



# RESEARCH

# Maximizing the fixation strength of modular components by impaction without tissue damage

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TUHH – Hamburg University of Technology, Hamburg, Germany **Objectives** 

Taper junctions between modular hip arthroplasty femoral heads and stems fail by wear or corrosion which can be caused by relative motion at their interface. Increasing the assembly force can reduce relative motion and corrosion but may also damage surrounding tissues. The purpose of this study was to determine the effects of increasing the impaction energy and the stiffness of the impactor tool on the stability of the taper junction and on the forces transmitted through the patient's surrounding tissues.

#### **Methods**

A commercially available impaction tool was modified to assemble components in the laboratory using impactor tips with varying stiffness at different applied energy levels. Springs were mounted below the modular components to represent the patient. The pull-off force of the head from the stem was measured to assess stability, and the displacement of the springs was measured to assess the force transmitted to the patient's tissues.

#### Results

The pull-off force of the head increased as the stiffness of the impactor tip increased but without increasing the force transmitted through the springs (patient). Increasing the impaction energy increased the pull-off force but also increased the force transmitted through the springs.

## **Conclusions**

To limit wear and corrosion, manufacturers should maximize the stiffness of the impactor tool but without damaging the surface of the head. This strategy will maximize the stability of the head on the stem for a given applied energy, without influencing the force transmitted through the patient's tissues. Current impactor designs already appear to approach this limit. Increasing the applied energy (which is dependent on the mass of the hammer and square of the contact speed) increases the stability of the modular connection but proportionally increases the force transmitted through the patient's tissues, as well as to the surface of the head, and should be restricted to safe levels.

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Keywords: Tissue damage, Implant failure, Modular connection

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## **Article focus**

- The aim of this study was to determine the influence of impactor design and applied impaction energy on the stability of modular connections of hip joint arthroplasty components and on the forces transmitted through the patient's tissues.
- It was postulated that increasing the impactor stiffness would increase stability

without increasing forces transmitted to the patient.

## **Key messages**

- The stiffness of current impactor designs already allows the maximum strength of a modular hip connection to be approached for a given applied impaction energy.
- Increasing the applied impaction energy (hammer mass and velocity) increases

the strength of the modular junction but also increases forces transmitted through the patient's tissues.

# **Strengths and limitations**

- Strengths: This is the first study to define the parameters influencing taper strength and forces transmitted through the patient's tissues during the assembly of modular components.
- Limitations: Maximum tolerable forces and their time periods remain to be determined and, as such, safe levels of impaction energy cannot yet be prescribed.

#### Introduction

Modular taper connections between the head and neck components of a femoral implant are failing in increasingly large numbers.<sup>1-3</sup> This has been attributed to fretting corrosion and wear<sup>1,4-7</sup> which can occur when relative motion at the interface between the two materials abrades the surfaces.<sup>1,8</sup> To prevent relative motion, a press fit must be generated with sufficient friction capacity to resist interface shear stresses generated during physiological activities. This press fit is generated by intraoperative impaction of the head onto the stem once the stem has been implanted in the femur. The surgeon applies a hammer to an impactor tool that has a plastic tip on the end, which is placed on the head component.

The strength of the taper connection has been shown to increase with an increase in the applied peak assembly force9-11 and corrosion has been shown to be reduced.12 The assembly force increases with an increase in the applied energy, which means a 'harder' impaction. But as the impaction energy is increased, there is the possibility of damaging the surrounding tissues. In fact, intraoperative periprosthetic fracture is reported to be frequent.<sup>13,14</sup> For a given impaction energy, increasing the impactor stiffness will increase the peak force while decreasing the time period of the applied impulse. It has been proposed that a peak force of 4 kN generates an adequate press fit between head and stem.9 To what extent the time period of the impulse is important in generating modular taper fixation strength has not been addressed. Using a very stiff impactor system, it should be possible to achieve a very high peak force with a short impulse period. On the other hand, it seems possible that for an extremely short impulse period there may be no gain in taper fixation strength, despite a very high peak force. Furthermore, it is unclear what proportion of the applied impulse is transmitted through the surrounding tissues for varying impactor stiffness. This is important as the forces due to impaction could be related to trauma intraoperatively, including periprosthetic fracture. 13-16

In this study, the following questions were addressed:

1) Does an increase in impactor stiffness increase the peak applied force, leading to increased taper fixation strength?

2) Does an increase in impactor stiffness lead to a greater force transmission that could result in tissue damage?

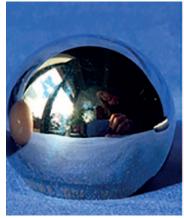




Fig. 1

Modular components: left)  $\emptyset$  32 mm cobalt-chrome femoral head; right) 12/14 replica titanium alloy stem taper. The threaded distal end of the replica stem taper was necessary for anchorage to the base plate.

A cobalt-chrome head was impacted onto a titanium taper using an impactor of varying stiffness. The taper assembly was mounted on a sprung mass, representing the patient's tissues. Pull-off forces, as well as spring forces, were recorded to assess taper stability and tissue forces, respectively.

#### **Materials and Methods**

Cobalt chrome femoral heads (Isodur®-F, CoCr29Mo, diameter 32 mm, 12/14 taper, size M, Aesculap AG, Tuttlingen, Germany, Fig. 1 left) were assembled onto titanium alloy stem taper replicas (Ti6Al4V, 12/14 taper; Aesculap AG, Tuttlingen, Germany Fig. 1 right). The mean head taper angle ( $\pm$ SD) was 5.75  $\pm$  0.03° with a smooth surface. The stem taper had a mean angle ( $\pm$ SD) of 5.65  $\pm$  0.02°, a length of 10 mm and a surface finish with a very fine threaded profile (ridge height 12 µm, ridge spacing 210 µm). For anchorage, one end of the taper replica was supplied with a 6 mm diameter screw thread. The heads had each been assembled onto a taper once previously and then disassembled.

The replica taper was fixed to a base plate, separated from the bench either by three springs with known stiffness or by three metal tubes to generate a 'rigid' support condition (Fig. 2). The moving parts (i.e. taper and metal plate) had a mass of 0.275 kg. A frame was constructed with a low friction sleeve, representing the surgeon's hand, to stabilize the vertical position of a commercially available impactor (Articular Surface Replacement Head Pusher Handle; DePuy, Leeds, United Kingdom, mass = 0.575 kg), the lower end of which was located on the head. The standard impactor is a metal rod with a handle and flat end for impaction. On one end, there is a screw-on plastic tip that locates on the head to protect the bearing surface during impaction.

The femoral head was placed firmly on the taper by hand and rotated around the taper axis. Impaction was

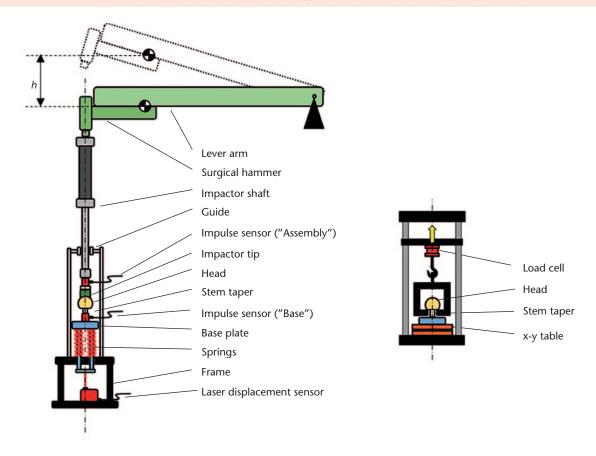


Fig. 2

Left) Impaction apparatus with the hammer on a lever arm dropping onto an impactor shaft with exchangeable impactor tips and instrumented with an impulse sensor. Another impulse sensor was mounted below the taper to measure the patient tissue force for the 'rigid' base condition. The taper was screwed to a plate mounted on springs to represent the patient's tissues. A laser displacement sensor was mounted below the sprung plate to derive the spring force. Right) Schematic of the frame for quasi-static disassembly of the femoral head from the stem taper, according to international standards (ISO) 7206-10 and ASTM F2009, 2011.

provided by a metal surgical hammer fixed to one end of a lever arm, which was anchored via a bearing to a frame at the other end. The centre of mass of the arm/hammer construction with mass m (kg) was dropped from a predefined height h (m) to provide a known impaction energy E (J) where  $E = 9.81 \cdot \text{m} \cdot \text{h}$ . The mass m of the arm and hammer was 0.9 kg.

**Input variables.** Impactor tips with five different stiffnesses  $(S_{tip})$  were tested (tip 1 to tip 5, Fig. 3. See supplementary material for measurement of tip stiffness), with three different base plate stiffnesses  $S_{base}$  ('Soft': 0.5 N/m, 'Stiff': 5.0 N/m, 'Rigid': >10<sup>5</sup> N/m) for two different impaction energies ( $E_{High}$ =2.2 J,  $E_{Low}$ =1.1 J). 1.1 J is prescribed for similar testing of modular components by the ASTM standard (ASTM F2009, 2011).<sup>17,18</sup> It represents a typical head-stem assembly using a hammer with a mass of 0.5 kg dropped from a height of 20 cm. Each of the 30 possible combinations was tested, and repeated three times (n = 3). A total of 20 heads and 40 tapers were available and were reused a maximum of two times (no effect of repeated use was measurable in preliminary tests).

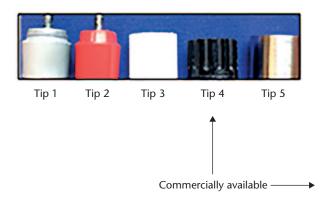
**Output variables.** The impactor force impulse was measured just above the tip of the impactor using an impulse

sensor (capacity 22 kN, Model 208C05; PCB Piezotronics Inc., Depew, New York, sampling rate 500 kHz).

Parameters employed in the analysis were the peak assembly force  $F_{\rm assembly}$  (measured with the impulse sensor in the impactor) and the time period of the assembly force  $T_{\rm assembly}$ , defined between 10% of  $F_{\rm assembly}$  and  $F_{\rm assembly}$  (Fig. 4).

The pull-off force  $F_{\rm off}$  of the head from the taper was measured to assess the taper fixation strength of the modular connection.  $F_{\rm off}$  was measured quasi-statically at 0.008 mm/s (according to ISO 7206-10 and ASTM F2009, 2011)<sup>17,18</sup> using a uni-axial testing machine (capacity 10 kN, Zwick/Roell Z010; Zwick GmbH & Co. KG, Ulm, Germany) with a custom grip<sup>9-11</sup> (according to ISO 7206-10 and ASTM F2009, 2011)<sup>17,18</sup> (Fig. 2).

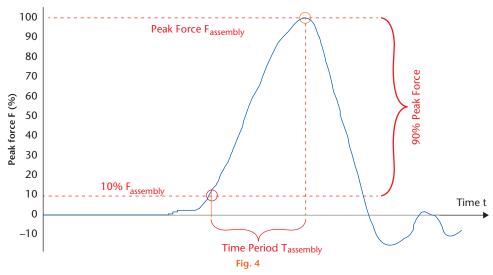
The force in the springs  $F_{\rm base}$ , and the time period  $T_{\rm base}$  of their deflection, were derived from the measurement of their deflection using a laser sensor (range 10 mm, accuracy 0.005 mm, Model PT660021; ipf electronic gmbh, Lüdenscheid, Germany).  $F_{\rm base}$  and  $T_{\rm base}$  were calculated from the resulting force-time data according to Figure 4. For the 'rigid' case, the springs were replaced by metal tubes with very high stiffness (estimated



		Tip Stiffness				
		[N/mm]				
	Material	mean	sd			
Tip1	Rubber1	34	1			
Tip2	Rubber2	242	9			
Tip3	PE	2422	91			
Tip4	POM	6472	248			
Tip5	Steel	11167	270			

Fig. 3

The tips were screwed to the end of the impactor and rested on the bearing surface of the head. The tip stiffness was determined by measuring the force-displacement characteristic between the top of the impactor tips and the bottom of the head, and estimated by dividing the peak force by the peak displacement. The peak force considered was that applied for the 2.2 J energy level for each tip (see supplementary material for method of determining tip stiffness). Mean and standard deviation (SD) are given for three measurements of each tip. PE, Polyethylene; POM, Polyoxymethylene.



Representation of the evaluation scheme for analysis of the peak force ( $F_{assembly}$  or  $F_{base}$  for the applied impulse and base plate force, respectively) and the time period ( $T_{assembly}$  or  $T_{base}$  for the applied impulse and base plate force, respectively) of the dynamic impaction assembly process under all test conditions.

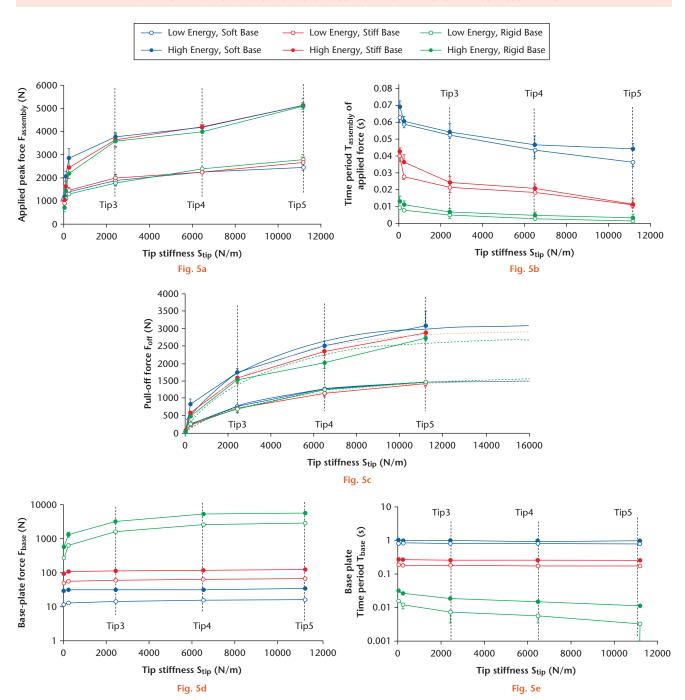
analytically to be  $10^5$  N/m). In this case, no displacement could be measured so an impulse sensor below the taper (PCB Piezotronic Model 208C05) was used to measure the force  $F_{\rm base}$ . This sensor remained in the system for all experiments, also when not in use, during measurements using springs.

Applied peak force  $F_{assembly}$ , base plate force  $F_{base}$ , pull-off force  $F_{off}$ , applied time period  $T_{assembly}$  and base plate time period  $T_{base}$  were compared statistically between impactor tip stiffness  $S_{tip}$ , base stiffness  $S_{base}$  and impaction energy E, using a parametric analysis (two-way analysis of variance (ANOVA)) and post hoc test (Tukey), or a non-parametric analysis (Kruskal-Wallis) with the probability of a Type I error set to  $\alpha = 0.05$  (SPSS Statistics 22;

IBM Corp., Armonk, New York). All results are reported as mean and SD.

# Results

**Applied force** *versus* **tip stiffness and energy.** The peak force magnitude of the applied impulse  $F_{assembly}$  increased with tip stiffness  $S_{tip}$  (p < 0.001), but with decreasing gains (Fig. 5a). The applied time period  $T_{assembly}$  decreased with increasing tip stiffness  $S_{tip}$  (p < 0.001) (Fig. 5b). The applied force  $F_{assembly}$  was found to increase with the magnitude of the applied energy E (p < 0.001), but not to be statistically dependent on the stiffness of the base  $S_{base}$  (p = 0.864) (Fig. 5a). Conversely, the time period of the applied force  $T_{assembly}$  was not found to depend



All plots are mean/SD plotted against the same impactor tip stiffness  $S_{\rm tip}$  scale on the horizontal axis and for three base plate stiffnesses  $S_{\rm base}$  (blue: 'soft' 0.5 N/m; red: 'stiff' 5.0 N/m; green: 'rigid'  $> 10^{\rm 5}$  N/m) representing the mechanical compliance of the patient and two energy levels (open points: 1.1 J; solid points: 2.2 J). Tips 3 to 5 are labelled. Tip 4 is a commercially available plastic tip, and tip 5 is metal and was the stiffest tested. Note that the SD bars that are not visible are too small to be observed. a) Peak force  $F_{\rm assembly}$  of the impulse applied to the head. b) Time period  $T_{\rm assembly}$  of the impulse applied to the head, defined in Figure 3. c) Pull-off force  $F_{\rm off}$  of the head from the taper. Exponential functions were fitted to each curve, according to Table II. d) Peak force  $F_{\rm base}$  generated in the base plate springs. e) Time period  $T_{\rm base}$  of the force generated in the base plate springs defined in Figure 4.

on the applied energy E (p = 0.145), it decreased with increasing stiffness of the base  $S_{\text{base}}$  (p < 0.001) and was not dependent on the impactor stiffness  $S_{\text{tip}}$  (p = 0.225) (Fig. 5b). Since the applied force  $F_{\text{assembly}}$  increased with increasing tip stiffness  $S_{\text{tip}}$  (Fig. 5a) as the time period  $T_{\text{assembly}}$  decreased (Fig. 5b), an increasing loading rate with increasing tip stiffness  $S_{\text{tip}}$  is indicated.

The base plate time period  $T_{\text{base}}$  decreased with the stiffness of the base  $S_{\text{base}}$  (p < 0.001), increased with applied energy E (p < 0.001), and was not statistically dependent on the impactor stiffness  $S_{\text{tip}}$  (p = 0.988) (Fig. 5e).

**Pull-off force.** The pull-off force  $F_{\text{off}}$  was found to increase with tip stiffness  $S_{\text{tip}}$  (p < 0.001) but with decreasing

**Table I.** Least squares best-fit of an exponential function relating the pull-off force  $(F_{\text{off}})$  to the tip stiffness  $(S_{\text{tip}})$  data (Fig. 5c) is given by  $F_{\text{off}}[N] = a_1 \cdot e^{(a_2 \cdot S_{\text{tip}}(N/m))} + a_3$  for varying base plate stiffness  $S_{\text{base}}$  and applied energy E

Applied energy E	Low energy			High energy		
Base plate stiffness Sbase	Soft base	Stiff base	Rigid Base	Soft base	Stiff base	Rigid Base
Constant a <sub>1</sub>	-1417	-1446	-1499	-2764	-2696	-2504
Constant a	-2.71E-04	-2.14E-04	-2.15E-04	-2.74E-04	-2.71E-04	-2.65E-04
Constant a <sub>3</sub> (Maximum fit force in N)	1513	1552	1610	3120	2937	2716
R <sup>2</sup>	0.990	0.986	0.983	0.948	0.977	0.959
F <sub>off</sub> (tip 4)/Maximum fit force (%)	84	74	78	81	80	75
F <sub>off</sub> (tip 5)/Maximum fit force (%)	96	92	92	100	58	101

The fit tends to a constant maximum pull-off force  $F_{\text{off}}$  (max) (given by constant  $a_3$  in (N)). The maximum forces  $F_{\text{off}}$  for tip 4 (commercially available) and tip 5 (metal) are compared with the maximum predicted force according to the fit exponential function.

**Table II.** Ratio of pull-off forces  $F_{\text{off}}$  for low and high applied energies for all tip stiffnesses  $S_{\text{tip}}$  and base stiffnesses  $S_{\text{base}}$ 

Tip	Tip Stiffness	High Energy / Low Energy [-]			
	[N/m]	Soft Base	Stiff Base	Rigid Base	
Tip1	34	2.5	1.9	2.2	
Tip2	242	2.4	1.9	2.1	
Tip3	2422	2.2	1.9	2.0	
Tip4	6472	2.0	1.9	2.1	
Tip5	11167	2.1	1.9	1.9	
	Mean	2.2	1.9	2.1	
	Std	0.2	0.0	0.1	

Low energy, 1.1 J and High energy, 2.2 J.

gains (Fig. 5c), apparently tending towards asymptotic (maximum) force magnitudes (Table I, exponential best-fit function). Forces for the commercially available plastic tip 4 were within 30% of the predicted maximum, while forces for metal tip 5 were within 10% of the predicted maximum (Table I). The pull-off force  $F_{\rm off}$  increased proportionally to the applied energy magnitude E for a given tip stiffness  $S_{\rm tip}$  (p < 0.001, pull-off forces doubled for double the applied energy, Table II) and was not clearly dependent on base stiffness  $S_{\rm base}$  (p = 0.984).

**Base plate force.** The peak force  $F_{\text{base}}$  measured in the supporting base was not dependent on the impactor tip stiffness  $S_{\text{tip}}$  for sprung support conditions ('soft' and 'stiff' springs,  $S_{\text{base}}$  ('soft'): p = 0.135,  $S_{\text{base}}$  ('stiff'): p = 0.148) but increased with tip stiffness  $S_{\text{tip}}$  for a 'rigid' base (Fig. 5d) (p < 0.001). The period of the spring force  $T_{\text{base}}$  increased with tip stiffness  $S_{\text{tip}}$  as the peak force  $F_{\text{assembly}}$  increased (Fig. 5e). The peak force  $F_{\text{base}}$  acting through the base increased with the magnitude of the applied energy E (p < 0.001). The peak force  $F_{\text{assembly}}$  roughly doubled for double the applied energy E regardless of tip stiffness  $S_{\text{tip}}$  or base stiffness  $S_{\text{base}}$  (Fig. 5a, Table II).

## **Discussion**

**Research questions.** Increasing the stiffness of the impactor tip was found to increase the taper fixation strength of a cobalt chrome head on a titanium stem taper. Furthermore, for a sprung base representing the mechanical compliance of the patient, an increasing tip stiffness

did not increase forces below the taper for a given applied impaction energy. Increasing the impaction energy increased the fixation strength but also increased the force below the taper which represents greater load transfer through the tissues. This suggests that taper fixation strength should be maximized by increasing the stiffness of the impactor tip, rather than the applied energy, which could damage the patient's tissues. However, the strategy of maximizing tip stiffness is limited by potentially damaging the head during impaction.

The impactor shaft is made of metal and is stiff relative to the standard plastic impactor tip. The impactor tip is sufficiently soft to protect the bearing surface of the head. It has a concave surface to locate on the surface of the femoral head. The tip could potentially be made stiffer, by using a material with a higher elastic modulus, by decreasing its thickness or by conforming its geometry to the spherical surface of the head. The maximum practical elastic modulus for the impactor tip would be that for a ceramic-type material, which is roughly double that of steel or cobalt chrome, and roughly two orders of magnitude greater than that for the plastic tips used in current designs. The thickness could be reduced, in principal, to a very thin layer. The greater the conformity of the tip to the head (conical or spherical), the greater its stiffness will be since Hertzian contact deformation is reduced. These strategies could be used to maximize impactor stiffness by being incorporated in a tool providing a pre-defined impulse energy, to prevent damage to the head.

How much strength can be gained by increasing tip stiffness?. In previous studies, the fixation strength of the head-neck junction has been related to the peak force with apparently linear relationships, both under quasistatic and dynamically applied assembly forces using a rigid base plate.<sup>9-11,19</sup> In the current study, the peak force was applied over a greater range, revealing a steep increase in pull-off force for low tip stiffness, becoming flatter at higher tip stiffnesses (Fig. 5c). An exponential function relating pull-off force to tip stiffness revealed a good fit ( $R^2 > 0.94$ ) and suggested decreasing gains in strength with increasing tip stiffness until a maximum is achieved (given by constant  $a_3$  in Table I). The metal tip

(tip 5) generated pull-off forces that were within 10% of the projected maximum and the plastic POM tip (tip 4), used in commercially available designs, generated pull-off forces of within 30% of the projected maximum. Thus, current systems employing hard plastic tips may already be close to generating the maximum possible seating for a given impaction energy.

Why does assembly force increase with tip stiffness but not with base stiffness?. The applied energy is provided by the gravitational potential of the hammer which is directly proportional to its mass and height above the impactor and is converted to the kinetic energy of the impaction. The hammer strikes the metal impactor shaft, which accelerates the impactor tip against the head. The softer the tip, the longer the time period over which the impactor shaft will accelerate. Assuming energy losses are low, the contact force Fassembly between impactor tip and head will decrease as the period T<sub>assembly</sub> increases (Figs 5a and b, respectively), since momentum is conserved and the area below the force-time impulse function remains constant. The impaction force F<sub>assembly</sub> was unaffected by the sprung base stiffness S<sub>base</sub> because the head-neck taper is very stiff and seating is completed more rapidly (within a period of the same order of magnitude as the applied impulse T<sub>assemblv</sub>) than the deflection of the much softer, and more massive sprung base system (Tassembly is an order of magnitude lower than T<sub>base</sub>. Compare Fig. 5b with Fig. 5e).

**Standard Testing.** It is noted that the ASTM testing procedure for modular components specifies an assembly energy but does not address the force-time characteristic of the applied impulse. This study clearly demonstrates that very different seating behaviour can be achieved for a given applied energy ( $E_{low} = 1.1$  J in the current study is specified by the ASTM standard)<sup>17,18</sup> due to the dependency of the applied force on the stiffness of the impactor. However, although it is recommended in the ASTM standard that the apparatus be placed on a soft base, it is also noted here that seating is independent of the stiffness of the base plate, so that simple rigid fixation of the modular components should be adequate for studies of taper strength.

Why does force transmitted to surrounding tissues increase with energy but not with tip stiffness?. Assembly forces are modulated by the tip stiffness due to their effects on the acceleration of the impactor. However, assuming small losses due to friction between head and stem tapers, for example, the assembly energy must be transferred through the modular connection to the springs, which deform according to the magnitude of the energy applied. The taper connection seats rapidly due to its high stiffness, regardless of the applied assembly force (tip stiffness). In contrast to the experimental construction with a sprung base described above, the force transmitted to the rigid base plate increased with tip stiffness (Fig. 5d) because the rate of loading is more similar to the

fundamental frequency of the base, thereby providing dynamic coupling.

How does the base plate stiffness relate to the mechanical compliance of patients?. The rigid base plate construction (with the springs exchanged for metal tubes) can be assumed to represent an unrealistically high reference stiffness in which it was shown that the force transferred to the base plate (Fig. 5d) was slightly greater than the applied peak force (Fig. 5a) for the two stiffest tips (< 130%). However, although a representative stiffness and mass for a patient on the operating table are not known, it can be assumed that the rigid condition does not exist and that the force transmitted to the surrounding tissues (Fig. 5d) is lower than the applied assembly force (Fig. 5a), as observed for the sprung experiments. Purely subjective observation of the intraoperative situation by the authors suggests that a patient's leg, which has been incised at the hip and has had the femoral head removed in preparation for implantation, is at least as soft in the direction of head impaction as the stiffer springs tested experimentally. This would lead to tissue forces that are at least an order of magnitude lower than the applied force (Fig. 5d). According to the data presented, the compliance of the patient may indeed help to maintain safe stress magnitudes in the soft tissues. It is noted that although there are reports of periprosthetic fracture due to cavity preparation or stem impaction into the bone, 13-16 there are no reports of intraoperative tissue damage specifically due to impaction of the head onto the stem taper. However, if safe seating of the head is to be ensured, applied energy levels may need to be increased.

The mechanical compliance of the patient on the operating table was modelled using springs below the base plate. This is a simple but defined approach in which the mass of the sprung system, as well as the spring constant, are known. The input and output parameters in the current study can therefore be used to validate mechanical models, leading to a clearer understanding of the load transfer mechanism. The assembly load is transferred from the head to the stem, then to the femur, then to the soft tissues, and finally to the operating table and to ground. Three-dimensional geometry, non-linear timedependent tissue properties and complex boundary conditions will certainly lead to a force-displacement response that is not represented by the mass on elastic springs employed in the current study. However, it seems fair to assume that the acceleration of the impactor mass combined with the deformation of the tissues will be high enough to allow a few millimetres of motion of the tissues under the applied load. This is provided experimentally by the springs, in contrast to the less realistic rigid condition. The two spring stiffnesses employed in the current study merely provided a parametric variation, demonstrating that less force is transferred though the tissues of an effectively softer patient (Fig. 5d) (albeit for a longer period, Fig. 5e). Whether the stiffness and mass parameters relate to larger or smaller patients, different surgical approaches, or are modified by the position of the patient on the table, is unclear. Complete modelling of the patient would probably necessitate 3D geometry and dynamic stress-strain properties, as well as mass distributions of the tissues. Damage to tissues may be dependent not only on stress magnitudes, but also on their duration.<sup>13-16</sup>

In other studies, the mechanical compliance of the patient has been represented by a foam pad below the base plate but its influence on the taper fixation strength was not discussed.<sup>20,21</sup>

The clinical situation. The current experiment was conducted using a standard cobalt chrome head on a replica titanium stem taper. Similar combinations have recently been reported to fail due to corrosion of the cobalt chrome component, leading to metal ion release and biological reaction or fracture of the neck.<sup>7,22-24</sup> Failure of the titanium taper has also been noted due to massive wear. 1 Both processes are related to abrasion of the metal surfaces, which occurs due to relative motion between the components.7 Increasing the initial press fit by increasing the assembly force has been shown to decrease corrosion.<sup>12,22</sup> Increasing the impactor stiffness and the applied energy will increase fixation strength and may thereby decrease corrosion and wear. These trends should hold for all metal-on-metal head-neck modular taper junctions but critical assembly force magnitudes for each design remain to be determined.

Measurements of tissue loading during component assembly would be necessary, in combination with dynamic models of the patient, in order to estimate energy levels that maintain tissue stresses within safe magnitudes. Note that the energy applied is theoretically proportional to the mass of the hammer and the height from which it is dropped. Doubling the applied energy doubled the deflection of the base plate springs and, therefore, the force acting in them. This finding should be interpreted as a warning to the surgeon.

**Other limitations.** It is noted that the force below the taper was derived differently for the sprung and rigid bases. For the sprung base, the force was calculated from the measured deflection and the spring constant. This is the force acting in the spring, representing the compliance of the patient. However, for the rigid system, the springs were replaced by stiff metal tubes and no displacement could be measured. The force was therefore measured directly below the taper by an impulse load cell and the effective mass and stiffness of the base were assumed to tend to infinity, providing an extreme reference.

In conclusion, this study demonstrates that increasing the tip stiffness of the impactor increases the fixation strength of the head on a neck taper and that this does not influence the forces transmitted through the patient's tissues below the modular components. The impactor stiffness should therefore be as high as possible without damaging the surface of the head but this limit would need to be determined experimentally and implemented by the manufacturers. On the other hand, it seems that tip designs currently used may generate interface strengths that are within 30% of an apparent maximum possible for a given applied energy. To increase the strength further, the applied energy can be increased, but this will increase forces transmitted through the patient's tissues. The surgeon is responsible for energy application, which is theoretically proportional to the mass of the hammer (and the surgeon's arm), and to the square of the impaction velocity (or to the drop height). The assembly forces required to eliminate dangerous levels of corrosion are yet to be determined. They will be necessary, along with the determination of maximum safe levels of applied energy, to prevent corrosion-related pathology, wear and dislocation, patient tissue damage and damage to the bearing surface, for a particular implant system and given patient. An impaction device could be employed that delivers a predefined impulse, providing a sufficient assembly force, without damaging the head or the patient.

# **Supplementary material**

Further information and a table providing the method of determining tip stiffness are available alongside the online version of this article at www.bjj. boneandjoint.org.uk

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#### **Author Contributions**

- A. Krull: Study design, Data collection, Data analysis and writing.
- M. M. Morlock: Study design, Data collection, Data analysis and writing.
  N. E. Bishop: Study design, Data collection, Data analysis and writing.

#### **Conflict of Interest Statement**

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