SCIENTIFIC ARTICLE

Treatment of Traumatic Elbow Instability With an Internal Joint Stabilizer

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Purpose Current options for treating elbow instability include bony and/or ligamentous fixation with orthosis or cast immobilization, transarticular cross-pinning, temporary bridge plating, and hinged or rigid external fixation. Our purpose was to evaluate the recently developed internal joint stabilizer (IJS), which acts as an internal external fixator of the elbow. Our primary end point was to assess whether use of the device results in a stable and congruent reduction of the ulnohumeral and radiocapitellar joints in patients with acute or chronic elbow instability as a result of trauma. In our series, patients with elbow instability as a result of acute or chronic trauma were treated with an IJS.

Methods This retrospective study reviewed 20 patients who underwent placement of a U.S. Food and Drug Administration (FDA)—approved IJS for elbow instability. Serial physical examinations and radiographs were performed to verify stability. Patients were instructed that, if they are dissatisfied with their postoperative motion, a secondary contracture release operation will be offered to them. Patients were asked to complete outcome-scoring questionnaires including the Disabilities of the Arm, Shoulder, and hand (DASH) and Mayo Elbow Performance (MEP) score. Complications were monitored for all patients.

Results Twenty patients who underwent placement of an IJS for persistent elbow instability were reviewed. Patients with a flexion-extension arc of 70° or less at 12 weeks were offered a staged arthroscopic contracture release. The average MEP score improved from 12.2 ± 12.4 to 82.5 ± 14.3 and the average DASH score improved from 85.3 ± 23.0 to 37.26 ± 29.3. The average postoperative flexion-extension arc at most recent follow-up was 124.3° ± 14.9°, with a median follow-up of 17 months (8 weeks—25 months).

Conclusions Use of an IJS allows for early, congruent, and stable ulnohumeral and radiocapitellar range of motion in instances of persistent elbow instability. *(J Hand Surg Am. 2019;44(2):161.e1-e7. Copyright © 2019 by the American Society for Surgery of the Hand. All rights reserved.)*

Type of study/level of evidence Therapeutic IV.

Key words Elbow fracture, elbow dislocation, terrible triad, elbow instability, internal joint stabilizer.

Complex fracture-dislocations of the elbow involve damage to both the osseous and ligamentous stabilizers of the ulnohumeral and radiocapitellar joints. While the classic pattern for elbow fracture-dislocation is the so-called terrible triad involving fractures of the radial head and coronoid with associated rupture of the lateral ulnar collateral ligament (LUCL), in practice, a variety of fracture

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patterns and ligamentous injuries may present. Surgical management of these injuries generally involves a combination of open reduction and internal fixation of fractures, ligamentous repair or reconstruction, and postoperative immobilization.[1] Usually, repairing the injured structures can restore stability; however, this is not always possible. Highly comminuted, unreconstructable coronoid fractures, stretching of the LUCL repair, posteromedial instability, delayed treatment of fracture-dislocations, or obesity because the elbow is held in a varus position, are scenarios in which there may be persistent instability. In such situations, options for postoperative immobilization include placement of a static or hinged external fixator, transarticular cross-pinning with orthosis or cast immobilization, or bridge plating.[2] However, none of these options achieve the desired goal of permitting range of motion exercises while reliably maintaining a stable, anatomical, and concentric reduction. Hinged external fixators theoretically come closest to realizing this ideal, but consistent reproduction of the precise axis of motion is problematic, as are pin-track–related complications and issues with patient tolerance of the external device.[3–5] The long lever arms of hinged external fixators, required by extra-articular placement of the pins and the need to avoid radial nerve injury, magnify any error in axis placement and, thus, either restrict motion or potentially increase displacement forces on damaged structures, compounding the instability issue.

Posttraumatic elbow instability is a serious and unsolved problem, despite advancements in radial head arthroplasty and ligament repair and reconstruction. Some cases present acutely and, yet, even after fixation are still not stable. Other cases present with persistent instability despite operative treatment. These patients all remain unstable in spite of all the existing treatments to stabilize an elbow.

Recently, Orbay and Mijares[6] developed an internal joint stabilizer (IJS) as a means to treat elbow instability. Functioning as an internal, "external fixator," these devices are similar to hinged external fixators in that they provide maintenance of concentric joint reduction while allowing for immediate postoperative range of motion. With a very short moment arm, the device makes it easier to reliably reproduce the axis of motion and avoid the multiple pin-site–related complications associated with external fixation. This study reviews 20 cases of complex elbow instability resulting from trauma that, in addition to open reduction and internal fixation with ligamentous repair or reconstruction, were treated with placement of an IJS device to maintain a concentric joint reduction during early postoperative range of motion.

MATERIALS AND METHODS

This is an institutional review board–approved retrospective case series of 20 patients with posttraumatic elbow instability after traumatic dislocation, treated with an IJS by a single surgeon (M.R.H.) at a single institution from 2013 to 2016. This is a sample of convenience and there is no control group. This same surgeon participated in the U.S. Food and Drug Administration (FDA) phase 3 trial for the Internal Joint Stabilizer (Skeletal Dynamics, Miami, FL). In the case of acute trauma, bony fractures and ligamentous injuries were first repaired using standard operative techniques. In the case of chronic instability, a combination of revision open reduction and internal fixation and/or ligamentous repair or reconstruction was undertaken depending on the specific pathology. Lateral structures were fixed initially. Then, after moving the elbow through a range of motion, if there was medial instability, necessary ligament reconstruction was performed. Persistent instability after appropriate surgical fixation was the indication for use of the IJS.

To place the IJS, an axis pin was inserted through the distal humerus and the position confirmed with an image intensifier. The axis pin was then linked to the plate on the posterior aspect of the proximal ulna to stabilize the ulnohumeral and radiocapitellar joints (Fig. 1). Patients were evaluated for either arthroscopic capsular release or manipulation under anesthesia if they were not felt to be progressing well after surgery. In general, this was offered in patients with an arc of motion of approximately 70° or less at 12 weeks; however, the possibility of a need for further surgery was discussed with each patient prior to the index surgery as well as afterward. Patient preference for improvements in range of motion was taken into account. Any further surgical interventions for complications or symptomatic hardware were recorded. Patient demographics and range of motion at the most recent follow-up were collected and analyzed. In addition, 16 patients responded to the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire and the Mayo Elbow Performance (MEP) score questionnaire.

RESULTS

Twenty patients (13 male, 7 female) with an average age of 48.8 years (range, 17–74 years) presented

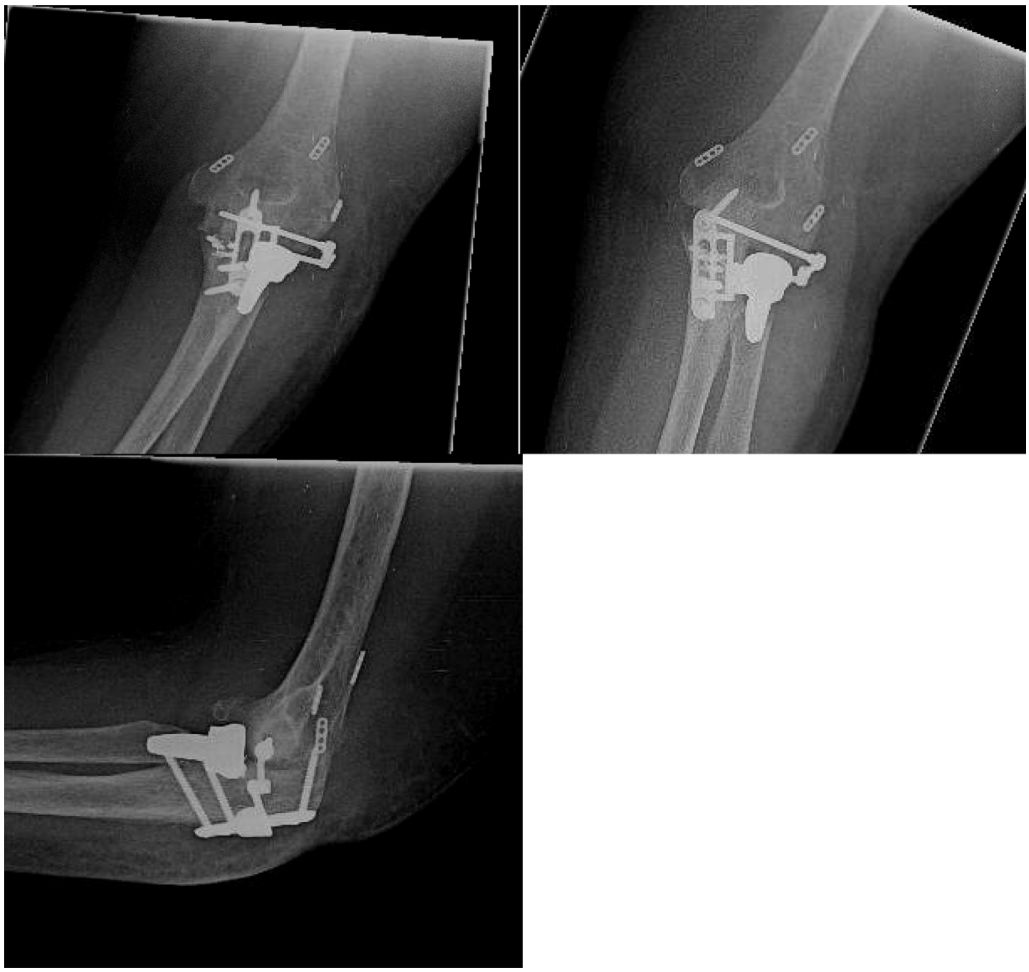

FIGURE 1: Anteroposterior, oblique, and lateral plain postoperative radiographs of an elbow after placement of the IJS.

with posttraumatic elbow instability. Table 1 provides baseline data for the patients. Nine of the patients presented with acute elbow fracture-dislocations—8 with terrible triad–type injuries and 1 with a Monteggia fracture-dislocation. These patients were treated with open reduction and internal fixation of the fractures and medial and lateral ligament reconstruction, as indicated. Placement of the IJS was based on the presence of persistent instability during passive range of motion after appropriate operative fixation. Eleven patients presented with chronic elbow instability after a previous elbow dislocation. Ten patients were referrals for whom the original injury had been managed initially at outside institutions. Eight of these patients had previously undergone open reduction and internal fixation with or without external fixation and 3 had been treated nonsurgically with immobilization. In the instance of chronic instability, revision open reduction and internal fixation, radial head arthroplasty, and medial and lateral ligamentous reconstruction or repair was performed as deemed necessary. Of the 11 patients with chronic instability, 1 patient did not have an associated fracture. He had been treated initially for chronic ligamentous instability with medial collateral ligament reconstruction using palmaris longus, and LUCL repair. One year after surgery, the patient dislocated after a fall and was found to be unstable.

TABLE 1. Baseline Patient Data

Total	20
Sex	13 M, 7 F
Age (y)	48.8 (17–74)
Follow-up (mo)	11.3 (2–25)
Acute instability	9
Chronic instability	11
Flexion-extension arc	124.3° ± 14.9°
IJS removed	6
Prior care at outside institution	10
Manipulation under anesthesia	1
Arthroscopic contracture release	10

Of the patients referred for chronic instability, 3 were notable for presenting with extensive and complex past surgical histories. One had undergone remote open reduction and internal fixation and LUCL reconstruction at an outside hospital followed by removal of hardware and presented with persistent posterolateral elbow instability in addition to extensive heterotopic ossification and elbow contracture. Another patient had undergone open reduction and internal fixation for a Monteggia fracture-dislocation and presented 5 months after the index operation with a chronic dislocation and a severe elbow contracture. One patient had suffered multiple gunshot injuries to the elbow resulting in a distal humerus fracture with an associated elbow dislocation and injuries to the median and radial nerves. The patient underwent open reduction and internal fixation of the distal humerus fracture, which went on to malunion, and then the patient presented with persistent posterolateral elbow instability, significant heterotopic ossification, and elbow contracture.

After the index surgical fixation and placement of the IJS, patients were immobilized for 1 week. All patients were given indomethacin 25 mg 3 times daily for 2 weeks after surgery. After 1 week, there were no motion restrictions. Patients were offered a planned, staged arthroscopic capsulectomy and contracture release at 12 weeks after surgery if they were unable to reach an acceptable and functional arc of motion with therapy and static-progressive orthosis fabrication. This is consistent with our philosophy of prioritizing healing of the ligaments and bone in a stable, concentrically reduced position rather than combining reconstruction and aggressive rehabilitation in 1 stage. A total of 11 of 20 patients had staged operative procedures: 1 patient underwent a manipulation under anesthesia, 9 patients underwent a single arthroscopic release, and 2 patients underwent 2 arthroscopic releases. Arthroscopic release involves excision of heterotopic ossification and sequential release of thickened scar and capsule. The average time prior to the first staged procedure was 16.8 weeks after index placement of the IJS (Table 1). The average postoperative flexion-extension arc at most recent follow-up was 124.3° ± 14.9°, with an average follow-up of 16.3 months, median follow-up of 17 months, and range of 2 to 25 months.

During the follow-up period, all patients were asked to complete both the DASH and the MEP questionnaires. Data were collected for 16 of 20 patients (Table 2). The mean preoperative MEP score was 12.2 ± 12.4, improving to 82.5 ± 14.3 after the final operative procedure. Similarly, the mean DASH score improved from 85.3 ± 23.0 to 37.3 ± 29.3. Follow-up measures were taken at an average follow-up time of 16.3 months (range, 2–25 months).

TABLE 2. Patient Outcome Scores

Functional Testing	Mean Score
Preoperative MEP score	12.2 ± 12.4
Final postoperative MEP score	82.5 ± 14.3
Preoperative DASH score	85.3 ± 23.0
Final postoperative DASH score	37.26 ± 29.3

Postoperative complications are listed in Table 3. Four patients with postoperative stiffness and heterotopic ossification developed ulnar nerve paresthesias without motor or sensory deficits. We do not routinely transpose the ulnar nerve at the index surgery because it would preclude a safe secondary arthroscopy surgery. These patients as well as the other patients who underwent arthroscopic contracture release undergo ulnar nerve decompression at that time. This is similar to other reports of elbow contracture release suggesting prophylactic ulnar nerve decompression is indicated in patients unable to flex beyond 90° before surgery or with less than a 50° arc of motion.[7,8]

All ulnar nerve symptoms resolved after surgery. One patient noticed clicking 6 months after surgery and was found on radiograph to have fractured a component of the IJS boom arm. This patient was indicated for revision or removal of hardware. She was found to be persistently unstable during surgery. The axis pin was well fixed in the distal humerus and, therefore, the broken component was replaced with a new component and connected to the axis pin. One patient developed postoperative wound drainage and erythema 6 months after surgery. Initially, this patient was seen in the emergency room for cellulitis. He was undomiciled and unable to comply with antibiotics or frequent observation. He developed wound drainage and radiographic loosening at the location of the axis pin. Despite the surgical site infection, he maintained elbow range of motion from 5° to 95°. He was indicated for wound washout and removal of the IJS. His elbow was stable during surgery. His infection has since resolved and he has maintained a concentrically reduced, stable elbow. Six patients underwent complete removal of the IJS—1 for complaints of prominent hardware, 4 requested removal despite lack of any hardware-associated symptoms, and 1 device was removed for postoperative infection as discussed previously. Also, as discussed previously, 1 device was revised owing to broken hardware.

TABLE 3. Complications

Complication	n	Treatment
Hardware failure	1	Revision surgery with replacement of broken hardware and update to IJS system
Infection	1	Hardware removal, washout and closure, antibiotics
Ulnar neuropathy	4	*In situ* nerve decompression

DISCUSSION

Treatments of complex elbow fracture-dislocations have been associated with high complication rates and low patient satisfaction scores.[9] A recent systematic review of 312 patients who underwent operative fixation for terrible triad injuries reported a 22.4% reoperation rate owing to postoperative complications.[10] Although the options for surgical fixation have been well described and are generally agreed upon,[1] significant debate still exists regarding the best method for postoperative immobilization for persistent instability despite fracture and ligament repair. Historically, persistent instability of the elbow after operative fixation was treated either with cast or orthosis immobilization or static external fixation; however, significant elbow arthrosis from prolonged immobilization was reported.[11] More recently, both hinged external fixators and transarticular cross-pinning have gained popularity as a means to maintain joint congruency while preventing postoperative arthrosis. Cramer et al[12] reported on 17 patients with unstable elbow fracture-dislocations who underwent transarticular ulnohumeral cross-pinning with a smooth Steinmann pin and long-arm cast immobilization. The cast and transarticular pin were removed after soft tissue healing and early range of motion was initiated. At 1 year follow-up, the average flexion-extension arc of motion was reported to be 102°. An overall complication rate of 23.5% (4 of 17) was reported, with 3 pin-related complications including 2 superficial pin-site infections and 1 pin breakage. In their comparison of transarticular cross-pinning to hinged external fixation, Ring et al[2] retrospectively reviewed the results of 10 patients who underwent transarticular cross-pinning and reported a final arc of motion of 128° and 1 instance of pin-track inflammation. More robust data exist regarding the outcomes of hinged external fixation. The popularity of hinged external fixators owes to the theoretical possibility of maintaining a stable reduction while permitting early range of motion.[13] A number of small retrospective reviews have demonstrated good average postoperative flexion-extension arcs of motion, ranging from 99° to 146°, with a majority of investigators achieving approximately 120° of motion.[14–18] However, a high rate of pin-related complications have been associated with external-fixator usage and placement including pin-site infections, pin breakage, pin-site–related fractures, transient radial and ulnar nerve palsies, and joint incongruity.[6,14,18–20] Also, although not well documented in the literature, achieving consistently accurate placement of the fixator axis of rotation is challenging and misplacement can exacerbate instability issues. This has led many to abandon hinged fixators. In the most comprehensive review to date, Cheung et al[3] reviewed 100 patients with persistent elbow instability after fracture-dislocation treated with hinged external fixation and reported a 15% minor complication rate, defined as local pin-site erythema or drainage, and a 10% major complication rate, defined as pin-site infection or loosening. In the only prospective study published to date, Iordens et al[4] reviewed 27 patients who underwent hinged external fixator placement and reported a 37% overall complication and a 26% reoperation rate including 2 pin-site–related fractures. Recently, Orbay and Mijares[6] published on the usage of an IJS, utilizing a bent Steinmann pin as a spanning internal, external fixator as a means to achieve stable joint reduction while allowing for early postoperative range of motion and thus avoiding the high complication rates associated with transcutaneous pins and external fixator usage. Early results on the first 10 patients to undergo the procedure demonstrated a flexion-extension arc of 115°. Whereas 4 complications were reported, only 1 of these was related to the joint-spanning Steinmann pin (prominent hardware requiring removal). Since the initial publication by Orbay and Mijares,[6] an FDA-approved IJS device has been developed for treatment of persistent elbow instability. This study presents the use of an IJS as a modification of the Steinmann pin technique as described by Orbay and Mijares[6] as a means to achieve stable, congruent postoperative range of motion while avoiding the complications associated with external fixator usage.

Our secondary operation is a planned part of this procedure for most of our IJS patients and we do not consider it as a complication. We believe that it assists in creating a stable, functional elbow. Two recent studies report that length of time to treating elbow contracture with open or arthroscopic release is predictive of outcome, highlighting the importance of

early intervention.[7,8] In 1 study, 10% of patients had to have rerelease owing to failure to improve and recurrence of heterotopic ossification and contracture. This is the nature of this difficult group of patients.[7] We realize there are some people who are satisfied with a stiffer elbow as long as it is stable and they do not wish to undergo another operative procedure, whereas other patients are interested in another procedure to help improve motion and function. We would like to highlight that our main end point and primary purpose for this case series is to show that the IJS device is a useful instrument for the upper extremity surgeon to use in these extremely challenging cases that will help provide stability to the elbow.

The IJS guidelines recommend removing the device at 6 to 8 weeks. This is because, over time, the hinge of the device would likely fail. In our opinion, this may not be a problem once the elbow is stable and reduced and no longer relies on the IJS device. Some patients feel it is prominent and would like for it to be removed. We do not regularly remove the device unless a patient requests it. If we noticed loosening or subsidence over time, then we would remove the device. In our series thus far, we have removed 6 of the 20 (30%) IJS devices. All devices were removed after the suggested period of 8 weeks. It is unknown at this time if more patients will request or require device removal. If someone were having an open contracture release, we could remove the device through the incision, but with arthroscopic release, we do not want to add the risk of wound complications by creating another surgical incision.

Utilizing this technique, in addition to postoperative arthroscopic capsular releases and/or manipulations under anesthesia as necessary, an average postoperative range of motion of 124° was achieved with no cases of persistent instability. Other current options for severe elbow instability after bony and ligamentous stabilization include external fixators, transarticular pinning, and bridge plating. In addition to pin-site–related infections, these options have shown rates of persistent instability as high as 15%.[18] In our series thus far, we have no instances of persistent instability after IJS. Furthermore, because it is an all-inside device, there is no risk for pin-site–related infections.

There were 4 patients with ulnar neurapraxias that resolved after neurolysis, 1 postoperative wound infection that was treated with hardware removal and surgical washout, and 1 hardware failure that required revision of the IJS. Since the hardware failure, the IJS system has released more length options for the boom arm component. We believe these are now sufficient for an obese patient. We believe in this case the patient's obesity warranted a longer moment arm than was available at the time. Six of 20 patients (30%) had the IJS removed owing to prominent hardware, patient request, or loosening owing to infection.

The results of this study regarding postoperative range of motion are consistent with reported results utilizing both transarticular cross-pinning and hinged external fixators in terms of range of motion outcomes, and superior results in terms of maintaining elbow stability. Because this construct does not utilize transcutaneous pins and is placed under direct visualization, placement of the pin in the anatomical axis of ulnohumeral rotation is easily reproducible. We were conservative with regard to postoperative exercises and therapy, and given the stability achieved with the IJS construct, it is likely that more aggressive early therapy could be safely performed and that this could obviate the need for secondary release in some patients. This is comparable with both placement of a transarticular pin or a hinged external fixator, both of which, by nature, require a secondary procedure for removal. Furthermore, the outcome data with regards to DASH and MEP scores were consistent with similar data reported in the literature regarding hinged external fixator usage.[11,18,21]

The limitations of this study include the small number of patients, the short follow-up for some cases and its retrospective nature. For the majority of our patients, we have follow-up data for over 1 year. We did choose to also include patients in our study with less than a year of follow-up because we felt it was important to reveal that all of our patients with an implanted IJS device have maintained stability. Eleven of 20 patients underwent either a staged arthroscopic capsular release, manipulation under anesthesia, or a combination of both for failure to progress with flexion-extension arc of motion, a step either not utilized or not reported on in other publications reviewing the results of either transarticular cross-pinning or hinged external fixator placement. Given the significant stability conferred by the IJS device, it is possible that more aggressive manipulations and capsular releases in the early postoperative period may be possible without concern for further instability; however, this was not studied in this case series. Although our patients improved in both MEP and DASH scores, their average DASH scores at last follow-up were 37.3 ± 29.3, indicating substantial residual patient-reported disability. As stated

previously, elbow fracture-dislocations are devastating injuries with a high risk of chronic pain, stiffness, posttraumatic arthritis, and ulnar nerve symptoms. We believe this is an extremely challenging group of patients and that the IJS assists in helping to create a stable, functional elbow. It is likely that a stable, congruent joint would be associated with better outcome scores, but we cannot prove this in the absence of a control group.

Finally, outcome measures were able to be collected on 16 of 20 patients (80%). Because this represents 1 of the earliest reports of the usage of an internal, external fixator, more data must be collected regarding outcomes, complications, and biomechanical stability.

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