

Biaxial Total-Wrist Arthroplasty

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Sixty-four consecutive biaxial total wrist arthroplasties performed in 52 patients between March 1983 and June 1988 were reviewed. Fifty-seven cases involving 45 patients were followed for a minimum of 5 years or until failure. Of the remaining 7 patients, 6 had died and 1 was lost to follow-up study. For the 46 intact implants in living patients, the mean follow-up period was 6.5 years (range, 5–9.9 years). The mean patient age at operation was 58 years. The underlying diagnosis was rheumatoid arthritis in 63 cases and juvenile rheumatoid arthritis in 1 case. At follow-up evaluation, pain was reported as none in 75%, mild in 19%, moderate in 3%, and severe in 3%. Patients rated their improvement as much better in 62%, better in 30%, some improvement in 4%, and worse in 4%. Range of motion at last follow-up averaged 36° extension, 29° flexion, 10° radial deviation, and 20° ulnar deviation. Grip strength improved from 4.1 kg preoperatively to 5.9 kg at last follow-up evaluation. Pain was likewise significantly improved at 1 year and 5 years. Failures occurred in 11 cases. The causes of failure were loosening of the distal implant in 8 cases and infection, dislocation, and progressive soft tissue imbalance in 1 case each. An abnormal resting stance and distal implant subsidence (≥ 3 mm) at 1 year were associated with implant failure at final follow-up evaluation. The Kaplan-Meier probability of survival free of revision was 83% at last follow-up evaluation. (J Hand Surg 1996;21A:1011–1021.)

A silicone wrist implant spacer was described by Swanson^{1,2} in the late 1960s. Wrist implant design became more complex with the emergence of Meuli's^{3,4} and Volz's⁵ total-wrist joint prostheses, which were designed on the basis of previous experience with hip prostheses. These designs and subsequent modifications were used at the Mayo Clinic in the mid-1970s and through the mid-1980s. Because of an unacceptable loosening rate with this ball-and-socket design and balance problems with the Volz design, research was initiated to design a better implant.⁶ The biaxial implant, an ellipsoidal device with convex-concave articulating surfaces oriented in the planes of wrist motion, was developed between 1978 and 1982.

This implant has been in use at the Mayo Clinic without modification since 1983. Two-year (minimum) data were presented in 1990 (Beckenbaugh RD, Brown ML, read at the annual meeting of the American Society for Surgery of the Hand, Toronto, September 24–27, 1990). There have been no published series on this design. This paper reviews the 5-year minimum follow-up results of total wrist arthroplasty with the biaxial implant.

Materials and Methods

The Total Joint Registry at our institution was used to locate 64 consecutive biaxial total-wrist arthroplasties performed in 52 patients between March 1983 and June 1988. Data were prospectively collected on total-wrist arthroplasty sheets for all total-wrist arthroplasties. The data collected on these sheets included pain (none, mild, moderate, and severe), grip strength (kg), range of motion (supination, pronation, extension, flexion, radial deviation, and ulnar deviation), resting posture (normal, radial deviation, ulnar deviation, flexion, extension, and other), response to operation (much better, better, same, and worse), and complications (infections,

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loosening, dislocation, reoperation, prosthetic failure, components replaced, components removed, bony fracture, and other). The mean follow-up period for this series was 6.0 years (range, 2.0–9.9 years). At the time of follow-up evaluation, 11 cases had resulted in implant removal, 6 patients had died, and 1 was lost to follow-up study. Of the remaining 46 cases, all were followed for a minimum of 5 years. The mean follow-up period was 6.5 years for these 46 cases (median, 6.0 years; range, 5.0–9.9 years). Anteroposterior and lateral radiographs were examined for signs of loosening, subsidence, and implant position. The mean patient age at operation was 57.5 years (range, 24–77 years). There were 45 women and 7 men. The underlying diagnosis included rheumatoid arthritis in 63 cases and juvenile rheumatoid arthritis in 1 case. Unilateral procedures were performed in 40 patients and bilateral in 12 patients. The dominant side was involved in 34 of the 64 cases.

Statistical Methods

The cumulative probability of remaining free of revision was estimated as a function of time since initial operation by using the Kaplan-Meier survivorship method. Comparisons of individual survivorship curves were made with log-rank tests. The relationships of continuous variables such as age and implant size to revision were evaluated with Cox models. Changes in continuous variables, such as grip strength, over time (eg, from 1 year to last follow-up evaluation) were evaluated by using either paired Student's *t*-tests or Wilcoxon signed-rank tests. The changes in ordinal variables, such as pain, over time were evaluated with Wilcoxon signed-rank tests; *p* values less than .05 were considered statistically significant.

Most patients were evaluated at 1, 2, and 5 years as per protocol for our Total Joint Registry. However, because postoperative follow-up evaluations were not conducted within exactly the same time frame for all patients, 2 follow-up variables were created. An early follow-up variable included data collected at or near the end of the first postoperative year. A late variable included the last follow-up evaluation. The 1-year and last follow-up evaluation endpoints were constructed from data derived only from Total Joint Registry total-wrist arthroplasty sheets for variables such as pain and satisfaction. The mean follow-up was 417 days (1.1 years) for the 1-year variable and 6.0 years for the last follow-up variable. Pain, patient satisfaction, and range of motion were com-

pared with respect to early versus late results to determine if a change occurred over time. Preoperative data were also compared to outcome based on both 1-year and last follow-up variables.

Prosthesis Design

The biaxial total-wrist prosthesis has a nonconstrained articulating interface. The articulation is a convex-concave ellipsoidal surface that provides a more physiologic type of motion than other prostheses.⁷ The prosthesis is composed of a metacarpal (distal) and a radial (proximal) component. The prosthesis stems have porous-coated surfaces. The radial component is a concave, metal-backed polyethylene component. The proximal articulating surface is offset ulnarily and palmarly. The distal component has a single long stem designed for insertion into the third metacarpal and a small stud that is inserted into the trapezoid to stabilize rotation. The distal component has an ellipsoidal, metallic articulating surface (Fig. 1). The components are made in 3 sizes. The small components were used in 25 cases, the medium in 9 cases, and the large in 30 cases.

Radiographic Evaluation

Standardized radiographic views were evaluated for lucent lines around the implants, implant subsi-

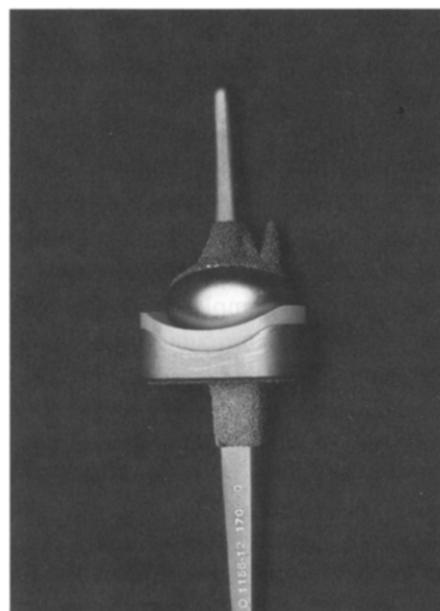


Figure 1. Biaxial total-wrist prosthesis. The distal component has a single long stem for insertion into the third metacarpal and a small stud that is inserted into the trapezoid to provide rotational stability.

dence and shift, and erosion of the tip of the implant through the cortex. Subsidence for the distal implant was estimated by measuring from the tip of the metacarpal stem to the distal extent of the metacarpal on the immediate postoperative film. This measurement was compared with subsequent radiographs. Because of possible measurement error due to film obliquity, a measurement of 3 mm or more was considered significant subsidence. The subsidence of the proximal implant was estimated in a similar fashion by using the distal ulna as a reference point. However, because of distal ulnar excision with subsequent changes due to bone resorption and formation and also because proximal component loosening has not occurred in any implant to date, data on proximal implant subsidence were omitted from analysis.

Radiographic zones were developed to allow a more accurate description of location of radiographic lucency (Fig. 2). The width of the lucent line, when present, was measured in millimeters for each zone

for each radiograph. For the radial component, zone 1 includes the metaphyseal region on the ulnar aspect; zone 2, the central portion of the ulnar aspect; zone 3, the 1 cm about the tip of the prosthesis; zone 4, the central radial aspect; and zone 5, the metaphyseal region on the radial aspect. Zones were also characterized for the distal component as follows: zone 1, the ulnar aspect of the base of the third metacarpal; zone 2, the remainder of the ulnar aspect of the component; zone 3, the distal 1 cm of the component; zone 4, the central portion of the radial aspect of the component; zone 5, the radial aspect about the base of the third metacarpal; and zone 6, the region over the stud for the trapezoid. Radiographic lucent scores were devised by summing the width in millimeters for each zone. Radiographic loosening was defined as progression of width of lucent lines (≥ 2 mm), erosion of the tip of the implant through the cortex, or subsidence of 3 mm or more.

Surgical Technique

The surgical technique has been carefully outlined in previous publications.⁸⁻¹⁰ The following section provides the main points of surgical technique for biaxial total-wrist arthroplasty.

Templates (6% magnification) are used to determine the appropriate prosthesis size and the amount of bone to be resected in each case. Prostheses are sized as small, medium, or large. In general, the largest prosthesis possible is used.

A dorsal approach is used through a straight longitudinal incision over the dorsum of the wrist (Fig. 3). The skin and subcutaneous flaps are elevated sharply from the underlying extensor retinaculum. The retinaculum is incised longitudinally over the fourth compartment and carefully elevated and preserved to allow closure at the conclusion of the procedure (Fig. 4). The third dorsal compartment is opened and the extensor pollicis longus tendon is exposed, protected, and retracted. The radial flap of the retinaculum is elevated off of Lister's tubercle to expose the tendons of the second dorsal compartment, which are retracted. The tendons of the first dorsal compartment are approached in a subperiosteal manner and carefully protected during the bony resection of the distal radius. Extensor tenosynovectomies are performed as necessary.

The common digital extensors are retracted radially. The capsule of the distal radioulnar joint is opened and the distal ulna is resected just proximal to the sigmoid notch of the radius (Fig. 5).

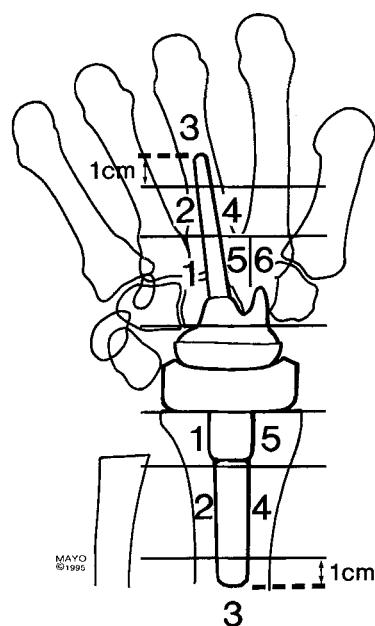


Figure 2. Zones of radiographic lucency. Proximal component: zone 1, metaphyseal region on ulnar aspect; zone 2, central portion of ulnar aspect of implant; zone 3, 1 cm about tip of prosthesis; zone 4, central portion of radial aspect of implant; and zone 5, metaphyseal region on radial aspect. Distal component: zone 1, base of the third metacarpal on ulnar aspect; zone 2, central portion of ulnar aspect; zone 3, 1 cm about distal tip of prosthesis; zone 4, central portion of radial aspect of component; zone 5, base of third metacarpal on radial side; and zone 6, region over trapezoid stud. (By permission of Mayo Foundation.)

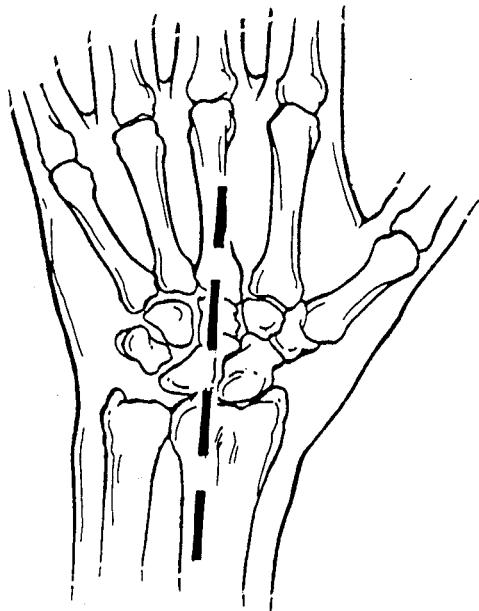


Figure 3. A straight incision is centered over the third metacarpal. (From Cooney WP, Linscheid RL, Dobyns JH. The wrist: diagnostic and operative treatment. St. Louis: Mosby-Year Book [in press]. By permission of Mayo Foundation.)

The dorsal wrist capsule is entered through a T incision (Fig. 6). The longitudinal component of the T incision aligns with the axis of the third metacarpal. The distal end of the radius is exposed

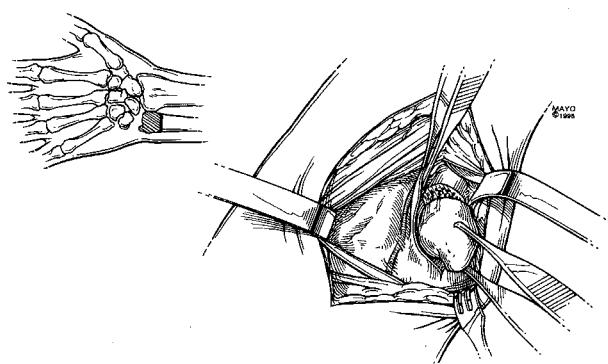


Figure 5. The distal ulna is exposed subperiosteally and resected just proximal to the sigmoid notch. (From Cooney WP, Linscheid RL, Dobyns JH. The wrist: diagnostic and operative treatment. St. Louis: Mosby-Year Book [in press]. By permission of Mayo Foundation.)

subperiosteally and resected perpendicular to the long axis of the radius at the level of the middle of the sigmoid notch. The amount of bone resected is individualized to ensure proper tension. The tendons of the first dorsal compartment must be protected during resection of the radial styloid. A sagittal saw is used to prepare a slightly concave resection of the carpus through the distal carpal row. Bone resection is based on the preoperative template and should result in an approximately 2.5-cm-wide space for the prosthesis (Fig. 7). The capsule should be preserved if possible.

The third metacarpal shaft is exposed subperiosteally with Hohman retractors. The canal is then prepared for the distal component by placing a sharp

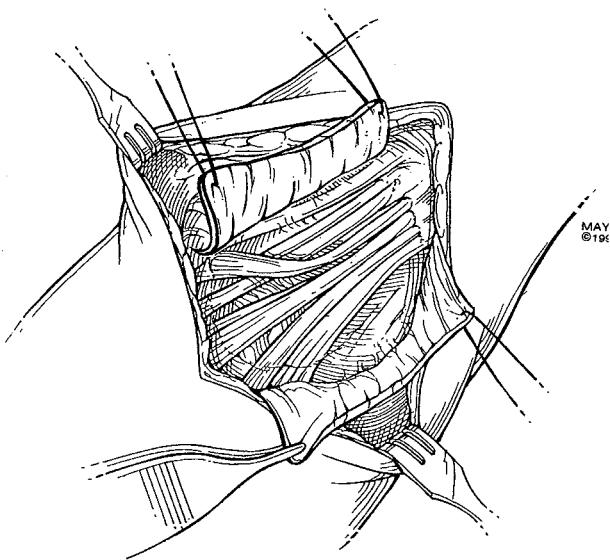


Figure 4. The tendons of the second through the fourth dorsal compartments are exposed. (From Cooney WP, Linscheid RL, Dobyns JH. The wrist: diagnostic and operative treatment. St. Louis: Mosby-Year Book [in press]. By permission of Mayo Foundation.)

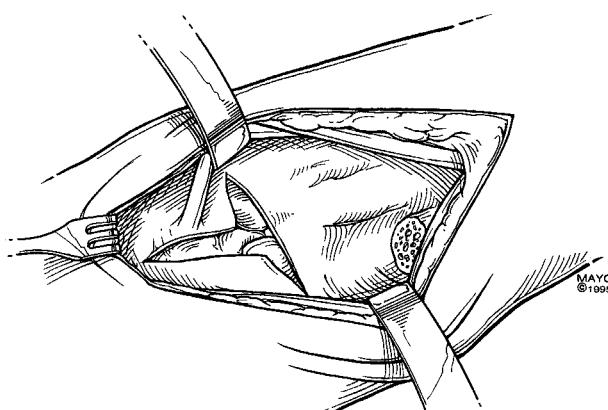


Figure 6. The dorsal wrist capsule is entered through a T incision. (From Cooney WP, Linscheid RL, Dobyns JH. The wrist: diagnostic and operative treatment. St. Louis: Mosby-Year Book [in press]. By permission of Mayo Foundation.)

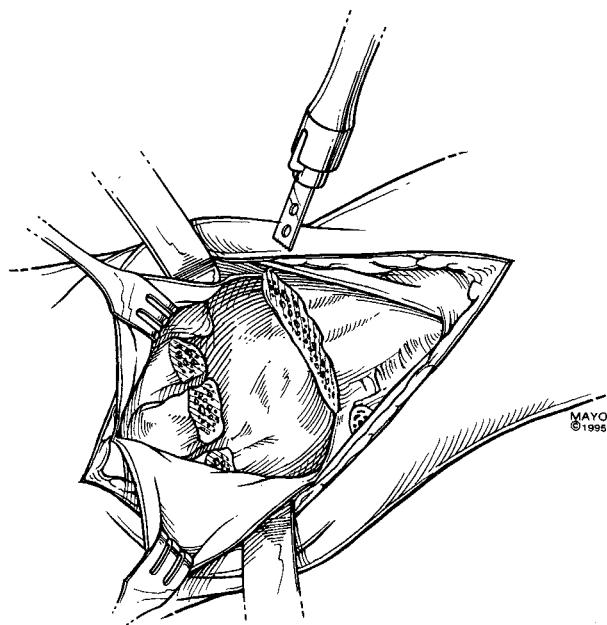


Figure 7. The distal radius and proximal carpal row are resected. Level of resection is based on preoperative templating and should ensure a relatively tight fit. (From Cooney WP, Linscheid RL, Dobyns JH. *The wrist: diagnostic and operative treatment*. St. Louis: Mosby-Year Book [in press]. By permission of Mayo Foundation.)

awl through the remaining portion of the capitate bone and into the medullary canal of the third metacarpal (Fig. 8). A blunt awl is passed down the canal to its distal extent. The canal is gradually

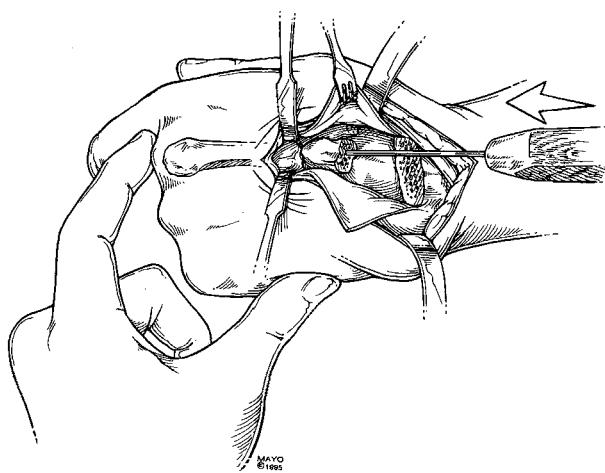


Figure 8. An awl is placed through the remaining portion of the capitate and into the medullary canal of the third metacarpal. (From Cooney WP, Linscheid RL, Dobyns JH. *The wrist: diagnostic and operative treatment*. St. Louis: Mosby-Year Book [in press]. By permission of Mayo Foundation.)

expanded by progressively increasing the size of the awl and then with the use of presized rasps and power burs as necessary to allow placement of the prosthesis. A separate channel is similarly prepared for the small stud in the trapezoid or index metacarpal (or both) (Fig. 9). Medial and lateral burring is performed as necessary to allow placement of the trial distal component.

An awl is used to open the midportion of the medullary canal of the distal radius. Radial rasps are impacted into the intramedullary canal (Fig. 10). The cavity is enlarged progressively to the proper size. The proximal trial component is then inserted and the distal end of the radius is trimmed as necessary to allow a flat surface and appropriate soft tissue tension with the trials in place.

For primary total-wrist arthroplasties, cement is used for the distal component. Methyl methacrylate cement is placed into the previously prepared canal for the distal component in a pressurized manner. A 12-mL plastic syringe with the tip widened by an awl or straight hemostat is used for cement placement (Fig. 11). Cancellous bone is impacted distally in the intramedullary canal of the third metacarpal to act as a plug before application of cement. The distal component is placed into position and pressure is maintained while the cement is hardening. The radial component is then placed and the tension and range of motion are tested. Bone is resected as necessary to

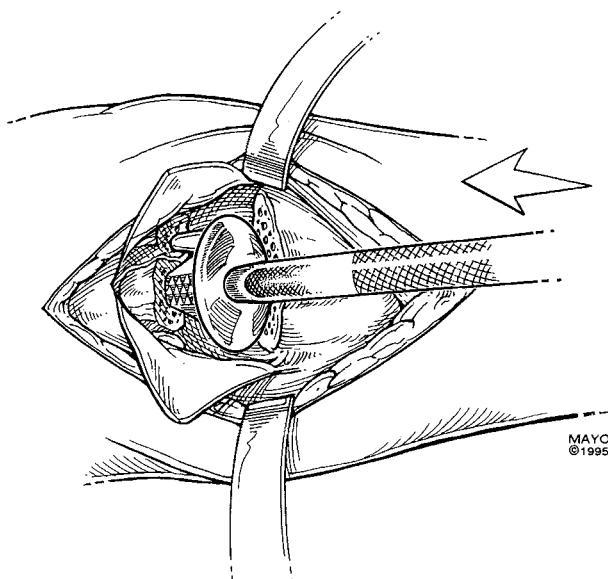


Figure 9. Bone preparation for distal implant with rasp. (From Cooney WP, Linscheid RL, Dobyns JH. *The wrist: diagnostic and operative treatment*. St. Louis: Mosby-Year Book [in press]. By permission of Mayo Foundation.)

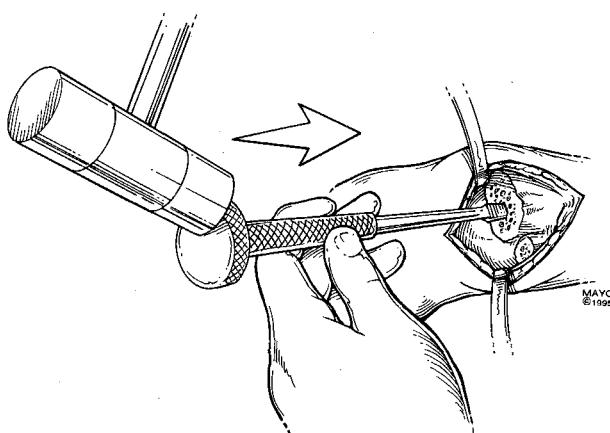


Figure 10. Bone preparation for proximal implant with rasp. (From Cooney WP, Linscheid RL, Dobyns JH. *The wrist: diagnostic and operative treatment*. St. Louis: Mosby-Year Book [in press]. By permission of Mayo Foundation.)

prevent impingement. Position of the implant is assessed radiographically before closure. The capsule is closed tightly over a drain. The subcutaneous tissue and skin are likewise closed over suction drains. A bulky, long-arm compressive dressing with plaster splints is applied with the elbow in 90° flexion, the forearm in supination, and the wrist in neutral radioulnar deviation.

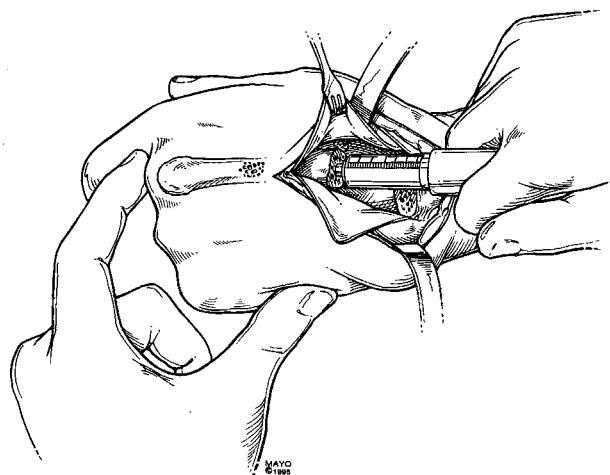


Figure 11. Methyl methacrylate cement is placed under pressure into canal prepared for distal implant. (From Cooney WP, Linscheid RL, Dobyns JH. *The wrist: diagnostic and operative treatment*. St. Louis: Mosby-Year Book [in press]. By permission of Mayo Foundation.)

Results

Preoperative Evaluations

Patients rated their pain as none in 1 case (2%), mild in 10 cases (17%), moderate in 27 cases (46%), and severe in 21 cases (36%). This variable was not recorded in 5 cases. The mean range of motion was 23° for extension ($SD \pm 24$; range, 65° to 40°), 34° for flexion ($SD \pm 18$; range, 64° to 25°), 69° for pronation ($SD \pm 15$; range, 25° to 90°), 65° for supination ($SD \pm 18$; range, 10° to 90°), 5° for radial deviation ($SD \pm 12$; range, -25° to 35°), and 16° for ulnar deviation ($SD \pm 13$; range, -15° to 60°). Variables were not recorded in 2 cases for arc of flexion, in 7 cases for pronation and supination, and in 3 cases for radial and ulnar deviation.

Cement was used for both the proximal and distal components in 46 cases, the distal component only in 12 cases, and in neither component in 6 cases.

Seven patients were receiving methotrexate and 32 were receiving prednisone. Of those receiving prednisone, the mean dose was 6.4 mg (range, 1–15 mg) and the mean length of treatment was 103 months (range, 10–250 months).

Subjective Outcome

Patients rated pain as none in 75% of cases, mild in 19%, moderate in 3%, and severe in 3% at 1-year follow-up examination. Patients rated the pain as none in 81% of cases, mild in 16%, and moderate in 4% at last follow-up evaluation. Pain was significantly improved for both variables, 1-year follow-up evaluation ($p = .0001$) and last follow-up evaluation ($p = .0001$), compared with preoperative pain. Patients rated their symptoms as much better in 59% and better in 31% at 1 year and much better in 62% and better in 30% at last follow-up evaluation (Table 1).

Clinical Evaluation

Mean pronation and supination improved from 69°/65° preoperatively to 73°/67° at 1 year after surgery ($p > .05$) and to 73°/68° at last follow-up evaluation ($p > .05$). Mean flexion decreased from 34° preoperatively to 29° at 1 year after surgery ($p = .01$) and at last follow-up evaluation ($p = .01$). Mean extension values improved from 23° preoperatively to 39° at 1 year after surgery ($p = .0001$) and 36° at last follow-up evaluation ($p = .0004$). Mean radial deviation was 5° preoperatively, 9° 1 year after surgery ($p = .03$), and 10° at last follow-up evaluation ($p = .02$). Mean ulnar deviation remained relatively stable, changing from 16° preoperatively to

Table 1. Subjective Data

	Cases					
	Preoperative		1 Year After Surgery		Last Follow-up Evaluation	
	No.	%	No.	%	No.	%
Pain						
None	1	2	27	75	46	81
Mild	10	17	7	19	9	16
Moderate	27	46	1	3	2	4
Severe	21	36	1	3	0	0
Number missing	5		28		7	
Patient satisfaction						
Much better	NA		19	59	29	62
Better	NA		10	31	14	30
Same	NA		1	3	2	4
Worse	NA		2	6	2	4
Number missing	NA		32		17	

NA, not applicable.

15° at 1 year after surgery ($p = .81$). At last follow-up evaluation, the mean ulnar deviation was 20° ($p = .05$) (Table 2). Significant improvements were found in mean preoperative grip strength (4.1 kg), 1-year postoperative grip strength (6.5 kg) ($p = .005$), and last follow-up postoperative grip strength (5.9 kg) ($p = .03$).

The resting stance of the wrist was abnormal in 21 cases. Ulnar deviation was present in 8 cases at 1 year and in 12 cases at last follow-up evaluation. Radial deviation was present in 4 cases at 1 year and in 8 cases at last follow-up examination. Flexion deformity occurred in 1 case at last follow-up evaluation.

Radiographic Evaluation

Fracture of the cement was observed on postoperative radiographs around the metacarpal component in 1 case at 1 year and in 6 cases at last follow-up examination. Cortical bone resorption was present around the metacarpal component in 3 cases and around the radial component in 1 case at 1 year. At 5

years, cortical bone resorption was observed around the metacarpal component in 9 cases, the radial component in 1 case, and both components in 1 case. Reactive bone was noted to form about the tip of the metacarpal implant in 2 patients at 1 year postoperatively and in 10 patients at last follow-up evaluation. Angulation of the distal component occurred such that the distal tip translated in a dorsal direction and had partially penetrated the dorsal cortex of the metacarpal at follow-up evaluation in 7 cases and completely in 8 cases. Of the 8 cases in which the tip was completely through the cortex, 3 occurred intraoperatively; gradual erosion through the cortex occurred in the remaining 5 cases. Four of the last 5 went on to revision operation for distal implant loosening, and the remaining implant is loose radiographically.

Lucent zones were present around the distal tip of the distal component in 7 cases at 1 year. All zones at 1 year were 1 mm wide (Table 3). The width of radiolucency ranged from 1 to 7 mm at last follow-

Table 2. Range of Motion (Degrees)

Motion	Preoperative				1 Year After Surgery				Last Follow-up Evaluation			
	Range		Mean	SD	Range		Mean	SD	Range		Mean	SD
	Minimum	Maximum			Minimum	Maximum			Minimum	Maximum		
Supination	65	18	10	90	67	16	20	90	68	18	0	90
Pronation	69	15	25	90	73	15	20	90	73	12	40	90
Extension	23	24	-40	65	39	18	0	70	36	20	-10	70
Flexion	34	18	-25	64	29	13	5	55	29	21	-45	80
Radial deviation	5	12	-25	35	9	7	0	25	10	14	-45	35
Ulnar deviation	16	13	-15	60	15	10	0	35	20	13	-20	65

Table 3. Lucent Zones*

Zone	1 Year After Surgery		Last Follow-up Evaluation	
	Cases (no.)	Width (mm)	Cases (no.)	Width (mm)
Proximal component				
1	0	0	4	4
2	0	0	2	4
3	0	0	0	0
4	0	0	0	0
5	0	0	1 1 2	1 2 4
Distal component				
1	2	1 6	5 6	1 2
2	4	1 4 4	5 4 4	1 2 3
3	7	1 4 2	6 4 2	1 2 3
4	4	1 2 4	5 2 4	1 2 3
5	2	1 5 2 1	2 5 2 1	1 2 3 7
6	4	1 2 1 1	8 2 1 1	1 2 3 4

*Measured from radiographs.

up examination. No lucent lines were observed around the proximal component at 1 year. At last follow-up evaluation, lucent zones occurred around the metaphyseal portion of the proximal component in 4 cases. The largest zone was 4 mm wide.

Progression (≤ 2 mm) of lucent zones about the distal implant occurred in 12 cases. The number of zones with progression ranged from 1 to 6. Seven of these resulted in failure requiring implant removal. Those cases that required revision operation had progression of 4 (mean) zones (range, 1 to 6 zones), compared to cases with intact implants, which had progression of a mean of 2.4 zones (range, 2 to 4). This difference was statistically significant ($p = .0001$).

The mean radiographic lucent score (sum of width of lucent lines for all 6 zones of distal implant) for those cases that failed was 8 (median, 10; range, 0–14), compared with a mean score of 1.1 (median, 0; range, 0–10) for those cases that did not require revision ($p = .0001$).

Subsidence of the distal implant occurred in 7 cases (mean, 4 mm; range, 1–15 mm) at 1 year and in 20 cases (mean, 7 mm; range, 1–20 mm) at last follow-up evaluation. Subsidence of the proximal component was less common, occurring in 1 case (1 mm) at 1 year and in 5 cases (mean, 3 mm; range, 1–4 mm) at last follow-up examination. Fourteen patients had subsidence of the distal component of 3 mm or more. Of these, 8 required revision due to loosening, compared with none of the 32 patients who had subsidence of 3 mm or less ($p = .0001$). None of the patients with subsidence of the proximal component required revision for proximal component loosening.

The radiographic appearance at 1 year was analyzed for ability to predict failure at a later date. Only 4 patients had subsidence at 1 year. Three of these patients had subsequent revision. Those wrists with subsidence at 1 year have a significantly higher probability of failure ($p = .002$) by 6 years, compared with 10 wrists without subsidence at 1 year.

This is in contrast to the 1-year lucent score: a mean of 0.3 (median, 0; range, 0–6) for survival without need for revision, compared with a mean of 1.0 (median, 0; range, 0–6) for cases that later required revision surgery ($p = .11$).

Radiographic loosening occurred in 14 cases (22%); 7 of these had progression of lucent lines (≥ 2 mm), 8 had erosion of the tip of the implant through the cortex, and all 14 had subsidence (≥ 3 mm). Of the 14 cases with radiographic loosening, 8 have been revised.

Failure

Failure occurred in 11 cases. The cause of failure was loosening of the distal component in 8 cases, infection in 1 case, dislocation in 1 case, and progressive soft tissue imbalance in 1 case. Eight cases were revised, 2 cases underwent arthrodesis, and 1 case underwent component removal.

Technical difficulties at operation that may have contributed to failure were identified in 5 cases. In 1 case, the distal tip of the distal component was placed through the palmar cortex of the third metacarpal. Progressive loosening and subsidence occurred. This patient underwent arthrodesis at 2.3 years. A similar failure pattern was observed in a second case in which the distal tip of the distal implant extended through the palmar cortex of the third metacarpal. Three years after surgery, the distal component was radially deviated, with lucent lines and 15 mm of subsidence.

In another case the distal component was placed in 14° of ulnar deviation with respect to the third metacarpal. By 2 years, the angulation had progressed to 16° with soft tissue imbalance, resulting in a resting position of 45° of ulnar deviation of the distal component, with gross loosening of the distal component. Two additional cases had a distal component inserted in a slightly angulated position, and the components subsequently showed loosening, subsidence, and migration. However, angular variation in stem position was not always associated with failure.

Hematogenous infection occurred in 1 patient in whom a total-knee arthroplasty infection also developed. Arthrodesis of the wrist was performed 4.5 years after the index operation. A progressive soft tissue imbalance occurred in 1 case that progressed to ulnar deviation of 85° at 4 years.

Complications

Intraoperative complications included perforation of the cortex of the third metacarpal in 4 cases, per-

foration of the cortex of the third metacarpal and a soft tissue imbalance resulting in 10° of nonprogressive ulnar deviation in 1 case, and radial deviation of 15° that progressed to 30° at 5-year follow-up evaluation in 1 case.

Short-term complications included development of a hematoma and wound breakdown in 1 case. These complications resolved without additional operations and without any long-term sequelae.

Long-term complications included loosening of the distal component in 8 cases, dislocation in 4 cases, extensor tendon rupture in 4 cases, flexor tendon rupture in 1 case, radiocarpal subluxations in 3 cases, and infection in 1 case. One late dislocation was treated with revision and the others were successfully treated with closed reduction and immobilization.

Implant Survival and Data Analysis

The Kaplan-Meier survival analysis demonstrated an 83% (95% confidence interval [CI], 72%–93%) probability of survival free of revision at last follow-up examination. Implant failure was not significantly associated with age ($p = .63$), implant size ($p = .77$), or type of fixation ($p = .41$). The 5-year survival free of revision was 67% (95% CI, 25%–100%) for the 6 cases in which cement was not used, 83% (95% CI, 59%–100%) for the 12 cases in which cement was used around the distal component only, and 86% (95% CI, 74%–96%) for the 46 cases in which cement was used on both components. The lack of significance here may relate to the small number of events and the small sample size of cases in which cement was not used in either component.

Thirty-two patients were being treated with prednisone at the time of operation. The 5-year probability of survival free of revision was 86% in these patients, compared with 84% in the 25 patients not being treated with prednisone at the time of operation ($p = .57$) and the 7 patients being treated with methotrexate at the time of operation. The 5-year Kaplan-Meier survivorship free of revision was 80% and 100% for these two groups, respectively ($p = .19$).

The effect of soft tissue imbalance resulting in radial and ulnar deviation as noted by documentation of an abnormal resting stance was evaluated. Survivorship free of revision was 25% (95% CI, 0%–67%) for those patients with radial deformities, compared with 87% (95% CI, 71%–93%) for those patients without radial deformities ($p = .001$). The 5-year probability of survival free of revision for patients with and without ulnar deviation of the wrist

was 88% (95% CI, 61%–100%) and 82% (95% CI, 71%–99%), respectively ($p = .68$).

The effect of subsidence on survivorship free of revision was evaluated. The probability of survival was 53% (95% CI, 32%–81%) for those with subsidence of 3 mm or more, compared with 97% (95% CI, 90%–100%) for those who did not have radiographic subsidence ($p = .0002$).

Effect of Time on Outcome

Numerous variables were assessed at 1 year and last follow-up examination to determine the effect of time on these variables. The mean grip strength at 1 year was 6.5 kg ($SD \pm 4.6$; range, 1–18 kg), compared with 6.2 kg ($SD \pm 4.2$; range, 1–14 kg) at last follow-up evaluation ($p = .77$). Additional variables that did not change significantly over time included pain, supination, pronation, extension, flexion, radial deviation, occurrence of infection, dislocation, and patient satisfaction.

Zones of lucency were assessed for statistically significant progression of lucent lines. Only zone 3, involving the distal tip of the distal component, demonstrated a significant change from the 1-year to the last follow-up evaluation ($p = .02$).

Discussion

Total-wrist arthroplasty is an evolving procedure that has yet to achieve the success and reliability of total-joint arthroplasty of some other joints such as the hip and the knee. One in five total-wrist arthroplasty cases will fail by 6 years, requiring revision arthroplasty or arthrodesis. Three of four failures occur because of distal implant loosening. Implant subsidence appears to be the best early radiographic indicator of implant loosening. Experience with total-hip arthroplasty has shown that femoral component debonding may not necessarily lead to implant failure.¹¹ Perhaps a similar mechanism is responsible for the inability of 1-mm radiolucent lines at 1 year to predict later failure. Data on total-hip arthroplasty have shown that clinical failure may lag behind radiographic failure by 5 or even 10 years. Therefore, the significance of 1-mm lucent lines at 1-year follow-up evaluation may not be appreciated in this study, since the maximum follow-up period was only 10 years. Clearly, progression of lucent lines around the distal implant is associated with loosening and failure. This is consistent with findings of other implant studies. Proximal implant loosening has not been a problem with the biaxial design.

Angulation of a loose distal implant generally occurs with palmar translation of the proximal aspect of the metacarpal component and dorsal migration of the distal tip of the metacarpal component. This modality of failure is common to other designs of total-wrist arthroplasty as well.¹² Design modifications, including two long metacarpal stems, have demonstrated some success in revision total-wrist arthroplasty and may also be of value in primary total-wrist arthroplasty.

When distal implant loosening occurs, the distal tip of the implant often erodes through the dorsal aspect of the third metacarpal. As this process occurs, pain may not be present. However, the process is progressive and may result in considerable bone loss and deformity. Therefore, it is necessary that patients be followed closely in order to recognize this process at an early phase. Radiographs should be examined for subsidence and progression of lucent zones around the distal implant, and revision should be planned. Lucent lines appear first and progress most frequently in zone 3, around the distal tip of the metacarpal. Loosening of the proximal implant has not proved to be a concern. Patients may perceive only a bump on the dorsum of the hand as reactive bone is formed over the tip of the dorsally migrating metacarpal implant.

Several technical considerations were identified during this review. Penetration of the metacarpal cortex can easily complicate this procedure and may lead to implant failure. The metacarpal should be fully exposed with 2 Hohman retractors to prevent penetration of the cortex during medullary canal preparation. Another technical consideration that increases failure rate is soft tissue imbalance. Bone resection and implant placement should restore carpal alignment. The longitudinal axis of the implant should be aligned with the anatomic axis of the extremity. Small degrees of malalignment, especially in radial deviation, may progress and result in implant failure.

The variable resting stance was based on the relative position of the hand, wrist, and forearm at the time of follow-up evaluation. This was not quantitated and could not be critically analyzed. Furthermore, although many patients had an abnormal resting stance postoperatively, the status of some improved in comparison with preoperative status.

The early results of this procedure are encouraging, but late failures occur. A significant progressive rate of loosening, subsidence, angulation, and distal tip migration through the metacarpal cortex was observed for the metacarpal implant. The late failure

rate has been almost exclusively due to failure of the distal implant. Eight (13%) of the cases in this series involved revision surgery for implant loosening. An additional 6 implants (9%) are loose radiographically. Three other cases involved revision surgery for reasons other than implant loosening.

Arthrodesis remains a reliable method of treating patients with radiocarpal joint destruction and should be recommended in most cases.^{13,14} However, some patients are not able to compensate for the lack of wrist mobility associated with wrist fusion because of multiple joint arthropathies, as is commonly seen in patients with rheumatoid arthritis. For these patients, total-wrist arthroplasty might best be described as a high-risk/high-reward procedure. Although wrist arthrodesis is the standard for treatment of radiocarpal arthritis, the incidence of major long-term complication has been 5%–20% in most long-term series.^{15–18} Recent publications report fewer complications after arthrodesis; however, 14%–28% of patients require reoperation for plate removal.^{19,20} The same studies report 87%–88% patient satisfaction. This is compared with an 83% probability of survival and 92% patient satisfaction for biaxial total-wrist arthroplasty at a minimal follow-up period of 5 years.

Pain was significantly decreased, with respondents reporting no pain in 81% of cases, mild pain in 16%, moderate pain in 4%, and severe pain in no cases at last follow-up examination. Of those patients whose arthroplasty had failed and were eligible for revision total-wrist arthroplasty, 80% elected revision arthroplasty over recommended arthrodesis.

Activities of daily living require 30° extension, 5° flexion, 10° radial deviation, and 15° ulnar deviation.⁷ The mean range of motion for this group was 36° extension, 29° flexion, 10° radial deviation, and 20° ulnar deviation.

We conclude that biaxial total-wrist arthroplasty provides good pain relief and satisfactory range of motion, but it is associated with a significant loosening rate for the distal implant. This procedure is best reserved for low-demand patients with rheumatoid arthritis who are not able to compensate for wrist fusion. They should be advised of a 1 in 5 chance of failure by 6 years. The predictable nature of the metacarpal implant failure and identification of technical problems that contribute to failure should allow for continued improvement in implant survival through technique modifications, as described here, and alteration in implant design such as use of long-stemmed multipronged distal components, as are

currently used in revision cases and for patients with poor bone stock.

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