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Mechanical Performance of Ceramic Acetabular Liners under Conditions of Impingement

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Abstract

Although new generation alumina ceramics have exhibited a reduced incidence of fracture, concern still persists about the behavior of ceramic acetabular liners under impact-impingement conditions. The objective of this study was to explore if fracture of a new generation alumina ceramic liner was likely to occur *in vivo*.

Ceramic liners were impacted with forces of 23, 21, 15, and 12 kN (n=3 at each force). At 23 kN, all three ceramic liners fractured on the first impact; at 12 kN none of the ceramic liners fractured after 20 impacts. The threshold force of 12 kN is large in comparison with estimated physiological forces on the hip during falls or stumbling, suggesting that ceramic liner fracture caused by impingement is unlikely to occur *in vivo*.

Keywords: ceramic acetabular liner, impingement, impact, total hip arthroplasty, alternate bearings, alumina.

Introduction

Alumina ceramic (Al_2O_3) is a hydrophilic, low friction, thermodynamically and chemically stable material [1]. Medical grade alumina for joint replacements has a smooth surface finish [2] and, when implanted as the articulating surfaces of a total hip replacement, generally exhibits reduced wear rates compared to more traditional metal-on-plastic bearing materials [3,4]. A disadvantage of ceramic joint replacements, however, is their clinical history of sudden fracture – both of the femoral head and of the acetabular component.

The early incidence of ceramic head fracture was as high as 13% in the 1970s [5]. Most of these fractures were attributed to large grain size, impurities, poor manufacturing tolerances between the ceramic head and the metallic trunnion, inadequate process control, poor design, and surgical error [6]. Improvements in manufacturing have led to much smaller grain sizes (less than $1.8 \mu\text{m}$ in the 1990s compared to $4.5 \mu\text{m}$ in the 1970s). Combined with higher raw material purity, improved manufacturing tolerances and 100% proof testing of ceramic heads [7], the current incidence of ceramic head fracture is reported to be less than 0.01 % [8].

Evidence of femoral neck-acetabular rim contact (or ‘impingement’) has recently been recognized as a common occurrence in total hip arthroplasty, with impingement observed in as many as 56% of retrieved polyethylene acetabular liners [9,10]. Impingement between a metallic femoral neck and the rim of a polyethylene liner may generate additional wear debris [9, 11]. Impingement might also generate increased shear stresses at the implant-bone interface, though given the ductile nature of polyethylene; the problem should not be as severe as with a ceramic liner. Likewise, fracture of a polyethylene liner is usually localized to the site of impingement, leading to pitting and delamination. However, fractures of ceramic liners

often lead to complete disruption of function, with a reported incidence as high 1% in the 1970s [5, 12, 13].

The possibility of ceramic liner fracture due to neck/liner impingement has resulted in features designed to protect the rim of the ceramic liner from impingement: a recessed ceramic liner (where the non-recessed metallic shell becomes the contact site for impingement); a polyethylene layer that covers the face of the ceramic liner; and a sandwich concept where a layer of polyethylene acts as a cushion between the ceramic liner and metallic shell [14]. These design features may be unnecessary if the new generation of ceramic liners is sufficiently strong to resist fracture. More importantly, they may reduce the chances of liner fracture, but at the expense of limiting implant longevity, for example, by introducing the potential for polyethylene wear and osteolysis into an otherwise polyethylene-free joint.

No published data exist to establish the impact resistance of ceramic acetabular liners or to justify the need for features designed to protect the rim of the ceramic liner from fracture. In this study, we designed a test that simulates impact-impingement of ceramic liners by the neck of the femoral component. Our aim was to establish the efficacy of the test in exploring if fracture of a new generation alumina ceramic liner was likely to occur *in vivo*. The experimental design was intended to establish a threshold force below which the ceramic liner did not fracture under multiple impacts and to compare this threshold force to forces likely to occur physiologically, thus establishing whether or not fracture would likely occur *in vivo*.

Materials and Methods

The acetabular component was a modular design; a titanium alloy shell into which an alumina ceramic liner is press-fit at the time of surgery. Each ceramic liner (n=12) was inserted into its metallic shell using a CeraLock Insertion Instrument (CeramTec, Plochingen, Germany) with three arms that contact the face of the liner and a trigger that, when pressed, releases the liner into the shell. Each liner was then tapped gently into place using a custom-designed insertion device that uniformly contacted the rim of the liner (Ceramtec, Plochingen, Germany). The assembled acetabular component was seated into a hemi-spherical cavity in a custom designed aluminum holder (Fig. 1), and a locking rim was placed over the face of the shell to fix it securely to the holder. The holder was pinned and bolted to the base of the testing machine.

A replica of the femoral neck (hereafter referred to as the indenter) was machined from precipitate-hardened stainless steel (17-4PH 42-44RCX). The indenter was designed with a radius of curvature of 6 mm on the impact face. The back end was threaded for attachment to the upper platen. The fixation points for the acetabular holder and the indenter to the test machine were designed so that the impact site on the liner rim was aligned with the central axis of the test machine. This ensured that the ceramic liner was impacted at a reproducible location at the corner of the ceramic rim, and that during impact any unwanted indenter deflection was avoided.

The ceramic liners were tested using a drop weight impact machine (Rosand, Gloucestershire, UK) capable of impacting specimens at velocities of up to 4.4 m/s in a free-fall configuration over a drop height of 2 m. The upper platen was electronically driven by a cable system to a predefined height and clamped. Upon activation, the platen with the indenter was released and

allowed to fall towards the liner. The leading face of the upper platen and indenter passed optical transducers, preset to a height of 1 mm above the impact site, that were used to trigger data acquisition. Loads were recorded continuously using a piezoelectric load washer (Kistler 9061A, Kistler, Amherst, NY). A high-speed digital camera (Motionscope PCI series, Redlake Imaging, Vianen, The Netherlands) visually recorded the impact at a rate of 1000 images per second.

Four loading conditions were simulated with impact velocities of 1.25, 1.04, 0.79, and 0.61 m/s, which resulted in average maximum impact forces of 23, 21, 15, and 12 kN, respectively. Three ceramic liners were tested at each condition. After each impact, video footage of the impact was reviewed frame-by-frame to ensure that a single impact occurred; and the liner was macroscopically and microscopically examined for evidence of fracture. If no damage was evident, the ceramic liner was re-impacted under the same conditions. Since the impact machine was not designed for repeated impact tests, a condition was established to indicate the completion of a test: if a ceramic liner exhibited no damage after 20 impacts, it was considered to have survived the test.

Results

Force vs. time plots (Fig. 2) for the three liners impacted at the highest force show similarity in terms of duration of impact (1.0 ms), peak force ($23 \text{ kN} \pm 1.5 \text{ kN}$), and loading rate ($49 \text{ MN/s} \pm 5 \text{ MN/s}$). The time to peak force for all four loading conditions averaged 0.5 ms ($\pm 0.03 \text{ ms}$).

In the 23 kN group, all three ceramic liners fractured on the first impact (Fig. 3). At 21 kN, one sample fractured after seven impacts, while the other two samples did not fracture after 20

impacts. At 15 kN, one sample fractured after four impacts, but again the other two samples did not fracture after 20 impacts. Finally, at 12 kN, none of the three samples fractured after 20 impacts.

None of the impacts except those that caused fracture created any evident damage on any of the liners. Fracture of the ceramic liner did not result in gross dislodgment of ceramic pieces; the ceramic pieces remained contained within the acetabular shell (Fig. 4). Even after fracture of the liners, considerable manual force was required to break the taper lock between the liners and the shells.

Discussion

A new generation modular ceramic acetabular replacement was subjected to a novel test to establish the impact resistance of the liner. A threshold of 12 kN was established below which the ceramic liners did not fracture even after 20 impacts. Whether this threshold is sufficient to ensure that the ceramic liner design can withstand *in vivo* impact conditions hinges upon the clinical relevance of the test conditions i.e., the likelihood that an acetabular liner would be subjected *in vivo* to a 12 kN impingement force at an impact velocity of 0.6 m/s and a time to peak force of about a half a millisecond.

The impingement forces on the acetabular component of a total hip replacement have never been directly measured. Hip joint forces of up to 8 times body weight (4.4 kN to 4.8 kN) occurred when two patients, who had received telemeterized hip replacements, stumbled while data were being recorded from their implants [15]. Even if a total hip patient was to stumble and the neck was to impinge the acetabular liner with this amount of force, a factor of safety of

2.5 would exist (the ratio of the 12kN threshold force to the 4.8kN functional force from the stumble).

Another approach to establishing the clinical relevance of our findings is to compare the threshold force to that estimated from biomechanical models. For example, estimates from a numerical spring-damper model of the peak impact forces on the greater trochanter in a sideways fall from standing height ranged from 2.9 kN to 9.9 kN depending on patient weight, impact velocity, and soft tissue coverage [16]. Even if a total hip patient were to fall during which the neck impacted the liner, the safety factor remains above one ($12\text{kN}/9.9\text{kN} = 1.21$).

A numerical mass-spring-damper model was combined with input data derived from a pelvis release experiment in which subjects lay on their side and were released from a small height onto a force plate [17]. The model was extrapolated to quantify the forces that the proximal femur would experience in a fall. Peak forces for male and female subjects when falling with their muscles relaxed increased from 2 kN to 6 kN as the fall height increased from 0.1 m to 1.2 m. These values are again well below the threshold force measured in our study (safety factor = $12\text{ kN}/6\text{kN} = 2$). However, when a male subject with clenched muscles falling from a height of 1.2m was modeled, peak forces of 16 kN were estimated. Although this value exceeds the threshold measured in this study, it is likely that the femur or pelvis (rather than the ceramic liner) would fracture under these loads [18, 19, 20].

In another study, volunteers were induced to fall in a variety of configurations and the velocities of their pelvi were measured at impact [21]. Impact velocities averaged 1.51 ± 0.50 m/s across a number of types of disturbances and gait speeds associated with the fall. The

impact velocities simulated in the our study – 1.25 m/s to 0.61 m/s – are similar, suggesting that the impact velocities used in the ceramic liner impingement tests reasonably simulated a fall. However, soft tissues and elastic/plastic bone deformation absorb impact forces, a feature not included in our experimental method; the rate at which impact forces are transmitted to the liner (or the time to reach peak force during the impact) are, therefore, a feature of this test design that requires further consideration.

No direct measures have been made of the time to peak force as experienced in the acetabular component of a total hip replacement during a fall. However, the mass-spring-damper model [17] showed that the time to peak force that might be experienced by a femur during a fall ranged from about 12 ms to 28 ms. The impact measured in our study was almost two orders of magnitude faster than this at 0.5 ms. During a stumble, a time to peak force of 0.25 s was measured for the implanted telemetrized hip [15] again, many times slower than measured in our experiment. We might assume, however, that a small time to peak force simulates the case where no other structures exist between the ground and the acetabular liner – thus no element of the impact force is absorbed before it reaches the acetabular rim.

The strain rate dependency of ceramic strength is largely determined by the rate of sub-critical crack growth [22]; the faster ceramic is loaded, the less time is allowed for slow crack growth, therefore the stronger the material behaves [23]. However, little information exists in the literature to suggest whether alumina exhibits strain-rate dependency under impact. More importantly, since the rate of loading during a fall or other traumatic event is unknown, the effect that the seemingly high load rate simulated in our study may have on the threshold force cannot be estimated.

A limitation to our study was the small number of components that were tested, necessitating repeated impacts on the same specimen and precluding any statistical analysis of our results. Acquiring ceramic liners represents a significant cost, and damage to test fixtures by repeatedly removing and inserting liners is a definite drawback. Nonetheless, our experimental results showed a well-delineated threshold below which fracture did not occur and above which fracture was a distinct probability.

In a study of 190 elderly residents in geriatric centers, the rate of falls was 0.66 per person per year [24]. Even if each fall resulted in hip impact, it would take at least 30 years before the hip was exposed to the 20 impacts simulated in our study. The authors believe that 20 impacts is a reasonable cut-off point for the tests herein described. Caution should be used, however, in drawing too strong a conclusion; if we had increased the number of impacts beyond 20, we may have created fractures below our stated threshold.

In conclusion, we designed a test to simulate impact-impingement of the femoral neck on the ceramic liner and applied the test to a series of a dozen liners. The liners fractured at an impact force of 23 kN, but below a threshold force of 12 kN, fracture did not occur, even after repeated impact cycles. This threshold force is large in comparison with most estimated physiological forces to which the hip is subjected during falls or stumbling, suggesting that ceramic liner fracture caused by impingement is unlikely to occur *in vivo*.

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Figure Legends

Figure 1: Acetabular holder and indenter. Note: a ring is placed over the face of the ceramic liner and bolted to the dark grey zone of the shell.

Figure 2: Force plotted against time for three ceramic liners that fractured on first impact (on average 23 kN forces were applied at impact velocities of 1.25 m/s). The entire impact lasted an average of 1.0 ms.

Figure 3: Maximum force applied to each sample at impact plotted against the number of impacts for all twelve ceramic liners. The average threshold force, below which no fracture occurred, is marked as a dark horizontal dashed line.

Figure 4: Examples of fractured liners. Cracks were stained to aid in visualization.

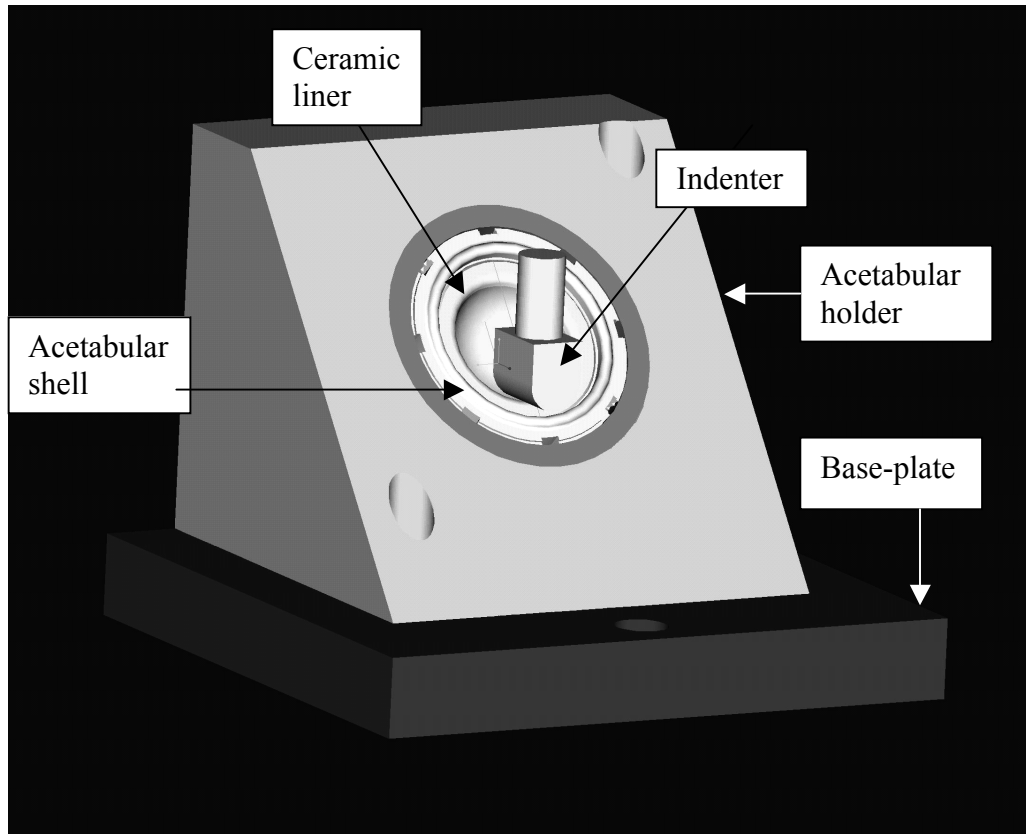


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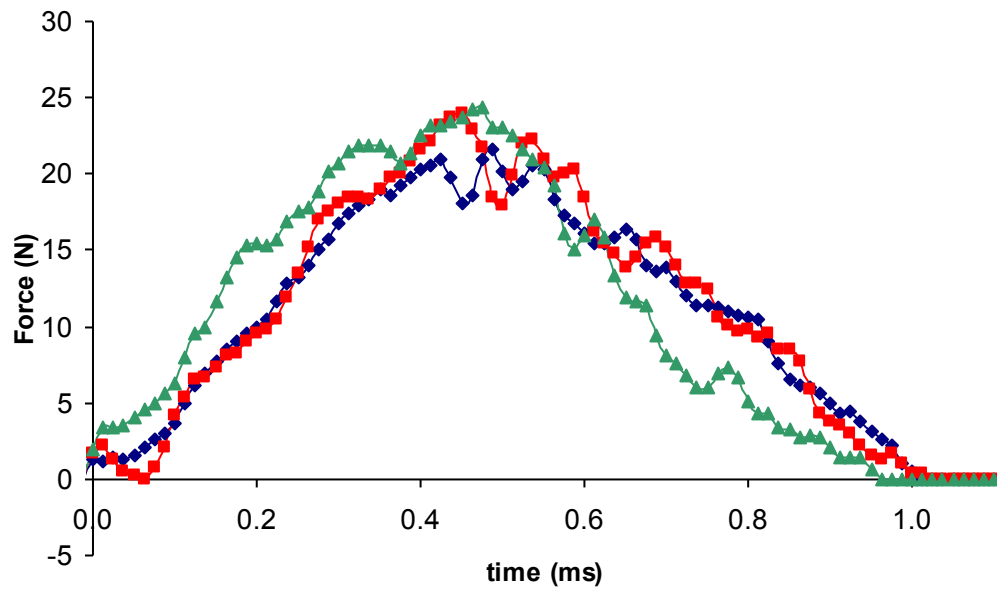


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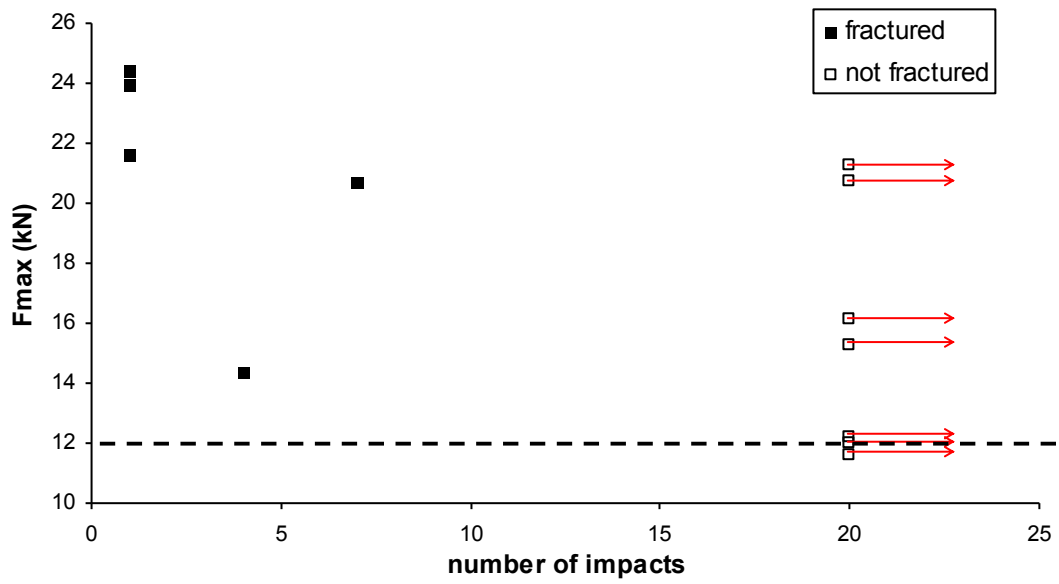


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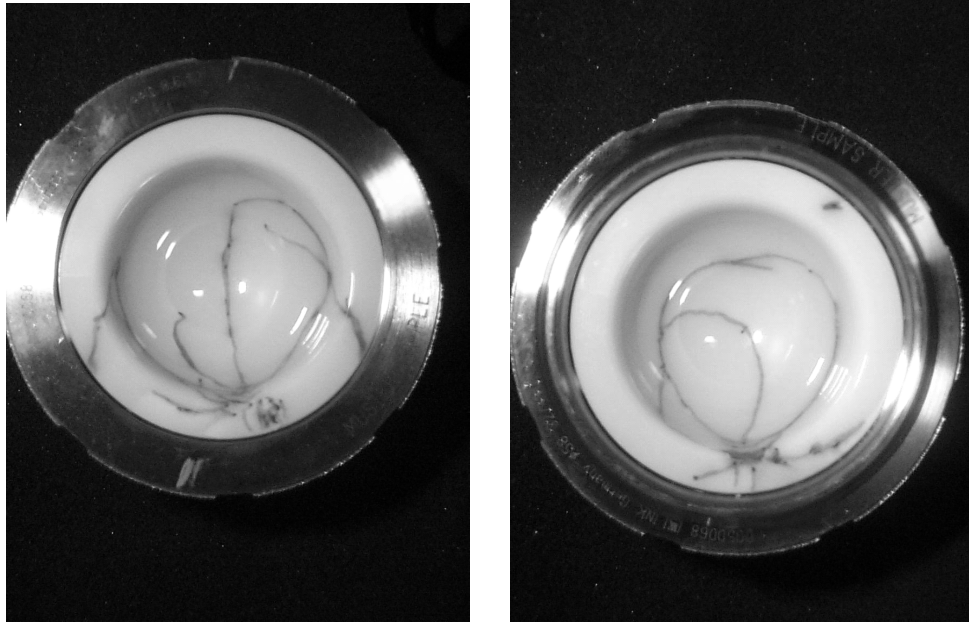


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