



ELBOW

# A survivorship study of 838 total elbow replacements: a report from the Norwegian Arthroplasty Register 1994-2016



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**Background:** The aim of this study was to present the long-term survivorship (20 years) of total elbow arthroplasty (TEA) for a relatively large population and to compare different prosthesis brands and patient subgroups.

**Methods:** Between 1994 and 2017, a total of 838 primary TEAs were reported to the Norwegian Arthroplasty Register. Implant survival was calculated using the Kaplan-Meier method. Risk differences were examined using Cox regression analyses and exact Cox regression for rare events. We compared the survivorship of the 8 most frequently used implant brands, the different diagnoses leading to TEA, and the influence of the fixation technique.

**Results:** The overall 5-, 10-, 15-, and 20-year survival rates for all elbow arthroplasties were 92%, 81%, 71%, and 61%, respectively. Risk factors for revision were a diagnosis of sequelae after trauma and cementless fixation of the ulna component.

There were some differences between the implant brands. The Norway prostheses had higher survival compared with the Kudo after 15 years of follow-up (78% and 66%, respectively;  $P < .001$ ). Among the implants with shorter follow-up, the IBP and NES had inferior survivorship compared with the Norway. The frequently used Discovery had promising survivorship up to 5 years. The most frequent reason for revision surgery was aseptic loosening, followed by defective polyethylene, infection, and dislocation. The revision causes were to some degree implant specific.

**Conclusion:** Fairly good results in terms of prosthesis survival were obtained with TEA, although results were poorer than for knee and hip arthroplasties.

**Level of evidence:** Level II; Prospective Cohort Design; Treatment Study

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**Keywords:** Elbow arthroplasty; prosthesis survival; national arthroplasty register; inflammatory arthritis; osteoarthritis; acute elbow fracture; fixation method

Most papers on total elbow arthroplasty (TEA) are reports on a single design.<sup>3,4,11,20,22,35,37,38</sup> To our knowledge, no randomized studies comparing different brands have been published. However, there are some systematic reviews and a few national register studies.<sup>24,48,49</sup> Most of the publications have a follow-up time of 10 years or less.

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**Table I** Description of the different prosthesis brands

Prosthesis brand	No.	Linked	Cemented	Period used	Hospitals	No. of hospitals ≥10 operations	No. of hospitals ≥20 operations
Discovery	190	Yes	Yes/no	2003-2016	4	3	1
Norway	179	No	Yes	1994-2004	8	5	4
Kudo	162	No	Yes/no	1994-2003	11	6	3
IBP	135	No	Yes/no	1999-2013	11	4	2
GSB III	77	Yes	Yes	1999-2015	4	3	3
NES	54	No	Yes	2001-2009	5	1	1
Nexel	16	Yes	Yes	2015-2016	2	1	0
MUTARS	8	Yes	Yes/no	2007-2015			
IBP Reconstruction	5	No	Yes	2002-2004	1	0	0
Coonrad/Morrey	5	Yes	Yes	2002-2015	1	0	0
Latitude	3	No/yes	Yes	2011-2014	1	0	0
Souter-Strathclyde	2	No	Yes	1994	2	0	0
Latitude EV	2	No/yes	Yes	2014	1	0	0
Total	838				23	13	10

Van der Lugt and Rozing described the 8 most frequently used TEAs. Loosening, infection, and dislocation were the most common complications. The distributions of the complications between the designs were different.<sup>48</sup> In a systematic review from 2011, the rate of complications after TEA was reported to range from 20% to 45% and was clearly higher than in hip and knee replacements.<sup>49</sup>

The 10-year TEA survival ranges from 69% to 88% in different papers.<sup>9,26,39,46,48,49</sup> The functional outcomes have been reported to be good or excellent in approximately 80% of the patients. Unlinked and fixed hinge designs seem to have inferior survivorship compared with sloppy-hinged (semiconstrained) TEAs.<sup>24</sup>

To our knowledge, only 3 studies have reported survivorship with 15 years of follow-up or more.<sup>17,41,45</sup> In these studies, the survival at 19-20 years was 68%-90%.

The major goal of this study was to present long-term survivorship (0-23 years) of TEA in terms of implant survival on a national level. Furthermore, we wanted to study potential risk factors for revision, such as diagnosis, fixation technique, and implant brand.

## Materials and methods

This paper is performed according to the REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) checklist<sup>2</sup> (<http://www.record-statement.org>).

Data for the study were obtained from the Norwegian Arthroplasty Register (NAR), which was established in 1987 as a hip arthroplasty register and was designed to observe the patients prospectively from the primary surgery until any subsequent revisions. From 1994, the register was extended to include all other joints (except the jaw) including the elbow.<sup>12</sup> The NAR receives information on TEAs from all hospitals in Norway that perform this procedure. Information on patient demographics, date of primary surgery, diagnosis, implant (catalogue numbers), use of thrombosis prophylaxis and antibiotics, fixation method, any perioperative complications, and date

and cause of revision surgery is derived from the forms that are filled in by the operating surgeon just after surgery.<sup>10</sup> The completeness of the NAR data was analyzed in a study by Espehaug et al.<sup>7</sup> They found that 87% of all primary TEAs were reported to the NAR for the period 1999-2002. This analysis has been repeated, and for the period 2008-2014, 94% of the primary TEAs in Norway were reported.

A description of the different prosthesis brands is found in Supplement I and Table I.

The fixation method was defined as all-cemented, uncemented, or hybrid (Table II). The bone cement contained antibiotics in 97% of the elbows. Some patients had bilateral replacements, and 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. The observation time was the time from primary TEA until revision or until the end of the study (date), the patient's emigration, or death. The date of death was obtained from Statistics Norway ([www.ssb.no/english/](http://www.ssb.no/english/)). Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, seronegative arthritis, and systemic lupus erythematosus were grouped and categorized as inflammatory arthritis. Several causes could be given for each revision; however, we made a hierarchic table in which what we believed to be the primary revision causes are listed (Table III). For instance, infection was considered the primary reason for revision when combined with other causes (eg, loosening, fracture, pain). Pain was considered the primary cause of revision only if no other causes were given. No cases were revised because of implant fracture. Comparisons between implant brands were made only for brands that had been used in >50 cases.

During the period 1994-2017, 838 primary TEAs were performed in 709 patients. There were 552 women who had a unilateral TEA, and 103 women had bilateral TEA; 157 men had a unilateral TEA, and 26 men had bilateral TEA. The mean age at surgery was 63 years.

Thirteen different prosthesis brands were used during the study period (Table I). Among these, 5 were unlinked and 8 were linked (Table I). Most of the linked prostheses in this study allow some degree of varus-valgus and rotational laxity. The MUTARS TEA, in contrast, is a fully constrained hinge that does not allow these movements. The unlinked prostheses are not hinged and generally

**Table II** Demographics and diagnosis of patients and fixation method according to prosthesis brands

Variable	All	Discovery	Norway	Kudo	IBP	GSB III	NES	Other
No.	838	190	179	162	135	77	54	41
Age (y), mean (SD)	63.0 (13.3)	64.6 (13.5)	60.7 (13.8)	63.4 (13.0)	61.4 (13.0)	64.8 (12.6)	62.3 (11.4)	67.9 (14.0)
<60 y, %	36.4	34.2	39.7	35.2	37.8	32.5	42.6	31.7
Women, %	78.2	71.6	79.9	85.8	76.3	80.5	79.6	70.7
Follow-up, median (y)	8.9	5.0	14.6	13.2	11.3	8.7	11.0	1.6
Diagnosis, No. (%)								
RA + inflammatory arthritis	659 (78)	104 (55)	167 (93)	153 (94)	116 (86)	57 (74)	47 (87)	15 (37)
Fracture sequelae	65 (8)	40 (21)	2 (1)	2 (1)	4 (3)	5 (7)	2 (4)	10 (24)
OA	44 (5)	12 (6)	3 (2)	4 (3)	11 (8)	6 (8)	4 (7)	4 (10)
Acute fracture	40 (5)	22 (12)	—	—	—	8 (10)	—	10 (24)
Other	30 (4)	12 (6)	7 (4)	3 (2)	4 (3)	1 (1)	1 (2)	2 (5)
Fixation, No.								
Cemented	641	183	175	102	19	75	52	37
Uncemented	26	3	0	5	17	0	0	1
Reverse hybrid—cemented humerus	5	1	0	1	0	0	0	3
Hybrid—cemented ulna	153	0	0	53	98	0	1	1
Unknown	13							
Revisions, No.	158	13	32	47	36	9	18	3

RA, rheumatoid arthritis; OA, osteoarthritis.

**Table III** Reasons for revisions, hierarchic

Reason for revision (hierarchic)	Frequency	%
Infection	18	11.4
Aseptic loosening	66	41.8
Defective plastic liner	28	17.7
Metallosis	2	1.3
Periprosthetic fracture	4	2.5
Luxation	16	10.1
Instability	6	3.8
Incorrect axis	2	1.3
Other	13	8.2
Only pain	3	1.9
Total	158	100.0

may not be used in patients with significant bone loss, instability, or arthritis mutilans. In these cases, the ligaments and muscles are not intact, and increased support is needed to obtain stability of the joint.

The most commonly used implants were the Norway, Kudo, Discovery, and IBP brands, all used in >100 patients. The Kudo and IBP were used in 11 different hospitals, the Norway in 8, and the Discovery in only 4 hospitals.

We performed comparisons between the Norway and the Kudo prostheses because they both had the longest follow-up. Comparisons between the IBP and the Discovery prostheses were done because they were used in the same period and in a similar number. We performed comparisons between the Norway and the NES because they had a similar design and between the Norway and the Discovery because they were used in different times.

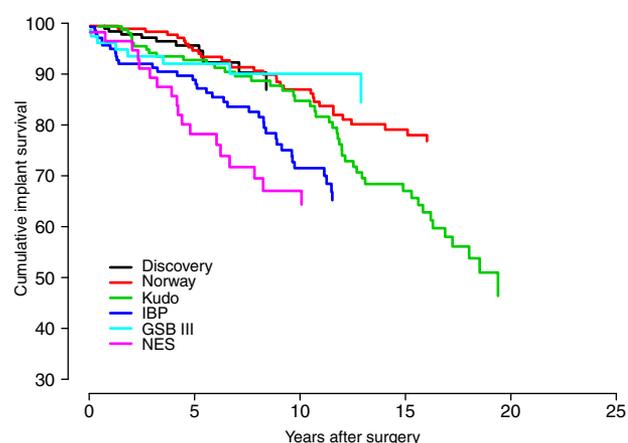
## Statistical methods

Survival time was calculated using the Kaplan-Meier method. The main end point was revision regardless of cause, and survival curves for different subgroups of patients (ie, patients with different diagnoses or different implant brands) were constructed. The log-rank test was used to test any differences between groups. When fewer than 10 patients remained at risk, the curves were terminated. Cox analyses were used to study the influence of factors such as brand, fixation, age, gender, and diagnosis. The follow-up time was calculated using the reverse Kaplan-Meier method. *P* values lower than .05 were considered statistically significant, and the *P* values were 2 tailed.

As seen from the survival curves for the Norway and the Kudo prostheses, there was a clear deviation from nonproportionality, with a breakpoint at 10 years (Fig. 1). Hence, separate analyses on the relative risks in the Cox model before and after 10 years of follow-up were performed.

Revisions for each cause, such as dislocation or loosening, had only a limited number of cases each (Table III). Because of the small number of events, models for exact Cox regression were constructed. These models were set up as discrete time models and analyzed using the exact logistic module, with a logit link-function, in the statistical package Stata version 14 (StataCorp LP, College Station, TX, USA). These methods were performed according to the description by Samuelsen.<sup>40</sup>

Poisson regression analyses were used to analyze trends in the incidence of TEA. Yearly population rates for the Norwegian



**Figure 1** Survival curves for the 6 most frequently used prosthesis brands. (For interpretation of the color in this figure, the reader is referred to the web version of this article.)

population were obtained from Statistics Norway. The figures show absolute numbers, not incidences. All analyses, except the exact regression analyses, were performed using SPSS 23.0 software (IBM Corp, Armonk, NY, USA).

## Ethics

The NAR has permission from the Norwegian Data Inspectorate to collect patient data, based on obtaining written consent from the patient. (Permission was last issued September 15, 2014; reference No. 03/00058-20/CGN.)

## Results

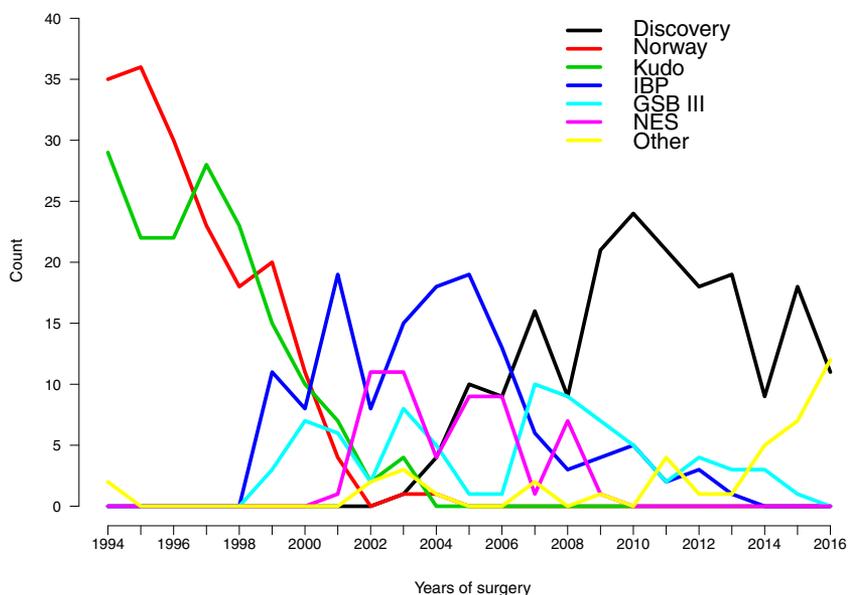
The different prosthesis brands were used in different time periods (Table I and Fig. 2).

Some of the hospitals had a relatively large volume of operations, whereas others performed only a few (1-6) during the whole study period (Table I). The Kudo and Norway prostheses were the most frequently used brands in the first 6 years of the study period. From 2000, the GSB III, IBP, and NESimplavit prevailed; and from 2005 and onward, the Discovery and Nexel dominated (Fig. 2). The mean age was similar for the different brands ( $P = .064$ ), but there were differences in gender ( $P = .034$ ; not shown in the table). Inflammatory arthritis was the most common diagnosis (79%) (Table IV).

From 1994 to 2016, the incidence of TEA significantly decreased ( $P < .001$ ; Fig. 3). The decrease was caused by a decline in operations in patients with inflammatory arthritis ( $P < .001$ ).

The median follow-up time was 8.9 years for the whole study group but varied from 0.7 year (Nexel) to 14.6 years (Norway) (Table II).

The overall survival rates at 5, 10, 15, and 20 years were 92%, 81%, 71%, and 61%, respectively (Table IV). Adjusted survival curves for the 6 most commonly used TEA brands are shown in Figure 1.



**Figure 2** The annual number of total elbow arthroplasties according to prosthesis brand. (For interpretation of the color in this figure, the reader is referred to the web version of this article.)

There were 158 revisions reported. The most frequent cause (hierarchical model) was aseptic loosening of 1 or both components ( $n = 66$ ), followed by defective polyethylene liner ( $n = 28$ ), infection ( $n = 18$ ), dislocation ( $n = 16$ ), instability ( $n = 6$ ), fracture ( $n = 4$ ), metallosis ( $n = 2$ ), and incorrect axis ( $n = 2$ ) (Table III).

In a Cox model adjusted for gender and age, we found that the primary diagnosis influenced the risk of revision. Patients with fracture sequelae had the poorest prognosis compared with inflammatory arthritis (relative risk [RR], 1.86; 95% confidence interval [CI], 1.012-3.41), and osteoarthritis had a risk of revision similar to that of inflammatory arthritis (RR, 0.73; 95% CI, 0.30-1.80). The unadjusted survivorships are shown in Table IV.

There were 641 total all-cemented cases; 26 cases were uncemented, 153 were hybrids with cemented ulna, and 5 cases were hybrids with cemented humerus (Table II).

The risk of revision was higher for uncemented than for cemented TEAs (RR, 3.00; 95% CI, 1.56-5.75;  $P = .001$ ; Table IV). In a Cox model adjusted for gender and age, we found that the cases with an uncemented ulna component regardless of humeral fixation ( $n = 31$ ) had a 3 times higher risk for revision compared with those with a cemented ulnar component (RR, 2.98; 95% CI, 1.55-5.72;  $P = .001$ ; Fig. 4).

### Brand-specific survivorship

The 5-, 10- and 15-year survival rates were 93%, 85%, and 66% for the Kudo and 94%, 86%, and 78% for the Norway prosthesis. The 20-year survival for the Norway prosthesis was 76%. NES had significantly poorer 5-year survival than the Discovery, the Norway, and the Kudo prostheses (Fig. 1).

In a model adjusted for gender and age, the risk for revision in the first 10 years was similar for the cemented Kudo prosthesis (RR, 1.37; 95% CI, 0.68-2.73;  $P = .38$ ) and the cemented Norway prosthesis. However, from 10 years on, the risk for revision was significantly higher for the Kudo prosthesis (RR, 2.58; 95% CI, 1.16-5.76;  $P = .021$ ). Using the same model, we found that the cemented NES had a higher risk for revision compared with the cemented Norway prosthesis (RR, 2.57; 95% CI, 1.29-5.10;  $P = .007$ ). The unadjusted survivorships are given in Table IV.

There were 43 Kudo prostheses that were revised. The most frequent reasons for revision were aseptic loosening of 1 or both components (18 revisions) and defective polyethylene liner (10).

There were 28 Norway prostheses that were revised. The most frequent reason for revision was found to be aseptic loosening of 1 or both components (21). No revisions were performed because of defective polyethylene liner in this particular prosthesis brand.

In the first 10 years, the IBP had statistically significant higher risk of revision compared with the Norway prosthesis (RR, 2.34; 95% CI, 1.34-4.09;  $P = .003$ ). No statistically significant differences were found in comparing the risk of revisions between Norway and Discovery in the first 10 years (RR, 1.01; 95% CI, 0.49-2.09;  $P = .97$ ).

The overall risk for revision of the cemented NES prosthesis was higher than that of the cemented Norway prosthesis (RR, 2.31; 95% CI, 1.23-4.35;  $P = .009$ ). The risk for revision due to defective liner was significantly higher for the NES compared with the Norway (RR, 23.7; 95% CI, 2.85-197.3;  $P = .003$ ). The Norway prosthesis also had significantly lower risk for revision due to defective liner compared with the Discovery prosthesis (RR, 0.03; 95% CI, 0.00-0.34).

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

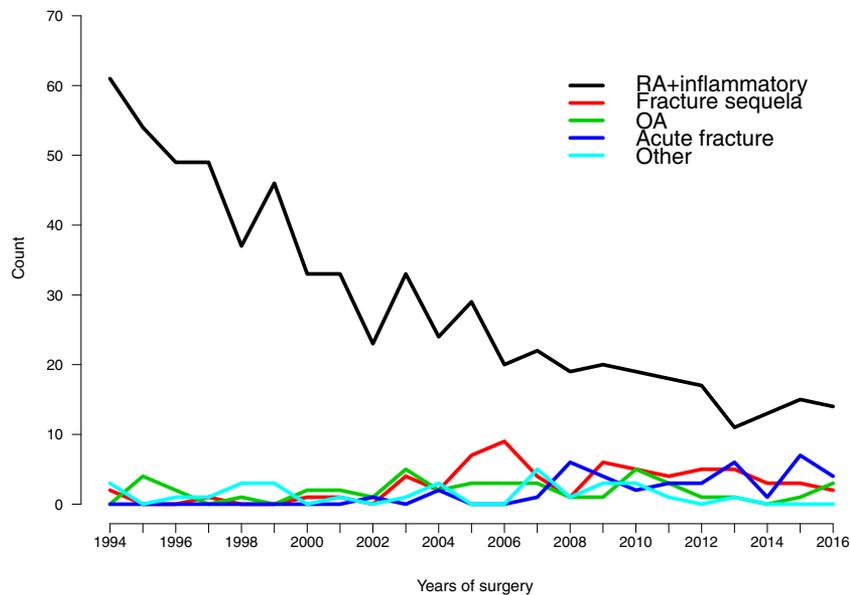
	No.	Revisions	5-year survival (95% CI)	10-year survival (95% CI)	15-year survival (95% CI)	20-year survival (95% CI)	RR (95% CI)	<i>P</i>
All	838	158	91.5(89.5-93.5)	81.4 (78.1-84.7)	70.7 (66.2-75.2)	61.2 (54.7-67.7)		
Age								
<60 y	305	88	91.4 (88.1-94.7)	79.7 (74.6-84.8)	65.7 (59.0-72.3)	53.8 (45.4-62.1)	1.47 (1.07-2.02)	.020
≥60 y	533	70	91.7 (89.2-94.2)	82.8 (78.6-87.1)	75.8 (69.4-82.1)	73.8 (66.5-81.1)	1 (reference)	
Gender								
Men	183	36	86.6 (81.1-92.1)	71.8 (62.7-80.8)	69.8 (60.2-79.4)	62.0 (45.3-78.7)	1.34 (0.92-1.95)	.12
Women	655	122	92.8 (90.6-95.0)	83.4 (79.9-86.9)	71.4 (66.3-76.4)	61.6 (54.6-68.5)	1 (reference)	
Year of surgery								
1994-1999	317	75	93.1 (90.2-96.0)	85.7 (81.3-90.0)	72.2 (66.1-78.4)	62.3 (54.7-69.9)	1 (reference)	
2000-2005	213	52	87.8 (83.3-92.3)	75.9 (69.6-82.2)	69.8 (62.5-77.1)	—	1.31 (0.91-1.89)	.15
2006-2010	163	24	92.8 (88.7-96.9)	79.9 (71.4-88.4)	—	—	1.27 (0.78-2.06)	.34
2011-2016	145	7	92 (85.7-98.3)	—	—	—	1.04 (0.46-2.35)	.93
Prosthesis								
Discovery	190	13	95.4 (92.1-98.7)	—	—	—	1.01 (0.49-2.09)*	.97
Norway	179	32	94.4 (90.9-97.9)	86.4 (80.7-92.1)	78.1 (70.8-85.4)†	75.7 (67.9-83.5)	1 (reference)*	
Kudo	162	47	92.8 (88.7-96.9)	84.6 (78.3-90.9)	66.4 (57.0-75.8)†	—	1.18 (0.63-2.18)*	.61
IBP	135	36	88.6 (83.1-94.1)	70.9 (62.1-79.7)	—	—	2.34 (1.34-4.09)*	.003
GSB III	77	9	91.9 (85.6-98.2)	89.8 (82.5-97.1)	—	—	0.97 (0.41-2.29)*	.94
NES	54	18	77.2 (65.8-88.6)	65.8 (52.5-79.1)	—	—	3.20 (1.68-6.12)*	<.001
Other	41	3	—	—	—	—	—	
Diagnosis								
RA + inflammatory arthritis	659	129	92.2 (90.0-94.4)	82.1 (78.6-85.6)	71.6 (66.8-76.4)	61.5 (54.7-68.3)	1 (reference)	
Fracture sequelae	65	13	87.7 (79.1-96.3)	72.2 (56.2-88.1)	—	—	2.00 (1.12-3.58)	.019
OA	44	6	95.2 (88.7-100)	84.1 (70.6-97.6)	—	—	0.78 (0.35-1.78)	.56
Acute fracture	40	5	82.0 (67.3-96.7)	—	—	—	1.68 (0.68-4.13)	.26
Other	30	5	89.1 (77.5-100)	—	—	—	0.95 (0.39-2.33)	.91
Type of fixation								
Cemented	641	110	91.8 (89.5-94.1)	82.9 (79.2-86.5)	70.7 (65.3-76.2)	—	1 (reference)	
Uncemented	26	10	87.8 (74.8-100)	—	—	—	3.00 (1.56-5.75)	.001
Reverse hybrid	5	0	—	—	—	—	—	—
Hybrid	153	37	90.6 (85.8-95.3)	81.3 (74.4-88.2)	72.9 (64.4-81.5)	—	1.18 (0.81-1.71)	.96
Missing	13	1	—	—	—	—	0.42 (0.06-3.02)	.39
Fixation of the ulna component								
Cemented	800	148	91.5 (89.4-93.6)	82.5 (79.2-85.7)	71.3 (66.7-75.9)	61.6 (55.1-68.1)	1 (reference)	
Uncemented	31	10	89.6 (78.4-100)	—	—	—	2.43 (1.28-4.62)	.007
Missing	7	0	—	—	—	—	—	—
Articulation type‡								
Nonlinked	530	133	90.6 (88.1-93.1)	79.7 (75.8-83.6)	68.9 (64.0-73.8)	59.9 (53.2-66.6)	1 (reference)	
Linked	267	22	94.4 (91.5-97.3)	88.7 (83.2-94.2)	—	—	0.66 (0.42-1.05)	.067

CI, confidence interval; RR, relative risk; RA, rheumatoid arthritis; OA, osteoarthritis.

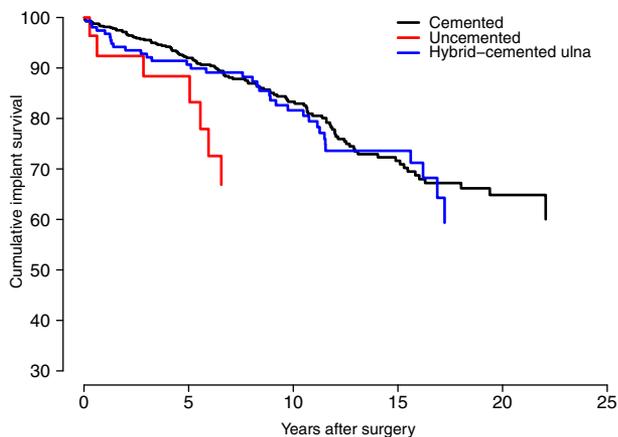
\* Results with up to 10 years of follow-up.

† Kudo compared with Norway after 10 years of follow-up: RR = 3.38 (95% CI, 1.70-6.71); *P* < .001.

‡ Only total elbow arthroplasty brands used in >50 cases are included.



**Figure 3** The annual number of total elbow arthroplasties according to diagnosis. *RA*, rheumatoid arthritis; *inflammatory*, inflammatory arthritis; *OA*, osteoarthritis. (For interpretation of the color in this figure, the reader is referred to the web version of this article.)



**Figure 4** Survival curves for different fixation methods. (For interpretation of the color in this figure, the reader is referred to the web version of this article.)

The risk for revision for any reason was significantly higher for hybrid IBP (unlinked) compared with cemented Discovery (linked) (RR, 2.17; 95% CI, 1.01-4.64;  $P = .048$ ).

## Discussion

We found that the survivorship of TEA in our national cohort of 838 cases was 92% at 5 years, 84% at 10 years, 71% at 15 years, and 61% at 20 years. The 2 prostheses with the longest follow-up, the Norway and the Kudo prostheses, had similar survival in the first 10 years, but the Norway prosthesis performed better than the Kudo after 10 years. The 15-year survival was 78% and 66%, respectively. The 20-year survival for Norway prosthesis was 76%. These designs were

discontinued in 2003-2004, but we believe these historical data are interesting still.

The Discovery, the Norway, and the Kudo had significantly better 5-year survival rate (95%, 94%, and 93%, respectively) compared with the NES prosthesis (77%). To our knowledge, this is a rare report on the long-term survivorship of TEA.

The overall 5- and 10-year survival rates are similar to those reported by Ikävalko et al,<sup>16</sup> who found 96% survival at 5 years and 84% at 10 years. Similar survivorship has been found by others.<sup>9,41,46,48</sup> Some authors found poorer survivorship.<sup>23,39</sup> All these studies but 2 were done on the Souter-Strathclyde prosthesis. In this study, only 2 cases with this implant were identified. However, the Kudo, the Norway, and the IBP prostheses are also nonlinked implants, and we believe that our results may be compared with these studies. In a review article on 3000 cases of TEA with a mean follow-up of 60 months, 13% were revised.<sup>24</sup>

Early designs of TEA had rigid hinges, and the survivorships were poor because of loosening.<sup>5,28,38</sup> This caused the development of unlinked implants and linked implants that allowed some degree of movement other than flexion-extension. Some studies of the unlinked prosthesis Souter-Strathclyde reported comparable survival rates with those of the Kudo and Norway in this study.<sup>16,38,46</sup> One report on 50 Kudo prostheses, followed up at the center where the prosthesis was developed, showed better survivorship than we found for the Kudo prosthesis, reporting survival of 90% at 16 years.<sup>45</sup>

As far as we know, only 1 earlier study has reported >20-year follow-up data.<sup>41</sup> It reported a survival of 92% at 10 years, 83% at 15 years, and 68% at 20 years for the Coonrad-Morrey prosthesis, which is slightly better than our overall results but inferior to our findings for the Norway prosthesis

(76% at 20 years). Another study reported 19-year survival<sup>17</sup> of 77%, and this is similar to our finding for the Norway prosthesis but superior to our overall survivorship.

The NES had a higher risk of revision compared with the Norway prosthesis (Table IV). There are only minor design differences between the Norway and the NES prosthesis; however, this may indicate that minor changes of the implant may affect the outcome dramatically. The dimensions and design of the NES are the same as those of the Norway prosthesis, but the ulnar and humeral components are made of cast cobalt-chromium-molybdenum alloy instead of titanium. The polyethylene (ultrahigh-molecular-weight polyethylene) bobbin articulates against a ceramic-coated axle (titanium nitride coating) on the NES. Modifications done to a well-functioning implant are of course intended to improve its performance, but history has shown that we do not fully understand the impact of such modifications, however insignificant they may appear.<sup>15,27</sup>

From the year 2002 and onward, a mix of different implants were used (linked and unlinked designs), and diagnoses other than inflammatory arthritis became more frequent. Implant survivorship depended on both the implant itself and other factors, such as the diagnosis. There were some differences between the designs in terms of patient diagnosis, and we could not discern whether the implant or another factor, such as elbow disease, was causing the failures. Surgeons may also have chosen linked designs in the treatment of severely destroyed elbows, whereas unlinked designs could have been used in less severely damaged elbows. This could have skewed our results.

According to a number of papers, the most frequent cause of revision TEA is aseptic loosening.<sup>16,24,39</sup> That was also the case in our study. The most frequent reason for revision in our study was aseptic loosening, representing 41% of the revision cases. This finding is similar to other register studies.<sup>34,42</sup>

A frequency of revisions for infection up to 9% has been reported in some studies.<sup>16,24,39</sup> In our study, 18 of 158 (11.4% of revisions) elbows were revised because of deep infection. The incidence of revision for infection therefore was 2.15%. The number may be even higher because only infections leading to the removal or exchange of parts of the prosthesis were reported to the register until 2011. Soft tissue revisions with retention of the implants were not registered. Roizing<sup>39</sup> and Ikävalko et al<sup>16</sup> recorded the infections in the same manner. In our study, only 3 cases underwent soft tissue revision with retention of the implant parts because of infection from 2011 to 2017. In the review by Little et al,<sup>24</sup> the rate of deep infection was 5%, but this number may also include cases of infection that were not revised. Espeshaug et al<sup>7</sup> reported that only 80% of revisions were reported to the NAR. It has also been shown in the same paper that for total hip arthroplasty, revisions done for infection have poor registration.<sup>7</sup> The number of TEA revisions due to infection may be underestimated.

We found that patients with fracture sequelae had a higher risk of revision compared with those with inflammatory arthritis

(RR, 2.00;  $P = .019$ ). This has also been shown by others.<sup>21</sup> The reason for this is unknown, but it may be that a lower level of activity protects the TEA against wear and loosening in rheumatoid patients. Furthermore, the “threshold” for revision surgery may be higher in patients with severe systemic disease. The threshold for revision surgery is not, however, only patient dependent; it is also surgeon dependent. In other words, a surgeon’s decision to offer revision surgery takes into account the surgeon’s judgment as to the likelihood of success. Consequently, a surgeon is therefore more likely to offer revision surgery for a design such as the Kudo elbow as the components have relatively short stems (particularly the ulna component), and it is much more easily (and safely) revised than designs with longer stems, such as the Norway elbow.

In our study, we found revision due to loosening of the ulnar component to be slightly more frequent ( $n = 46$ ) than loosening of the humeral component ( $n = 41$ ). There is no clear evidence in the literature on which component is at the highest risk for loosening. Some found the ulnar component to be more prone to loosening<sup>23,35,45,47</sup> and others, the humeral component.<sup>3,45</sup> The focus on optimal cementing technique has not been as strong as in other procedures, such as hip arthroplasty. Modern cementation technique could probably improve the survivorship of TEA.

In a study by van der Heide et al, revision of the ulna component was more likely with uncemented fixation than with cemented fixation.<sup>47</sup> Similarly, in this study, the use of uncemented ulnar components was a risk factor for revision.

The annual number of TEAs performed decreased during the study period. The opposite trend has been documented for knee and hip arthroplasties, which are mainly performed in patients with osteoarthritis. We believe that an improvement in the medical treatment of rheumatoid arthritis is the main cause for the decreased incidence of TEA in our country.<sup>10,13,18,25,31,33,36,43</sup> Our finding is in accordance with a general trend toward less arthroplasty surgery and also surgery in general in patients with inflammatory arthritis.<sup>8,30</sup>

The literature on TEA in patients with diagnoses other than inflammatory arthritis is rare.<sup>4,23,32,37,44,48</sup> Papers on TEA in osteoarthritis or fracture generally deal with a small number of patients, and therefore the survivorship of TEA in these groups is not well known.<sup>6,14,21,29</sup>

The overall 10-year survivorship was 84% in our study. This is similar to the results in the Finnish register<sup>42</sup> and the Danish register<sup>34</sup> but slightly inferior to the results from the Scottish register.<sup>19</sup> The number of hospitals performing >20 TEAs of a particular prosthesis brand is low in our study (Table I). In a study on knee arthroplasty, the investigators found a significantly higher revision rate at low-volume hospitals compared with high-volume hospitals.<sup>1</sup> In a study from the Scottish register, better survival rate of the implants of surgeons who perform >10 cases per year were demonstrated. It is reasonable to believe that the same goes for TEA in our country.

In our study, there seemed to be a slight increase in the use of TEA for diagnoses other than inflammatory arthritis.

This may lead to the increasing use of TEA with time. Still, only 20-30 TEAs were performed annually in our country of 5 million inhabitants.

We are aware that register-based study has some limitations. We were not able to report patient-rated outcomes or disease-specific quality of life measurements. Furthermore, radiographic analyses were not possible to conduct.

## Conclusion

We found that in a nationwide register study of 838 TEAs, the overall survival rate was 92% at 5 years, 85% at 10 years, 71% at 15 years, and 61% at 20 years. At 20 years, 61% of cases were not revised. These survivorships are clearly inferior to hip and knee arthroplasty but similar to other reports on TEA. Post-trauma indications, uncemented fixation of the ulnar component, and some implant brands were risk factors for revision.

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## Supplementary data

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