Development of Six Degree of Freedom Mechanical Testing for Assessing The Primary Stability of Cementless Tibial Trays

Pleun Hemelaar, BSc¹, Boyin Ding², Richard Stanley³, Clare K. Fitzpatrick⁴, John Costi, PhD⁵, Mark Taylor, PhD⁶.
¹Radboud University, Nijmegen, Netherlands, ²University of Adelaide, Adelaide, Australia, ³Flinders University, Adelaide, Australia, ⁴University of Denver, Denver, CO, USA.


Introduction: Cementless tibial fixation has been used for over 30 years in total knee arthroplasty. There are several potential advantages including preservation of bone stock and ease of revision. More importantly, for young active patients there is the potential for increased longevity of fixation. However, the clinical results have been variable, with reports of extensive radiolucent lines, rapid early migration and aseptic loosening. Problems appear to stem from a failure to become sufficiently osseointegrated, which in turn suggests a lack of primary stability. In order to achieve boney ingrowth, interface micromotions should be less than 50 microns, whereas fibrous tissue formation is known to occur if micromotions are in excess of 150 microns. The degree of micromotion at the bone-implant interface are dependent on the kinematics and kinetics of the replaced joint. The tibial tray experiences complex six degree of freedom (6DOF) loading as a consequence of activities of daily living (ADL) comprising a combination of axial, anterior-posterior and medial-lateral loads as well as flexion-extension, varus-valgus and internal-external moments. Until recently our knowledge of the magnitude and temporal variation of these forces and moments has been limited, but recent data from telemetric implants [1, 2] have now given detailed information that will prove invaluable for pre-clinical testing. In vitro studies investigating primary stability have used simplified loading conditions incorporating a static axial load in combination with internal-external moments [3, 4], AP shear forces [4, 5] and ML forces [5]. Typically, these studies have used a force equivalent to the peak load which occurs during the stance phase of gait. To date only computational studies have been able to simulate the 6DOF loading conditions for a variety of activities [6]. This study aims to develop an in vitro testing protocol capable of applying six degree of freedom loads for ADL’s in order to assess the primary stability of cementless tibial trays.

Methods: A cadaveric tibia, with no signs of disease or gross defects, was retrieved and stored at -20 degrees Celsius. Prior to testing, the tibia was defrosted and cleaned of all soft tissue. The tibia was implanted with an idealized stainless steel, cementless tibial tray, which had a single conical keel (based on the geometry of the LCS, DePuy Inc). There were no coatings applied to the tray and cone, which only had a course grit blasted finish. The tibia was resected approx. 100mm below the distal tip of the prostheses and potted into a fixture using liquid metal. The mechanical tests were performed on a custom developed six degree of freedom Hexapod Robot (Stewart platform), which has been designed to achieve high load (~20 kN/1500 Nm), high precision (~10 microns) performance and can precisely reproduce the six degree of freedom (6DOF) loads histories of activities of daily living. The distal tibia was rigidly attached to the base of the machine and the tibial tray rigidly attached to the actuator. The 6DOF forces (anterior-posterior, medial-lateral and inferior-superior forces and flexion-extension, abduction-adduction and internal-external moments) associated with the stance phase of level gait were applied directly to the tibial tray, based on data derived from Orthoload.com (subject K2) [1]. Due to the limits of the control system, the forces were applied quasi-statically, with loading frequency of 0.001Hz. All forces and moments were scaled to a peak axial load of 1500N. Previous computational studies have shown the micromotion to be dominated by lift-off the tibial tray. Therefore, the vertical micromotion of the tray relative to the bone on the medial, lateral and anterior aspects of the implant was recorded at a frequency of 2Hz using linear variable displacement transducers, with a measurement resolution of 5 microns.

Results: The Hexapod robot successfully achieved the desired six of degree of freedom loading profile. For example there was an RMS error of 29N for the axial load. The 6DOF forces resulted in anterior liftoff of the tray (Figure 1), with a peak of 332 micron which occurred at approx. 15% of the gait cycle, just after heel strike. The micromotion appeared to be dominated by the applied axial load and the flexion moment, with the peak micromotion occurring due to a combination of a high axial load (1400N) and the peak flexion moment (approx. 12Nm). The other loading components (anterior-posterior and medial-lateral shear forces and abduction-adduction and internal-external moments) appeared to have less of an influence on axial micromotion. The effects of the anterior lift was also evident in the medial and lateral micromotion data, with axial micromotions of 106 and 88 microns respectively, suggesting that the anterior lift off resulted in a wedge shaped gap that extended beyond the AP midpoint of the tray.

Discussion: In order to fully evaluate the behaviour of cementless tibial trays, there is a need for designs to be subjected to all of the forces that occur in vivo for a wide range of activities, including level gait, stair ascent/descent, chair rise and a deep squat. This can be achieved using finite element analysis [6], but to date, reproducing the 6 DOF loading in vitro has been difficult due to the limitations of conventional materials testing machines. Using a 6DOF Hexapod and data derived from telemetric implants,
this study has successfully assessed the micromotions of a tibial tray subjected to the complex loads experienced during the stance phase of gait. The applied loads resulted in an anterior gap being generated as a result of the combination of the high axial loads and flexion moments. There are a number of limitations with this study. Only axial micromotion were assessed and shear micromotions were not measured. The other loading components, particularly internal-external moments and anterior-posterior forces may have a greater influence on shear micromotions. Also, the geometry and surface finish of the tibial tray may not be representative of cementless tibial trays used clinically. However, this pilot study has demonstrated that this approach has potential to explore a wide range of activities and provide a method for validating finite element models of the implanted proximal tibia subjected to complex loads.

**Significance:** A novel in vitro test method has been developed to assess the primary stability of cementless tibial trays, which applies the loads associated with all six degrees of freedom over an entire activity. This is a significant advance for the pre-clinical testing of existing and new devices.

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**References:**
6. Taylor, M., D.S. Barrett, and D. Deffenbaugh, Influence of loading and activity on the primary stability of cementless tibial