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ORIGINAL STUDY

Results with Kudo elbow prostheses in non-traumatic indications : A study of 36 cases

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With a mean follow-up of 62 months, we reviewed 13 Kudo type 4 and 23 Kudo type 5 elbow prostheses implanted for non-traumatic indications in 30 patients. Clinical results were assessed with the Mayo Clinic Performance Index (MCPI) taking into account pain, mobility, stability and daily activities. Postoperatively, pain disappeared or decreased, ulnar nerve dysfunction was improved and the functional status was significantly improved. The average range of motion increased by 7.8° in extension and by 11.5° in flexion ; pronation and supination remained unchanged. Clinically, 89% of patients scored poorly on the MCPI preoperatively, whereas 61% had excellent or good scores postoperatively. Twenty-two patients out of 30 were satisfied. There were two early prosthetic dislocations, and prosthetic instability, assessed clinically, was found in 6 cases (17%). The rate of loosening was 28% (10/36) and seven elbows were revised. Metallosis, loosening and instability were significantly correlated. The survival rate of 82% at 54 months (SD = 7) is lower than that reported for non-constrained and semi-constrained prostheses in the literature.

INTRODUCTION

Preservation of a functional and painless elbow is essential for patients affected by rheumatoid arthritis (RA) (*45*). RA represents the most frequent non-traumatic indication for elbow arthroplasty (*4*). Other indications include juvenile chronic arthritis, psoriatic arthritis, haemophilic arthropathy and primary elbow osteoarthritis.

Elbow prostheses are classified according to the presence or absence of an intra-articular hinge (*32*). The Kudo prosthesis is a non-constrained surface replacement with intramedullary stems (only for the last three types 3, 4 and 5). The prototype was originally developed by Kudo in 1972. A long-term study of the first-generation Kudo prostheses type 1 and 2, implanted between 1972 and 1982, without intramedullary stems, showed frequent aseptic loosening (*25*). The second-generation type 3 to 5 Kudo prostheses were provided with intramedullary stems. The type 3 Kudo prosthesis was implanted with cement from 1980 (*26*). In 1988 the Kudo type 4 in titanium alloy with porous-coated stems, was developed with the aim of cementless fixation. In 1994 marked metallosis, osteolysis and

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Fig. 1. — Kudo type 5 elbow prosthesis

fracture of the humeral component were reported with a type 4 Kudo prosthesis (*23*). The type 5 Kudo prosthesis has been in use since 1994 (*24*). The humeral component is made of cobalt-chromium alloy. Half of the surface of the intramedullary stem is porous-coated with plasma sprayed titanium alloy. The ulnar component may be all-polyethylene or metal-backed. The ulnar component remained unchanged from type 4 to type 5. Figure 1 shows the Kudo type 5 elbow prosthesis.

The aim of our study was to evaluate the clinical (pain, mobility, stability) and radiological (radiolucent lines, loosening, loss of bone, heterotopic bone formation) results of 36 Kudo types 4 and 5 elbow prostheses used in indications other than trauma, at a mean follow-up of 62 months.

MATERIALS AND METHODS

Patients

From September 1988 to March 2002, 41 Kudo prostheses were implanted in 35 patients. Among these 35 patients, one had died (the latest follow-up visit was at 29 months) and four were lost to follow-up. Thirty patients were thus included in this retrospective study. There were 23 women and 7 men, with a mean age of 57 years (range : 32 to 80). An average of 15 years (range : 2 to 44) had elapsed between the diagnosis of the disease and elbow arthroplasty. The mean follow-up was 62 months (range : 14 to 114). Of the 30 patients (29 right-handed, 1 left-handed), six (20%) underwent bilateral elbow arthroplasty ; 36 prostheses could thus be evaluated. Most of the patients (90%) were sedentary or without any occupation.

The 24 patients (80%) with rheumatoid arthritis fulfilled the diagnostic criteria of the American Rheumatism Association (*3*). Rheumatoid arthritis was medically well controlled. Elbow arthroplasty was the first operation for only 6 patients (20%). The other 18 had undergone on average two or three articular operations (from 0 to 7) : hand and wrist surgery (13 cases), total hip replacement (10 cases), forefoot surgery (8 cases), total knee replacement (6 cases), total shoulder replacement (4 cases), hindfoot surgery (2 cases) and cervical spine fusion (2 cases). Most of the patients with rheumatoid arthritis (25 patients, or 82%) were preoperatively in the functional class III of Steinbrocker (*47*) (table I). Three patients had non-RA inflammatory arthropathy (juvenile chronic arthritis in two, psoriatic arthritis in one). There were two patients with haemophilic arthropathy, and one with primary elbow osteoarthritis.

There had been no previous local treatment in 72% of the elbows, while 28% had received intra-articular steroid injections. Radioisotope synovectomy had been performed in 5 elbows. None had prior surgical synovectomy or radial head resection. There was no history of trauma in any case.

All patients were examined by the same physician (CDR) who was not directly involved in their treatment and who did not participate in the surgical procedures.

The Visual Analogue Scale (VAS scale) and Gschwend's classification (*15*) were used for comparison between preoperative and postoperative pain (table II). Pain, range of motion, elbow stability and daily function were recorded in the Mayo Clinic Performance Index (*35*) (table III). To assess elbow stability, the

Table I. — Functional classification according to Steinbrocker

Class I	No functional limitation in daily activity
Class II	Normal daily activity with some difficulty in one or more joints
Class III	Functional status limited, possible autonomy in daily activity
Class IV	Confined in the bed or armchair. A third person is necessary for daily activity

Table II. — Gschwend's classification for pain

Pain	Characteristics	Visual Analogical Scale
Severe	Incapacitating	8-10/10
Moderate	Frequent, limiting activity	5-7/10
Mild	Occasional, with intensive activity	1-4/10
None	None	0/10

Table III. — The Mayo Clinic performance index

Functions	Number of points
Pain (45 points)	
None	45 points
Mild	30 points
Moderate	15 points
Severe	0 point
Arc of motion (20 points)	
100 degrees	20 points
50-99 degrees	15 points
< 49 degrees	5 points
Stabi1ity (10 points)	
Stable	10 points
Moderate instability	5 points
Gross instability	0 point
Daily function (25 points)	
Combing hair	5 points
Feeding oneself	5 points
Hygiene	5 points
Putting on shirt	5 points
Putting on shoes	5 points
Maximum possible total	100 points

elbows were tested at 30° and 90° flexion and in maximal extension with the forearm pushed into valgus or varus. A laxity greater than 10° was defined as gross instability. To assess function, five daily activities (hair combing, feeding, hygiene, dressing, and putting on shoes) were taken into account. Ulnar nerve dysfunction was systematically looked for before and after operation. The main indications for arthroplasty were pain (30 elbows), loss of motion (5 elbows) and instability (1 elbow). Patient satisfaction was assessed at the last follow-up visit.

Surgical technique

The operation was performed under general anaesthesia with the patient in a lateral position with the arm placed on a support across the body. Under pneumatic tourniquet control, a posterior approach was used in all cases. The ulnar nerve was dissected free from its bed and was carefully retracted. The fibrous arch of the flexor carpi ulnaris was opened in all cases. A distally based triangular flap in the triceps tendon was raised down to the lateral and medial border of the olecranon. The muscular part of the triceps brachii was then split longitudinally into two halves, medial and lateral. Posterior synovectomy was performed and the elbow was then dislocated posteriorly. Anterior synovectomy followed after dislocation, to be completed after the bony preparation. Osteophytes, when present, were removed, humeral and ulnar articular surfaces were debrided and the radial head was resected. Humeral and ulnar medullary canals were opened with a power air-drill ; preparation of the articular surfaces was performed using the ancillary instruments. After placement of the trial components and reduction of the posterior dislocation, the decision whether or not to cement one or both of the components was based on the quality of fixation of the trial components. The range of mobility was checked, as was elbow stability. For cementing, a cement gun was used for the humeral cavity, whereas cement was finger-packed into the ulna. The central part of the trochlea of the humeral component was systematically filled with bone graft from the radial head, in an attempt to enhance fixation through fusion between the graft and both humeral columns. An intra-articular drain was inserted. Soft tissues were carefully reconstructed, without anterior transposition of the ulnar nerve. The stability of the elbow prosthesis was tested once more after soft tissue reconstruction. The elbow was placed in a posterior splint at 90° flexion.

Table IV. — Classification system of Larsen

Stage 0	Normal
Stage 1	Discrete modifications : Thickening of soft tissue, osteoporosis, discrete joint narrowing
Stage 2	Small resorption and joint narrowing
Stage 3	Moderate destruction with marked resorption and joint narrowing
Stage 4	Severe destruction : bone resorption et important joint line narrowing with bone deformity
Stage 5	Severe mutilans deformity with disappearance of joint space

Table V. — Classification system of Morrey and Adams

Grade 1	Osteoporosis (synovitis)
Grade 2	Joint narrowing without alteration in joint architecture
Grade 3	Alteration of architecture of the joint (thinning of the olecranon or resorption of the trochlea or capitulum)
Grade 4	Gross destruction of the joint with severe bone resorption and spontaneous fracture

During the operation, a displaced fracture of the medial humeral condyle occurred, requiring screw fixation in two cases, and a non-displaced fracture of the coronoid process, not requiring surgical repair, in two other cases.

Prostheses

Among the 36 Kudo prostheses, 23 were type 5 and 13 were type 4. Both the humeral and the ulnar components were implanted without cement in 18 elbows (50%) ; the ulnar component was implanted with cement and the humeral component without cement in 11 “hybrid” elbows (30.5%). The humeral and ulnar components were both cemented in 7 elbows (19.5%). There was no instance of a cemented humeral component associated with an uncemented ulnar component. Overall, the humeral component was implanted without cement in 29 elbows (81%) and the ulnar component in 18 (50%).

Postoperative rehabilitation

The drain was removed on the second postoperative day. The splint was kept for an average of 15+/-4 days (range : 7 to 28). Passive extension, active flexion and active pronation-supination usually started on the third day (range : 2 to 30). Patients stayed in hospital for an average of 7 days (range : 5 to 15). In most cases (27 elbows in 22 patients, or 74%), rehabilitation was performed in a specialised center for an average duration of 30 days (range : 21 to 45). Active extension was started after four weeks, when the triceps tendon was considered to be healed.

Radiographic assessment

Anterior-posterior (AP) and lateral radiographs were made before operation and at every follow-up visit. We used Larsen’s and Morrey’s classifications (*28, 34*) (tables IV and V). The status of the lateral and medial columns of the humerus and the status of the olecranon were taken into account.

The quality of cementation of each component was defined as good when the cement mantle was homogeneous and sufficient around the sides and beyond the tip of the stem, as fair when there was no cement beyond the tip of the stem or when the cement mantle around the stem was heterogeneous, and as poor when the cement did not reach the tip of the stem or when the cement mantle around the stem was deficient.

The orientation of the humeral (H) and ulnar (U) components in the coronal (C) and sagittal (S) planes (i.e. CH and SH, UC and US) was analysed. Some other radiographic parameters were recorded, such as radiolucent lines, displacement of each component and osteolysis. The status of the bone-cement and bone-metal interfaces was carefully assessed by comparing the annual radiographic films, allowing to define the thickness (< 1 mm, between 1 and 2 mm, > 2 mm), the extent (“partial” < 50% or > 50%, “complete around the prosthesis”, and “loosening”) and the location of the radiolucent lines (humeral and/or ulnar). Loosening was defined as a progressive radiolucent line with a thickness of 1 mm or more, or with displacement (subsidence, shift into flexion or into varus) of one of the components.

Statistical analysis

The SPSS 9.0 software was used for the statistical analyses. For comparison of two quantitative data, the quantitative tests used were the *z-test* and *Student’s t-test*. For comparison of two qualitative data, a non-

Table VI. — Clinical results

Case	Age	Sex	Disease	Follow-up (months)	Type	Mayo Clinic preop	Mayo Clinic postop	Fracture	Metallosis	Instability preop	Instability postop	Loosening
1	56	F	RA	61	5	35	75					
2	51	M	RA	97	4	32.5	37.5				+	
3	44	F	Ha	85	4	50	95	+	+			
4	44	F	RA	14	5	67.5	95					
5	62	F	RA	17	5	60	95					
6	62	M	RA	18	5	45	95					
7	62	F	RA	22	5	32.5	75					
8	73	M	RA	18	5	52.5	92.5					
9	80	F	Pso	96	4	37.5	100					
10	70	F	RA	49	5	37.5	72.5			+		
11	42	M	RA	69	5	32.5	95					
12	69	F	RA	69	5	37.5	87.5					
13	56	F	RA	17	5	32.5	70					
14	74	F	RA	106	4	42.5	65	+			+	
15	48	F	RA	49	5	27.5	95					
16	54	F	RA	86	4	60	100					
17	32	F	JCA	60	5	60	60					
18	70	F	RA	35	5	27.5	92.5					
19	38	F	RA	47	5	37.5	100					
20	55	M	RA	54	5	15	67.5		+	++	+	+
21	69	F	RA	114	4	32.5	57.5					
22	54	M	RA	61	5	37.5	95					
23	71	F	RA	97	4	37.5	100					
24	63	F	RA	58	5	27.5	100					
25	64	M	RA	98	4	27.5	100					
26	53	F	RA	24	5	15	75					+
27	69	F	RA	42	5	42.5	67.5		+			+
28	57	F	RA	70	5	27.5	82.5					
29	70	F	RA	42	5	52.5	42.5					+
30	66	F	OA	66	4	37.5	57.5	+				+
31	61	F	RA	73	4	27.5	52.5	+	+			+
32	46	F	JCA	62	5	57.5	55				+	+
33	61	F	RA	114	4	37.5	85					+
34	74	F	RA	53	5	37.5	42.5				+	+
35	35	M	RA	85	4	40	27.5		+		++	+
36	60	F	Ha	108	4	52.5	90					

F : female ; M : male ; RA : rheumatoid arthritis ; OA : primitive osteoarthritis ; JCA : juvenile chronic arthritis ; Pso : psoriatic arthritis ; Ha : haemophilic arthritis.

parametric W*ilcoxon test* was used. For comparison of two percentages, a *Mac Nemar* X_2*-test* and *Fisher*'s *exact test* were used. Linear regression analysis was performed with ANOVA to compute the correlation between different parameters. The level of significance was set at $p < 0.05$. The survival rate was performed according to *Kaplan-Meier's* method.

RESULTS

Clinical assessment

Clinical assessments are presented in table VI.

Pain

Preoperatively, 24 elbows (67%) were severely painful ; only two (5%) were painless, but were unstable with clinical and electrophysiological impairment of the ulnar nerve. Postoperatively, 12 elbows (33%) had mild (3 cases) or occasional (9 cases) pain and 21 (58%) were painless. Postoperative pain was severe in three elbows (8%) ; these elbows exhibited radiographic signs of loosening.

Preoperatively, the average pain score was 7.2 (SD = 2.6, range 0 to 8) on the visual analogic scale from 0 to 10. Postoperatively, the average pain score was 2.1 (SD = 2.9, range 0 to 10). Pain decreased on average 5.1 points on the visual analogic scale ; the difference was highly significant ($p < 0.001$).

Function

Preoperatively, 4 patients (13%) were in Steinbrocker‘s class II, 25 in class III and one in class IV. Postoperatively, 22 patients (73%) were in Steinbrocker‘s class II. All the patients who were in class II preoperatively remained in class II postoperatively. Of the 25 patients who were in class III preoperatively, 18 (72%) were in class II postoperatively. The improvement of the functional status after surgery was highly significant ($p < 0.001$).

With regard to daily function of the upper limb, the average preoperative score was 8.2 points (SD = 5.1), versus 18.4 after operation (SD = 6.5). Overall daily function was improved on average by 10 points. The improvement in all the five daily functions tested was highly significant ($p < 0.001$).

Range of motion

Preoperatively, two elbows (6%) had a range of motion above 100°, 7 (19%) had a range of motion below 50°, and 27 (75%) between 50° and 99°. Postoperatively, 12 elbows (33%) had a range of motion above 100°, 3 (8%) below 50°, and 21 elbows (58%) between 50° and 99°. Postoperatively, two patients were not satisfied because of a severe flexion contracture. In the first case, the patient suffered from primary elbow osteoarthritis and his range of motion was 80° preoperatively (120°/-40°), whereas postoperatively it was only 10° (100°/-90°) ; subsequent elbow arthrolysis was unsuccessful. In the second case, the patient suffered from juvenile chronic arthritis and the preoperative range of motion was 0° (90°/-90°) because of bony ankylosis of both elbows. Postoperatively, the range of motion of the elbow was 15° (80°/-65°). A marked flexion contracture was noted in a third elbow (reflex sympathetic dystrophy) with a postoperative range of motion of 45° (110°/-65°), versus 90° preoperatively (130°/-40°).

The average angle of extension before operation was -46.6° (SD = 17.8), versus -38.8° (SD = 12.5) postoperatively. The difference (+7.8°) was significant ($p < 0.05$). Full extension was achieved in no instance postoperatively. The smallest flexion deformity was -20°.

In contrast to this modest improvement regarding extension, flexion improved markedly, from an average of 111.2° (SD = 13.4) preoperatively to an average of 122.7° (SD = 14.5) postoperatively. This increase (+11.5°) was highly significant ($p < 0.001$).

Rotation of the forearm was not significantly altered after elbow surgery. The average angle of pronation was 77.3° (SD = 20.2) preoperatively compared with 78.4° (SD = 18.5) postoperatively. The average angle of supination was 76.3° (SD = 19.8) preoperatively compared with 78.9° (SD = 18.9) postoperatively (table VII).

Function

Preoperatively, 32 elbows (89%) had been rated as poor in the total score of the Mayo Clinic Performance index (< 60 points) ; postoperatively, 16 elbows (44%) were rated as excellent (> 90 points), 6 (17%) as good (from 75 to 89 points) and 6 (17%) as fair (from 60 to 74 points). Postoperative performance was poor in 8 elbows (22%) (table VIII).

Instability

Preoperatively, no instability was noted in 34 elbows (94%). Only one elbow had gross instability (3%) and one had moderate instability (3%). Postoperatively, 30 elbows were stable (83%), one

Table VII. — Comparison between preoperative mobility and mobility at final follow-up

Preoperative motion *Postoperative motion* Gain	Average (SD)	Min. and Max.
Flexion +11.5°	111.2° (13.4) *122.7°* (*14.5*)	65° / 130° *80° / 150°*
Extension +7.8°	-46.6° (17.8) *-38.8°* (*12.5*)	-95° / -30° *-80° / -20°*
Range in flexion-extension +19.2°	64.4° (25.6) *83.6°* (*23.3*)	0° / 100° *15° / 120°*
Pronation +1.1°	77.3° (20.2) *78.4°* (*18.5*)	20° / 90° *20° / 90°*
Supination +2.6°	76.3° (19.8) *78.9°* (*18.9*)	20° / 90° *20° / 90°*

Table VIII. — Comparison between preoperative and postoperative Mayo Clinic Performance index

Functions	Preop	Latest follow-up visit
Pain		
None (45 points)	2 (5%)	21 (59%)
Mild (30 points)	4 (11%)	9 (25%)
Moderate (15 points)	6 (17%)	3 (8%)
Severe (0 point)	24 (67%)	3 (8%)
Arc of motion		
100 degrees (20 points)	2 (6%)	12 (33%)
50-99 degrees (15 points)	27 (75%)	21 (59%)
< 49 degrees (5 points)	7 (19%)	3 (8%)
Stabi1ity		
Stable (10 points)	34 (94%)	30 (83%)
Moderate instability (5 points	1 (3%)	5 (14%)
Gross instability (0 point)	1 (3%)	1 (3%)
Daily function		
0 point	5 (14%)	1 (3%)
2.5 points	6 (17%)	1 (3%)
5 points	1 (3%)	0
7.5 points	5 (14%)	0
10 points	1 (3%)	1 (3%)
12.5 points	16 (44%)	7 (19%)
15 points	2 (6%)	1 (3%)
17.5 points	0	6 (17%)
20 points	0	6 (17%)
22.5 points	0	0
25 points	0	16 (44%)
Total score		
Excellent (>89 points)	32 (89%)	8 (22%)
Good (75-89 points)	4 (11%)	6 (17%)
Fair (60-74 points)	0	6 (17%)
Poor (< 60 points)	0	16 (45%)

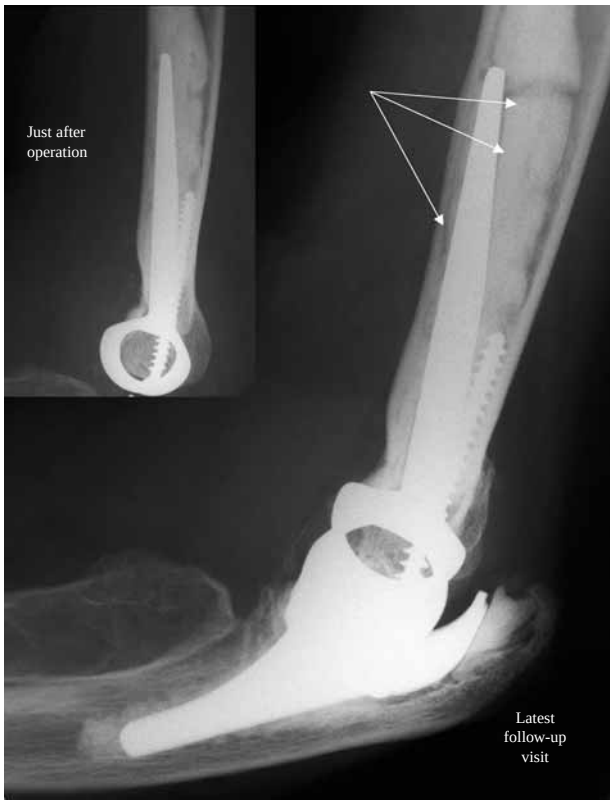


Fig. 2. — Loosening of a Kudo elbow prosthesis

exhibited gross instability (3%) and five moderate instability (14%). The rate of instability evolved from 6% preoperatively to 17% postoperatively. Postoperatively, posterior dislocation occurred in two elbows, on the first and sixth day respectively. Reduction was unsuccessful and surgical tightening of the loose fascial structures was necessary at one week in the first case, after three weeks in the second case. At the latest follow-up visit, for the first case, the elbow had no instability, whereas for the second case, the elbow exhibited gross instability associated with osteolysis of the lateral humeral condyle and metallosis requiring revison with a semiconstrained prosthesis.

Ulnar nerve

Preoperatively, 14 elbows (39%) exhibited paraesthesiae ; objective sensory or motor disturbances of the ulnar nerve were noted in no instance. Postoperatively, two elbows showed transient paraesthesiae (6%) and one elbow (3%) persistent hypoaesthesia in the area of the ulnar nerve, requiring neurolysis and anterior transposition. Of the three cases with postoperative dysfunction of the ulnar nerve, only one elbow presented paraesthesiae before and after operation. Of the 14 elbows with paraesthesiae preoperatively, 13 had no more paraesthesiae postoperatively. This decrease was significant ($p < 0.05$).

Patients' satisfaction

Postoperatively, 8 patients (27%) were not satisfied with their elbow. Three presented severe flexion contracture (juvenile chronic arthritis, primary elbow osteoarthritis, reflex sympathetic dystrophy), 3 patients had severe postoperative pain (2 with loosening and 1 with metallosis), one patient had moderate postoperative pain (1 loosening) and one patient (3%) had deep infection requiring prosthesis removal. Of the 8 patients, 4 (3 with loosening and 1 with metallosis) accepted reoperation. Overall, 22 patients (73%) were satisfied and 26 patients (87%) would undergo the operation again.

Revisions

At the latest follow-up visit, 7 elbows (19%) had been revised because of loosening of the prosthesis (fig 2). Loosening affected the humeral component in three cases, the ulnar component in three and both humeral and ulnar components in one case.

Thirteen reoperations were performed (36%). Loosening was the most frequent indication (7/13 reoperations). Others indications were early posterior dislocation in two cases, severe metallosis without loosening in one case, severe flexion contracture requiring elbow arthrolysis in one case, ulnar nerve dysfunction requiring neurolysis and anterior transposition in one case, and deep infection requiring prosthesis removal and external fixation of the elbow in one case.

One superficial wound infection did not require surgical treatment. In one case, fracture of the olecranon occurred after a fall on the elbow 6 months after revision of the ulnar component for aseptic loosening ; it healed with conservative treatment.

Radiographic assessment

Preoperative status

Preoperatively, all the elbows were Larsen 3-4-5 (17, 15 and 4 elbows, respectively) and Morrey 3-4 (26 and 10 elbows, respectively). The lateral and medial columns were preserved in most cases (23 and 30 elbows, respectively). Thinning of the olecranon was present in most cases (mild in 27 elbows and severe in 6 elbows).

Position of the prosthetic components

On the early postoperative radiographs, 28 prostheses were correctly positioned (78%), 7 prostheses showed a moderate position flaw (19%) and one prosthesis was incorrectly positioned (3%). Among 18 cemented prostheses, cementation was good in 14 (78%), fair in three (17%) and poor in one (5%). Deficient cement mantles were mostly noted around the ulnar component.

Radiolucent lines and migration

On the radiographs made at the latest follow-up visit, 29 elbows (81%) showed no radiolucent line around the humeral component and 25 elbows (69%) showed no radiolucent line around the ulnar component. Nine elbows (25%) exhibited "partial" radiolucent lines over less than 50% of the cemented area and 1 elbow (3%) a "partial" radiolucent line over more than 50%. "Partial" radiolucent lines were more frequent around the ulnar component (7/10) (fig 3). One elbow showed a "partial" radiolucent line < 50% around both the humeral and ulnar components. Three cases of radiographic loosening (8%) were noted, of which two showed a progressive 1 to 2 mm radiolucent line and one showed a progressive radiolucent line > 2 mm. Among the 36 prostheses, mobilisation of the humeral component was noted in 4 cases and of the ulnar component in one case. For the humeral component, mobilisation consisted in an anterior and lateral shift of the prosthetic stem from its original position. Displacement of the humeral component resulted in its proximal migration, with erosion of the anterior and lateral walls of the humerus.

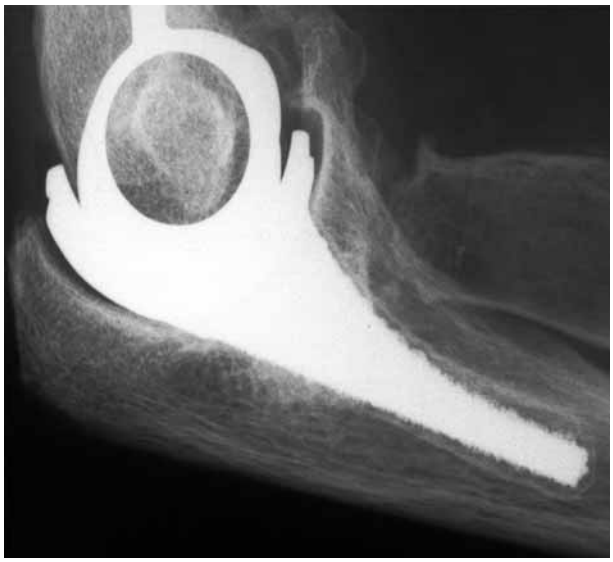


Fig. 3. — "Partial" radiolucent lines around the ulnar component.

Postoperatively, 3 elbows exhibited osteopenia (8%) and 6 had major bony erosions in the olecranon (4 cases) and the trochlea (2 cases) owing to resorption of the radial head graft. Two elbows showed severe bone loss in the lateral column of the humerus.

Heterotopic bone formation

Postoperatively, 8 elbows (22%) had heterotopic bone formation, 6 anterior (5 in front of the coronoid process and 1 in front of the trochlea), 2 posterior (olecranon) and 1 in the proximal radioulnar joint. In one elbow, heterotopic bone formation was anterior and posterior.

Broken humeral components

Of the 13 Kudo type 4 prostheses, 4 (31%) were broken (fig 4). No Kudo type 5 humeral component was broken. The type 4 was significantly correlated to humeral component fracture ($p < 0.05$). The stability and the range of motion of these elbows were not significantly modified by the fracture of the prosthesis. Fractures were localised at the junction between the trochlear portion and the humeral stem. Fractures occurred on average 6 years

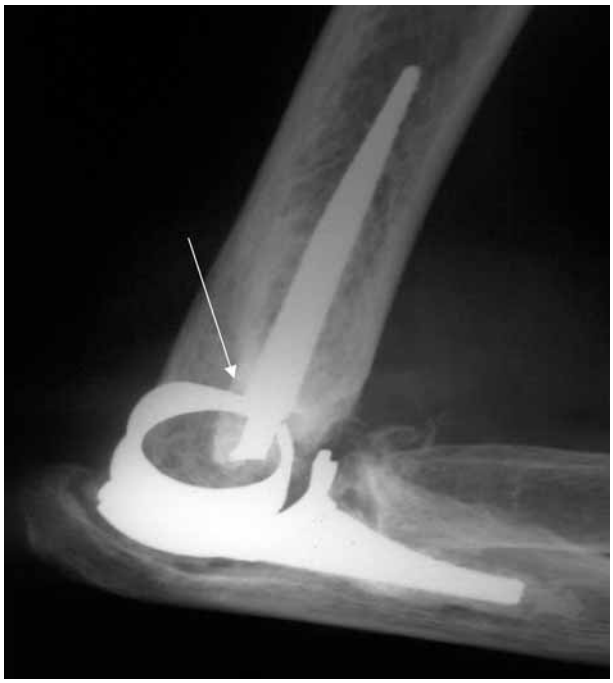


Fig. 4. — Fracture of the humeral component

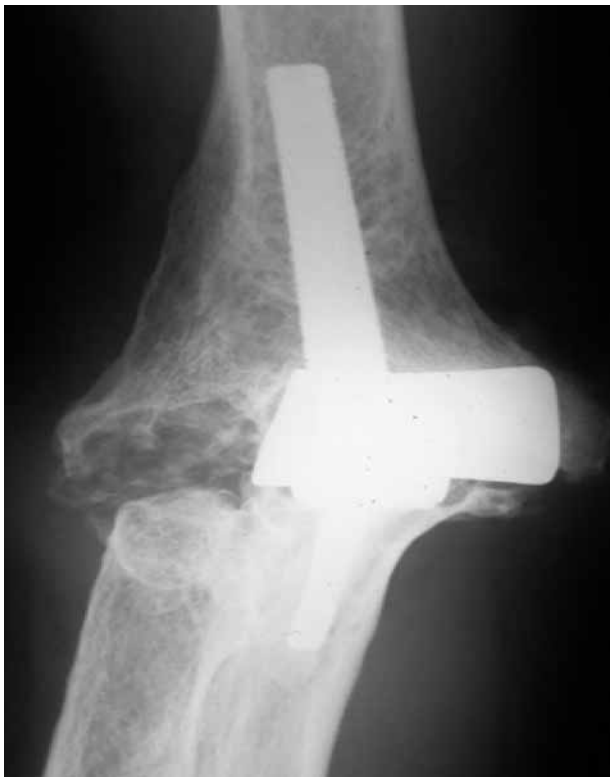


Fig. 5. — Wear debris from titanium alloy and polyethylene were responsible for massive destruction of the capitulum and the lateral column in this patient.

(range : 4 to 9) after the operation. Two humeral component fractures were associated with humeral loosening, one with ulnar loosening. The last case exhibited no loosening at follow-up. No correlation was found between fracture and loosening of the prosthesis.

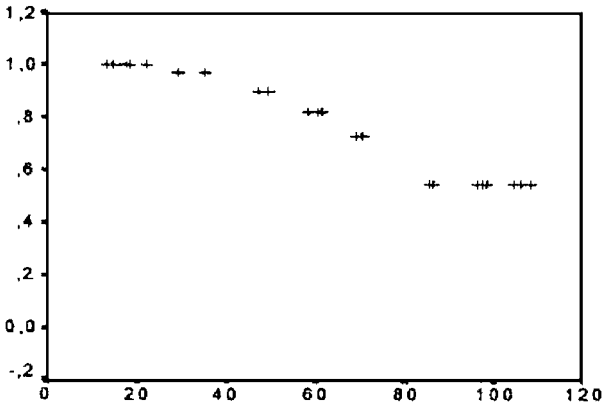
Bone resorption and osteolysis

Bone resorption or osteolysis mostly occurred inside the trochlea of the prosthesis, in the lateral and medial columns of the humerus and in the olecranon. Osteolysis was observed in 3 cases of aseptic loosening with metallosis. In one elbow, marked metallosis with severe polyethylene wear was observed, without loosening of the prosthesis. Wear debris from titanium alloy and polyethylene were responsible for massive destruction of the capitullum and lateral column (fig 5). In two revisions for aseptic loosening, we noted on microscopic examination of the triceps tendon, the presence of metal debris and a reactive proliferation of histiocytic cells. Metallosis was significantly correlated to loosening ($p < 0.01$) and instability was significantly correlated to metallosis ($p < 0.01$). We recorded 5 elbows with metallosis (4 Kudo types 4 and 1 Kudo type 5). No significant correlation was found between Kudo prosthesis type and metallosis.

Loosening and revisions

The rate of prosthetic loosening was 28% (10/36). Seven revisions have indeed been performed for prosthetic loosening and 3 more are planned. An average period of 55 months (24-85, SD = 20.9) was recorded between primary elbow prosthesis implantation and revision in the 7 cases already revised. The number of loosenings markedly increased from 3 to 6 years after operation : 6 loosenings (60%) became manifest during this period (24-114 months ; SD = 25.2).

Table IX. — Survival rate according to Kaplan-Meier



Postoperatively, moderate or severe pain was correlated with prosthesis loosening ($p < 0.01$).

Survival rate

The date of inclusion corresponded to the date of implantation of the prosthesis. The date of latest follow-up visit depended of the occurrence or not of prosthetic revision between the date of implantation and the latest follow-up visit. For the date of latest follow-up, we took into account the deceased patients and those lost to follow-up. Concerning the deceased patients, the follow-up was 29 months. For the patients with prosthetic revision, the date of latest follow-up visit corresponded to the date of prosthetic revision. The survivor rate of the Kudo prosthesis in our study was 82% (SD = 7) at 54 months (table IX).

DISCUSSION

Non-constrained prostheses

Indication

The main indication for elbow arthroplasty in our study was severe pain. The Kudo prosthesis relieved or decreased pain in the majority of the patients. Our results are in good agreement with those from other studies on the Kudo prosthesis (*6, 7, 19, 24*). In our series some patients complained of moderate or severe pain at the latest follow-up visit. Rozing (*40*) stated that postoperative pain was mainly due to loosening. In our study, 3 moderately and 3 severely painful elbows were the consequence of loosening.

Mobility

The Kudo prosthesis significantly improves the arc of motion of the elbow, particularly in flexion. Postoperatively, full extension was not achieved in any case and an average flexion deformity of -38.8° was recorded. The study of Verstreken *et al* (*50*) showed an average angle of -43.7° for postoperative extension. According to the literature, no study on Kudo prostheses reports an average postoperative angle lower than -30° in extension. Our results on postoperative range of motion are in good agreement with those of other series (*6, 7, 19, 23-25, 27, 37, 39*). In our study, the Kudo prosthesis did not significantly improve forearm rotation, contrary to the studies by Kudo *et al* (*23-26*). In our series, wrists were most often operated on before elbow surgery while Kudo usually performed wrist surgery at the same time as elbow surgery. The average gains in forearm rotation and elbow flexion–extension are not significantly different from those in the study by Chantelot *et al* (*6, 7*). We noted that the gain in motion was maintained at 5 years follow-up. For Gallagher (*13*), the gain in motion achieved with the Kudo prosthesis is maximal at 6 months postoperatively and subsequently remains unchanged. The studies of Ikävalko *et al* (*21*) and of Rozing (*40*) concerning the Souter prosthesis also show no change in the gain in motion in long-term follow-up, with similar motions recorded at 4 years and at 8 years for Ikävalko *et al* (*21*) and at 1 year, 5 years and 10 years for Rozing (*40*). According to literature, the Kudo prostheses types 2-3-4-5 do not improve the arc of motion. Our results regarding elbow mobility are similar to those reported with other non-constrained elbow prostheses (*2, 10, 13, 21, 30, 33, 36, 41, 44, 50, 51*). Consequently, the type of non-constrained prosthesis does not seem to influence the postoperative arc of motion. For Rahme (*37*), the Kudo prosthesis improves the functional status of the patients, as a result of pain relief and increased mobility.

Instability

In our study, we observed at the latest follow-up visit an increasing number of unstable elbows. In 1998, Kudo *et al* (*27*) published excellent results with 6 Kudo prostheses at an average of 4 years and 6 months follow-up (2 Kudo type 3, 1 Kudo type 4 and 3 Kudo type 5) implanted in unstable elbows with bone loss. In 1999, the study of Kudo *et al* (*24*) concerning 43 Kudo type 5 prostheses with an average of 3 years and 10 months follow-up showed mixed results. Preoperatively, four elbows showed severe instability, 30 moderate instability and 9 good stability ; postoperatively, only 11 of 32 reviewed had good stability. In our study, loosening may have increased instability of the elbow as a result of migration of the components. The study by Redfern *et al* (*39*) showed that 21% of the non-constrained prostheses revisions (22 Souter, 14 Wadsworth, 1 Cavendish, 1 Kudo, 2 Triaxial, 1 Capitellocondylar) were made necessary by instability or recurrent dislocation of the prosthesis and 73% were the consequence of loosening. According to Souter (*46*), 12.5% of revisions of a Souter prosthesis were due to prosthetic instability. Concerning the rate of prosthetic instability, comparison between our results and other series of Kudo or Capitellocondylar prostheses is difficult because most of the authors restrict elbow instability to prosthetic dislocation. Furthermore, the clinical assessment of elbow instability is sometimes difficult, as the elbow can never be tested in full extension. Verstreken *et al* (*50*) found that 12.5% of Kudo type 5 prostheses were unstable at the time of revision. In comparison with the Guepar 1 prosthesis (*2, 30*), the Kudo prosthesis seems to be responsible for a greater rate of postoperative instability. In our study, we observed two early prosthetic dislocations (6%). According to the literature (*2, 6, 7, 10, 13, 19, 21, 23, 24, 26, 27, 30, 37, 39, 42, 44, 50*), the rate of dislocation after non-constrained elbow arthroplasty ranges from 0% to 10.5%. For Meyer zu Reckendorf and Allieu (*33*), elbow dislocation is the main complication of hingeless prostheses. For Ewald *et al* (*11*), sufficient bone, integrity of ligamentous structures and appropriate operative technique are essential to achieve stability with non-constrained elbow prostheses. For Fontaine *et al* (*12*), the factors responsible for dislocation or instability of non-constrained prostheses are a poor osseous and ligamentous status and previous surgical synovectomy with resection of the radial head. For Mansat *et al* (*30*), prosthesis instability in valgus is probably the consequence of the absence of the radial head. The designers of the Guepar 1 (*1*) and 2 prostheses provided the prostheses with a radial head component (Guepar type 3) to prevent or limit prosthetic instability. For Schemitsch *et al* (*42*), the posterior surgical approach damages the capsuloligamentous complex and does not allow effective repair of the medial ligamentous structures, contrary to the lateral approach, which does not damage the medial capsuloligamentous structures. For Gallagher (*13*), the small size of the ulnar component could be responsible for prosthetic dislocation. For King *et al* (*22*), the Capitellocondylar prosthesis had an average laxity of 4.3° (+/-2.4). For Schneeberger *et al* (*43*), the Souter-Strathclyde prosthesis had an average laxity of 1.8°. For some surgeons (*13, 24*), repair of the triceps seems to give good results in cases with instability of a Kudo prosthesis. In our study, 97% of the Kudo prostheses were well implanted and only one Kudo prosthesis had an incorrect orientation. Consequently, we cannot explain the high rate of unstable Kudo prostheses by errors in positioning of the components. In our study, preoperative instability was also not correlated to postoperative instability.

Humeral component fractures

In our series, fractures of the prosthesis were noted only with the Kudo type 4. This is in accordance with the literature (*6, 7, 23*).

Loosening

In our study, loosening was the main indication for prosthesis revision. For Redfern *et al* (*39*), the main indication for revision was pain, which was mostly the consequence of aseptic loosening. Our study shows that loosening first became apparent 3 to 6 years after the operation. The average follow-up of the different studies on the Kudo prosthesis is mostly insufficient to allow disclosing clinical and

radiological signs of loosening (*6, 7, 19, 23, 24, 39*). With an average follow-up of 5 years our series allowed us to diagnose the first cases of loosening. Further cases of loosening will presumably become evident with longer follow-up. Only another series showed high rates of progressive radiolucent lines for the Kudo elbow type 3 (70% around humeral and 5% around ulnar components) with an average follow-up of 9 years and 6 months (*26*).

The high rate of loosening noted in our study explains the lower survival rate in comparison with others studies on non-constrained prostheses. In our study, postoperative instability and loosening appear to be correlated. Secondary valgus instability of the elbow may be explained by progressive weakening of the medial capsuloligamentous complex, probably as a result of their slackening in rheumatoid disease and by the absence a radial head component in the Kudo prosthesis. For some authors (*2, 9, 30*), the change in design from the Guepar 1 to the Guepar 3 prosthesis (addition of a radial head) seems to decrease the rate of loosening. This could be due to a better stability, which could prevent secondary slackening of the medial capsuloligamentous structures. While loosening of the Kudo type 3 prosthesis mostly affected the humeral component (*26*), we noted as other authors (*6, 7, 23, 24, 37*) that loosening mainly affected the ulnar component for the Kudo type 4 and 5 prostheses. Absence of any modification of the ulnar component design despite successive modifications of the humeral component design could explain the predominance of radiolucent lines around the ulnar component. Furthermore, the quality of cementation of the ulnar component is limited by the narrow ulnar cavity, by the unsuitable instrumentation to cement the ulnar component and the risk of fracture of the ulna during implantation of the prosthesis.

Semiconstrained prostheses

Instability

Disassembly of the prosthetic components is a specific complication (13.8%) of the GSB III prosthesis (*16*) encouraged initially by inadequate ligament balance and later by wear of the polyethylene ring of the humeral component and severe erosions of the humeral condyles. This complication may be responsible for dislocation or loosening of the prosthesis. Polyethylene wear, noted in 14.4% of cases, is a specific complication of the Coonrad-Morrey prosthesis (*5*). In our study, the increase in prosthetic instability postoperatively had to be balanced against the high rate of prosthetic disassembly and polyethylene wear with the semi-constrained prosthesis. Furthermore, according to Gschwend *et al* (*17, 18*), the results of a meta-analysis (828 GSB III prostheses) showed that the rate of postoperative instability with the GSB III prosthesis varies from 7 to 19% and the rate of postoperative dislocation is about 4.2%. Le Nen *et al* (*29*) reported a 6% rate of postoperative instability with the GSB III prosthesis. For Mansat *et al* (*31*), only one of 14 Coonrad-Morrey prostheses (7.1%) presented slight instability.

Loosening

The literature (*5, 8, 16, 29*) reports diverse rates of loosening, ranging from 0 to 29% for the GSB III prosthesis and from 0 to 14.2% for the Coonrad-Morrey prosthesis (*20, 31, 35, 38*). These diverging results are probably related more to the use of different definitions of loosening than to the differences in follow-up length. For Mansat *et al* (*31*), loosening is defined as the presence of a progressive circumferential radiolucent line wider than 2 mm. For Canovas *et al* (*5*), loosening is defined as a radiolucent line wider than 1 mm between bone and cement with a change in position of the prosthesis. For Rahme *et al* (*37*), loosening is limited to the cases where a radiolucent line wider than 2 mm is present around one of the prosthetic components. In our study, loosening was defined as a progressive radiolucent line of 1 mm or more or with a change in the position of the prosthesis. Consequently, our definition of loosening tends to increase the rate of loosening in comparison with that reported for semi-constrained and non-constrained prostheses.

Table Xa. — Survival rates with non-constrained elbow prostheses

Authors	Prosthesis	Survivor rates	Average follow-up
Tanaka *et al*	Kudo 3	90%	13 years
Gallagher *et al*	Kudo 5	97.6% 86.7%	5 years 10 years
Ruth *et al*	Ewald	83%	5.5 years
Ikävalko *et al*	Souter	96% 85%	5 years 10 years
Souter	Souter	84%	10 years
Trail *et al*	Souter	87%	12 years
Rozing *et al*	Souter	69%	10 years
Our study	Kudo 4 and 5	89% 77.2%	42 months 62 months

Table Xb. — Survival rates with semi-constrained elbow prostheses

Authors	Prosthesis	Survival rates	Average follow-up
Gschwend *et al*	GSB III	87.9% 87.7%	10 years 13.5 years
Gill *et al*	Coonrad-Morrey	94.4% 92.5%	5 years 10 years
Our study	Kudo 4 and 5	89% 77.2%	42 months 62 months

Survival rates

In our study, the survival rate of Kudo type 4 and 5 prostheses is lower than survival rates noted with other non-constrained (*13, 21, 40, 41, 46, 48, 49*) or semi-constrained prostheses (*14, 16*) (table Xa and b).

CONCLUSION

The findings in this study incite us to discontinue using the Kudo type 4 and 5 prosthesis and its further evolutions, such as the iBP prosthesis, whose design appears to us insufficiently modified, and to use another total elbow prosthesis. Considering the risk of secondary prosthetic instability, especially in valgus, we now intend to use a total elbow prosthesis with a radial component, such as the Guepar 3.

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