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Long-term outcomes of total elbow arthroplasty for distal humeral fracture: results from a prior randomized clinical trial



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Background: Total elbow arthroplasty (TEA) is a reliable treatment for elderly patients with comminuted intra-articular distal humeral fractures. However, the longevity and long-term complications associated with this procedure are unknown. The objectives of this study were to examine long-term outcomes and implant survival in elderly patients undergoing TEA for fracture.

Methods: Patients from a previously published randomized controlled trial of 42 patients in which TEA was compared with open reduction–internal fixation (ORIF) were followed up long term. Patients were aged 65 years or older with comminuted intra-articular distal humeral fractures. Outcomes included patient-reported grading of function and pain, revision surgical procedures, and implant survival.

Results: Data were obtained for 40 patients, 15 treated with ORIF and 25 treated with TEA, with a mean follow-up period of 12.5 years for surviving patients and 7.7 years for deceased patients. The reoperation rate was 3 of 25 in the TEA group and 4 of 15 in the ORIF group ($P = .39$). Of the 25 patients with TEAs, only 1 required (early) revision arthroplasty; 7 were living with their original arthroplasty, and 15 died with a well-functioning implant in situ. Three were lost to follow-up.

Conclusions: TEA is an effective and reliable procedure for the treatment of comminuted distal humeral fractures in the elderly patient. Our study reveals reliable implant long-term survival, with no patient requiring a late revision. For the majority of these patients, a well-performed TEA will give them a well-functioning elbow for life and will be the last elbow procedure required.

Institutional Review Board approval was received from St. Michael's Hospital Research Ethics Board (REB # 14-164).

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Total elbow arthroplasty (TEA) has become an increasingly accepted procedure for the treatment of elderly patients with acute comminuted distal humeral fractures. Multiple retrospective studies have documented good to excellent clinical outcomes at short- to moderate-term follow-up.^{2,3,14} Compared with the standard treatment of open reduction–internal fixation (ORIF), a meta-analysis of the literature including retrospective trials has demonstrated equivalent clinical outcomes with a trend toward increased complication and reoperation rates following ORIF.⁷ A previously published multicenter randomized trial reported superior Mayo Elbow Performance Scores in the TEA group for up to 2 years after surgery.⁹

A major concern regarding TEA for trauma in this setting has been the potential need for revision surgery in this elderly population. Long-term patient-rated outcomes and implant survival in this specific population have not been well established. A recent publication from the Danish National Patient Register demonstrated a relative risk of revision of 1.75 for TEA secondary to trauma for patients older than 60 years.¹² This group included “fracture sequelae” that have been suggested to have higher loosening rates than acute fractures treated primarily with TEA.¹⁰ A more recent Scottish registry report demonstrated 10- and 18-year survival rates of 98% for primary TEA performed for trauma, although age was not specified.⁸

The purpose of this study was to examine long-term outcomes and survivorship of semiconstrained TEA performed for acute trauma compared with patients having undergone ORIF. It was our hypothesis that these elderly patients undergoing TEA for fracture treatment would have excellent long-term outcomes with a high implant survival rate.

Methods

A retrospective review of a previously published multicenter randomized controlled trial (RCT) comparing TEA and ORIF for the treatment of distal humeral fractures in elderly patients was performed (Fig. 1).⁹ This RCT included 42 patients who underwent either TEA or ORIF for the treatment of distal humeral fractures between 2000–2006. The inclusion criteria for the RCT included the following: patients aged 65 years or older, Orthopaedic Trauma Association type 13-C fractures, Gustilo grade 1 open fractures treated within 12 hours of injury, and definitive surgery performed within 21 days of injury. Patients were excluded if they had a vascular injury present at the time of initial injury, prior ipsilateral distal humeral fracture,

pathologic fracture, fracture with a diaphyseal extension of 8 cm or greater, pre-existing severe joint disease, Gustilo grade 2 or higher open fracture, inability to comply with rehabilitation, or impending death due to significant medical comorbidities. For patients who were randomized to ORIF, intraoperative conversion to TEA was acceptable if sufficient stability could not be obtained with ORIF after intraoperative assessment. Formal follow-up for this RCT concluded at 2 years postoperatively. Research ethics board approval was obtained for the initial RCT, as well as the current study investigating long-term outcomes.

Regarding this study, patients were identified from available research records. A chart review was performed identifying the latest follow-up visit. Data from the most recent follow-up visit were then collected regarding complications, implant survival, and secondary operations related to the elbow since the index procedure.

Patients were contacted via telephone to question the status of their elbow, inquire about their functional outcomes, and ask if any reoperations were performed since their last visit. Patients were asked to report on overall function and satisfaction as graded on a 10-point scale, with 10 being a normal elbow and 1 being nonfunctional. Lastly, they were asked to report on the average daily pain level, with 10 being severe pain for the majority of the day and 1 being no pain. If the patient was deceased, a family member was questioned regarding elbow function and the need for revision surgery for the elbow in question.

Statistical analysis was performed on grouped continuous data to assess for statistical significance using the Student *t* test. A pretest *P* value of .05 was accepted as the threshold for statistical significance. Binary or categorical data were assessed for statistical significance using the Fisher exact test. Kaplan-Meier survival analysis was performed to assess the survivorship of the initial operation, as well as the need for revision surgery.

Results

Of the originally randomized 42 patients, 2 died early in the first month postoperatively due to unrelated medical issues (1 in each group), and were excluded from analysis. Of the remaining patients, 82% were women (33 of 40); the mean age was 78 years. Patient demographic characteristics are outlined in Table I. Of the 40 patients, 25 had undergone TEA and 15 had undergone ORIF for acute treatment of a distal humeral fracture (Fig. 2). Five patients randomized to ORIF were found to have fractures that were not amenable to fixation and were therefore treated with TEA. These patients were analyzed in the TEA group. All TEA patients received a cemented semiconstrained Coonrad-Morrey TEA (Zimmer, Warsaw, IN, USA).

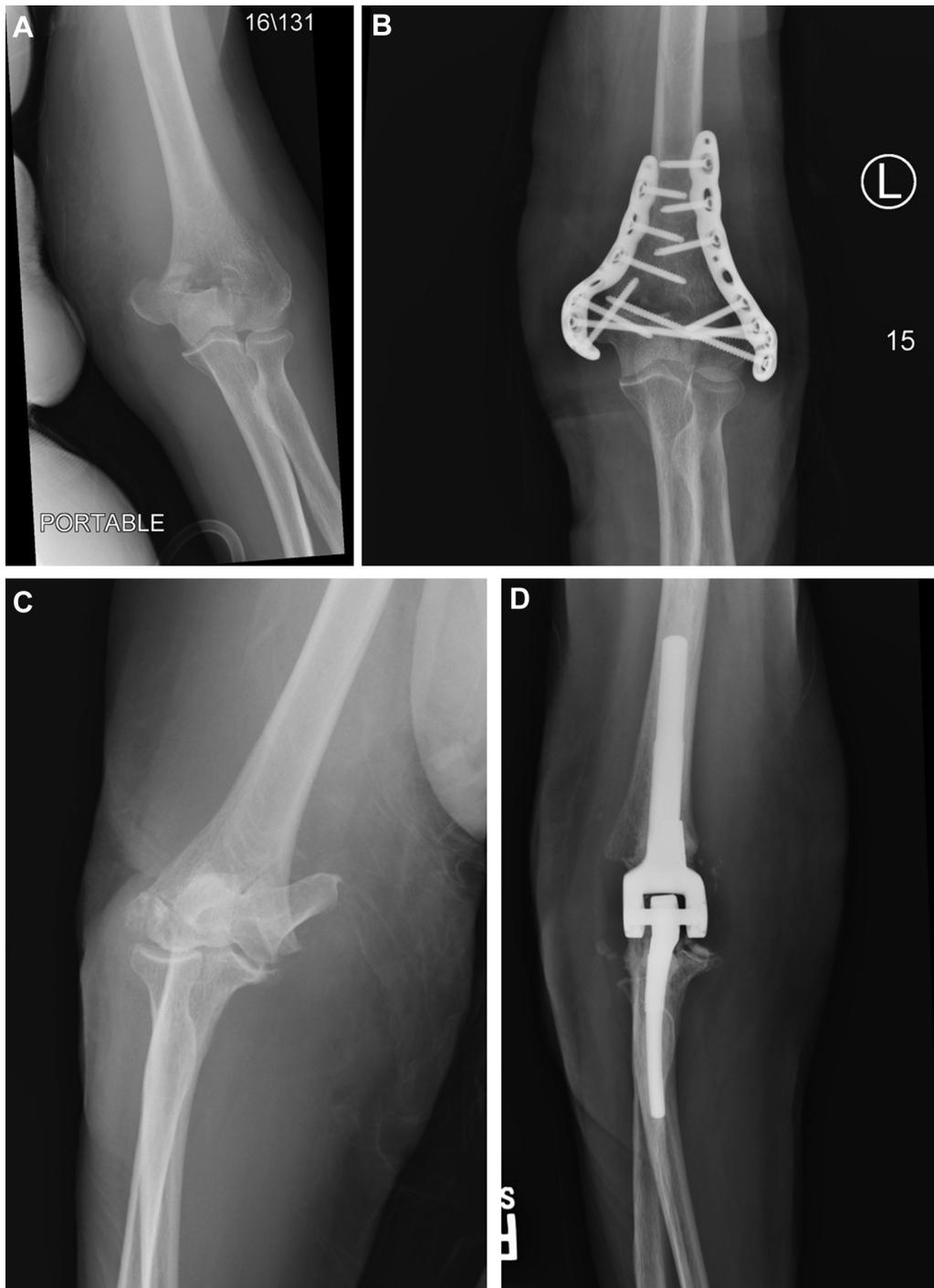


Figure 1 Open reduction–internal fixation and total elbow arthroplasty for treatment of distal humeral fractures in elderly patients. Representative radiographs are shown for patients who underwent either open reduction–internal fixation with bi-columnar plating (**A, B**) or total elbow arthroplasty with the Coonrad-Morrey semiconstrained implant (**C, D**) following a comminuted intra-articular distal humeral fracture.

Early reoperations

Seven patients underwent secondary surgical procedures. Of the 15 patients in the ORIF group, 4 (27%) underwent a second surgical procedure. Two patients underwent hardware removal at a mean of 1.9 years postoperatively

because of pain and ulnar neuritis. A wound infection developed in 1 patient, requiring hardware removal as well as irrigation and débridement at 1.3 years postoperatively, and 1 patient underwent conversion to TEA for a nonunion at 8 months after injury. One patient in the ORIF group had a subsequent fall, and fracture occurred above the prior

Table I Patient characteristics and outcomes

| Patients | TEA (n = 25) | ORIF (n = 15) | P value |
|--------------------------------|---------------|---------------|---------|
| Patient characteristics | | | |
| Mean age at time of injury, yr | 78 | 77 | .56 |
| Female, n (%) | 22 of 25 (88) | 11 of 15 (73) | .24 |
| Mean follow-up, yr | 7.7 | 7.6 | .97 |
| Patient outcomes, n (%) | | | |
| Secondary surgery | 3 of 25 (12) | 4 of 15 (27) | .39 |
| Confirmed death | 15 of 25 (60) | 10 of 15 (67) | .71 |

TEA, total elbow arthroplasty; ORIF, open reduction–internal fixation.

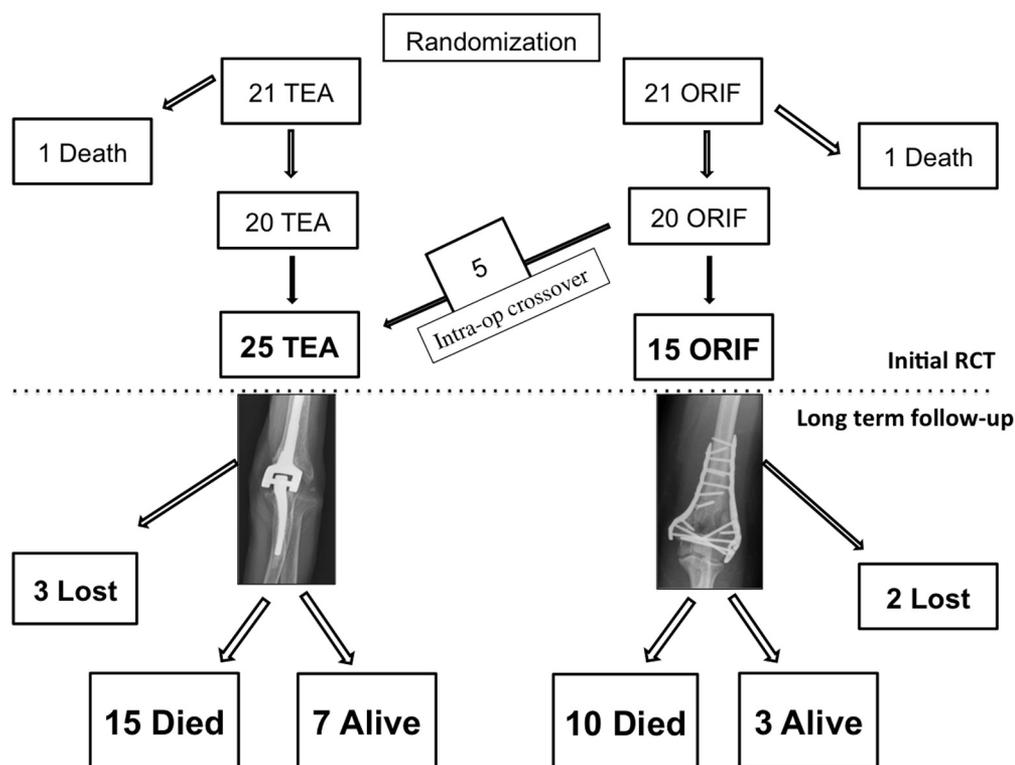


Figure 2 Randomization scheme and number of patients available for long-term follow-up. TEA, total elbow arthroplasty; ORIF, open reduction–internal fixation; *Intra-op*, intraoperative; RCT, randomized controlled trial.

fixation. This secondary fracture went on to heal without operative intervention.

Of the 25 patients in the TEA group, 3 (12%) underwent a secondary procedure. One patient underwent resection for heterotopic ossification at 4 months postoperatively. One patient underwent irrigation and débridement as well as revision TEA for a deep infection at 11 months postoperatively, and a third patient underwent elbow release for stiffness at 14 months postoperatively (Fig. 3).

All reoperations occurred within the first 2 years postoperatively and were reported in the initial RCT.⁹ No difference was found between the 2 groups regarding rates of revision surgery ($P = .39$). No documented reoperations occurred in the long term in either group.

Implant survival

The mean follow-up period was 7.7 years (range, 1.0–14.7 years). The mean follow-up period was 7.6 years for the TEA group and 7.7 years for the ORIF group. A significant proportion of patients were deceased when we attempted to contact them by telephone for this study. There were 25 confirmed deaths (63%) at a mean of 7.5 years after injury, whereas 10 patients were still alive (26%). We were unable to locate 5 patients (12%) who were assumed to be lost to follow-up after the initial RCT period. One patient was assessed at 4.1 years postoperatively, with no revision surgery, whereas the other 4 patients had no long-term follow-up beyond the initial RCT (2.0 years of follow-up).

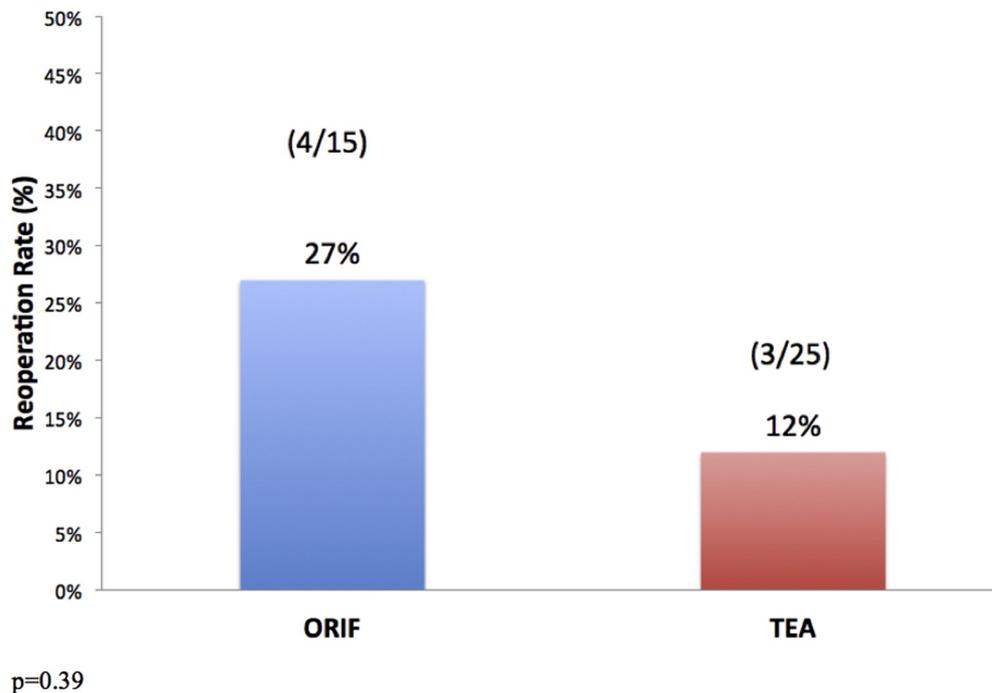


Figure 3 Reoperation rates for elderly patients treated with total elbow arthroplasty (TEA) and open reduction–internal fixation (ORIF).

Of the 25 patients with TEAs who were followed up long term, 28% (7 of 25) were still living with their original arthroplasty and were contacted by telephone (mean follow-up, 12.5 years); 60% (15 of 25) had died with a well-functioning implant in situ; 12% (3 of 25) were lost to follow-up (2 had 2-year data and 1 had 4.1-year data available); and 4% (1 of 25) had required an early revision. All 15 patients who died had a well-functioning elbow, without the need for revision of their elbow prosthesis. A Kaplan-Meier survival analysis was performed to compare survival time with revision elbow surgery, which revealed no difference between the 2 groups ($P = .27$) (Fig. 4).

Long-term patient-rated outcomes

Surviving patients were contacted by telephone at a mean of 12.6 years following initial surgery. Seven patients in the TEA group and 3 in the ORIF group were alive and contacted. The mean elbow function as reported by patients was 7.7 of 10 in the ORIF group and 8.9 of 10 in the TEA group. Reported daily pain as reported by patients was 1.7 of 10 in the ORIF group and 1.1 of 10 in the TEA group. Because of the low number of survivors, statistical analysis on these outcomes was not performed.

Discussion

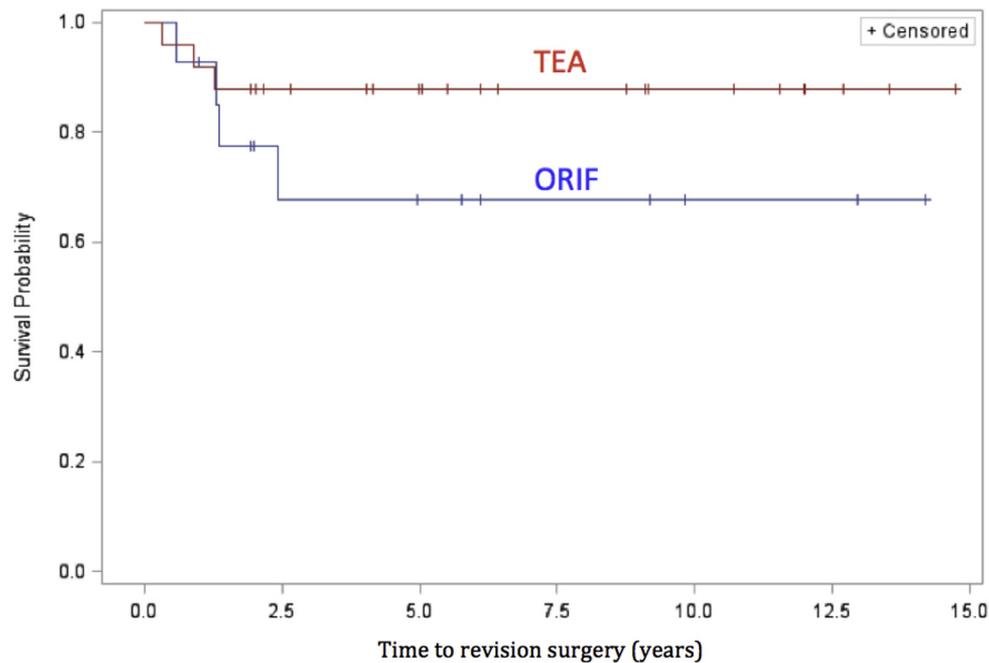
Comminuted intra-articular distal humeral fractures are difficult injuries to treat. These are particularly difficult in

the elderly population because of a number of commonly encountered factors, including underlying osteoporotic bone, poor soft tissue, and significant articular and metaphyseal comminution. Treatment options for these patients include nonoperative treatment, ORIF, and TEA. Although nonoperative treatment has been used extensively in the past and continues to be appropriate in a minority of cases, it is associated with a high complication rate and poor functional outcomes.^{6,11}

ORIF is applicable for the majority of patients with intra-articular fractures of the distal humerus. It is recognized, however, that not all distal humeral fractures are amenable to ORIF, especially in the elderly population. A prior RCT of elderly patients with Orthopaedic Trauma Association type 13-C fractures demonstrated that in 25% of cases, the fracture was not amenable to surgical fixation and required intraoperative conversion from ORIF to TEA.⁹ Similarly, another study of elderly patients reported failure of fixation in approximately 25% of patients who underwent ORIF, in whom conversion to TEA was then required.⁵

Primary TEA for fractures also has the potential to improve function in these elderly patients. The prior RCT found, in addition to a more rapid return to function, improved Mayo Elbow Performance Scores for up to 2 years in the TEA group compared with the ORIF group.⁹ However, a recent meta-analysis that took into account retrospective data found equivocal restoration of range of motion and patient-reported function.⁷

A persistent concern regarding the use of primary TEA in the treatment of elderly patients with distal humeral



$p=0.27$

Figure 4 Kaplan-Meier survival analysis for implant survival (time to revision surgery). *TEA*, total elbow arthroplasty; *ORIF*, open reduction–internal fixation.

fractures has been the unknown long-term durability of the prosthesis. Although data up to 2 years have been reported with a minimal need for revision (0%),⁵ long-term data have been deficient. However, recent evidence has suggested a low risk of reoperation in this select group of patients.

A Scottish registry of 1146 primary TEA procedures reported that 12% were performed for trauma, with 10- and 18-year survival rates of 98%.⁸ Another study of 37 non-rheumatoid patients treated with TEA for distal humeral fractures reported a high mortality rate at 10 years, with only 53% of patients surviving.¹³ Of the 19 patients with minimum 10-year follow-up data, 3 underwent revision surgery: 1 underwent revision for aseptic loosening, 1 underwent revision for bushing exchange, and 1 underwent a 2-stage revision for infection prior to the 10-year follow-up. The authors indicated that implant survivorship was 89.5% at 10 years in those patients followed up for a minimum of 10 years. A recent study reported on 44 patients undergoing TEA for distal humeral fractures and found an 18% rate of implant revision or resection at 10 years' follow-up.¹ Patients with rheumatoid arthritis had lower rates of survival at 10 years than non-rheumatoid patients (76% vs 92%), although this difference was not statistically significant. After conducting a multivariable analysis, the authors reported that male sex was the only significant factor for revision surgery (hazard ratio, 12.6; $P = .013$).

Our study is in agreement with the aforementioned studies. There was a high mortality rate (60% in the TEA

group) in this elderly patient population, and only 1 of 25 TEAs required revision arthroplasty at a mean of 12.6 years postoperatively. Although our study had significant demographic-influenced patient attrition, this appears to be comparable to other series.¹³ Our high rate of patient mortality and low rate of revision surgery demonstrate the survivorship of the TEA for the remainder of the patient's life in this elderly population, without the need for revision surgery.

It must be stressed that the implant survival rate of TEA following trauma is contingent on appropriate patient selection. There is a concern for unacceptably high failure rates and poor function in young patients undergoing TEA.⁴ In contrast, the relatively sedentary lifestyle of appropriately selected elderly patients allows for excellent clinical outcomes with, as documented by our study, a very low revision rate. The majority of patients in our study died with a well-functioning elbow prosthesis, and the small number who were alive expressed good functional outcomes.

Our patient population was initially randomized, which limits initial selection bias. However, the present study has a number of limitations inherent to a retrospective review, including relying on charted information and indirect follow-up (ie, from patients' families or caregivers). The 1- to 10-point survey was an expedient but unproven technique for assessing patients' pain and function and may not be a reproducible method of assessing outcomes. In addition, the small sample size and attrition due to patients'

deaths limit the statistical power of our observations. Lastly, the surgeons who performed the majority of procedures in both groups were fellowship-trained upper-extremity surgeons, limiting the overall generalizability to a community orthopedic surgeon. There has been some suggestion in the literature that patients requiring primary TEA for underlying joint disease should be referred to a central facility for the procedure, as overall survival rates are improved in the hands of a surgeon performing 10 or more TEAs per year.⁸ This advantage likely would be applicable to the trauma setting as well.

Conclusion

TEA is an effective and reliable procedure for comminuted fractures of the distal humerus in elderly patients. Our study revealed that long-term survival of the implant is excellent, with no patient requiring a late revision. This finding, combined with the better functional results and rapid rehabilitation compared with ORIF that we have previously reported, confirms the utility of TEA in this elderly and low-demand population. For the overwhelming majority of these patients, a well-performed TEA will give them a well-functioning elbow for life and be the last elbow procedure they require.

Disclaimer

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Niloofar Dehghan has immediate family members who receive royalties and consulting fees related to the distal humeral plate fixation system.

Laura Schemitsch has immediate family members who receive royalties and consulting fees related to the distal humeral plate fixation system.

Emil H. Schemitsch receives royalties and consulting fees related to the distal humeral plate fixation system.

Michael McKee receives royalties and consulting fees related to the distal humeral plate fixation system.

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