

# Development and Validation of a Method for Preclinical Durability Evaluation of Linked Semiconstrained Total Elbow Replacement Prostheses

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Ravikumar Varadarajan, PhD<sup>1</sup> and Brian L Kincaid, MS<sup>1</sup>

## Abstract

Total elbow replacement (TER) is a clinically successful procedure yet isolated, gross mechanical complications associated with implant durability persist. The objectives of this study were to (1) develop a clinically relevant in vitro methodology to replicate the reported damage modes and (2) demonstrate durability improvements of a next-generation linked, semiconstrained design. Two TER prostheses were tested on a biaxial test frame at 1.4 Hz in  $37 \pm 3^\circ$  deionized water through  $0^\circ$  to  $130^\circ$  flexion/extension at various load levels simulating high demand, posttraumatic patients until either component failure or run out to 200 000 cycles. The damage patterns of tested components were qualitatively compared to retrieved components to establish the clinical validity of the methodology. The run out load of design 1 was equivalent to 100 N weight in hand (WIH). Specimens tested at higher load levels exhibited multimodal damage consistent in appearance with the clinical literature. The minimum run out load of design 2 was 110 N WIH with no significant damage observed on the components. The methodology developed here was shown to reproduce the clinical damage modes associated with TER in high demand, posttraumatic patients. The method was able to distinguish performance differences within and between 2 different linked, semiconstrained designs.

## Keywords

Arthroplasty, elbow, prosthesis, polyethylene, linkage, fracture, replacement, revision, disassociation

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## Introduction

Total elbow replacement (TER) provides a successful treatment option for degenerative and posttraumatic conditions of the elbow joint. Many of the contemporary TER implants that replace the humero-ulnar (HU) joint utilize a linked, semiconstrained metal-on-polyethylene articulation (a.k.a. “sloppy hinge”). One such design has been clinically successful with multiple retrospective studies of long-term survivorship greater than 90% at 10 years with rheumatoid arthritis as the primary indication for TER.<sup>1,2</sup> Yet complications after TER persist, limiting even greater long-term survivorship (83% at 15 years and 68% at 20 years)<sup>3</sup> at rates commonly reported for total hip and knee replacement.<sup>4-6</sup> Isolated incidences of gross mechanical complication with the articular complex of linked semiconstrained TER have been reported in the clinical literature. Severe delamination, fracture, and “wear through” of

the ultra-high molecular weight polyethylene (UHMWPE) bushings resulting in metal-on-metal (MoM) articulation as well as modular linkage disassociation or fracture have been reported and are most frequently associated with younger, high-demand patients with posttrauma sequelae or acute distal humerus fracture as the primary indications for TER.<sup>2,5,7-15</sup> Although overall incidences of implant failure necessitating revision surgery are low, 4% and 1.7%, respectively, relative to other etiologies such as infection and neuropathy,<sup>4,6</sup> they typically require implant replacement and

<sup>1</sup>Zimmer Biomet Global Extremities Research & Development, Warsaw, Indiana

### Corresponding Author:

Ravikumar Varadarajan, Zimmer Biomet, 56 E Bell Drive, PO Box 587, Warsaw, IN 46581, USA.

Email: Ravikumar.Varadarajan@zimmerbiomet.com



additional bone resection as a result of the osteolytic response to the UHMWPE and metallic debris. Day et al. reported on wear, delamination, and isolated incidences of UHMWPE bushing fracture in retrieved Coonrad/Morrey (C/M) (Zimmer Biomet, Inc., Warsaw, IN) TER components.<sup>8</sup> Wright and Hastings reported bushing wear or disassociation of the “c-ring” linkage mechanism in 10 (n=10) patients who underwent primary TER using an older generation of the C/M.<sup>15</sup> Seitz et al. reported a 6.1% disassociation or fracture rate of the current C/M “snap-pin” linkage mechanism in a retrospective analysis on 82 TER patients.<sup>13</sup> Three (n=3) patients performed strenuous activities (wood splitting, lifting over 8 kg [20 lbf]) against medical advice and the limits prescribed by the manufacturer.<sup>16</sup> Similarly, Figgie et al. and Madsen et al. reported disassembly in 9 of 170 (5.3%) and 4 of 23 (17%) patients utilizing the Osteonics (Stryker) and Pritchard II (DePuy Orthopedics) sloppy hinge elbow prostheses, respectively.<sup>10,17</sup> Hastings et al. reported screw loosening and back out in 3 of 46 patients (6.5%) who underwent TER using the Discovery Total Elbow System (DJO Global, Vista, CA).<sup>18</sup>

Improvement in the durability of the articulation interface and the linkage mechanism(s) of linked semi-constrained TER requires better understanding of the elbow joint mechanics and validated in vitro test methods for the preclinical assessment of TER designs under a variety of loading conditions. Unfortunately, to the knowledge of the authors, there are no consensus international test standards (ASTM/ISO) for the durability evaluation of contemporary TER. A summary of the elbow biomechanics literature and proposed in vitro TER loading profiles was recently published.<sup>19</sup> The objective of this study therefore was to utilize this information to (1) develop a clinically relevant in vitro test methodology to accurately replicate the gross mechanical damage of the articular complex reported in the TER literature and (2) demonstrate improvements in the durability performance of a next-generation linked, semiconstrained TER design.

## Materials and Methods

This is an in vitro biomechanical study reporting on development of a durability bench test simulating the articular interface behavior in linked semiconstrained TER implants under aggressive use conditions.

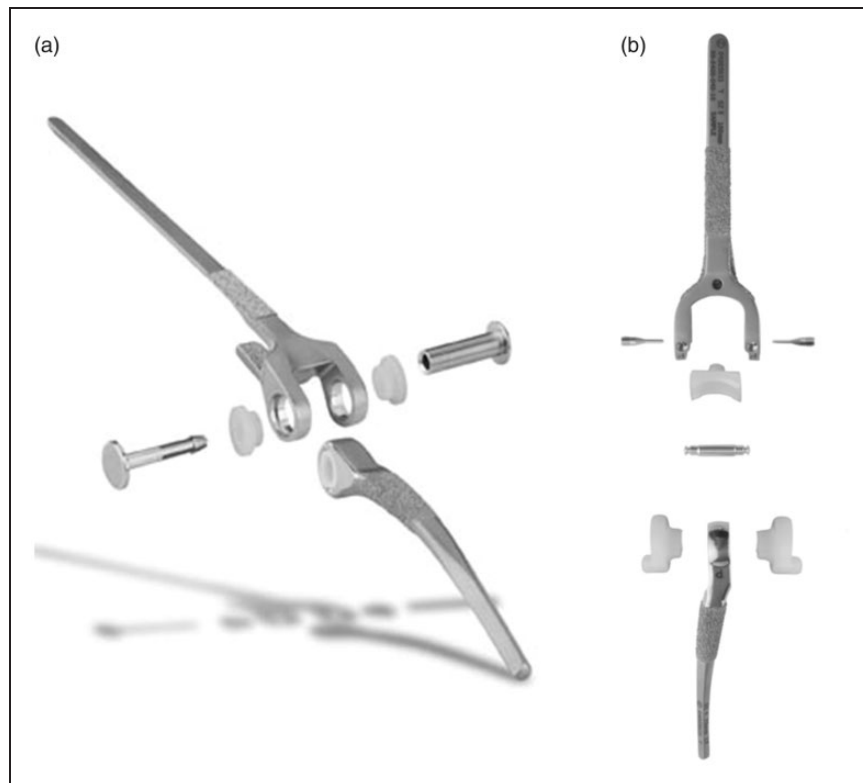
## Materials

The implants used in this study are designed to replace the HU joint only. The C/M consists of Titanium alloy (Ti6Al4V) humeral and ulnar stems joined intraoperatively by a transverse, 2 piece Cobalt Chrome alloy

(CoCrMo)/Titanium alloy (Ti6Al4V) “snap-pin” linkage. The articular interface utilizes 3 bushings (2 humeral and 1 ulnar) machined from conventional compression-molded GUR 1050 UHMWPE bars (CPE), packaged in nitrogen, and gamma-irradiation sterilized at  $37 \pm 10\%$  kGy, see Figure 1(a). The Nexel™ Total Elbow (Nexel; Zimmer Biomet, Warsaw, IN) is a next-generation TER design that consists of Ti6Al4V alloy humeral and ulnar stems linked intraoperatively with a solid CoCrMo alloy axial-pin secured with 2 CoCrMo alloy headless humeral screws with thread locking technology. The articulation utilizes 3 bushings (2 ulnar and 1 humeral), all manufactured from highly cross-linked UHMWPE stabilized with the antioxidant vitamin E (VE-HXPE) (Figure 1(b)).

The VE-HXPE bushings are machined from compression-molded pucks of vitamin E blended GUR 1020 resin and electron beam cross-linked at  $>100$  kGy, packaged in air, and ethylene oxide sterilized (Vivacit-E, Zimmer Biomet). In addition, the proximal ulnar “eye” is hardened by nitrogen ion implantation technology (*IonGuard*® N2 Biomedical, Bedford, MA) to mitigate particle shedding and possible third-body particle abrasion.

The C/M and Nexel TERs are available in several sizes with the differences most pronounced in the humeral and ulnar stem geometries. Stem geometry would be expected to have minimal impact on articular linkage durability performance assuming well fixed stems. Specific to the present study, however, the humeral “yoke” medial/lateral (M/L) width is wider on the Size Small and Regular C/M and Size 5 and 6 Nexel humeral stems, respectively. Consequently, a longer linkage is needed in these sizes to compensate for the added M/L yoke width as compared to the Size Extra Small C/M and Size 4 Nexel humeral stems. Because the longer pin results in larger bending stresses under the same loading conditions, the Size Small/Regular C/M and Size 5/6 Nexel humeral stems were defined as a worst case, with the Size Regular C/M and Size 5 Nexel ulnar and humeral stems arbitrarily chosen for testing. Test boundary conditions need to simulate the worst-case loading scenario for the modular articulation where the components experience the entire joint load. This was accomplished by a test fixture design which assumes rigid fixation of the stems in the bone and thus constitutes a “worst case” by which to study behavior under variable loading conditions. It also has the advantage of eliminating the complexity and variability inherent in using full implant constructs fixated in simulated or cadaveric bone and thus can produce more repeatable results for purposes of design evaluation and benchmarking. Test fixtures manufactured with the same materials, critical dimensions, and surface finish as production components were developed to isolate the



**Figure 1.** Total elbow replacement implants (a) Coonrad-Morrey and (b) Nexel.

proximal ulnar and distal humeral stem geometries in order to facilitate testing and direct all the loading through the modular interfaces. Commercially available bushing replacement kits (all bushings with the metallic linkage components) for both TER designs were utilized to link the components together using the prescribed surgical techniques and instrumentation, as applicable.

## Methods

### *Durability Test Method Development*

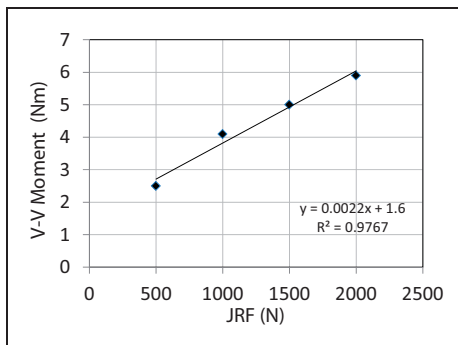
**Load/motion profiles.** The “dynamic” load/motion profile proposed by Kincaid and An was adopted here as the basis for the test machine input waveforms.<sup>19</sup> Utilizing equation (1),<sup>19</sup> joint reaction force (JRF) waveforms were generated for various assumed weight in hand (WIH) (eg, activity levels) with the peak JRF occurring at approximately 10° of elbow flexion. The flexion/extension range of a natural elbow is reported from 0° to 146° where 0° is defined as the ulna in full extension and coincident with long axis of the humerus in the sagittal plane, but Morrey et al. demonstrated that most activities of daily living (ADLs) can be accomplished within a 100° arc between approximately 30° and 130° of elbow flexion.<sup>20</sup> As shown in Figure 3 of Kincaid and An, HU JRFs are maximum early in the flexion cycle (0°–30°),

are minimum from 130° to 150°, with a rapid decrease after 130° of flexion which is beyond the range of most ADL that involve generation of significant JRFs such as lifting heavy objects.<sup>19</sup> Therefore, motions beyond 130° were deemed to have little impact on durability performance, and a flexion/extension arc of 0° to 130° was employed here. In addition, the orientation of the JRF acting relative to the mechanical (long) axis of the distal humeral in the sagittal plane has been shown to “lag” the actual elbow flexion angle due to the main flexor muscle’s line of action.<sup>19</sup> Due to the limitations of the test set up, the humeral implant was fixed at 10° relative to the machine coordinate system so that the peak compressive JRF was applied at the anatomically correct orientation (–10°), consistent with the initial lag reported by Kincaid and An, but not time dependent with flexion angle as also demonstrated to occur.<sup>19</sup>

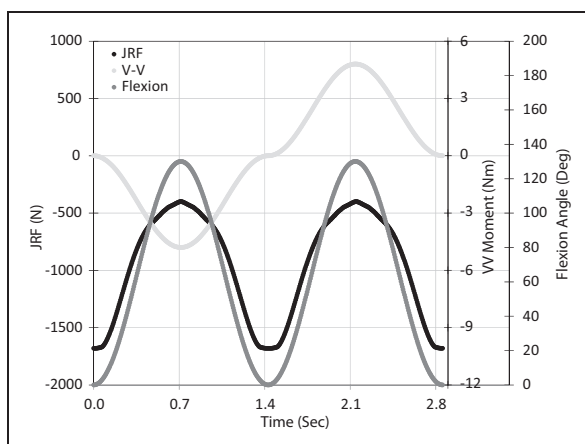
**Varus–valgus.** The C/M was designed with a maximum  $\pm 3.5^\circ$  varus–valgus (VV) laxity (“sloppy hinge”) in the humero-ulnar linkage, yet analysis of retrieved C/M bushings and clinical reports of VV angles measured radiographically at the time of revision surgery indicate deviations in excess of  $\pm 4^\circ$  are associated with TER revised for complications associated with bushing “wear.”<sup>1,15,21</sup> Therefore, the VV moment required to induce a 4.5° varus (medial) deviation of the ulnar

component relative to the humeral in the frontal plane was determined for a size Regular C/M at 4 discrete peak JRFs using a validated Finite Element model, see Figure 2. Linear regression was used to produce an equation to allow the moment to be scaled with any applied peak JRF and then converted to a VV load given the fixed, known moment arm created by the test specimen (C/M = 14.5 mm, Nexel = 27.2 mm). A combination of sinusoidal and ramp waveforms were utilized to generate a JRF profile, with a sinusoid used for both the VV load and flexion waveforms. The waveform was constructed such that it applied the VV load magnitudes equally over the course of 2 complete flexion/extension cycles, alternating between varus and valgus loading each cycle, see Figure 3.

**Test frequency and duration.** Little information is available regarding the activity-dependent frequency and speed of



**Figure 2.** Relationship between JRF and VV moment for C/M TER. JRF, joint reaction force; VV, varus–valgus.



**Figure 3.** Representative durability test waveform (2 complete flexion/extension cycles shown). One full cycle constitutes flexion from 0° to 130° and extension return from 130° to 0°. Negative JRF values denote compressive loads, negative VV denotes varus loading, and positive denotes valgus loading. JRF, joint reaction force; VV, varus–valgus.

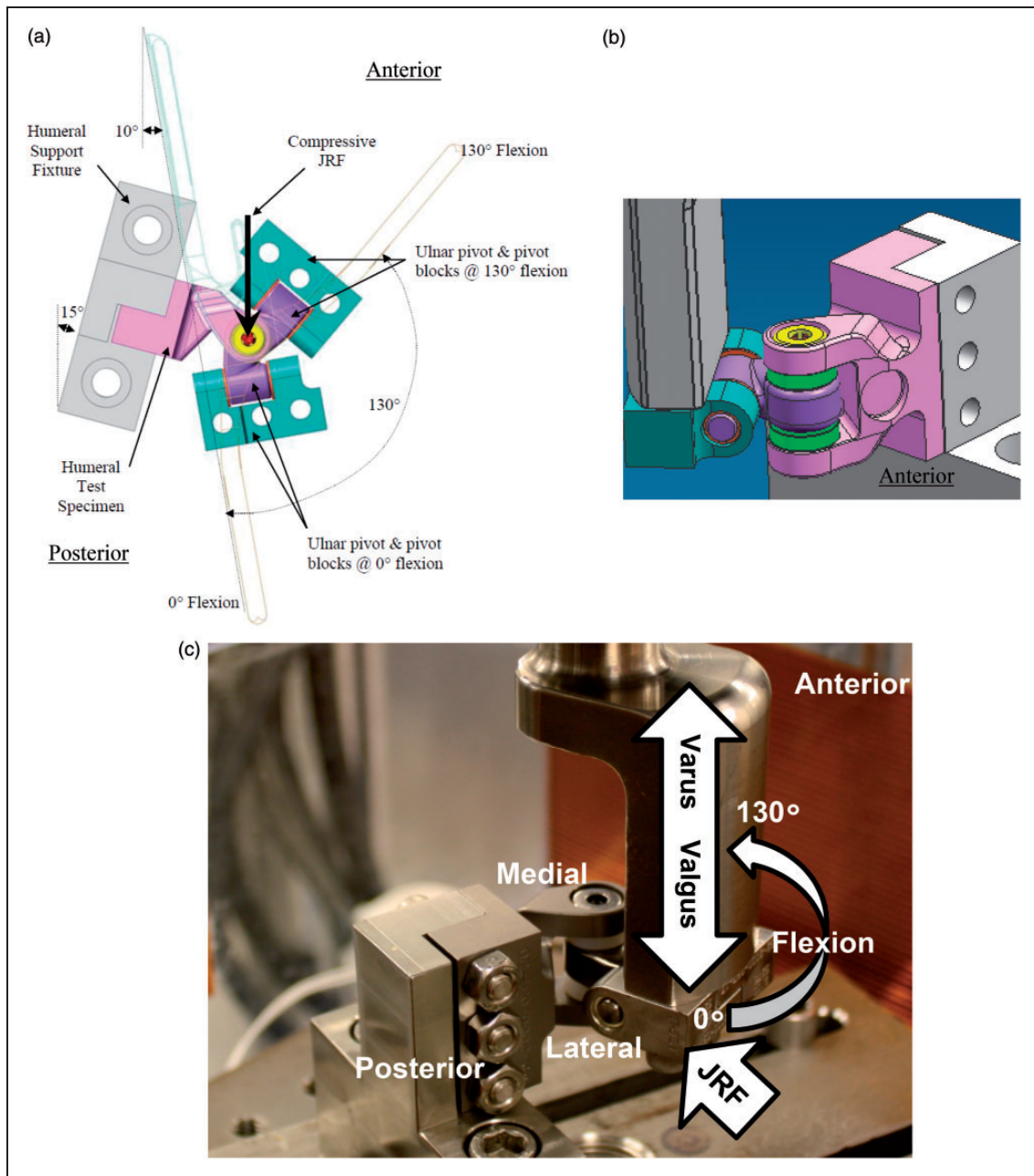
elbow flexion/extension movements. Fast movements of the arm may be as quick as 0.2 s/cycle, with large initial peak accelerations followed by a prolonged constant torque, but the movement of the upper extremities tends to be slower than that of the lower extremities during high-demand ADLs<sup>22</sup>; 0.7 Hz was chosen to represent the slower flexion frequency associated with strenuous ADL<sup>22</sup> simulated here while allowing adequate test machine response and controllability. Thus, a machine cyclic frequency of 1.4 Hz was employed here, as one test cycle was defined as full flexion and return to full extension. Kincaid and An proposed 20 cycles/day for strenuous ADL, which equates to approximately 150 000 cycles over 20 years.<sup>19</sup> Anglin et al. had previously proposed 25 cycles/day (186 000 over 20 years) for simulating high-load activities in the shoulder.<sup>23</sup> The conservative estimate of 25 cycles/day was used here and conservatively rounded to 200 000 as the target “run-out” test duration.

### Test Protocol

Testing was performed using a biaxial servo-hydraulic testing machine with torsional capabilities (FlexTest<sup>®</sup>, MTS, Eden Prairie, MN) in the Fatigue and Fracture Mechanics Test Laboratory at Zimmer Biomet (Warsaw, IN). A schematic and the actual test setup are shown in Figure 4(a) and (b), respectively. The alternating varus and valgus loads and elbow flexion/extension motion were applied using the vertical (tension/compression and torsion) actuator of the machine in load and displacement control modes, respectively, while the compressive JRF was applied through the orthogonal table utilizing load control. The ulnar test fixture assembly was designed so that it can sweep through a 0° to 130° elbow flexion arc while simultaneously applying alternating varus and valgus moments through the use of an arbor and pivot block assembly (Figure 4(a) and (b)).

Igus J-flange bushings (p/n JFI-0405-06, JFI-0506-0, Igus Inc, East Providence, RI) were utilized in the ulna pivot assembly to provide low friction articulation of the pivot mechanism and were replaced after each run. All articular test specimens were assembled per the applicable surgical technique and instrumentation, as needed. A calibrated torque sensor (Futek Advanced Sensor Technology Inc., Irvine, CA) was used to install the Nexel Humeral Screws. Three specimens each were torqued to lower and upper tolerance range of the Nexel humeral screw surgical torque driver. The same instrument was used to measure the removal torque of the humeral screws posttest.

Testing was conducted at 1.4 Hz in 37°C deionized water at various loading levels in order to obtain run out. Run out was defined by no severe delamination or



**Figure 4.** (a) Schematic of the durability test setup (C/M humeral and ulnar stems shown superimposed for reference only). (b) Actual test setup (C/M shown in valgus for representative purposes only). JRF, joint reaction force.

fracture of the bushings resulting in MoM articulation or linkage fracture and/or concomitant dissociation of the test specimen(s) prior to reaching 200 000 cycles. A total of 9 C/M assemblies were tested beginning at 133 N (30 lbf) WIH and “stepping down” utilizing ~10% increments until run out was achieved. Additional samples (n = 3) were run to confirm the run-out load level. Six (n = 6) Nexel test specimens were then tested under the same conditions but at a 10% higher load level than the C/M run-out load. The appearance of the C/M

components posttest was qualitatively compared to images of components retrieved at the time of revision surgery from both internal (Zimmer Biomet) and external studies to assess the clinical validity of the methods prescribed here.

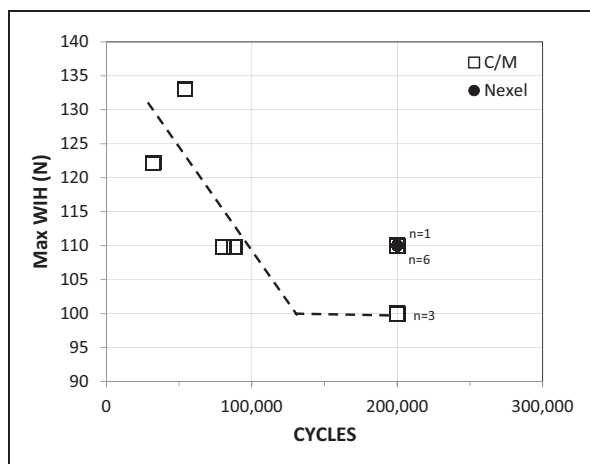
## Results

C/M test results are shown in Table 1 and Figure 5. Three (n = 3) specimens tested at an equivalent of 100

**Table 1.** C/M Elbow Durability Test Results.

WIH N (lbf)	Max JRF (N)	Max VV Moment (Nm)	Results
133 (30.0)	2014	6.0	Outer snap-pin backed out at 54 113 cycles. Severe damage of ulnar bushing. MoM.
122 (27.5)	1847	5.7	Outer snap-pin backed out at 32 741 cycles. Severe damage of ulnar bushing. MoM.
110 (25.0)	1679	5.3	Outer snap-pin backed out at 89 182 cycles. Severe damage of ulnar bushing. MoM.
110 (25.0)	1679	5.3	At the end of 200 000 cycles, severe damage of ulnar bushing. MoM.
110 (25.0)	1679	5.3	Run out
110 (25.0)	1679	5.3	Outer snap-pin backed out at 81 633 cycles. Severe damage of ulnar bushing. MoM.
100 (22.5)	1511	4.9	Run out
100 (22.5)	1511	4.9	Run out
100 (22.5)	1511	4.9	Run out

Abbreviations: MoM, metal-on-metal; JRF, joint reaction force; VV, varus–valgus; WIH, weight in hand.



**Figure 5.** C/M and Nexel elbow durability test results. C/M, Coonrad/Morrey; WIH, weight in hand.

N (22.5 lbf) WIH (peak 1511 N JRF and 4.9 Nm VV moment) ran out to 200 000 cycles. An additional run out was achieved at 110 N (25 lbf), but other specimens tested at this load level did not complete testing prior to fracture and MoM articulation.

The typical appearance of the ulnar bushing components at run out is shown in Figure 6(a) and (b). All exhibited severe creep in the longitudinal and transverse direction, with crack initiation at the outer edge in one sample, similar in appearance to revised bushing components described in the literature.

The humeral bushings exhibited creep where ulnar stem contact occurred resulting in asymmetric “flat” wear at the outer edge of the flange, also consistent with the appearance of retrieved components. During testing, this was observed to result in ulnar-humero bushing contact producing poly-on-poly articulation resulting in burnishing and “grooving” of the humeral bushing in all tested specimens, also similar in appearance to revised components (Figure 6(c)). Specimens tested at higher load levels all exhibited clinically

relevant damage modes including mass delamination and wear through of the ulnar bushing resulting in MoM articulation of the ulnar eye with the snap-pin (Figure 7(a) and (b)), asymmetric thinning and grooving of the humeral bushings (Figure 6(c)), and snap-pin “back-out” and/or fracture (Figure 7(c)). The MoM articulation with ulnar eye produced dark wear scars on the outer snap-pin similar in appearance to revised components (Figure 7(d)).

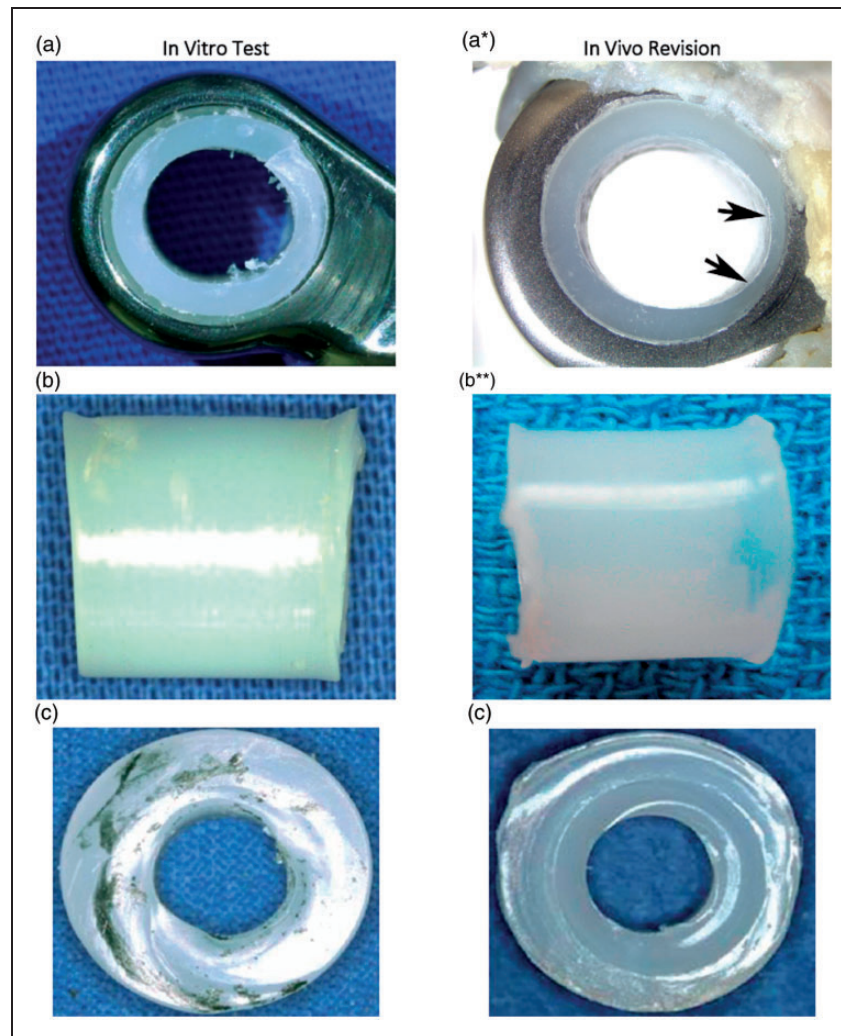
By contrast, all 6 Nexel elbow test specimens tested at the equivalent of 110 N (25 lbf) WIH (peak JRF 1680N and VV 5.3 Nm) ran out to 200 000 cycles without linkage fracture/disassociation or gross mechanical overload of the VE-HXPE bushings and concomitant MoM articulation. The VE-HXPE bushing exhibited some minor creep and burnishing but no evidence of crack initiation (Figure 8(a) and (b)).

All humeral screws had measurable torque upon disassembly (Table 2) and displayed minor signs of wear at the axle pin/screw interface, but no indication of yielding or fatigue crack initiation under 50× visual examination.

No significant wear or damage was observed on any of the humeral or ulnar metallic components (Figure 9), and no qualitative differences were noted between the specimens run to the lower versus upper bounds of the Nexel torque driver tolerance band.

## Discussion

The scalable, biaxial test method developed here has been shown to repeatedly reproduce the appearance of several C/M durability-related complications reported in the clinical literature associated with younger, high demand, posttraumatic, and/or noncompliant patients. Furthermore, the frequency and severity of the damage has been shown to increase with increasing simulated patient activity, as expected, also consistent with the clinical experience.<sup>5,13,15</sup> Mode 1, mode 2, and mode 4 “wear” as defined by Goldberg et al. was consistently produced by the test method, with the degree of



**Figure 6.** C/M Elbow bushings post run out compared to revised bushings (a and b) ulnar and (c) humeral.

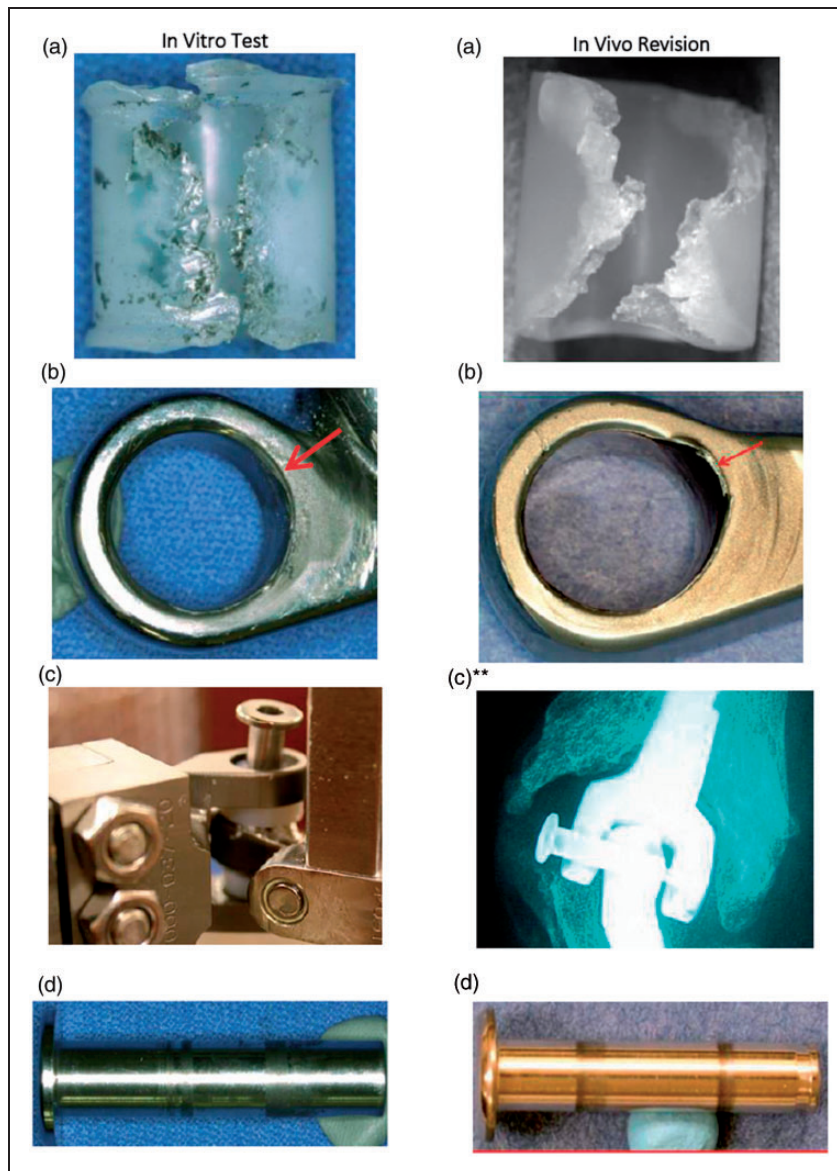
\*Reprinted from Steven Goldberg, Robert Urban, Joshua Jacobs, et al, Modes of Wear After Semiconstrained Total Elbow Arthroplasty, *Journal of Bone & Joint Surgery*, Volume 90 – Issue 3 – p 609–619 Vol 90 (3), [http://journals.lww.com/jbjsjournal/Fulltext/2008/03000/Modes\\_of\\_Wear\\_After\\_Semiconstrained\\_Total\\_Elbow.19.aspx](http://journals.lww.com/jbjsjournal/Fulltext/2008/03000/Modes_of_Wear_After_Semiconstrained_Total_Elbow.19.aspx), with permission from Wolters Kluwer Health, Inc.

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damage commensurate with loading level.<sup>21</sup> Snap-pin back-out and/or concomitant linkage dissociation, gross delamination and wear through of the ulnar bushing resulting in MoM articulation (mode 2 and mode 4), and asymmetric thinning and “grooving” of the humeral bushings due to poly-on-poly articulation (mode 1) were observed on specimens when tested at loads corresponding to 110 N (25 lbf) WIH and higher. It is important to note that high joint loads and moments representative of noncompliant, highly active patients, and/or gross anatomic deformity resulting in component malalignment were necessary to produce damage consistent with literature observations of C/M components at the time of revision surgery.<sup>2,5-7,13-15</sup> This is consistent with high demand and/or posttraumatic patients where excessive

loads and moments would be expected due to the lack of humeral condyles, soft tissues ligamentous structures, and action of flexor pronator mass and extensor origin muscles, all of which may constrain VV loading across the HU joint at the extremes of medial/lateral ulnar excursions.<sup>15</sup> Run out was consistently achieved at load levels representative of 100 N (22.5 lbf) WIH while still producing clinically relevant damage patterns to the ulnar and humeral bushings. These findings correlate well to the overall good clinical history of the C/M TER reported in the literature, particularly in compliant, non-posttraumatic patients.<sup>1,2</sup>

All 6 Nexel test specimens ran out at load levels corresponding to 110 N (25 lbf) WIH, a load level 10% higher than the C/M run-out load. The components



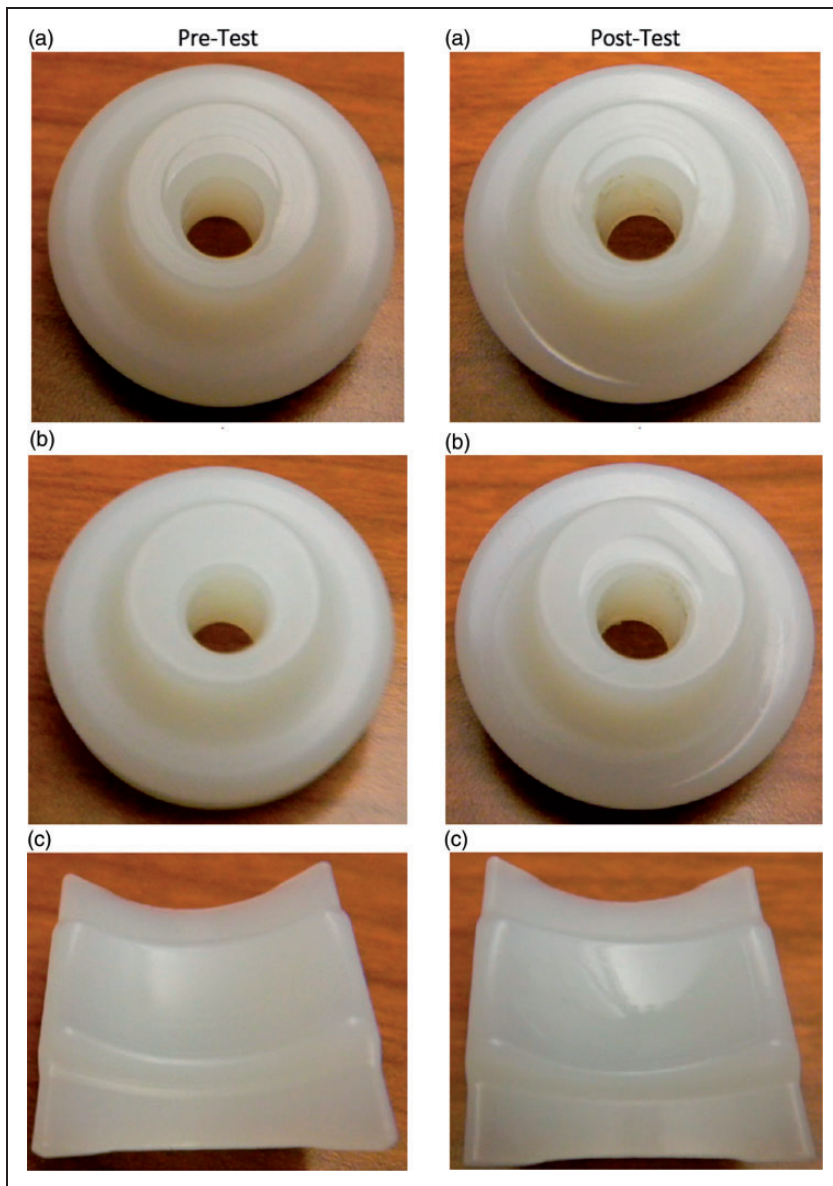
**Figure 7.** C/M MoM posttest compared to revised components (a) ulnar bushing, (b) proximal ulnar eye, (c) snap-pin back out, and (d) outer snap-pin.

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exhibited only minor damage and remained intact and functional despite these aggressive test parameters. Assuming a binomial distribution, 6 consecutive run outs equates to 98.4% confidence ( $N=6$ ,  $n=0$  fractures,  $P=.5$ ; Minitab, College Station, PA) that the mean durability strength of the Nexel elbow design is at least 110 N (25 lbf) WIH when tested in the manner described here. The durability improvements realized with the Nexel design are attributed to the Vivacit-E material and/or thicker and more conforming bushings which

reduce contact stresses due to edge loading, particularly under high VV loading scenarios. The addition of the humeral bushing at the base of the humeral “yoke” prevents unintended MoM articulation between the ulnar and humeral as well as better distributes joint loads, further reducing stresses on the ulnar bushings. Finally, the Nexel modular linkage is designed to be self-reinforcing under compressive JRFs with the posteriorization of the locking mechanism limiting exposure to repetitive VV bending moments. Incorporation of locking thread





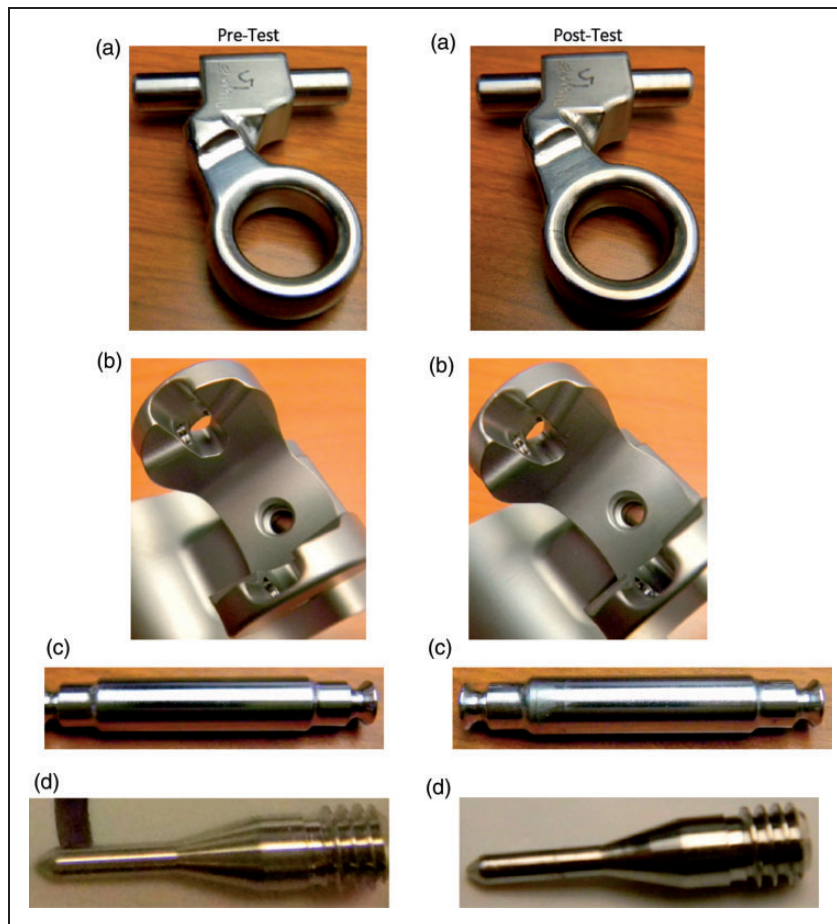
**Figure 8.** Nexel elbow bushings pre and post run out (a and b) ulnars and (c) humeral yoke.

**Table 2.** Nexel Elbow Durability Test Results.

Specimen	WIH N (lbf)	Max JRF N (lbf)	VV Moment Nm (in-lbf)	Assembly Torque Nm (in-lbf)		Disassembly Torque Nm (in-lbf)	
				Top <sup>a</sup>	Bottom	Top	Bottom
1	110 (25)	1680 (378)	5.3 (46.9)	1.48 (13.1)	1.39 (12.3)	0.68 (6.0)	0.81 (7.2)
2				1.46 (12.9)	1.48 (13.1)	0.62 (5.5)	0.73 (6.5)
3				1.45 (12.8)	1.45 (12.8)	0.44 (3.9)	0.87 (7.7)
4				1.21 (10.7)	1.12 (10.5)	0.63 (5.6)	0.66 (5.8)
5				1.22 (10.8)	1.20 (10.6)	0.54 (4.8)	0.64 (5.7)
6				1.20 (10.6)	1.20 (10.6)	0.41 (3.6)	0.54 (4.8)

Abbreviations: MoM, metal-on-metal; JRF, joint reaction force; VV, varus–valgus; WIH, weight in hand.

<sup>a</sup>Top and bottom with respect to the orientation of the humeral test specimen in the test setup.



**Figure 9.** Nexel elbow metallic components pre and post run out: (a) ulnar eye, (b) humeral, (c) axel pin, and (d) humeral screws.

technology reduces the likelihood of screw “back-out” which has previously been identified as a reason for revision for this style of modular connection.<sup>18</sup>

There are several limitations of this study. The methodology employed here limits the application of the test protocol to devices that replace the HU joint only. Modifications of load distribution and fixtures would be needed to accommodate linked or unlinked devices that incorporate radioulnar articulation. The absence of the stem geometry and use of the test fixtures limits the conclusions of this study to the durability performance of articular connection interfaces. The absence of pronation/supination rotational motions may have underestimated damage that was compensated for here by elevating the JRF and VV loads to induce the clinical damage modes in the C/M design. Damage due to third-body particulate (mode 3) was not observed, nor was third-body damage the focus of this study. The bushings were not artificially aged prior to testing which is in contrast to the highly oxidative state of many older generation CPE components reported in the literature.<sup>2,8,21</sup> This would be expected to exacerbate the damage to the in vitro CPE components while

having minimal impact on VE-HXPE components.<sup>24</sup> Finally, a larger sample size and inclusion of other prosthesis designs would allow better exploration of test resolution and implant capabilities. Additional testing of Nexel at higher load levels is necessary to determine actual design maximum run-out load under laboratory conditions. Despite these limitations, the methodology presented in this study replicated the clinically observed durability damage mechanisms under aggressive loading conditions in linked, semiconstrained style TER.

## Conclusions

A scalable, biaxial in vitro durability test methodology was developed here and shown to reproduce many of the reported clinical complications associated with the C/M TER in high-demand, posttraumatic patients. The various loading levels applied were able to distinguish performance differences within and between 2 different linked semiconstrained TER designs. Thus, the test method is considered validated for benchmarking the durability performance of the articular and linkage complex of linked, semiconstrained TER designs. The run-

out load for the C/M TER was determined to be 100 N (22.5 lbf) WIH, whereas a minimum run-out load of 110 N (25 lbf) WIH was determined for the Nexel design. Further clinical evaluation of Nexel is necessary to determine if this translates into reduced complications of TER associated with durability.

### Acknowledgments

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### Declaration of Conflict of Interest

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Zimmer Biomet did not play any role in the study design, the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. Ravikumar Varadarajan, PhD, and Brian Kincaid, MS, are both employees of Zimmer Biomet.

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### References

- Gill D, Morrey BF. The Coonrad-Morrey total elbow arthroplasty in patients with rheumatoid arthritis: a ten to fifteen-year follow-up study. *J Bone Joint Surg.* 1998;80A(9):1327–1335.
- Lee BP, Adams RA, Morrey BF. Polyethylene wear after total elbow arthroplasty. *J Bone Joint Surg.* 2005;87-A(5):1080–1087.
- Sotelo SJ, Baghdadi YMK, Morrey BF. Primary linked semiconstrained total elbow arthroplasty for rheumatoid arthritis. *J Bone Joint Surg.* 2016;98:1741–1748.
- Little CP, Graham AJ, Carr AJ. Total elbow arthroplasty: a systematic review of the literature in the English language until the end of 2003. *J Bone Joint Surg Br.* 2005;87:437–444.
- Throckmorton T, Zarkadas P, Sanchez-Sotelo J, et al. Failure patterns after linked semiconstrained total elbow arthroplasty for posttraumatic arthritis. *J Bone Joint Surg.* 2010;92A(6):1432–1441.
- Voloshin I, Schippert DW, Kakar S, et al. Complications of total elbow replacement: a systematic review. *J Shoulder Elbow Surg.* 2011;20(1):158–168.
- Aldridge JM III, Lightdale NR, Mallon WJ, et al. Total elbow arthroplasty with the Coonrad/Coonrad-Morrey prosthesis: a 10- to 31-year survival analysis. *J Bone Joint Surg.* 2006;88-B(4):509–514.
- Day JS, Baxter RM, Ramsey ML, et al. Characterization of wear debris in total elbow arthroplasty. *J Shoulder Elbow Surg.* 2013;22(7):924–931.
- Kraay MJ, Figgie MP, Inglis AE, et al. Primary semiconstrained total elbow arthroplasty. Survival analysis of 113 consecutive cases. *J Bone Joint Surg Br.* 1994;76:636–640.
- Madsen F, Søjbjerg JO, Sneppen O. Late complications with the Pritchard Mark II elbow prosthesis. *J Shoulder Elbow Surg.* 1994;28;3(1):17–23.
- Matarese W, Stuchin SA, Kummer FJ, et al. Polyethylene bearing component failure and dislocation in the triaxial elbow. A report of two cases. *J Arthroplasty.* 1990;5:365–367.
- Pritchard RW. Long-term follow-up study: semiconstrained elbow prosthesis. *Orthopedics.* 1981;4:151–155.
- Seitz WH, Bismar H, Evans PJ. Failure of the hinge mechanism in total elbow arthroplasty. *J Shoulder Elbow Surg.* 2010;19(3):368–375.
- Sheeraz A, Stirrat AN. Complete disassembly of the Coonrad-Morrey elbow replacement. *JBJS Case Connector.* 2010;92(4):958–962.
- Wright TW, Hastings H. Total elbow arthroplasty failure due to overuse, C-ring failure, and/or bushing wear. *J Shoulder Elbow Surg.* 2005;14(1):65–72.
- Zimmer Biomet, Coonrad-Morrey Surgical Technique. <http://www.zimmer.com/content/dam/zimmer-web/documents/en-US/pdf/surgical-techniques/elbow/Coonrad-Morrey-Total-Elbow-Surgical-Technique-97-8106-102-00-Rev-3-04-2011.pdf>. Accessed April 18, 2018.
- Figgie MP, Su EP, Kahn B, et al. Locking mechanism failure in semiconstrained total elbow arthroplasty. *J Shoulder Elbow Surg.* 2006;15(1):88–93.
- Hastings H, Lee DH, Pietrzak WS. A prospective multicenter clinical study of the Discovery elbow. *J Shoulder Elbow Surg.* 2014;23(5):e95–e107.
- Kincaid BL, An KN. Elbow joint biomechanics for pre-clinical evaluation of total elbow prostheses. *J Biomech.* 2013;46(14):2331–2341.
- Morrey BF, Askew LJ, Chao EY. A biomechanical study of normal functional elbow motion. *J Bone Joint Surg Am.* 1981;63(6):872–877.
- Goldberg SH, Urban RM, Jacobs JJ, et al. Modes of wear after semiconstrained total elbow arthroplasty. *J Bone Joint Surg Am.* 2008;90(3):609–619.
- Amis AA, Dowson D, Wright V. Analysis of elbow forces due to high speed forearm movements. *J Biomech.* 1980;13:825–831.
- Anglin C, Wyss UP, Pichora DR. Mechanical testing of shoulder prostheses and recommendations for glenoid design. *J Shoulder Elbow Surg.* 2000;9(4):323–331.
- Bracco P, Oral E. Vitamin E-stabilized UHMWPE for total joint implants: a review. *Clin Orthop Relat Res.* 2011;469(8):2286–2293.