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Original Article

Results of Total Elbow Arthroplasty with Cementless Implantation of an Alumina Ceramic Elbow Prosthesis for Patients with Rheumatoid Arthritis

Keiichiro Nishida[a,b]*, Kenzo Hashizume[c], Masatsugu Ozawa[b], Ayumu Takeshita[b], Daisuke Kaneda[b], Ryuichi Nakahara[d], Yoshihisa Nasu[e], Yasunori Shimamura[b], Hajime Inoue[b], and Toshifumi Ozaki[b]

Department of [a]Human Morphology, [b]Orthopaedic Surgery, [d]Musculoskeletal Traumatology, and [e]Medical Materials for Musculoskeletal Reconstruction, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama 700-8558, Japan, [c]Department of Rehabilitation, Japan Labour Health and Welfare Organization, Okayama Rosai Hospital, Okayama 702-8055, Japan

We investigated the long-term clinical results of total elbow arthroplasty (TEA) by cementless fixation of alumina ceramic unlinked elbow prostheses (J-alumina ceramic elbows: JACE) for the reconstruction of elbow joints with rheumatoid arthritis (RA). Seventeen elbows in 17 patients (aged 44-72 years, average 54.8) replaced by JACE TEA without bone cement were investigated. The average follow-up period was 10.7 (range, 1.0-19.3) years. Clinical conditions of each elbow before and after surgery were assessed according to the Mayo Elbow Performance Index (MEPI). Radiographic loosening was defined as a progressive radiolucent line of more than 1 mm that was completely circumferential around the intramedullary stem. The average MEPI significantly improved from 46.8 points preoperatively to 66.8 points at final follow-up ($p = 0.0226$). However, aseptic loosening was noted in 10 of 17 elbows (58.8%) and revision surgery was required in 7 (41.2%). Most loosening was observed on the humeral side. With radiographic loosening and revision surgery defined as the end points, the likelihoods of prosthesis survival were 41.2% and 51.8%, respectively, up to 15 years by Kaplan-Meier analysis. The clinical results of JACE implantation without bone cement were disappointing, with high revision and loosening rates of the humeral component.

Key words: total elbow arthroplasty, rheumatoid arthritis, alumina ceramic, unlinked elbow, JACE

The elbow joint is affected in 25-53% of patients with rheumatoid arthritis (RA) [1]. Total elbow arthroplasty (TEA) has been a reliable procedure for reconstruction of severely damaged RA elbows, and acceptable implant survivals have been reported in both linked and unlinked elbow prostheses [2-9].

We recently reported the favorable clinical results of alumina ceramic TEA with the stemmed Kyocera-type I (SKC-I) prosthesis for patients with RA. When SKC-I is implanted with bone cement, the survival rate of the prosthesis for up to 20 years is 92.6% or 86.3% with loosening or implant revision defined as end points, respectively [10]. The J-alumina ceramic elbow (JACE; Kyocera Medical Co., Osaka, Japan) is an alumina ceramic elbow prosthesis that was introduced for clinical application in 1997. The implant design was subsequently changed based on the short- to medium-term clinical results obtained with the SKC-I prosthesis. The humeral sapphire stem and ulnar ceramic stem were

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*Corresponding author. Phone: +81-86-235-7273; Fax: +81-86-223-9727
E-mail: knishida@md.okayama-u.ac.jp (K. Nishida)

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abolished, and exchanged for a titanium (Ti) stem coated by arc plasma deposition, with the expectation that cementless fixation of the components would be employed (Fig. 1). Between 1997 and 2000, the cementless-type JACE was used for all RA elbows without bone cement. In the current retrospective study, we reviewed the long-term clinical results of JACE TEA.

Patients and Methods

The current retrospective study was approved by the Ethics Committee of our institute (No. 576). All patients met the American Rheumatism Association 1987 revised criteria for RA [11]. Twenty-two elbows of 22 RA patients underwent primary TEA with a JACE prosthesis at our institute and affiliated hospitals from 1997 to 2000. Three patients (3 elbows) died before the minimum 2-year follow-up of causes unrelated to the surgery and were excluded from the analysis. Two elbows (two patients) who underwent "hybrid" fixation (cementless fixation of the humeral component and cemented fixation of the ulnar component) were also excluded from the analysis. As a result, 17 elbows in 17 patients (17 women, aged 44-71, mean age 55.8 years) were enrolled in the current study. One surgeon (H.I.) implanted 16 prostheses in 16 elbows; the other surgeon (K.N.) implanted the remaining prosthesis in one elbow. Three patients (3 elbows) died during the study period after more than 2 years of follow-up, and their records at the final visit were used for analysis. In patients who underwent revision surgery, clinical data just before the revision surgery were used as the data of the final follow-up. The mean follow-up period was 10.7 (range 1.0-19.3) years (Table 1). Resection of the distal ulnar end (Darrach procedure) was combined with TEA in patients with wrist joint deterioration of Larsen's grade III or IV, to improve the pain at the distal radio-ulnar joint, and forearm rotation [10].

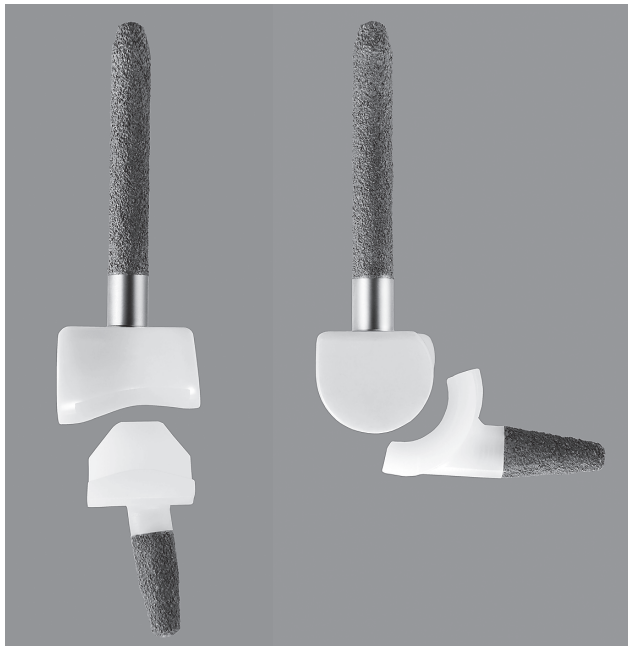

Fig. 1 Photographs of cementless-type JACE prostheses (prostheses for the left elbow). The humeral and ulnar components consist of a solid ceramic trochlea and high-density polyethylene, respectively, with an intramedullary Ti stem. The stem of the humeral component is 60 mm in length and 8 mm in diameter, and the ceramic trochlea has two width options (28 and 30 mm). The width of the ulnar surface is 20 mm, and the stem of the ulnar component has two thickness options (10 and 12 mm).

The clinical condition of each elbow before and after surgery was assessed according to the Mayo Elbow Performance Index (MEPI; 0-100 points) [12]. On the basis of this system, the overall results were defined as excellent (> 89), good (75-89), fair (60-74), and poor (< 60). Radiographic loosening was defined as a progressive radiolucent line of more than 1 mm in the circumferential direction around the intramedullary stem [13].

Statistical analysis. Statistical analysis was performed by the Wilcoxon signed rank test to compare pre- and post-operative data. For survival analysis for revision surgery including implant removal, with or without reinsertion of a new implant, the period between the initial surgery and revision surgery was used for Kaplan-Meier analysis. All analyses were conducted using Prism software (version 5.0a; Graph-Pad Software, San Diego, CA, USA) with a value of $p < 0.05$ regarded as significant.

Results

Darrach's procedure was simultaneously combined with TEA in 4 cases (4 wrists) for patients with restricted forearm rotation. Results of the clinical assessment with MEPI are summarized in Table 1. At the final follow-up, pain scores improved significantly from 18.5 (range 0-45) points preoperatively to 30.0 (range 0-45) points postoperatively ($p = 0.0165$), but 6 patients (6 elbows) had moderate to severe pain. Scores for range of motion were 15.1 (range 5-20) points preoperatively

Table 1 Results of clinical assessment

	Pre-op.	Post-op.	P*
Pain (no. of elbows)			
None	1	8	
Mild	6	3	
Moderate	6	4	
Severe	4	2	
Pain score (mean, range)	18.5 (0–45)	30.0 (0–45)	0.0165*
ROM (no. of elbows)			
Arc > 100 degrees	3	5	
Arc 50 to 100 degrees	13	8	
Arc < 50 degrees	1	3	
ROM score (mean, range)	15.1 (5–20)	14.7 (5–20)	0.6788
Stability (no. of elbows)			
Stable	4	10	
Moderately unstable	12	3	
Grossly unstable	1	4	
Stability score (mean, range)	5.9 (0–10)	6.8 (0–10)	0.5071
Function score (mean, range)	7.1 (0–25)	15.3 (0–25)	0.0201*
Mayo Elbow Performance Index (mean, range)	46.8 (20–80)	66.8 (30–100)	0.0226*
Overall results (no.) (Excellent/good/fair/poor)	0/2/2/13	7/2/0/8	

ROM: range of motion.
*Wilcoxon signed rank test to compare the pre- and post operative data. $P < 0.05$ regarded as significant.

and 14.7 (range 5-20) points postoperatively. Preoperative and postoperative motion arcs were 78 and 81 degrees in flexion/extension, and 118 and 147 degrees in pronation/supination, respectively (Table 2). Preoperative and postoperative stability scores were 5.9 (range, 0-10) and 6.8 (range, 1-10), and function scores were 7.1 (range, 0-25) and 15.3 (range, 0-25), respectively. MEPI scores were significantly improved from 46.8 (range, 20-80) points preoperatively to 66.8 (range, 30-100) points postoperatively ($p = 0.0226$). Overall results were good in 2, fair in 2, and poor in 13 elbows preoperatively, and excellent in 7, good in 2, and poor in 8 postoperatively (Supplemental Table).

Although 10 of 17 elbows were still *in situ* at the final follow-up (Fig. 2), complications were noted in 11 elbows in 11 patients (64.7%). An intraoperative humeral fracture was noted in 2 elbows, and both elbow fractures were healed conservatively. However, ulnar neuritis occurred in one of 2 elbows, and required ulnar nerve release. Up to the final follow-up, 10 of 17 elbows (58.8%) showed radiographic loosening. The average period before identification of loosening was 1.5 ± 0.9 years after surgery. Of these cases, one patient died for reasons unrelated to the surgery, and 2 patients declined surgery because the loosening did not cause elbow joint instability or pain during the follow-up period. Seven elbows (41.2%) showed progressive loosening around the humeral stem (Fig. 3), and required revision surgery with implant removal at an average of 7 ± 3.7 years after surgery. Of these, 5 humeral components were revised using a cemented humeral component with or without a long stem. One elbow also showed loosening of the ulnar component, and was replaced using a thick ulnar component with

Table 2 Pre- and Post-operative range of motion after JACE TEA without cement fixation

Direction	Range of motion (degrees)	
	Pre-op.	Post-op.
Flexion	111 (75–135)	118 (90–140)
Flexion contracture	33 (0–70)	37 (0–70)
Flexion/extension arc	78 (40–120)	81 (35–120)
Pronation	63 (20–90)	68 (15–90)
Supination	55 (0–90)	79 (30–90)
Pronation/supination arc	118 (30–180)	147 (75–180)

Average (range)

Supplemental Table Pre- and post-operative clinical features of cementless JACE TEA

Ptient No.	age at operation	Gender	Side	F-U period (years)	Pre-operative										Post-operative									
					Range of Motion				Mayo Elbow Performance Index					overall Result	Range of Motion				Mayo Elbow Performance Index					overall result	comments
					Flexion	Extension	Pronation	Supination	Pain	Motion	Function	Stabiity	Total score		Flexion	Extension	Pronation	Supination	Pain	Motion	Function	Stabiity	Total score		
1	69	F	R	7.9	120	−70	90	45	15	5	0	5	25	Poor	125	−30	90	90	45	15	25	10	95	Excellent	
2	56	F	L	19.3	95	−45	45	45	15	5	0	5	25	Poor	140	−15	90	90	45	20	25	10	100	Excellent	
3	50	F	R	17.6	105	−55	30	0	45	5	10	10	70	Fair	140	−50	30	90	45	15	20	10	90	Excellent	Darrach
4	44	F	R	8.8	110	0	20	70	0	20	5	5	30	Poor	110	0	20	70	0	20	10	5	35	Poor	loosening revision
5	48	F	L	16.4	135	−50	60	90	30	15	20	10	75	Good	95	−40	80	90	30	15	20	10	75	Good	loosening
6	54	F	R	11.9	100	−45	80	60	0	15	0	5	20	Poor	125	−60	90	90	45	15	20	10	90	Excellent	
7	70	F	R	7.8	130	−10	90	90	30	20	25	5	80	Good	140	−20	70	90	45	20	25	10	100	Excellent	
8	52	F	L	9.1	100	−5	90	90	15	15	10	10	50	Poor	100	−5	90	90	30	15	10	0	55	Poor	loosening revision
9	54	F	L	12.7	105	−35	20	70	15	15	10	5	45	Poor	115	−30	80	80	45	15	25	5	90	Excellent	loosening
10	55	F	R	12.3	120	−30	80	45	30	15	15	5	65	Fair	110	−30	30	80	15	15	5	0	35	Poor	loosening revision
11	45	F	R	11.2	130	−45	90	70	15	15	0	5	35	Poor	105	−70	90	90	15	5	10	10	40	Poor	loosening
12	59	F	L	10.9	100	−45	45	60	30	15	0	0	45	Poor	110	−60	90	30	45	15	15	10	85	Good	Darrach
13	51	F	R	17.8	75	−35	80	0	30	5	0	5	40	Poor	130	−30	90	45	45	20	20	10	95	Excellent	
14	56	F	R	6.5	90	−10	70	70	15	15	0	5	35	Poor	120	−30	90	90	30	20	0	0	50	Poor	Darrach loosening revision
15	59	F	R	3.7	100	−10	20	60	0	15	5	10	30	Poor	125	−70	45	90	0	5	15	10	30	Poor	loosening revision
16	72	F	L	7.8	135	−60	90	0	30	5	0	5	40	Poor	90	−45	15	60	15	5	10	5	35	Poor	Darrach loosening revision
17	54	F	R	1.0	130	−10	70	70	0	20	25	5	50	Poor	120	−45	70	80	15	15	5	0	35	Poor	loosening revision

Fig. 2 Anteroposterior (A, C, E) and lateral (B, D, F) radiographs of the right elbow of a 56-year-old woman before surgery (A, B), at the time of surgery (C, D) and 19 years after cementless fixation of JACE (E, F). A medial epicondyle fracture of the humerus occurred intra-operatively, and bone union was obtained with conservative treatment. No loosening is seen around either the humeral or ulnar component. MEPI improved from 35 to 94 points at the final follow-up.

bone cement, whereas no loosening was noted around the ulnar component of the other 3 elbows. The remaining 2 elbows were replaced using linked elbow prostheses (Coonrad-Morrey [12] and PROSNAP [14]). With loosening and revision as the end points, Kaplan-Meier analysis resulted in survival rates for the cementless prosthesis of 41.2% and 51.8%, respectively, for up to 15 years (Fig. 4).

Discussion

The alumina ceramic elbow prosthesis was first designed in the late 1970s, based on a measurement study of Japanese cadaveric elbows [15]. The design of the implant was an unlinked surface replacement prosthesis using polycrystalline alumina ceramic as a solid trochlea on high-density polyethylene (Kyocera-type I) [16]. In 1986, the first model change was made to an unlinked stemmed type-type (SKC-I); however, 8 elbows implanted without cement fixation showed early tilt or subsidence of the humeral component. When used with bone cement fixation, SKC-I showed excellent mid- to long-term clinical outcomes [10].

There is still debate regarding possible advantages and disadvantages of cemented and cementless fixation of the joint prosthesis in terms of ease of revision, complications of cementing, and long-term survival of the prosthesis [17]. JACE is the third-generation alumina ceramic elbow after SKC-I, and was developed with the expectation of cementless fixation of the prosthesis.

Fig. 3 Anteroposterior (**A**, **C**, **E**) and lateral (**B**, **D**, **F**) radiographs of the right elbow of a 55-year-old woman before surgery (**A**, **B**), and at 3 weeks (**C**, **D**) and 10 years after cementless fixation of the JACE (**E**, **F**). Loosening is seen around the humeral component with anterior tilting of the stem and subsidence of the component. The MEPI before the revision surgery was 42 points.

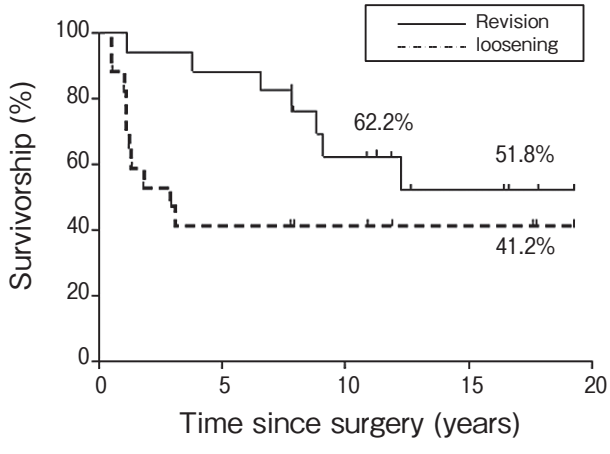

Fig. 4 Kaplan-Meier survivorship curves for cementless JACE; loosening (dotted line) and revision (solid line) with implant removal are used as end points.

Tachihara *et al.* reported favorable early clinical results of JACE prosthesis in 34 RA elbows, but found loosening in 5 elbows (15%) [18]. The current study showed disappointing long-term clinical results of cementless JACE, with a revision rate of 41.2%. This is considerably higher than the revision rate of TEA in RA patients reported in the systematic review by Little *et al.* [7]. The main reason for revision surgery was implant loosening (58.8%), and the survival rate at 15 years was 41.2% when loosening was defined as the end point. The possible factors affecting loosening might include patients' bone quality, the design of the prosthesis (a solid trochlea, a short and relatively thin stem for the patient's humeral diameter), and stress loaded by the shoulder and wrist joints with restricted range of motion in RA patients. Most loosening was observed on the humeral side with the tip of the components displaced anteriorly

and articulation displaced posteriorly, accompanied by subsidence of the component, similar to the loosening pattern of the Souter-Strathclyde prosthesis [19]. In the English literature, the Kudo prosthesis is the only unlinked elbow in which cementless fixation succeeded [20]. In addition to component stabilization with the intramedullary stem, the round-cap structure of the humeral component holds the distal humerus. Because the solid trochlea seen in the JACE and Souter-Strathclyde prostheses does not resist the predominantly posteriorly-directed forces during flexion–extension, the intramedullary stem is the only structure that stabilizes the humeral component of the JACE prosthesis. The stem of the humeral component (60 mm length and 8 mm diameter) might not be sufficient for intramedullary fixation when used for osteoporotic patients without bone cement, and might need variation in length and thickness.

In conclusion, cementless implantation results in a high complication rate with loosening of the humeral component and a high revision rate. Although the cementless-type JACE is still on the market, we no longer use this type of JACE, and the cemented-type is now standard for the reconstruction of RA elbows.

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