Development of a Laboratory Wear Test Methodology for the Evaluation of Total Elbow Prostheses

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INTRODUCTION

Although total elbow arthroplasty (TEA) is a clinically successful procedure, long-term complications due to bushing wear and osteolysis are a few of the reasons for limited long-term survivorship.[Goldberg, 2008] There is no published information on *in vitro* wear simulations of total elbow prostheses to characterize and predict *in vivo* performance nor are there any currently accepted test standards (ASTM/ISO) for wear specific to the elbow. Therefore, the objective of this study was to develop a laboratory wear test methodology and validate the results against clinical evidence from gross observations of explanted Coonrad-Morrey (CM) (Zimmer, Inc., Warsaw, IN) total elbow components.[Goldberg 2008, Day 2009]

METHODS

The load and motion curves were developed from a survey of the relevant elbow biomechanics literature.[An 1985] A dynamic, time-varying compressive axial load as a function of elbow flexion angle combined with a mediolateral ("varus/valgus") malalignment was applied to size "extra small" (XS) CM components. Custom test fixtures were designed to isolate the articulation interface between the humeral and ulnar stems. The ulnar fixture was designed to have a 4.5° valgus deviation with respect to the humeral component representative of stem malalignment that is known to occur clinically (Figure 1).[Goldberg 2008] This purposefully exceeded the design envelope of the CM prosthesis (±3.5°) and was representative of a worst-case scenario which, based upon retrieval information, created contact between the ulnar stem and the humeral bushings (mode 1) as well as between the ulnar bushing and lateral humeral bushing (mode 2). A variable compressive load (peak value of 840 N) was applied while simulating flexion/extension through an 85˚ arc at a frequency of 1 Hz. This loading profile was meant to approximate strenuous activities of daily living with a 5.7 kg (12.5 lbf) mass in the hand. The total test duration was 3.0 Mc, representative of an estimated 5 years *in vivo*.

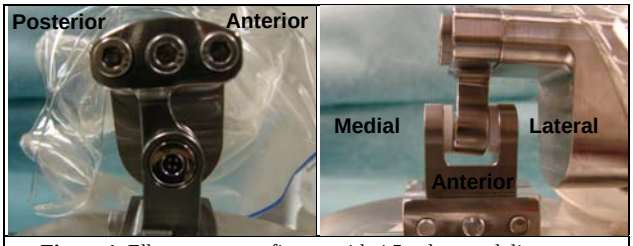
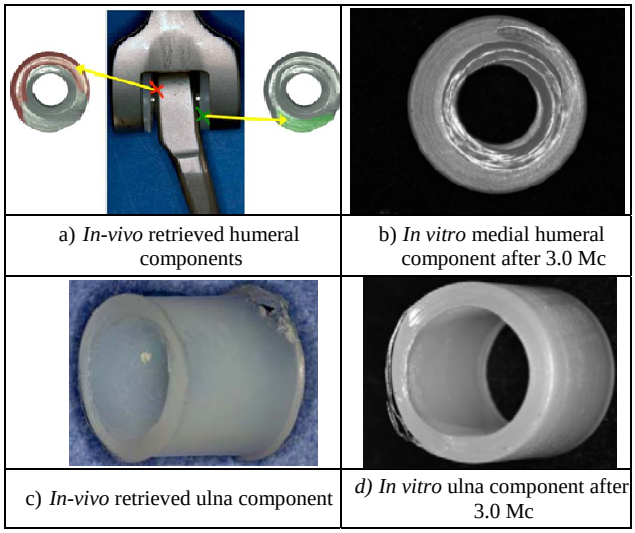


Figure 1. Elbow wear test fixture with 4.5 valgus malalignment.

Testing was performed using an AMTI 6-station knee simulator (AMTI, Inc., Watertown, MA) with adaptive control. Each specimen consisted of the test fixtures, the two-piece "snap" hinge pin component, ulnar and two humeral GUR 1050 ultra high molecular weight polyethylene (UHMWPE) bushings (Figure 1). Bushings were tested in the sterilized but unaged condition and without 3rd body particles, as were noted present in the retrievals. Each specimen was tested in an environmentally sealed chamber with bovine calf serum (3 g/L sodium azide and 9 g/L disodium EDTA) lubricant diluted to a protein concentration of 20 mg/ml which was circulated and maintained at 37 ± 3 °C. In lieu of load soak controls, the UHMWPE specimens were pre-soaked in bovine calf serum prior to testing until weight gain of the bushings stabilized. Specimens were weighed every 0.5 million cycles (Mc) and serum was salvaged at 0.5, 1.0 and 1.5 Mc for debris characterization.

RESULTS

At 3.0 Mc, all bushings exhibited evidence of mode 1 and mode 2 wear, wear "scars", asymmetric thinning and creep, all consistent with retrieval observations. Fracture initiation in one ulna bushing as a result of component thinning was observed which is also consistent with retrieval observations. A qualitative comparison showing similarities of the explanted *in vivo* components and the tested *in vitro* components is shown in Figure 2.



a) *In-vivo* retrieved humeral components | b) *In vitro* medial humeral component after 3.0 Mc

c) *In-vivo* retrieved ulna component | *d) In vitro* ulna component after 3.0 Mc

Figure 2. Comparison of explanted components to *in vitro* components.

The mean total mass loss for all three UHMWPE components at 3.0 Mc was 29.2 mg equating to a total mean volumetric wear rate of 9.1 mm^3/Mc. The ulna bushings demonstrated the highest mass loss (17.8 mg), followed by the lateral and medial humeral bushings (10.4 and 0.9 mg, respectively). This equates to an annualized volumetric *in vitro* wear rate of 3.8, 2.2 and 0.2 mm^3/yr, respectively. The mean annualized volumetric wear rates estimated from the retrieved ulna, lateral and medial components were 10.3, 8.6 and 7.8 mm^3/yr, respectively. The mean equivalent circle diameter (ECD) and aspect ratio (AR) of the UHMWPE debris taken from a sampling of the tested serum are presented in Table 1. The mean ECD and AR of debris isolated from periprosthetic tissue from the explanted components was <1.0 µm and 2.1 (±0.04).[Baxter, 2010]

Table 1. *In Vitro* Debris Analysis Summary: Mean (Std Dev)

	0.5 Mc	1.0 Mc	1.5 Mc
ECD (µm)	0.17 (±0.02)	0.17 (±0.02)	0.17 (±0.01)
Aspect Ratio	1.9 (±0.05)	1.9 (±0.06)	2.0 (±0.18)

DISCUSSION

A novel laboratory method was developed in order to evaluate wear of semi-constrained total elbow prosthesis. The results demonstrated the testing methodology was able to reproduce the appearance and two primary modes of wear observed in explanted UHMWPE components. The estimated *in vitro* wear rates, the ratio of ulnar bushing wear to lateral humeral bushing wear as well as the debris morphology are in relatively good agreement with the values estimated from retrieved components. The oxidative state and presences of 3rd body likely contributed to the higher overall wear rates reported for the retrieved components. The fixed, displacement controlled valgus angle in the test method likely contributed to the lower *in vitro* wear of the medial humeral bushing. It is concluded the test methodology produces results consistent with clinical observations and thus provides a basis for pre-clinical wear characterization of total elbow designs.

SIGNIFICANCE

This study is significant in that, to the knowledge of the authors, it represents the first report on a laboratory wear simulation specific to total elbows. Furthermore, the methodology has been validated against clinical evidence obtained from retrieved CM components and shown to produce similar results.