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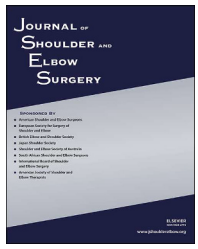

Cohort of 101 consecutive Nexel total elbow arthroplasties

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ABSTRACT

Background: The Nexel total elbow arthroplasty (TEA) was introduced as an enhancement of the Coonrad-Morrey TEA, which through design modifications aimed to improve patient outcomes. However, high revision rates due to loosening have been reported for this implant.

Methods: A review of 101 consecutive primary Nexel TEAs performed between 2015 and 2021 at a single institution was conducted using data from the Norwegian Arthroplasty Register, electronic medical records, and radiographic evaluations. Implant revision, other secondary surgery, and complications were investigated. Serial radiographs were examined for implant loosening using established criteria. Clinical outcomes, including Mayo Elbow Performance Score, range of motion, and pain, were assessed.

Results: After an average of 44 (range 13-84) months from surgery to case review, 5 implant revisions were performed among the 101 cases, with 2 revisions related to aseptic loosening. Radiographic evaluation of nonrevised cases revealed an additional 4 cases of suspected aseptic loosening proportion. There were 38 secondary surgeries performed in 18 of 101 elbows and 27 complications in 22 of the elbows. Clinical outcomes were good or excellent in 81% of cases, including revised elbows, according to Mayo Elbow Performance Score classification. The mean flexion-extension arc was 113° at last follow-up vs. 87° preoperatively. Mean pain at rest (numerical rating scale) improved from 4.0 to 0.8 at last follow-up and pain during activity from 7.9 to 1.7.

As the project makes secondary use of noninterventional registry data for quality assessment purposes, it falls outside the scope of the Health Research Act and therefore does not require prior approval from REK or review by a formal ethics committee (EC) or institutional review board (IRB). The Data Protection Officer has reviewed and advised on the project to ensure that all processing of personal data is in accordance with applicable data protection legislation, including the GDPR.

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Conclusion: There were 5 implant revisions performed among the 101 cases, 2 due to aseptic loosening. An additional 4 suspected aseptic loosenings were identified in serial radiographs. Reoperations and complications were frequent but within the expected range for TEA in a mixed population. Most of the patients showed a marked clinical improvement from the procedure, with the best results found among those with acute fractures and the least favorable in those with fracture sequelae.

Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Nexel; TEA; total elbow arthroplasty; implant revision; elbow; radiographic loosening

The Nexel total elbow arthroplasty (TEA) (Zimmer-Biomet, Warsaw, IN, USA) is a further development of the well-documented Coonrad-Morrey TEA (Zimmer-Biomet, Warsaw, IN, USA).[18] However, reports of high-implant revision rates due to early loosening have caused concern.

The Coonrad-Morrey TEA is a linked, semiconstrained elbow prosthesis, which has demonstrated good clinical outcomes in patients with inflammatory arthritis and a 10-year implant survival of 92%.[23] However, advances in drug treatment for rheumatoid arthritis and other inflammatory arthritic conditions have significantly reduced the need for joint implant surgery in these patients,[12] and traumatic conditions have replaced inflammatory arthritis as the leading indication for TEA.[17] In populations with mixed indications for surgery, 10-year survival has been reported at 83-86%.[4,15] Male gender, younger age, obesity and fracture sequela as indication for surgery are known negative predictors of TEA survival.[4,7,24,26] The Nexel TEA, approved by the U.S. Food and Drug Administration in 2013, introduced design enhancements with the aim of improving implant survival for a broadening patient group.

Implant loosening, bushing wear, and mechanical breakdown of the implant coupling, are among the known modes of failure of TEA.[9,21,29] Among the proposed advantages with the Nexel TEA were the addition of cross-linked vitamin-e enriched polyethylene, thicker bushing, and improved joint implant congruency. The aim was to improve load distribution, and thereby reduce the risk of polyethylene wear and bushing breakage.[13,20]

However, 2 studies published in 2021 and 2022 challenged that the Nexel TEA represented an improvement over its predecessor, reporting frequent aseptic early loosening requiring implant revision.[18,25]

The objective of the current study was to investigate the occurrence of early aseptic loosening both among implant revisions and from radiographic evaluation, in a cohort of consecutive Nexel TEA cases. We also examined short- to mid-term implant revision, secondary surgery, and complication rates. Additionally, we assessed clinical outcomes, including the Mayo Elbow Performance Score (MEPS), range of motion (ROM), and numerical rating scale (NRS) of pain at rest and during activity.

Material and methods

Study design and data collection

The study evaluated outcomes in a cohort of consecutive patients operated with primary Nexel TEAs performed at a single institution (Diakonhjemmet Hospital, Oslo, Norway) between 2015 and 2021. The data were obtained from an in-house quality registry, approved by an internal review board and the Norwegian Arthroplasty Register (NAR). The NAR provided demographic and surgical data, which were cross-verified and supplemented with data from the patient's medical records. Clinical data and patient-reported outcomes at the time of surgery and follow-up were extracted from the in-house quality registry. The study was approved by the hospital's data protection officer on the condition that written consent was provided for individually presented cases.

Patients

All patients operated with a primary Nexel TEA at our institution from 2015 to 2021 were included and reviewed using the available resources. Patients with prior radial head arthroplasty were classified as implant revision cases according to the NAR protocol and thus excluded.

Implants

A Nexel TEA implant was used in all cases. All ulna and humerus components were standard, with lengths 4, 5, or 6, and no custom or long stem implants were used.

Surgical technique, general method

All procedures were performed by a team of 2 orthopedic surgeons, whereof at least one was a consultant at the section for upper-extremity surgery. All components were fixated with high-viscosity bone cement containing gentamicin (Palacos R + G, Heraeus Medical, Hanau, Germany), except for the first case in the series, where Palacos LV + G (Heraeus Medical, Hanau, Germany) was used. Native bone plugs were used as cement restrictors where possible, commercial alternatives if not. The cement was pressurized and administered through a conical nozzle that allows retrograde filling. The coronoid and olecranon tips were excised, and a bone chip was placed under the anterior flange of the humeral component in all cases. A tourniquet was used only during cementation.

Radiographic evaluation

Radiographic assessments were performed by a dedicated in-house radiologist. Anteroposterior and lateral radiographs were obtained preoperatively and postoperatively, at 3 months, 1 year, 5 years, and at every 5 years thereafter.

Patients who did not have a recent examination were offered an extra follow-up. Radiographs were taken with a 25 mm diameter calibration sphere. Index radiographs were taken from the 3-month visit, if available, or the postoperative visit, if not. Follow-up radiographs, taken a minimum of 1 year after index surgery, were compared to the index radiograph for signs of loosening. Radiographic loosening of the TEA implant was concluded if at least one of the following criteria were met[11,16]: (1) Progressive widening of ≥1 mm of the bone-cement interface or cement-prosthesis interface ≥50% of the circumference of the implant on lateral or anteroposterior radiographs; (2) fragmentation or fracture of cement; (3) prosthetic component migration of ≥2 mm; and (4) bead shedding in porous-coated prostheses.

It has been proposed that excess coronoid height after TEA surgery could be a cause of ulnar component loosening.[8] The remaining coronoid height was therefore measured on the calibrated radiographs as the length from the tip of the coronoid to the perpendicular intersection with the ventral aspect of the ulnar implant stem (Fig. 1*a*). Periprosthetic fractures and the status of the radial head were noted.

Clinical evaluation

Clinical evaluations were conducted by a physiotherapist, using the MEPS.[16] The MEPS is a functional evaluation of the elbow ranging from 5-100 points, with classifications: excellent (>90), good (75-89), fair (60-74), and poor (<60). Its Minimal Clinically Important Difference (MCID) and the substantial clinical benefit are 12.2 and 17.3, respectively.[28] ROM was measured using a goniometer. Pain at rest and activity during the last four weeks, was measured using an NRS from 0 (no pain) to 10 (worst imaginable), which has an MCID of 2 points.[10] and Boonstra et al[5] have categorized as (0 = no pain, 1-5 = mild pain, 6-7 = moderate pain, and 8-10 = severe pain).

Statistical analysis

Survival analysis was performed using implant revision as the primary endpoint. Cases were censored at patient death or at the time of review. Descriptive statistics summarized demographic, clinical, and radiographic data. For those whose last clinical evaluation was done by telephone, ROM was imputed using the last available observation. Differences in patient age and body mass index (BMI) by revision/implant loosening status were analyzed using a two-sided Welch's t-test. Comparison of residual pain was done using a Mann-Whitney U test. IBM SPSS Statistics version 30.0 (IBM Corp, Armonk, NY, USA) was used for analysis.

Results

Patients, baseline demographics

The study included 101 consecutive primary Nexel TEAs in 93 patients, 71 female patients (76 elbows) and 22 male patients (25 elbows). Eight patients had bilateral arthroplasties. The mean age at index surgery was 69 (range: 42-95) years, and the mean BMI was 26 (range: 18-43). In 19 cases, the BMI was >30. According to the American Society of Anesthesiologists (ASA) Physical Status Classification System, the ASA score was II or III in 92% of cases. The primary indications for TEA surgery were inflammatory joint disease (n = 39), idiopathic osteoarthritis (n = 9), acute fracture in 23 cases, and fracture sequela in 28 cases. The remaining 2 TEA procedures were performed due to sequela from hemophilia and from septic arthritis. Among the acute fracture cases, 7 patients also had inflammatory joint disease. Previous surgeries had been performed in 44 of the 101 elbows (1 to 9 procedures, mean 1.8). At the time of review, 12 patients with a total of 13 Nexel TEAs were deceased at an average of 31 (0-82) months from surgery. All cases have been reviewed for recorded adverse events. Instead of excluding cases based on lack of clinical and/or radiographic data, we present the whole cohort to better reflect our overall practice and results. The number of cases available for radiographic and clinical review are listed in chapters 4.4 and 4.6 (Table I, baseline demographics).

Surgical technique

A posterior triceps tongue approach as described by Rajeev and Pooley[22] was used in 61 cases, lateral para-olecranon approach[27] in 34 cases, modified Alonso-Llames approach[3,6] in 4 cases, a trans-olecranon fracture approach in 1 case, and a two-incision triceps sparing approach[1] in 1 case. The ulnar nerve was transposed prior to the arthroplasty in 7 cases, transposed during surgery in 9 cases and partially released and left in its anatomical bed in the remaining 85 cases. The anterior capsule was loosened on the humeral side in 69 cases and resected in 32. The radial head was already excised or eroded in 15 cases, left intact in 20, and resected during index surgery in 66 cases. Ligament repair with sutures or anchors was performed in 18 cases. The median duration of the procedure was 135 (range: 74-300) minutes. Correction of a major deformity from childhood trauma with humeral shortening osteotomy was performed in 1 case, parallel plating for distal humerus fracture in one other case.

Implant revisions and other secondary surgery

At the time of data retrieval from NAR, the average time since index surgery was 44 (range 13-84) months. Implant revisions are defined as secondary surgeries, where implant components are removed or replaced, including isolated bushing exchange. Among the 101 TEA cases, there were 5 implant revisions (5 different patients) after a mean of 16 (range, 0-61) months (Table II, implant revisions). Two of the revisions were due to aseptic loosening, one of the ulnar and one of the humeral components. Both loosenings occurred in the bone-cement interface and were revised with impaction grafting. Metallosis was looked for during surgery but recorded as not observed. One of these revisions was successful (Fig. 1 *a*–*c*), in the other a second loosening occurred during follow-up. Of the 3 other implant revision surgeries, one was an implant removal due to deep infection, one a bushing exchange as part of a Debridement, Antibiotics, and Implant Retention procedure, where no infection was found, and in one, the ulna component was revised due to periprosthetic fracture, resulting from ulna shaft perforation and cement leakage at index surgery.

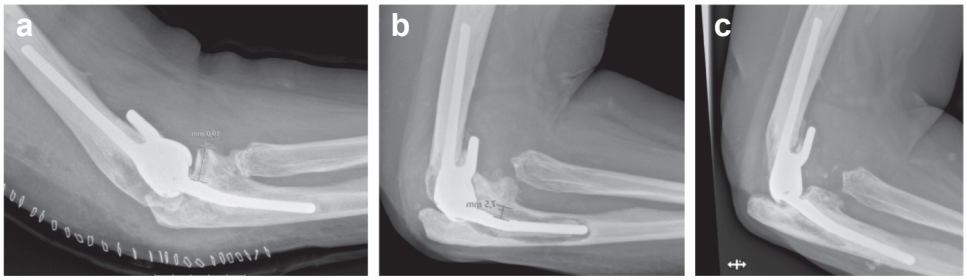

Figure 1 – (a) Highest coronoid measured at 19 mm perpendicular to ulna component. Postoperative x-ray. (b) Same case as 3a, 8 months after index surgery, before implant revision. (c) Same case as 3a, 16 months after ulna component revision, with bone impaction.

Table I – Baseline demographics per case for revised and non-revised cases

Variable	Selection														
	Revised					Not revised					All cases				
	N	N %	Mean	Min	Max	N	N %	Mean	Min	Max	N	N %	Mean	Min	Max
Gender															
Male	3	(60%)				22	(23%)				25	(25%)			
Female	2	(40%)				74	(77%)				76	(75%)			
Total	5	(100%)				96	(100%)				101	(100%)			
Age at index			61	56	66			70	42	95			69	42	95
Body mass index			31	27	35			26	18	43			26	18	43
Main indication															
Other	0	(0%)				9	(9%)				9	(9%)			
Rheumatoid joint disease	1	(20%)				39	(41%)				40	(40%)			
Osteoarthritis	1	(20%)				7	(7%)				8	(8%)			
Acute fracture	0	(0%)				16	(17%)				16	(16%)			
Fracture sequelae	3	(60%)				25	(26%)				28	(28%)			
Smoker															
No	3	(60%)				82	(87%)				85	(86%)			
Yes	2	(40%)				12	(13%)				14	(14%)			
ASA class															
ASA I	1	(20%)				5	(5%)				6	(6%)			
ASA II	1	(20%)				55	(57%)				56	(55%)			
ASA III	3	(60%)				35	(36%)				38	(38%)			
ASA IV	0	(0%)				1	(1%)				1	(1%)			
ASA V	0	(0%)				0	(0%)				0	(0%)			

ASA, American Society of Anesthesiologists Physical Status Classification System.

Microbiological samples taken at the 5 revision surgeries were all negative, though 2 of the revised elbows were subsequently infected.

The patients who were subject to implant revision surgery had a mean age of 61 (range: 56-66) years, a mean BMI of 31 (range: 27-35), 3 of 5 revisions were in male patients and 3 of 5 were fracture sequela cases. The Kaplan-Meier estimate of implant survival is illustrated in Figure 2.

Out of a total of 101 elbows, there were 38 secondary surgeries; 20 were performed on the 5 implant revision cases; and 18 among the remaining 96 elbows. In 83 of the elbows (82%), there were no secondary surgeries, in 12 (12%) there was one, in 5 (5%) between 2 and 4, and in 1 implant revision case, 10 secondary surgeries were performed. All but 2 secondary surgeries were performed in-house (Table III Secondary surgery).

Radiographic evaluation and implant loosening

Follow-up radiographs were available for 84 of 96 unrevised elbows, with radiographs obtained at an average of 42 (12-86) months after index surgery. There were missing data in 12 cases, 2 patients declined radiological follow-up and in 10 cases, the patient was deceased without adequate radiographs. The criteria for radiographic loosening were met in 4 of the 84 elbows, 2 with signs of isolated ulnar component loosening and 2 with signs of isolated humeral component loosening (Table IV Implant loosening cases). All 4 cases showed a widening of the bone-cement interface (criterion 1), and one also showed prosthetic component migration (criterion 3). The 2 implant revision cases with confirmed aseptic loosening both had criterion 1 and criterion 3 changes on retrospective review of

Table II – Implant revision cases

Age/sex	Indication primary	Indication revision	Time to revision	Type of revision	No reoperations	MEPS*	ROM*	NRS pain rest/activity*	Comment
65/F	Seroneg rheumatoid arthritis	Periprosthetic fracture ulna (Ulna perforated during index surgery, cement leakage)	2 weeks	Ulna revised to long stem Proximal ulna plating	4	65	75	1/6	Cultures neg at revision, but infection after secondary surgery.
60/M	Idiopathic osteoarthritis	Infection after ulnar nerve release post index surgery	4 mnts	Removal of implant	10	65	70	0/7	Multibacterial infection, demanding multiple revision post-removal. No reimplantation at time of review
56/M	Fracture sequela	Humeral loosening	61 mnts	Humerus revised + impaction grafting No metallosis, neg cultures, visually intact poly	3	40	85	6/10	Revision implant loosened on follow-up
63/F	Fracture sequela	Ulnar stem loosening	12 mnts	Ulna revised + impaction grafting No metallosis, neg cultures	2	95	105	0/0	Well-fixed revision implant on follow-up.

MEPS, Mayo Elbow Performance Score; *ROM*, range of motion; *NRS*, numerical rating scale; *M*, male; *F*, female.
* At last follow-up after revision. One bushing exchange case was left out due to inability to reach the patient for written consent to publish individual data.

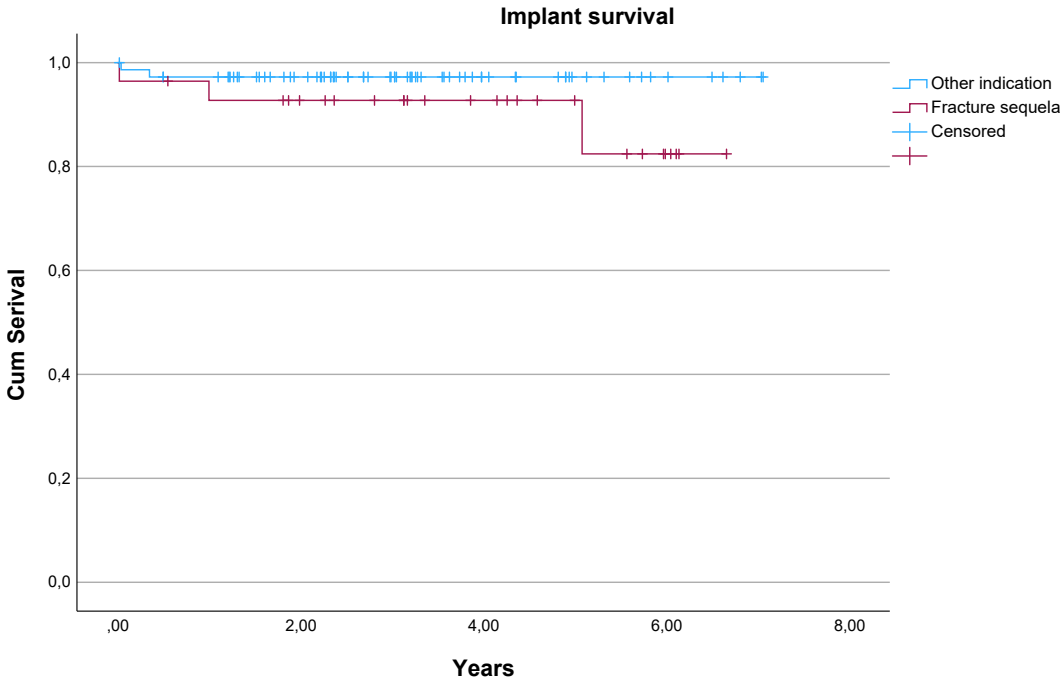

Figure 2 – Kaplan-Meier survival plot, fracture sequela versus other indication for index surgery.

Table III – Summary of secondary surgical procedures in revised and nonrevised elbows

Secondary surgery procedures	Revised cases	Non-revised cases	Total
Bushing exchange	1		1
Ulna stem revision	2 (2 elbows)		2 (2 elbows)
Humeral stem revision	1		1
Total implant removal	1		1
Fracture fixation	3 (2 elbows) olecranon	1 radial condyle	4 (3 elbows)
Other hardware removal	1	4 (4 elbows)	5 (5 elbows)
Deep wound debridement	8 (1 elbow)		8 (1 elbow)
Superf. wound debridement	1	7 (4 elbows)	8 (5 elbows)
PRUJ stabilization		1	1
Tendon transfer		1 radial nerve damage	1
Joint aspiration	1	1	2 (2 elbows)
Closed mobilization under anesthesia		1	1
Nerve release	1	2 (2 elbows)	3 (3 elbows)
Total procedures	20	18	38
Cases/elbows involved	5	13	18

PRUJ, proximal radioulnar joint.
Implant revision surgeries are included.

prerevision radiographs. The radial head had been removed at index surgery in all 6 loosening cases.

The mean coronoid height was 10.3 (range 6.0-19.0, standard deviation [SD] 2.4) mm. We did not find an association between implant loosening and remaining coronoid height. However, the only elbow revised due to ulnar component loosening had the highest remaining coronoid of 19 mm. Focal osteolysis was seen in 1 elbow that did not meet the criteria for loosening.

Among the 4 intact elbows with suspected radiographic loosening, one was known to be loose, and the patient was therefore monitored, showing only minor symptoms and little progression of the loosening over time, and an MEPS rated as good. The remaining 3 elbows were not recognized as having implant loosening prior to the study, one was rated as excellent, and two as good, based on MEPS, and 2 of the patients reported no pain (Fig. 3).

We did not find a statistically significant relationship between aseptic loosening and patient age (mean 69 y) or gender (1/6 were male), 2 factors known or suspected to predispose to implant failure. Among the 6 cases with implant loosening, whereof 2 had been revised, 5 had a BMI $\geq$ 30, while only 14 of 96 in the nonimplant loosening group had a BMI $\geq$30. The mean BMI in cases with aseptic loosening was 31 (range 24-

Table IV – Cases with confirmed or radiographically suspected loosening

Age/sex	BMI	Smoker	Diabetes	Cortico-steroids	Last MEPS	Pain NRS (rest/activity)	Revised	Ulna loose	Humerus loose	Criteria met*	Radial head removed	Coronoid height
63/F	35	Yes	No	No	95*	0/0*	Yes	Yes	No	1 and 3	Yes	19 mm
56/M	33	No	Yes	No	40*	6/10*	Yes	No	Yes	1 and 3	Yes	15 mm
77/F	31	No	No	Yes	85	0/3	No	No	Yes	1	Yes	7 mm
65/F	33	No	No	No	100	0/0	No	Yes	No	1	Yes	12 mm
79/F	31	No	No	No	80	0/0	No	Yes	No	1 and 3	Yes	10 mm

BMI, body mass index; *MEPS*, Mayo Elbow Performance Score; *NRS*, numerical rating scale; *M*, male; *F*, female.
Cases 1 and 2 are implant revision cases, case 3 through 6 are nonrevised.
* Clinical results at last follow-up after revision. One case is left out due to inability to reach the patient for written consent to publish individual data.

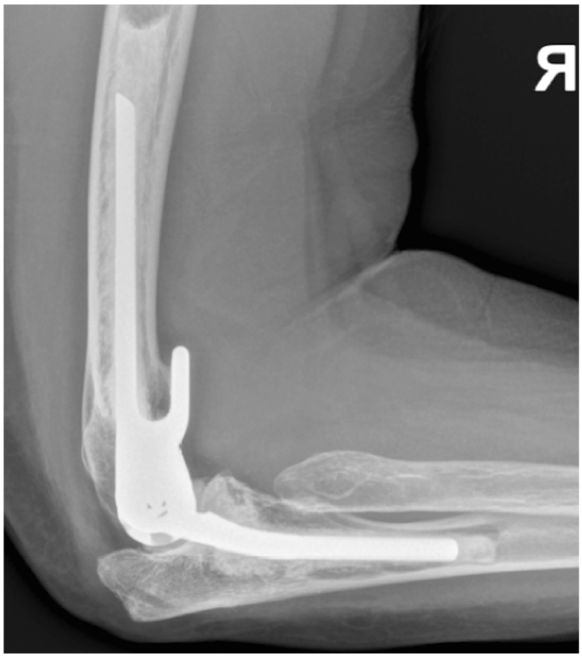

Figure 3 – Radiographic progressive loosening 5 years after index surgery. MEPS 100, no pain, and ROM 115°. *MEPS*, Mayo Elbow Performance Score; *ROM*, range of motion.

35). Fracture sequela was the main indication in 5 of 6 aseptic loosening cases and in 21 of 89 cases without known loosening.

Adverse events

There were 27 complications among 22 of the 101 elbows: Two implant loosenings leading to implant revision; 2 deep infections, both occurring after secondary procedures in implant revision cases; 3 suspected superficial wound infections were treated surgically without implant exposure, 1 had positive cultures; 3 periprosthetic fractures; 5 cases of ulnar nerve symptoms occurring or worsening; 1 permanent radial nerve palsy in 1 acute fracture case, where parallel plating of the distal humerus was performed at the index surgery; 2 hematomas; 1 stiffening requiring closed manipulation; 1 plexopathy; 2 cases of heterotopic ossification, whereof 1 resolved spontaneously; 1 case of instability of the proximal radius; 3 acute fracture cases where Steinmann pins used for condyle fixation loosened and required removal; and 1 humeral plate that required removing.

Clinical results

Clinical follow-up data at an average of 39 (3-94) months from index surgery were available in 95 of the 101 cases. Of the remaining cases, 1 patient declined follow-up and 5 patients (5 elbows) were deceased without follow-up data past 3 months. Fifteen patients (15 elbows) attended a follow-up at one of 10 other Norwegian hospitals. For 3 of these (4 elbows), the follow-up was conducted by telephone and an x-ray taken at the patient's local hospital. To provide the most complete picture of the status of the entire cohort, we have also included data from the most recent follow-up of the 5 revised elbows. Clinical results per main indication are summarized in Table V.

Mayo Elbow Performance Score (MEPS)

The mean MEPS was 87 (range, 30-100), with 53% of cases classified as excellent, 28% as good, 11% as fair, and 8% as poor. Preoperative MEPS was unavailable in elbow fracture cases. However, preoperative MEPS was available in 70 of 78 of the other cases, and the MEPS score improved in all except in 1 implant revision case. The mean increase in MEPS was 40 (0-90, SD 19) points, 93% of cases scoring above the MCID threshold, and 84% above the substantial clinical benefit threshold.

ROM

The mean elbow flexion-extension arc was 113° ± 19° (N = 95, range 35°-145°), with a mean flexion of 134° (range 105°-151°) and mean extension of 21° (range-75°-0°). Mean pronation was 79° (range 15°-100°), and mean supination was 72° (range 0°-90°). A flexion-extension arc of at least 100° was achieved in 71 (82%) of the patients at follow-up. Preoperative ROM was available for 72 of the 78 nonfracture elbows. Eight of these elbows had a decreased flexion-extension arc at final follow-up, mean decrease 20° (5°-40°); 4 cases were unchanged from preoperatively; and the remaining 60 had an improvement in the flexion-extension arc with a mean increase of 25° (2°-100°).

Pain

The mean self-reported pain at rest over the past four weeks was 0.8 (range 0-10; SD 1.8) points on the NRS scale, and mean

Table V – Clinical outcome

Main indication	MEPS pre		MEPS last		ROM pre	ROM last	NRS rest pre	NRS rest last	NRS activity pre	NRS activity last
	Valid N	Mean	Valid N	Mean	Mean	Mean	Mean	Mean	Mean	Mean
Other	4	56.3	9	85.6	93.5	102.8	2.8	8	8.5	1.8
Rheumatic joint disease	37	47.8	38	88.6	90.9	116.7	4.2	6	7.8	1.4
Osteoarthritis	7	45.0	8	85.0	90.6	105.8	3.9	8	8.4	1.6
Acute fracture	0	.	12	92.1	.	116.7	.	0	.	8
Fracture sequelae	26	46.0	28	82.7	80.9	111.3	4.0	1.6	7.7	2.5
Total	74	47.4	95	86.7	87.4	112.9	4.0	8	7.9	1.7

MEPS, Mayo Elbow Performance Score; *ROM*, range of motion; *NRS*, numerical rating scale.
Other: combination of acute fracture and rheumatic joint disease (N = 6), hemophilia (N = 1), and septic arthritis sequela (N = 1). Pre: before index surgery. Last: Last follow-up (after implant revision for revised cases).

pain during activity was 1.7 (0-10; SD 2.2). Seventy-four percent reported no pain at rest, and 18% reported mild pain. Pain during activity was absent in 52% and mild in 40% of cases.

Among the 78 cases with NRS at rest recorded preoperatively, 56 cases reported a preoperative pain at rest of 2 points or higher. Among these, 81% reported a reduction exceeding the MCID threshold (−2 points) and up to −8 points. Similarly, among cases with NRS at activity recorded preoperatively, 60 cases had a preoperative NRS of 2 or above (range 2-10). An improvement at the MCID or above (range 2-10) was found in 92% of these cases.

Residual pain was lowest in cases with acute fracture as main indication with mean pain at rest 0.0 and in activity 0.8. Compared with the rest of the cohort, the fracture sequela cases had significantly more pain at rest (mean 1.6 versus 0.5, $P = .013$) but not in activity (mean 2.5 versus 1.3, $P = .151$).

Discussion

In this cohort of 101 consecutive patients operated with primary Nexel TEAs, there were 5 implant revisions, 2 of which were due to aseptic loosening. Radiographic loosening was observed in 4 additional cases. Complication and reoperation rates were high, but within the expected range for TEA in a mixed population. Overall, most patients reported good or excellent functional results postsurgery, with low levels of pain. Interestingly, in only one of the 4 cases with radiographic loosening, there was migration of the implant. All 4 cases with only radiographic signs of loosening had a good or excellent MEPS score, and none have yet been revised (Table IV).

Siala et al[25] reported implant revision in 2 of 9 (22%) Nexel TEA elbows due to humeral implant loosening with a mean follow-up time of 28 months. The patients in this study had a mean age of 61 years, 2 male and 7 female and the indication for TEA surgery was posttraumatic or inflammatory arthritis. Morrey et al[18] reported implant revision in 12 of 35 (34%) primary Nexel TEA cases at an average of 2.2 years. Eleven implant revisions were due to aseptic loosening and one to septic loosening. Radiographic evaluation of nonrevised elbows revealed humeral component loosening in an additional 2 elbows.

Frequent early implant revisions due to aseptic loosening in the reports by Siala et al and Morrey et al was the backdrop and inspiration to conduct this review of our own Nexel cases. The overall implant revision rate found in our study is considerably lower than that reported by Morrey et al (5% vs. 34%). Furthermore, our study showed a substantially lower rate of aseptic loosening (7% vs. 37%). Our reoperation rate was 18% compared with 50% in Morrey et al's study. Complication rates are also lower in our study at 22% of cases vs. 56% in Siala et al's and 60% in Morrey et al's study. While our complication rate might also be considered high, it is within the expected range for linked TEA of 16-38%.[31,32] In comparison with Morrey's material, our patients were on average older (69 vs. 65 years), and the mean BMI was lower (26 vs. 29). There were proportionally fewer men in our study (24% vs. 43%). We also had relatively fewer fracture sequela cases (28% vs. 49%), and our follow-up time is limited. These are all factors that might have contributed favorably to our study. Apart from the use of methylene blue and antibiotic mixed in the bone cement in Morrey et al's study, we have not noticed any major differences in surgical technique that could help explain the differences in outcome. All loosenings in both our study and Morrey et al's study also occurred at the bone-cement interval, indicating that the quality of the cement itself is not likely to be the cause of loosening.

Two more recent studies by Owen et al[19] and Ahmed et al[2] have reported no implant revisions or reoperations in 11 elbows after 4.4 years and only 1 implant revision in 36 elbows after 5.5 years, respectively. In the first series, there was 1 radiographic humeral loosening, in the second there was a loosening rate of 5.3% in nonrevised patients. There was only 1 post-traumatic arthritis in the first series and 23% in the second.

Registry reports on survival of the Nexel TEA have also shown mixed results. A 2018 registry study from the NAR involves too few Nexel TEAs involves too few Nexel TEAs to provide useful information on implant survival in Norway.[14] A 2019 report from the Australian OA National Joint Replacement Registry showed similar implant revision rates between the Nexel, Coonrad-Morrey, Discovery, and Latitude implants.[30] This study included 121 Nexel implants with a maximum follow-up of 5 years. A report from the New Zealand National Joint Registry comparing survival rates of 149 Nexel and 350 Coonrad-Morrey TEAs showed a hazard ratio of

1.75 (not statistically significant) of implant revision of the Nexel versus the Coonrad-Morrey TEA.[33] Patient age- and gender-distribution was similar, the percentage of patients with rheumatoid arthritis was lower in the Nexel group (39% vs. 56%), and loosening of the Nexel implants were equally distributed between the ulnar and humeral components.

In our material, the patients with revised elbows had a higher mean BMI and a lower mean age, compared with the nonrevised patients. Male sex and fracture sequelae as primary indication for surgery was overrepresented among implant revision cases. Aseptic loosning cases had a higher mean BMI than the rest of the cohort and fracture sequela was the main indication in 5 of 6 loosening cases.

Morrey reported finding titanium particles in the polyethylene of removed implants and questioned the choice of a titanium-on-polyethylene articulation in the Nexel TEA. In our 2 cases with implant revision for aseptic loosening, the operative reports state that no metallosis was observed.

In our data, the implant loosenings were distributed evenly between the humeral and ulnar components. A pistoning effect due to impingement between the coronoid process and the anterior flange of the humeral implant has been suggested as a possible cause of ulnar component loosening.[8] It was thought that the impingement caused a pull-out mechanism of the ulnar component. The rotational center of the Nexel TEA is more posterior to that of the Coonrad-Morrey TEA. This might make the Nexel TEA more susceptible to this problem.[18] We have measured the coronoid height perpendicular to the ulnar stem in an attempt to identify whether this could be a possible cause of impingement and ulnar component loosening. Although we did not find a correlation between coronoid height and radiographic signs of loosening, the only patient revised for aseptic ulna stem loosening had the highest recorded coronoid (19 mm). Furthermore, we found that the radial head was removed in all our cases involving aseptic loosening and thus eliminating impingement of the radial head against the distal humerus as a possible cause of loosening.

High BMI was associated with early loosening in our data, as also shown in other publications.[4,17] This might be attributable to higher forces (eg, rotational) on the implant due to a heavier arm. Another possible explanation may be soft tissue impingement creating a pull on the components in elbow flexion, predisposing for implant loosening over time.

Although our data demonstrate less implant revision and loosening compared with the studies or Siala et al and Morrey et al, there is still a relatively high number of early confirmed or suspected aseptic loosenings. Overall, we cannot conclude that the Nexel TEA stands out favorably compared to older TEA designs in terms of loosening and implant revision. Our study confirms the clinical efficiency of TEA as measured by improvements in MEPS scores and pain. Varying degrees of residual pain at activity were however reported at final follow-up in half of the population, whereas most of the patients were pain free at rest.

Our study has limitations. The study lacks a control group, and the follow-up time is short- to medium-term. Since the latest follow-up registered was used in the study, the follow-up time for each case varied. The material consists of a heterogenic group of patients, with different indications for surgery. We have some missing data for radiographic evaluation and clinical evaluation, particularly regarding preoperative clinical evaluation. However, all preoperative and follow-up clinical evaluations were performed by experienced physiotherapists, and a single trained radiologist performed all radiographic reviews. As for the strengths of the study, this is to the best of our knowledge, the largest single center study on the Nexel TEA to date. We have attempted to paint as accurate a picture as possible of the state of the total population of patients operated with this implant at our institution, thus the choice of excluding only revision TEA and presenting clinical scores including for patients who died during follow-up and who underwent implant revision surgery. The surgery has been performed by a small group of surgeons with relatively consistent surgical technique yet allowing for custom accommodations to suit the individual case.

Conclusion

In this consecutive cohort of 101 elbows operated with Nexel TEA, there were 5 implant revisions, of which 2 were due to aseptic loosening. Additionally, radiographic signs of loosening were observed in 4 nonrevised elbows. Although complication and reoperation rates were relatively high, around 80% of cases achieved good or excellent results. Further long-term follow-up is required to determine the longevity of the implant.

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