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FEATURED ARTICLES

A multicenter, prospective, randomized, controlled trial of open reduction—internal fixation versus total elbow arthroplasty for displaced intra-articular distal humeral fractures in elderly patients

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Summary We conducted a prospective, randomized, controlled trial to compare functional outcomes, complications, and reoperation rates in elderly patients with displaced intra-articular, distal humeral fractures treated with open reduction−internal fixation (ORIF) or primary semiconstrained total elbow arthroplasty (TEA). Forty-two patients were randomized by sealed envelope. Inclusion criteria were age greater than 65 years; displaced, comminuted, intra-articular fractures of the distal humerus (Orthopaedic Trauma Association type 13C); and closed or Gustilo grade I open fractures treated within 12 hours of injury. Both ORIF and TEA were performed following a standardized protocol. The Mayo Elbow Performance Score (MEPS) and Disabilities of the Arm, Shoulder and Hand (DASH) score were determined at 6 weeks, 3 months, 6 months, 12 months, and 2 years. Complication type, duration, management, and treatment requiring reoperation were recorded. An intention-to-treat analysis and an on-treatment analysis were conducted to address patients randomized to ORIF but converted to TEA intraoperatively. Twenty-one patients were randomized to each treatment group. Two died before follow-up and were excluded from the study. Five patients randomized to ORIF were converted to TEA intraoperatively because of extensive

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comminution and inability to obtain fixation stable enough to allow early range of motion. This resulted in 15 patients (3 men and 12 women) with a mean age of 77 years in the ORIF group and 25 patients (2 men and 23 women) with a mean age of 78 years in the TEA group. Baseline demographics for mechanism, classification, comorbidities, fracture type, activity level, and ipsilateral injuries were similar between the 2 groups. Operative time averaged 32 minutes less in the TEA group ($P = .001$). Patients who underwent TEA had significantly better MEPSs at 3 months (83 vs 65, $P = .01$), 6 months (86 vs 68, $P = .003$), 12 months (88 vs 72, $P = .007$), and 2 years (86 vs 73, $P = .015$) compared with the ORIF group. Patients who underwent TEA had significantly better DASH scores at 6 weeks (43 vs 77, $P = .02$) and 6 months (31 vs 50, $P = .01$) but not at 12 months (32 vs 47, $P = .1$) or 2 years (34 vs 38, $P = .6$). The mean flexion-extension arc was 107° (range, 42°-145°) in the TEA group and 95° (range, 30°-140°) in the ORIF group ($P = .19$). Reoperation rates for TEA (3/25 [12%]) and ORIF (4/15 [27%]) were not statistically different ($P = .2$). TEA for the treatment of comminuted intra-articular distal humeral fractures resulted in more predictable and improved 2-year functional outcomes compared with ORIF, based on the MEPS. DASH scores were better in the TEA group in the short term but were not statistically different at 2 years' follow-up. TEA may result in decreased reoperation rates, considering that 25% of fractures randomized to ORIF were not amenable to internal fixation. TEA is a preferred alternative for ORIF in elderly patients with complex distal humeral fractures that are not amenable to stable fixation. Elderly patients have an increased baseline DASH score and appear to accommodate to objective limitations in function with time.
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Treatment of displaced intra-articular fractures of the distal humerus is one of the most technically challenging procedures in elbow surgery. In young patients, open reduction−internal fixation (ORIF) with plate fixation of both columns is the gold standard. However, elbow stiffness, malunion, nonunion, failure of fixation, and ulnar neuropathy are common sequelae, with overall complication rates of over 35% reported.[13,15,16,22,27] In elderly patients, combinations of osteoporotic bone, metaphyseal comminution, poor soft-tissue conditions, and limited tolerance for joint immobilization have resulted in less predictable outcomes with internal fixation.[6,9,10,13,25,27,28]

In addition to revision internal fixation with bone grafting, semiconstrained total elbow arthroplasty (TEA) is a well-established treatment option for the complications of internal fixation of distal humeral fractures.[16-18,20] TEA is considered effective for nonunion, malunion, post-traumatic arthritis, and post-traumatic instability after these serious injuries, with the literature describing good and excellent results in 85% to 90% of patients at 5 to 10 years after surgery.[17,18,20] However, TEA in elbows with these injuries is technically difficult, and complication rates are higher than in elbows that have not had prior operative procedures.[16,17]

In 1997, Cobb and Morrey[3] reported a series of 21 elderly patients (mean age, 72 years) who had primary TEA for comminuted fractures of the distal humerus. They reported good or excellent results in 95% at a mean follow-up of 3.3 years, with a reoperation rate of 5% (1 elbow). More recently, Frankle et al[5] performed a retrospective comparison of ORIF with TEA for intra-articular distal humeral fractures in 24 women aged older than 65 years. At a minimum of 2 years, TEA resulted in excellent or good results in all 12 patients, with improved range of motion and less physical therapy required compared with ORIF patients. Failure of fixation occurred in 25% of patients with ORIF and required revision to TEA. Although primary TEA may be a viable treatment option for comminuted intra-articular distal humeral fractures in older patients, the current recommendations are based solely on retrospective reviews from single institutions.[1,6,7,21]

The purpose of this study was to compare the effectiveness of ORIF with primary TEA for the treatment of displaced, comminuted intra-articular distal humeral fractures in elderly patients (age >65 years). Our primary outcome measure was reoperation rate, and secondary outcome measures were patient function as measured with the Mayo Elbow Performance Score (MEPS) and Disabilities of the Arm, Shoulder and Hand (DASH) instrument.

Methods

We performed a prospective, randomized, double-blind clinical trial beginning in January 2001 at 4 university-affiliated Canadian academic medical centers: St Michael's Hospital, University of Toronto (Toronto, Ontario); Royal Columbian and Vancouver General Hospitals, University of British Columbia (New Westminster/Vancouver, British Columbia); and McMaster Medical Center, McMaster University (Hamilton, Ontario). Each patient was randomly assigned by sealed envelope drawn by the site coordinator to be treated with either ORIF or semiconstrained TEA.

The study protocol was reviewed and approved by the institutional research ethics review board of each participating institution. All patients provided written informed consent.

The sample size was estimated by use of an equation appropriate for comparing 2 independent group means[29] and was based

on a 2-sided α level of .05 having 80% power to detect a 40% difference in reoperation rate. Previous experience at one of the participating institutions with patients having this type of fracture indicated a clinical reoperation rate of 40% (ie, nonunion, malunion, infection, removal of prominent hardware, elbow release, and ulnar neuropathy). A comparative retrospective study by Frankle et al[5] showed a 42% reoperation rate in the ORIF group compared with the TEA group.

The patients included in the study were men or women aged over 65 years with displaced, comminuted, intra-articular fractures of the distal humerus (AO/Orthopaedic Trauma Association [OTA] classification type 13C)[23] requiring operative treatment. Closed fractures, Gustilo grade I open fractures treated within 12 hours of injury, and Gustilo grade I open fractures treated elsewhere by irrigation and debridement within 12 hours of injury and then referred secondarily by the attending surgeon were included in the study. For a patient to be included in the study, definitive surgery was required within 21 days of injury.

Exclusion criteria included (1) extra-articular or partial articular fractures of the distal humerus (AO/OTA classification types 13A and 13B), (2) intra-articular fracture of the distal humerus (type 13C) that did not require surgical intervention, (3) Gustilo grade I open fractures that had not had irrigation and debridement within 12 hours of occurrence, (4) Gustilo grade II, IIIa, IIIb, and IIIc open fractures, (5) associated vascular injury, (6) previous ipsilateral distal humeral fracture, (7) pathologic fractures, (8) fractures with diaphyseal extension of 8 cm or greater, (9) definitive surgery more than 21 days after injury, (10) pre-existing severe joint disease (eg, rheumatoid arthritis), and (11) limited life expectancy because of significant medical comorbidity. In addition, patients with dementia, inability to comply with rehabilitation or form completion, and unwillingness to be followed up for 2 years were excluded.

All patients underwent a standardized preoperative assessment by a physician and a research assistant. Preoperative radiographs (anteroposterior and lateral views) of the affected elbow were obtained before surgery.

Patients were not stratified by surgeon or institution. Randomization was performed after consent was obtained and before the patient entered the operating room. A random number generator was used to create a 1:1 allocation scheme for randomization (Figure 1). A sealed envelope containing the randomly assigned treatment group allocation was opened by the study coordinator, not the surgeon.

In total, 6 surgeons performed the procedures in this study. Preoperative prophylactic antibiotics were given to all patients, and all procedures were performed with the patient under general anesthesia. All surgeries followed standardized protocols. ORIF was performed via a posterior approach with anatomic reduction of the fracture and provisional Kirschner wire fixation. A midline triceps split or triceps-sparing approach was used for TEA, and a midline triceps split or olecranon osteotomy was used for ORIF.[15] With the triceps-sparing approach, the surgeon uses the working space created by the condylar resection to perform TEA without detaching the triceps from the olecranon.[1,16,17] In the ORIF group, definitive fixation was performed with 2 small-fragment compression plates in all cases, 1 on the medial column and 1 on the lateral column. In 10 cases, plates were placed at 90° to each other (direct lateral/posteromedial or direct medial and posterolateral), and in 5 cases, parallel plating was used (direct medial and direct lateral plates). There were fifteen precontoured

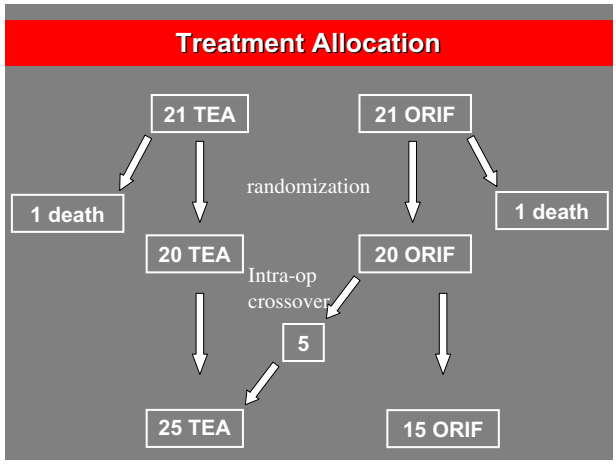

Figure 1 Randomization scheme. *intra-op*, Intraoperative.

plates, nine 3.5-mm pelvic reconstruction plates, and six limited-contact 3.5-mm compression plates used: no one-third tubular or locking plates were used in this study. The use of iliac crest bone autograft and additional fixation (Herbert bone screws) was recorded. Intraoperative conversion to TEA was anticipated as part of the protocol and acceptable if, in the opinion of the operating surgeon, sufficient stability to allow early mobilization could not be obtained with ORIF. Semiconstrained TEA was performed via a posterior approach with resection of distal bone fragments. A Coonrad-Morrey elbow prosthesis (Zimmer, Warsaw, IN) was implanted with antibiotic-impregnated bone cement (40 g of Simplex Bone Cement powder plus 1 g of tobramycin; Stryker Canada, Hamilton, Ontario) in all cases. The ulnar nerve was transposed into an anterior subcutaneous position at the conclusion of all surgical procedures.

Antibiotics were administered after surgery for a period of 24 hours for closed fractures and a period of 48 hours for open fractures. Both ORIF and TEA treatment groups had the same rehabilitation protocol. A splint was applied with the elbow at 90°. Active-assisted flexion and gravity-assisted extension of the elbow were begun on the second postoperative day in the hospital. A resting elbow splint was provided to help support the extremity. Patients progressed to unrestricted elbow motion at 6 weeks and strengthening at 8 weeks, depending on wound healing.

A research assistant, blinded to the treatment group, and the attending physician, who was not blinded, performed a standardized clinical assessment of all patients preoperatively; at 6 weeks postoperatively; and at 3, 6, 12, and 24 months postoperatively. At each evaluation, the patients completed a patient-oriented and limb-specific measurement questionnaire (DASH).[2,8] Baseline questionnaires (preinjury DASH and preinjury Short Form 36) were completed before patient discharge from the hospital. At each follow-up evaluation, the MEPS was calculated based on pain, range of motion, stability, and function.[19] Standard anteroposterior and lateral radiographs were obtained at each follow-up evaluation. In the ORIF group, radiographs were used to determine the quality of reduction and fixation, presence or absence of union, and evidence of arthritic change. In the TEA group, radiographs were used to determine the presence or absence of radiolucent lines.

The primary outcome measurement was the reoperation rate. The secondary outcome measures were patient outcome (ie, pain,

motion, stability, and daily function) based on both objective elbow performance scores (MEPS) and patient-rated upper extremity disability and symptoms (DASH). Complication rates (ie, malunion/nonunion, refracture, loss of mechanical fixation, infection, wound breakdown, and ulnar neuropathy) were also analyzed.

Data analysis

The statistical software used was SPSS for Windows, version 13.0 (SPSS, Chicago, IL). All scale variables were tested for normality with the Kolmogorov-Smirnov test. The main effect of treatment on DASH scores and MEPSs was analyzed by use of a 2-way analysis of variance with treatment (ORIF and TEA) and time (6, 12, 24, 52 and 104 weeks) as independent factors, and the Tukey post hoc method was used for the comparison of means. The Student *t* test was used for the comparison of means for parametric scale variables in independent groups. Nominal variables were tested by the χ^2 test or Fisher exact test. All tests were 2-sided. The results were considered to be significant at $P < .05$.

Two analyses were conducted on the postoperative data. The first was an intention-to-treat analysis in which all patients, regardless of further treatment (ie, intraoperative conversion or postoperative crossover), remained in their original group. The second analysis was an on-treatment analysis in which patients were analyzed by the treatment actually received instead of that randomly allocated (the 5 patients randomized to ORIF who were converted intraoperatively to TEA because of the inability to stabilize the fracture adequately). A conservative efficacy analysis was performed for the single case of postoperative crossover (ORIF failure converted to TEA at 6 months postoperatively) in which the patient's last score before he or she crossed over to the other treatment group was identified and carried forward through the remaining evaluations.[29]

Table I Baseline patient demographics of ORIF and TEA randomization groups

	ORIF (n = 20)	TEA (n = 20)	*P* value
Age (y)	78	77	.56
Male/female ratio (No.)	4:16	1:19	.34
Weight (lb)	157	148	.44
Smoker/nonsmoker ratio (No.)	0:20	0:20	
Injury severity score	5.85	4.55	.21
Prior diagnosis of osteoporosis	5	7	.73
Diabetes	4	2	.66
DASH baseline	9	16	.19
Baseline activity level			.61
Active	19	17	
Sedentary			
Cane	1	3	
Walker	0	0	
Mechanism of injury			.06
Low-energy fall	13	19	
Fall from height	6	1	
Motor vehicle accident	1	0	
Fracture type			.08
Closed	18	17	
Grade I treated within 12 h	0	3	
Grade I treated with irrigation and debridement within 12 h	2	0	
OTA classification			.27
13C1.1	2	0	
13C1.2	4	1	
13C1.3	0	0	
13C2.1	1	3	
13C2.2	0	1	
13C2.3	1	1	
13C3.1	3	8	
13C3.2	2	1	
13C3.3	7	5	

Results

Forty-two patients were enrolled in the study. Two died of unrelated causes before complete follow-up and were excluded from the analysis of data. Data were, therefore, collected on 40 patients: 20 randomized to ORIF and 20 randomized to TEA.

Baseline variable for the groups after randomization are summarized in Table I. There were no significant differences between the groups in terms of age, gender, weight, baseline preinjury DASH, injury severity score, mechanism of injury, smoking status, baseline activity, and fracture type.

All patients had an AO/OTA type 13C fracture of the distal humerus that was confirmed intraoperatively. Five randomized to the ORIF group were converted to TEA intraoperatively because of extensive comminution and inability to obtain fixation stable enough to allow early mobilization in the judgment of the attending surgeon. This intraoperative conversion group consisted of 4 women and 1 man with a mean age of 81 years. The mechanism of injury was a low-energy fall in the women, whereas the man had a fall from a height. This resulted in 15 patients treated with ORIF and 25 patients treated with TEA after the initial surgical procedure. Baseline variables for the groups after initial operative treatment are summarized in Table II. The results presented in this report were derived from the on-treatment analysis. There was a significantly decreased operative time (mean, 32 minutes) in the TEA group. The mean operative time was 140 ± 38 minutes in the ORIF group and 108 ± 21 minutes in the TEA group ($P = .001$). The length of hospitalization averaged 9.3 ± 9.7 days (range, 3-42 days) in the ORIF group and 7.7 ± 6.3 days (range, 2-28 days) in the TEA group ($P = .5$).

One patient in the ORIF group was converted to TEA 6 months postoperatively, and a conservative efficacy analysis was used to accommodate the data. In this patient, a nonunion had developed with an incongruent joint space greater than 2 mm. Six months after ORIF, the range of motion was 115° flexion, 50° extension, 90° supination, and 70° pronation, and the MEPS was 55. Six months after TEA, the range of motion was 150° flexion, 30° extension,

Table II Baseline patient demographics of ORIF and TEA treatment groups (crossover)

	ORIF (n = 15)	TEA (n = 25)	*P* value
Age (y)	77	78	.72
Male/female ratio (No.)	4:16	1:19	
Weight (lb)	157	149	.49
Smoker/nonsmoker ratio (No.)	0:15	0:25	
Injury severity score	6.13	4.64	.16
Prior diagnosis of osteoporosis	3	9	.28
Diabetes	3	3	.49
DASH baseline	9	14	.34
Baseline activity level			.59
Active	14	22	
Sedentary			
Cane	1	3	
Walker	0	0	
Mechanism of injury			.04
Low-energy fall	9	23	
Fall from height	5	2	
Motor vehicle accident	1	0	
Fracture type			.08
Closed	13	22	
Grade I treated within 12 h	0	3	
Grade I treated with irrigation and debridement within 12 h	2	0	
OTA classification			.16
13C1.1	2	0	
13C1.2	3	2	
13C1.3	0	0	
13C2.1	0	4	
13C2.2	0	1	
13C2.3	1	1	
13C3.1	2	9	
13C3.2	2	1	
13C3.3	5	7	

90° supination, and 70° pronation, and the MEPS was 70. The overall results of the intention-to-treat and on-treatment analyses were not significantly different from those of the conservative efficacy analysis (data not shown).

Reoperation was required after the initial procedure in 7 patients, 4 (27%) who had ORIF and 3 (12%) who had TEA ($P = .2$) (Table III). However, if the 5 patients converted intraoperatively from ORIF to TEA were considered to have failed treatment and required reoperation, then the patients randomized to the ORIF group would have a reoperation rate of 45% (9/20) compared with 15% (3/20) for the TEA group ($P = .04$). No evidence of humeral or ulnar component loosening that required revision arthroplasty developed in any of the patients who required intraoperative or postoperative conversion from ORIF to TEA.

The mean MEPS was significantly improved in patients who had TEA compared with ORIF at 3 months (83 vs 65, $P = .01$), 6 months (86 vs 68, $P = .003$), 12 months (88 vs 72, $P = .007$), and 2 years (86 vs 73, $P = .015$) (Figure 2). At 2 years, the distribution of MEPS (excellent, ≥90 points; good, 75-89 points; fair, 60-74 points; and poor, <60 points) for patients with TEA compared with ORIF was significantly different ($P = .035$). In the ORIF group, the outcome was excellent in 1, good in 7, fair in 6, and poor in 1. In comparison, in the TEA group, the outcome was excellent in 12, good in 9, fair in 3, and poor in 1. The poor result in the ORIF group was in a patient involved in a motor vehicle collision with a prolonged hospital course and development of significant post-traumatic elbow stiffness necessitating hardware removal and a capsular release. The 6 fair results comprised 1 patient with fixation failure after ORIF, 1 with a wound complication and ulnar nerve symptoms, 1 with ulnar nerve motor and sensory deficits that partially resolved by 2 years, 2 with post-traumatic stiffness, and 1 with an incongruent joint who also had a proximal humeral fracture at 6 months. The poor result in the TEA group was because of severe post-traumatic stiffness that required a capsular release. The 3 fair results comprised 1 patient with mild pain, a stable elbow, and a flexion-extension arc of 85° but limited function because of a rotator cuff tear that developed at 1 year; 1 patient initially converted to a TEA intraoperatively with mild pain, a flexion-extension arc of 100°, and a stable elbow but limited function; and 1 patient with mild pain, a flexion-extension arc of 100°, and a stable elbow but limited function because of advanced age (89 years).

Although there was a trend toward improved motion in the TEA group (by 12°), the mean extension, flexion, and arc of motion of flexion-extension were not significantly different between the ORIF group and TEA group at 2 years. In the ORIF group, the mean extension was 28° (range, 5°-60°), mean flexion was 123° (range, 90°-150°), and mean arc of motion of flexion-extension was 95° (range, 30°-140°). In the TEA group, the mean extension was 26° (range, 0°-72°), mean flexion was 133° (range, 90°-155°), and mean arc of motion of flexion-extension was 107° (range, 42°-145°). The mean pronation-supination arc at 2 years was 160° (range, 90°-180°) in the ORIF group and 172° (range, 110°-180°) in the TEA group ($P = .13$).

DASH scores showed a significant improvement for TEA compared with ORIF between 6 weeks (43 vs 77, $P = .02$) and 6 months (31 vs 47, $P = .04$) but not at 12 months (31 vs 47, $P = .07$) and 2 years (32 vs 43, $P = .18$) (Figure 3). Of the patients in the TEA group, 53% returned to within 10 points of their baseline DASH score (Figure 4), as compared with only 8% of ORIF patients (Figure 5).

The number of complications was similar for treatment with ORIF and TEA (Table IV). Eight patients treated with ORIF and ten with TEA had at least 1 complication ($P = .4$). Four ORIF and three TEA patients had more than 1 complication. Ulnar nerve symptoms were the most common overall complication and were present in 20% of patients, including 5 treated with ORIF and 3 treated with TEA. Two required ulnar neurolysis for persistent

Table III Details of reoperations in patients undergoing ORIF and TEA

Patient No.	Procedure	Indication	Group	Time (wk)
1	Removal of hardware, capsular release	Stiffness	ORIF	70
2	Removal of hardware, ulnar neurolysis	Ulnar neuropathy	ORIF	68
3	Manipulation under anesthesia	Stiffness	ORIF	20
4	Revision to TEA	Nonunion	ORIF	30
5	Irrigation and debridement, 2-stage revision TEA	Deep infection	TEA	47
6	Capsular release	Stiffness	TEA	60
7	Excision of heterotopic ossification, ulnar neurolysis	Stiffness, ulnar neuropathy	TEA	17

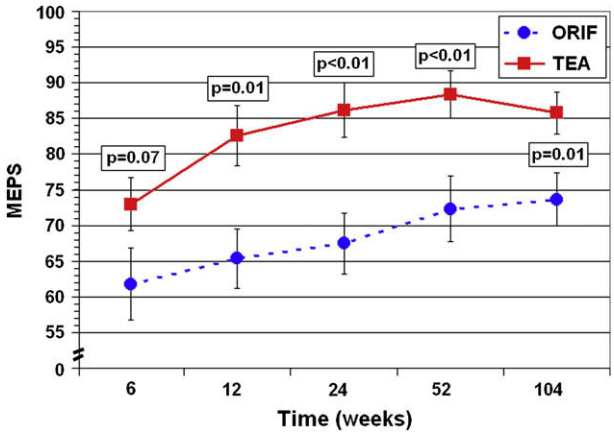

Figure 2 MEPS was significantly improved at 3 months (83 vs 65, $P = .01$), 6 months (86 vs 68, $P = .003$), 12 months (88 vs 72, $P = .007$), and 2 years (86 vs 73, $P = .015$) in patients with TEA (*solid line*) compared with ORIF (*dashed line*). *Error bars* represent SE.

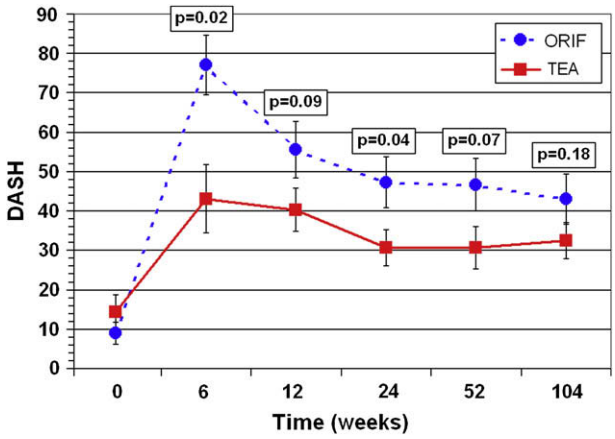

Figure 3 DASH scores showed a significant improvement for TEA (*solid line*) compared with ORIF (*dashed line*) between 6 weeks (43 vs 77, $P = .02$) and 6 months (31 vs 47, $P = .04$) but not at 12 months (31 vs 47, $P = .07$) and 2 years (32 vs 43, $P = .18$). *Error bars* represent SE.

symptoms, one with ORIF and one with TEA. Problems with wound healing without signs of infection (delayed healing, skin edge necrosis, hematoma) were encountered in 2 patients in the ORIF group and 4 in the TEA group. In 5 patients (2 in ORIF group and 3 in TEA group), post-traumatic stiffness developed, with 2 in each group undergoing reoperation, including a capsular release. The remaining patient in the TEA group was an 82-year-old woman who had range of motion from 20° to 90° but had no pain and had good daily function (MEPS of 85) and wished to avoid further surgical intervention.

Radiographs taken for the fractures treated with ORIF that healed without revision (14 patients) showed that 10 had an anatomic reduction, and 4 had greater than 2 mm of articular incongruity with stable fixation. There was no evidence of arthritic change (at this early point) in these individuals. One patient treated with ORIF had Brooker type III heterotopic ossification with extension of 50°, flexion of 95°, and a 135° supination-pronation arc. Three patients treated with TEA had Brooker type III heterotopic ossification, with one undergoing resection and revision ulnar nerve transposition at 4 months postoperatively. At 2 years, this patient had an excellent outcome (MEPS of 100) with extension of 25°, flexion of 140°, and full supination and pronation. The 2 remaining TEA patients with type III heterotopic ossification had ranges of elbow flexion-extension of 40° to 135° and 20° to 90°, with MEPs of 80 and 85, respectively.

Radiographic evaluation in the TEA group indicated that the implant was associated with a progressive radiolucency of the ulnar component in 1 patient. In this patient, an early wound problem with persistent drainage had developed, and subsequently, a deep infection developed at 9 months, requiring a successful 2-stage revision elbow arthroplasty. None of the patients (n = 5) with open Gustilo grade I injuries had any evidence of infection during the course of the study.

Discussion

Displaced, comminuted, intra-articular fractures of the distal humerus are difficult to treat because of the complex anatomy of the elbow. Although osteosynthesis with double-plate fixation is the recommended treatment in adults, the presence of osteoporotic bone, metaphyseal comminution, poor-quality soft tissue, and intolerance for joint immobilization increases the challenge in the

Figure 4 Preoperative anteroposterior (**A**) and lateral (**B**) radiographs and postoperative anteroposterior (**C**) and lateral (**D**) radiographs in 88-year-old woman with a type C3 distal humeral fracture treated with TEA.

elderly.[5,10,12,13,27] Loss of basic elbow function can severely affect activities of daily living: for an elderly patient with comorbid illnesses and limited mobility, these injuries can lead to the loss of independence.[16]

This problem can be expected to become more prominent with time, as the incidence of osteoporotic fractures of the distal humerus is increasing dramatically. Palvanen et al[24] used national hospital discharge data to determine trends in the incidence of osteoporotic fractures of the distal humerus in Finnish women aged 60 years or older and found that the annual rate increased significantly from 11 per 100,000 in 1970 to 30 per 100,000 in 1995 (with a 9-fold increase in women aged >80 years). Both prior studies and our data show a large female preponderance; we observed an overall 7:1 ratio of women to men. John et al[10] reported a 5:1 ratio of women to men, whereas Korner et al[13] found that women comprised 80% of their patients aged older than 60 years. North American demographics dictate a similar trend and reinforce the need to identify the optimal treatment for comminuted distal humeral fractures in the elderly to maximize functional outcome and maintain independence.

Although there is substantial evidence of the benefits of ORIF in younger patients,[14-16,22] the results have been highly variable in the elderly, with a significant failure/poor outcome rate.[9,10,13,25,28] John et al[10] reviewed the results of

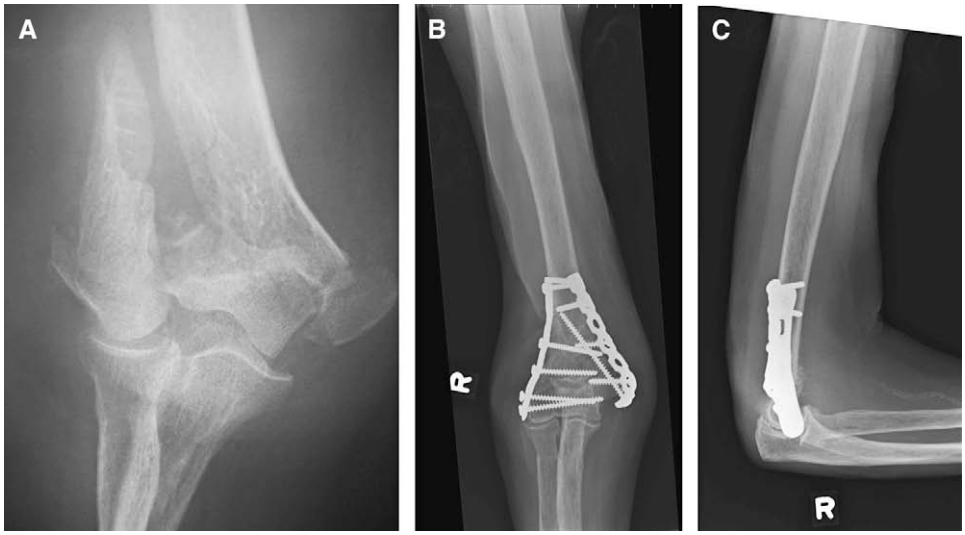

Figure 5 Preoperative radiograph (**A**) of displaced, comminuted, intra-articular distal humeral fracture in an 84-year-old woman and anteroposterior (**B**) and lateral (**C**) radiographs after fixation with a precontoured lateral J plate and a medial pelvic reconstruction plate.

Table IV Complications in patients undergoing ORIF and TEA

Complications	ORIF (n = 15)	TEA (n = 25)
Ulnar nerve		
Sensory deficit	5	3
Motor deficit	1	2
Radial nerve palsy (temporary)	1	0
Wound complication	2	4
Post-traumatic stiffness	2	3
Malalignment >5°	3	1
Incongruent reduction >2 mm	4	0
Nonunion	1	0
Infection		
Deep	0	1
Superficial	1	1
Type III heterotopic ossification	1	3
Total	21	18

49 patients with a mean age of 80 years (range, 75-93 years) treated with ORIF of the distal humerus after a mean of 18 months. Of the fractures, 28 (57%) were classified as AO/OTA type C. Fair and poor functional results were observed in 26%, with an overall complication rate of 18%. Korner et al[13] reported on the outcome of 45 patients with a median age of 73 years (range, 61-92 years) and a minimum follow-of 2 years. Overall, 19 patients (42%) had a fair or poor outcome according to the MEPS; in patients with AO/OTA type C fractures, only 45% had an excellent or good outcome. Srinivasan et al[28] reported their results with ORIF for these fractures in 21 patients with a mean age of 85 years (range, 75-100 years) and found fair or poor outcomes in 43%. Frankle et al[5] compared the results of ORIF and TEA in the treatment of AO/OTA type C distal humeral fractures in 24 women aged older than 65 years. In the 12 patients with ORIF, only 66% had good to excellent results, and ORIF failed completely in 25%.

Our study supports previous literature reporting that advanced age itself is not a contraindication for ORIF, because good or excellent functional results can be achieved in selected patients with AO/OTA type C fractures. ORIF was performed by fellowship-trained orthopaedic trauma and upper extremity surgeons in our study using standard goals (anatomic articular restoration, plates on both the medial and lateral columns, early postoperative motion); however, 47% of patients achieved a poor to fair MEPS. This figure is consistent with the literature and suggests that these current fixation strategies are not optimal in the elderly. The use of newer anatomic locking plates[22] or alternative fixation strategies, such as parallel plating,[26] may be better suited to this specific patient group if ORIF is chosen.

Several studies suggest that primary TEA is a reliable treatment for severe intra-articular distal humeral fractures in the elderly. Cobb and Morrey[3] reported on primary TEA in 20 patients (21 elbows) with a mean age of 72 years (range, 48-92 years) and a mean follow-up of 3.3 years. On the basis of the MEPS, 15 elbows had an excellent result and 5 had a good result. The mean arc of flexion was 25° to 130°, and 1 patient required revision for a fracture of the ulnar component. Gambirasio et al[6] reported on 10 women (mean age, 85 years) treated with primary TEA. Of these, 8 had an excellent outcome and 2 had a good outcome based on the MEPS. Garcia et al[7] evaluated 16 patients with a mean age of 73 years (range, 61-95 years) treated by primary TEA at a mean follow-up of 3 years (range, 1.5-5 years). The mean DASH was 23 (range, 1-63), and the mean MEPS was 93 (range, 80-100). Frankle et al[5] had 11 excellent, 1 good, no fair, and no poor results in their patients with TEA.

Despite the abundance of retrospective reviews, to our knowledge, there has not been a study that compares ORIF and TEA in the elderly population in a prospective, randomized fashion. In our study, patients treated with TEA had significantly improved MEPSs at all time points in the follow-up period, up to and including 2 years, despite the inclusion of the 5 worst fractures originally randomized to the ORIF group (this would have the potential to bias results against the TEA group). The improvements in the TEA group were especially marked early in the post-operative period, which coincides with our (and others') subjective impression of faster recovery with TEA in this situation. Again, a large difference in perceived disability was seen early in the patient-based DASH scores, with a 34-point superiority in the TEA group at 6 weeks post-operatively. The DASH scores were significantly improved in the TEA group in terms of self-perceived functional outcome from 6 weeks to 6 months but began to converge after 1 year, despite continued physician-observed differences between treatment groups based on the MEPS (Figures 2 and 3).

There are several potential explanations for the ongoing statistical advantage of the TEA group in MEPSs as the DASH scores tend to converge. One is a true and genuine continued improvement in the ORIF group that is only detected by the more sensitive patient-based scores. The second is a numeric one, resulting from the increased variability in the scores of the DASH, which makes statistical significance more elusive as the magnitude of difference diminishes. The third (the option that we believe is most plausible) is that elderly patients in our study adapted over time to their perceived disability despite consistent objective limitations.

When one is performing TEA for fracture, it has been argued that resecting the humeral condyles may have a significant detrimental effect on forearm strength and elbow stability.[4] In this study, we routinely resected the fractured condyles in the TEA group, as has been described previously.[3,5,6] Although this mandates the use of a semi-constrained prosthesis and careful soft-tissue repair, it has not been shown objectively to decrease the strength of muscle groups that originate on the condyles (flexor-pronator mass, common extensor origin), although the long-term effect on humeral component longevity is unknown.[17] This approach also led to a significantly shorter operating time (mean, 32 minutes) in the TEA group.

Although the reoperation rate was higher in the ORIF group (4/15 [27%]) than in the TEA group (3/25 [12%]), this was not statistically significant ($P = .20$). In addition, there were 5 fractures (25%) initially randomized to ORIF that underwent intraoperative conversion to TEA because of severe comminution and inability to obtain stable fixation. The study protocol allowed this, as we believed that it would be unethical to accept inadequate fixation when conversion to TEA was clearly indicated in the surgeon's opinion. Frankle et al[5] observed an identical rate of fixation failure after ORIF requiring conversion to TEA (25%). We had only 1 patient (7%) treated with ORIF in whom a nonunion developed with evidence of failure of fixation and postoperative revision to TEA was required. We believe that these data suggest that approximately 25% of comminuted intra-articular distal humeral fractures in elderly patients are not amenable to fixation and will rapidly fail. We speculate that had these patients been treated with ORIF (as they were randomized to), failure of fixation would have produced a much higher reintervention rate in the ORIF group.

Regardless of which operative treatment patients received, postoperative ulnar nerve problems were the single most common complication in our study. The increased incidence is probably related to our careful, independent surveillance for these complications in a prospective, patient-based fashion. Although most cases improved significantly with time, there is clearly room for improvement. We routinely transposed the nerve at the conclusion of the procedure; this may not be the optimal form of management for the ulnar nerve with a fracture in elderly patients.

The strengths of our study include the prospective randomized design, the use of standardized modern operative techniques, evaluation with comprehensive patient-oriented and surgeon-based outcomes, and complete follow-up. However, we believe that there are 2 main weaknesses. One is that the sample size was relatively small, and we identified several trends (such as the reoperation rate of 27% in the ORIF group vs 12% in the TEA group [$P = .20$] or the 12° improvement in flexion-extension arc in the TEA group as compared with the ORIF group [$P = .19$]) that may have been shown to be statistically significant with a larger sample size (a type II or β statistical error). A greater sample size may also have allowed us to identify prognostic factors for outcome with a higher degree of accuracy. Second, our follow-up was only 2 years, which represents a relatively short time in terms of arthroplasty surveillance. Whereas prior TEA studies would indicate that a group of elderly (mean age at present, 80 years), low-demand women would have intrinsically good prosthesis longevity (85%-90% at 7-10 years), we plan continued monitoring before definitive recommendations about the long-term effectiveness of primary TEA can be made.[1,17,18,20] Kamineni and Morrey,[11] in a recent retrospective review with a mean follow-up of 7 years, reported that 5 of 49 patients required revision arthroplasty, with septic loosening in 1, periprosthetic fracture or component fracture related to a fall in 3, and aseptic loosening in 1. However, 3 of the 5 patients were aged less than 65 years. The potential long-term disadvantage of aseptic prosthetic loosening must be weighed against the more predictable, significantly improved short-term outcomes observed in this study.

In conclusion, this is the first randomized prospective trial to evaluate the efficacy of ORIF compared with TEA

for comminuted distal humeral fractures in patients aged over 65 years. Primary semiconstrained TEA was superior to ORIF as measured by both surgeon-based (MEPS) and patient-based (DASH) outcome scores, especially in the early postoperative period. Operative time was shorter by a mean of 32 minutes in the TEA group. There were trends toward a reduced reoperation rate and improved range of motion in the TEA group, which were not statistically significant. In addition, 25% of patients randomized to ORIF required intraoperative conversion to TEA, a consistent figure in multiple studies that we believe represents a subset of individuals with this fracture type who are not amenable to ORIF. We believe that our study supports the use of primary TEA in elderly patients with comminuted, intra-articular distal humeral fractures.

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