SHOULDER & ELBOW

Mid-term results of alumina ceramic unlinked total elbow arthroplasty with cement fixation for patients with rheumatoid arthritis

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Aims
The aim of this study was to report the mid-term clinical outcome of cemented unlinked J-alumina ceramic elbow (JACE) arthroplasties when used in patients with rheumatoid arthritis (RA).

Patients and Methods
We retrospectively reviewed 87 elbows, in 75 patients with RA, which was replaced using a cemented JACE total elbow arthroplasty (TEA) between August 2003 and December 2012, with a follow-up of 96%. There were 72 women and three men, with a mean age of 62 years (35 to 79). The mean follow-up was nine years (2 to 14). The clinical condition of each elbow before and after surgery was assessed using the Mayo Elbow Performance Index (MEPI, 0 to 100 points). Radiographic loosening was defined as a progressive radiolucent line of >1 mm that was completely circumferential around the prosthesis.

Results
The mean MEPI scores significantly improved from 40 (10 to 75) points preoperatively to 95 (30 to 100) points at final follow-up (p < 0.0001). Complications were noted in ten elbows (ten patients; 11%). Two had an intraoperative humeral fracture which was treated by fixation and united. One had a postoperative fracture of the olecranon which united with conservative treatment and one had a radial neuropathy which resolved. Further surgery was required for one with a dislocation, three with an ulnar neuropathy and one with a postoperative humeral fracture. Revision with removal of the components was performed in one elbow due to deep infection. There was no radiographic evidence of loosening around the components. With any revision surgery or revision with implant removal as the endpoint, the rates of survival up to 14 years were 93% (95% confidence interval (CI), 83.9 to 96.6) and 99% (95% CI 91.9 to 99.8), respectively, as determined by Kaplan-Meier analysis.

Conclusion
With the appropriate indications, the mid-term clinical performance of the cemented JACE TEA is reliable and comparable to other established TEAs in the management of the elbow in patients with RA.

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The elbow joint is involved in between 20% and 60% of patients with rheumatoid arthritis (RA).1,2 Although recent advances in the medical treatment for RA have resulted in better control, a significant proportion of patients still require replacement of the elbow.3 Improvements in the design and materials of elbow prostheses during the last three decades have made total elbow arthroplasty (TEA) a reliable option for these patients. As most modern elbow prostheses use a cobalt-chromium alloy and high-density polyethylene (HDP) there is little information about the outcome of prostheses using a ceramic humeral trochlea and HDP. An alumina ceramic unlinked elbow prosthesis was first designed in the late 1970s and had an anatomical articulation, based on a study of Japanese cadaveric elbows.4 A mid- to long-term study of a cemented second-generation alumina ceramic unlinked elbow prosthesis, the stemmed Kyocera type I (SKC-I),5 undertaken between 1987 and 1999, showed no breakage of the brittle ceramic trochlea. There were, however, major complications in 16 of 54 elbows (29.6%), including six with dislocation, four with aseptic loosening, three requiring revision surgery, and two requiring removal of components. The design
was therefore modified and the J-alumina ceramic elbow (JACE, Kyocera Co., Kyoto, Japan) was introduced in 1997. The width of the ceramic trochlea in the anteroposterior plane was extended by 3 mm, and the articular surface of the ulnar component was extended by 2.3 mm anteriorly to the coronoid process, to reduce the risk of dislocation (Supplementary figure aa). The humeral sapphire stem and ulnar ceramic stem were exchanged for a titanium (Ti) stem coated by arc plasma deposition for cementless fixation. After the early disappointing result of cementless fixation, the cemented type, which has a humeral component with a Ti stem without plasma-arc-coating, and an all-polyethylene ulnar component (Fig. 1), was added as an option in 1999. In addition to the modified design and cement fixation, diligent selection of appropriate patients improved the outcome.

Our aim was to undertake a retrospective review of the clinical results of cemented JACE components in patients with RA.

Patients and Methods

Between 2000 and 2015, 136 JACE TEAs were undertaken in 117 patients with RA. All patients met the American Rheumatism Association 1987 revised criteria for RA. In the previous study, we indicated alumina ceramic unlinked prosthesis (stemmed Kyocera type I) even for the reconstruction of Larsen grade V RA elbows with massive bone loss and instability. This challenge resulted in a high complication rate (29.6%) including 11% of dislocations. After a design change, JACE, the third-generation alumina ceramic prosthesis, was introduced for clinical application. Recognizing anew the importance of preserving the medial collateral ligament (MCL), the indications for the use of the JACE TEA mainly involve elbows with Larsen grade III and IV RA. Because of the anatomical configuration and low intrinsic stability, JACE is not suitable for use in elbows with inflammatory tears of the MCL or bony destruction of its humeral or ulnar insertions.

No patients in the current study were included in the previous study. We excluded 22 elbows (19 patients) in which cementless ulnar components were used with cemented humeral components between 2000 and 2003. We also excluded 22 elbows (20 patients) which were undertaken between 2013 and 2015 and had less than five-year follow-up. A total of five elbows (five patients) who were lost to follow-up were also excluded. Thus, the study involved 87 cemented JACE TEAs in 75 patients which were undertaken between August 2003 and December 2012, with a follow-up rate of 95.7%. Data at the final follow-up for these six patients were included in the reporting of complications and the survivorship analysis. There were 72 women and three men, with a mean age of 61.8 years (35 to 79). The mean follow-up was 8.9 years (2 to 14). The preoperative radiographic condition of the elbow was Larsen grade III in four, IV in 78 and V in five elbows. TEA was combined with a Darrach’s procedure in nine patients (ten wrists), and with a Sauvé–Kapandji procedure in three (three wrists) to improve rotation of the forearm.

Clinical follow-up was carried out by four authors (KN, KH, YN, KF) at three, six, and 12 months after the surgery, and annually thereafter. The condition of each elbow before and after surgery was assessed using the Mayo Elbow Performance Index (MEPI, 0 to 100 points), which assesses pain (0 to 45 points), range of movement (ROM; 0 to 20 points), stability (0 to 10 points) and function (0 to 25 points) (Supplementary table i). The ROM was measured using a goniometer, and expressed as follows; 0° being normal extension > 0° measuring the flexion arc and < 0° reflecting hyperextension, (On examination, stability was graded as stable (10 points), mildly unstable (5 points) or unstable (0 points). On the basis of this system, the overall evaluation was defined as excellent (> 89 points), good (75 to 89), fair (60 to 74) and poor (< 60).

Radiographic evaluation. Postoperative radiographs were taken at least biennially and were digitized at 12-bit pixel depth (4096 shades of grey) with a pixel size of 148 μm and transferred to a workstation. The images allowed the assessment of radiolucent lines in periprosthetic zones as described by de Vos et al with some modification (Fig. 2). Two authors (KN and YN) independently reviewed the pre- and postoperative radiographs in order to record the width of radiolucent lines in each zone, and reached agreement. Radiographic loosening was defined as a progressive radiolucent line of > 1 mm that was completely circumferential around a component.

Surgical technique. The components are introduced as described for the SKC-I, using a longitudinal posterior approach with the patient in the lateral position. The ulnar nerve is identified and dissected proximally and distally, but without routine anterior transposition. The triceps tendon is dealt with as
achieved.

and trial reduction repeated until smooth articulation is

ulnar component, the ulnar bed is recut to correct the rotation

determination of the appropriate rotation of the ulnar

joint, the preserved MCL functions as a hinge contributing to

and stability and mobility established. During reduction of

the stem of the component. The trial components are introduced

create a flat bed for the body of ulnar component.

sacrificing the medial collateral ligament). The articular surface

this spur piecemeal from within the joint allows complete

resection of the radial head. The mean range of pronation/
supination was 86° (0° to 165°) and 119° (50° to 155°) in flexion/extension, and 130° (30° to 180°) and 165° (50° to 180°) in pronation/supination, respectively. The mean ROM scores were 14.3 (5 to 20) points preoperatively and 18.9 (15 to 20) points postoperatively. The mean pre- and postoperative scores were 6.0 (0 to 10) and 9.2 (0 to 10) for stability and 9.6 (0 to 25) and 22.8 (0 to 25) for function, respectively. The mean MEPI scores significantly improved from 39.5 (10 to 75) points preoperatively to 94.7 (30 to 100) points at final follow-up (p < 0.0001). The elbows were rated as good in three, fair in 11, and poor in 73, preoperatively, and excellent in 78, good in six, fair in two, and

poor in one postoperatively, respectively (Table I).

Statistical analysis. Statistical analysis was performed by

paired Student’s t-test and Wilcoxon’s signed-rank test to compare pre- and postoperative data. Survival involving revision surgery with removal of components with or without the reintroduction of new components, and the time when revision surgery was undertaken, was performed using the Kaplan-Meier method. All analyses were conducted using Prism software (version 5.0a; GraphPad Software, La Jolla, California) with p < 0.05 regarded as significant.

Results

Clinical outcome. The mean pain scores improved from 9.7 points (0 to 45) preoperatively to 43.8 points (15 to 45) at final follow-up. The mean range of extension/flexion was -35° (SD 22°)/120° (SD 21°) preoperatively and -17° (SD 16°)/137° (SD 12°) at the final follow-up. The mean range of pronation/supination was 69° (SD 23°)/61° (SD 31°) preoperatively and 81° (SD 18°)/84° (SD 15°) at final follow-up. The range of these movements all improved significantly (p < 0.0001). The mean pre- and postoperative arcs of movement were 86° (0° to 165°) and 119° (50° to 155°) in flexion/extension, and 130° (30° to 180°) and 165° (50° to 180°) in pronation/supination, respectively. The mean ROM scores were 14.3 (5 to 20) points preoperatively and 18.9 (15 to 20) points postoperatively. The mean pre- and postoperative scores were 6.0 (0 to 10) and 9.2 (0 to 10) for stability and 9.6 (0 to 25) and 22.8 (0 to 25) for function, respectively. The mean MEPI scores significantly improved from 39.5 (10 to 75) points preoperatively to 94.7 (30 to 100) points at final follow-up (p < 0.0001). The elbows were rated as good in three, fair in 11, and poor in 73, preoperatively, and excellent in 78, good in six, fair in two, and poor in one postoperatively, respectively (Table I).

With any revision surgery and revision with removal of components as the endpoints, the survival rates, up to 14 years, were 93% (95% confidence interval (CI) 83.9 to 96.6) and 99% (95% CI 91.9 to 99.8), respectively (Fig. 5).

Radiographic outcome

In the anteroposterior view, radiolucenties were noted between the medial and lateral condyle and the ceramic trochlea in 18

shown in Figure 3. The annular ligament is divided longitudinally for later reattachment under tension, as determined by the situation after resection of the radial head.

A capsulo-synovectomy is performed with preservation of the anterior fibres of the medial collateral ligament (MCL), and the joint is opened on the intact MCL complex. When dislocation of the joint is difficult, resection of the tip of the olecranon and the coronoid process provides wide exposure of the distal humerus. The distal aspect of the humerus is trimmed and reaming is performed with the aid of a guide wire. The guide instrument is introduced and a square bone cut is made to remove the damaged trochlea so as to place the humeral trial component with between 3° and 5° of internal rotation in relation to the epicondylar line. This resection further provides wide access to the joint, making synovectomy and anterior capsular release easier, and allowing access to the bony spur arising from the sublime tubercle along the MCL. Removal of this spur piecemeal from within the joint allows complete dislocation without dividing the anterior fibres of the MCL (see online for a video showing how to dislocate the elbow without sacrificing the medial collateral ligament). The articular surface of the ulna is removed using a saw in a freehand manner to create a flat bed for the body of ulnar component. Intramedullary reaming is carried out to create a circular bed for the stem of the component. The trial components are introduced and reaming is performed with the aid of a guide wire. The guide wire is introduced and a square bone cut is made to

In the anteroposterior view, radiolucencies were noted between the medial and lateral condyle and the ceramic trochlea in 18

Radiographic outcome

In the anteroposterior view, radiolucenties were noted between the medial and lateral condyle and the ceramic trochlea in 18
TEAs (21.4%) in Zone 4 and 17 (19.5%) in Zone 5. This was considered to represent either stress shielding or a gap created by over resection of the trochlea. There were no radiolucent lines around the humeral component. In the lateral view, radiolucencies were noted in Zone 6 of one elbow with a fracture of the olecranon, and in Zones 4, 5, and 6 of another elbow. In the latter elbow, there was a probable radiolucent line (< 1 mm) between bone and cement which was not considered to reflect loosening. Aseptic loosening was not observed around either component during follow-up.

Complications were noted in ten elbows of ten patients (11%) (Table II). There were no triceps-related failures. A fracture of the medial condyle occurred during the insertion of the humeral trial component in two elbows (two patients). The fracture was fixed with a Kirschner wire (K-wire) and tension band during the primary surgery. Postoperative fractures were seen in one elbow at the olecranon and in one in the humeral shaft due to trauma. These were treated conservatively and by open reduction and fixation, respectively. Three patients (three elbows) had persistent symptoms from the ulnar nerve postoperatively requiring release and anterior transposition. In one elbow, intraoperative anterior escape of cement led to posterior interosseous nerve palsy, which spontaneously recovered after three months. One elbow required revision surgery due to deep infection after the introduction of Adalimumab medication. Both components were removed with the subsequent use of an orthosis, resulting in a poor result. Dislocation was noted in one elbow three weeks postoperatively. This patient had undergone arthroscopic synovectomy before TEA, and a relatively peripheral setting of
the ulnar component caused dislocation. In spite of reconstruction of the lateral collateral ligament (LCL) and the MCL, the elbow remained unstable, and required an orthosis.

Discussion

There are two reports on the use of the JACE TEA in the English literature as well as our report on the cementless type of JACE.6 The first report by Tachihara et al14 described the clinical outcome of three types of TEA including JACE for 34 rheumatoid elbows with a mean follow-up of 3.5 years. The rates of loosening for the JACE, STABLE, (Kyocera Co., Kyoto, Japan) and Kudo (Type 5, Zimmer Biomet, Warsaw, Indiana) prostheses were 15%, 23%, and 0%, respectively, and this rate decreased to 2.5% when the humeral component was fixed with cement. The more recent report by Okabayashi et al15 described the results of 22 rheumatoid elbows replaced by JACE TEAs with a mean follow-up of 83.5 months, with no aseptic loosening, dislocation, deep infection or ulnar nerve palsy, but two intraoperative fractures. Although these series are small with shorter follow-up, these results reflect the reproducibility of this TEA. The current retrospective study is first to report the mid-term outcome of JACE TEA implanted with cement.

As unlinked implants have no physical connection between the components, the stability of the elbow relies on the design of the bearing surfaces and the integrity of the soft tissues.16 The primary static constraints of the elbow include the ulnohumeral architecture, the anterior and posterior capsule, the anterior bundle of the MCL and the LCL complex.17 The LCL is the primary stabilizer of the ulnohumeral joint, and deficiency causes posterolateral rotatory instability. Recognizing the importance of LCL, the annular ligament is temporarily dissected in our procedure to facilitate the synovectomy and radial head resection, but should be repaired at the end of the operation. Floris et al,18 however, showed that complete division of anterior bundle of MCL causes valgus and internal rotatory instability throughout the arc of flexion. Amis19 also reported that the MCL complex is more important than the LCL complex for functional stability.

During our TEA, the radial head, which is an important secondary valgus stabilizer of the elbow joint, is resected routinely. Morrey et al20 reported that valgus stability is equally divided between the MCL, the anterior capsule and the bony articulation in full extension, whereas, at 90° of flexion, the MCL provides approximately 55% of the stabilizing contribution to valgus stress. More recently, Beingessner et al21 examined the varus-valgus laxity in elbows after resection of the radial head and found that transection of LCL with pronation of the forearm, and transection of LCL and/or MCL with supination significantly increased the laxity. When using other unlinked arthroplasties such as the Kudo or Souter–Strathclyde (Stryker UK, Newbury, United Kingdom), relatively high intrinsic stability of the prosthesis may prevent dislocation, yielding the transection of MCL during the surgery. Complete release of the MCL is recommended when using the Kudo TEA,22-24 while anterior fibres of the MCL must be preserved when using the Souter–Strathclyde TEA,1 or it should be preserved “when possible” when using either.25 As the JACE TEA has anatomical configuration with less intrinsic stability, the MCL functions as a main static stabilizer of the joint after resection of the radial head, and should be preserved.

During the same period as the current study, between 2000 to 2015, 48 rheumatoid elbows were replaced in our institution using a linked TEA; 15 in 13 patients using a Coonrad–Morrey TEA,12 (Zimmer Biomet, Warsaw, Indiana) and 33 in 31 patients using a PROSNAP TEA26 (Kyocera Co., Kyoto, Japan) for Larsen grade V joint destruction or bony ankylosis, revision TEA, or a humeral or ulnar fracture associated with a rheumatoid elbow. Thus, we used a JACE TEA for 73% of rheumatoid elbows during this time, and we occasionally
prepared a linked device as an option for the surgery in patients with a severe contracture of the elbow, when ossification of the MCL is anticipated.

The complication rates of primary TEA ranged from 11% to 45% in recent systematic reviews. Clinical loosening was the most frequent complication (7%), followed by deep infection (3%) and ulnar nerve palsy (3%). Another recent systematic review reported that aseptic loosening was the most frequent indication for revision (38%), followed by deep infection (19%) and periprosthetic fracture (12%). We found that complications were seen in 10 elbows (11%), which was comparable to previous reports. However, the types of complication were different. The most frequent complication was ulnar neuropathy (three elbows, 3%), followed by intraoperative fracture (two elbows, 2%) and postoperative fracture (two elbows, 2%).

The loosening rate of previously reported cementless JACE TEA was disappointing, with a high revision rate (38%), even though 17 TEAs (62%) of the implants, with a mean follow up of 10.7 years, were functioning well. This was considerably higher than the revision rate of TEA in rheumatoid patients (10%) reported in the systematic review by Little et al. In our series, neither aseptic loosening or radiolucencies were seen around either component when a JACE TEA was used with cement. The operation requires preservation of the MCL, which allows the proper setting of the implants. Furthermore, preservation of both MCL and LCL might contribute to a reduction of rotational and varus-valgus stress transmitted at the bone-cement interface. This might have contributed the relatively low incidence of radiographic loosening. In contrast, Tanaka et al concluded that all-polyethylene components should not be used in rheumatoid patients based on the results of the type-5 Kudo prosthesis. This might partly be due to differences in the constrained fashion of the joint and the strength of the rotational moment transmitted to the ulnar component between the JACE and Kudo TEAs. Potter et al suggested that loss of the normal ulnohumeral orientation caused by the valgus tilt of the Kudo prosthesis might be

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**Table I. Changes in the Mayo Elbow Performance Index (MEPI) of 87 cemented J-alumina ceramic elbow (JACE) total elbow arthroplasties (TEAs)**

| Outcome | Preoperative | Postoperative |
|---------|--------------|---------------|
| Pain category, elbows, n (%) | | |
| None | 3 (3) | 82 (94) |
| Mild | 8 (9) | 3 (3) |
| Moderate | 31 (36) | 2 (2) |
| Severe | 45 (52) | 0 (0) |
| Mean pain (range) | 9.7 (0 to 45) | 43.8 (15 to 45) |
| Range of movement, elbows, n (%) | | |
| Arc > 100° | 25 (29) | 64 (74) |
| Arc 50° to 100° | 43 (49) | 23 (26) |
| Arc < 50° | 19 (22) | 0 (0) |
| Mean range of movement (range) | 14.3 (5 to 20) | 18.9 (15 to 20) |
| Stability category, elbows, n (%) | | |
| Stable | 32 (37) | 74 (85) |
| Moderately unstable | 41 (47) | 12 (14) |
| Grossly unstable | 14 (16) | 1 (1) |
| Mean stability (range) | 6.0 (0 to 10) | 9.2 (0 to 10) |
| Mean function (range) | 9.6 (0 to 25) | 22.8 (0 to 25) |
| Mean MEPI (range) | 39.5 (10 to 75) | 94.7 (30 to 100) |
| Overall results, n | | |
| Excellent | 0 | 78 |
| Good | 3 | 6 |
| Fair | 11 | 2 |
| Poor | 73 | 1 |

**Table II. Complications noted in ten of 87 cemented J-alumina ceramic elbows (JACEs) and their management**

| Complications | Elbows, n | Management | Outcome |
|---------------|-----------|------------|---------|
| Intraoperative humeral fracture | 2 | Intraoperative wire fixation | Union |
| Postoperative fracture (humerus, 1; ulna, 1) | 2 | Conservative treatment for olecranon fracture; ORIF for humeral shaft fracture | Nonunion; union |
| Ulnar neuropathy | 3 | Ulnar nerve release + anterior transposition | Two recovered, one sensory disturbance |
| Radial nerve palsy | 1 | Conservative treatment | Recovered |
| Deep infection | 1 | Open debridement + implant removal | Grossly unstable |
| Dislocation | 1 | Ligament reconstruction | Moderately unstable |

ORIF, open reduction and internal fixation
associated with a risk of edge loading, wear and loosening of the all-polyethylene ulnar component.

The infection rate of primary TEA in rheumatoid patients has been reported to range from 0% to 8.1%,22,27,31–35 In our series, there was deep infection in only one elbow (0.9%). This presented one year postoperatively and required removal of the components. It is possible that the use of a tumour necrosis factor (TNF)-inhibitor (Adalimumab) made a subclinical infection overt in this patient. Caution should be exercised not only during perioperative management but also for the development of late infection in rheumatoid patients being treated with biological agents.36,37

The survival and complication rates of TEA are still not as favourable as those of total hip and knee arthroplasties.27 A recent systematic analysis reported an overall survival rate of TEA of 79.2% after 11.1 years.27 The rates of survival of specific TEAs with revision as the endpoint with more than five years’ follow-up have been reported separately to be between 70% and 97% for the Souter–Strathclyde TEA,38,39 between 84% and 100% for the Kudo TEA,35,40 between 70% and 87% for the GSBIII TEA;41,42 (Zimmer Biomet, Warsaw, Indiana) and between 68% and 92% for the Coonrad–Morrey TEA.25,33,43 Similar rates of ten-year cumulative survival of 88% for the Coonrad–Morrey, 89% for the GSBIII, 88% for the Capitello condylar (Johnson & Johnson, New Brunswick, New Jersey) and 72% for the Souter–Strathclyde TEA have been reported from the Danish National Joint Registry.44 The cemented JACE TEA had a longer survival rate than the cementless JACE, and the 99% survival rate for cemented JACE at 14 years was presented one year postoperatively and required removal of the components. It is possible that the use of a tumour necrosis factor (TNF)-inhibitor (Adalimumab) made a subclinical infection overt in this patient. Caution should be exercised not only during perioperative management but also for the development of late infection in rheumatoid patients being treated with biological agents.

In conclusion, we report satisfactory mid-term results with the anthropometric measurement-based alumina ceramic TEA for use in rheumatoid elbows when implanted with bone cement. We found that the survival rate of the cemented JACE TEA was comparable with that reported for other established TEAs when used in these patients.

Take home message:

- Complications were noted in 10 elbows of 10 patients (11%).
- The likelihood of survival up to 14 years was 93% and 99% with any revision surgery and revision with implant removal as the end point, respectively.
- Proper patient selection and the specific surgical procedure to preserve MCL are important for this unlinked prosthesis.

Supplementary material (available online)

A table showing the categories of the Mayo Elbow Performance Index (MEPI) and a figure demonstrating the differences in design between the stemmed Kyocera type I (SKC-I) and the J-alumina ceramic elbow (JACE).

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