J Shoulder Elbow Surg (2017) ■■, ■■–■■

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

ORIGINAL ARTICLE

In vitro wear of ultrahigh-molecular-weight polyethylene and vitamin E blended highly cross-linked polyethylene in linked, semiconstrained total elbow replacement prostheses

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Background: The objectives of this study were to develop a clinically relevant in vitro elbow wear test and to compare the polyethylene wear of 2 total elbow replacement prostheses, one that uses conventional gamma-irradiated polyethylene (CPE) and one that uses vitamin E blended and cross-linked polyethylene (VE-HXPE) bushings.

Materials and methods: The test protocol applied 0° to 85° flexion-extension motions and imposed a constant 4.5° varus malalignment of the ulnar relative to the humeral implant under a variable joint load profile at a frequency of 1 Hz. The implants were tested for 3 million cycles (Mc) in a bovine serum lubricant at 37°C ± 3°C. Polyethylene wear was determined gravimetrically. Wear particles were isolated and characterized.

Results: Clinically relevant polyethylene bushings wear mechanisms were observed. After 3 Mc, the mean CPE wear rate was 9.3 ± 2.8 mm^3/Mc, significantly lower than that reported for hip and knee implants but comparable to that of ankle (7.4 ± 1.3 mm^3/Mc) devices. The mean VE-HXPE wear rate was 0.8 ± 0.2 mm^3/Mc, comparable to that of hip and knees devices. The mean equivalent circle diameter and aspect ratio were 0.17 ± 0.01 µm and 1.99 ± 0.18 for the CPE and 0.15 ± 0.02 µm and 1.81 ± 0.16 for the VE-HXPE particles.

Conclusion: The test replicated clinically observed failure modes for CPE devices. The use of VE-HXPE led to an order of magnitude reduction in polyethylene wear. Further clinical evaluation is necessary to determine if this translates into reduced complications of total elbow replacement associated with wear.

Level of evidence: Basic Science Study; Tribological Testing

Keywords: Elbow; prosthesis; polyethylene; wear debris; in vitro test protocol; arthroplasty; tribology

The human elbow joint has 3 articulating interfaces—the humeroulnar, the humeroradial, and the proximal radioulnar—that provide flexion-extension, pronation-supination, and abduction-adduction (varus-valgus) motions of the arm, respectively. The elbow joint can be affected by rheumatoid arthritis, post-traumatic arthritis, ankylosis, instability, humeral fracture, and cartilage wear.[10,11,15,31,33] These may result in severe pain, flail function, and loss of motion, leading to difficulties in performing simple activities of daily living (ADLs), such as brushing the teeth, lifting a child, eating, bathing, or carrying a beverage. Total elbow replacement (TER) is a solution

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1058-2746/$ - see front matter © 2017 Journal of Shoulder and Elbow Surgery Board of Trustees. All rights reserved.
http://dx.doi.org/10.1016/j.jse.2016.12.066

when initial treatments, such as viscosupplementation, débridement with external fixation, and open reduction with internal fixation, become ineffective.[10,28,32,37,40] Many of the contemporary TER implants that replace the humeroulnar joint use a so-called sloppy hinge linked, semiconstrained-style metal-on-polyethylene articulation. One such TER has been clinically successful, with multiple reports of 20-year survivorship of 90% using revision surgery as the end point.[1,15,18,21] As is the case of other metal-on-polyethylene articulation–based total joint arthroplasties, long-term survivorship of TERs may be limited by polyethylene wear, oxidative embrittlement, delamination, particle-mediated osteolysis, and aseptic loosening.[16,23,36,39,44,48] TER implants undergo modes of wear and degradation mechanisms similar to those of the larger hip and knee joint implants in vivo[16,26]; thus, polyethylene bushing exchange, analogous to acetabular liner/tibial insert exchanges in hip and knee arthroplasties, is a leading reason for TER revision surgery.[1,18,21,23,25,47]

Preclinical wear evaluation through in vitro simulation studies using the conditions prescribed in international standards such as ISO 14242[17] and ISO 14243[17] is a prerequisite for regulatory approval of articulating polyethylene devices used in hip and knee arthroplasties.[46] Clinical results bear out the predictions of these in vitro simulations as demonstrated by follow-up studies that compare femoral head penetration in patients who were treated with electron beam highly cross-linked polyethylene (HXPE) acetabular liners with those treated with conventional gamma-irradiated polyethylene (CPE) liners.[9,14,22] Unfortunately, no international standards exist to guide the evaluation of in vitro polyethylene bushings wear behavior of TER devices, hence the paucity of TER tribology data in the peer-reviewed literature. A recent review[19] summarized the available elbow joint biomechanics data and provided clinically relevant inputs for further development of clinically relevant in vitro polyethylene wear simulations.

The objectives of this study were to establish a clinically relevant in vitro polyethylene wear test protocol for TERs and to evaluate the in vitro wear behavior of 2 commercially available TER designs: the Coonrad-Morrey (C/M) Total Elbow (Zimmer Biomet, Inc., Warsaw, IN, USA), which uses conventional gamma-irradiated ultrahigh-molecular-weight polyethylene (CPE) bushings, with >30 years of clinical history; and the next-generation Nexel Total Elbow (Zimmer Biomet, Inc.), which uses vitamin E blended cross-linked ultrahigh-molecular-weight polyethylene (VE-HXPE) bushings.

Materials and methods

This is an in vitro biomechanical study that developed a polyethylene wear protocol for TERs and simulated the polyethylene bushings wear behavior in 2 semiconstrained linked TER implants.

Materials

The implants used in this study are designed to replace the humeroulnar joint only. The C/M implant (Fig. 1, *A*) consists of Ti6Al4V alloy humeral and ulnar components that are joined in-

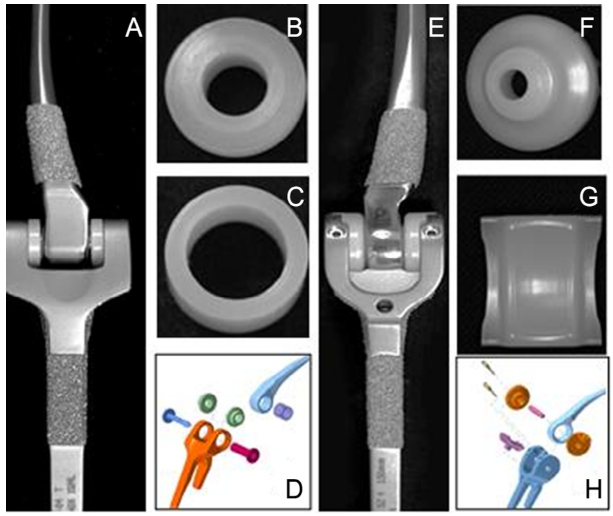

Figure 1 The Coonrad-Morrey (**A-D**) and the Nexel (**E-H**) total elbow replacement implants used in this study.

traoperatively by a 2-piece CoCrMo/Ti6Al4V alloy snap pin (Fig. 1, *D*). There are 2 humeral (Fig. 1, *B*) and 1 ulnar (Fig. 1, *C*) CPE bushings on the C/M elbow. The Nexel implant (Fig. 1, *E*) also has Ti6Al4V alloy humeral and ulnar components joined together intraoperatively by a linkage mechanism that consists of 2 VE-HXPE (Fig. 1, *F*) bearings, a CoCrMo alloy axle pin, and 2 CoCrMo alloy humeral screws (Fig. 1, *H*). A third VE-HXPE (Fig. 1, *G*) bearing is installed at the base of the humeral component "yoke." The proximal articular region of the Nexel ulnar component is hardened by nitrogen ion implantation to mitigate particle shedding and possible third-body particle abrasion. During articulation, the C/M implants experience CoCrMo/CPE, Ti6Al4V/CPE, and CPE/CPE contacts, whereas the Nexel ones experience CoCrMo/VE-HXPE, nitrogen ion–implanted Ti6Al4V/VE-HXPE, and VE-HXPE/VE-HXPE contacts in vivo. The CPE bushings are machined from compression-molded GUR 1050 ultrahigh-molecular-weight polyethylene bars, packaged in nitrogen, and gamma-irradiation sterilized at 37 ± 10% kGy. The VE-HXPE bushings are machined from compression-molded pucks of vitamin E blended GUR 1020 resin (vitamin E wt% <1) and electron beam cross-linked at >100 kGy (Vivacit-E, Zimmer Biomet Inc.), packaged in air, and ethylene oxide sterilized.

Methods

Wear test protocol development

Load/motion waveforms. The load/motion profiles were adopted from biomechanical reviews of the elbow joints and are shown in Figure 2.[2-6,20,24,29,34,38,41] Most of the commercially available TER implants restrict patients to a weight-carrying limit of 2.3 kg (5 pounds). In this study, 5.5 kg (12 pounds) weight in hand was assumed, and the equation from Kincaid and An[19] was used to generate a loading curve with a peak joint reaction force (JRF) of 840 N occurring at approximately 10° of elbow flexion as shown in Figure 2, *A*. Morrey et al demonstrated that most ADLs can be accomplished within a 100° arc between approximately 30° and 130° of elbow flexion.[30] The simulators used in this study were limited to ±90° flexion-extension motion, and thus the elbow flexion arc simulated here was