

Mechanical Disassembly of Retrieved Long-Stem Total Knee Replacements with Taper Modularity

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Statement of Purpose: During revision total knee replacement (TKR), patients with poor bone quality or defects leading to complications with achieving fixation often require the use of modular TKR components that incorporate intramedullary stem extensions for improved stability and bone fixation [1]. Although taper-locking junctions are commonly utilized to attach modular stem extensions in joint prostheses and osteosynthesis hardware, there have been clinical reports of fretting and corrosive activity as a result of mechanical instability [2,3,4]. Because these corrosion mechanisms release metallic particulate debris causing adverse tissue reactions and impact device longevity [5,6] careful monitoring of modular taper-lock junctions in TKR is warranted. The purpose of this study is to evaluate explanted tibial and femoral modular long-stem TKR components and characterize the mechanical stability of the taper-lock junctions by measuring the force required to disassemble the junctions.

Methods: In this institutional review board approved study, 17 tibial and femoral modular long-stem TKR components were retrieved from 10 patients during revision surgery after an average of 35 ± 42 months of in vivo function. Three different modular taper designs were identified, labeled A, B, and C (Figure 1). A servohydraulic test system (model 8874, Instron Corp., Norwood, MA) was used to disassemble the modular stem extensions following international test standards (ISO 7206-10:2003; ASTM F2009-00). The test setup was designed to apply a pure axial tensile load and the maximum force required to disassemble the taper-lock junction was recorded for each component. All set screws and bolts engaging the taper junction were removed prior to testing. The difference in the mean disassembly forces for femoral and tibial components was compared using an equal variance t-test.

Results: Two taper-lock junctions disassembled under the preload condition of 150N and two were designed with the stem locking to the base via a threaded interface, and thus were disassembled by hand. For the remaining 13 components, maximum disassembly forces to disengage the taper-lock junctions ranged between 390N and 5550N (Figure 2). In general, the taper-lock junctions exhibited linear behavior during testing until the disassembly force was reached, as evidence by a sharp decrease in load. Average disassembly forces for the tibial components were significantly higher than those for the femoral components (t-test, $p=0.020$). There were no correlations between disassembly force and patient demographics or prosthesis in-situ time.

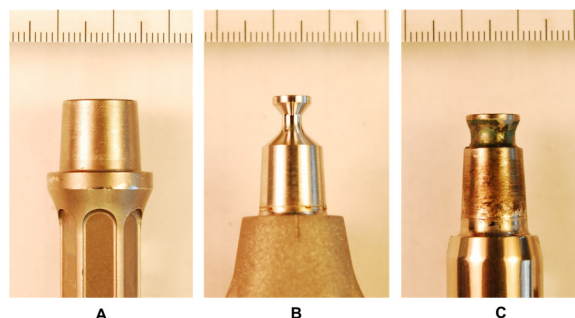


Figure 1. Taper designs involved in the study. Tick marks are in 1mm increments. Design A: Through bolt with male taper on stem and female taper on base; Design B: 1 set screw with female taper on stem and male taper on base; Design C: 2 set screws with male taper on stem and female taper on base.

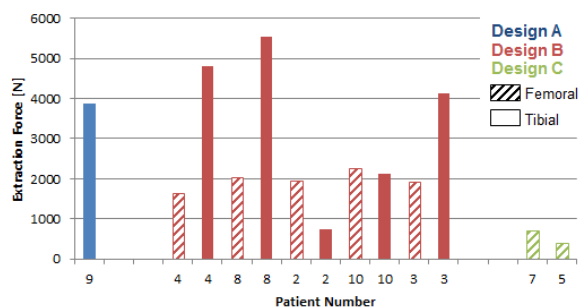


Figure 2. Maximum disassembly forces grouped by design type.

Conclusions: Based on these results it is evident that taper junctions have varying mechanical strength even within the same design. These measured load magnitudes are within the range previously reported for modular taper-lock junctions of hip stems [3,7]. Although there was no visual evidence of gross failure of any taper-lock junction and all appeared to have endured the prior physiological loading without metal fracture, gross changes degrading the surface finish of several modular taper-lock junctions were noted.

References: [1] Jazrawi, et al. *J Arthroplasty* 2001. [2] Harman, et al. *J Biomed Mater Res: Appl Biomater* 2011. [3] Lieberman JR, et al. *Clin Orthop* 1994. [4] Jones, et al. *J Bone Joint Surg* 2001. [5] Kop, et al. *J Arthroplasty* 2009. [6] Jani, et al. *Modularity of Orthopedic Implants* 1997. [7] Csernica et al. *Orthopaedic Research Society* 2013.

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