Fatigue Strength Evaluation of Total Elbow Prostheses Humeral and Ulnar Stems

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Disclosures:
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Introduction: Isolated stem fractures have been reported for total elbow replacements (TER) and are most frequently associated with 1) younger patients with high activity levels and 2) poor boney support conditions associated with post-traumatic arthritis [1-4]. No international test standards exist to evaluate fatigue strength of humeral and ulnar stems of a TER. Therefore, a test method was developed here to characterize the fatigue strength of the Coonrad/Morrey (C/M) Total Elbow (Zimmer, Inc.) and validate results against retrieved C/M stem components. The method was further utilized to characterize the fatigue strength of the Nexel™ Total Elbow (Zimmer, Inc.) humeral and ulnar stems (Figure 1).

Methods: The C/M and Nexel designs employ humeral and ulnar stems manufactured from Tivanium® Ti-6Al-4V (TiV) alloy with similar stem cross-sectional geometries and both are offered in three sizes with multiple stem lengths. The ulnar stems of both the C/M and Nexel designs have a porous coating of TiV plasma spray. The C/M humeral stem has a porous coating of sintered titanium beads, while the Nexel stem has a coating of TiV plasma spray. A computational stress analysis was performed to determine the worst case (highest tensile stress) stem sizes and orientation for testing utilizing elbow joint reaction force (JRF) magnitudes and orientations at various elbow flexion angles obtained from the literature [5]. To simulate worst case boney support conditions, critical stem cross sections were defined; 34 mm from the ulnar eye center near the distal end of the plasma spray for the ulnar stems and 41 mm from the center of rotation for the humeral stems, both consistent with retrieval observations. The humeral anterior flange was not included in the analysis, simulating no incorporation of the extracortical bone graft. Size “Small” C/M (Size 5 Nexel) humeral stems and size “Extra Small” C/M (Size 4 Nexel) ulnar stems were determined to be the worst case sizes, with the highest tensile stress occurring at 120° and 115° elbow joint flexion when the JRF is directed posteriorly along a vector at 68° and 64° for the humeral and ulnar stems respectively, with respect to the fixed humeral stem axis. Seven (n=7) C/M humeral stems, eight (n=8) Nexel humeral stems, eight (n=8) C/M ulnar stems and twelve (n=12) Nexel ulnar stems were tested under ambient laboratory conditions using a uni-axial MTS servo-hydraulic test machine (Figure 2). Stems were potted at the worst-case orientations at the critical cross section(s) in poly methyl methacrylate (PMMA) bone cement and compressive loading was applied through a thrust ball bearing fixture (Figure 2). Stems were tested at unique load levels using a sinusoidal load waveform with an R ratio (min/max load) of 0.1 at 20 Hz for 3 million cycles (Mc) or until fracture in order to construct an “s-n” curve. The load level at which 5 “runouts” (no fractures prior to 3.0 Mc) were obtained is reported as the fatigue strength of the stem. This demonstrates 97% percent confidence that the median fatigue strength is greater than or equal to the runout load (Binomial distribution with n=5, p=0.5, 0 fractures).
Results: The fatigue strength of C/M and Nexel humeral stems was determined to correspond to a weight in hand (WIH) of 91 N (20.5 lbf) and 133 N (30 lbf), respectively [5]. The fatigue strength of C/M and Nexel ulnar stems were 99 N (22.2 lbf) and 109 N (24.4 lbf) WIH, respectively (Figure 3). The stem fractures observed during testing of the C/M components at 5% above their runout load levels were similar to clinical observations and retrievals.

Discussion: Highly aggressive joint loads equivalent to ~90-110 N (20-25 lbf) WIH under simulated poor support conditions were necessary to induce clinically relevant fractures in C/M components. The fatigue strength of Nexel humeral stem is 52% higher than that of the C/M humeral stem and is attributed primarily to the change to the TiV plasma spray coating. The fatigue strength of the Nexel ulnar stem is 10% higher than that of the C/M ulnar stem. Both the C/M and Nexel elbow package inserts counsel patients to not lift more than ~2.25 kg (5 lbf) with the operated arm after first three postoperative months [6,7]. No fracture of the current generation TiV plasma spray coated C/M ulnar stem design implanted since 1999 have been reported in the literature [8].

Significance: To our knowledge, this study represents the first report on fatigue strength evaluation of TER humeral and ulnar
This methodology was able to reproduce clinically relevant fractures in C/M components thereby validating the test. The results indicate that highly aggressive joint loads applied with poor support conditions are necessary to induce fractures in C/M stems which is consistent with the clinical experience. Nexel elbow stems have higher fatigue strength than clinically successful C/M elbow stems.

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