A novel test method to evaluate the dynamic performance of tibial insert-baseplate locking mechanism

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INTRODUCTION: In Total Knee Arthroplasty (TKA), the tibial insert locking mechanism is critical for preventing backside wear and supporting implant stability and longevity [1]. Some of the common tibial insert-baseplate locking mechanisms include peripheral capture, snap fit, dovetail and anti-rotational islands. Stryker's Triathlon tibial inserts utilize a full peripheral locking rim, a metal locking wire that is retained by the tibial tray's locking barbs and an anti-rotational island as part of its locking mechanism. While previous studies have looked at micromotion [2] and backside wear [3] of fixed bearing TKA, the structural integrity of the locking mechanisms hasn't yet been evaluated under dynamic loading. The goal of this study is to develop a method to specifically evaluate the dynamic structural performance of the metallic locking wire that can discriminate between different locking wire designs.

METHODS: Two groups of six locking wires were used in this study: Group A was comprised of Triathlon's intact metallic locking wires, and Group B is comprised of "notched" metallic locking wires, which have had the inferior 50% of the locking wire thickness machined away beneath the two areas that are located under the tibial baseplate retaining barbs' contact areas. These wires were assembled into the thickest and smallest Condylar-Stabilized (CS) tibial inserts representing worst-case for this evaluation, as the shortened moment arm created by this geometry results in the highest reaction forces on the locking wire compared to larger sizes of inserts within the Triathlon family. The two groups of CS inserts were machined to remove the press-fit around the central island, to focus the test on the structural integrity of the locking wire.

A tibial baseplate was machined to create visualization windows beneath the interior barbs that retain the tibial insert locking wires to help determine if the wires have passed or failed post-testing. This baseplate is fixed at a 3-degree posterior slope into a stainless-steel block using PMMA bone cement. The test setup and fixtures are shown in Figure 1. A size 1 femoral component set at 90-degree knee flexion and 0-degree internal/external (I/E) rotation was used in this study. Non-contact surfaces of the baseplate and the femoral component were coated in a black-and-white speckle pattern applied using flat spray paint, for use with the ARAMIS Digital Image Correlation (DIC) system (Zeiss, Oberkochen, Germany).

The modified CS inserts of each group were impacted into the tibial baseplate fixture, and deionized (DI) water was applied to the sulci. For each sample, the femoral component was aligned to the theoretical sulcus location of each insert. The ARAMIS DIC system was then used to take anterior images containing painted portions of both the tibial baseplate and the femoral component and analyzed to generate 3D surface maps of those painted portions, which were then used to determine if the sulcus position was accurately located. If not, anterior/posterior (A/P) adjustments were then made, and ARAMIS images were retaken to ensure that the initial sulcus position was within 10 μm of the theoretical position. Once the sulcus-loading position was confirmed, the bath was filled with DI water, heated up to 37deg C, covered in plastic wrap to minimize evaporation, and the test was started.

The test method involves applying a continuous load of 2275 N, with the A/P actuator sinusoidally translating the insert from 0.0mm to a set maximum posterior loaded position (starting with 5.0mm), at 1Hz for 220,000 cycles utilizing a multi-axis servo-hydraulic load frame (MTS, Eden Prairie, Minnesota). The loading and number of cycles were consistent with ASTM F2777-23 for a deep flexion activity. Following median fatigue convention, if the wire was observed to be broken, the sample was deemed to have failed, and the maximum posterior loaded position of the next sample was decreased by 0.5mm, thereby imparting a lesser load on the locking wire. Otherwise, if the wire was observed to have passed, the maximum posterior loaded position of the next sample was increased by 0.5mm, thereby imparting a greater load on the locking wire. The median fatigue values of the maximum posterior displacement were determined by the tables of Little et al [4] for each group, along with standard deviations (SDs) and median 95% confidence intervals (95% CIs).

RESULTS SECTION: Group A had a median fatigue maximum posterior displacement value of 4.91mm, SD of 0.54mm, and median 95% CI of [4.38mm, 5.45mm]. Group B had a median fatigue posterior displacement value of 3.91mm, SD of 0.54mm, and median 95% CI of [3.38mm, 4.45mm]. A full summary of the test results is shown in Figure 2, A Two Sample T-Test with α=0.05 rejected the Null Hypothesis (sample means are equal), with a p-value of 0.009.

DISCUSSION: The test method presented in this study was able to evaluate the dynamic structural performance of tibial locking wires and distinguish between two different groups, and hence, could be utilized to rank different designs and materials for locking wires. One limitation of this study is that it is restricted to evaluating locking mechanism designs with a locking wire. This method could be expanded in the future to evaluate the structural integrity of different locking mechanisms used in fixed bearing TKA.

SIGNIFICANCE/CLINICAL RELEVANCE: It is crucial to have an adequate tibial locking mechanism in a fixed-bearing TKA which helps minimize backside wear and aids with implant stability and longevity [1]. This study presents a novel method to evaluate the dynamic structural performance of a locking mechanism utilizing a metallic locking wire.

REFERENCES:
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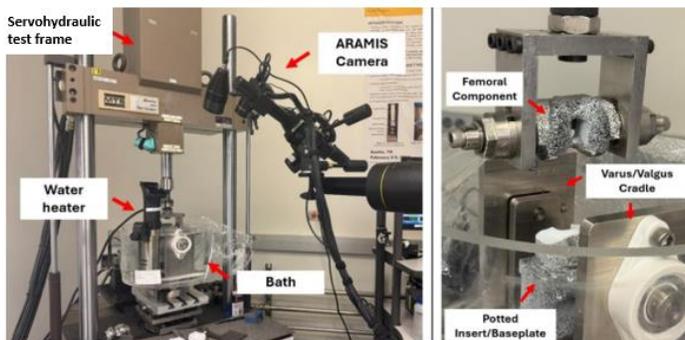[4] ASTM STP731 Tables for Estimating Median Fatigue Limits, R.E. Little

Figure 1

Sample ID	Group Name - A		Group Name - B	
	Translation	Result	Translation	Result
1	5.0	Fail	4.0	Pass
2	4.5	Pass	4.5	Fail
3	5.0	Fail	4.0	Fail
4	4.5	Pass	3.5	Pass
5	5.0	Pass	4.0	Fail
6	5.5	Fail	3.5	Pass
Median =	4.91		3.91	
Stdv =	0.54		0.54	
95% CI of median =	[4.38, 5.45]		[3.38, 4.45]	
N =	6		6	

Figure 2

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