



ELBOW

Results of custom-fit, noncemented, semiconstrained total elbow arthroplasty for inflammatory arthritis at an average of eighteen years of follow-up



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Background: The literature available on the results after noncemented total elbow arthroplasty (TEA) in inflammatory arthritis is limited.

Methods: Ten patients (7 women, 3 men; 14 elbows total) who underwent custom, noncemented TEA from 1988 to 1995 were retrospectively reviewed. The average age was 28 years (range, 17-45 years). Four patients (4 elbows) had rheumatoid arthritis, and 6 patients (10 elbows) had juvenile rheumatoid arthritis. The mean follow-up was 18 years. All patients underwent a custom, noncemented, semiconstrained TEA with a plasma spray surface designed from preoperative computed tomography scan to achieve metaphyseal fit. The primary outcome was the Mayo Elbow Performance Score, and secondary outcomes were flexion and rotation arc of motion. Intraoperative and postoperative complications and revisions performed were also recorded. Radiographs taken at final follow-up were evaluated for evidence of loosening.

Results: The Mayo Elbow Performance Score improved from a mean of 35 preoperatively to a mean of 91 postoperatively. Flexion arc of motion improved from 50° preoperatively to 111° postoperatively, and rotation arc improved from 75° preoperatively to 145° postoperatively. Four patients underwent bushing revision at 8, 8, 22, and 22 years (29%), respectively, and there was 1 deep infection (7%). One patient had an intraoperative fracture in the humerus that did not require further treatment. On final radiographic follow-up at a mean of 18 years, all the components were fully ingrown, and there was no evidence of loosening or loss of fixation.

Conclusion: In the younger population with inflammatory arthritis, noncemented TEA has reliable outcomes clinically and radiographically at long-term follow-up.

Level of evidence: Level IV, Case Series, Treatment Study.

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Keywords: Noncemented; custom; total elbow arthroplasty; inflammatory arthritis; young; osseointegration

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Total elbow arthroplasty (TEA) has evolved dramatically during the last century. Original TEA designs were noncemented, simple hinges, which commonly led to failures in fixation because of overconstraint and failed osseointegration. As a result of early failures and an

improved understanding of the anatomy of the elbow joint, 3 main designs emerged: semiconstrained, nonconstrained, and convertible prostheses. Despite advances in TEA implants, polymethylmethacrylate bone cement is still used for implant fixation in the majority of cases. In an era when noncemented total hip and knee implants are becoming more common and are as successful as cemented implants in younger patients,¹⁰ the majority of surgeons still think that cement is necessary for TEA. Potential reasons for the lack of trust for noncemented implants include early published failure rates of simple hinged noncemented implants, lack of long-term outcome data available in the literature, fear of failed osseointegration or initial fixation in patients with poor bone biology (i.e., inflammatory arthritis),⁹ and lack of noncemented implant designs available.

The published literature on noncemented TEA is limited by short- to medium-term follow-up, hybrid fixation in most series, and small cohorts of patients.^{2,7,9,12,13} However, biologic fixation of TEA components is clearly possible in the short to medium term, and noncemented semiconstrained and unconstrained designs have published radiographic and clinical success rates of 80% to 90%.^{2,7,9,12,13} Patients with inflammatory arthritis who undergo semiconstrained or nonconstrained, cemented TEA have published rates of success of 77% to 92%; however, aseptic loosening remains a common complication, especially in semiconstrained prostheses, in which increased stresses occur at the bone-cement interface.^{4,6} Whereas the patient with the greatest risk of aseptic loosening is the young patient with osteoarthritis or traumatic arthritis,^{1,8} achieving long-term durability of a TEA implant in young patients with inflammatory arthritis can be challenging because of the patient's young age and poor bone quality. Thus, the objective of the current study was to assess the long-term clinical and radiographic outcomes of custom, noncemented, semiconstrained total elbow prostheses in young patients with inflammatory arthritis. We hypothesized that despite the altered bone biology in young patients with inflammatory arthritis, osseointegration of a noncemented elbow arthroplasty can be reliably achieved, leading to clinical and radiographic success rates that compare with those of cemented prostheses at a minimum of 15 years of follow-up.

Materials and methods

Of the 106 total elbow arthroplasties performed by the senior author from 1988 to 1995, 10 patients (7 women, 3 men; 14 elbows total) who underwent custom, noncemented, semiconstrained TEA were retrospectively reviewed. Patient records were used in those patients with recent follow-up; further, patients who had not been followed up for several years were called back to the office for a repeat examination and radiographs. The average age of the patient at the time of TEA was 28 years (range, 17-45 years). Four patients (4 elbows) had rheumatoid arthritis, and 6 patients (10 elbows) had juvenile rheumatoid arthritis. The mean follow-up was 18 years (range, 15-22 years).

All patients underwent a custom, noncemented, semiconstrained TEA. As described later, the custom implant possessed a plasma spray surface, and the design was made from a preoperative computed tomography (CT) scan to achieve metaphyseal fit. The primary outcome was the Mayo Elbow Performance Score, and secondary outcomes were flexion and rotation arc of motion. Self-reported patient outcome questionnaires were not obtained. Postoperative complications, number of revisions, and reason for revision were recorded. Anteroposterior and lateral radiographs were taken at preoperative, first postoperative, and final follow-up visits and were evaluated by 2 independent observers for change in the position of the stem of either the humeral or ulnar component as well as for the presence of osteolytic or radiolucent areas around the stem of either component.

Custom implants design

The custom total elbow implants used the Osteonics Total Elbow bearing mechanism (Osteonics, Allendale, NJ, USA). The articulation was identical to the standard implant, but the stems were designed to provide intimate fit in the metaphyseal region. Porous coating was applied near the joint (i.e., distal on the humerus, proximal on the ulna). For the humeral component, the stems were increased in diameter (around 9-12 mm) to match the patient's humerus and were made longer than the standard component. Custom humeral components were curved to match the curvature of the humerus, as determined from the preoperative CT scan. The distal 20 mm of the humeral component was shaped to fit the endosteal surface of the humerus and was porous coated. This porous coating was also applied farther distally on the medial and lateral surfaces of the flanges of the humeral component. The ulnar component had a conical distal stem, and the proximal 10 to 15 mm was fit to the endosteal surface and porous coated. Additional porous coating was applied to the posterior surface of the implant farther proximally to the fit region.

The location of the articulation was matched to the pre-morbid joint center. This usually involved translating the mechanism on the humerus more anterior than with the standard device. A carrying angle of around 5° on the humeral component and around 2° on the ulna was also designed into the components. In this semiconstrained implant, the articulation used a polyethylene bushing and a polyethylene bearing with a metal axle that locks into a C retaining clip contained within the lateral portion of the humeral component.⁵ Thus, the load is central along the concave polyethylene surface. The remaining portion of the ulnar component articulates only with the condylar portion of the humeral bushing at extremes of motion. Laxity of approximately 5° of varus/valgus, rotational, and side-to-side motion is allowed by design. The axle and bearing take load only with out-of-plane motion or distraction, thus providing protection against dislocation. Finally, the axle is held in place by a retaining clip with tight tolerances.⁵

Surgical procedure

The surgical incision used was an extensile, curvilinear, posteromedial incision, which was a modification of the initial surgical approach described by Bryan and Morrey.³ After the ulnar nerve was identified and protected, the triceps expansion was raised as a

continuous flap from the medial to the lateral side of the elbow. The radial head was then osteotomized and removed at the level of the annular ligament. The capsule was resected, and the medial collateral ligament was elevated off its insertion on the sublime tubercle. At this point, the elbow was dislocated. A preliminary cut was made on the ulna that approximated the level of the custom implant, the canal was identified, and custom rasps were used to achieve metaphyseal fit. Preliminary cuts were then made on the humerus, and custom rasps were used to achieve secure fit; the preliminary cuts on both the ulna and humerus were later modified (after use of the custom rasps) to fit the actual implant. The custom rasps were used for a trial reduction, and the elbow was taken through a range of motion. After the rasps were removed, the final custom implants were impacted into position. Of note, all custom implants that were produced were successfully implanted; however, a high-speed burr was used to contour the bone in situations in which the custom implants did not fit adequately. Tight diaphyseal stem fit was not a goal of surgery to avoid stress shielding. The tourniquet was then released, and hemostasis was achieved. After the bushing was placed, the elbow was reduced, and the axle was placed through the lateral side. A portion of the olecranon tip was excised, and then the triceps flap was reapproximated to the ulna with absorbable sutures with a deep drain in place. The ulnar nerve was then replaced in its anatomic position, unless there was tension on the nerve, in which case the nerve was transposed anteriorly. After a layered closure, the elbow was placed in a few degrees of elbow flexion with a bulky dressing and a posterior plaster splint. Within the first 24 hours, the drain was removed. Range of motion exercises in an adjustable, hinged Orthoplast splint were begun on postoperative day 2, provided the wound was satisfactory. Patients were advised to alternate nights sleeping with the elbow flexed and extended in the Orthoplast splint for 6 weeks postoperatively. The postoperative therapy protocol was identical to that for our cemented elbows performed during the same period, and braces were used to protect the triceps as the modified Bryan-Morrey approach was used. Patients were typically reminded to avoid lifting more than 10 pounds at every follow-up visit and were asked if they have been adhering to this limitation.

Results

Mayo Elbow Performance Scores improved from a mean of 35 preoperatively to a mean of 91 postoperatively. The average flexion arc of motion improved from 50° preoperatively to 111° postoperatively, and the rotation arc improved from 75° preoperatively to 145° postoperatively, on average. Four elbows underwent isolated bushing change at 8, 8, 22, and 22 years (29%), respectively, without revision of the ulnar or humeral components (Fig. 1). The presentation of bushing wear varied in our cohort. In 2 patients, the axle failed and the elbow disarticulated. In 1 elbow, the patient presented with squeaking, which in retrospect was due to full-thickness bearing wear and unintended metal-on-metal contact. The fourth patient presented with increased pain, probably from synovitis due to wear. In addition to the 4 bushing revisions, 1 patient developed a deep implant infection (7%) that required implant removal. Finally, 1 patient (7%) developed



Figure 1 Anteroposterior radiograph of a patient who had a bushing failure at 8 years postoperatively, which required isolated bushing exchange.

an intraoperative crack along the anterior cortex of the humerus that did not require further treatment and healed uneventfully. No patients developed a postoperative fracture, metallosis, dislocation, or persistent sensory ulnar neuropathy. The patient outcomes are summarized in [Appendix Table I](#).

On final radiographic follow-up at a mean of 18 years, all the retained components were fully ingrown. No evidence of translucent lines surrounding either component, radiolucent (or osteolytic) areas distal to the porous coating, or change in the stem position was seen in any of the patients' serial radiographs at final follow-up (Fig. 2).

Discussion

The objective of this retrospective case series was to determine the clinical and radiographic outcomes of custom, noncemented, semiconstrained total elbow prostheses in young patients with inflammatory arthritis at long-term follow-up. Proving our hypothesis, we found that in young patients with inflammatory arthritis, osseointegration of a noncemented elbow arthroplasty was reliably achieved as no implants were revised for loosening, leading to clinical and radiographic success rates that are at least comparable to those of the published results of cemented prostheses at long-term follow-up.

It is unclear why the use of noncemented linked or unlinked total elbow prostheses is not more prevalent. In all reports of hybrid fixation, in which the humeral component

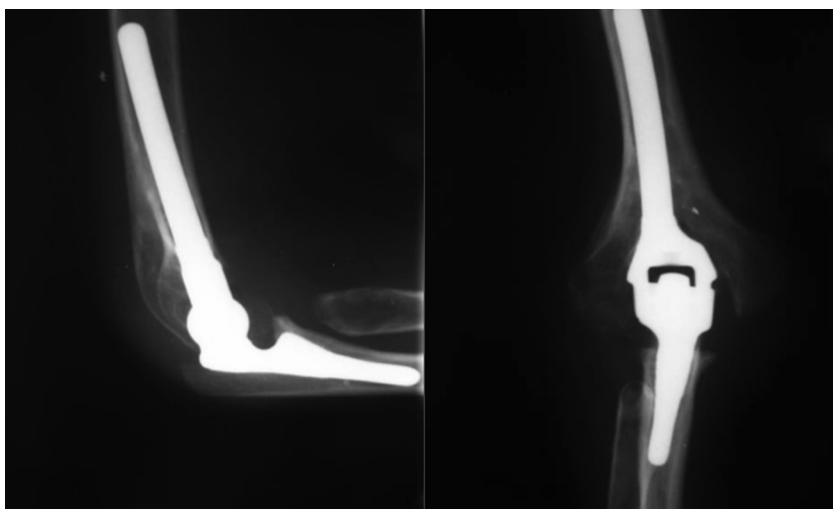


Figure 2 Anteroposterior and lateral radiographs of an elbow at 17 years of follow-up with no evidence of radiographic loosening of the components.

was uncemented and the ulnar component was cemented, the large majority of failures from loosening (i.e., failures in fixation) occurred on the cemented ulnar side.^{7,9,11} Kleinlugtenbelt et al⁷ published their results of hybrid TEA in rheumatoid arthritis patients, in which the ulnar component was cemented and the humeral component was uncemented; of 20 elbows in their series at an average follow-up of 49 months, 6 cases had radiographic loosening of the cemented ulnar component without any clinical symptoms, but no cases of loosening were seen in the uncemented humeral component. Kudo et al,⁹ however, had more failures in their noncemented humeral components; the main mechanisms of failure in the early designs were due to stem breakage at the junction of the humeral component and the diaphyseal stem and metallosis with subsequent osteolysis around the humeral condyles from bearing wear. However, biologic fixation was achieved in nearly all cases of the noncemented TEA implants at short- to medium-term follow-up.⁹ Later, after addressing the problems of stem breakage published by Kudo et al,⁹ van der Heide et al¹³ published their results of hybrid ($n = 40$) or noncemented ($n = 49$) Kudo (Biomet, Warsaw, IN, USA) type-5 total elbow prostheses implanted at midterm follow-up (average, 5.8 years) in patients with rheumatoid arthritis; in their series, the authors published worse outcomes than we observed in our cohort, with 7 elbows displaying progressive radiolucencies in the noncemented design and 3 elbows with hybrid fixation having progressive radiolucencies. However, the mean age of their cohort was 55 years, compared with 28 years in our series. The current case series represents the longest follow-up for noncemented, semiconstrained total elbow implants in the published literature. At a mean of 18 years, there were no failures in osseointegration or aseptic loosening in any of the components and an isolated bushing revision rate of 29%. In young patients with inflammatory arthritis,

noncemented, semiconstrained prostheses have *at least* comparable results to those of cemented, semiconstrained designs; thus, we recommend that in this patient population, noncemented components be considered.

The custom implants described here are based on principles similar to those used in some noncemented total hip designs. The goal of custom TEA is to achieve metaphyseal fit and to use the stem for bending loads only. Thus, porous coating was applied primarily to the metaphyseal regions, and tight diaphyseal stem fit was not a goal of surgery. The variable contours of the distal humerus have traditionally led to difficulty in achieving appropriate fit with standard implants. An advantage of custom implants therefore is that a preoperative CT scan is used for design, and thus modifications can be made to the implant and fixation surfaces that would not be possible with 2-dimensional imaging, such as plain radiography. However, financially, custom total implants might not be practical at present; still, joint arthroplasty is moving toward not only custom total knee replacement but also custom cutting blocks. Thus, custom total elbow implants may have a future expanded role.

The current study was retrospective and thus is limited by the inherent flaws of this study design. However, selection bias, which is prevalent in retrospective studies, was minimized, as we had 100% long-term follow-up of these 14 elbows. A second limitation was the relatively small sample size. However, noncemented, semiconstrained total elbow implants were not common when the senior author performed these surgeries; in fact, only 13% of the total elbow arthroplasties performed by the senior author during this time were uncemented custom prostheses. Uncemented custom prostheses were selected by the senior author in this cohort because of the young age of the patients. A need for biologic fixation was identified because of the risk of loosening over time in young patients with inflammatory arthritis with use of standard implants and polymethyl

methacrylate bone cement and an increased need for durability given the average age of the patients. Thus, as a result, this represents the longest known follow-up of noncemented, semiconstrained TEA for young patients with inflammatory arthritis. Finally, the results presented in this manuscript may be used as safety data to support the development of noncustom uncemented implants. However, the information provided may not be generalizable to all surgeons because the cost of custom implants may be prohibitive at some institutions, and thus custom implants may not be accessible to all surgeons.

Conclusion

In the young population with inflammatory arthritis, noncemented, semiconstrained TEA has reliable outcomes clinically and radiographically at long-term follow-up with no components revised for loss of fixation or loosening and an isolated bushing exchange rate of only 29%.

Disclaimer

Denis Nam receives stock or stock options from OrthAlign, Inc.

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Appendix Table I Patient demographics and outcomes

| Elbow number | Date of operation | Age at operation | Side | Diagnosis | Revision surgeries | Intraoperative complications | Aseptic loosening of components |
|--------------|-------------------|------------------|------|-----------|------------------------------------|--|---------------------------------|
| 1 | 5/15/1990 | 16.7 | L | JRA | None | None | No |
| 2 | 5/31/1990 | 16.74 | R | JRA | None | None | No |
| 3 | 7/10/1995 | 27.52 | L | RA | None | None | No |
| 4 | 5/9/1994 | 44.58 | R | RA | Bushing revised | None | No |
| 5 | 9/1/1992 | 36.68 | R | RA | Bushing revised | Small crack anterior aspect of humerus | No |
| 6 | 7/13/1994 | 38.55 | L | RA | Removal of TEA 3/13/96 (infection) | None | No |
| 7 | 7/14/1989 | 22.42 | L | JRA | Bushing revised | None | No |
| 8 | 7/21/1989 | 22.44 | R | JRA | Bushing revised | None | No |
| 9 | 12/21/1992 | 40.4 | R | RA | None | None | No |
| 10 | 4/7/1988 | 18.27 | R | JRA | None | None | No |
| 11 | 7/12/1993 | 43.55 | R | RA | None | None | No |
| 12 | 7/14/1993 | 36.22 | L | JRA | None | None | No |
| 13 | 9/14/1994 | 18.18 | R | JRA | None | None | No |
| 14 | 12/14/1994 | 18.43 | L | JRA | None | None | No |

RA, rheumatoid arthritis; JRA, juvenile rheumatoid arthritis; TEA, total elbow arthroplasty.