

ORIGINAL ARTICLE

Multi-surgeon assessment of total hip arthroplasty head–trunnion assembly forces using a surgical simulator

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Abstract

Background: Total hip arthroplasty failures due to adverse local tissue reaction or gross mechanical failure at the femoral head–trunnion junction are being increasingly reported. If the head–trunnion junction is not coupled with enough force (≥ 4 kN), unintended motion can occur between the head and trunnion, increasing the potential for a subsequent adverse local tissue reaction and/or gross mechanical failure. We developed three hypotheses: (1) and (2) surgeons strike metallic and ceramic heads, respectively, with at least one mallet blow producing an effective coupling force ≥ 4 kN, and (3) surgeons strike metallic and ceramic heads with similar force. **Methods:** A surgical simulator capable of measuring forces acting along the central femoral head bore–trunnion axis was constructed. Fifty-five surgeons followed a standardized simulation protocol and were instructed to select a mallet that most closely resembled their surgical mallet and to strike the simulator in a manner identical to their intraoperative head–trunnion coupling routine for 36 mm metallic and ceramic femoral heads. **Results:** 25.9% and 16.4% of surgeons applied an effective coupling force ≥ 4 kN for metallic and ceramic heads, respectively. Surgeons applied significantly more force to metallic (3.06 kN) heads than to ceramic (2.62 kN) heads ($P < 0.001$). Demographic data collected from participants was used for additional post-hoc analyses. Surgeons who selected a mallet mass > 800 g had 4.23 greater odds of reaching the ≥ 4 kN threshold ($P = 0.047$). **Conclusion:** This investigation indicates that most total hip arthroplasty surgeons do not apply enough force to optimally couple metallic or ceramic heads to the trunnion. Improved surgical coupling of this junction could decrease the incidence of trunnion-related total hip arthroplasty failure.

Keywords: Trunnion; coupling; trunnionosis; impaction force; total hip arthroplasty

Introduction

Health care utilization of total hip arthroplasty (THA) continues to increase¹ because it has been shown to provide a high level of patient satisfaction, significant improvements in quality of life², and robust survival of the implant.³ Despite this, it has become increasingly clear that a small but significant subset of metal on polyethylene (MoP) and ceramic on polyethylene (CoP) THA articulations fail from mechanical or biological issues that arise as a result of the modular head–trunnion junction.⁴ To date, investigations of gross trunnion failures (e.g., head–trunnion dissociation) have failed to conclusively correlate this phenomenon with stem material, head size, trunnion geometry, etc.^{3,5} Similarly, analyses of adverse local tissue reactions after MoP or CoP THA have concluded that this negative biological consequence of metal ions and/or corrosion products

generated at the head trunnion junction is multifactorial in nature.^{3,6}

The coupling force applied to the THA head–trunnion junction at the time of surgery could be an important variable contributing to mechanical and biological failure mediated by the head–trunnion junction. It is accepted that inadequate coupling force can lead to unintended motion at the head–trunnion junction,⁷ which is known to encourage mechanically assisted corrosion. Previous investigations have indicated that some surgeons apply different forces to femoral heads constructed of different materials,⁴ and others have indicated that surgeons do not apply enough force to a ceramic femoral head during surgery to optimally couple it to the trunnion.⁸ Additional studies have indicated that differing femoral head material and femoral stem material couplings may require different optimal coupling forces.⁴

Previous studies have tried to quantify the mallet forces applied by surgeons to the THA head–trunnion junction at the time of surgery and correlate it with the force required to disassemble the head–trunnion couple.^{9,10} These surgical simulations have demonstrated significant variation in mallet forces that surgeons apply to the head–trunnion junction and confirmed that the force required to disassemble the coupled head–trunnion junction is roughly proportional to the maximum force measured at the strike surface of the mallet. Although these investigations have advanced our knowledge of the forces occurring at the mallet face during THA femoral head–trunnion coupling, they have not measured the forces occurring along the central femoral head–trunnion axis (effective coupling force) and have been limited by the small numbers of surgeons assessed.

Previous biomechanical investigations of pull-off forces and turn-off moments have estimated optimal THA femoral head–trunnion coupling forces for different head and stem materials to be at least 4 kN.⁴ Another investigation suggested an effective coupling force of 2 kN may be too low to overcome the frictional forces needed to engage the head on the trunnion and recommended an effective coupling force greater than 2.5 kN.¹¹ Experiments responsible for producing these estimates were performed using mechanically generated forces applied along the central axis of the femoral head bore and femoral stem trunnion. Although these experiments and estimations have provided guidance regarding how much force is necessary to optimally couple the head–trunnion junction, there have been no subsequent investigations that have characterized the effective coupling force produced along the central axis of the femoral head and trunnion as a result of surgeon-applied mallet blows.

To better understand the effective coupling force generated during ceramic and metallic femoral head coupling to the THA trunnion, we developed a surgical simulator and simulation protocol capable of measuring the forces acting along the central head–trunnion axis as a result of surgeon-delivered mallet blows. Before surgeon assessment, a literature review was carried out, and using recommended optimal coupling forces⁴, we developed the following hypotheses:

- (1) When simulating the coupling of a 36-mm metal head to the femoral trunnion, all surgeons apply at least one mallet blow resulting in an effective coupling force ≥ 4 kN (900 lbf).
- (2) When simulating the coupling of a 36-mm ceramic head to the femoral trunnion, all surgeons apply at least one mallet blow resulting in an effective coupling force ≥ 4 kN (900 lbf).

- (3) When simulating the coupling of a 36-mm head to the femoral trunnion, there is no difference in the peak force that surgeons apply to ceramic and metallic femoral heads.

We then collected demographic information from 55 orthopedic surgeons who currently perform THA and assessed their femoral head–trunnion coupling routine. Data obtained were then analyzed to test the hypotheses and characterize the head–trunnion coupling routine of these surgeons. The primary aim of this study was to determine and understand the forces currently used by surgeons when coupling the head and trunnion.

Materials and methods

A THA head–trunnion coupling simulator was developed that was capable of measuring the forces along the central femoral head–trunnion axis as a result of mallet blows by the surgeon (Fig. 1). The simulator is constructed of a one-piece 36-mm diameter sham femoral head (strike surface) with cylindrical piston attached, a conformal polyethylene bushing that guides the piston, and a piezoelectric force sensor (PCB Piezoelectronics, Depew, NY) capable of measuring 0 to 22.24 kN (0 to 5000 lbf). The force sensor and the polyethylene bushing are mounted on a metal baseplate attached to a ball and socket mount that allows for positional adjustment in three planes.

Surgeons were recruited by the senior author to participate in the study, and data were collected at the First Annual American Association of Hip and Knee Surgeons Spring Meeting in Washington, DC. All recruited surgeons were educated regarding the purpose and protocol of the simulation in a standardized fashion. Demographic data were collected from all participants, including the level of training, annual THA volume, annual ceramic head volume, most frequently used femoral stem geometry and type, and preferred THA surgical approach.

Surgeons were encouraged to handle and then choose the mallet most similar to the one they use at the time of THA from a selection of five different surgical mallets (310 g, 567 g, 778 g, 910 g, and 1275 g). Surgeons then adjusted the simulator strike surface to reproduce the position of the femoral head and trunnion as viewed during their usual THA approach. A standardized head impaction device was used for all surgeons and simulations. Each surgeon was allowed to apply a set of practice mallet strikes to the simulator to ensure appropriate simulator strike surface height and orientation and to become familiar with the simulator. Surgeons were blinded to the amount of force produced as a result of their mallet blows.

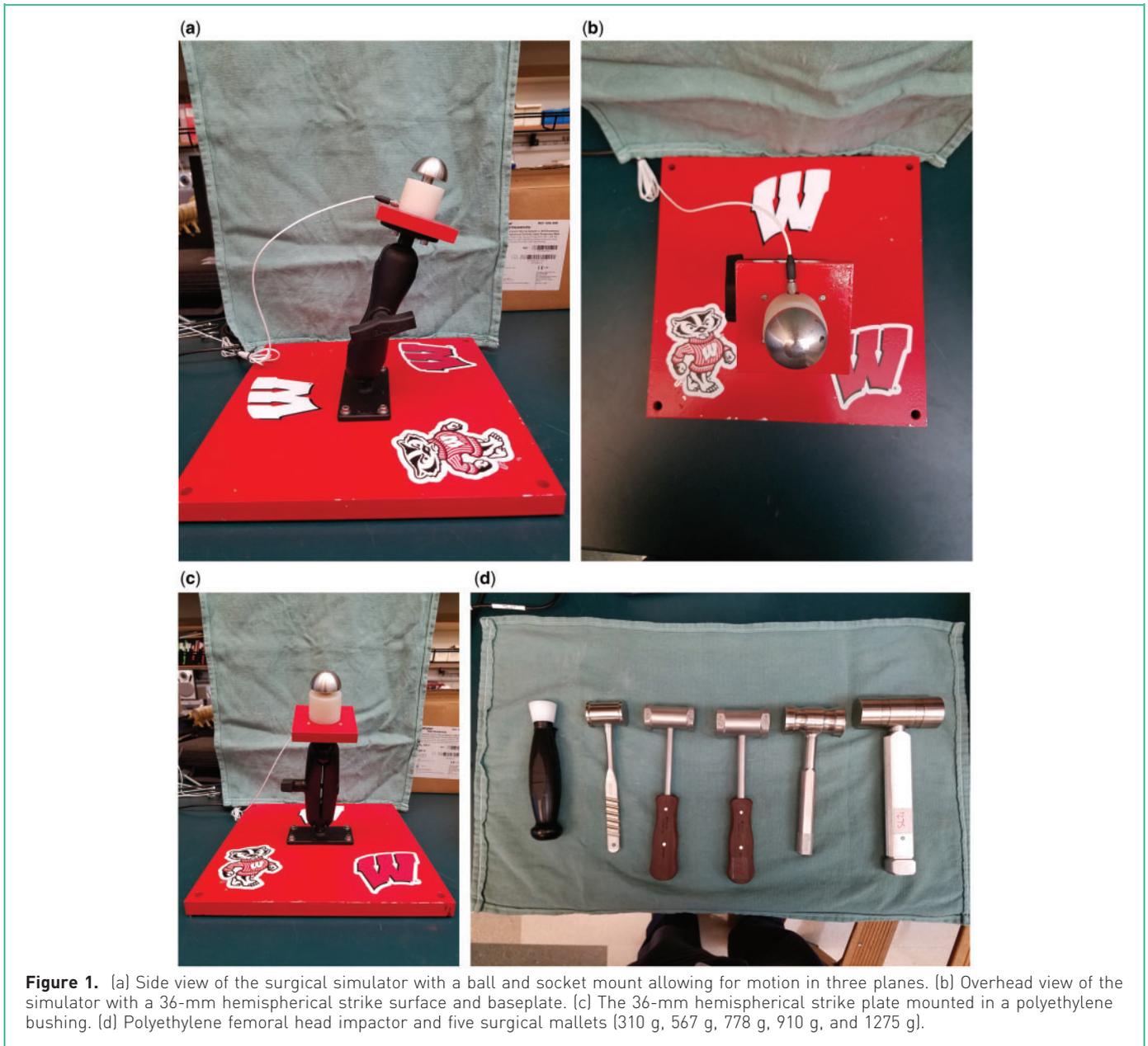


Figure 1. (a) Side view of the surgical simulator with a ball and socket mount allowing for motion in three planes. (b) Overhead view of the simulator with a 36-mm hemispherical strike surface and baseplate. (c) The 36-mm hemispherical strike plate mounted in a polyethylene bushing. (d) Polyethylene femoral head impactor and five surgical mallets [310 g, 567 g, 778 g, 910 g, and 1275 g].

Two separate simulations were then performed, one for coupling a metallic (CoCrMo) head to a trunnion and one for coupling a ceramic head to a trunnion. A sham silver metallic strike surface was placed in the simulator, and surgeons were instructed to strike the simulator as they would during THA surgery when coupling a CoCrMo head to the femoral stem trunnion. The number of mallet blows delivered and the force produced as a result of each mallet blow were recorded. After each surgeon completed this phase of the simulation, the sham metallic strike surface was removed, and a different pink-colored sham femoral head strike surface was placed in the simulator. The surgeon was then instructed to strike the simulator as

they would during THA surgery when coupling a ceramic head to the femoral stem trunnion. The number of mallet blows delivered and the force produced as a result of each mallet blow were recorded. During all simulations, the participants were blinded to the forces produced by their mallet blows. Surgeons were allowed to select a mallet that most closely resembled what they would use in the operating room.

Simulator force data were acquired using LabVIEW (National Instruments; Austin, TX). The software was configured to record a broad spectrum of inputs, including peak force measured by the simulator and the number of

mallet blows each surgeon delivered. Data from the simulator were exported into Microsoft Excel (Microsoft; Redmond, WA).

Statistical analysis was performed in R version 3.3. Percentages and 95% confidence intervals (CIs) of attaining at least a single blow greater than a defined force threshold were reported, and comparison of the percentages between head types was performed with McNemar's test. Comparison of these percentages based on mallet mass greater than or less than 800 g was conducted with generalized estimating equations while controlling for head type and accounting for multiple measures from the same surgeon. Mean (standard deviation) and 95% CI were calculated based on head type, number of THAs, number of ceramic heads, fellowship status, mallet mass, surgical approach/position, and primary stem geometry. Differences between these subgroups were assessed by using repeated measures ANOVA with surgeon as a random effect. Post-hoc subgroup analysis tests were adjusted for multiple testing with Tukey's honest significant difference test.

Weaknesses of the investigation are commensurate with its simulation-based nature. It is difficult to replicate the environmental cues present during THA surgery, and this could have introduced a systematic bias influencing the force measurements. This *ex vivo* simulation measures forces in the context of rigid body contact mechanics. The *in vivo* trunnion–head force contact mechanics have not been defined and are likely to behave in a more complex way than simple rigid bodies as simulated and measured in this system. The more complex *in vivo* system present at the time of THA might significantly dissipate forces of mallet blows experienced at the trunnion–head junction and thereby result in decreased effective coupling forces. This study may be subjected to selection bias because participants were attendees at the hip and knee specialty meetings.

Results

Forty-six fellowship trained hip arthroplasty surgeons and nine non-fellowship trained orthopedic surgeons participated in the study. One surgeon only completed the simulation for coupling a ceramic head. Of the simulation participants, 41 surgeons reported they performed more than 100 THAs per year. Twenty-four surgeons estimated they used more than 100 ceramic heads per year. In order of decreasing frequency, the most common surgical approaches reported by participants were posterior ($n=36$), anterior ($n=16$), and anterolateral ($n=3$). Approach statistics were analyzed based on the patient being positioned in the supine or lateral decubitus position.

Thirty-seven surgeons used a medial-lateral taper geometry stem, 16 used a metaphyseal filling stem, and two used a cemented stem as their primary stem geometry.

During the simulated coupling of a CoCrMo head to THA trunnion, 25.9% of participants delivered at least one mallet blow to the simulator producing an effective coupling force ≥ 4 kN (900 lbF). When simulating coupling of a ceramic head to THA trunnion, 16.4% of participants delivered at least one mallet blow to the simulator producing an effective coupling force of ≥ 4 kN (900 lbF). There was no significant difference between these two groups ($P=0.131$), as surgeons were not more likely to produce an effective coupling force ≥ 4 kN (900 lbF) for either a CoCrMo or a ceramic head.

The mean peak effective coupling force applied by the surgeons during simulated coupling of a CoCrMo head to a THA trunnion was 3.06 ± 1.63 kN (688 ± 366 lbF). For simulated coupling of ceramic heads, the mean peak effective coupling force produced by the surgeons was 2.62 ± 1.41 kN (589 ± 318 lbF). Statistical testing indicated that surgeons applied greater peak effective coupling force during simulated coupling of CoCrMo heads to trunnion compared with ceramic heads ($P < 0.001$).

Post-hoc analysis of the simulation force data revealed wide variation in how hard surgeons strike the femoral head when coupling CoCrMo and ceramic heads to the THA trunnion (Fig. 2). The percentage of surgeons delivering at least one mallet blow resulting in an effective coupling force ≥ 1 kN, 2 kN, 3 kN, and 4 kN is displayed in Table 1.

Mallet selection correlated with production of an effective coupling force (Fig. 3). When surgeons selected a mallet > 800 g compared with a mallet < 800 g, they averaged 1.07 kN (95% CI, 0.34–1.81) (241 lbF, 95% CI, 76–407) higher effective coupling forces ($P=0.004$). During the simulation, 23 separate peak mallet blows to the simulator produced an effective coupling force ≥ 4 kN (900 lbF). Nineteen of these were from a mallet > 800 g. Thus, surgeons who selected a mallet mass > 800 g had more than four times greater odds of reaching the ≥ 4 kN (900 lbF) threshold ($P=0.047$). In addition, surgeons were more likely to reach the 2, 3, and 4 kN thresholds when they selected a mallet mass > 800 g (Table 2).

Surgeons who reported using < 100 ceramic heads per year applied less force during simulated coupling of ceramic heads compared with CoCrMo heads when coupling them to the THA trunnion ($P=0.010$). This is in contrast to the group of surgeons who use more than 100 ceramic heads per year, who apply similar force to CoCrMo and ceramic heads when coupling them to the THA trunnion. Additional post-hoc comparisons are displayed in Table 3.

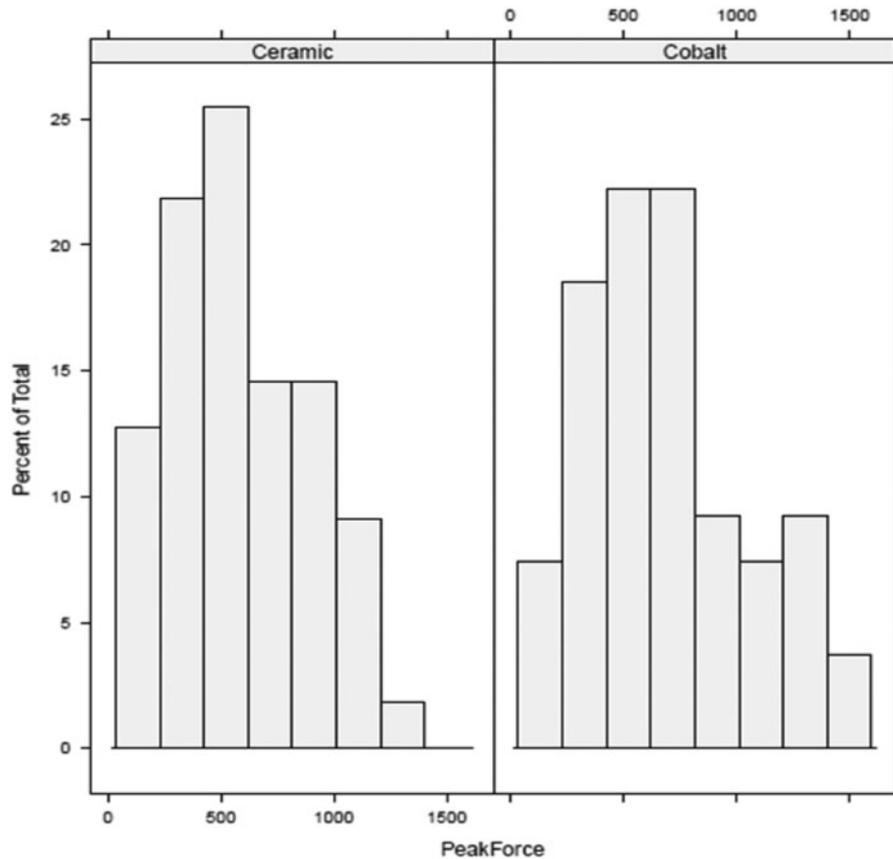


Figure 2. Histogram of each surgeon's effective coupling force (lbF) for cobalt and ceramic heads.

Table 1. Frequency of surgeons applying at least one mallet blow greater than the threshold force for ceramic and cobalt chromium heads

Effective coupling force	Ceramic, % (95% CI)	Cobalt chromium, % (95% CI)	<i>P</i> value ^a
≥ 1 kN (225 lbF)	87.3 (74.9–94.3)	92.6 (81.3–97.6)	0.248
≥ 2 kN (450 lbF)	63.6 (49.5–75.9)	64.8 (50.6–77.0)	1
≥ 3 kN (675 lbF)	38.2 (25.7–52.3)	44.4 (31.2–58.5)	0.343
≥ 4 kN (900 lbF)	16.4 (8.2–29.3)	25.9 (15.4–39.9)	0.131

^aMcNemar's test.

Discussion

There is an increasing body of evidence that the technique by which the femoral head is coupled to the femoral stem can affect the performance of this junction.^{4,7,9,10,12,13} Fluid contamination of the trunnion during head–trunnion assembly has been shown to significantly decrease the resistance required to disassemble the head from the femoral stem.¹³ In addition, it has been shown that inadequate force applied to the femoral head during assembly of the

head–trunnion junction results in lower moments required to precipitate rotation of the femoral head on the trunnion⁴ and smaller forces required to disassemble the head from the trunnion.^{4,9,11,12,14} Motion at the head–trunnion junction has been previously speculated to play a critical role in mechanically assisted corrosion,¹⁵ which is associated with increased blood cobalt and chromium levels,¹⁶ material fatigue, and gross mechanical failure,⁵ as well as adverse local tissue reactions.³

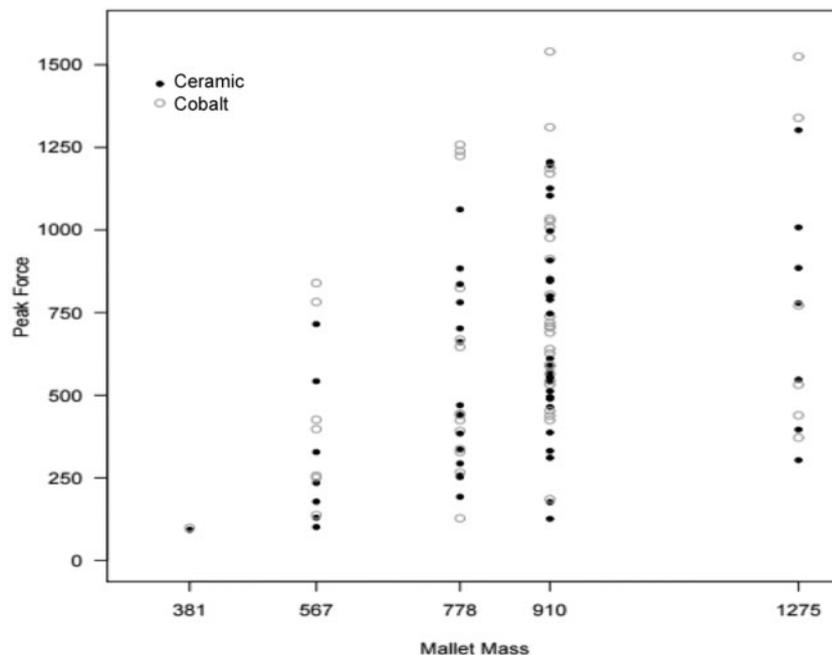


Figure 3. Scatter plot of the effective coupling force (lbF) versus mallet mass with 1, 2, 3, and 4 kN thresholds identified.

Table 2. Odds ratios of achieving an effective coupling force with mallet mass >800 g with mallet mass <800 g as the reference

Effective coupling force	Odds ratio (95% CI)	P value
≥1 kN (225 lbF)	4.68 (0.77–28.47)	0.094
≥2 kN (450 lbF)	2.77 (0.95–8.08)	0.001
≥3 kN (675 lbF)	2.77 (0.95–8.08)	0.062
≥4 kN (900 lbF)	4.23 (1.02–17.58)	0.047

Values shown in bold type are statistically significant.

We had hypothesized that, during the simulation, all surgeons would apply a peak force of coupling a CoCrMo and ceramic head to a THA trunnion of ≥ 4 kN (900 lbF); therefore, hypotheses 1 and 2 were found to be false. We had hypothesized that surgeons would apply the same force during simulated coupling of CoCrMo and ceramic heads to a trunnion; therefore, hypothesis 3 was found to be false.

Previous investigations have recommended 4 kN as the minimum safe coupling force necessary for all femoral head and stem material combinations and bearing combinations including large head metal on metal articulations.⁴ The current surgical simulation study of femoral head–trunnion coupling revealed that most participating THA surgeons failed to apply an effective coupling force ≥ 4 kN to either metallic (74%) or ceramic (85%) femoral heads. For well-

functioning and optimally positioned 36 mm MoP, CoP, and CoC bearings that have relatively low frictional torque,¹⁵ the minimum safe force necessary to produce optimal head–trunnion coupling may be as low as 2 kN;⁴ however, another study suggests 2.5 kN as the minimum safe effective coupling force.¹¹ The present study demonstrates approximately 35% and 60% of participants failed to produce 2 kN and 3 kN coupling forces, respectively. If the participants in the present study are representative of THA surgeons as a whole, suboptimal coupling of the THA head–trunnion junction is likely to be a common occurrence.

Ex vivo investigations of the head–trunnion junction have improved our understanding of its mechanical properties and the forces required for optimal coupling; however, these investigations have not characterized how the head–trunnion junction behaves at the time of THA. Previous studies of the mechanical stability of the head–trunnion junction used to provide estimates of minimum safe coupling forces have been performed in idealized laboratory settings.^{4,7,9,10,13} These investigations have used mechanically applied coupling forces that are co-linear with the central head–trunnion axis in the presence of rigid body contact mechanics. During THA surgery, it is likely that significant loss of force occurs at the time of head–trunnion coupling as a result of plastic and elastic deformation of hard and soft hip tissues as well as mallet blows that may not be co-linear with the central head–trunnion axis. Force

Table 3. Mean effective coupling force (lbF/kN) for post-hoc subgroup comparisons

Post-hoc subgroup	Mean peak effective coupling force (lbF/kN)		
	CrCoMo head	Ceramic head	P value
< 100 THAs/year (n=14)	744/3.31	640/2.85	< 0.05
> 100 THAs/year (n=41)	669/2.98	571/2.54	
< 100 ceramic heads/year (n=31)	692/3.08	575/2.56	< 0.01
> 100 ceramic heads/year (n=24)	692/3.08	607/2.70	
Non-fellowship trained (n=9)	732/3.25	496/2.21	< 0.01
Fellowship trained (n=46)	679/3.02	607/2.70	
Mallett mass < 800 g (n=22) ^a	537/2.39	449/2.00	
Mallett mass > 800 g (n=33) ^a	789/3.51	682/3.03	< 0.05
Wedge taper stem (n=37)	658/2.93	580/2.58	
Filling/cemented stem (n=18)	749/3.33	607/2.70	< 0.05
Supine position (n=15)	751/3.34	637/2.83	
Lateral decubitus position (n=40)	663/2.95	569/2.53	< 0.05

P values < 0.05 are significant.

^aP < 0.05 when comparing the mean peak effective coupling force for CoCrMo heads with mallet mass > 800 g and < 800 g.

measurement techniques in the current investigation effectively resolve off-axis mallet blows into the force acting along the central head–trunnion axis but do not account for loss of force as a result of hard and soft hip tissue deformation at the time of head implantation. Therefore, a mallet blow that generates an effective coupling force measuring 2 kN in the current simulation may result in a smaller effective coupling force at the time of THA surgery, thereby resulting in suboptimal coupling of the head–trunnion junction.

Strengths of this investigation are multiple. This is the first study to the authors' knowledge to utilize a force measurement technique that quantifies the force vector imparted along the central head–trunnion axis as a result of a mallet strike that may be divergent from the central head–trunnion axis. The current study uses an adjustable simulator capable of reasonably replicating the intraoperative positioning of the femoral head and trunnion so that all simulation participants may address the strike surface as they would during their usual surgical head–trunnion coupling routine. This study allowed surgeons to choose a mallet they felt closely matched the mass and inertia characteristics of their customary surgical mallet, whereas previous studies on this topic have used a single instrumented mallet that may not have the appropriate mass or inertia characteristics for most surgeons. Lastly, this investigation sampled the surgical practice technique of more than 50

THA surgeons from a wide variety of geographic regions and with a broad spectrum of surgical experience and volume.

Conclusion

Inadequate force applied to the modular femoral head–trunnion junction leads to suboptimal resistance of this junction to motion, which can precipitate gross mechanical or biologically mediated THA failure. This investigation demonstrates that many THA surgeons do not strike this junction with enough force to produce optimal coupling of the femoral head to the femoral stem at the time of THA.

Conflict of interest

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. No conflict of interest declared.

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