J Shoulder Elbow Surg (2020) 29, 2364–2374

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Quantitative ultrahigh-molecular-weight polyethylene wear in total elbow retrievals

Judd S. Day, PhD[a,b,*], Daniel W. MacDonald, MS[a], Matthew L. Ramsey, MD[c], Joseph A. Abboud, MD[c], Steven M. Kurtz, PhD[a,b]

[a]*Implant Research Center, School of Biomedical Engineering, Science, and Health Systems, Drexel University, Philadelphia, PA, USA*
[b]*Exponent, Inc., Philadelphia, PA, USA*
[c]*Rothman Institute, Philadelphia, PA, USA*

Background: The purpose of this study was to evaluate ultrahigh-molecular-weight polyethylene (UHMWPE) wear and damage from retrieved total elbow arthroplasty components and compare in vivo wear with wear produced in vitro.
Methods: Explanted total elbow components were collected at revision surgery. UHMWPE damage was characterized visually, whereas penetration and wear were quantified using micro–computed tomography and gas pycnometry. Volumetric wear rates were compared with historical hip data, and wear data were compared with reported in vitro wear test data.
Results: Humeral bushing damage primarily occurred in the form of burnishing, scratching, and pitting at the articular face in the region of contact with the ulnar component. Wear of the ulnar bushings was concentrated on the edge of the component at the point of contact with the axis pin. Pitting and embedded debris were dominant damage modes, in addition to burnishing and delamination. Backside wear was negligible. The median linear penetration rates of the lateral, medial, and ulnar bushings were 0.14 mm/yr (range, 0.01-0.78 mm/yr), 0.12 mm/yr (range, 0.03-0.55 mm/yr), and 0.11 mm/yr (range, 0.01-0.69 mm/yr), respectively. The volumetric wear rates of the lateral, medial, and ulnar bushings were 5.5 mm^3/yr (range, 0.7-37.2 mm^3/yr), 5.9 mm^3/yr (range, 0.6-25.5 mm^3/yr), and 5.5 mm^3/yr (range, 1.2-51.2 mm^3/yr), respectively.
Conclusions: The observed wear rates were similar to those reported in well-functioning total hip replacement patients with conventional UHMWPE bearings. We found limitations in reported in vitro testing resulting in wear that was not consistent with our retrieval data. We recommend further investigation to clinically validate in vitro simulation to provide appropriate loading protocols for elbow wear simulation.
Level of evidence: Basic Science Study; Tribology

Keywords: Total elbow arthroplasty; UHMWPE; wear; retrieval; semiconstrained; linked

All investigations were conducted in conformity with ethical principles of research, and the study was approved by the institutional review boards at Drexel University (protocol no. 18246) and the Rothman Institute at Jefferson University (protocol no. 02F.387R).

*Reprint requests: Judd S. Day, PhD, Exponent, 3440 Market St, Ste 600, Philadelphia, PA 19104, USA.

E-mail address: jday@exponent.com (J.S. Day).

Aseptic loosening after total elbow arthroplasty has historically been a common failure mode. The axis of rotation of the elbow is polyaxial in nature. As a result, the historical use of fixed-axis constrained hinges that could not accommodate this motion resulted in a high rate of mechanical loosening. The use of semiconstrained hinge designs coupled with a stabilizing anterior flange on the humeral component and modern cementing technique has

1058-2746/$ - see front matter
https://doi.org/10.1016/j.jse.2020.03.026

dramatically reduced the rate of early mechanical loosening.[39,56] As a result, survival rates, with revision as an endpoint, have been reported at >90% at 10 years' follow-up in patients treated for rheumatoid arthritis.[12,30] However, total elbow arthroplasty is increasingly being used to treat higher-demand degenerative and post-traumatic indications.[11,25,51]

With the improved early survival of total elbow prostheses and expanded indications, long-term implant durability and resistance to wear have been identified as technical challenges. Computational models indicate that elbow loads can be >10 times the weight of an object held in the hand and may be up to 3 times the body weight during strenuous activities of daily living.[4,24] Loading of the elbow with an object in the hand may occur 500,000 times/yr.[4] As a result, catastrophic polyethylene wear and locking-mechanism failure have been reported for several implant designs.[9,17,23,36,42,58] Furthermore, radiographic polyethylene wear is increased in high-demand patients such as younger patients or those treated for post-traumatic conditions, particularly when associated with preoperative deformity.[28,58] Wear particle–induced osteolysis and loosening have therefore been cited as mid- to long-term concerns.[13,23,27,58]

Polyethylene wear, particularly accelerated wear due to edge loading of the ulnar component, has been raised as a potential issue of concern for semiconstrained total elbow designs.[13,58] The periprosthetic tissue response to polyethylene wear debris is believed to be modulated by patients' biological factors,[10,14,26,33-35,55] the quantity of debris produced,[6-8,54] design factors such as patched porous surfaces that can affect the effective joint space,[16,46] and characteristics such as the size and shape of the resulting particles.[15,19,31,45] We have previously found that the polyethylene particles in retrieved periprosthetic elbow tissues were of a similar volume, size, and morphology to those found in periprosthetic hip tissues.[5]

Few published data quantifying the wear of total elbow components in vivo are available. Furthermore, no standard test methods exist for in vitro evaluation of ultrahigh-molecular-weight polyethylene (UHMWPE) wear in total elbow systems. In vitro testing may be used during preclinical development to characterize the durability of candidate product designs under adverse loading conditions or to estimate the wear produced during activities of daily living. Although the loads experienced by any device in vivo will vary between patients, standardized loading profiles can be used to compare between devices. Therefore, developing an increased understanding of the in vivo wear behavior of total elbow arthroplasty is essential not only for evaluating the clinical importance of wear at the elbow but also for developing a basis for comparison of designs and validation of in vitro wear testing.

Currently, there is not a recognized standard method for preclinical wear testing of total elbow arthroplasty systems. Kincaid and An[24] presented a review of elbow joint biomechanics providing a rationale for preclinical evaluation of total elbow prostheses including "worst-case" loading profiles. In vitro wear simulation based on these data was used by Popoola et al[43] to compare the same semiconstrained elbow design used in our study with a design with modern UHMWPE and a more conforming bearing surface. A sagittal-plane joint reaction force that varied between 325 and 840 N was applied with a fixed varus angle of 4.5° for 3 million cycles (Mc). The authors reported average wear rates of 5.8, 3.7, and 0.3 mm^3/Mc for the ulnar, medial humeral, and lateral humeral bushings, respectively. In a separate in vitro study, Willing[57] used joint loads adapted from those previously proposed for durability testing of the axis pin of a total elbow system.[52,53] Components were subjected to 200,000 cycles of either of 2 loading protocols. The first protocol, "high joint reaction force" loading, applied a sagittal-plane joint reaction force that varied between approximately 400 and 1250 N over a 100° range of flexion coupled with a 5-Nm varus-valgus moment, which alternated every flexion-extension cycle. This resulted in humeral and ulnar volumetric wear rates of 48 and 180 mm^3/Mc. The second protocol, "high varus moment" loading, was based on the loading incurred by performing 45 sit-to-stand activities daily (approximately 16,500 cycles/yr) and applied 100° of flexion, up to 275 N of compressive loading, and a varus moment of up to 12 Nm. Humeral and ulnar volumetric wear rates of 43 and 189 mm^3/Mc, respectively, were reported.

In this study, we analyzed components retrieved at revision total elbow arthroplasty to characterize the observed damage and quantify the linear penetration and volumetric wear of the UHMWPE bearing surfaces. We hypothesized that the volumetric wear rates of our retrieved components would be less than those reported for historical hip arthroplasty cohorts with conventional UHMWPE bearing surfaces. We further investigated whether in vivo edge loading of the ulnar bushings, as reported in the literature, would result in accelerated wear of the ulnar bushings in comparison to the humeral bushings. Finally, we compared the patterns of wear from retrieved components with those reported from in vitro elbow testing.

Materials and methods

Materials were retrieved from 35 patients undergoing revision surgery or bushing exchange of a semiconstrained total elbow prosthesis (Coonrad/Morrey; Zimmer Biomet, Warsaw, IN, USA) in a multicenter retrieval study. The index procedures were performed between 1980 and 2010, and the components were retrieved after being implanted for between 1.3 and 23.8 years (average, 7.6 years; standard deviation, 4.9 years). The polyethylene in these retrievals was gamma sterilized in air or in a nitrogen package and hence falls into the category of either historical (gamma air) or conventional (gamma inert) polyethylene; none of the polyethylene components were highly cross-linked.

Table I Demographic information

Patient no.	Sex	Age at index procedure, yr	Dominant arm	Initial Dx	Revision Dx	Time implanted, yr
MC-01	M	64	Y	PTA	Loosening	5.5
MC-02	M	48	Y	PTA	Loosening	8.6
MC-03	F	69	N	PTA	PE wear	14.6
MC-04	F	34	N	RA	Contracture	14.6
MC-05	M	36	Y	PTA	Loosening	23.8
MC-06	F	NA	Y	RA	Loosening	9.0
MC-07	F	63	Y	RA	Loosening	7.1
MC-08	F	51	Y	RA	Fx	2.5
MC-09	F	41	N	RA	Loosening	13.5
MC-10	M	57	Y	PTA	PE wear	7.3
MC-11	M	45	N	PTA	Loosening	5.0
MC-12	M	37	N	PTA	Loosening	5.1
OC-01	F	63	N	PTA	Loosening	12.8
OC-02	F	72	N	Malunion or nonunion	Fx	5.1
OC-03	F	50	Y	RA	Loosening	4.3
OC-04	M	52	N	PTA	Loosening	5.3
RI-01	M	32	Y	PTA	Loosening	NA
RI-02	M	63	Y	Malunion or nonunion	Loosening	9.5
RI-03	M	20	N	Malunion or nonunion	Loosening	15.3
RI-04	F	70	Y	Malunion or nonunion	Loosening	10.0
RI-05	M	45	N	PTA	Infection	8.2
RI-06	F	31	Y	PTA	Loosening	3.3
RI-07	M	59	Y	RA	Infection	12.4
RI-09	M	56	N	Malunion or nonunion	Loosening, axis disengagement	5.0
RI-10	M	73	Y	PTA	Infection	3.3
RI-11	F	67	N	Malunion or nonunion	Infection	8.0
RI-12	F	NA	Y	OA and acute Fx	Loosening	NA
RI-13	M	73	Y	PTA	Infection	1.25
UP-01	F	82	NA	Malunion or nonunion	Loosening	6.1
UP-02	F	52	Y	OA	Loosening	6.0
UP-03	F	62	N	RA	Loosening	5.3
UP-05	F	66	Y	PTA	PE wear	2.4
UP-06	F	81	NA	Malunion or nonunion	Infection	1.3
UP-08	NA	64	NA	RA	PE wear	2.2
UP-09	NA	NA	NA	NA	NA	11.6

Dx, diagnosis; *M*, male; *Y*, yes; *PTA*, post-traumatic arthritis; *F*, female; *N*, no; *PE*, polyethylene; *RA*, rheumatoid arthritis; *NA*, not available; *OA*, osteoarthritis; *Fx*, fracture.

The average age of the patients at the time of the index procedure was 57 years (standard deviation, 14 years); their ages ranged from 20 to 82 years. Patients underwent revision for aseptic loosening (n = 21), infection (n = 6), polyethylene wear (n = 4), fracture (n = 2), or other reasons (n = 2). The index diagnoses were noninflammatory arthritis (n = 16), rheumatoid arthritis (n = 9), malunion or nonunion (n = 8), and other diagnoses (n = 2). Clinical details for the 35 patients are summarized in Table I.

A total of 67 humeral and 33 ulnar bushings were available for analysis. The bushings were removed from the components during bushing exchange using the bushing removal tool supplied in the instrument set. For implants that were received intact, a press and a polymeric push rod were used to remove the bushings. Explanted components were cleaned using institutional procedures before characterization of surface wear and damage using an inspection microscope. Seven damage mechanisms were assessed using the modified semiquantitative Hood scoring method.[18] In brief, we used a 4-point scale (0-3) to assess the presence of abrasion, burnishing, delamination, embedded debris, pitting, scratching, and surface deformation (creep) of the humeral and ulnar bushings. For each bushing, the entire component was inspected for the presence of these damage mechanisms using the naked eye and, if needed, a stereoscope.

The volume of each implant was determined using a gas pycnometer (AccuPyc II 1340; Micromeritics, Norcross, GA, USA). The volumetric wear of each retrieved UHMWPE bushing was then calculated by comparing the volume determined using the pycnometer with that derived from solid models constructed using design drawings supplied by the manufacturer. When historical designs were encountered that were not an exact match to the drawings, a model was reverse engineered based on the unworn surfaces. We have validated this method by comparing as-manufactured components with the mechanical drawings. The method was determined to slightly overestimate the total wear but to be accurate to within 5 mm^3.

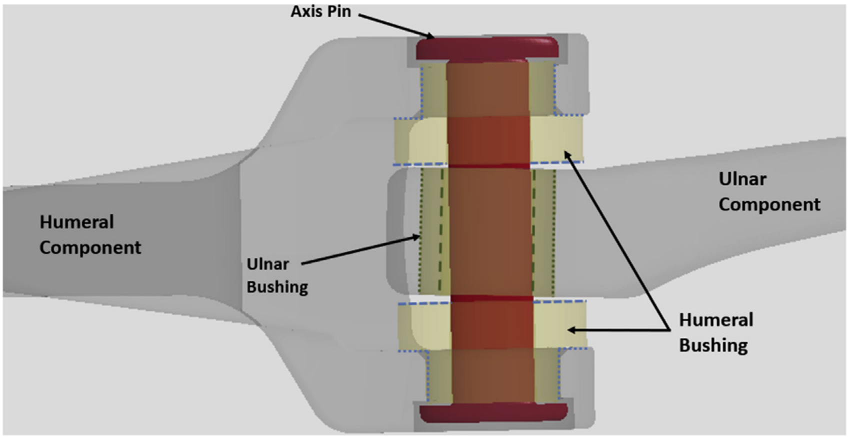

Figure 1 Primary ultrahigh-molecular-weight polyethylene bearing wear occurred at the interface between the ulnar component and humeral bushings (*dashed line* on humeral bushing) and at the interface between the ulnar bushing and the axis pin (*dotted dashed line* on ulnar bushing). The backside surfaces of the humeral and ulnar bushings were used as fiducial planes for registration (*dotted lines*).

Linear penetration of the UHMWPE bearing surfaces was calculated using micro–computed tomography scans of each bushing. This method measures both creep and wear, and the term ‘‘penetration’’ describes the combination of these processes. Each bushing was scanned at an isotropic resolution of 20 μm (μCT 80 system; Scanco Medical, Wangen-Brüttisellen, Switzerland). The resulting data set underwent thresholding and was registered manually so that the unworn backside surface of the retrieved bushing was aligned with the backside surface of the solid model (Analyze, version 8.0; AnalyzeDirect, Overland Park, KS, USA) (Fig. 1). Once the image data sets were aligned, a custom computer program (MATLAB; The MathWorks, Natick, MA, USA) was used to determine the penetration by comparing the thickness of the bearing surface of the worn component with that of the solid model. The repeatability and reproducibility of the method were determined using a gage R&R (repeatability and reproducibility) study design. The resulting repeatability and reproducibility (expressed as 1 standard deviation) were 11 and 28 μm, respectively, for the ulnar components and 19 and 9 μm, respectively, for the humeral components.

Statistical analysis was performed using SPSS software (IBM, Armonk, NY, USA). The effect of bushing position on wear rate was investigated using a nonparametric Friedman test. The effect of initial diagnosis (rheumatoid arthritis vs. other), sex, and implantation date (2000 or earlier vs. 2001 or later) were investigated using a nonparametric Mann-Whitney test. Nonparametric correlation was used to investigate the relation between wear rate and age, as well as wear rate and implantation time.

Results

Wear and damage of the UHMWPE bushings were observed primarily at the ulnar bushing–axis pin interface and at the humeral bushing–ulnar component interface (Fig. 1). Surface wear and deformation of the humeral components conformed to the geometry of the ulnar component in varus and valgus, resulting in a grooved wear pattern at the point of proximal contact and a flat wear pattern at the point of distal contact (Fig. 2). Burnishing was the most common damage mechanism on the surface of the humeral bushings and was present in 96% of retrieved humeral bushings (64 of 67). A ring of material loss was present on the surface of the humeral bushings in a position consistent with contact with an extruded portion of the ulnar bushing; however, the appearance of this feature varied widely between components (Fig. 3). Pitting was present in 76% of the humeral bushings (51 of 67), and scratching was present in 72% (48 of 67). Embedded debris included metal beads and bone cement. Embedded metal beads were only observed in the presence of a loose component. Metallic wear debris was also present in components that experienced full-thickness wear of the bushings. Scratching and pitting were most commonly observed on the inner surface of the humeral bushing owing to contact with the axis pin. However, wear at this interface appeared to be comparatively minor. Backside wear was limited but primarily located on the medial and lateral backside faces directly underneath the ulnar bearing surface. Abrasive wear due to unintended contact between the humeral bushings and either bone or cement from the ulnar side was seen in 49% of the humeral bushings (33 of 67) (Fig. 4). Delamination of the UHMWPE was observed in 30% of the humeral bushings (20 of 67).

The ulnar component was worn primarily on the edges of the distal surface owing to contact with the axis pin, in addition to contact with the humeral bushings. Pitting (85%, 28 of 33) and embedded debris (79%, 26 of 33) were the most prominent wear mechanisms on this surface, followed by burnishing (58%, 19 of 33) and delamination (55%, 18 of 33). Embedded debris was most commonly in the form of bone cement, metallic wear debris, or metal beads from the porous coating (79%, 26 of 33). Although we have previously reported burnishing of the ulnar component resulting in periprosthetic titanium debris, we did not see substantial evidence of staining of the humeral or ulnar bearing surfaces due to this failure mode. In the ulnar bushings, backside wear was observed mostly in the

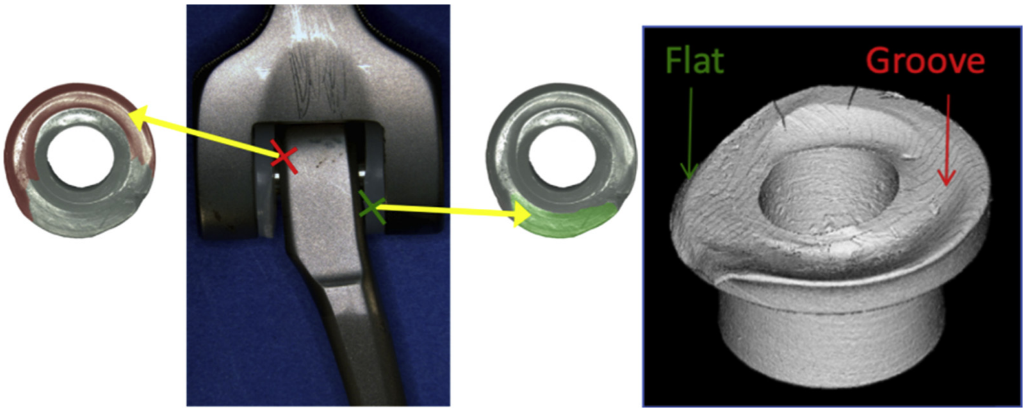

Figure 2 Contact of the ulnar component in varus and valgus creates a grooved wear pattern on the humeral bushings at the proximal point of contact (*red*) and a flat wear pattern at the point of distal contact (*green*).

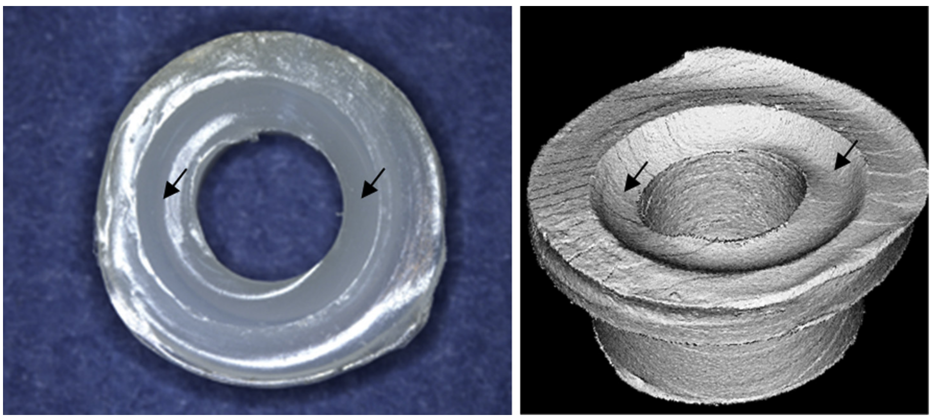

Figure 3 Burnishing was the predominant wear mechanism seen in humeral bushings. A circular pattern of wear (←—) was also observed in most humeral bushings due to ultrahigh-molecular-weight polyethylene–on–ultrahigh-molecular-weight polyethylene contact between the ulnar and humeral bushings. The depth of this feature varied widely between patients. This is one of the most extreme examples observed.

form of mild burnishing and pitting but was negligible in comparison to damage to the bearing surface.

Surface penetration maps were created for each retrieved bushing; an example is included in Figure 5. Generally, the penetration of the humeral faces was consistent with contact between the metal ulnar component and the humeral bushings as illustrated in Figure 2. Wear of the humeral face due to UHMWPE-on-UHMWPE contact, with few exceptions, was separately discernible only in bushings with little face penetration and was not the dominant wear mechanism for most of the highly worn components. A full set of penetration maps has been included in Supplementary Appendix S1. The median linear penetration rates of the lateral, medial, and ulnar bushings were 0.14 mm/yr (range, 0.01-0.78 mm/yr), 0.12 mm/yr (range, 0.03-0.55 mm/yr), and 0.11 mm/yr (range, 0.01-0.69 mm/yr), respectively (Fig. 6). There was no significant difference between bushings for the linear penetration rates (P = .536, Friedman test). Total volumetric wear rates, calculated for components with complete bushing sets only, ranged from 2.9 to 101.4 mm^3/yr (median, 17.6 mm^3/yr). The volumetric wear rates were not significantly different between the lateral (median, 5.5 mm^3/yr; range, 0.7-37.2 mm^3/yr), medial (median, 5.9 mm^3/yr; range, 0.6-25.5 mm^3/yr) and ulnar (5.5 mm^3/yr; range, 1.2-51.2 mm^3/yr) bushings (P = .697, Friedman test). Linear and volumetric wear data are plotted in Figure 6 and Figure 7, respectively.

When examined by individual patient, the wear of the bushings was correlated, with Spearman correlations ranging between 0.65 and 0.8 (ie, patients with high wear experienced this on all bushings). No significant difference in volumetric wear rates was found for patients with rheumatoid arthritis vs. other diagnoses (P = .25), by sex (P = .13), or for elbows implanted before 2001 vs. later (P = .10). No significant relation was noted between average bushing wear rate and patient age (P = .08); however, we did detect a negative correlation between bushing wear rate (linear and volumetric) and implantation time (Spearman ρ = –0.66 to –0.41, P = .021).

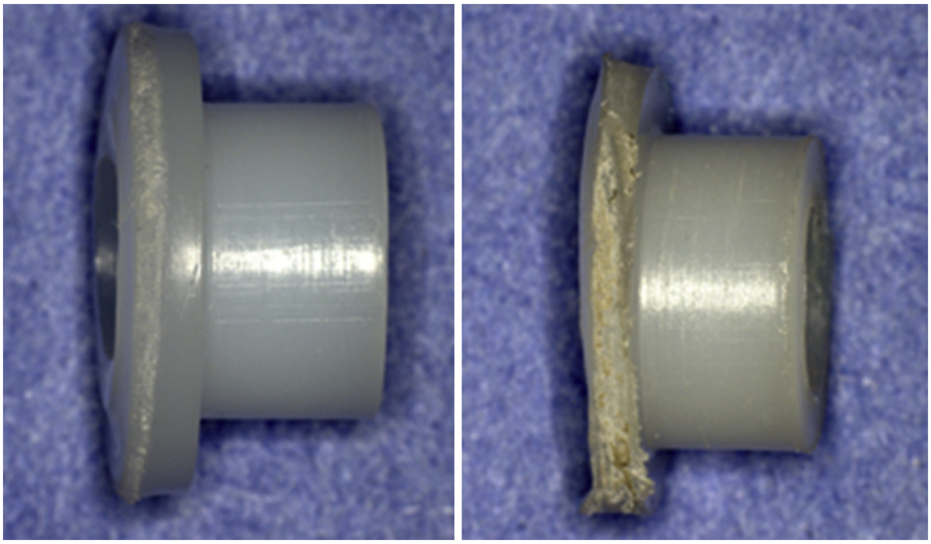

Figure 4 Unintended contact, likely with bone or cement, caused varying degrees of abrasive wear in 30% of the retrieved humeral bushings. It should be noted that this effect was prominent in bushings that were revised for ulnar loosening, in which pistoning of the ulnar component was observed.

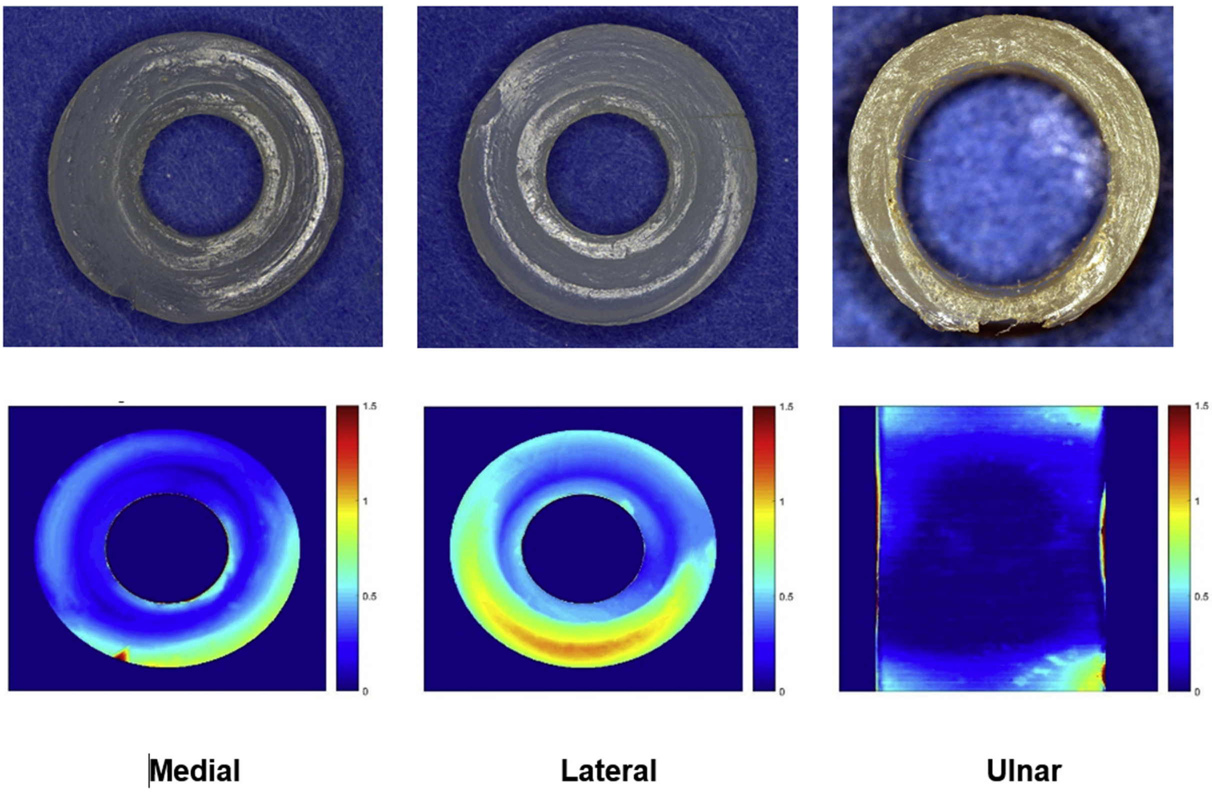

Figure 5 Example photographs and penetration maps for one set of bushings. Heat maps of penetration are scaled to a maximum value of 1.5 mm. The maximum penetration values of the medial, lateral, and ulnar bushings are 0.5, 1.1, and 0.8 mm, respectively. These values exclude the iatrogenic notch on the face of the medial bushing and the small regions of full-thickness loss on the edges of the ulnar component due to ultrahigh-molecular-weight polyethylene–on–ultrahigh-molecular-weight polyethylene contact with the humeral bushing face.

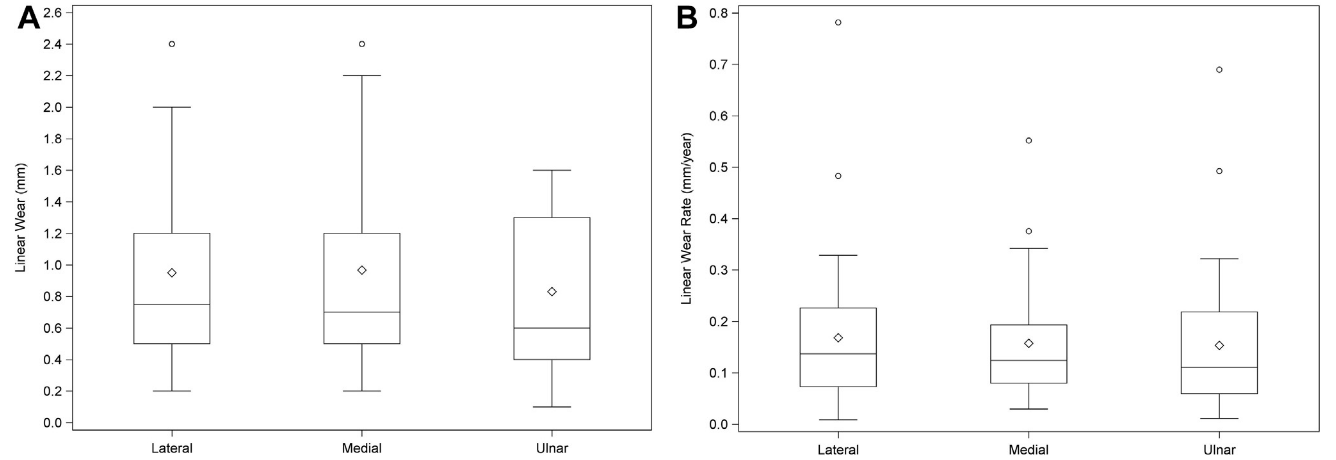

Figure 6 Quantitative linear penetration data segregated by bushing type. No differences in linear penetration **(A)** or in the linear penetration rate **(B)** were observed between groups.

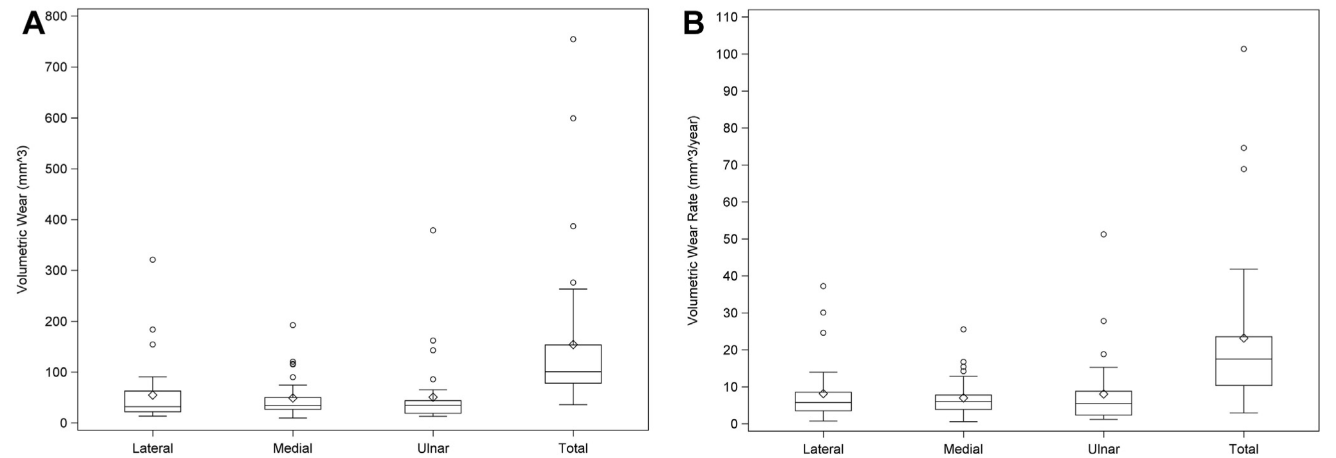

Figure 7 Quantitative volumetric wear data, segregated by bushing type, for retrievals with complete bushing sets only. No differences in volumetric wear **(A)** or in the volumetric wear rate **(B)** were noted between groups.

Discussion

Our study provides quantitative, in vivo linear and volumetric wear data for semiconstrained total elbow arthroplasty. The semiconstrained design that we studied has an established clinical history and can therefore provide a benchmark for wear performance of total elbow arthroplasty.[1,2,21,28-30,37,38,44,48] Although we observed edge loading of ulnar bushings, linear penetration rates and volumetric wear rates did not differ for the ulnar and humeral bushings. No significant relation was found between the wear rate and the index diagnosis, implantation date, or patient age.

For well-performing hips with historical UHMWPE, an average volumetric wear rate of approximately 40 mm^3/yr has been reported.[3,6,20,22,40,41,50] However, periprosthetic osteolysis has been identified as a clinically relevant issue for historical UHMWPE, with increasing volumetric wear rates, in general, associated with an increased risk of osteolysis development. One study showed that with each 40-mm^3/yr increase in wear volume, the risk of osteolysis development increased by approximately 3 times.[41] Similarly, another study reported that osteolysis was uncommon at volumetric wear rates of 62-80 mm^3/yr and greatly increased at a volumetric wear rate of 120 mm^3/yr.[6,7] However, it is not only the total wear volume that determines the biological response to debris but also the concentration that is within the critical size range of 0.1-1.0 μm.[15,19] We have previously demonstrated that the particle morphology, size, and tissue concentration observed in periprosthetic elbow tissues are similar to those seen in the hip.[5] The volumetric wear rates observed in the current study were generally of a similar magnitude to the rate observed in well-functioning hips. However, there were a small number of outliers with a wear rate of approximately 100 mm^3/yr (Fig. 7). The 3 elbows with the highest volumetric wear rates were retrieved from male patients who

Table II Comparison of volumetric wear rates from in vitro simulation data with current study

	Ulnar	Humeral	
		Lateral	Medial
Current study, mm^3/yr	5.5 (1.2-51.2)	5.5 (0.7-37.2)	5.9 (1.2-51.2)
Popoola et al,[43] mm^3/511,000 cycles	2.9 ± 0.9	0.15 ± 0.05	1.9 ± 0.7
Willing[57]			
High JRF, mm^3/7300 cycles	1.3 ± 0.03	0.18 ± 0.02	0.18 ± 0.02
High VM, mm^3/16,500 cycles	3.2 ± 0.3	0.4 ± 0.02	0.4 ± 0.02

JRF, joint reaction force; *VM*, varus moment.
Data are presented as median (range) or mean ± standard deviation. Reported wear rates were converted to annualized volumes based on the assumptions stated in each publication. It should be noted that Willing reported humeral bushing wear rates as the average of both bushings.

were young at the time of implantation (aged 45-57 years) and were treated for post-traumatic arthritis.

Comparison of prior in vitro test results with the wear rates observed in our study reveals limitations associated with the reported protocols (Table II). Popoola et al[43] assumed that there are approximately 500,000 loading cycles/yr with some weight in the patient's hand.[24] On the basis of this assumption, their testing protocol slightly underestimated the wear of the ulnar bushing compared with our population of revision patients. Furthermore, because their protocol used a fixed varus angle rather than a varus-valgus moment, wear of the humeral bushings, particularly the lateral bushing, was underestimated. The wear rates reported under the high–joint reaction force loading protocol described by Willing[57] (0.18 mm^3/7300 cycles for humeral bushings and 1.3 mm^3/7300 cycles for ulnar bushings) resulted in a similar magnitude of wear to the finding of Popoola et al but also resulted in increased wear of the ulnar bushings relative to the humeral bushings. The wear rates reported under the high–varus moment loading protocol of Willing would result in approximately 0.7-3 mm^3/yr of wear per bushing due to sit-to-stand loading alone, as compared with median values of approximately 5-6 mm^3/yr observed in our retrieval population, and once again exaggerated the ulnar bushing wear. We conclude that the loading modes reported previously, particularly the application of varus-valgus moments, used by Varadarajan and Kincaid[52] and by Willing, provide results that have similarities in appearance to those observed in our retrieval population. However, the exaggerated wear magnitude of the ulnar bushing compared with the humeral bushings was not consistent with our data. We believe that further refinement of biomechanical testing is necessary to determine loading protocols that appropriately load both the ulnar and humeral bushings.

Sharifi and Willing[49] reported further on high–joint reaction force loading, combining in vitro simulation data with finite element modeling. They proposed that the higher contribution of the ulnar component to the total wear observed in their testing was the result of UHMWPE-on-UHMWPE contact resulting from extrusion of the ulnar bushing under edge loading. However, the disproportionate ratio between ulnar wear and humeral wear observed in these simulation studies is not consistent with the results of our study. Although we observed evidence of UHMWPE-on-UHMWPE wear in a number of retrieved bushings, the extent of involvement was limited for most patients and rarely resulted in the deep grooving of the humeral bushings observed by Sharifi and Willing (wear maps are shown in Supplementary Appendix S1). It is likely that the elevated sagittal-plane joint reaction force used in the simulation studies overemphasized the effect of ulnar bushing extrusion and contributed to the artificially increased ulnar bushing wear.

Our study had several limitations, some of which are inherent to retrieval studies. Although we only studied a single semiconstrained design, the design and manufacturing of this device have changed multiple times over its market life. Changes include the surface finish of the ulnar component (sintered beads, polymethyl methacrylate precoating, and plasma spray), axis-pin design, humeral bearing surface design, UHMWPE resins (with and without calcium stearate), and packaging environment for the UHMWPE components (air and nitrogen). It has been demonstrated that the ulnar-component finish affects the clinical performance of the device, with higher rates of loosening reported for the precoated ulna.[21] The resultant pistoning of the loose stem can create third-body cement and titanium debris and result in unintentional contact with the distal edge of the humeral bushings, accelerating bushing wear. In our collection, 8 of 18 retrieved ulnar components were precoated. Each of these was loose at revision. The pitting that we observed in both the humeral and ulnar components, as well as the presence of embedded materials in the bearing surfaces, is consistent with both the presence of loose components and the occurrence of unintentional contact at the bearing surface. These failure modes were intentionally not included in the referenced in vitro testing and may affect the observed wear rates. Additionally, gamma sterilization of UHMWPE in the presence of air can promote oxidation and degradation of the mechanical properties of the UHMWPE.[32] Approximately one-half to two-thirds of the implants in this study were packaged prior to 2001. Prior to this date, bushings were packaged in air rather than an inert environment. Although we did not find a significant effect of implantation date on wear rates, we did observe delamination in 30% of the humeral bushings and 55% of the ulnar bushings. However, we would expect reduced oxidation for the current generation of conventional UHMWPE.

A further limitation of our study is a lack of data regarding patient activity levels. It has been demonstrated that wear of lower-extremity arthroplasty is correlated to activity level, assessed using a simple questionnaire.[47] When our study was initiated, we were unable to identify a validated clinical survey that could quantify patients' activity levels for the upper extremity. However, we did not find an effect of sex, age, or initial diagnosis on wear rates.

Another limitation is that our observations are limited to patients who underwent revision surgery including isolated bushing exchange, as well as revision for wear and loosening, and may not be representative of patients who do not require revision. A study of semiconstrained total elbow arthroplasty found that 1.3% of patients underwent bushing exchange for wear at an average of 7.9 years after implantation.[28] These patients underwent revision specifically for UHMWPE wear and represent a small segment of the entire population of total elbow patients. Similarly, it has been demonstrated that wear rates in well-functioning hip patients are lower than those for implants retrieved at revision surgery.[3] It is therefore expected that the extent of wear and damage observed in our study is higher than that in the population of patients who do not undergo revision. Although we did not see statistically significant effects with respect to indication, year of implantation, or patient age, care must be taken when interpreting these results because of limitations in the number of components available for analysis. For both implantation date and patient age, we observed trends that may not have reached significance because of the sample size.

Conclusion

We have characterized the wear and damage of retrieved total elbow UHMWPE bushings. The wear rates were similar to those observed previously for total hip replacement patients with conventional UHMWPE. We found limitations in reported in vitro testing that used a fixed varus angle and a maximum joint reaction force of 840 N and resulted in reasonable ulnar component wear but underestimated humeral bushing wear.[43] The wear patterns reported using a system that could apply both a sagittal-plane joint reaction force and a varus-valgus moment were more consistent with those observed in our retrievals.[53,57] However, the use of a 1250-N joint reaction force coupled with a 5-Nm varus-valgus moment resulted in elevated wear rates and in disproportionate ulnar bushing wear that was not consistent with our retrieval data. We recommend the use of a system that can apply both a sagittal-plane joint reaction force and a varus-valgus moment, but we recommend further investigation using finite element modeling and/or simulator testing to determine representative load levels. The data presented in this study can be used to clinically validate in vitro simulation and provide appropriate loading protocols for elbow wear simulation.

Acknowledgments

The authors thank Bernard Morrey, MD, and Patrick M. Connor, MD, for contributing retrievals to this study.

Disclaimer

This project was funded by Zimmer Biomet, which also provided engineering drawings and exemplar components to aid in the analysis. Zimmer Biomet was not involved in data collection, data analysis, or preparation or editing of our manuscript; a draft of the manuscript was provided to Zimmer Biomet, as a courtesy, prior to submission.

Judd S. Day reports grants and nonfinancial support from Zimmer Biomet, during the conduct of the study, and reports that he is an employee of Exponent.

Daniel W. MacDonald reports grants from Zimmer, during the conduct of the study, as well as grants from Stryker and grants and personal fees from CeramTec.

Matthew L. Ramsey reports personal fees from Zimmer Biomet.

Joseph A. Abboud reports other support from Mid Atlantic Shoulder and Elbow Society, Marlin Medical Alliance, Shoulder JAM, Parvizi Surgical Innovation, Aevumed, OBERD, and Dolevium; nonfinancial support from the Department of Defense, Orthopedic Research and Education Foundation (OREF), DePuy Synthes, Arthrex, OrthoSpace, and Tornier; and personal fees from Tornier, Mininvasive, Trice Medical, Curical Technologies, Dolevium, Zimmer Biomet, DJO, Globus, Integra, Wolters Kluwer Health–Lippincott Williams & Wilkins, Slack Orthopedics, and Flexion Therapeutics.

Steven M. Kurtz reports institutional support from Zimmer Biomet, during the conduct of the study. Dr. Kurtz reports that he is an employee and shareholder of Exponent and that institutional support is received as a principal investigator from Invibio, Smith & Nephew, Stryker Orthopedics, Zimmer Biomet, DePuy Synthes, Medtronic, Stelkast, Formae, Kyocera Medical, Wright Medical Technology, Ceramtec, DJO, Celanese, Aesculap, Spinal Motion, Active Implants, Ferring Pharmaceuticals, and Lima Corporate.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jse.2020.03.026.

References

1. Aldridge JM III, Lightdale NR, Mallon WJ, Coonrad RW. Total elbow arthroplasty with the Coonrad/Coonrad-Morrey prosthesis. A 10- to 31-year survival analysis. J Bone Joint Surg Br 2006;88:509-14. https://doi.org/10.1302/0301-620X.88B4.17095
2. Barthel PY, Mansat P, Sirveaux F, Dap F, Mole D, Dautel G. Is total elbow arthroplasty indicated in the treatment of traumatic sequelae? 19 cases of Coonrad-Morrey((R)) reviewed at a mean follow-up of 5.2 years. Orthop Traumatol Surg Res 2014;100:113-8. https://doi.org/10.1016/j.otsr.2013.10.012
3. Berzins A, Sumner DR, Galante JO. Dimensional characteristics of uncomplicated autopsy-retrieved acetabular polyethylene liners by ultrasound. J Biomed Mater Res 1998;39:120-9.
4. Davis PR. Some significant aspects of normal upper limb functions. London: Mechanical Engineering Publications for the Institution of Mechanical Engineers; 1977.
5. Day JS, Baxter RM, Ramsey ML, Morrey BF, Connor PM, Kurtz SM, et al. Characterization of wear debris in total elbow arthroplasty. J Shoulder Elbow Surg 2013;22:924-31. https://doi.org/10.1016/j.jse.2013.02.001
6. Dowd JE, Sychterz CJ, Young AM, Engh CA. Characterization of long-term femoral-head-penetration rates. Association with and prediction of osteolysis. J Bone Joint Surg Am 2000;82-A:1102-7.
7. Dumbleton JH, Manley M, Edidin AA. A literature review of the association between wear rate and osteolysis in total hip arthroplasty. J Arthroplasty 2002;17:649-61. https://doi.org/10.1054/arth.2002.33664
8. Elke R, Rieker CB. Estimating the osteolysis-free life of a total hip prosthesis depending on the linear wear rate and head size. Proc Inst Mech Eng H 2018;232:753-8. https://doi.org/10.1177/0954411918784982
9. Figgie MP, Su EP, Kahn B, Lipman J. Locking mechanism failure in semiconstrained total elbow arthroplasty. J Shoulder Elbow Surg 2006;15:88-93. https://doi.org/10.1016/j.jse.2005.05.007
10. Gallo J, Mrazek F, Petrek M. Variation in cytokine genes can contribute to severity of acetabular osteolysis and risk for revision in patients with ABG 1 total hip arthroplasty: a genetic association study. BMC Med Genet 2009;10:109. https://doi.org/10.1186/1471-2350-10-109
11. Gay DM, Lyman S, Do H, Hotchkiss RN, Marx RG, Daluiski A. Indications and reoperation rates for total elbow arthroplasty: an analysis of trends in New York State. J Bone Joint Surg Am 2012;94:110-7. https://doi.org/10.2106/JBJS.J.01128
12. Gill DR, Morrey BF. The Coonrad-Morrey total elbow arthroplasty in patients who have rheumatoid arthritis. A ten to fifteen-year follow-up study. J Bone Joint Surg Am 1998;80:1327-35.
13. Goldberg SH, Urban RM, Jacobs JJ, King GJ, O'Driscoll SW, Cohen MS. Modes of wear after semiconstrained total elbow arthroplasty. J Bone Joint Surg Am 2008;90:609-19. https://doi.org/10.2106/JBJS.F.01286
14. Gordon A, Kiss-Toth E, Stockley I, Eastell R, Wilkinson JM. Polymorphisms in the interleukin-1 receptor antagonist and interleukin-6 genes affect risk of in patients with total hip arthroplasty. Arthritis Rheum 2008;58:3157-65. https://doi.org/10.1002/art.23863
15. Green TR, Fisher J, Stone M, Wroblewski BM, Ingham E. Polyethylene particles of a 'critical size' are necessary for the induction of cytokines by macrophages in vitro. Biomaterials 1998;19:2297-302.
16. Harris WH. "The lysis threshold": an erroneous and perhaps misleading concept? J Arthroplasty 2003;18:506-10. https://doi.org/10.1016/s0883-5403(03)00153-0
17. Hastings H II, Theng CS. Total elbow replacement for distal humerus fractures and traumatic deformity: results and complications of semiconstrained implants and design rationale for the Discovery Elbow System. Am J Orthop (Belle Mead NJ) 2003;32:20-8.
18. Hood RW, Wright TM, Burstein AH. Retrieval analysis of total knee prostheses: a method and its application to 48 total condylar prostheses. J Biomed Mater Res 1983;17:829-42.
19. Ingham E, Fisher J. Biological reactions to wear debris in total joint replacement. Proc Inst Mech Eng H 2000;214:21-37.
20. Jasty M, Goetz DD, Bragdon CR, Lee KR, Hanson AE, Elder JR, et al. Wear of polyethylene acetabular components in total hip arthroplasty. An analysis of one hundred and twenty-eight components retrieved at autopsy or revision operations. J Bone Joint Surg Am 1997;79:349-58.
21. Jeon IH, Morrey BF, Sanchez-Sotelo J. Ulnar component surface finish influenced the outcome of primary Coonrad-Morrey total elbow arthroplasty. J Shoulder Elbow Surg 2012;21:1229-35. https://doi.org/10.1016/j.jse.2011.08.062
22. Kawamura H, Bourne RB, Dunbar MJ, Rorabeck CH. Polyethylene wear of the porous-coated anatomic total hip arthroplasty with an average 11-year follow-up. J Arthroplasty 2001;16:116-21.
23. Kelly EW, Coghlan J, Bell S. Five- to thirteen-year follow-up of the GSB III total elbow arthroplasty. J Shoulder Elbow Surg 2004;13:434-40. https://doi.org/10.1016/j.jse.2004.01.028
24. Kincaid BL, An KN. Elbow joint biomechanics for preclinical evaluation of total elbow prostheses. J Biomech 2013;46:2331-41. https://doi.org/10.1016/j.jbiomech.2013.07.027
25. Klug A, Gramlich Y, Buckup J, Schweigkofler U, Hoffmann R, Schmidt-Horlohe K. Trends in total elbow arthroplasty: a nationwide analysis in Germany from 2005 to 2014. Int Orthop 2018;42:883-9. https://doi.org/10.1007/s00264-018-3818-x
26. Kolundzic R, Orlic D, Trkulja V, Pavelic K, Troselj KG. Single nucleotide polymorphisms in the interleukin-6 gene promoter, tumor necrosis factor-alpha gene promoter, and transforming growth factor-beta1 gene signal sequence as predictors of time to onset of aseptic loosening after total hip arthroplasty: preliminary study. J Orthop Sci 2006;11:592-600. https://doi.org/10.1007/s00776-006-1069-y
27. Landor I, Vavrik P, Jahoda D, Guttler K, Sosna A. Total elbow replacement with the Souter-Strathclyde prosthesis in rheumatoid arthritis. Long-term follow-up. J Bone Joint Surg Br 2006;88:1460-3. https://doi.org/10.1302/0301-620X.88B11.17807
28. Lee BP, Adams RA, Morrey BF. Polyethylene wear after total elbow arthroplasty. J Bone Joint Surg Am 2005;87:1080-7. https://doi.org/10.2106/JBJS.D.02163
29. Lee KT, Singh S, Lai CH. Semi-constrained total elbow arthroplasty for the treatment of rheumatoid arthritis of the elbow. Singapore Med J 2005;46:718-22.
30. Little CP, Graham AJ, Karatzas G, Woods DA, Carr AJ. Outcomes of total elbow arthroplasty for rheumatoid arthritis: comparative study of three implants. J Bone Joint Surg Am 2005;87:2439-48. https://doi.org/10.2106/JBJS.D.02927
31. Liu A, Richards L, Bladen CL, Ingham E, Fisher J, Tipper JL. The biological response to nanometre-sized polymer particles. Acta Biomater 2015;23:38-51. https://doi.org/10.1016/j.actbio.2015.05.016
32. Lu S, Orr JF, Buchanan FJ. The influence of inert packaging on the shelf ageing of gamma-irradiation sterilised ultra-high molecular weight polyethylene. Biomaterials 2003;24:139-45. https://doi.org/10.1016/s0142-9612(02)00271-5
33. MacInnes SJ, Del Vescovo E, Kiss-Toth E, Ollier WE, Kay PR, Gordon A, et al. Genetic variation in inflammatory and bone turnover pathways and risk of osteolytic responses to prosthetic materials. J Orthop Res 2015;33:193-8. https://doi.org/10.1002/jor.22755

34. Malik MH, Bayat A, Jury F, Kay PR, Ollier WE. Genetic susceptibility to total hip arthroplasty failure–positive association with mannose-binding lectin. J Arthroplasty 2007;22:265-70. https://doi.org/10.1016/j.arth.2006.02.163
35. Malik MH, Jury F, Bayat A, Ollier WE, Kay PR. Genetic susceptibility to total hip arthroplasty failure: a preliminary study on the influence of matrix metalloproteinase 1, interleukin 6 polymorphisms and vitamin D receptor. Ann Rheum Dis 2007;66:1116-20. https://doi.org/10.1136/ard.2006.062018
36. Matarese W, Stuchin SA, Kummer FJ, Zuckerman JD. Polyethylene bearing component failure and dislocation in the triaxial elbow. A report of two cases. J Arthroplasty 1990;5:365-7.
37. Morrey BF. Fractures of the distal humerus: role of elbow replacement. Orthop Clin North Am 2000;31:145-54.
38. Morrey BF, Bryan RS, Dobyns JH, Linscheid RL. Total elbow arthroplasty. A five-year experience at the Mayo Clinic. J Bone Joint Surg Am 1981;63:1050-63.
39. Morrey BF, Sanchez-Sotelo J. The elbow and its disorders. Philadelphia: Saunders Elsevier; 2009.
40. Oparaugo PC, Clarke IC, Malchau H, Herberts P. Correlation of wear debris-induced osteolysis and revision with volumetric wear-rates of polyethylene: a survey of 8 reports in the literature. Acta Orthop Scand 2001;72:22-8.
41. Orishimo KF, Claus AM, Sychterz CJ, Engh CA. Relationship between polyethylene wear and osteolysis in hips with a second-generation porous-coated cementless cup after seven years of follow-up. J Bone Joint Surg Am 2003;85-A:1095-9. https://doi.org/10.2106/00004623-200306000-00018
42. Owens BD, Osuch D, Morgan WJ. Rapid osteolysis in semiconstrained total elbow arthroplasty: case report and review. J Shoulder Elbow Surg 2006;15:252-5. https://doi.org/10.1016/j.jse.2005.02.018
43. Popoola OO, Kincaid BL, Mimnaugh K, Marqueling M. In vitro wear of ultrahigh-molecular-weight polyethylene and vitamin E blended highly cross-linked polyethylene in linked, semiconstrained total elbow replacement prostheses. J Shoulder Elbow Surg 2017;26:846-54. https://doi.org/10.1016/j.jse.2016.12.066
44. Ramsey ML, Adams RA, Morrey BF. Instability of the elbow treated with semiconstrained total elbow arthroplasty. J Bone Joint Surg Am 1999;81:38-47.
45. Schmalzried TP, Campbell P, Schmitt AK, Brown IC, Amstutz HC. Shapes and dimensional characteristics of polyethylene wear particles generated in vivo by total knee replacements compared to total hip replacements. J Biomed Mater Res 1997;38:203-10.
46. Schmalzried TP, Jasty M, Harris WH. Periprosthetic bone loss in total hip arthroplasty. Polyethylene wear debris and the concept of the effective joint space. J Bone Joint Surg Am 1992;74:849-63.
47. Schmalzried TP, Shepherd EF, Dorey FJ, Jackson WO, dela Rosa M, Fa'vae F, et al. The John Charnley Award. Wear is a function of use, not time. Clin Orthop Relat Res 2000:36-46.
48. Schneeberger AG, Meyer DC, Yian EH. Coonrad-Morrey total elbow replacement for primary and revision surgery: a 2- to 7.5-year follow-up study. J Shoulder Elbow Surg 2007;16:S47-54. https://doi.org/10.1016/j.jse.2006.01.013
49. Sharifi KD, Willing R. Development of a hybrid computational/experimental framework for evaluation of damage mechanisms of a linked semiconstrained total elbow system. J Shoulder Elbow Surg 2018;27:614-23. https://doi.org/10.1016/j.jse.2017.10.020
50. Sychterz CJ, Moon KH, Hashimoto Y, Terefenko KM, Engh CA Jr, Bauer TW. Wear of polyethylene cups in total hip arthroplasty. A study of specimens retrieved post mortem. J Bone Joint Surg Am 1996;78:1193-200.
51. Triplet JJ, Kurowicki J, Momoh E, Law TY, Niedzielak T, Levy JC. Trends in total elbow arthroplasty in the Medicare population: a nationwide study of records from 2005 to 2012. J Shoulder Elbow Surg 2016;25:1848-53. https://doi.org/10.1016/j.jse.2016.04.021
52. Varadarajan R, Kincaid BL. Development and validation of a method for preclinical durability evaluation of linked semiconstrained total elbow replacement prostheses. J Shoulder Elbow Surg 2019;3:1-11. https://doi.org/10.1177/2471549219826365
53. Varadarajan R, Kincaid BL, Ramsey ML, Morrey BF. In-vitro durability evaluation of linked semi-constrained total elbow prostheses. Paper presented at: 68th Annual Meeting of the American Society for Surgery of the Hand; October 3-5, 2013. San Francisco, CA, USA.
54. Wilkinson JM, Hamer AJ, Stockley I, Eastell R. Polyethylene wear rate and osteolysis: critical threshold versus continuous dose-response relationship. J Orthop Res 2005;23:520-5. https://doi.org/10.1016/j.orthres.2004.11.005
55. Wilkinson JM, Wilson AG, Stockley I, Scott IR, Macdonald DA, Hamer AJ, et al. Variation in the TNF gene promoter and risk of osteolysis after total hip arthroplasty. J Bone Miner Res 2003;18:1995-2001. https://doi.org/10.1359/jbmr.2003.18.11.1995
56. Williams GR, Yamaguchi K, Ramsey ML, Galatz LM. Shoulder and elbow arthroplasty. Philadelphia: Lippincott Williams & Wilkins; 2005.
57. Willing R. Comparing damage on retrieved total elbow replacement bushings with lab worn specimens subjected to varied loading conditions. J Orthop Res 2018;36:1998-2006. https://doi.org/10.1002/jor.23847
58. Wright TW, Hastings H. Total elbow arthroplasty failure due to overuse, C-ring failure, and/or bushing wear. J Shoulder Elbow Surg 2005;14:65-72. https://doi.org/10.1016/j.jse.2004.04.015