■ SHOULDER AND ELBOW

Mid-term clinical results of a modern convertible total elbow arthroplasty

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Unlinked, linked and convertible total elbow arthroplasties (TEAs) are currently available. This study is the first to report the clinical results of the convertible Latitude TEA. This was a retrospective study of a consecutive cohort of 63 patients (69 primary TEAs) with a mean age of 60 years (23 to 87). Between 2006 and 2008 a total of 19 men and 50 women underwent surgery. The mean follow-up was 43 months (8 to 84). The range of movement, function and pain all improved six months post-operatively and either continued to improve slightly or reached a plateau thereafter. The complication rate is similar to that reported for other TEA systems. No loosening was seen. Remarkable is the disengagement of the radial head component in 13 TEAs (31%) with a radial head component implanted.

Implantation of both the linked and the unlinked versions of the Latitude TEA results in improvement of function and decreased pain, and shows high patient satisfaction at mid-term follow-up.

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The indications for total elbow arthroplasty (TEA) currently include advanced degenerative changes of the elbow due to rheumatoid disease (RhA) or osteoarthritis (OA) as well as complex fractures of the distal humerus in elderly patients or in those with post-traumatic arthritis.^{1,2}

In general, three types of TEA are available: unlinked devices, in which there is no linkage between the components; linked devices, which include an axle or link joining the humeral component to the ulnar component; and convertible devices, which can be used either as a linked or an unlinked version.¹¹ The native radial head can either be preserved, resected or replaced by a radial head component, depending on the status of the elbow joint, the surgeon's preference and the type of TEA.³

The Latitude (Tornier, Stafford, Texas) is a convertible TEA which can be used either as an unlinked or a linked version, depending on the integrity of the collateral ligaments and the amount of bone loss.⁴ The linked version is a 'sloppy-hinge' TEA with restricted freedom of movement in both valgus and varus directions. Biomechanical evaluation has shown that linking the Latitude results in increased valgus stability.⁵ Furthermore, it has been shown that in elbows with intact ligaments, and good bone stock, the radial head component contributes only slightly to the stability of the elbow.⁶ To the best of our knowledge, no clinical data on the Latitude TEA have been published.

The purpose of this study was to assess the mid-term clinical results of the convertible Latitude TEA. In addition, we sought to characterise the clinical improvement and investigated how patient factors, implant-related factors and surgical technique affected the clinical outcome.

Patients and Methods

We undertook a retrospective study of a consecutive cohort of patients who were treated using the Latitude TEA in two centres between 2006 and 2008. All patients who received a primary Latitude TEA for advanced arthritis of the elbow due to RhA, primary OA or post-traumatic deformities were included. There were 63 patients (18 men; 29% and 45 women; 71%) with 69 TEAs. Five women and one man underwent bilateral procedures. The mean age of the patients at the time of surgery was 60 years (23 to 87). There were 32 left-sided and 37 right-sided TEAs, and 38 involved the dominant side. The indication for surgery was RhA in 37 elbows (54%), primary OA in 14 (20%) and post-traumatic OA in 18 (26%) (Table I).

The pre-operative medical history was recorded and routine post-operative assessments were undertaken at six months, one year, and biannually thereafter. A physician-assistant (A.V.) who specialised in upper limb pathology recorded the clinical findings. The

Table I. Patient demographics, indication, and types of prostheses implanted

Patient demographics		n	(%)
Number of patients		63	
Number of prostheses		69	
Mean age (range)		60	(23 to 87)
Gender	Male	18	(29)
	Female	45	(71)
Side	Right	37	(54)
	Left	32	(46)
	Dominant	38	(55)
Indication	Primary osteoarthritis	14	(20)
	Rheumatoid arthritis	37	(54)
	Post traumatic arthritis	18	(26)
Type of prosthesis	Linked	57	(83)
	Unlinked	12	(17)
	Radial head component	42	(61)

Fig. 1a

Fig. 1b

Anteroposterior (AP) (a) and lateral (b) radiographs showing the zones used for the assessment of radiolucency: black for the humerus, red for the ulna, and yellow for the radius. Radiolucency around the radial head component is only assessed on the AP radiograph.

stability of the medial collateral ligament was assessed according to the opening of the joint space at 60° of flexion under valgus load (grade 0, no instability; grade 1, mild instability; grade 2, moderate instability; and grade 3, severe instability). Pain at rest and during activities was scored from 0 (no pain) to 10 (maximal pain) using visual analogue scales. Three questionnaires, the Elbow Functional Assessment Scale (EFAS),⁷ the functional Rating Index of Broberg and Morrey (FRIBM)⁸ and the Modified Andrews Elbow Scoring System (MAESS),⁹ were used to assess pain, range of movement, stability and function.

During each post-operative review the patients were asked whether they were satisfied with the outcome. They could only answer 'yes' or 'no'.

At each review, standard anteroposterior (AP) and lateral radiographs of the elbow were obtained and analysed for subsidence, peri-prosthetic fracture and (sub)luxation. Radiolucency in the zones shown in Figure 1 was recorded in millimetres. Heterotopic ossification was scored as described by Hastings and Graham.¹⁰

Surgical technique. Prophylactic intravenous antibiotics were given routinely before surgery. The operations were undertaken by two surgeons (MJV, 58 (84%) and DE, 11 (16%)). The components were introduced as described by Gramstad et al¹¹ and by Szekeres and King⁴ using a triceps-tongue technique. The ulnar nerve was routinely identified but not mobilised or transposed. The annular ligament was released from the ulna with a small chip of bone that could

easily be re-fixed with a transosseous suture, as described in the Wrightington approach.¹² In eight elbows an osteotomy of the medial epicondyle was performed to release the medial collateral ligament in order to dislocate the elbow. This was subsequently re-fixed using two non-absorbable sutures, as described by De Vos et al.¹³ In all other patients dislocation of the elbow was achieved by subperiosteal release of the medial collateral ligament.

Post-operatively the elbow was immobilised in a posterior splint in 90° of flexion for five days. Thereafter, the elbow was mobilised under supervision of a specialised physiotherapist, avoiding active extension for six weeks.

Statistical analysis. Descriptive statistics were used to summarise the data with numbers (percentages) or means with ranges where appropriate. Estimate regression parameters with standard error (SE) were reported. The primary outcome measures were the EFAS, FRIBM and MAES scores, as they are specific to the elbow and assess three important domains: movement, pain and function. Secondary outcome measures included flexion, extension-deficit, pronation and supination, pain at rest and during activity, and stability.

Paired Student's *t*-tests and Wilcoxon's signed ranks tests were used to assess the improvement between the pre-operative scores and those six months post-operatively. Linear mixed models were used to compare primary and secondary outcome measures at the different follow-up periods (six, 12, 36 and 60 months), adjusting for indication of surgery (RhA, primary OA or post-traumatic OA), constraint of the components, excision of the radial head, surgery on the dominant side, the presence of an osteotomy of the medial epicondyle, age, and baseline values of the respective outcome measures. Age at the time of surgery was dichotomised as either '< 60 years' or '≥ 60 years'. Missing data were assumed to be missing at random. Surgeon was included as a random factor, and a *p*-value < 0.05 was considered statistically significant. The statistical analyses were performed using R version 3.0.2. (R Foundation, Vienna, Austria).

Results

The mean follow-up was 43 months (8 to 84); for 58 TEAs follow-up was for more than two years. Of the 11 patients with follow-up of < two years, four (four TEAs) had died of unrelated causes and seven (seven TEAs) were lost to follow-up. The linked version was used in 57 TEAs (83%). A radial head component was used in 42 TEAs (61%). The linked version with a radial head component was used in 32 TEAs (46%) and an unlinked TEA without a radial head component was used in two TEAs (3%).

Range of movement. There was a significant improvement in the range of movement six months post-operatively compared with pre-operative values, except for supination. Using the range of movement six months post-operatively as a reference, after six months it either continued to improve slightly or reached a plateau. There were no statis-

tically significant improvements in the range of movement between the follow-up time points (Fig. 2).

It was only possible to identify a few predictors of an increase in range of movement. Patients with a reduced pre-operative range of movement had a significantly reduced post-operative range of movement (flexion (coefficient 0.2; SE 0.05, *p* < 0.001), extension-deficit (coefficient 0.2; SE 0.09, *p* = 0.04), pronation (coefficient 0.2; SE 0.07, *p* = 0.005), and supination (coefficient 0.5; SE 0.08, *p* < 0.001). An osteotomy of the medial epicondyle was associated with a higher mean post-operative flexion (coefficient 7.4; SE 3.3, *p* = 0.030), and surgery on the dominant side with reduced supination (coefficient -12.8; SE 4.6, *p* = 0.007). Age, indication, RhA, constraint of the prosthesis and implantation of a radial head component did not significantly influence post-operative function.

Pain. There was a significant improvement in the mean pain scores six months post-operatively compared to the pre-operative values (Table II). Using the mean pain scores six months post-operatively as a reference, the scores either continued to improve slightly or reached a plateau thereafter. There were no statistically significant improvements in the mean pain scores between the follow-up time points (Fig. 2). None of the covariates showed any significant effect on the post-operative pain scores.

Function. There was a significant improvement in the functional scores six months post-operatively (Table III). Using the functional scores six months post-operatively as a reference, the scores either continued to improve slightly or reached a plateau thereafter. However, there were no statistically significant improvements in functional scores at all further post-operative follow-up moments (six, 12, 36 and 60 months), adjusting for indication of surgery (RhA, primary OA or post-traumatic OA), constraint of the components, excision of the radial head, surgery on the dominant side, the presence of an osteotomy of the medial epicondyle, age, and baseline values of the respective outcome measures (Fig. 2).

It was only possible to identify a few predictors of improvement in functional scores. Patients with a higher pre-operative EFAS score had a significantly higher post-operative EFAS score (coefficient 0.2; SE 0.09, *p* = 0.03). Baseline FRIBM and MAESS scores did not predict post-operative functional scores. Using a radial head component resulted in higher functional scores (EFAS (coefficient 9.8; SE 3.7, *p* = 0.01), FRIBM (coefficient 9.7; SE 3.1, *p* = 0.003), and MAESS (coefficient 10.7; SE 3.6, *p* = 0.004). In addition, an osteotomy of the medial epicondyle was associated with higher post-operative EFAS (coefficient 11.3; SE 5.3, *p* = 0.04) and FRIBM (coefficient 9.5; SE 4.3, *p* = 0.03) scores. Age, indication, RhA and constraint of the prosthesis did not significantly influence the functional outcome.

Stability. A total of 19 elbows (27.5%) had grade 2 or 3 instability. In 14 of these RhA was the indication for surgery, and in 17 a linked version was used. In 40 of the remaining 50 elbows a linked version was used.

Fig. 2a

Fig. 2b

Fig. 2c

Fig. 2d

Graphs showing the mean values (95% confidence intervals) for a) the flexion, b) the extension-deficit, (c) the functional rating index of Broberg and Morrey⁸ (FRIBM) and d) the visual analogue score (VAS) 60 months post-operatively for the whole group. The mean flexion and FRIBM increase and then stabilise. The mean VAS action and the extension-deficit decrease and then stabilise.

The mean scores for stability six months post-operatively were not significantly improved compared with the pre-operative values ($Z = -2.1$, $p = 0.2$), and there was no statistically significant improvement in stability scores between the follow-up time points, using the scores six months post-operatively as a reference. Elbows with a higher mean baseline valgus stability showed significantly higher valgus stability scores post-operatively (coefficient 0.2; SE 0.09, $p = 0.02$). An osteotomy of the medial epicondyle was associated with a higher mean post-operative stability score (coefficient 0.6; SE 0.2, $p = 0.02$). Age, indication, RhA and constraint of the prosthesis did not significantly influence post-operative stability.

Radiographic analysis. The number and sites of the radiolucencies are shown in Table III. Those around the humeral component were seen in zones 1 and 5 (Fig. 1) and were all < 1 mm wide. Those around the ulnar component were all around the proximal body, in zones 1 and 3, and were all

< 2 mm wide. Those around the radial head were only seen just below the collar, in zones 1 and 3, and were all < 1 mm wide. All immediate post-operative radiographs showed an intact radial head component, but in 13 elbows it subsequently became disengaged (Fig. 3).

The disengagement did not statistically significantly influence the outcome. In none of the elbows with disengagement was there radiolucency around the radial head component. Pain was the indication for revision surgery in only one of the elbows with disengagement of the radial head; three months later it disengaged again and was removed.

The osteotomies of the medial epicondyle all united satisfactorily.

Complications

The complications are shown in Table III. In six out of nine elbows with a sensory neuropathy this resolved within a

Table II. The clinical outcome at different post-operative intervals. Values given as mean (range) unless stated otherwise

	Pre-operative	Post-operative				p-value
	Baseline	6 months	12 months	36 months	60 months	
Flexion (°)	115 (20 to 150)	126 (95 to 145)	129 (110 to 145)	128 (100 to 145)	128 (110 to 140)	< 0.001
Extension-deficit (°)	33 (0 to 90)	25 (0 to 65)	27 (0 to 75)	25 (0 to 65)	19 (0 to 50)	0.03
ROM (°)	82 (0 to 150)	101 (30 to 130)	102 (40 to 145)	103 (45 to 135)	109 (65 to 135)	< 0.001
Pronation (°)	62 (0 to 90)	72 (30 to 90)	69 (20 to 90)	72 (35 to 90)	70 (10 to 90)	0.004
Supination (°)	53 (-10 to 90)	59 (-20 to 90)	60 (-20 to 90)	59 (-35 to 90)	65 (10 to 90)	0.3
VAS rest*	3.4 (0 to 10)	0.6 (0 to 5.5)	0.4 (0 to 3.5)	0.5 (0 to 6.0)	0.1 (0 to 1.5)	< 0.001
VAS activity*	6.5 (0 to 10)	1.4 (0 to 7.0)	1.1 (0 to 8.0)	1.1 (0 to 9.0)	0.9 (0 to 7.0)	< 0.001
EFAS	49 (5 to 93)	77 (30 to 98)	81 (35 to 100)	81 (31 to 100)	79 (52 to 98)	< 0.001
FRIBM	55 (23 to 105)	74 (41 to 99)	76 (46 to 95)	77 (48 to 100)	79 (44 to 104)	< 0.001
MAESS	47 (15 to 100)	80 (20 to 100)	79 (40 to 100)	78 (30 to 100)	85 (60 to 100)	< 0.001
Stability**	0 (0 to 3)	1 (0 to 3)	1 (0 to 2)	1 (0 to 3)	1 (0 to 3)	0.2

VAS, visual analogue score; ROM, range of movement; EFAS, elbow functional assessment scale; FRIBM, functional Rating Index of Broberg and Morrey; MAESS, modified Andrews elbow scoring system. P-values were derived using paired Student's *t*-test and Wilcoxon's signed rank test used to assess the improvement between the pre-operative scores and those six months post-operatively.

* Wilcoxon's signed rank test

† median (range)

Table III. Complications

Complication	n (%)	Diagnosis (RA/POA/PTA)
Neurological		
Sensory	9 (13)	(3/3/3)
Motor	2 (3)	(0/1/1)
Disengagement of the radial head component*	13 (31)	(8/5/0)
Infection	3 (4)	(3/0/0)
Fracture of the humerus	1 (1)	(1/0/0)
Ulnar fracture	2 (3)	(1/1/0)
Instability	2 (3)	(2/0/0)
Radiolucency		
Humeral	4 (6)	(2/2/0)
Ulnar	3 (4)	(1/2/0)
Radial*	2 (5)	(1/1/0)
Loosening	0 (0)	-
Heterotopic ossification	0 (0)	-
Triceps problems	0 (0)	-

* The percentage of disengagements of the radial head component and the percentage of radiographs with radiolucency around the radial head component is calculated from the 42 elbows in which a radial head component was inserted. All other percentages are calculated based on the 69 elbows included in the study. The right column shows the distribution of the complications according to the indication for surgery

year. There was a combined sensory and motor deficiency of the ulnar nerve in two elbows. In one of these the motor deficiency resolved within two years, leaving a slight sensory deficit. In the other, decompression of the ulnar nerve was performed without symptomatic improvement. All three deep infections were managed by extensive lavage and antibiotic therapy. One of the ulnar fractures was identified peri-operatively and was treated with a cerclage wire, with subsequent satisfactory union. The other was noted post-operatively and was managed conservatively and healed unremarkably. One of the humeral fractures involved the medial epicondyle and was fixed with a Kirschner wire and healed satisfactorily. In two elbows with significant instability about three years post-operatively an ulnar cap was introduced to link the components, resulting in decreased pain scores and improved satisfaction. The stability, however, improved in only one.

Satisfaction. A total of four patients (four TEAs, 6%) were not satisfied with the outcome six months post-operatively; three of these patients subsequently became satisfied. In the patient who remained dissatisfied, the radial head disengaged five months post-operatively and again after revision surgery. There were three patients who were 'not satisfied' during later follow-up, having been satisfied six months post-operatively. In one of these the elbow was unstable 31 months post-operatively. An ulnar cap was introduced to link the components, with a satisfactory outcome. One other patient had a combined motor and sensory ulnar neuropathy, as described above.

Discussion

The biomechanical properties of the Latitude TEA are well documented.^{5,6} To the best of our knowledge, this study is the first to report the clinical results.

Fig. 3a

Fig. 3b

Radiographs showing a) disengagement of the radial head component (arrow) and b) an intact radial head component.

In up to 65% of the early papers describing the outcome after TEA RhA was the indication for surgery.¹⁴ The indications have since changed.^{1,15-19} Advances in the medical management of RhA have led to a decrease in joint destruction and, together with advances in implant design, TEA is now often used in post-traumatic conditions and in patients with primary OA.^{1,17} In this study RhA was the indication in 54% of the patients. This relatively high proportion might be due to the fact that one of the clinics in this study is a referral centre for rheumatoid patients. RhA can lead to loss of bone stock and impairment of the collateral ligaments, leading to instability of the elbow. Thus, grade 2 or 3 valgus instability was found in 14 elbows (33%) with RhA, and in only four elbows (15%) without RhA. A linked version of the TEA was used in 17 (89%) of the elbows with grade 2 or 3 valgus instability pre-operatively. The use of a high percentage of linked TEAs in unstable elbows appears logical. However, surprisingly, a linked version was also used in 40 (80%) of the elbows with grade 0 and 1 instability pre-operatively. The assessment of stability pre-operatively does not appear to correlate with the intra-operative findings. This might be due to ankylosis of the elbow joint, which contributes to the pre-operative stability. Linking the TEA is performed at the end of the operation. After insertion of the components the valgus and varus stability of the unlinked TEA are assessed manually through the range of flexion, and linking is undertaken if there is significant instability. Bassi et al.²⁰ reported the early results of another modular TEA, the Acclaim (DePuy Orthopedics Inc., Warsaw, Indiana). An unlinked version was used in 34 of 36 elbows. Two of the unlinked TEAs (5.9%) required revision for instability. The high percentage of unlinked TEAs that were used compared

to our study might reflect a different intrinsic constraint within the design.

Our findings confirm that the Latitude TEA improves the function of the elbow and reduces pain, and overall patient satisfaction is high. The mean range of movement obtained was similar to that with other commonly used TEAs (Coonrad-Morrey (Zimmer, Warsaw, Indiana),²¹⁻²⁴ Acclaim (DePuy Orthopedics Inc, Warsaw, Indiana),²⁰ Souter-Strathclyde (Stryker Howmedica Osteonics, Limerick, Ireland)^{22,25} and Kudo (Biomet Inc, Warsaw, Indiana).^{22,26}

In order to achieve dislocation of the joint, an osteotomy of the medial epicondyle as described by De Vos et al¹³ was performed in eight elbows. Although statistical analysis showed a significant difference with a mean of 0.5 points more valgus instability in the patients with an osteotomy, we do not think this is clinically relevant. Radiological analysis showed union of the osteotomy in all elbows. Osteotomy of the medial epicondyle contributes to the ease of dislocation, especially when identification of the medial collateral ligament is difficult, as in post-traumatic OA or RhA.

A total of 11 patients were lost to follow-up. We chose not to exclude these patients from the statistical analysis as the study group was a consecutive cohort of patients undergoing surgery during a period of three years.

Advances in implant design and operating technique in TEA have reduced rates of complication, but the incidence is still considerably higher than with arthroplasty of the hip and knee. A recent large systematic review²⁷ reported an overall complication rate of 24.3% in primary TEA, and in other studies^{18,26-29} complication rates of up to 45% have been described. Long-term complications include aseptic

loosening, dislocation, ulnar neuropathy and infection. Peri-operative complications, such as peri-prosthetic fractures, delayed wound healing, infection, pulmonary embolism and death,^{15,30} are less commonly seen. In this study the rate of complication was comparable to those described previously. One of the major complications is aseptic loosening due to high torsional loads to the bone–cement and cement–prosthesis interfaces, or to osteolysis related to debris from cement or polyethylene wear. Voloshin et al²⁷ reported a small but statistically significant difference in the rate of aseptic loosening between linked and unlinked TEAs (13.7% and 10.1%, respectively, $p < 0.05$). This should favour the unlinked version where possible, and a higher percentage of unlinked TEAs in this study might be expected. In contrast to studies involving other TEAs, no aseptic loosening was seen at mid-term follow-up in our patients.

The importance of the radial head in axial load-bearing and valgus stability has been emphasised in the native elbow. In elbows with insufficiency of the medial stabilising structures the contribution of the radial head to valgus stability increases.^{31–33} Depending on the amount of flexion, axial loads of up to 60% pass through the radiohumeral joint.³⁴ Since the introduction of the Latitude TEA, the role of the radial head in providing valgus stability in patients with an intact medial collateral ligament seems limited.^{5,6} As the integrity of the medial structures is often impaired, we reconstruct the radiohumeral joint by implanting a radial head component. The decision to use this component is usually made at the beginning of the operation, and is influenced by the integrity of the bone of the radius and of the annular ligament. A remarkable finding in this study was the disengagement of the radial head component in 13 patients (31%) (Fig. 3). The bipolar radial head component of the Latitude TEA has a snap-fit metal articulation that permits 10° of valgus/varus movement. The disengagement is usually best seen on a standard lateral radiograph, showing the round taper of the base component, which is cemented in the radius. In two patients the ‘disengaged’ radial head was subsequently ‘engaged’ on standard radiographs. Few authors have described disengagement of a bipolar radial head prosthesis.^{35–39} The disengagement did not affect the outcome and these patients were closely followed without intervention. The functional scores that were used might not be sensitive enough to assess the effect of disengagement of the radial head component. Theoretically, disengagement could lead to increased polyethylene wear and loosening. This, together with the findings in previous biomechanical studies^{5,6} showing that implantation of a radial head component contributes only minimally to the stability of the elbow, might suggest that the bipolar radial head component of the Latitude TEA need not be used, and that, when possible, leaving the native radial head in place should be favoured. We extensively analysed the cause of disengagement of the radial head component, but could not identify it. Theoretically, a designer’s error, or limited resection of the radius with high placement of the

radial head, allowing the annular ligament to separate from the head, could be the cause of the disengagement. We still use a radial head component and, with the late adjustments of the aiming devices for resection of the radius, hope to overcome the problem of disengagement.

A limitation of this study is the absence of data on the body mass index (BMI) of the patients. The potential adverse influence of a high BMI on the survival of primary TEA was recently reported by Baghdadi et al.⁴⁰ In a study including 723 primary, semi-constrained TEAs, they reported that a high BMI causes statistically significant increased failure due to mechanical and aseptic loosening ten and 15 years post-operatively, whereas no difference is seen five years post-operatively. In our study, at a mean follow-up of 43 months no loosening was seen, and therefore loosening could not be correlated to a high BMI; the follow-up might be too short to draw a conclusion.

Other limitations to the study include its retrospective nature and the fact that follow-up for 11 patients was less than two years; also, in eight patients a slightly different surgical approach was used.

In conclusion, satisfactory mid-term results are obtained when using both the linked and unlinked versions of the Latitude TEA, with high levels of patient satisfaction. The post-operative function of patients with a Latitude TEA is comparable to that with other total elbow systems with similar complication rates, although no aseptic loosening has been seen so far.

Author contributions:

M. L. Wagener: Data collection, Data analysis, Writing the paper.

M. J. de Vos: Surgeon, Writing the paper.

G. Hannink: Statistical analysis, Writing the paper.

M. van der Pluijm: Data collection, Writing the paper.

N. Verdonchot: Data analysis, Writing the paper.

D. Eygendaal: Surgeon, Data analysis, Writing the paper.

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