Table 2
Operative Time and Blood Loss.

	Operative Time (min)		Total Blood Loss (ml)[a]		Estimated Blood Loss (ml)[b]	
	Mean ± SD	P[c]	Mean ± SD	P	Mean ± SD	P
Simultaneous	58 ± 11[d]	–	317 ± 161	–	677 ± 185	–
Stage 1	65 ± 12	<0.05	375 ± 203	n.s.	792 ± 292	n.s.
Stage 2	64 ± 9	<0.05	341 ± 165	n.s.	763 ± 263	n.s.

n.s., not significant.

[a] Total blood loss was determined as intraoperative blood loss plus volume from suction drain until 2 days postoperatively.

[b] Estimated blood loss (ml) was determined using the following formula: Total circulated blood (70 ml/kg × body weight) × (postop. hemoglobin − preop. hemoglobin)/postop. hemoglobin.

[c] Stage 1/2 versus simultaneous TKA.

[d] Operative time for simultaneous bilateral TKA is expressed as the mean operative time per knee.

difference in the incidence of DVT was seen among the three groups (Fig. 4B).

Short-term recovery of symmetrical knee function has been proposed as an advantage of simultaneous bilateral TKA, but few clinical studies to date have confirmed this. Assuming a KSS Function score of 80 as the target of the present TKA series, recovery time to a score of 80 was 2 months earlier with simultaneous bilateral TKA than with stage 2 TKA (Fig. 5A). Regarding temporal changes in KSS Knee score, both simultaneous and staged bilateral TKAs showed a similar trend, in that the score reached >85 within the first 2 months, followed by a gradual increase to 95 (Fig. 5B). Regarding improvement of range of motion (ROM), once the patient was discharged from hospital, flexion angle somewhat worsened compared to baseline, with the lowest value at 2 months postoperatively for staged bilateral TKA and at 3 months postoperatively for simultaneous bilateral TKA. Thereafter, knee flexion angle gradually reached >125° at a mean of 11 and 13 months postoperatively for staged and simultaneous bilateral TKA, respectively (Fig. 5C).

In terms of postoperative complications over the mean follow-up of 38 months, simultaneous bilateral TKA included asymptomatic PE (decreased SaO_2 alone, $n = 2$), heart failure ($n = 1$), heterotopic ossification ($n = 1$), confusion presumably related to fat embolism ($n = 3$) and arthrofibrosis ($n = 3$). Stage 1 TKA patients encountered asymptomatic PE ($n = 1$), symptomatic outpatient DVT ($n = 1$), heart failure ($n = 1$), myocardial infarction ($n = 1$), and arthrofibrosis ($n = 1$), while stage 2 TKA patients experienced asymptomatic PE ($n = 1$), intraoperative fracture (medial femoral condyle, $n = 1$), confusion ($n = 1$), and arthrofibrosis ($n = 1$). No significant differences in frequency of postoperative complications were identified between the three groups (Table 3).

Discussion

Numerous authors have raised the issue of an increased risk of postoperative morbidity after simultaneous bilateral TKA. According to perioperative changes in laboratory markers in this study, decreased levels of hemoglobin and increased levels of CRP, CPK, and D-dimer following simultaneous bilateral TKA might suggest a predisposition of this procedure toward postoperative complications. There has been a concern that acute blood loss and subsequent hemoglobin drop may cause ischemic injuries in the brain and heart, resulting in cerebral infarction and heart failure [16], as these organs are critical tissues that require a constant oxygen supply. To date, blood transfusion requirements have been reported as one of the drawbacks of simultaneous procedures [2,17–19]. In one study, a hemoglobin level <10 g/dl was considered a secure indication for blood transfusion after TKA [20]. In the present study, the mean minimum hemoglobin level detected on POD 7 was 9.5 mg/ml, but blood transfusion was only performed for three cases (5%) even with simultaneous bilateral TKA. Postoperative drain clamping combined with tranexamic acid administration contributed to substantially reduced blood transfusion rates in our TKA series. Several meta-analyses of randomized control trials have recommended use of tranexamic acid as an anti-bleeding agent, particularly by virtue of the absence of any increased risk of thromboembolic complications [21–23].

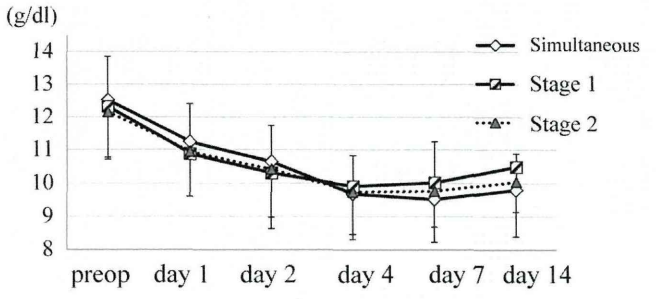

Fig. 2. Temporal changes in hemoglobin concentration up to 2 weeks after TKA. Values are given as the mean ± standard deviation.

The highest CRP level and CPK index were commonly observed on POD 2 in all three groups. These markers are known to be useful for identifying prosthetic infection and muscle damage after TKA [15], respectively, while D-dimer levels reflect fibrinolysis after hemorrhage. In this study, serum CRP level was used as an indicator for the degree of surgical damage. It is widely accepted that serum CRP level is influenced by multiple factors following TKA, such as bacterial infection, allergic reactions, heterotopic ossification and venous thromboembolism. In our TKA series, the CRP level commonly peaked on POD 2 in all three groups, and predominantly reflected acute reaction associated with surgical damage. We believe that the CRP level after POD 3 is influenced by factors other than surgical damage, whereas the CRP level on POD 2 reflects the degree of surgical damage.

The CRP level on POD 2, CPK index, and D-dimer level after simultaneous bilateral TKA potentially double due to theoretically doubled surgical trauma, and in this study, these values were indeed significantly higher with simultaneous bilateral TKA than with either stage 1 or 2 TKA. Although CRP level and CPK index declined to baseline by 2 weeks postoperatively, high levels of D-dimer remained even more than 2 weeks postoperatively, with greater levels in simultaneous bilateral TKA than in staged TKA. As D-dimer levels have been widely accepted and used as an indicator of VTE, greater thromboembolic risk should be taken into account with simultaneous bilateral TKA for more than 2 weeks postoperatively (Fig. 3A). This is corroborated by the fact that the incidence of DUS-proven DVT per knee tended to be higher in simultaneous TKA (Fig. 3B). However, expressed as the sum of incidences for stage 1 and 2 TKAs, the incidence of DVT in staged TKA greatly exceeded that of simultaneous bilateral TKA.

Numerous investigators have reported a greater perioperative risk of PE after simultaneous bilateral TKA than after unilateral TKA [4,11]. Barrett et al [9] reported that the risk of PE in the first 3 months after TKA is about 80% higher after a simultaneous procedure than after a staged procedure. Fortunately, in our study, no patients developed symptomatic PE postoperatively, although asymptomatic PE manifesting as decreased oxygen saturation was found in two cases with the simultaneous procedure and in one case each in the two-staged procedure. Asian patients are ethnically less likely to develop VTE and may securely undergo simultaneous bilateral TKA without accompanying clinically overt PE. This is potentially because of the lower frequencies of clinical prothrombotic risk factors, such as obesity, venous disease and hyperlipidemia and a paucity of susceptibility genes, such as factor V Leiden mutation and prothrombin promoter G20210A mutation [24,25].

Fat embolism characterized by pulmonary and neurological dysfunction is another complication of simultaneous bilateral TKA

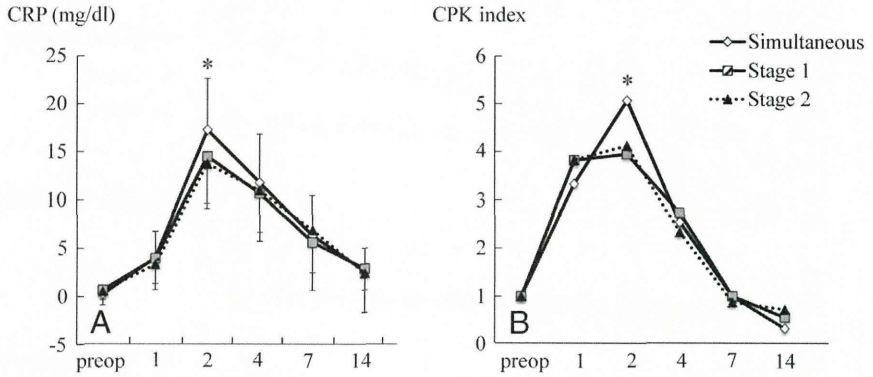

Fig. 3. Temporal changes in serum levels of CRP (mg/dl) (A) and CPK index (B) up to 2 weeks after TKA. Values are given as the mean ± standard deviation. *$P < 0.05$ simultaneous versus stage 1 or 2 TKA.

that should be brought to attention. Intra-medullary manipulation of bilateral femora and tibiae in a single operative session may induce entry of fat globules into the bloodstream, which is fundamental to the pathology of fat embolism. Clinically, higher incidence of fat embolism after simultaneous bilateral TKA compared to unilateral TKA has been reported even for Asian patients [26]. Indeed, in the present study, three patients undergoing simultaneous bilateral TKA presented with confusion, whereas one patient displayed confusion with two-staged bilateral TKA. Theoretically, computer-assisted surgery (CAS) or patient-specific instrumentation (PSI) in TKA could reduce the incidence of fat embolism due to lack of intramedullary rod insertion and subsequent elevation of intramedullary pressure. However, the impact of these intramedullary guide-independent technologies on fat embolism remains controversial. One study using trans-esophageal echocardiography revealed that CAS-TKA yielded fewer systemic emboli than conventional TKA [27], and another study suggested that CAS-TKA might be beneficial particularly in high-risk groups including patients undergoing simultaneous bilateral TKA [28]. In contrast, two independent studies have indicated that the inhibitory effects of CAS-TKA on fat embolism were insignificant [29,30]. Further research evidence is necessary to assess the potential advantages of CAS or PSI, particularly regarding the incidence of fat embolism after TKA.

Patient selection criteria remain an issue of concern for simultaneous bilateral TKA. Simultaneous bilateral TKA is reportedly associated with a 2-fold greater risk of cardiovascular complications than single unilateral TKA [4] and a 1.6-fold greater risk compared to staged bilateral TKA [7]. However, in these retrospective cohort studies, the true patient selection criteria and associated selection bias are unclear. Ritter et al [11] provided important insights into this unintentional selection bias. In their study, no indication was given as to whether the patients underwent either simultaneous or staged bilateral TKA, and no significant difference in complication rate was evident between the two types of bilateral TKA. In the present study, all patients were assessed for preoperative cardiac risk using echocardiography or cardiac catheterization. Patients undergoing percutaneous coronary intervention within 3 months were contraindicated for TKA. Actually, none of the patients primarily scheduled to undergo the simultaneous procedure were changed to a staged procedure, although three patients canceled either type of TKA based on preoperative cardiac risk assessment. The presence of cardiovascular comorbidity should be used for determining whether the patient undergoes TKA, but not for determining whether the patient undergoes simultaneous bilateral TKA or staged bilateral TKA. Shorter operative time and reduced blood loss would have substantially contributed to decreased incidence of cardiovascular complication after simultaneous bilateral TKA in this study.

Simultaneous bilateral TKA during a single session of anesthesia offers several potential advantages, including reduced duration of hospitalization, faster functional recovery, reduced cost, and lower

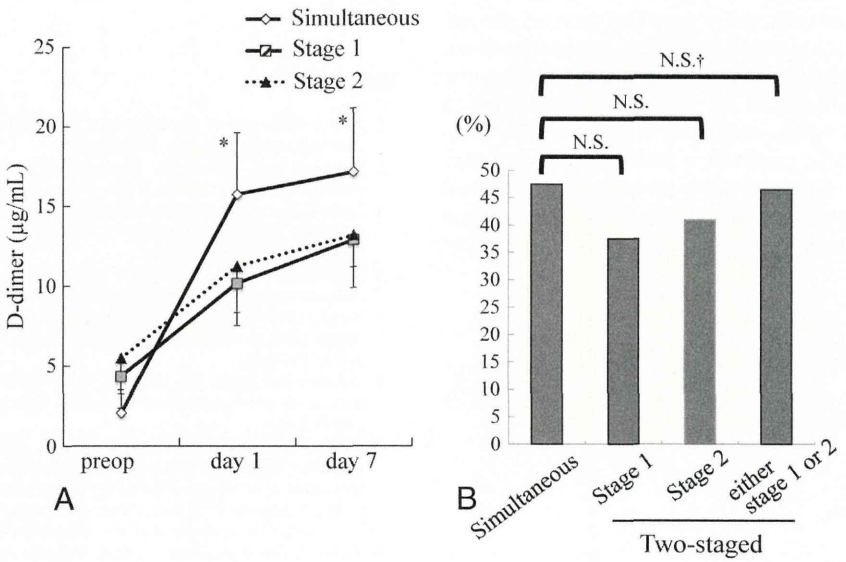

Fig. 4. Serum D-dimer levels (A) and the incidence of deep venous thrombosis (B) after TKA. The D-dimer levels are expressed as a mean ± standard deviation. *$P < 0.05$ simultaneous versus stage 1 or 2 TKA. †N.S., not significant.

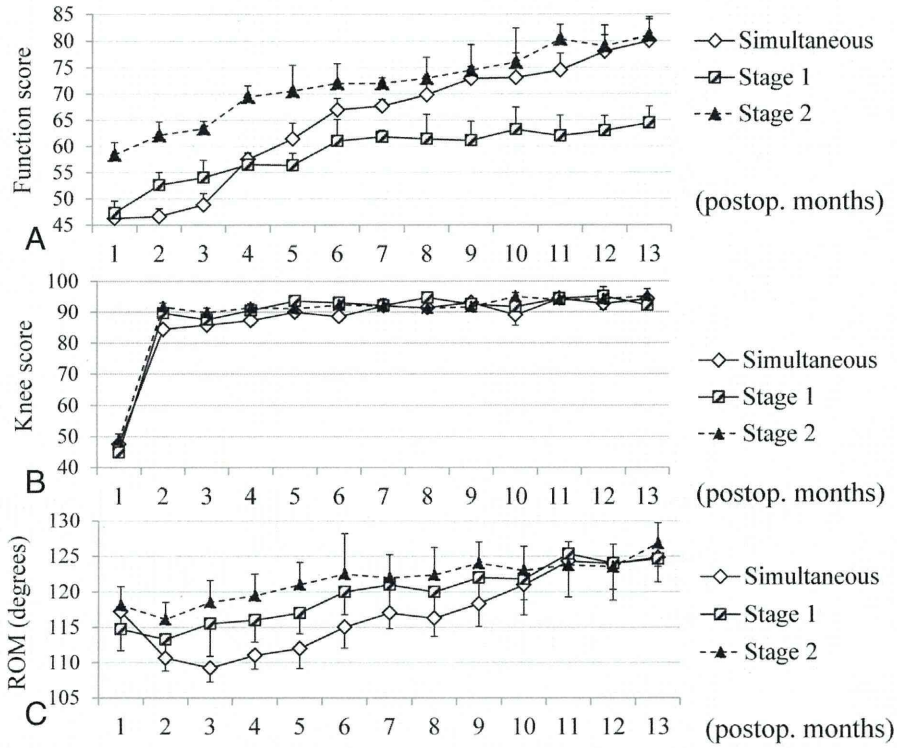

Fig. 5. Temporal changes in KSS function score (A), knee score (B), and range of motion of the knee (C) over 13 months postoperatively. Values are given as the mean ± standard deviation.

risk of infection and mechanical failure within the first year after TKA [7]. In this study, when KSS Function score of 80 was set as a target, mean recovery time to this target was 2 months shorter with stage 2 TKA than with simultaneous bilateral TKA (Fig. 4A). As the staged TKA group used a mean interval of 8 months, a total of about 6 months (8-month interval minus 2-month quicker recovery) was saved with simultaneous bilateral TKA. Past reports have advocated the cost-effectiveness of simultaneous bilateral TKA during a single anesthetic session based on a shorter hospital stay and rehabilitation time [31,32].

Finally, from the perspective of serological status for 2 weeks postoperatively, perioperative morbidity associated with simultaneous bilateral TKA does not seem to represent a critical issue of concern. We believe that a total operative time less than 60 min per knee at least contributed to the successful postoperative results in our simultaneous bilateral TKA series, since a short operative time was confirmed to exert beneficial effects on postoperative results in a recent meta-analysis [33]. Multiple benefits of a bilateral procedure, including time, cost, patient preference and satisfaction, may outweigh the possible risks of postoperative complications, if control of bleeding, anti-VTE prophylaxis, cardiac risk assessment, and shortening of operative time are properly provided. As the number of patients enrolled was relatively small, and the present study was not conducted in a randomized manner, a randomized controlled trial is warranted to clarify the superiority of simultaneous bilateral procedures over two-staged procedures. We continue to offer the option of a simultaneous bilateral procedure to patients who are sufficiently symptomatic to warrant bilateral TKA and will gain maximal benefit from symmetrical rehabilitation.

Table 3
Number of Patients With Major Postoperative Complications.

	Simultaneous	Stage 1	Stage 2
Asymptomatic PE (decreased SaO_2)	2	1	1
DVT (outpatient DVT)	0	1[a]	0
Heart failure with lung edema	1	1	0
Myocardial infarction	0	1	0
Fracture (medial femoral condyle)	0	0	1
Heterotopic ossification	1	0	0
Confusion	3	0	1
Arthrofibrosis	3	1	1

[a] Symptomatic DVT occurred at 1 month postoperatively.

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ORIGINAL ARTICLE

A 5–22-year follow-up study of stemmed alumina ceramic total elbow arthroplasties with cement fixation for patients with rheumatoid arthritis

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Abstract
Background We determined mid to long-term results of total elbow arthroplasty (TEA) by use of unlinked elbow prostheses with solid alumina ceramic trochleae, and ceramic ulnar stems (stemmed Kyocera type I; SKC-I) for patients with rheumatoid arthritis.
Patients and methods Fifty-four elbows of 39 patients were available for detailed clinical and radiographic review after a follow-up period of at least 5 years. The mean follow-up period was 12.6 years (range 5–22 years). Clinical condition before and after surgery was assessed by use of a modified version of the Mayo Elbow Performance Score (MEPS; 0–100 points) and a Japan Orthopaedic Association Elbow score (JOA score; 0–100 points). The radiographs were reviewed and loosening was defined as a progressive radiolucent line >1 mm wide that was completely circumferential around the prosthesis. Clinical records of post-operative events affecting the elbows were used for survival analysis of the prostheses using the Kaplan–Meier method.
Results The average modified MEPS and JOA scores improved significantly from 39.7 ± 14.3 to 44.7 ± 9.4, respectively, pre-operatively, to 89.7 ± 15.4 and 83.1 ± 12.8, respectively, post-operatively ($P < 0.0001$). The functional assessment score also improved from 4.9 ± 2.8 to 8.5 ± 3.3 points ($P < 0.0001$). With loosening or implant revision defined as end points, the likelihood of survival of the prosthesis for up to 20 years was 92.6 % (95 % confidence interval (CI), 85.6–100.0) or 86.3 % (95 % CI 75.0–97.6), respectively.
Conclusion Satisfactory clinical results were obtained after TEA using SKC-I prostheses, which provided excellent pain relief and functional range of motion. The results of our study reveal the high reliability over a long period of the cemented SKC-I prosthesis with an alumina ceramic component.

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Introduction

The elbow joint is affected in 25–53 % of patients with rheumatoid arthritis (RA) [1]. The mainstay of surgical treatment for RA elbows includes open or arthroscopic synovectomy for early-stage disease, and interposition and total elbow arthroplasty (TEA) for progressive and late-stage disease. TEA is primarily indicated for damaged RA elbows with painful stiffness, painful instability, and ankylosis. The clinical outcomes of TEA for the reconstruction of RA elbows were disappointing in the late 1970s, but modifications and improvements of elbow prostheses during the ensuing three decades has made TEA a reliable procedure with results that rival those of hip and

knee arthroplasties [2, 3]. The most successful prostheses identified by long-term follow-up studies have an unlinked (non-constrained) or linked (semi-constrained) design. The former includes Capitellocondylar [4], Souter–Strathclyde [5, 6], and Kudo elbows [7, 8]; the latter includes Coonrad-Morrey [9] and GSB III prostheses [10]. The unlinked design relies on the presence of sufficient bone stock to seat the prosthesis and the ligaments and capsular structures to provide stability of the elbow, whereas the linked design relies on mechanical linkage. Theoretically, the potential for instability or dislocation after a TEA is greater with the unlinked prosthesis, whereas loosening and wear are the major concerns associated with linked prostheses [2].

In 1979, on the basis of a measurement study involving Japanese cadaveric elbows, we developed an unlinked surface replacement prosthesis using polycrystalline alumina ceramic as a solid trochlea on high-density polyethylene (Kyocera type I; KC-I) and used this clinically [11]. The initial design of the KC-I prosthesis did not include the intra-medullary stem, and the results of a 3-year follow-up of prostheses implanted without bone cement in 21 RA elbows were disappointing, with loosening and subsidence of the humeral component caused by inadequate fixation [11]. In 1986, the first model change was made to an unlinked stemmed type (Stemmed Kyocera type I; SKC-I), and this was used in 15 RA elbows [15]. The initial 8 elbows were implanted without cement fixation and early tilt or subsidence of the humeral component was noted; consequently we decided to use cement fixation in all cases from late 1987, resulting in stable clinical outcomes. This retrospective case series reports mid to long-term results from cemented alumina ceramic TEA using an SKC-I prosthesis for reconstruction of RA elbows.

Patients and methods

In this retrospective study we reviewed clinical and radiographic outcomes of TEA using SKC-I unlinked elbow prostheses (Fig. 1). This study was approved by the Ethics Committee of our institute. The SKC-I prosthesis consists of a humeral component (polycrystalline alumina ceramic trochlea with a sapphire stem) and an ulnar component (high-density polyethylene; HDP) to which a plate is connected with a ceramic stem. The length of the stem was 6 cm for the humeral component and 2.5 cm for the ulnar component. The humeral articular surface was designed with 8° of valgus angulation and 23° of anterior flexion to the stem. The stem of the ulnar component was designed with 7° of valgus angulation to the ulnar articular surface. There was no size variation, but right and left discrimination was present. We used the SKC-I solely for RA elbows with painful flexion contracture of less than

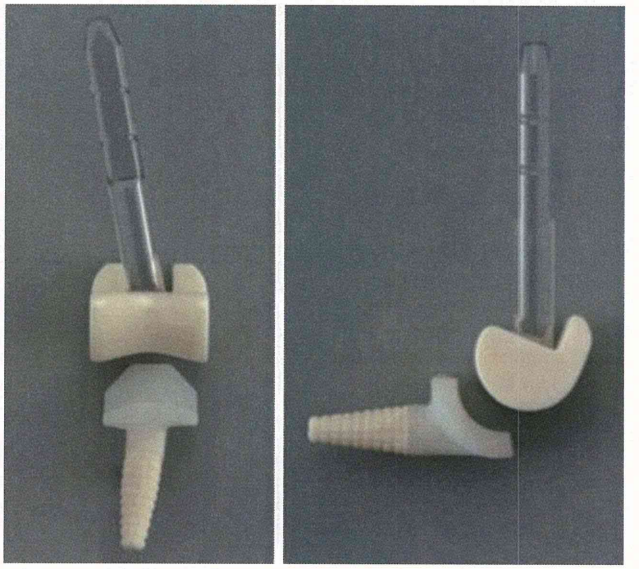

Fig. 1 Photograph of a stemmed Kyocera type I prosthesis (a prosthesis for the left elbow is shown). The humeral component consists of a solid ceramic trochlea and sapphire stem, and the ulnar component consists of a high-density polyethylene and ceramic stem. On the anterior/posterior plane, maximum curvature difference is 0.75 mm (range 0–0.75 mm) at the center of trochlea, and 1.25 mm (range 0.62–1.25 mm) at the lateral edge of trochlea. On the lateral/medial plane, maximum curvature difference is 1 mm (range 0–1 mm)

100° or painful instability causing extreme limitation of daily function. Joint destruction should be advanced beyond Larsen's grade IV [12] on radiographs. If either half of the humeral condyle or olecranon was absent with severe lateral or medial instability, a linked elbow prosthesis was indicated (Fig. 2).

We enrolled 83 patients (105 elbows) who underwent primary TEA with SKC-I prostheses using cement fixation between December 1987 and February 1999. All patients met the American Rheumatism Association 1987 revised criteria for RA. One surgeon (H.I.) implanted all of the prostheses. Fourteen patients (14 elbows) were lost to follow-up. Of the remaining 91 elbows in 69 patients, 37 elbows in 32 patients for whom follow-up was <5 years were excluded from survival analysis. Because two patients who underwent bilateral TEA were recorded in both the <5 years and the >5 years follow-up groups, data for 54 elbows in 39 patients were used for the 5-year minimum detailed clinical and radiographic reviews. All elbows were classified as Larsen's grade IV or V. Thirty-seven women and 2 men were enrolled; the patients' ages ranged from 43 to 72 years of age (average 59.0 years) at the time of surgery, with 28 right and 26 left elbow replacements. The average follow-up period was 150.6 months (range 61–269 months). Twelve patients (18 elbows) died; their pre-operative data and records at the final follow-up visit were used for analysis (Table 1). All patient data were

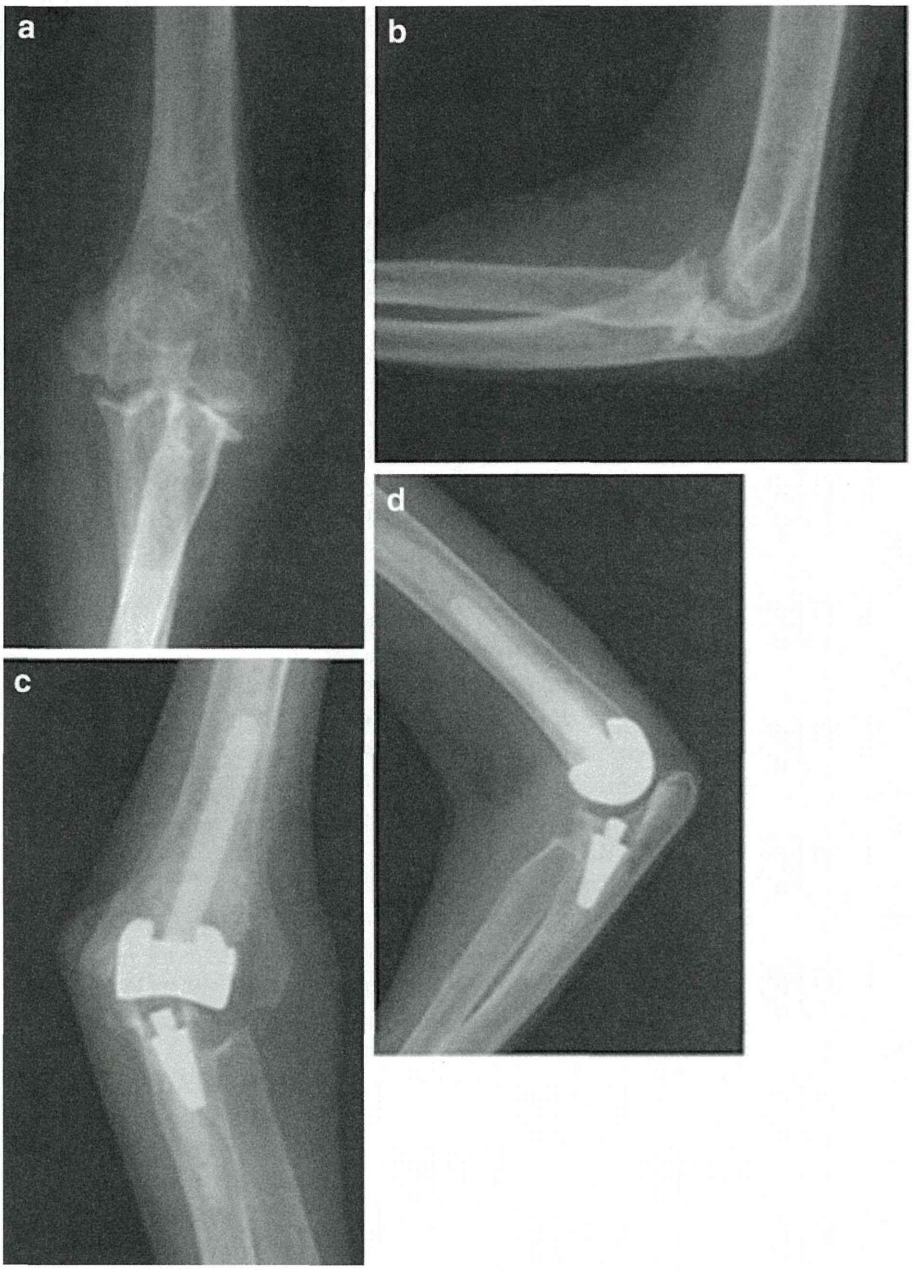

Fig. 2 Pre-operative anteroposterior (**a**) and lateral (**b**) radiographs of the left elbow of a 56-year-old woman (patient no. 9) who had rheumatoid arthritis, with Larsen's grade IV joint destruction. Anteroposterior (**c**) and lateral radiographs (**d**) of the left elbow 268 months after surgery using a stemmed Kyocera type I prosthesis with cement fixation. The Darrach procedure was added simultaneously to the left distal radio-ulnar joint

Table 1 Features of 54 elbows

Number of elbows (patients)	54 (39)
Age at time of surgery (years)	59.0 ± 8.7 (43–72)
Gender (female/male)	37/2
Side (right/left)	28/26
Follow-up period (months)	150.6 ± 59.4 (61–269)
Number of patient deaths during follow-up	12 (18 elbows)

originally recorded using the Japan Orthopaedic Association (JOA) elbow evaluation score [13], and it was difficult to convert our patients' records to the Mayo Elbow Performance Score (MEPS) [9]. Therefore, the clinical condition of each elbow before and after surgery was also assessed according to the modified MEPS for pain (0–60 points), range of motion (ROM; 0–30 points), and stability of the joint (0–10 points) [14]. On the basis of this system, the results were defined as good (75–100), fair (50–74), and poor (<50). Functional impairment was assessed separately using the JOA elbow evaluation score; activities assessed comprised washing the face, eating, fastening buttons (underwear), pouring a glass of water, self-hygiene, and putting on and taking off socks. Each activity was worth a potential 2 points (2: easy, 1: difficult, and 0: unable) giving a total of 12 points. The anteroposterior and lateral radiographs were reviewed carefully, and evaluated for the

position of the implant, the cement mantle, radiolucent lines, bone resorption, and osteolysis. Loosening was defined as a progressive radiolucent line >1 mm that was completely circumferential around the prosthesis [5].

Surgical procedure

The patient was placed in the full lateral position with the upper arm horizontal and the forearm hanging vertically. A posterolateral [15] or posterior surgical approach [16] was used. The ulnar nerve was identified and meticulous dissection was carried out proximally and distally to the first motor branch of the flexor carpi ulnaris. The posterior aponeurosis of the triceps tendon was reflected distally, and the deep part of the triceps was divided along the reflection of the musculotendinous expansion from the olecranon. After resection of the radial head, the elbow joint was further flexed and a synovectomy was performed. Resection of the tip of the olecranon gave broader access to the joint. The humeral end was trimmed and intramedullary reaming was performed along the central guide pin. The guide instrument was set and a square bone cut was made to remove the damaged trochlea. The joint was then dislocated without sacrificing the medial collateral ligament (MCL). If the bony spur expanding along the MCL disturbed the dislocation, the bony spur was resected piece-by-piece from the inside of the joint. After the ulnar surface had been cut away with a bone saw, thus making the thickness of the remaining olecranon approximately 10 mm, reaming was performed with a reamer, and a circular rasp was used to create a circular bed for the ulnar component. The humeral and ulnar trial prostheses were positioned to check the stability and mobility of the joint. After irrigation, the humeral and ulnar components were fixed with bone cement. Before closing the wound, the triceps tendon was firmly sutured to the olecranon by use of two drill holes at the olecranon. An ulnar nerve translocation was typically not needed.

Post-operative care

A splint was applied with the elbow at 90° of flexion; this remained in place until post-operative day 14. Passive range of motion (ROM) exercise was started around post-operative day 7, followed by active ROM exercise after post-operative day 14. By post-operative day 21–28, the active range of motion was expected to improve from 30°–125° in extension and flexion. A full range of daily activities was permitted after 6 weeks [17].

Statistical analysis

All continuous measurements are given as mean ± SD. Statistical analysis was performed by one-way analysis of variance. Survival of the prosthesis was analyzed by the Kaplan–Meier method with loosening, and revision with removal of the prosthesis with or without reinsertion of a new implant defined as the end point. All analysis was conducted by use of Prism software (version 5.0a; GraphPad Software, San Diego, CA, USA) with a $P < 0.05$ regarded as significant.

Results

Clinical assessment (Supplemental table)

Pain scores and range of motion (ROM) were markedly improved by surgery. Resection of distal ulnar end (Darrach procedure) was combined in 8 elbows (nos. 8, 11, 13, 19, 39, 44, 45, 46) to improve pain at the distal radio-ulnar joint, and forearm rotation. The average post-operative modified MEPS and JOA scores both improved significantly from 39.7 ± 14.3 and 44.7 ± 9.4, respectively, pre-operatively, to 89.7 ± 15.4 and 83.1 ± 12.8, respectively, post-operatively ($P < 0.0001$; Tables 2, 3). Functional assessment by use of the JOA score revealed significant improvement from 4.9 ± 2.8 pre-operatively to 8.5 ± 3.3 points post-operatively ($P < 0.0001$; Table 4). No clinical data were available for one patient who had suffered a humeral fracture (elbow no. 40) at final follow-up; this was, therefore, rated as a poor result. Of the 54 elbows, 2 were judged to be good, 20 were fair, and 32 were poor before surgery. At the final follow-up visit, 46 elbows were judged to be good, 5 were fair, and 3 were poor (Table 2).

Complications (Table 5)

Sixteen of 54 elbows had minor to major complications, so the incidence of complications was 29.6 %. One patient had persistent post-operative paresthesia in the distribution of the ulnar nerve (elbow no. 14). Intra-operative fractures of the humerus occurred in 2 elbows in 2 patients (elbow nos. 17, 53). A humeral epicondylar fracture (elbow no. 17) was treated by simultaneous Kirschner wire fixation. A fissure fracture occurred at the humeral shaft of elbow no. 53, but the bone fragment was stable after cement fixation of the humeral component and did not require internal fixation. In both elbows, bone union was seen within 3 months after surgery.

Post-operative fractures occurred as a result of trauma for 6 elbows of 6 patients (elbow nos. 2, 3, 4, 26, 40, 53). Four fractures occurred at the ulna and two at the humerus. For one elbow with an olecranon fracture resulting from a fall (elbow no. 2), the ulnar component was lost from the joint. Because the pain at the elbow joint was mild and the patient did not want re-implantation of the prosthesis, the

Table 2 Pre and post-operative clinical assessment by use of the modified version of the Mayo Elbow Performance Score

Criteria	Score (points)	Pre-operative	Post-operative
Pain (max., 60 points)		Number of elbows (%)	
None	60	1 (2)	42 (79)
Mild to occasional, no medication	40	2 (4)	8 (15)
Moderate to occasional, activity limited, medication	20	26 (48)	2 (4)
Severe to incapacitating	0	25 (46)	1 (2)
Motion (max., 30 points)		Number of elbows (%)	
Arc of extension/flexion			
>90	30	30 (56)	48 (91)
60–89	20	14 (26)	5 (9)
30–59	10	7 (13)	0
<30	0	3 (6)	0
Stability (max., 10 points)		Number of elbows (%)	
Effect on function of the elbow			
None or mild (does not limit activity)	10	11 (20)	26 (49)
Moderate (impairs certain functions)	5	25 (46)	15 (28)
Severe (markedly limits activity)	0	18 (33)	12 (23)
Total score (max., 100 points)		39.7	89.7
Overall results (good/fair/poor)		2/20/32	46/5/3

Post-operative clinical data were not available for elbow no. 40 because of humeral fracture

Table 3 Pre and post-operative clinical assessment by use of the Japanese Orthopaedic Association (JOA) Elbow score

Criteria	Pre-operative	Post-operative
Pain (max., 30 points)	8.8	27.8
Function (max., 20 points)	10.0	15.8
Range of motion (max., 30 points)	15.8	25.4
Flexion (°)	118.5	141.6
Extension (°)	−35.6	−18.4
Arc of flexion/extension (°)	82.9	123.2
Pronation (°)	49.6	78.8
Supination (°)	55.6	84.4
Arc of forearm rotation (°)	105.2	163.2
Instability (max., 10 points)	4.4	6.3
Deformity (max., 10 points)	5.8	7.8
Total JOA score (max., 100 points)	44.7	83.1

ulnar component was simply removed, with the cement fragments. This resulted in a fair result at the elbow joint with gross instability that required orthosis. Open reduction and internal fixation was performed for two elbows, one

Table 4 Pre and post-operative function of the elbow

Function (points)	Pre-operative ($n = 44$)		Post-operative ($n = 51$)		*P* value
	Average	SD	Average	SD	
Washing face (2)	0.7	0.7	1.7	0.7	<0.0001
Eating (2)	0.9	0.6	1.8	0.5	<0.0001
Fastening buttons (underwear) (2)	0.8	0.6	1.4	0.8	<0.0001
Pouring a glass of water (2)	1.0	0.6	1.5	0.8	<0.0001
Self-hygiene care (2)	0.8	0.7	1.4	0.8	0.0003
Putting on and taking off socks(2)	0.8	0.6	0.9	0.8	0.28
Total (12)	4.9	2.8	8.5	3.3	<0.0001

Each function was evaluated and rated as: easy; 2 points, difficult; 1 point, and unable; 0 points, according to the Japanese Orthopaedic Association (JOA) Elbow score. Data were obtained from the records of 44 patients pre-operatively and 51 patients post-operatively

SD standard deviation

P value <0.05 was regarded as significant

Table 5 Complications recorded for 54 elbows

Complications (number of elbows)	Elbow no. in supplemental table
Ulnar neuropathy(1)	14
Intra-op. fracture (2)	17, 53
Post-op. fracture (6)	2, 3, 4, 26, 40, 53
Post-op. implant fracture (1)	11
Dislocation or subdislocation (6)	9,18, 27, 35, 40, 52
Infection (1)	52
Aseptic loosening (4)	12, 19, 40, 53
Revision surgery (3)	3,11, 53
Implant removal (2)	2, 52

with an olecranon fracture (elbow no. 3) and another with a bi-condylar humeral fracture after loosening (elbow no. 53); both were treated by implant re-implantation with cement fixation. The remaining 3 elbows were treated conservatively. As a result, the outcomes were rated good in 3 cases, fair in one, and poor in 2 at final follow-up.

In this case series, 6 dislocations were noted among 6 patients (elbow nos. 9, 18, 27, 35, 40, 52). Three elbows had severe pre-operative joint destruction rated as Larsen's grade V (elbow nos. 18, 27, 52), one elbow was dislocated with humeral fracture (elbow no. 40), and the causes of dislocation of the remaining two elbows (elbow nos. 9, 35) were unknown. The time of dislocation varied among 4 elbows (1 month, 11 months, 6 years, and 6 years), and was not clear for 2 elbows. MCL repair was performed for 2 elbows (elbow nos. 9, 18), but the remaining 4 patients

declined the surgery, and were treated conservatively by orthosis. Of these 4 elbows, deep infection was noted for one elbow of one patient (elbow no. 52) 95 months after surgery, caused by repeated aspiration of synovial fluid for sub-cutaneal bursitis involving the lateral epicondyle of the humerus after dislocation. Both humeral and ulnar implants were removed and replaced by antibiotic-containing cement beads but theinfection could not be controlled. Finally, the elbow was treated by intensive debridement and continuous irrigation. This floppy elbow was then further treated by orthosis but the clinical result was poor.

Radiographic loosening occurred for 4 elbows in 4 patients. One patient (elbow no. 40) had been lost to follow-up until 254 months post-TEA, when she visited her local hospital with humeral fracture, massive loosening around the humeral component, and joint dislocation, and was treated conservatively. For the other 2 elbows (elbow nos 12, 19), a radiolucent line was visible around the ulnar stem but the loosening did not cause elbow joint instability during the follow-up period.

Revision surgery was performed for 3 patients (3 elbows) because of humeral fracture of one elbow (elbow no. 53) and ulnar fracture of one elbow (elbow no. 3) as described above, and ulnar component fracture of one elbow (elbow no. 11). The ulnar component fracture of elbow no. 11 was observed at the screw hole connecting the high-density polyethylene and the ceramic stem, and the elbow was treated by removal of the broken ulnar component, and re-implantation of a new ulnar component with cement fixation.

Of the 37 elbows in 32 patients with <5-years of follow-up, 1 peri-operative humeral fracture was recorded for 1 elbow, and post-operative fractures were recorded for 2 elbows. An implant fracture at the polyethylene–ceramic stem interface of the ulnar component was recorded for one elbow and required revision surgery. Aseptic loosening was noted for four elbows in 3 patients.

Survival analysis

Survival of implants was analyzed by the Kaplan–Meier method. Using loosening as end point, survival of prostheses used for 54 elbows was 92.6 % (95 % confidence interval (CI) 85.6–100.0) for up to 20 years. The first occurrence of loosening was observed at 0.8 years. For loosening as end point, survival did not decrease after reaching 92.6 % at 3.1 years (Fig. 3). However, the late report of loosening at 254 months (elbow no. 40) reduced survival to 61.7 %.

Using implant revision with removal as the definition of end point, survival of prostheses in 54 elbows was 86.3 % (95 % CI 75.0–97.6) for up to 20 years. The first occurrence of implant revision was observed at 7.9 years. For implant revision as end point, survival did not decrease after reaching 86.3 % at 12.3 years (Fig. 4).

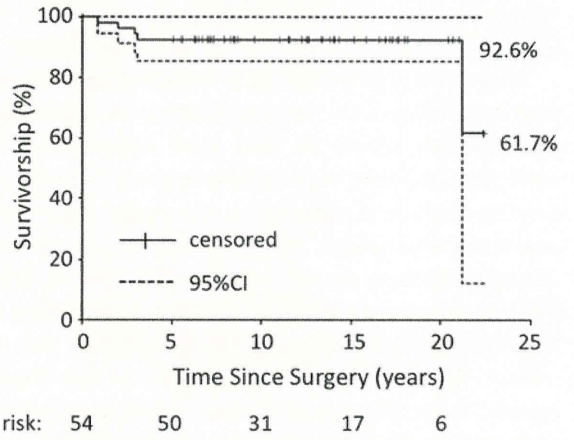

Fig. 3 Kaplan–Meier survival curve for loosening as the endpoint for 54 stemmed Kyocera type I prostheses. The *broken lines* indicate 95 % confidence intervals

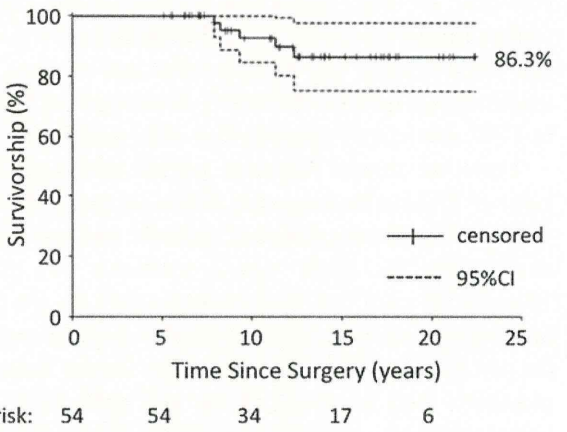

Fig. 4 Kaplan–Meier survival curve for revision with removal of the implant with or without re-insertion of a new implant as the endpoint for 54 stemmed Kyocera type I prostheses. The *broken lines* indicate 95 % confidence intervals

Discussion

Clinical outcomes of pharmaceutical treatment for RA have changed dramatically over the past decade, with new treatment strategies and the introduction of biologic agents [18]. Even for patients with long-standing disease, synovial inflammation has been reduced, and soft tissue disorganization has been much improved among patients who have a good response to treatment. Destructive bone resorption that was seen in the natural course of the disease has been replaced by osteoarthritis-like joint damage among some of the patient population after effective treatment with methotrexate and biological agents [19]. In this regard, a TEA with anatomic design might be indicated more widely than ever before, and preservation of the remaining soft tissue structure would be realistic for longer survival of the implant among younger patients. In this retrospective case series we report, for the first time, mid to long-term follow-