DIRECT MEASUREMENT OF THE FORCES AND MOMENTS ACTING AT THE HINGE OF AN INSTRUMENTED HUMERAL COMPONENT FOR TOTAL ELBOW REPLACEMENT

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Introduction

In 2021, the number of primary and revision Total Elbow Arthroplasties (TEA) procedures performed has increased by 31.5% compared to 2020, reaching a total of 1,024 individual cases[1]. Aseptic loosening radiographically remains the greatest problem encountered in TER procedures, with 17% of all patients experiencing the loosening of one or both components. To date, the in vivo forces in the elbow joint have yet to be quantified, representing a significant gap in our understanding of the mechanics of the elbow joint. This research aims to generate real-time in vivo force and moment data during activities of daily living (ADL) for the first time by internally instrumenting the custom humeral component of an unconstrained total elbow replacement to measure the 6 degrees of freedom (d.o.f) acting at the hinge axle.

Materials and Methods

i) Model Development & Finite Element Analysis (FEA). Using SolidWorks, a modified 3D model of a Discovery humeral component was developed with three cavities to house electronics and strain gauges. The mechanical loading of the model was evaluated in an FEA study carried out in COMSOL™ replicating the 6 d.o.f loads experienced by the joint in vivo. This study identified the optimum locations for strain gauges for sensitivity to all d.o.f and for selectivity.

ii) CNC Fabrication. A total of 10 titanium (Ti-6Al-4V) humeral implant prototypes were fabricated via CNC machining (fig.1). The cavities were sealed with lids welded via electron beam welding (EBW).

iii) Fatigue Testing. Four welded prototypes are being fatigue tested for durability, applying a sinusoidal waveform with a frequency of 5 Hz and a maximum joint reaction force (JRF) of 700N for 5 million cycles[2]. The loading profile of this test simulates the cyclic flexion/extension motions that are associated with the elbow during normal ADL (fig.2).

iv) Instrumentation and Calibration

Axle loads are sensed by strain rosettes mounted in each fork cavity and in the main cavity. Stem tip loads are sensed by gauges enclosed in an annular cavity near the tip. The instrumentation is housed within the main cavity. Implants will be calibrated using custom fixtures and a loading machine.

v) Biomechanical Study

The implantation of pre-calibrated internally strain-gauged humeral implants in the humerus sawbone will validate the load measuring ability of the implant and enable stem loosening to be modelled. Physiological loading conditions will be applied by loads that mimic the JRF during the primary d.o.f of the elbow.

Figure 1: Titanium prototype with cavities (left) and sealed lids (right)

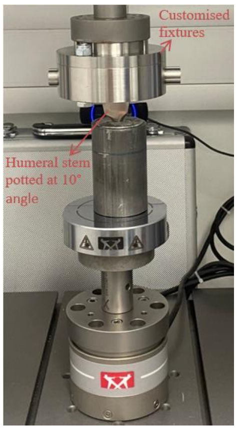

Figure 2: Fatigue Test setup

Results

The first cyclically loaded humeral component has successfully completed 5 million cycles at a peak load of 700N without failure. The load level at which 4 "runouts" are obtained with no fractures prior to 5 million cycles will be reported as the fatigue strength of the humeral stem. This demonstrates that the fatigue strength of the humeral component is greater than or equal to the runout load.

Discussion

Adding internal cavities to the humeral implant did not negatively impact its performance, as it was found to withstand the same loading conditions as previously tested humeral components[3]. After determining the fatigue strength of the 4 humeral components, it will be compared to that of Ti-6Al-4V, which has a known fatigue strength of 460 MPa[4]. The overall research project proposes to develop an instrumented humeral implant for TEA to measure hinge forces and moments.

References

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