Novel UKR Micromotion Assessment Method Utilizing Optical Measurement Techniques in Correlation with Finite Element Analysis

Robert Davignon, Ananth Gopalakrishnan, Gokce Yildirim
Stryker Orthopaedics, Mahwah, NJ

Statement of Purpose: Unicondylar Knee Replacements (UKR) have been available since the 1970s and cementless versions have recently been implanted. However, studies show that implants which move more than 150µm during the first eight weeks post-op are prone to fibrous tissue growth[1], which may lead to failure[2]. Cementless TKRs have been tested for micromotion[2] in Sawbones (Pacific Labs, WA) but no test method has been established to evaluate UKRs.

Methods: Data from Orthoload open source website was analyzed to determine the activities of daily living (ADL) that generates the highest forces. Stair ascent with 3.2BW load was determined to have the most potential to cause micromotion[3] (Fig 1). The compressive load profile was scaled to 60% (lower standard deviation-SD of patient data[4]) to prevent damage to the Sawbone substrate.

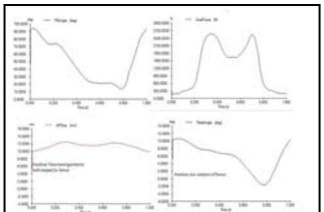

Figure 1: Load profile created from Orthoload and literature sources applied to displacement channels for the physical test.

A separate study was used to identify displacement profile. Lower boundaries of the SD values were applied to the posterior tibia[5]. Based on a study conducted to gage the frequency of ADLs by patients, 10,000 cycles were set as the test run-time accounting for 13% of ADLs for an 8 week period[4]. A four-axis test machine (MTS, Eden Prairie, MN) was used. The largest available cementless UKRs (Stryker, Mahwah, NJ) were prepared as per surgical technique. Baseplates were inserted into anatomic Sawbones block models which consist of cortical and cancellous regions of 40 and 12.5 pcf, respectively, to mimic the tibial bone interface[2]. Femoral components were cemented to an arbor. The medial compartment was considered for this test, while the lateral implants were attached to balance the joint (Fig 2).

Six tests were conducted with a new Sawbones block and insert for each test.

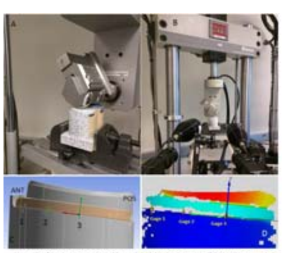

Figure 2. A) Test setup and tracking paint B) ARAMIS camera C) FEA with gages 1, 2, and 3 identified and D) Physical test data point locations and axis

Previous tests reported no change to the baseplate from Sawbones testing under physiological loads[6]. Each tibial assembly was spray painted with a speckle pattern and mounted onto the MTS test station. The ARAMIS System (GOM, Germany) was used to measure motion between the baseplate and the Sawbones in the 3 locations (Fig 2). Peak-Peak (P-P) motion was calculated in the compressive (Y), and A/P (X) shear directions at time 0 and after 10,000 cycles.

Additionally, an FEA study was conducted to compare with the physical test results. The same load/displacement profiles were used for static FEA using ANSYS (ANSYS, Inc. PA). The CoCr femoral component was used as a rigid load impactor assuming frictionless contact with the inserts. Material properties provided by Sawbones were used. Frictional contact between the porous implant was defined as 1.02 based on internal testing. The inserts were modeled as GUR1020. The baseplates were separated into solid and porous titanium. Relative deflection and P-P values were measured at the locations from physical test.

Results: Average compression values for 6 samples with the SD are reported on Figure 3 showing no statistically significant differences between two time points using a paired t-test. This shows that there was no change in micromotion between the two time periods.

Figure 3 also shows the comparison of FEA and the physical test results. Overall, the difference between two results did not exceed approximately 10 microns at any location. Both tests show gage 2 having the highest, and gage 1 the lowest compressive micromotion. Both tests show low micromotion compared to the values known to cause loosening. There was no liftoff seen.

Conclusions: Correlation of the results shows that the two test methods are sensitive enough to measure micromotion between implants that will survive or fail at the early fixation stages.

Results from the physical test show that gages 2 and 3 generate the highest compression. This is expected since

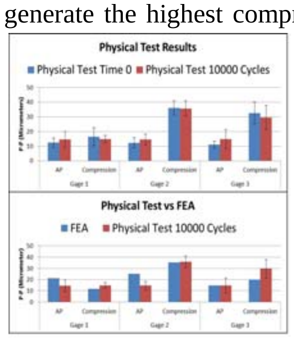

Figure 3. Physical test and FEA results

the force profile used applies the loads at those approximate locations. Compression results as a function of gage locations between the tests show the same micromotion within roughly 1 SD. The AP motion appears consistently low for all 3 gages which can be attributed to the implant design. AP micromotion in the FEA showed higher values for gages 1 and 2 than the physical test which is likely due to the simulation not modeling the press-fit. Additionally, the properties of the Sawbones and porous metal regions were modeled as solids. In reality they may have a nonlinear response to loading. The future studies aim to create more sophisticated FEA models which take these assumptions into account to better predict physical test results.

Based on these results, the implant is expected to maintain its fixation for 8 weeks and allow interdigitation for long-term fixation. We have shown that this method demonstrates a good level of correlation between physical testing and FEA.

References:

1. Bobyn D. Clin. Orthop Relat Res 263-70, 1980.**2.** Bhimji S. J of Arthop 29: 1503-06. 2014.**3.** Kutzner I. J of Biomech 43 pp. 2164-73, 2010. **4**. Bergmann G. PLoS ONE 9(1) e86035. 2014. **5.** Li J. Gait & Posture 38 (2013) 712–716.**6.** Yildirim G. #511. SFB Conference, Boston MA. 2013.