J, Jacobs J. Corrosion of Modular Titanium Alloy Stems in Cementless Hip Replacement. J ASTM Int 2005;2:12810. doi:10.1520/JAI12810.

[38] Wright G, Sporer S, Urban R, Jacobs J. Fracture of a Modular Femoral Neck After Total Hip ArthroplastyA Case Report. J Bone Jt Surg 2010;92:1518–21. doi:10.2106/JBJS.I.01033.

[39] Gill IPS, Webb J, Sloan K, Beaver RJ. Corrosion at the neck-stem junction as a cause of metal ion release and pseudotumour formation. J Bone Jt Surg - Br Vol 2012;94-B:895–900. doi:10.1302/0301-620X.94B7.29122.

[40] Esposito CI, Wright TM, Goodman SB, Berry DJ. What is the Trouble With Trunnions? Clin Orthop Relat Res 2014:3652–8. doi:10.1007/s11999-014-3746-z.

[41] Bolland BJRF, Culliford DJ, Langton DJ, Millington JPS, Arden NK, Latham JM, et al. High failure rates with a large-diameter hybrid metal-on-metal total hip replacement CLINICAL, RADIOLOGICAL AND RETRIEVAL ANALYSIS. J Bone Jt Surg [Br] 2011;93:608–15. doi:10.1302/0301-620X.93B5.

[42] Langton DJ, Sidaginamale R, Lord JK, Nargol AVF, Joyce TJ. Taper junction failure in large-diameter metal-on-metal bearings. Bone Joint Res 2012;1:56–63. doi:10.1302/2046-3758.14.2000047.

[43] Langton DJ, Jameson SS, Joyce TJ, Hallab NJ, Natu S, Nargol a VF. Early failure of metal-on-metal bearings in hip resurfacing and large-diameter total hip replacement: a consequence of excess wear. J Bone Jt Surg Br 2010;92:38–46. doi:10.1302/0301-620X.92B1.22770.

[44] Bishop NE, Hothan A, Morlock MM. High friction moments in large hard-on-hard hip replacement bearings in conditions of poor lubrication. J Orthop Res 2013;31:807–13. doi:10.1002/jor.22255.

[45] Ahmed P, Kumar D. Late Disassembly of Femoral Head and Neck of A Modular Primary Total Hip Arthroplasty. J Orthop Case Reports 2015;5:8–10. doi:10.13107/jocr.2250-0685.243.

[46] Karaismailoglu TN, Tomak Y, Gulman B. Late detachment modular femoral component after primary total hip replacement. Arch Orthop Trauma Surg 2001;121:481–2. doi:10.1007/s004020100275.

[47] Woolson ST, Pottorff GT. Disassembly of a modular femoral prosthesis after dislocation of the femoral component. A case report. J Bone Joint Surg Am 1990;72:624–5.

[48] Pellicci PM, Haas SB. Disassembly of a modular femoral component during closed reduction of the dislocated femoral component. A case report. J Bone Joint Surg Am 1990;72:619–20.

[49] Mroczkowski ML, Hertzler JS, Humphrey SM, Johnson T, Blanchard CR. Effect of impact assembly on the fretting corrosion of modular hip tapers. J Orthop Res 2006;24:271–9. doi:10.1002/jor.20048.

[50] Rehmer A, Bishop NE, Morlock MM. Influence of assembly procedure and material combination on the strength of the taper connection at the head-neck junction of modular hip endoprostheses. Clin Biomech 2012;27:77–83. doi:10.1016/j.clinbiomech.2011.08.002.

[51] Biomed Orthopedics. BIOLOX® delta Option Ceramic Femoral Head System Product Features and Instructions for Use, 01-50-0916 2012.

[52] JRI Orthopaedics LTD. Ceramic Femoral Heads and Acetabular Cup Liners, Important Information, 115-020 Issue 9 2012.

[53] Medacta International. MECTACER CERAMIC IMPLANTS - Instructions for use, 75.09.019 rev. 04 2007.

[54] Jauch SY, Coles LG, Ng L V., Miles a. W, Gill HS. Low torque levels can initiate a removal of the passivation layer and cause fretting in modular hip stems. Med Eng Phys 2014;36:1140–6. doi:10.1016/j.medengphy.2014.06.011.

[55] Nassutt R, Mollenhauer I, Klingbeil K, Henning O, Grundei H. [Relevance of the insertion force for the taper lock reliability of a hip stem and a ceramic femoral head]. Biomed Tech (Berl) 2006;51:103–9. doi:10.1515/BMT.2006.018.

[56] Heiney JP, Battula S, Vrabec G a., Parikh A, Blice R, Schoenfeld AJ, et al. Impact magnitudes applied by surgeons and their importance when applying the femoral head onto the Morse taper for total hip arthroplasty. Arch Orthop Trauma Surg 2009;129:793–6. doi:10.1007/s00402-008-0660-4.

[57] Morlock MM. The taper disaster - how could it happen? Hip Int 2015;00:0–0. doi:10.5301/hipint.5000269.

[58] Munir S, Walter WL, Walsh WR. Variations in the trunnion surface topography between different commercially available hip replacement stems. J Orthop Res 2015;33:98–105. doi:10.1002/jor.22741.

[59] Pennock AT, Schmidt AH, Bourgeault CA. Morse-type tapers. J Arthroplasty 2002;17:773–8. doi:10.1054/arth.2002.33565.

[60] Fallahnezhad K, Farhoudi H, Oskouei RH, Taylor M. Influence of geometry and materials on the axial and torsional strength of the head-neck taper junction in modular hip replacements: A finite element study. J Mech Behav Biomed Mater 2016;60:118–26. doi:10.1016/j.jmbbm.2015.12.044.

[61] MacLeod AR, Sullivan NPT, Whitehouse MR, Gill HS. Large-diameter total hip arthroplasty modular heads require greater assembly forces for initial stability. Bone Jt Res 2016;5:338–46. doi:10.1302/2046-3758.58.BJR-2016-0044.R1.

[62] Scholl L, Schmidig G, Faizan A, TenHuisen K, Nevelos J. Evaluation of surgical impaction technique and how it affects locking strength of the head-stem taper junction. Proc Inst Mech Eng Part H J Eng Med 2016;230:661–7. doi:10.1177/0954411916644477.

[63] Ihesiulor OK, Shankar K, Smith P, Fien A. Determination of the Pullout / Holding Strength at the Taper-Trunnion Junction of Hip Implants. Int J Medical, Heal Biomed Bioeng Pharm Eng 2015;9:723–6.

[64] Panagiotidou A, Meswania J, Hua J, Muirhead-Allwood S, Hart A, Blunn G. Enhanced wear and corrosion in modular tapers in total hip replacement is associated with the contact area and surface topography. J Orthop Res 2013;31:2032–9. doi:10.1002/jor.22461.

[65] Kocagoz SB, Underwood RJ, MacDonald DW, Gilbert JL, Day J, Kurtz SM. Quantitative taper angle measurement method for retrieved femoral heads and stems. ORS 2014 Annu. Meet., 2014.

[66] Weisse B, Affolter C, Stutz a, Terrasi GP, Köbel S, Weber W. Influence of contaminants in the stem-ball interface on the static fracture load of ceramic hip joint ball heads. Proc Inst Mech Eng H 2008;222:829–35. doi:10.1243/09544119JEIM374.

[67] Baxmann M, Jauch SY, Schilling C, Blömer W, Grupp TM, Morlock MM. The influence of contact conditions and micromotions on the fretting behavior of modular titanium alloy taper connections. Med Eng Phys 2013;35:676–83. doi:10.1016/j.medengphy.2012.07.013.

[68] Chu YH, Elias JJ, Duda GN, Frassica FJ, Chao EYS. Stress and micromotion in the taper lock joint of a modular segmental bone replacement prosthesis. J Biomech 2000;33:1175–9. doi:10.1016/S0021-9290(00)00058-0.