An Impact Testing Protocol for Evaluating the Fracture Resistance of Ceramic Femoral Components for Use in TKA

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Introduction: The purpose of this study was to evaluate the fracture resistance of a ceramic femoral component for use in TKA. Magnesia-stabilized zirconia (Mg-PSZ; ASTM F2393) has been shown to be stable in clinical use as a bearing surface in the hip [1], and recent knee wear simulator tests showed Mg-PSZ to have superior wear properties compared to cast cobalt chromium alloy (CoCr; ASTM F75) femoral components [2,3]. However, the recent fracture of a zirconia-toughened alumina (ZTA) femoral component due to a hard fall [4] underscores the need for robust mechanical testing of ceramic femoral components. Given the higher fracture toughness of Mg-PSZ compared to ZTA, we hypothesized that Mg-PSZ would withstand the typical loads experienced during press-fit implantation in TKA, and would not fracture in tests that simulate a hard fall on one knee.

Methods: Mg-PSZ femoral components (Symmetric Knee, Signal Medical Corp.) were manufactured specifically for these tests, and included plasma sprayed titanium porous coatings on the backside, packaging and sterilization with EtO gas. One femoral component of the same design but made of cast CoCr was also used for comparison purposes. Fourth-generation biomechanical femurs (Pacific Research Labs) were used as analogues for real bones [5], with their distal surface cut to receive a femoral component. After cutting the distal femur to length and potting the cut end in a fixture with acrylic cement, the biomechanical femurs were fixtureed to the load cell of a hydraulic test platform (Instron 8501) for seating/“implantation” tests. One surgeon was responsible for seating the femoral components with a series of hammer blows using femoral drivers, as in a standard TKA procedure, gradually increasing the applied force until the measured impact forces were well beyond that which was reported to be typical in TKA (2.6 kN) [6]. Force data from each group of hits were acquired at 14.4 kHz (DATAQ). The maximum force was also recorded.

After implantation, the biomechanical femurs were sectioned at the base of the potting fixture and sent to a crash test lab for dashboard impact tests [7]. These tests, where a pendulum is raised to a specified height and released so that its plate strikes one knee of a crash test dummy, were originally designed to predict fracture of the femur in an automotive crash when a knee strikes the knee bolster or lower dashboard, with the NHTSA specifying a maximum allowable force of 10 kN in the femur [8,9]. In the current study, dashboard impact tests were used to reproducibly model a patient falling hard on one knee. The cut end of the biomechanical bone was attached to a load cell on the femur of a 50th
percentile male Hybrid III dummy, with force also recorded at the pendulum along with g forces from accelerometers (sampling rate: 20 kHz) and pendulum velocity at impact (Figure 1). Each Mg-PSZ femoral component was hit five times, with the 26.2 kg pendulum raised slightly higher after each impact until a velocity of about 3 m/s and a force in excess of 10 kN was recorded at the femur’s load cell. High speed video was also recorded at peak impact forces. Specimens were then inspected for cracks in the ceramic and in the biomechanical bone.

Figure 1. Typical dashboard test setup, with the pendulum’s plate at rest against the ceramic femoral component.

Results: A total of seven Mg-PSZ femoral components were seated/“implanted” in biomechanical femurs, plus one CoCr component for comparison. Two of the Mg-PSZ specimens that were seated on improperly prepared femoral surfaces fractured at peak load (mean value of 10.3 kN), but did not shatter. Analysis of the fractured components revealed that the components were wedged open from within. The other five specimens sustained a mean peak load of 11.4 kN without fracturing. The CoCr component was implanted with hammer blows typical of those used in TKA, with peak loads of 8.8 kN. Thus far, a total of three Mg-PSZ femoral components have been subjected to dashboard impact tests. All sustained impacts in excess of 10 kN without fracture of the ceramic component. At the mean impact velocity of 3 m/s, the average forces recorded by the pendulum and by the femoral load cells were 12.3 kN and 11.1 kN, respectively (Figure 2). Fracture of the biomechanical bone was observed in two of the specimens, as a transverse supracondylar fracture on the medial side, and a crack below the lateral posterior condyle on a different specimen.

Discussion: This study was intended to evaluate the fracture resistance of Mg-PSZ ceramic femoral components during initial seating/implantation as part of TKA, and post op by simulating a hard fall on
one’s knee. Two of the Mg-PSZ femoral components fractured during implantation on improperly cut bone surfaces due to wedging open from within. This illustrates the importance of precise cuts for cementless/press fit implantation. However, they fractured at loads in excess of the NHTSA’s criteria for femoral fracture in an automobile wreck [9], suggesting that any patient whose femur experiences that magnitude of forces may well have more important problems. Finally, the measured “typical” impact force for seating a standard CoCr femoral component (7.7 kN) was found to be a factor of three higher than a previously reported value (2.6 kN) [6]; however, that study evaluated oxidized zirconium femoral components, which was not available as a cementless design at that time. Thus, the previously reported value of 2.6 kN may only be valid for seating of cemented designs.

None of the three specimens that have also been subjected to dashboard impact tests fractured as part of the test. Additional dashboard impact tests are expected to be completed soon, and will be included in revisions of this abstract. A cadaver study examining injuries sustained to intact knees in a dashboard test found impact loads in excess of 10 kN to cause fracture of the femoral head or neck [7], rather than at the distal femur. However, such a fracture mode was not possible in the current study. This study could be further improved by comparing press-fit Mg-PSZ femoral components to cemented ZTA femoral components in a dashboard impact test. However, such ZTA components are currently unavailable in the USA.

**Significance:** This study is the first to suggest a protocol to evaluate the fracture resistance of ceramic femoral components. Given its superior wear performance in knee simulator tests, Mg-PSZ ceramic femoral components may be indicated for younger/more active patients. Ceramic femoral components may also be appropriate for patients with sensitivity to metal ions and particles released from the surface of CoCr femoral components during normal use and wear [10].