

3D Printed Fixtures for Repeatable Testing of Cemented Exeter® Hip Stems

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INTRODUCTION: Total hip arthroplasty (THA) is a surgical procedure commonly used to treat end-stage osteoarthritis of the hip, or displaced intracapsular femoral neck fractures, where it involves implanting a composite beam or taper-slip stem to the hip joint using poly(methyl methacrylate), PMMA cement to provide stability and mobility [1]. For preclinical testing of orthopaedic implants, there are potential errors from misalignment of axes for the samples during mechanical testing [2]. Maximum pullout force testing is one preclinical assessment used to compare stem-cement fixation strength. Therefore, the purpose of this study was to develop a repeatable method to reduce variance during testing and to support and fix synthetic femurs in preclinical analysis of implants.

METHODS: Four fixtures were designed for: short (125 mm) and standard (150 mm) Exeter® V40 femoral stems, and the proximal and distal ends of a synthetic femur (Sawbones, USA). To produce consistent testing results, the fixture design requirements were: guide consistent cuts on femoral stems and synthetic femurs; provide stable support under constant compressive loading of 1335 N to the femoral neck taper during a 14 day incubation period; and, allow compatibility with the Bionix Servohydraulic Test System (MTS). Twelve cemented femoral stems (short, N=6 and standard, N=6) were used to validate the repeatability of the fixtures; where, the variance in maximum pullout forces were recorded and the stem subsidence pre and post compressive loading of the cemented femoral stem was measured with a vernier caliper. The femoral stems and the synthetic femur were first 3D laser scanned with the SG100 ShapeGrabber and then the scans were compiled (PolyWorks v12) to create digitized 3D solid models. Negative molds of each femoral stem and the proximal and distal ends of the synthetic femur were created (SolidWorks 2020). All fixtures consisted of two halves, each having holes and dowels with a locational fit for assembly (**Fig. 1**). The fixtures were 3D printed with the J850 PolyJet Technology machine using the “Vero” material. The fixtures for the two femoral stems served as guides for milling a notch (plane 8 mm x 10 mm, 10 mm deep, perpendicular to the stem axis) and a tapped M6 threaded hole. This fixture guided the alignment of the axis of the M6 threaded hole such that it was parallel to the center axis of the femoral stems to follow surgical procedures. Additionally, the M6 threaded hole was used to attach the stem to the MTS. For the proximal end fixture, two resection planes were defined using the anatomical landmarks from the digitized 3D model (**Fig. 2**). The first resection was a horizontal plane (defined as the plane passing through the distal most points of the medial and lateral condyles, perpendicular to the femoral bone axis) at the middle of the greater trochanter of the femur (“Cut 1” in **Fig. 2**). The horizontal plane of the resected proximal synthetic femur was also used to guide the insertion depth of the femoral stems by alignment with the femoral stem’s horizontal notch. Stem subsidence pre and post compressive loading was measured relative to this “Cut 1” resection plane. The second proximal resection was a 45° plane from “Cut 1” through the femoral neck at the lesser trochanter, following surgical procedures. The distal end fixture was designed to make a horizontal plane resection, 70 mm from the distal end of the femur. This resection aligned the direction of the constant compressive loading with the axes of the femoral stems and the M6 threaded hole. Six distal end fixtures were 3D printed to fix the distal end of the synthetic femur with cemented femoral stems during the compressive loading phase (**Fig. 3**). All twelve synthetic femur resections were performed by an experienced orthopaedic surgeon.

RESULTS: The four fixture designs aided consistent and repeatable resections of the short and standard femoral stems and the synthetic femur. The fixtures also provided compatibility with the MTS for testing. The distal end fixtures provided stability and support under the constant compressive loading of 1335 N throughout the 14 day incubation period. 1-3 mm of stem subsidence was measured after this period. The consistent cementing process of the short and standard femoral stems resulted in minimal variance with the maximum pullout force of 3940 ± 1178 N and 4910 ± 1309 N, respectively.

DISCUSSION: The presented 3D printed fixture designs demonstrate a promising and novel method for consistent and repeatable biomechanical testing of orthopaedic implants. The femoral stem fixtures guided the machine for the notches and M6 threaded holes. The fixtures acted as stable clamps and protected the stems from damage. The proximal end fixture was effective, efficient, and repeatable for the resections. Each synthetic femur was resected at the same position with the help of the proximal end fixture. Similarly, the distal end fixture ensured that the synthetic femur was aligned with the compressive loading direction, the stem axis, and the axis of the M6 threaded hole. To improve the functionality of the distal end fixture, a wider base would increase its stability.

CLINICAL RELEVANCE: This study presented a novel 3D printed fixture design and demonstrated its benefit to promote repeatable alignment of bone-implant systems for reduced variance in preclinical orthopaedic implant testing. This approach was performed on cemented hip stems, but could be adapted for biomechanical testing of various types of implants.

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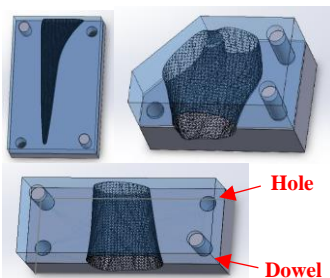


Fig. 1. 3D printed fixtures (clockwise: 125 mm Exeter® Short Stem, Proximal end, Distal End).



Fig. 2. Resections on synthetic femur (Sawbones, USA).



Fig. 3. Distal end fixture during constant compressive loading phase in incubator at 23°C.