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Micromotion of the Souter-Strathclyde total elbow prosthesis in patients with rheumatoid arthritis

21 elbows followed for 2 years

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ABSTRACT – 21 elbows in 18 patients with rheumatoid arthritis were treated with a Souter-Strathclyde total elbow prosthesis. 18 elbows were included in a radiostereometry (RSA) study. The aim of this clinical RSA study was to assess the three-dimensional micromotion pattern of the Souter-Strathclyde prosthesis, and thereby gain insight in the aseptic loosening process of this prosthesis. Implants were defined as at risk of aseptic loosening when the translation rate during the second postoperative year was more than 0.4 mm along one or more coordinate axes and/or the rate of rotation was more than 1° about one or more coordinate axes.

Clinical examination revealed an increase in the range of motion and a marked reduction in pain. The RSA showed that 8 of 18 humeral components were at risk of aseptic loosening, although no signs of such loosening—defined as a complete radiolucent line of 2 mm or more—were found on the plain radiographs. In 7 humeral components, an anterior tilt about the transverse axis was seen that resulted in an anterior translation of the proximal tip and a posterior translation of the component's trochlea. Long-term studies of the Souter-Strathclyde prosthesis, have shown that this rotation is a specific pattern of failure in some implants. None of the ulnar components was at risk for aseptic loosening.

Improvements in fixation of the Souter-Strathclyde total elbow arthroplasty should focus on the humeral component. At present, the lateral flange of the implant is enlarged to improve rotational stability about the transverse and longitudinal axes. The effect of this change in design on micromotion of the Souter-Strathclyde total elbow prosthesis will be studied in a randomized RSA study comparing the new design to the existing one.

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Total elbow arthroplasty has become a well-accepted treatment for the arthritic elbow joint. Although it relieves pain and improves function, loosening of the humeral component is of concern (Pöll 1994).

In 1991, we studied 34 rheumatoid elbows which had been treated with a Souter-Strathclyde total elbow prosthesis (Pöll and Rozing 1991). After a follow-up of 4 (2–8) years, 5 implants were radiologically loose and 2 had to be revised. In a more recent study (Rozing 2000), a cohort of 66 patients was followed for 7.5 (5–12) years. In this group, 16 prostheses were revised, 8 (12%) of them for aseptic loosening. In addition, 4 elbows were radiologically loose, making a total of 12 cases of aseptic loosening. On the basis of these two studies, we conclude that the revision rate in total elbow arthroplasty is high and that it strongly increases with longer follow-up.

An explanation of the high revision rate may be that this type of implant is mainly used in patients suffering from severe rheumatoid arthritis with poor bone stock. Another explanation may be that the design of the implants does not provide adequate fixation in the bone.

Radiostereometric analysis (RSA) is an accurate method for studying fixation of implants by measuring micromotion (Selvik 1989, Kärrholm et al. 1997, Valstar 2001). In two clinical RSA studies (Kärrholm et al. 1994, Ryd et al. 1995), a correlation between excessive micromotion within the first 2 years postoperatively and revision of the implants as a result of aseptic loosening at the 10-year follow-up was found for total hip and total knee prostheses.

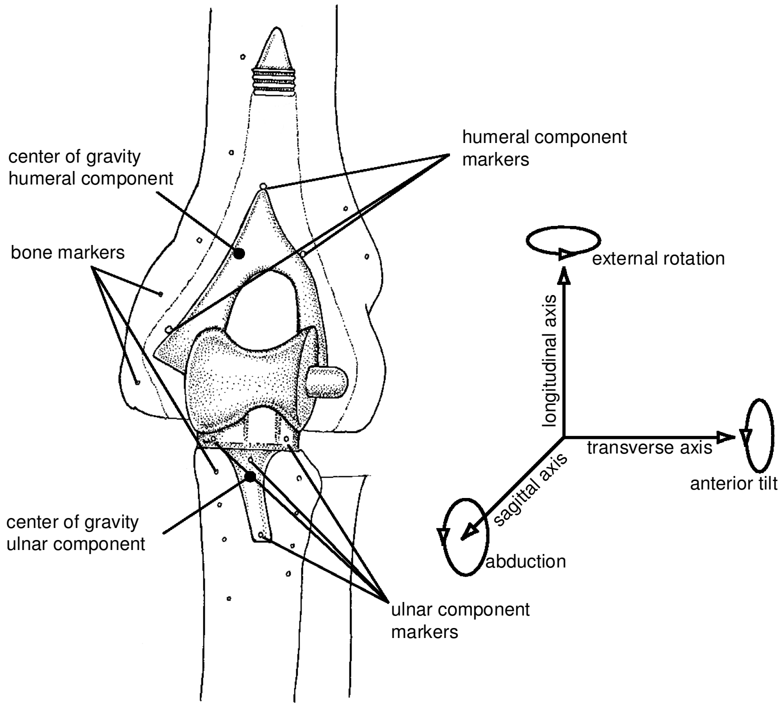

Figure 1. A Souter-Strathclyde total elbow prosthesis in situ. Note the humeral component which has Vitallium markers attached and the tantalum markers inserted in the humerus and ulna. The center of gravity of the markers in the humeral and ulnar component are indicated. In this anterioposterior view, the local humerus and ulna coordinate systems are similar, therefore only one coordinate system is shown. Positive directions of translations along the coordinate axes are medial-lateral (transverse axis), distal-proximal (longitudinal axis), and posterior-anterior (sagittal axis). Positive directions of rotations are anterior tilt (transverse axis), external rotation (longitudinal axis), and abduction (sagittal axis).

We assessed the three-dimensional micromotion pattern of the Souter-Strathclyde prosthesis, to gain insight in how aseptic loosening occurs with this prosthesis. This may provide a basis for modifying the prosthesis and thereby preventing early migration and subsequent aseptic loosening.

Patients and methods

18 patients with rheumatoid arthritis (14 females) underwent total elbow arthroplasty and participated in this study. In 3 patients, a bilateral procedure was performed. Thus, a total of 21 (11 right) elbows were included. Our institution's ethics committee approved the study and the patients gave their informed consent.

The average age of the patients was 63 (49–79) years. 4 elbows had previously been subjected to synovectomy. The radiographic destruction at the humero-ulnar joint was grade 4 in 8 elbows and grade 5 in 13 elbows with Larsen et al.'s method (1977).

All patients received a Souter-Strathclyde total elbow prosthesis (Stryker Howmedica Osteonics, Kalamazoo, MI, USA) which consists of a humeral component of Vitallium and an ulnar component of high-density polyethylene. In one case, where the olecranon and coronoid face were severely damaged, we used a semi-constrained metal-backed ulnar component. The senior author (PMR) implanted the prostheses in accord with the designer's instructions. Prophylactic intravenous antibiotics were given routinely. The cut bone surfaces were mechanically pulse-lavaged with a device manufactured by Zimmer (Warsaw, IN, USA), before applying Palacos bone cement (Schering, Kenilworth, NJ, USA).

The manufacturer prepared the implants used in this RSA study (Figure 1). 3 2-mm Vitallium markers were attached to the metal of the humeral component and 4 0.8-mm tantalum markers were inserted into the polyethylene of the ulnar component. A specially designed instrument was used to insert 3–8 1-mm tantalum markers into the humerus and ulna. These markers defined a local coordinate system in relation to which the motion of the implant was calculated.

The patients were evaluated preoperatively and at 1 week, 3 weeks, 6 weeks, 3 months, 6 months,

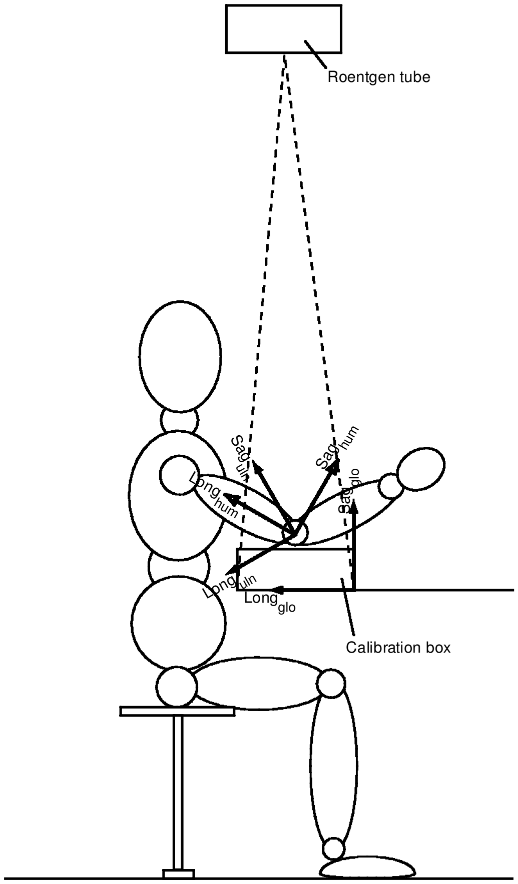

Figure 2. The RSA set-up from a lateral view. The longitudinal and sagittal axes of the coordinate systems are indicated: ($Long_{glo}$, Sag_{glo}) of the global coordinate system, as defined by the calibration box; ($Long_{hum}$, Sag_{hum}) of the humeral coordinate system; and ($Long_{uln}$, Sag_{uln}) of the ulnar coordinate system.

1 year, and 2 years postoperatively. At each evaluation, the clinical status was assessed and radiographs for RSA were made. Immediately after the operation, at the 1-year and 2-year follow-ups, standard anteroposterior and lateral radiographs were also taken.

The RSA set-up consisted of two synchronized roentgen tubes positioned at about 1.5 m above the roentgen film, with each roentgen tube aimed at one half of the film (total area of the film, 24 by 30 m). The angle of each roentgen tube with the vertical was 20º. The roentgen film was simultaneously exposed with both roentgen tubes. A calibration box was placed beneath the patient's elbow (Figure 2). This box had tantalum markers placed in the plane adjacent to the film (fiducial markers) and in the plane distant from the film (control markers). The locations of the box markers, accurately smeasured with a mechanical measuring device that had an accuracy of 0.001 mm, defined the global coordinate system and were used to assess the roentgen foci positions.

Since all elbows, except one, had a flexion contracture, the coordinate systems of the humerus and ulna were not parallel to the global coordinate system as defined by the calibration box, but both coordinate systems had an angle with the global coordinate system that was equal to half the flexion contracture. In this study, the largest angle between the global coordinate system and each of the local coordinate systems was 25°, and the median angle was 13.5°. To present the data in an unambiguous manner, the translations and rotations of both prosthesis components are expressed in the local humerus and ulna coordinate systems (Figure 2). The centers of gravity of both sets of prosthesis markers defined the origin of these coordinate systems (Figure 1). Positive directions for translations along the coordinate axes were medial-lateral (transverse axis), distal-proximal (longitudinal axis), and posterior-anterior (sagittal axis). Positive directions for rotations about the coordinate axes were anterior tilt (transverse axis), external rotation (longitudinal axis), and abduction (sagittal axis).

With a Vidar VXR-12 scanner (Vidar, Lund, Sweden), the radiographs were scanned at 150 dots per inch resolution and 8-bit gray scale resolution. The measurement of marker coordinates in the digitized radiographs, the three-dimensional reconstruction of the marker positions, and the micromotion analysis were done with RSA-CMS (MEDIS, Leiden, The Netherlands), a software package that automatically performs the RSA procedure on digitized or digital radiographs (Vrooman et al. 1998, Valstar et al. 2000, Valstar 2001).

To assess micromotion of the implant with high accuracy, the bone markers must be well fixed in the bone. Bone markers were regarded as unstable when they moved more than 0.3 mm in relation to the other bone markers and were not included in the analysis.

In most RSA studies (Nilsson et al. 1991, Kärrholm et al. 1994, 1997), the accuracy of micromo-

Table 1. Accuracy of RSA measurements based on repeated scanning and measurement of the first postoperative RSA radiograph of each elbow (translations: n 18; rotations humerus n 10; rotations ulna n 5). Numbers are the upper limits of the 95% confidence intervals (1.96 × Standard Deviation)

	Translation, mm			Rotation, degrees		
	transverse	longitudinal	sagittal	transverse	longitudinal	sagittal
Humeral	0.13	0.14	0.34	0.56	0.43	0.23
Ulnar	0.15	0.05	0.17	0.68	0.34	0.16

tion measurements is assessed with double examinations—i.e., radiographs are taken twice on one of the follow-up examinations. Apart from errors in measurement, changes in positions of the patient and of the roentgen tube are taken into account. It is better than methods that only use repeated scanning and analysis of radiographs, which overestimate the accuracy of the measurements. However, our institution's ethics committee did not grant us permission to use the double examination method, and we therefore did repeated scanning and analysis of the first postoperative RSA radiographs of adequately marked elbows. The upper limits of the 95% confidence intervals are shown in Table 1.

If the bone-cement interface is good, a cemented prosthesis should be stable and such an implant should not be at risk of aseptic loosening. In an RSA study by Ryd et al. (1995), a micromotion rate of 0.2 mm or more during the second postoperative year was shown to predict loosening of total knee implants at a 10-year follow-up. This is the first RSA study of total elbow arthroplasties and the predictive value of RSA must still be determined. However, to help assess the number of implants at risk of aseptic loosening, we divided implants into those at risk and those not at risk of aseptic loosening. Implants were placed in the former group when the micromotion rate during the second postoperative year exceeded the accuracy of the RSA measurements. When the translation rate during the second post-operative year was more than 0.4 mm along one or more coordinate axes and/or the rotation rate exceeded 1° about one or more coordinate axes, implants were regarded as at risk of loosening.

Results

Clinical results

The preoperative and postoperative range of motion of the elbow are given in Table 2. All postoperative measurements were made at the 2-year follow-up, except in 5 patients. In 1 patient, the elbow luxated 1 year after surgery and therefore the ulnar component was changed to a snap-fit type. In another, the elbow was infected with Haemophilus influenzae and the implant was removed after 3 months. 1 patient died after 3 months from causes unrelated to the operation, 1 was unable to return to the hospital because of a malignant tumor after 6 weeks, and 1 refused to return since the study was regarded as too exhausting after 1 year. Another patient fractured the humerus 6 weeks postoperatively after a fall on the arm. The fracture was about 10 cm proximal from the tip of the humeral component and was fixated by an allograph and a plate. The follow-ups of this patient were continued in the usual way.

The average motion in flexion ranged from 42° to 117° before operation vs. 27° to 131° after operation—i.e., an improvement of 29°; a reduction of 15° in flexion deformity and an increase of 14° in

Table 2. Preoperative and postoperative range of motion (n 21; in °). All postoperative data were determined at the 2-year follow-up, except in 5 patients who had a shorter follow-up

	Flexion deformity		Flexion		Pronation		Supination	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Mean	42	27	117	131	60	74	32	48
Min	20	0	50	90	20	30	–45	0
Max	70	50	135	150	90	90	90	80

flexion. The mean pronation and mean supination were 60° and 32°, respectively, before operation vs. 74° (an increase of 14°) and 48° (an increase of 16°), respectively, at the 2-year follow-up.

Preoperatively, all patients had moderate or severe pain in the elbow. After surgery, 3 patients complained of mild pain and 3 occasional pain.

Radiographic findings

On the plain radiographs, we found no signs of loosening, such as migration or a complete radiolucency of 2 mm or more. 2 patients had a complete radiolucency of less than 1 mm about the humeral component. 2 elbows showed a partial radiolucency of less than 1 mm at the distal tip of the humeral component and in one humeral component, a partial radiolucency about the supracondylar ridges was found.

No radiolucent lines were seen about the shaft of the ulnar components. In the area of the coronoid face, a complete radiolucency of less than 1 mm was present in 6 ulnar components, and a partial radiolucency of less than 1 mm was noted in 4 components. This is probably because cement cannot be well pressurized in this area. In the deep olecranon region, 2 ulnar components showed a complete radiolucency of less than 1 mm and 6 components a partial one.

RSA results

We encountered some problems with marking the humerus and ulna. In a few cases, less than 3 markers were used to mark the bone, so rotations could not be calculated. In some others, markers were not well spread or they could not be seen because of overprojection, or were unstable and had to be excluded from the analysis. In the humerus, a total of 10 unstable markers were excluded from the analysis and in the ulna, a total of 6 unstable markers were excluded.

It proved difficult to obtain an appropriate marker distribution, especially in the ulna, since they could not be placed far enough away from the ulnar central axis since it is a tubular bone of small diameter. In the humerus, this was less of a problem since they could be introduced into the epicondyles.

18 elbows were included in the RSA analysis. 3 elbows with a follow-up of 3 months or less were excluded from the analysis. Translations could be assessed for all humeral components included and for 15 ulnar components. The metal-backed ulnar component had no markers in the polyethylene and was 1 of the 3 components for which the translations could not be assessed. At the 1-year follow-up, rotations could be calculated for 10 humeral components and at the 2-year follow-up, due to unstable markers, this number was reduced to 8. At the 2-year follow-up for 5 ulnar components, rotations could be determined. Since the markers could not be scattered away from the longitudinal axis, rotations of the ulnar components about this axis were sensitive to measurement errors and could not be assessed reliably in all cases.

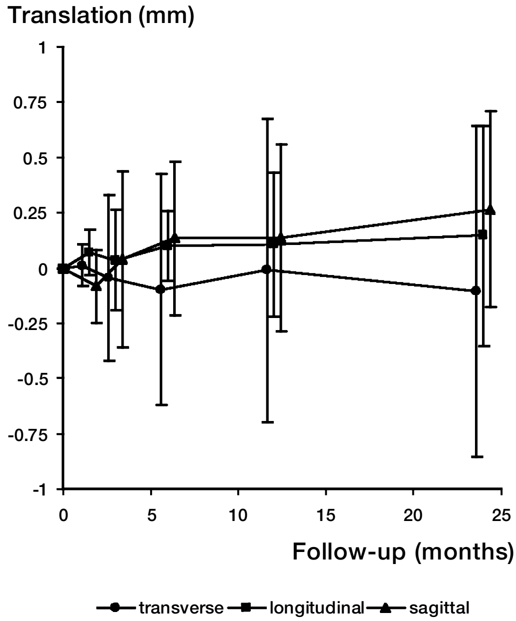

Figure 3. Translation of the humeral components along the three coordinate axes (n 18, mean ± standard deviation).

Humeral components

Initially, all humeral components migrated (Figure 3), but after 1 year most implants stabilized. However, the translation of 6 humeral components did not stabilize during the second postoperative year. During that time, all of these components translated more than 0.4 mm along one or more of the coordinate axes. On the plain radiographs, 5 of these patients had no radiolucency about the humeral component, but 1 had a partial radiolucency at the

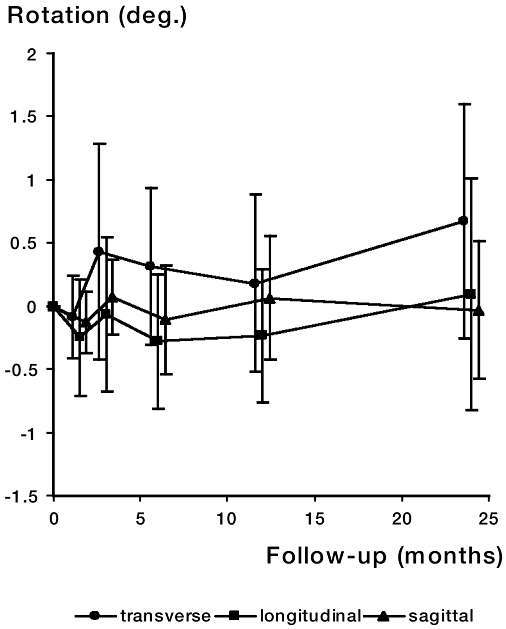

Figure 4. Rotation of the humeral components around the three coordinate axes (n 8; mean ± standard deviation).

supracondylar ridges. The maximal translation of any humeral component was 2.68 mm along the transverse axis, –1.14 mm along the longitudinal axis, and 1.01 mm along the sagittal axis.

Along the longitudinal axis, the main direction of translation was the distal-proximal one. In 7 of 8 components that had significant translations along the sagittal axis, the translation of the center of gravity of the markers was directed anteriorly. This translation may have been due to rotation about the transverse axis.

The patient with the fractured humerus had a translation of –0.30 mm along the transverse axis, –0.28 mm along the longitudinal axis, and 0.71 mm along the sagittal axis. The sagittal translation was the second largest translation about that axis found in this study and, although it was thought that the impact that caused the fracture would not have affected fixation of the humeral component, it did. Unfortunately, rotations of this implant could not be assessed.

Rotations of the humeral component could be evaluated in 8 elbows at the 2-year follow-up (Figure 4). In 7, the humeral component rotated in a positive direction about the transverse axis. In 2 other humeral components with only a 1-year follow-up, positive rotation about the transverse axis was also found. This rotation causes the proximal tip of the component to translate in an anterior direction and the trochlea of the component to translate posteriorly. In general, rotations about the transverse and longitudinal axes were larger than those about the sagittal axis.

Both humeral components with a complete radiolucency of 1 mm, had translated slightly, but had the largest rotations in this study. The first patient had the largest rotations about the transverse and longitudinal axes after 1 year, 1.17° and –1.04°, respectively. In the other patient, at the 2-year follow-up, the humeral component rotated about the three coordinate axes with 1.60°, –1.39°, and –0.67°, respectively. The rotation about the transverse axis was the largest in this study and the rotations of this component did not stabilize during the second postoperative year. At the 2-year follow-up, one of the two humeral components with a partial radiolucency at the distal tip had the second largest rotation about the transverse axis (1.71°) and the other one had the largest rotation about the longitudinal axis (1.54°). Both components did not stabilize in the second postoperative year, but rotated more than 1° during that period. Unfortunately, we could not determine the rotations of one of the components that had a partial radiolucency in the supracondylar ridges. However, these findings seem to indicate that there is a relation between radiolucency and rotation of the implants.

Ulnar components

Although more radiolucent lines were found about the ulnar components, micromotion of these implants was less marked than of the humeral components (Figure 5). The translations of the ulnar components were small compared to those of the humeral components. The largest translations were 0.38 mm, 0.32 mm, and 0.26 mm, respectively, along the 3 coordinate axes. Unlike the humeral components, all ulnar components stabilized after initial migration.

We calculated the rotation of 5 ulnar components. The maximal rotations of the ulnar components were –0.60° about the transverse axis, –1.10° about the longitudinal axis, and 0.73° about the sagittal axis. (Figure 6). During the second post-opera-

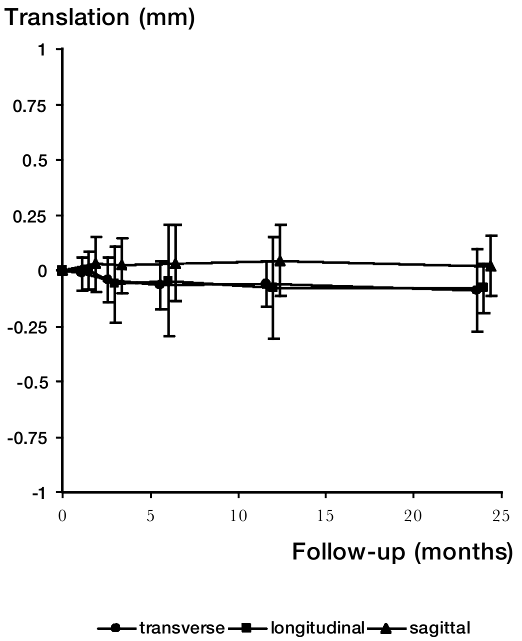

Figure 5. Translation of the ulnar components along the three coordinate axes (n 15; mean ± standard deviation).

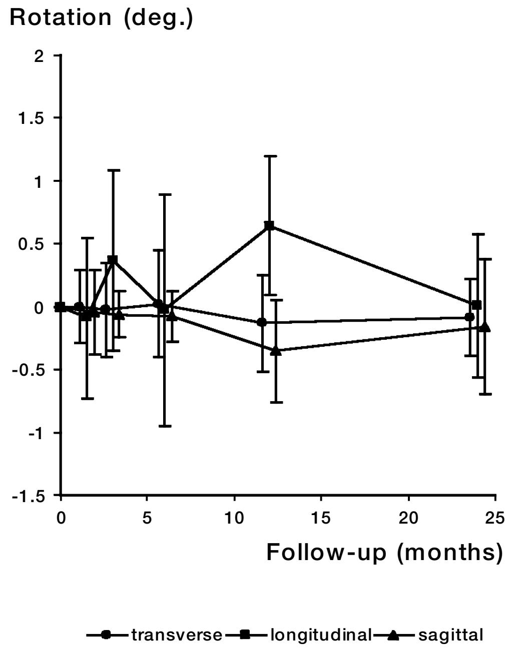

Figure 6. Rotation of the ulnar components around the three coordinate axes (n 5; mean ± standard deviation).

tive year, the rotation of all components about the transverse and sagittal axes stabilized. However, the rotations of none of the components about the longitudinal axis did not stabilize. The rotation rate was between 0.3° and almost 1° during the second postoperative year. This is probably due to problems with adequate marking of the ulna.

Discussion

After the arthroplasty, most patients became free of pain and the range of motion increased. These findings accord with those reported in studies of unconstrained total elbow arthroplasty (Kudo and Iwano, 1990, Pöll and Rozing 1991, Ewald et al. 1993, Pöll 1994, Lyall et al. 1994, Sjödén et al. 1995, Rozing 2000). The radiographs showed no loosening of any humeral or ulnar component when we defined loosening as a complete radiolucency of 2 mm or more. This also accords with results of other studies with a limited follow-up (Pöll and Rozing 1991, Ruth and Wilde 1992, Ewald et al. 1993, Lyall et al. 1994).

However, because of the high accuracy of RSA, we found continuous translation of 6 of the 18 humeral components and rotations of 3 humeral components which also did not stabilize. This resulted in 2 additional unstable components, since 1 of the components translated continuously. Thus 8 of 18 humeral components had continuous translation and/or rotation. According to Kärrholm et al. (1994) and Ryd et al. (1995), implants which do not show stabilization of migration are at risk of loosening. Although the micromotion of these implants did not stabilize, the largest translation of any humeral component was less than 3 mm. These translations cannot be detected with measurements on plain radiographs since they are not sufficiently accurate.

Rotations of the humeral components about the sagittal axis were small. Rotations were larger about the transverse and longitudinal axes. In previous long-term follow-up studies of the Souter-Strathclyde elbow, humeral components that had to be revised showed a characteristic pattern of loosening in which the component rotates in an anterior tilt. This rotation results in anterior translation of the proximal tip of the component, with subsequent ballooning of the anterior cortex, and posterior translation of the trochlea of the component (Figure 7; Pöll and Rozing 1991, Pöll 1994,

Figure 7. An elbow with a Souter-Strathclyde total prosthesis that was included in a previous long-term clinical study, taken 1 year (a) and 4 years postoperatively (b). These radiographs show the characteristic pattern of loosening of the humeral component. The component rotates in anterior tilt which causes anterior translation of the proximal tip of the component, with subsequent ballooning of the anterior cortex, and posterior translation of the trochlea of the component.

Dent et al. 1995, Sjödén et al. 1995, Trail et al. 1999, Rozing 2000). In the present study, this finding was confirmed at a micromotion level since 7 of the 8 humeral components with rotations which could be assessed had an anterior tilt. Moreover, there seems to be a relation between the amount of rotation and the presence of radiolucency on the plain radiographs.

The ulnar componentss showed good fixation in the ulna. Thus, any reduction in the revision rate for aseptic loosening in total elbow arthroplasty should concentrate on improving the fixation of the humeral component. Our findings indicate that reduction in rotation about the transverse and longitudinal axes may improve the fixation of the humeral components. An increase in the length of the intramedullary stem can reduce these rotations. Stresses on the implant may be transmitted to the bone over a larger cement-bone interface, thus providing better resistance to external forces and more stability. Although the number of revisions due to aseptic loosening may be reduced by such a modification, revision surgery will also become more complicated since more cement will have to be removed from the intramedullary canal. Another drawback of this modification may be stress shielding of the epicondylar region and, in consequence, more bone resorption will occur in that area. Another approach that does not have the disadvantage of stress shielding in the epicondylar ridge is enlargement of the lateral flange of the implant to provide better rotational stability about the transverse and longitudinal axes. This change in design is currently being implemented.

We plan to study the effect of this change on micromotion of the Souter-Strathclyde total elbow prosthesis in a randomized RSA study in which the new design will be compared to the existing one.

This study was sponsored by Stryker Howmedica Osteonics Corp., Kalamazoo, MI, USA.

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