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## Unexpected high early failure rate of the Nexel total elbow arthroplasty



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**Background:** Aseptic loosening, polyethylene wear, and mechanical failure have limited the use of total elbow arthroplasty (TEA) in physically demanding patients. Newer implant designs have been introduced to improve mechanical performance. The purpose of this study was to report the results obtained after implantation of the Nexel TEA.

**Methods:** Over a 3-year period, 2 surgeons implanted a total of 35 consecutive Nexel primary TEAs. The average patient age was 65 years, and standard TEA indications were utilized. Elbows were evaluated for pain, motion, the Mayo Elbow Performance Score, complications, and reoperations.

**Results:** Twelve elbows underwent a revision surgery with removal of either a part of or all Nexel components at an average of 2.2 years. All revision surgeries performed at our institution revealed gross loosening of the component(s). Metallic debris and periprosthetic fractures were present in 45% and 50% of cases, respectively. Radiographic evaluation of existing components revealed humeral component loosening and periprosthetic fractures in 2 and 4 elbows, respectively. Overall, 17 of 35 (50%) elbows underwent reoperation, and 20 of 35 (60%) elbows sustained at least 1 postoperative complication.

**Conclusion:** Primary TEA with implantation of this implant was associated with an unacceptably high rate of early implant loosening, periprosthetic fracture, and reoperation. We hypothesize that this early unexpected mechanical failure could be explained by both the utilization of a titanium-on-polyethylene bearing surface and a more posterior center of rotation causing premature anterior impingement with flexion leading to failure of the bonding interface, secondary titanium particle shedding, polyethylene wear, and osteolysis.

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Total elbow arthroplasty (TEA) often serves as the best surgical solution for many patients with severe destruction of the elbow joint secondary to inflammatory arthritis or trauma and their sequelae.<sup>22</sup> Although the results of TEA regarding pain relief and restoration of elbow stability and function are satisfactory, reported complications and failure rates are relatively high, ranging between 11% and 38%.<sup>23</sup> One of the most dreaded complications following TEA is mechanical failure and loosening after a previously well-functioning implant. Revision surgery of a failed TEA is often-times complicated by bone loss and other issues, and salvage is the reason many surgeons counsel patients regarding the need for life-long activity and lifting restrictions following TEA. Unfortunately,

these restrictions are not always practical, and compliance is questionable.<sup>3</sup> The annual growth rate of TEA has been estimated to be 8%, with expanding indications to younger and higher demand patients.<sup>6,22</sup> As such, new design features are being introduced into the market with the hope of providing a higher performance implant with increased durability over time.

The Coonrad-Morrey TEA is one of the most utilized implants in the field of TEA. Although satisfactory survivorship rates of this design have been reported in lower demand patients with rheumatoid arthritis,<sup>16</sup> the mechanical failure rate of this implant has been a concern in long-term follow-up studies on distal humerus nonunion,<sup>5</sup> post-traumatic arthritis,<sup>21</sup> and acute distal humerus fractures.<sup>22</sup> Mechanical failure of the Coonrad-Morrey TEA typically occurs due to complications that are secondary to osteolysis caused by polyethylene wear, such as loosening, periprosthetic fracture, or component fracture. Newer implants with alternative bearing designs were developed and introduced with the hope of reducing polyethylene wear and increasing durability; these include the

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**Figure 1** Radiograph depicting the Nexel TEA with radiolucent lines evident at the cement-bone interface. TEA, total elbow arthroplasty.

Discovery (DJO, Lewisville, TX, USA), the Latitude (Tornier; Stryker, Portage, MI, USA), and the Nexel prostheses (Zimmer Biomet, Warsaw, IN, USA).

The Nexel prosthesis was developed as an evolution of the Coonrad-Morrey TEA and was cleared for implantation by the Food and Drug Administration in 2013. With any new technology or implant design change, it is imperative to monitor for adverse events and failures. The lead author of this study adopted the Nexel prosthesis for approximately 3 years but discontinued using this system due to an unexpected high early failure rate. The purpose of this study was to formally review our early experience with the Nexel TEA and to identify possible design-related explanations for the unexpectedly high failure rate after a detailed analysis of retrieval implants at the time of revision.

## Materials and methods

After obtaining approval from our institutional review board, we queried our institutional total joint registry database to identify all primary TEAs performed with implantation of the Nexel TEA between 2013 and 2015. A total of 35 Nexel TEAs were performed consecutively at our institution by 2 experienced elbow arthroplasty surgeons within that time period. To minimize the learning curve nuances possibly associated with new implants and instrumentation, TEAs were performed by both operating surgeons together for the first 10 procedures; the remaining TEAs were performed by the lead author.

## Patients

The 35 patients (35 elbows) included in this study consisted of 20 female and 15 male patients with a mean age at the time of their index surgical procedure of 65 years (range, 29–95 years) and an average body mass index of 29 (range, 16–50). The indication leading to the procedure included failed open reduction and internal fixation or post-traumatic arthritis in 17 elbows, an acute fracture of the distal humerus in 9 elbows, and inflammatory arthritis in 9 elbows.

## Implants

The Nexel TEA humeral and ulnar component stem geometries are similar to those of the Coonrad-Morrey TEA. The main design changes in reference to the Coonrad-Morrey arthroplasty involve the use of vitamin-E-treated, highly cross-linked polyethylene bushings that are pressed onto an axis pin from either side of a highly polished titanium ulnar component. These bushings articulate with a larger diameter, rounded, polished surface of the titanium ulnar component. The geometry of the articulation was designed to increase polyethylene thickness and decrease edge loading compared to the Coonrad-Morrey TEA, while maintaining a “sloppy hinge” semi-constrained prosthesis (7 degrees of laxity in the coronal plane and a linked humerus and ulna). Once the bushings are coupled, the axis pin is inserted into 2 channels on either side of the humeral component and secured in place with 2 screws which link the humerus to the ulna. In addition, the axis of rotation referred to as the longitudinal axis of the humerus was offset posteriorly compared to the Coonrad-Morrey TEA, and a third bearing surface was added to the humeral yoke for increased compressive contact area by articulating with the outside polished surface of the ulnar component.

## Surgical technique

All procedures were performed by 2 elbow surgeons with specialized expertise and dedicated training in TEA; one of whom was on the design team for the prosthesis. All surgeries were performed in the supine position and under general anesthesia. Deep exposure was performed through a paraolecranon approach<sup>20</sup> in all 35 elbows. All components were cemented using antibiotic-loaded polymethylmethacrylate, with the addition of 1 mL of methylene blue and 1 gram of vancomycin per batch of cement. Modern cement techniques, including the use of restrictors, vacuum mixing, pulsatile lavage of the canals, and the use of a retrograde cement gun, and pressurization techniques were applied.

## Evaluation

All patients were followed up at regular intervals after surgery with physical examination and radiographs. Patients not able to return for a face-to-face follow-up evaluation were contacted by our total joint registry database personnel utilizing a mailed or telephone questionnaire that assessed pain, motion, the various elements of the Mayo Elbow Performance Score, complications, and reoperations. A retrospective chart review was completed to extract information from the electronic medical record prior to surgery and at the most recent follow-up. Variables recorded included pain, flexion, extension, the Mayo Elbow Performance Score, complications, and reoperations. Radiographs were evaluated to determine the quality of cementation at the time of the index arthroplasty as well as the presence of implant failure in the form of loosening or osteolysis at later follow-ups (Fig. 1). Loosening was defined as a change in component position and/or the



**Figure 2** Explanted Nexel TEA demonstrating failure at the bone-cement interface. TEA, total elbow arthroplasty.

development of a new, progressive radiolucent line around the bone-cement or cement-implant interfaces. After an increase in failure was recognized, subsequent implants retrieved at the time of reoperation were meticulously assessed macroscopically for evidence of polyethylene wear or other adverse findings.

## Results

### Revisions

Of the 35 elbows included in this study, 12 elbows (34%) underwent revision surgery with exchange or removal of 1 or both components. The mean time to revision surgery was 2.2 years. Eleven of the 12 elbows were revised at our institution, and 1 elbow was revised elsewhere. The indication for all revision surgeries was loosening of 1 or both components; the humeral and ulnar components were found to be loose in 9 and 6 elbows, respectively. Loosening occurred universally at the bone-cement interface (Fig. 2). By the time these elbows underwent revision for loosening, 6 elbows (50%) had an associated periprosthetic insufficiency fracture including humerus fracture in 4 elbows, ulnar fracture in 1 elbow, and fractures of both the humerus and ulna in 1 elbow.

Cultures were positive in 1 of the 12 elbows at the time of revision surgery, indicative of septic loosening; this patient had undergone a staged TEA for an infected fixation failure of a distal humerus fracture. Even though the index TEA was performed in a staged fashion, septic loosening was the result of the TEA failure. One additional failed TEA presented with increasing pain and humeral loosening at 6 months postoperatively in the setting of an elevated sedimentation rate but with a normal C-reactive protein and was presumed infected; however, cultures at the time of revision were negative, and the patient was subsequently diagnosed with psoriatic arthritis. Finally, 1 patient required irrigation, débridement, and bushing exchange 2 weeks after the index TEA for a distal humerus fracture and developed ulnar loosening 3.5 years later; cultures for this elbow were negative at the time of revision TEA.

### Complications and reoperations

For the 23 remaining elbows that were not revised for stem loosening, 9 complications occurred in 8 patients, with 5 patients requiring a reoperation. Complications included periprosthetic fracture treated nonoperatively ( $n = 4$ ), delayed wound healing



**Figure 3** Polyethylene wear, pitting, and metal particle embedding of an explanted Nexel TEA. Note that the titanium particles are located in the portions of the polyethylene that articulates with the titanium surfaces of the ulnar component. TEA, total elbow arthroplasty.

( $n = 2$ ), limitation of motion ( $n = 2$ ), and ulnar neuropathy ( $n = 1$ ). Reoperations included irrigation and débridement for wound dehiscence and drainage ( $n = 2$ ), exploration with transposition of the ulnar nerve for neuropathy ( $n = 1$ ), removal of painful retained wires ( $n = 1$ ), and radial head resection for impingement and decreased forearm rotation ( $n = 1$ ). When these complications and reoperations are added to the elbows that had undergone a revision surgery, the overall reoperation rate was 50% (17/34), and the overall complication rate was 60% (20/34).

### Radiographic results

For the 23 elbows with surviving implants, 2 additional humeral components were considered radiographically loose, for an overall aseptic loosening rate of 40%. Other findings noted in the radiographic review included the 4 periprosthetic fractures treated nonoperatively (2 medial epicondyle, 1 olecranon, and 1 humeral shaft).

### Surgical observations

Metallic debris embedded in the polyethylene bushings with associated pitting of the polyethylene bushing was recognized and documented in the last 5 of 11 revisions in this cohort (45%) (Fig. 3). After scrutiny, this phenomenon has been recognized in all revisions of this prosthesis subsequent to the study period once specific attention was brought to this issue.

## Discussion

Newer TEA designs have been introduced with the hope of providing higher performance implants that could potentially be associated with reduced rates of polyethylene wear and mechanical failure, even in younger, high-demand patients. The results of our study seem to indicate that unfortunately 1 newer implant, the Nexel TEA, seems to be associated with an unacceptably high rate of early failure leading to revision and reoperation. In the present study, the revision, reoperation, and complication rates in a consecutive series of 35 primary Nexel TEAs were 34%, 50%, and 60%, respectively. In addition, these failures oftentimes occurred within the first 2 years after implantation.

TEA is commonly considered to treat several pathologic processes about the elbow, including inflammatory arthritis, acute distal humerus fractures, osteoarthritis, post-traumatic arthritis, distal humerus nonunion, hemophilic arthropathy, and bone defects following tumor resection.<sup>22</sup> Despite a significant decline in TEA utilization for inflammatory arthritis since the advent of

disease-modifying antirheumatic drugs, overall trends in implantation of TEA in the United States have experienced an increase in both primary and revision TEAs (3-fold and 5-fold increase, respectively). This equates to an annual growth in the procedure rate of 7.6%.<sup>6,22</sup>

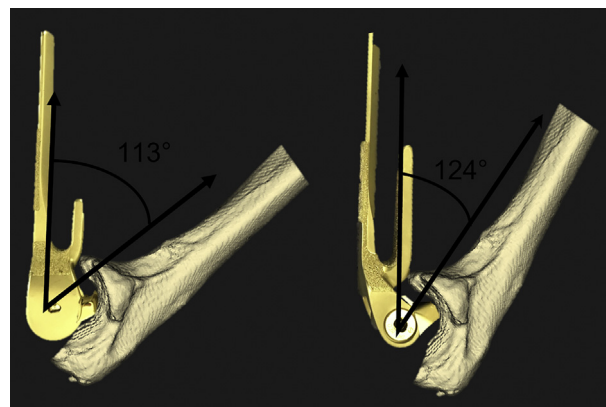
Certain designs, such as the Coonrad-Morrey, have provided satisfactory survivorship in elbows with inflammatory arthritis; however, mechanical failure secondary to polyethylene wear, osteolysis, and loosening has been reported more commonly in younger, active individuals.<sup>2,5,21</sup> The utilization of TEA secondary to trauma and its sequela has increased significantly over the years.<sup>8</sup> Several studies have demonstrated good results following the use of TEA for distal humerus fractures in the elderly, but unfortunately worse outcomes have been reported for its use in post-traumatic osteoarthritis.<sup>7,15,19</sup> As a result, several contemporary implants have been developed in the hopes of providing more durable long-term outcomes. With continued growth and utilization of the TEA in higher demand patients, it is imperative that newer design modifications be monitored for complications and failures.

The Nexel TEA introduced several modifications compared to its predecessor, the Coonrad-Morrey TEA. These included the use of thicker vitamin-E-treated highly cross-linked ultrahigh-molecular-weight polyethylene (Vivacit-E; Zimmer Biomet, Warsaw, IN, USA) bearings and larger bearing surfaces to decrease the stresses on the polyethylene. Additionally, a Titanium plasma spray (Zimmer Biomet, Warsaw, IN, USA) (Ti-6Al-4V) alloy for both humeral and ulnar components and a Zimaloy (Zimmer Biomet, Warsaw, IN, USA) (Co-Cr-Mo) linkage axis pin were introduced in an attempt to decrease mechanical loosening and pin failure, respectively. Finally, the Nexel TEA center of rotation is located 3 mm more posteriorly than the Coonrad-Morrey TEA, in an effort to provide better elbow extension.

Approximately half of the elbows included in this study underwent TEA for either an acute distal humerus fracture or post-traumatic osteoarthritis. When reviewing the results of the Coonrad-Morrey TEA for these same indications, Barco et al<sup>2</sup> reported that 18% of TEAs performed for acute distal humerus fractures followed up for 10 years required implant revision or resection; reasons for these revisions included infection, ulnar loosening, and ulnar component fractures.<sup>2</sup> Conversely, despite a significantly shorter follow-up in our study than those previously reported, the revision rate following the use of the Nexel prosthesis was significantly higher, 34% vs. 18%.

In addition to the failures of the Coonrad-Morrey TEA following its use for acute trauma and post-traumatic reconstruction,<sup>2</sup> Mansat et al<sup>12</sup> summarized overall failure rates, ranging from 5% to 50% depending on the preoperative diagnosis. The diagnoses in their study for utilizing the Coonrad-Morrey TEA that resulted in a failure rate greater than or equal to that seen following the use of the Nexel prosthesis in our study (34%) included ankylosed elbows (38–50%),<sup>13,14</sup> osteoarthritis (40%),<sup>10</sup> and distal humerus nonunions (34%).<sup>5</sup> Again, it is important to note that the follow-up periods in other studies were significantly longer than that in our study.

While it is well known that TEAs are associated with higher failure rates and complications than replacement of other joints, 1 major concern regarding the results of our study is how quickly the Nexel TEA design failed, with an average time to revision of just over 2 years. Siala et al<sup>18</sup> also recently reported on the early outcomes of 9 patients with the Nexel prosthesis with a 56% complication rate and 22% loosening rate at a mean of 28 months after the index surgery. We believe both cohorts report an unacceptably high failure rate at short-term follow-up.



**Figure 4** Illustration depicting earlier anterior impingement of the coronoid with Nexel TEA (left) compared to the Coonrad-Morrey TEA (right). TEA, total elbow arthroplasty.

The high unexpected early failure rate observed in our practice and documented in this study following the use of the Nexel TEA demands an attempt at a reasoned explanation. This is particularly important considering that the Nexel is essentially a Coonrad-Morrey design but with a new hinge mechanism, and stem loosening in the Coonrad-Morrey TEAs did not occur early nor often. After a careful analysis, we have hypothesized several potential explanations for early failure of this prosthesis.

A possible explanation is that the hinge mechanism of the Nexel prosthesis is a titanium-on-polyethylene articulation. Titanium-on-polyethylene has been recognized in the hip arthroplasty literature as a very poor bearing surface combination.<sup>1</sup> The original Coonrad-Morrey prosthesis had a titanium pin articulating with the polyethylene bearings, and we have substantial experience with revisions of those elbows for complications secondary to titanium wear debris from the hinge pin. It was subsequently changed to a cobalt-chromium alloy. Although the pin linking the ulnar and humeral components in the Nexel prosthesis is of cobalt-chromium alloy, the majority of the load bearing occurs between the titanium ring on the proximal end of the ulnar component and the polyethylene that is inserted into the humeral component. In about half of the revisions of the Nexel prosthesis performed at our institution, metal particles were clearly identified in the polyethylene bushing at the interface with the ulnar component, with gross polyethylene wear and pitting (Fig. 3). It is extremely important to note that the finding of metal in the articulation was likely much higher than reported, as it was not suspected initially and overlooked in early revision cases. As corroboration for this assumption is the fact that subsequent revisions of this implant after the study period ended have revealed that 100% have gross metallic debris embedded within the polyethylene. While the source of the titanium particles remains to be proven, we suspect their presence likely accelerates the generation of polyethylene particles, rapid osteolysis, and the very early loosening patterns seen at the cement-bone interface.

Another possible contributory mechanism for loosening relates to humeral/ulna pistoning or rotational stress due to anterior impingement. Previous studies have reported component loosening with linked TEA implants due to anterior impingement from premature contact between the coronoid process or ulnar cement mantle and the anterior flange of the humeral component, leading

to “component pistoning.”<sup>4,17</sup> This can also occur with thickened soft tissues or heterotopic ossification anteriorly. The center of rotation of the Nexel TEA is more posterior in reference to the humeral stem than the center of rotation of the Coonrad-Morrey TEA. While, in theory, a more posterior center of rotation may facilitate extension, it may also inadvertently lead to premature anterior impingement of the ulna and/or soft tissues against the humeral flange during elbow flexion, resulting in increased stresses on the prosthetic host interfaces (Fig. 4). Increased stress may lead to fatigue at the surfaces porous coated with Ti-6Al-4V plasma spray behind the flange of the prosthesis, the cement-bone interface, or both on the humeral or ulnar components. Interestingly, there are several other TEA designs with a more posterior center of rotation than the Coonrad-Morrey that have not resulted in such a high failure rate; these include the Latitude (Tornier) and the Discovery prostheses. However, unlike the Nexel, these other implant designs have an area within the implant that accommodates the coronoid during flexion. Therefore, we believe that coronoid accommodation during deep flexion mitigates the high stresses applied to the cement-bone interface conferred by the Nexel TEA.

One potential element that may be prone to metallic particle shedding is the novel Titanium (Ti-6Al-4V) alloy used in the plasma spray. While theoretically allowing for greater cement interdigitation than the Coonrad-Morrey prosthesis, unlike the Coonrad-Morrey which has a beaded surface on the humerus, the spray area is also located on the bone-implant interface behind the flange of the Nexel prosthesis. Micromotion at this junction due to impingement, rotational stress, or both may shear particulate debris from the coating, which can then lead to wear of one-third of the body and loosening of the cement-bone interface. Furthermore, while biomechanical studies have shown decreased stresses at the articulation, there has not been an investigation of stresses at the flange-bone interface, and this is a potential source of metallic particulate shedding, particularly in a titanium implant with greater ductility and therefore an increased possibility for micromotion at this junction.<sup>9</sup> Whatever the source of metallic debris, these factors may have led to the near-universal pattern of loosening in which a cast of the intramedullary bone-cement interface is created upon removal with fibrous tissue on the surface of the cement and behind the flange of the component. This pattern can be interpreted to be due to a pathologic biological process that has been activated. It resembles the process seen with osteolysis and loosening of the polymethyl-methacrylate (PMMA)-precoated ulnar component of the Coonrad-Morrey that had a high loosening rate due to osteolysis caused by wear particles.<sup>1,11</sup>

Our study has several limitations, including its retrospective nature. Our reported experience represents the use of a new TEA system during the learning curve, which could potentially explain the higher failure rate than expected. However, the surgeons were highly experienced with TEA, particularly the Coonrad-Morrey implant on which the Nexel had been based. Furthermore, even if the mechanisms discussed above are at play, technical failure during implantation such as a failure to remove impinging bone or increased depth of insertion of the ulna likely compounds the issues seen with impingement anteriorly and may contribute to the failures seen in this study. Also, while half of the elbows included in this study required arthroplasty to treat either a fracture or the sequelae of trauma, the overall number of elbows and varied diagnoses makes subgroup analysis impossible. The strengths of this study include performance of the arthroplasty by a single fellowship-trained shoulder and elbow surgeon in all cases, the collaboration of 2 surgeons with vast experience in TEA in the first

10 cases, as well as the relatively large sample size for a study on a new implant for primary TEA.

## Conclusion

Primary TEA using the Nexel system was associated with a very high early rate of aseptic stem loosening, complications, reoperations, and revision surgery. Improvements in the design of this implants might improve its overall performance in the future. However, at the present time, we have discontinued implantation of this system in our practice.

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