ELBOW

Results after 562 total elbow replacements: A report from the Norwegian Arthroplasty Register

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Background: The aim of this study was to give results of elbow arthroplasty for a relatively large population and compare different prosthesis brands and different patient subgroups.
Methods: Between 1994 and 2006, 562 total elbow replacement operations were reported to the Norwegian Arthroplasty Register. Revisions of prostheses were shown using Kaplan-Meier failure curves, and risk of revision was calculated using Cox regression analysis.
Results: The overall 5- and 10-year failure rates were 8% and 15%, respectively. There were only minor differences between the different implants. Patients who developed traumatic arthritis after fracture had the worst prognosis compared with inflammatory arthritis ($P = .005$). Risk of revision was also increased when the ulnar component was inserted without cement ($P = .02$.)
Conclusions: Good results in terms of prosthesis survival were obtained with total elbow arthroplasty, although results were worse than for knee- and hip arthroplasties. The best results were achieved in patients with inflammatory arthritis.
Level of evidence: Level 2; prospective cohort study.
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Keywords: Elbow arthroplasty; prosthesis survival; national arthroplasty register; inflammatory arthritis; osteoarthritis; acute elbow fracture; fixation method

The body of literature on elbow arthroplasty is increasing, but most studies include reports of a single prosthesis. No randomized study comparing different brands has, to our knowledge, been published. A systematic

review of the 8 most frequently used total elbow prostheses was published in 2004.[37] Loosening, infection, and dislocation were the most common complications after total elbow replacement (TER) but with different distribution for different prosthesis brands.

A few studies give survival results for elbow prostheses, and 10-year survival of 69% to 88% has been reported.[19,29,34,36] The functional results have been good or excellent in about 80% of patients, and better for sloppy-hinged devices than with unlinked or fixed-hinged implants.[17] The aim of the present study was to present long-term results with total elbow arthroplasty in terms of

Table I   Prosthesis brands used during the study period

				No. of hospital operations	
Prosthesis brand	TER	Prosthesis type*	Hospitals using the prosthesis, No.	≥ 10	≥ 20
Norway[†]	180	Nonconstrained	8	5	4
Kudo[†]	161	Nonconstrained	11	6	3
iBP	111	Nonconstrained	10	4	2
NES[‡]	45	Nonconstrained	5	1	1
GSB III[†]	33	Semiconstrained	2	2	1
Discovery	24	Semiconstrained	2	1	1
IBP Reconstruction	5	Semiconstrained	1	0	0
Souter-Strathclyde[†]	2	Nonconstrained	2	0	0
Coonrad-Morrey[†]	1	Semiconstrained	1	0	0
Total	562				

TER, Total elbow replacement.

 * The prostheses were either nonconstrained (unlinked) prostheses or hinged semiconstrained prostheses.

 † Described in article by Van der Lugt.

 ‡ NESimplavit Elbow System.

survival analyses in different subgroups of patients and for different prosthesis brands. Furthermore, we wanted to analyze trends in the use of elbow prostheses during a 13-year period.

Materials and methods

Data for the present study were obtained from the Norwegian Arthroplasty Register (NAR), which was established in 1987 as a hip arthroplasty register. From 1994, the register was extended to include data for replacements of other joints.[9] The NAR receives information on elbow arthroplasties from all hospitals in Norway at which the procedure is performed. Information on demographics, date of primary surgery, diagnosis, prosthesis brand, the use of thrombosis prophylaxis and antibiotics, fixation method, complications, and date and cause of revision surgery is derived from the forms filled in by the operating surgeon.[7] The completeness of the NAR was analyzed in an article by Espehaug et al.[5] They found that 87% of all primary elbow arthroplasties were reported to the NAR. Data on functional outcome are not recorded in the register and will not be considered in this article.

Nine different brands of prostheses were registered during the study period. Among these, 5 were unlinked (nonconstrained) and 4 were hinged semiconstrained (Table I). In contrast to the constrained prostheses that have fixed hinges, the hinged semiconstrained prostheses allow some degree of varus-valgus and rotational laxity. The unlinked prostheses are not hinged and generally may not be used in patients with significant bone loss due to trauma or arthritis mutilans. In these cases, the ligaments and muscles are not intact, and increased support is needed to obtain stability of the joint.

A description of designs and a picture of 5 of the prostheses (Coonrad-Morrey [Zimmer, Warsaw, IN], GSB III [Zimmer], Kudo [Biomet Ltd, South Glamorgan,UK], Norway, Souter-Strathclyde) is given in an article from 2004.[37] The GSB III is a semiconstrained cemented prosthesis with metal humeral and ulnar components, and the articular surfaces are coated with polyethylene.[8] The Kudo prosthesis is nonconstrained, with

a humeral component made of cobalt-chromium alloy, and half of the surface of the stem has a porous coat of titanium alloy.[15] The ulnar component is metal backed and may be inserted with or without cement. Only 5 patients in this study had a Kudo uncemented ulnar component. The iBP (Biomet Inc, Warsaw, IN) is a nonconstrained prosthesis with a cobalt chrome humeral component and an ulnar component of titanium alloy with an ArCom polyethylene bearing (Biomet). A linked prosthesis otherwise resembling the iBP is the iBP Reconstructive Elbow. The Discovery Elbow (Biomet Inc) is a semiconstrained prosthesis with a plasma sprayed titanium alloy humeral and ulnar component.

The *NE*Simplavit Elbow System (Implantcast, Buxtehude, Germany) is a nonconstrained joint replacement. The dimensions and design are the same as the Norway prosthesis, but the ulnar and humeral components are made of cast cobalt-chromium-molybdenum alloy instead of titanium (used for the Norway prosthesis). The bobbin articulates against a ceramic-coated axle (titanium nitride coating). The system is for cemented use only.

The fixation method was defined as either with or without the use of cement (containing antibiotics or not). In 7 cases, the fixation method (with or without cement) was not reported for one or both components.

Ninety patients had elbow replacements bilaterally during the study period. In these patients, each replacement procedure was considered a separate case. A revision was defined as the removal or exchange of a part of or the whole implant. No bushing exchange procedures were reported, but this procedure might have been registered as an exchange of part of the prosthesis. The observation time was the time from primary elbow replacement until revision or until end of study or death. The date of death was obtained from Statistics Norway (www.ssb.no/english/).

In Table II and Figure 1, rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis were grouped and categorized as inflammatory arthritis. Several causes of revision could be given in one patient (Table III). However, pain was only registered as the cause of revision in cases where this was the only recorded cause. Because no cases were revised due to implant fracture, "fracture" as the cause of revision means periprosthetic fracture (Table III).

Table II Survival analysis by Kaplan-Meier and Cox regression for revision after total elbow arthroplasty

Variable	No.*	Revisions	F_5, % (95% CI)[†]	F_{10}, % (95% CI)[†,‡]	RR (95% CI)	P
All	505	53	8 (6-11)	15 (11-20)		
Age, y						
0-59	196	25	9 (5-14)	14 (8-21)	1	
≥60	309	28	6 (3-9)	16 (9-23)	0.8 (0.46-1.4)	.42
Gender						
Women	407	40	6 (3-8)	14 (9-19)	1	
Men	98	13	15 (7-23)	20 (8-23)	1.7 (0.92-3.3)	.09
Year of surgery	…	…	…	…	0.94 (0.80-1.10)	.44
Prosthesis brand						
Kudo	156	19	6 (2-10)	15 (7-22)	1	
Norway	168	16	4 (7-10)	11 (5-17)	0.6 (0.30-1.20)	.15
iBP	107	11	12 (4-20)	…	2.6 (0.84-8.08)	.1
GSB III	30	1	3 (0-10)	…	0.55 (0.07-4.7)	.58
NES	44	6	…	…	4.7 (1.2-18.2)	.03
Diagnosis						
IA[§]	469	48	7 (5-10)	15 (10-19)	1	
OA[§]	24	2	5 (0-14)	…	0.85 (0.20-3.6)	.82
Fracture sequela	12	3	…	…	5.8 (1.7-19.7)	.005
Ulnar component						
Cemented**	478	47	7 (4-9)	14 (10-19)	1	
Uncemented	27	6	18 (2-35)	…	3.3 (1.3-8.4)	.02

CI, Confidence interval; *IA,* inflammatory arthritis; *OA,* osteoarthritis; *RR,* relative risk.

  * Only patients with one of 5 prosthesis brands and with 3 diagnoses were included in the analysis.

  † F_5 and F_{10} refer to unadjusted Kaplan-Meier 5-year and 10-year failure (revision) rates with 95% confidence intervals. No percentage was given when less than 10 patients were at risk. RR is relative risk of revision derived from the Cox model.

  ‡ In some subgroups, the observation time was less than 10 years and the 10-year failure rate could not be given.

  § Includes rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. The patients with acute fractures were excluded from the analysis.

  ** Fixation of ulnar prosthesis component. Cement with and without antibiotics were grouped.

Statistical methods

The *t* test was used to compare continuous variables (age). The significance level was set to 5% and all *P* values were 2-tailed. Median follow-up (observation) time was calculated using the reverse Kaplan-Meier method. Kaplan-Meier failure curves with revision for any reason as the end point were given for patient subgroups, and differences in revision rate between groups were tested using the log-rank test. The failure curves were discontinued when fewer than 10 patients were at risk.

Cox multiple regression analysis was used to calculate relative risk (RR) of revision according to prosthesis brand, elbow disease, the use of cement for fixation, age, gender, and year of primary operation (Table II). All RRs were adjusted for the other variables in the analysis.

The number of revisions due to specific causes such as loosening or luxation was small (Table III). Because of the small number of events, with occasional zeros, models for exact Cox regression were set up. The statistical program LogXact (Cytel Inc, Cambridge, MA) was used according to Samuelsen.[30] The models were adjusted for sex and age, prosthesis brand, shoulder disease, and the use of cement for fixation of the distal component. The results of these analyses are presented only in the text.

Poisson regression analysis was used to analyze trends in the incidence of total elbow arthroplasties. These analyses were performed based on yearly population rates for the Norwegian population obtained from Statistics Norway. The *P* values given in the text describing Figure 1, *B*, were derived from these Poisson analyses. However, the figures show absolute numbers, not incidences. All analyses, except the exact regression analyses, were performed using SPSS 13.0 software (SPSS Inc, Chicago, IL).

Results

During the period 1994 to 2006, 562 total elbow arthroplasties were performed in 452 women and 110 men. The mean age at surgery was 62 years. Nine different prosthesis brands were used during the study period (Table I). The most commonly inserted implants were Norway, Kudo, and iBP, all used in more than 100 cases. These were used in about 10 different hospitals each, some of which had a relatively large volume of operations (Table I). The unlinked prostheses, Kudo and Norway, were the most commonly used brands during the first 6 years, but from 2000, they were gradually replaced by GSB III, iBP, and *NE*Simplavit (Figure 1, *A*). No statistically significant difference was found in the age and gender distribution of the patients receiving the 5 most commonly used prostheses (Table IV; *P* = .25 for age and *P* = .13 for gender).

Rheumatoid arthritis was the most common diagnosis in patients undergoing TER and was seen in 85% (Table IV).
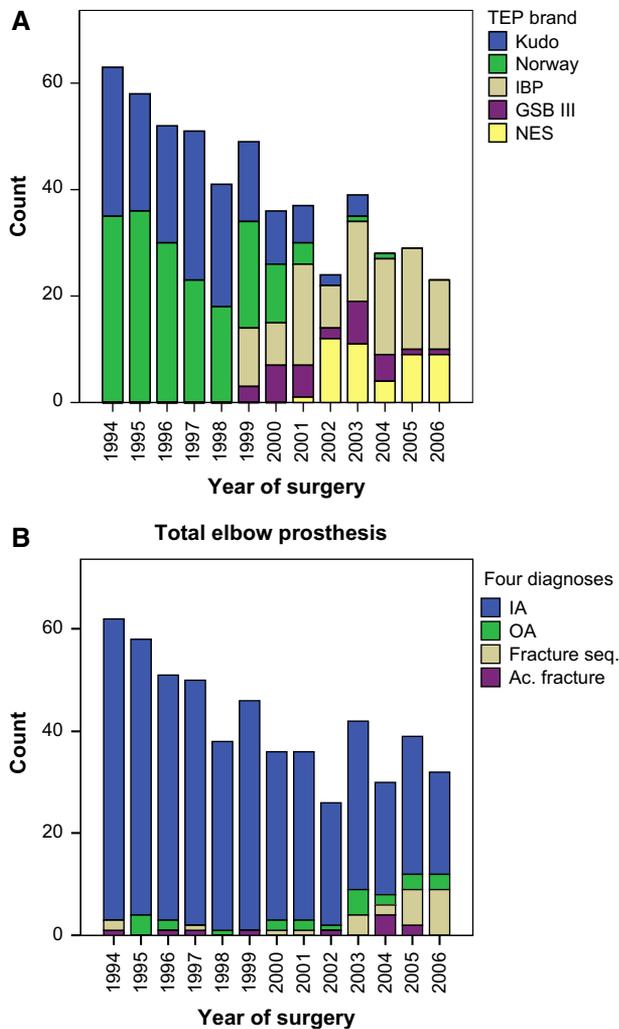
Figure 1 (**A**) Annual total elbow replacement according to prosthesis brand. (**B**) Annual total elbow replacement according to diagnosis. *IA*, Inflammatory arthritis; *OA*, osteoarthritis.

Osteoarthritis, acute fracture, and fracture sequela were other less frequent diagnoses leading to TER. From 1994 to 2006 the incidence of TER significantly decreased ($P < .001$, Figure 1, *B*). The decrease was due to a fall in the use of elbow prostheses among patients with rheumatoid arthritis ($P < .001$).

Median follow-up time was 6.2 years (95% confidence interval [CI], 5.7-6.7 years) for all patients, but varied from 2.9 years for the iBP to 8 years for the Kudo and to 8.9 years for the Norway prostheses (Table III). A total of 58 revisions were required. The major cause was aseptic loosening of the humeral or ulnar component, followed by luxation, instability, and fracture (Table III). Only 3 patients required a revision operation due to deep infection. Table III also reports major causes of revision for the most commonly used prosthesis brands.

The procedure at revision was exchange of the ulnar component in 7 cases, exchange of the humeral component in 9, and exchange of the entire prosthesis in 21. Removal

without replacement of the implant was done in 18 cases, of which the whole implant was removed in 16 and only the humeral component in 2. A new prosthesis was inserted during a later procedure in both the latter cases and in 14 of the 16 instances where the whole prosthesis was removed. This 2-stage procedure was performed in the 3 patients with deep infection as well as for some patients with fractures, luxations, or instability.

The overall 5- and 10-year failure rates for all elbow arthroplasties were 8% and 15%, respectively (Figure 2, *A* and Table II). Failure curves for the 5 most commonly used total prosthesis brands are shown in Figure 2, *B*. The 5- and 10-year survival rates were 6% and 15% for the Kudo and 4% and 11% for the Norway prosthesis. In the adjusted model, however, only the *NE*Simplavit had a significantly increased risk of revision compared with the Kudo (RR, 4.7; 95% CI, 1.2-18.2; Table II). The elbow disease influenced the risk of revision. Patients with sequela after fractures had the worst prognosis, with a RR of 5.8 compared with inflammatory arthritis (95% CI: 1.7-19.7, Table II).

Cement was used for fixation of both components of 391 total prostheses, only the ulnar component was cemented in 135, and only the humeral component was cemented in 7. In 22 cases, none of the components were fixated with cement. Failure curves according to cementation of the humeral (Figure 3, *A*) and ulnar (Figure 3, *B*) components showed that only cementation of the ulnar component influenced prosthesis survival. Although the use of cement for the humeral component did not influence survival ($P = .57$, Figure 3, *A*), cementation of the ulnar component was associated with increased prosthesis survival (Figure 3, *B*). The risk of revision without cement fixation of the ulnar component was 3 times that of patients with a cemented ulnar component (RR, 3.3; 95% CI, 1.3-8.4, Table II). Altogether, 27 patients received an uncemented ulnar component, comprising 16 iBP, 5 Kudo, 3 GSB III, 3 *NE*Simplavit, and 1 Norway.

When the risk of revision due to specific causes such as loosening of prosthesis components or luxation (Table III) was analyzed, fewer revisions were required due to fracture among patients with the GSB III prostheses compared with the other 4 most commonly used brands ($P = .03$). Otherwise, no statistically significant differences in the risk of revisions due to specific causes were found.

Discussion

The main findings of the present study were the overall 5- and 10-year failure rates of 8% and 15%, similar to those reported by Ikavalko et al,[12] who had 96% survival at 5 years and 84% at 10 years. Other studies have reported survival in the same range[34,36] or lower.[16,29] In all of these studies, the Souter-Strathclyde prosthesis was used. This prosthesis was used in only 2 patients in our study, but

Table III Causes of revision in total elbow replacement

Prosthesis	No.*	Revisions, No.[†]	Median follow-up, y	Aseptic loosening, No.		Luxation, No.	Instability, No.	Fracture, No.[‡]
				Humeral	Ulnar			
Norway	180	18	8.9	11	8	2	2	2
Kudo	161	20	8.0	4	5	4	1	5
IBP	111	11	2.9	0	2	6	5	0
NES	45	6	3.2	2	1	1	0	2
GSB III	33	1	4.0	0	0	1	0	0
Other	32	2		2	1	0	1	0
All TER[§]	562	58[§]	6.0	19	17	14	9	9

TER, Total elbow replacement.

* Total number of primary operations.

[†] Total number of revisions for any cause. Several reasons could be given for one revision (ie, loosening of both ulnar and humeral component).

[‡] Fracture is defined as a periprosthetic fracture.

[§] All TERs include all patients with all the 9 prosthesis brands. In addition to the revisions due to the given 5 causes, the following causes of revision were given: incorrect axis (4), deep infection (3), pain (3), and other (6).

Table IV Demographics and diagnosis in patients undergoing total elbow replacement according to prosthesis type

Variable	All*	Norway	Kudo	IBP	*NE*Simplavit	GSB III
Total, No.	562	180	161	111	45	33
Age, mean (SD), y	62.1 (13.5)	60.8 (13.9)	63.3 (13.0)	60.7 (13.5)	62.1 (11.8)	58.7 (11.0)
Gender (% women)	80	80	86	75	78	73
Diagnosis, No. (%)[†]						
Osteoarthritis	29 (5)	3	5	11	4	4
Rheumatoid arthritis	478 (86)	168 (93)	151 (94)	90 (81)	39 (87)	23 (70)
Acute fracture	12 (2)	2	1	0	1	2
Fracture sequela	41 (7)	4	6	6	1	4
Ankylosing spondylitis	6	0	0	4	0	1
Psoriatic arthritis	6	0	1	3	0	1
Other	16	6	3	1	1	2

SD, Standard deviation.

* All includes all patients with all prostheses. The characteristics are only given for the 5 most common prosthesis brands; consequently, the sum of these does not equal the numbers given for all prostheses.

[†] More than one diagnosis could be registered.

because the Norway, Kudo, and iBP prostheses are also nonconstrained prostheses, and because most survival data are given for the Souter-Strathclyde prosthesis, we believe our results may be comparable with these studies. An overall revision rate of 13% was given in a review article describing more than 3000 elbow arthroplasties; however, this was not related to a specific time after the primary surgery, although the mean follow-up time was 60 months.[17]

The failure rates were somewhat different for the main prosthesis brands. The *NE*Simplavit had a higher risk of revision compared with the Kudo. The failure curves might indicate better results with the GSB III, but the Cox analysis showed no difference in survival compared with the Kudo (*P* = .58, Table II). The median follow-up time varied for the different prostheses, which may have influenced the results to some degree. The *NE*Simplavit prosthesis has only been used since 2001, and the results may

have been influenced by the surgeons' limited experience with the prosthesis during the first years. There are only minor differences between the Norway and the *NE*Simplavit prosthesis, making it less likely that the inferior results are due to the *NE*Simplavit prosthesis design. We believe that more experience with the prosthesis is necessary before any conclusion about this prosthesis can be made.

Uncemented ulnar components were associated with an inferior prognosis, which might have influenced the overall results for the iBP because it was mainly this prosthesis that had uncemented ulnar components (n = 16). Although the Cox regression analysis indicated such a trend, the risk of revision was not significantly higher than for the Kudo (*P* = .10).

Early designs of implants for TER had rigid hinges, and the results were rather poor due to loosening.[3,20,28] This caused the development of unconstrained (unlinked) and
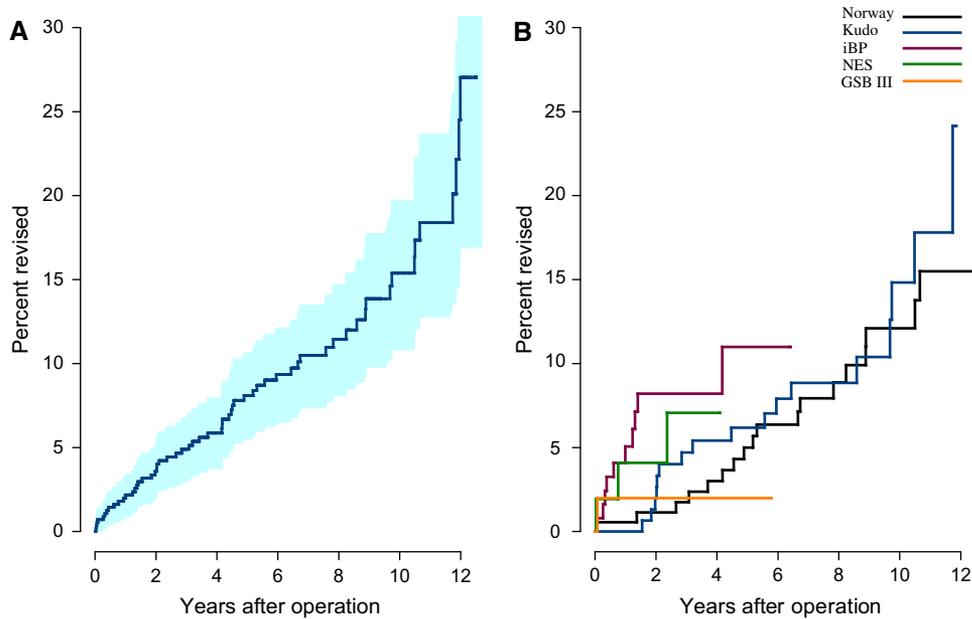
Figure 2 (**A**) Overall failure curve for total elbow replacement. The *shaded area* provides the 95% confidence interval. (**B**) Failure curves for the 5 most frequently used prostheses.
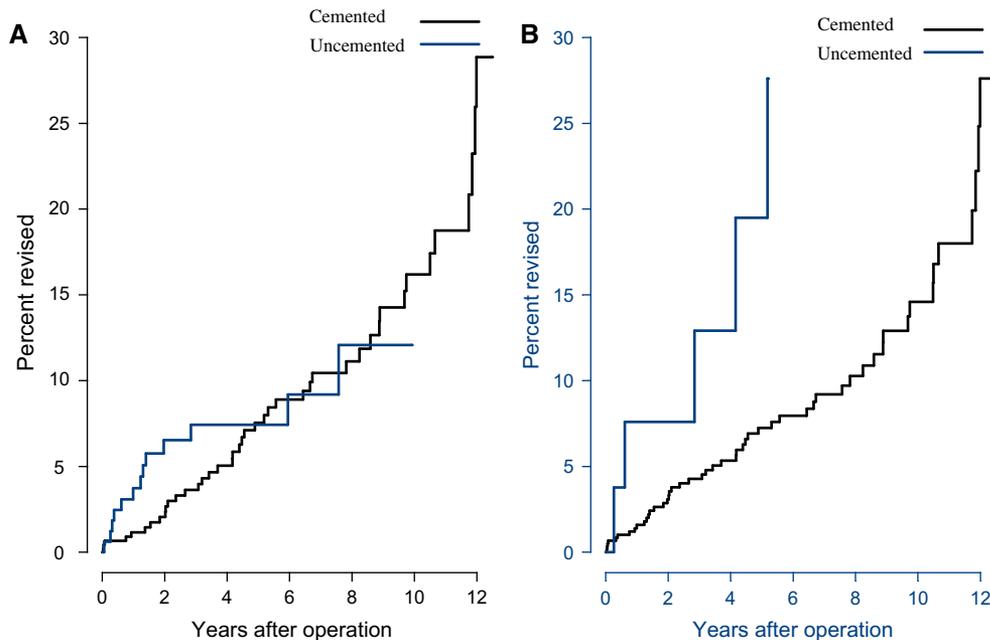

Figure 3 Revisions according to cement fixation for the (**A**) humeral component and (**B**) ulnar component.

hinged semiconstrained implant designs. Some studies of the unlinked prosthesis Souter-Strathclyde report comparable survival rates with those of the Kudo and Norway in our study.[12,34] One report on 50 Kudo prostheses showed better results than we found for the Kudo prosthesis, reporting survival of 90% at 16 years.[33]

A major cause of revision after elbow arthroplasty is aseptic loosening.[12,17,29] This was also, by far, the most common cause of revision in our study. Furthermore,

previous publications report a rather high frequency (up to 9 percent) of infections leading to revision.[12,17,29] In our study, only 3 elbows were revised due to deep infection. One reason for this may be that only deep infections leading to removal or exchange of prosthetic parts were reported to the NAR. Consequently, soft-tissue revision procedures not involving the prosthesis were not registered. The same was the case with the studies of Rozing[29] and Ikavalko et al,[12] whereas the study of Little et al[17] includes

several different studies, and the definition of deep infection was not necessarily infection leading to revision. Furthermore, there may have been revision procedures due to deep infection that were not reported to the register because 87%, not 100%, of all elbow prosthesis operations were reported to the NAR.

We found that the risk of revision was higher for patients operated on due to fracture sequela compared with those with inflammatory arthritis. Similar findings were reported in a study of 95 patients in which patients with inflammatory arthritis had the best prognosis.[14] One reason for the better results in inflammatory arthritis patients may be that they have a lower level of activity due to their generalized inflammatory joint disease, thus there is less strain on their prostheses.

In some previous studies, the ulnar component has been said to be the component most at risk of loosening,[16,25,33,35] whereas others found more loosening of the humeral component.[1,33] We found revision due to loosening of the humeral component to be equally as frequent as ulnar component loosening. In one recent study, revision occurred more often in elbows with uncemented compared with cemented ulnar components.[35] We also found that the use of uncemented ulnar components was associated with increased failure rates.

The incidence of total elbow arthroplasty decreased during the study period. We believe an improvement in the treatment for rheumatoid arthritis is the main cause of this development, because an opposite trend has been documented for knee and hip arthroplasties mainly performed in patients with osteoarthritis.[7,10,13,18,22,24,26,31] The finding is in accordance with a general trend toward less arthroplasty surgery in patients with inflammatory arthritis.[6]

Most previous studies on elbow arthroplasty only include patients with rheumatoid arthritis or inflammatory arthritis.[2,16,23,27,32,36] One study had a distribution of diagnoses resembling that of our study,[14] with about 85% inflammatory arthritis. A few articles report results on TER in patients with osteoarthritis or fracture, but the patient populations are small and survival analyses are lacking.[4,11,21] In our study, there seemed to be an increase in the insertion of TER due to diagnoses other than inflammatory arthritis. This may in time lead to increasing use of TER.

In conclusion, we found that in a national study of 562 patients, the total revision rate was 8% at 5 years and 15% at 10 years, which is an inferior result compared with hip and knee arthroplasty but in the same range as other reported elbow arthroplasty series. The diagnosis that resulted in the procedure and the fixation method of the ulnar component influenced the revision rate.

Acknowledgments

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