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Multicenter trial of an internal joint stabilizer for the elbow

Jorge L. Orbay, MD[a], David Ring, MD, PhD[b], Amir R. Kachooei, MD[c,d,*], Jose Santiago-Figueroa, MD[e], Luis Bolano, MD[f], Miguel Pirela-Cruz, MD[g], Michael Hausman, MD[h], Rick F. Papandrea, MD[i]

[a]*The Miami Hand & Upper Extremity Institute, Miami, FL, USA*
[b]*Department of Surgery and Perioperative Care, Dell Medical School, The University of Texas at Austin, Austin, TX, USA*
[c]*Orthopedic Research Center, Mashhad University of Medical Sciences, Mashhad, Iran*
[d]*Hand and Upper Extremity Service, Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA*
[e]*Department of Orthopaedic Surgery, University of Puerto Rico, San Juan, Puerto Rico*
[f]*Department of Orthopedics, Three Gables Surgical Hospital, Proctorville, OH, USA*
[g]*Department of Orthopaedic Surgery & Rehabilitation, Texas Tech University of Health Science, El Paso, TX, USA*
[h]*Department of Orthopedics, The Mount Sinai Medical Center, New York, NY, USA*
[i]*Orthopedic Association of Wisconsin, Waukesha, WI, USA*

Background: Our primary efficacy objective was to evaluate the effectiveness of the internal joint stabilizer of the elbow (IJS-E) in maintaining concentric location of the elbow during and after removal of the device in the treatment of persistent or recurrent instability after elbow fracture or dislocations, or both. The secondary study objectives were to assess range of motion, Broberg-Morrey functional score, Broberg-Morrey categorical rating, the Disabilities of the Arm, Shoulder and Hand score, and the rate of complications and adverse events after the use of IJS-E.

Methods: Twenty-four patients were studied in a multicenter, nonrandomized, prospective, single-arm study. The IJS-E was used to provide temporary stabilization of the elbow joint and allow a functional range of motion while ligaments and fractures healed.

Results: The elbow remained concentrically aligned in 23 of 24 patients. One coronoid-deficient elbow did not maintain concentric reduction. At the last evaluation a minimum of 6 months after device removal, the mean arc of elbow flexion was 119° (range, 80°-150°; standard deviation [SD], 18°), and the mean arc of forearm rotation was 151° (range, 90°-190°; SD, 24°). The mean and median Broberg-Morrey scores were 93 and 97, respectively. Categorically the results were excellent in 14, good in 8, fair in 1, and poor in 1. The mean Disabilities of the Arm, Shoulder and Hand score was 16 (range, 0-68; SD, 18).

The Massachusetts General Hospital Institutional Review Board approved the human protocol for this investigation under number 2006-P-000869/16.

*Corresponding author and reprint requests: Amir Reza Kachooei, MD, Hand and Elbow Surgery Service, Orthopedic Research Center, Ghaem Hospital, Mashhad University of Medical Sciences, Ahmad-Abad Street, Mashhad, Iran.

E-mail addresses: arkachooei@gmail.com, kachoeear@mums.ac.ir (A.R. Kachooei).

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Conclusion: The IJS-E maintains concentric reduction, allows elbow motion, and avoids the inconveniences and pin problems of percutaneous fixation.
Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Internal joint stabilizer; elbow fracture dislocation; persistent instability; recurrent instability; hinged; subluxation

After an acute injury, elbow stability can often be restored via fixation of a coronoid or olecranon fracture, repair of the lateral collateral ligament, and restoration of radiocapitellar contact.[12] In some patients treated acutely and many patients treated 2 weeks or more after injury, the elbow may not be able to resist subluxation or dislocation after fracture and ligament repair alone. In these situations, surgeons have used external fixation or cross pinning of the joint to hold the elbow concentrically located until the ligaments and fractures heal.[10]

External fixators can often maintain concentric reduction, but they are cumbersome and associated with pin track infection, broken or loose pins, fracture, and nerve injury.[2,7,10] In addition, the distance between the humeral and ulnar pins with external fixation allows sufficient flexibility that the elbow can subluxate and even dislocate in the device. Cross pinning of the elbow with cast immobilization more securely maintains the reduction but is associated with articular damage, pin infection (risking joint infection), and potential pin breakage. An internal hinge device fashioned from a Steinman pin was able to maintain concentric reduction and functional motion during the healing period.[8] This idea was developed into a specific device intended for use as a temporary internal hinged fixator: the internal joint stabilizer-elbow (IJS-E).

This study evaluated the effectiveness of the IJS-E. The primary study question was whether IJS-E is able to maintain concentric location of the elbow during and after removal of the device. The secondary study objectives were to assess range of motion, Broberg-Morrey functional score, Broberg-Morrey categorical rating, the Disabilities of the Arm, Shoulder and Hand (DASH) score, and the rate of complications and adverse events after the use of IJS-E.

Materials and methods

Study design

The first operation in this multicenter, nonrandomized, prospective, single arm, cohort study was performed on August 13, 2013, and the last on July 15, 2014. Inclusion criteria were age 21 years or older, sufficient bone quality and quantity to hold the device, patient willing and reliable to be available for the duration of the study, elbow subluxation or dislocation after initial repair of the injured ligaments or bones, or both, elbow subluxated or dislocated for more than 10 days before surgery, or the elbow subluxates or dislocates after surgical repair/reconstruction of the ligaments and articular fractures.

We excluded patients with limited elbow motion where instability was created through surgical release (including elbow contracture release, soft tissue release, removal of heterotopic ossification, or fascial interposition), active infection, bone loss greater than 30% of the total articulation, or fracture involving an entire column of the distal humerus, less than 50% of the coronoid height remaining as judged on a lateral elbow radiograph, osteoporosis preventing adequate screw purchase, material sensitivity to titanium and cobalt chrome, limited life-expectancy, inability to cooperate with study procedures, exercises, or return visits, any condition that might interfere with healing, prisoner status, and immature skeleton.

Twenty-six patients at 6 investigational sites met the eligibility criteria, signed the written informed consent, and entered the study. Two patients were lost before implant removal; 24 patients completed the study and were analyzed. Among 3 elbows with more long-standing subluxation or dislocation (between 1.5 and 23 months), the lateral collateral ligament was reconstructed with a tendon graft and the medial collateral ligament was also reconstructed with a tendon graft in 1 patient. Among the 16 radial head fractures, 1 was treated with open reduction and internal fixation, 8 were replaced with a prosthesis, 2 were replaced at a prior operation, and 5 were treated nonoperatively. Among the 14 coronoid fractures, 5 were repaired with a suture through drill holes, and 10 were treated nonoperatively. The 2 fractures of the proximal ulna had open reduction and internal fixation with a plate and screws. The most common indication for IJS-E was persistent instability after terrible triad injury, followed by chronic elbow dislocation. All of the patients had elbow dislocation at some point, with most patients having no surgery before the index procedure (Table I).

Device description

The IJS-E is intended to provide temporary stabilization of the elbow joint while ligaments and fractures heal and restore stability. The IJS-E consists of an axial hinge pin inserted along the axis of rotation of the distal humerus and connected to a base plate attached to the olecranon with screws (Figs. 1 and 2). A connecting rod and boom are adjusted to accommodate variations in anatomy (Fig. 3).

Study visits

Data were collected before the implantation of IJS-E, at the first office visit after the first procedure (1-10 days after implant surgery), at removal of the implant (approximately 6 to 8 weeks after implantation), and at 16 to 18 weeks and 24 to 26 weeks after implant removal (Fig. 4).

Anteroposterior and lateral elbow radiographs were obtained 4 times during the study period, including baseline images before