J Shoulder Elbow Surg (2020) ■, 1–7

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Patient outcomes for the Internal Joint Stabilizer of the Elbow (IJS-E)

Jordan B. Pasternack, MD*, Matthew L. Ciminero, MD, Jack Choueka, MD, Kevin K. Kang, MD

Department of Orthopaedic Surgery, Maimonides Medical Center, Brooklyn, NY, USA

Background: Recently, the Internal Joint Stabilizer of the Elbow (IJS-E) was developed as an internal dynamic fixator for use in the setting of traumatic elbow instability. This study reviews the patients who had an IJS-E placed at our institution. Specifically, postoperative complications, postoperative functional outcomes, and need for subsequent procedures were reviewed.

Methods: A retrospective chart review was conducted of patients in whom the IJS-E was implanted from June 2016 to July 2018. Indications for use, range of motion at final follow-up, and the need for subsequent procedures were reviewed. Disabilities of the Arm, Shoulder, and Hand (DASH) and Broberg-Morrey scores were also obtained.

Results: Ten IJS-E devices were implanted into 10 patients. Average length of follow-up was 13.4 months. Average flexion-extension and pronation-supination motion arcs at final follow-up were 106° and 141°, respectively. Seventy-eight percent of patients achieved >100° arcs of both flexion-extension and pronation-supination. Average DASH and Broberg-Morrey scores were 28.7 and 68.2, respectively. Four subsequent procedures were required in 4 patients: 2 contracture releases, 1 medial collateral ligament reconstruction, and 1 total elbow arthroplasty. There were no postoperative infections or nerve injuries.

Discussion: The IJS-E has replaced the use of external hinged fixation at our institution. Final range of motion was consistent with that reported for terrible triad and complex elbow dislocation injuries. The IJS-E is a good option for use in patients with traumatic elbow instability, as it restores motion and function without immediate postoperative complication. However, it does not eliminate the potential for future operative intervention in these complex injuries.

Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Internal joint stabilizer; traumatic elbow instability; elbow dislocation; terrible triad; external fixation; cross pinning

Elbow instability can represent a challenging problem for the treating clinician. Etiologies include elbow fracture, simple dislocation, and fracture dislocation. These are common injuries treated by the orthopedic surgeon, as the incidence of elbow dislocation has been reported at 5.21 per 100,000 person-years.[20] Additionally, 12%-63% of elbow dislocations are accompanied by other injuries about the elbow.[15] Elbow instability can be primary or recurrent and can present significant morbidity for patients. A specific injury pattern consisting of posterior ulnohumeral dislocation with associated radial head fracture, coronoid fracture, and lateral collateral ligament (LCL) injury, called the ''terrible triad,'' received its eponym from the persistent instability and subsequent arthrosis and stiffness that patients developed despite treatment. Some studies in the literature have suggested that radiographic elbow instability after a terrible triad injury is rare if operatively addressed in the first 2 weeks, assuming the radial head was replaced and the LCL was reattached.[23] When treated within 2 weeks,

Institutional review board approval was received from the Maimonides Medical Center (MMC) (study no. 2018-10-05).

*Reprint requests: Jordan B. Pasternack, MD, 927 49th St, Brooklyn, NY 11219, USA.

E-mail address: jbpasternack@gmail.com (J.B. Pasternack).

1058-2746/$ - see front matter © 2019 Journal of Shoulder and Elbow Surgery Board of Trustees. All rights reserved.
https://doi.org/10.1016/j.jse.2019.12.018

the incidence of subluxation or pseudo-subluxation was only 2% in the study by Zhang et al,[23] compared with 27% when surgery was delayed beyond 2 weeks from injury. Surgical management of complex elbow instability typically follows a specific algorithm.[12,21] First, fixation of the radial head and coronoid is achieved. Then the LCL is repaired. If instability is still present, the MCL can be addressed. In case instability still persists, hinged or static external fixation of the elbow is performed. Other ultimate options, such as cross-pinning the elbow, have been reported as well.[16] Cross-pinning with cast immobilization is a secure option to hold reduction but is not without associated problems. Articular damage, pin site infection with possible subsequent joint infection, and pin breakage have all been described.[1] Dynamic external fixators are associated with their own complications, such as pin site infection, broken and loose pins, iatrogenic fracture, wound complications, and nerve injury. Complication rates for dynamic external fixators have been reported to be from 15%-38%.[5,9,13,16] A more recent advent, the Internal Joint Stabilizer of the Elbow (IJS-E; Skeletal Dynamics, Miami, FL, USA) has introduced another option to stabilize an elbow when bony and ligamentous fixation is not sufficient.[14] This device was granted Food and Drug Administration approval in 2016 and was developed as an internal dynamic fixator to stabilize the elbow joint while allowing for passive and active range of motion.[14] This allows for healing of soft tissues and immediate postoperative range of motion with a decreased risk of elbow subluxation/dislocation, obviating the need for external fixation. The IJS-E is new, and thus there is a paucity of data on demographics and functional outcomes of the patients on whom it is used. This study will review the patients who had an IJS-E placed as part of their orthopedic care. Specifically, the indications for the device, postoperative complications, postoperative functional outcomes, and need for subsequent procedures were reviewed.

Materials and methods

Following institutional review board approval, a retrospective chart review of our practice's patients was performed. Inclusion criteria consisted of patients in whom the IJS-E was implanted from June 2016 to July 2018. Indications for use, range of motion at final follow-up, immediate postoperative complications, and the need for subsequent procedures were reviewed. The Disabilities of the Arm, Shoulder, and Hand (DASH)[10] and Broberg-Morrey[2] scores were reviewed as well. The DASH is a scoring system based on a 30-item questionnaire. The patient self-reports his or her ability to perform certain tasks; the severity of constant and activity-related pain, paresthesias, weakness, stiffness; and the effect on his or her social and work functioning, sleep, and self-image. Each question has 5 options, from 0 (no disability) to 5 (severe disability). Scores are then summed and scaled to yield a number from 0-100. Zero indicates no disability, and 100 indicates maximum disability. The Broberg-Morrey score is a 100-point system that is based on a physician's assessment of elbow motion, stability, strength, and pain. A score from 95-100 is considered excellent, 80-94 good, 60-79 fair, and less than 60 poor.

Index surgical procedure

IJS-E devices (Skeletal Dynamics) were used in traumatic acute or chronic elbow instability cases, or to augment fixation of fractures about the elbow when they were felt to compromise concentric elbow joint reduction. All procedures were performed by orthopedic surgeons specializing in trauma or upper extremity surgery (2 surgeons in total). All 10 patients had the IJS-E implanted during their index procedure. Patients were positioned in the supine position with the operative extremity placed on a hand table. A lateral approach to the elbow was used. A standardized approach was employed to address elbow pathology in these patients. Elbow reduction was performed first, if necessary. Any fracture present was then addressed, followed by soft tissue repair or reconstruction. Then, IJS-E placement was performed as follows. The center of rotation of the capitellum was marked with a sterile marking pen. A guide wire was placed at this site laterally and advanced to the medial cortex of the distal humerus (without penetrating the cortex), parallel to the elbow joint, using the system's aiming guide. The depth of the guide wire was then measured and a cannulated drill was used to drill the distal humerus in a lateral to medial fashion. The baseplate of the IJS-E was positioned on the posterior aspect of the olecranon. Three screws were then placed into the baseplate, securing it to the posterior aspect of the olecranon. The axis pin was then inserted through the eyelet of the proximal connecting rod and into the hole drilled in the lateral distal humerus. The elbow joint was then reduced and the IJS-E device was locked by tightening the screws on the connecting arm. Maintenance of concentric elbow reduction was verified fluoroscopically throughout the entire elbow motion arc. A nonsterile tourniquet was inflated before incision and deflated before wound closure to ensure hemostasis was obtained. Patients were placed into a sling initially and then early range of motion therapy was initiated.

Evaluation

Patients had routine postoperative follow-up, which included radiographs and clinical evaluation. Elbow range of motion was recorded at each visit. DASH and Broberg-Morrey scores were able to be obtained for 9 of the 10 patients in the series. IJS-E removal typically occurred after 6-10 weeks, when it was thought that fracture and soft tissue healing was adequate to maintain concentric elbow reduction. Additional procedures, if necessary, were indicated based on subjective symptoms (pain, instability, etc) or unacceptable motion arc.

Statistical analysis

Statistics (arithmetic means and standard deviation [SD]) were performed using Microsoft Excel Professional Plus 2010 (Microsoft Co, Redmond, WA, USA).

Results

Ten patients were identified as having an IJS-E implanted. Demographics, injury information, and outcome measures of the study population are shown in Table I. Average age

Table I Demographic, injury, procedure, and outcome data for the 10 patients in which the IJS-E was implanted in our institution

Patient no	Age, yr/Sex	Laterality	Dominant	Trauma	Injury	Index procedure	Follow-up, d	IJS-E implantation time, d	Motion arc, °	Prono supination, °	DASH	Broberg-Morrey	Additional Procedure(s)	Timing of additional procedures, d
1	70/F	R	N	Mechanical fall from standing	Terrible triad	RHA, LCL/ capsule repair	836	45	128	115	50	55.1	TEA	276
2	61/F	R	Y	Mechanical fall from standing	Lat condyle/ capitellum Fx, distal radius Fx	Lat condyle/ capitellum ORIF, LCL repair	701	55	75	95	25	77.5		
3	56/M	R	Y	Fall off of bicycle	Chronic elbow dislocation, olecranon Fx	Elbow open reduction, contracture release	235	137	105	150	N/A	N/A		
4	31/F	L	N	Fall while rock climbing	Acute elbow dislocation	LCL repair	388	41	132	155	0	99.6		
5	60/F	R	Y	Mechanical fall from standing	Terrible triad	Coronoid ORIF, RHA, LCL repair	278	87	30	120	54.2	18	MCL reconstruction, ROH	231
6	43/M	L	N	Fall from height (3 feet)	Terrible triad	L radial head replacement, IJS, LCL repair	316	86	135	155	42.5	83	Contracture & cubital tunnel release	213
7	51/M	L	N	Fall from height (10 feet)	Acute elbow dislocation, distal radius Fx	Distal radius ORIF, LCL repair	234	91	110	155	38.3	45		
8	53/F	L	N	Mechanical fall from standing	Terrible triad	LCL repair	118	66	138	155	9.2	93		
9	27/M	R	Y	Fall from height (3 stories)	Terrible triad	LCL repair	189	N/A	N/A	N/A	N/A	N/A		
10	56/F	L	N	Mechanical fall from standing	Terrible triad	RHA	719	55	105	165	10	74	Ulnar nerve transposition, contracture release, excision of HO, & capsule resection	203
Mean (SD)	50.8 (12.8)						401 (242)	74 (29)	106 (33)	141 (23)	28.7 (19.2)	68.2 (25.4)		231 (28)

SD, standard deviation; *F*, female; *M*, male; *R*, right; *L*, left; *N*, no; *Y*, yes; *Lat*, lateral; *Fx*, fracture; *RHA*, radial head arthroplasty; *LCL*, lateral collateral ligament; *ORIF*, open reduction and internal fixation; *IJS*, internal joint stabilizer; *IJS-E*, Internal Joint Stabilizer of the Elbow; *N/A*, not applicable; *DASH*, Disabilities of the Arm, Shoulder, and Hand; *TEA*, total elbow arthroplasty; *MCL*, medial collateral ligament; *ROH*, removal of hardware; *HO*, heterotopic ossification.

of the patient at the time of implantation was 50.8 years, with a SD of 12.8 years. There were 6 women (60%) and 4 men (40%). Six of the 10 patients had an acute terrible triad injury, 2 had an acute elbow dislocation, 1 had lateral condyle and capitellum fractures with elbow instability, and 1 had a chronic elbow dislocation (Fig. 1). Four patients (40%) had the IJS-E implanted into their dominant upper extremity (Figs. 2 and 3). Average follow-up was 401 days (range 118-836), or 13.4 months. The IJS-E was removed after an average of 74 days (range 41-137) in 9 of the patients. One patient has not had the IJS-E removed as he had developed significant heterotopic ossification following a terrible triad injury in association with a closed head injury and multiple extremity injuries. His outcome measures were excluded from analysis as he is currently awaiting surgical intervention for heterotopic ossification. All patients were performing active elbow range of motion prior to IJS-E explantation. Device removal consideration began at 6 weeks postoperatively and was delayed if radiologic or clinical healing was in question. No radiologic signs of hardware loosening or elbow subluxation were noted at any of the patients' follow-up.

The average flexion-extension arc of the patients at final follow-up was 106°, with an SD of 33° (range 30°-138°). Average pronosupination arc was 141°, with an SD of 23° (range 95°-165°). Seven of the 9 patients included (78%) achieved $>100°$ arcs of both flexion-extension and pronation-supination. The average DASH score at final follow-up was 28.7, with an SD of 19.2 (range 0-54.2). The average Broberg-Morrey score at final follow-up was 68.2, with an SD of 25.4 (range 18-99.6). With respect to the Broberg-Morrey categorical ratings, 1 patient (12.5%) had an excellent outcome, 2 (25.0%) had good outcomes, 2 (25.0%) had fair outcomes, and 3 (37.5%) had poor outcomes.

Of the 10 patients, 4 required additional procedures after IJS-E insertion (excluding returns to the operating room for IJS-E explantation, as no additional procedures were performed during explantation). These additional procedures occurred an average of 231 days (SD = 28) after IJS-E implantation. Patient number 1 required a total elbow arthroplasty 276 days after the index procedure because of the development of post-traumatic arthritis. Patient number 5 required an MCL reconstruction 231 days after the index procedure because of residual instability from coronoid deficiency. Patient number 6 underwent a contracture release and cubital tunnel release 213 days after the index procedure as his elbow flexion/extension arc was 35°-90° and he had decreased sensation in the ulnar nerve distribution. Patient number 10 underwent an ulnar nerve transposition, contracture release, excision of heterotopic ossification, and capsular resection 203 days after the index procedure. This treatment was indicated because of a lack of motion in the flexion/extension arc (65°-90°). No postoperative infections or neurovascular injuries occurred. During the study period, no external hinged fixation devices were used.

Discussion

This case series reviews the patients at our institution who had an IJS-E placed to maintain concentric reduction of the elbow joint in the setting of traumatic elbow instability. This

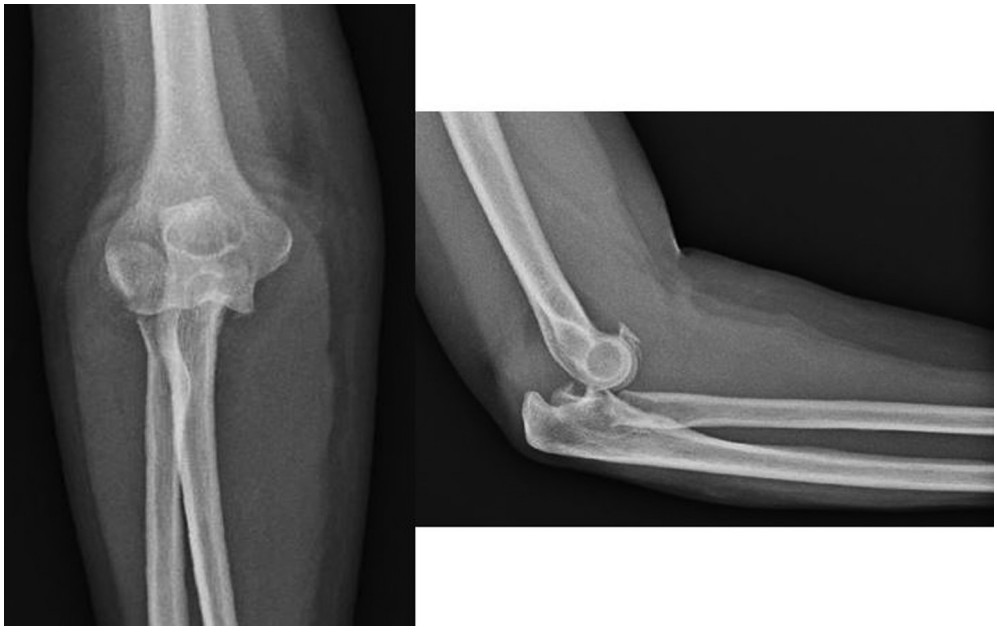

Figure 1 Anteroposterior and lateral injury radiographs of patient 5, who sustained a terrible triad injury.

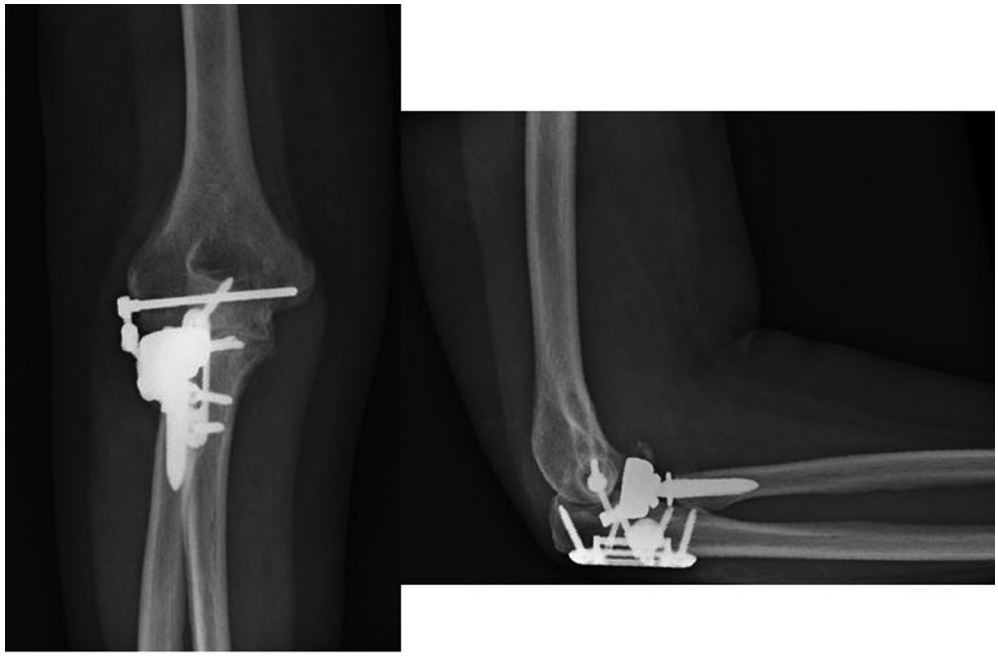

Figure 2 Anteroposterior and lateral injury radiographs of patient 5 status post coronoid open reduction and internal fixation, radial head arthroplasty, lateral collateral ligament repair, and IJS-E implantation. *IJS-E*, Internal Joint Stabilizer of the Elbow.

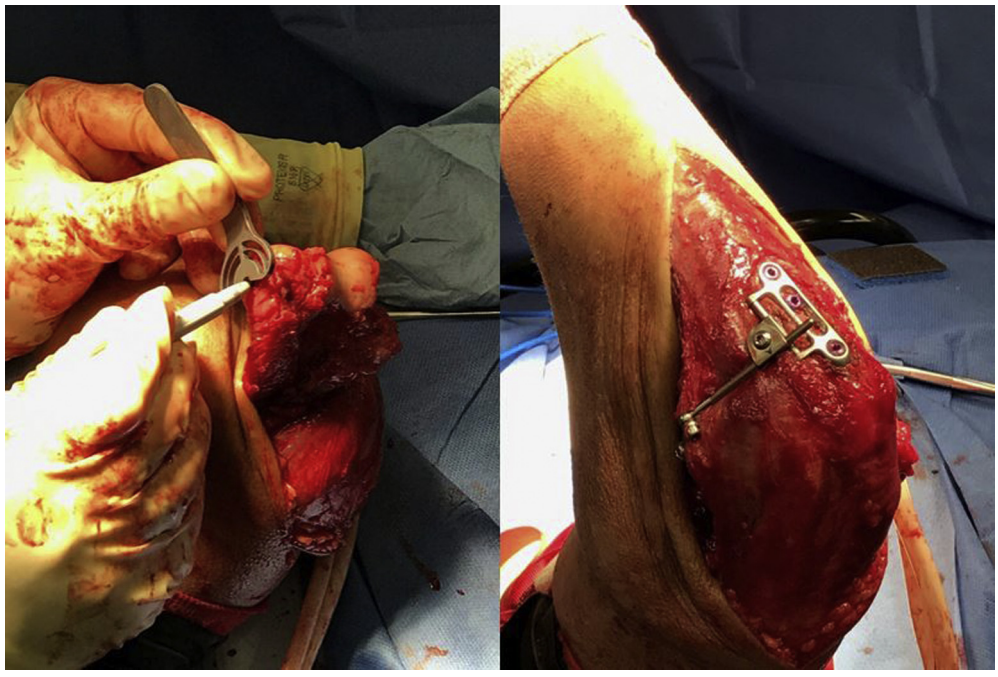

Figure 3 Intraoperative photographs of IJS-E placement. Marking of the capitellum center of rotation *(left)* and completed IJS-E implantation *(right)*. The patient was being treated for a chronic elbow dislocation, and thus required marked soft tissue releases. Typical exposure for a case involving IJS-E implantation is much less than that depicted here. *IJS-E*, Internal Joint Stabilizer of the Elbow.

device has eliminated the use of dynamic external fixators at our institution. Postoperative motion is consistent with what has been described for terrible triad injuries and complex elbow dislocations. Range of motion following terrible triad injuries has been considerably reviewed in the literature. Motion in the flexion-extension plane has been reported at 94°-99°,[16] 100°-119°,[11] 105°,[22] 109°,[3,7] 112°,[17] and 120°.[8] Motion in the pronosupination arc has been reported at 115°-142°,[7,16] 130°-141°,[11] 134°,[3] 137°,[8] 146°,[22] and 158°.[17] For complex elbow dislocations, flexion-extension

motion has been reported at 96° [19] and 120° [8] and pronosupination motion at 142°.[8] Using the IJS-E, Orbay et al[14] reported an average 119° of flexion-extension motion and 152° of forearm rotation in 24 patients. Another series of IJS-E patients found an average flexion-extension arc of motion of 124° with an average of 11.3 months of follow-up.[18]

Although elbow range of motion is an important indicator of disability following injury, more thorough metrics can yield greater insight into patients' functional status. The average DASH score of our series was 28.7, and the average Broberg-Morrey score was 68.2. DASH scores for patients with terrible triad injuries range from 15-28.7.[6,7,11,22] In patients in whom the IJS-E has been used, DASH scores have been reported at 16-37.3.[14,18] Broberg-Morrey scores for patients following traumatic elbow instability, including terrible triad injuries, have been reported at 76-93.[7,8,11,14,16,22] The DASH scores reported in this series correspond with the values reported for terrible triad injuries, and the Broberg-Morrey scores are slightly lower. Our average Broberg-Morrey score, however, falls into the same average Broberg-Morrey categorical rating as in some other studies (poor, 60-79).[7,22]

Reoperation rate is an important metric to understand with use of the IJS-E, as a primary indication for the device (acute traumatic elbow stability) is itself associated with a high rate of subsequent procedures. Four of the 10 patients (40%) in this series underwent subsequent procedures following IJS-E placement at an average of 231 days after implantation, and a fifth patient will undergo a subsequent procedure in the future. IJS-E removal was not considered a subsequent procedure, as the guide for this device advises explantation once elbow stability is achieved via bony and ligamentous healing. Indications for our subsequent procedures included pain, joint subluxation, stiffness, and ulnar neuropathy. Lindenhovius et al[11] reported that terrible triads treated acutely had a higher reoperation rate (28%) than those treated subacutely (7%). Most of the reoperations they report were indicated for stiffness or ulnar neuropathy. In a systemic review of terrible triad studies, Chen et al[4] found that reoperation rates ranged from 0%-54.5%. Indications in these studies included persistent instability, stiffness, pain, nonunion, infection, and ulnar neuropathy. A case series of IJS-E use in 20 patients reported a reoperation rate of 55% (11/20).[18] It should be noted, however, that the authors of the series anticipated many of these reoperations as they were part of staged procedures to regain motion not prioritized in the index procedure. Regardless, the risk of reoperation is something that should be discussed with patients before IJS-E implantation.

Limitations of this study include its retrospective design and small sample size. A prospective, randomized controlled trial comparing the IJS-E to a hinged external-fixator would allow for a better understanding of the advantages and disadvantages of each. An increased sample size will come with time, as this is a relatively new implant (US Food and Drug Administration approval was granted in 2016). This study provides insight into the patient outcomes of the IJS-E, a new addition to the trauma/upper extremity surgeon's armamentarium for traumatic elbow instability. The IJS-E is a good option for use in patients with traumatic elbow instability, as it restores motion and function without immediate postoperative complication. However, it does not eliminate the relatively high reoperation rate associated with the injuries that necessitate its use.

Conclusion

This study examined clinical outcomes of patients in whom the Internal Joint Stabilizer of the Elbow (IJS-E) was implanted. This device was used in the setting of traumatic acute or chronic elbow instability cases, or to augment fixation of fractures about the elbow when they were felt to compromise concentric elbow joint reduction. The device provided adequate stability and range of motion for patients without immediate postoperative complications. However, it did not decrease the relatively high reoperation rate associated with the complex elbow injuries that it was employed to treat.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

References

1. Brazel PW, McPhee IB. Inappropriate secretion of antidiuretic hormone in postoperative scoliosis patients: the role of fluid management. Spine 1996;21:724-7.
2. Broberg MA, Morrey BF. Results of delayed excision of the radial head after fracture. J Bone Joint Surg Am 1986;68:669-74.
3. Chemama B, Bonnevialle N, Peter O, Mansat P, Bonnevialle P. Terrible triad injury of the elbow: how to improve outcomes? Orthop Traumatol Surg Res 2010;96:147-54. https://doi.org/10.1016/j.rcot.2010.02.008
4. Chen HW, Liu GD, Wu LJ. Complications of treating terrible triad injury of the elbow: a systematic review. PLoS One 2014;9:e97476. https://doi.org/10.1371/journal.pone.0097476
5. Cheung EV, O'Driscoll SW, Morrey BF. Complications of hinged external fixators of the elbow. J Shoulder Elbow Surg 2008;17:447-53. https://doi.org/10.1016/j.jse.2007.10.006
6. de Aquino Santos A, Tonelli TA, Matsunaga FT, Matsumoto MH, Netto NA, Tamaoki MJ. Result from surgical treatment on the terrible triad of the elbow. Rev Brasil Ortop 2015;50:403-8. https://doi.org/10.1016/j.rboe.2015.06.010

7. Egol KA, Immerman I, Paksima N, Tejwani N, Koval KJ. Fracture-dislocation of the elbow functional outcome following treatment with a standardized protocol. Bull NYU Hosp Jt Dis 2007;65:263-70.
8. Forthman C, Henket M, Ring DC. Elbow dislocation with intra-articular fracture: the results of operative treatment without repair of the medial collateral ligament. J Hand Surg 2007;32:1200-9. https://doi.org/10.1016/j.jhsa.2007.06.019
9. Hopf JC, Berger V, Krieglstein CF, Muller LP, Koslowsky TC. Treatment of unstable elbow dislocations with hinged elbow fixation-subjective and objective results. J Shoulder Elbow Surg 2015;24:250-7. https://doi.org/10.1016/j.jse.2014.09.034
10. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). Am J Ind Med 1996;29:602-8.
11. Lindenhovius AL, Jupiter JB, Ring D. Comparison of acute versus subacute treatment of terrible triad injuries of the elbow. J Hand Surg 2008;33:920-6. https://doi.org/10.1016/j.jhsa.2008.02.007
12. Mathew PK, Athwal GS, King GJ. Terrible triad injury of the elbow: current concepts. J Am Acad Orthop Surg 2009;17:137-51. https://doi.org/10.5435/00124635-200903000-00003
13. McKee MD, Bowden SH, King GJ, Patterson SD, Jupiter JB, Bamberger HB, et al. Management of recurrent, complex instability of the elbow with a hinged external fixator. J Bone Joint Surg Br 1998;80:1031-6.
14. Orbay JL, Ring D, Kachooei AR, Santiago-Figueroa J, Bolano L, Pirela-Cruz M, et al. Multicenter trial of an internal joint stabilizer for the elbow. J Shoulder Elbow Surg 2017;26:125-32. https://doi.org/10.1016/j.jse.2016.09.023
15. Regan W, Morrey BF. Classification and treatment of coronoid process fractures. Orthopedics 1992;15:845-8.
16. Ring D, Bruinsma WE, Jupiter JB. Complications of hinged external fixation compared with cross-pinning of the elbow for acute and subacute instability. Clin Orthop Relat Res 2014;472:2044-8. https://doi.org/10.1007/s11999-014-3510-4
17. Seijas R, Ares-Rodriguez O, Orellana A, Albareda D, Collado D, Llusa M. Terrible triad of the elbow. J Orthop Surg 2009;17:335-9. https://doi.org/10.1177/230949900901700319
18. Sochol KM, Andelman SM, Koehler SM, Hausman MR. Treatment of traumatic elbow instability with an internal joint stabilizer. J Hand Surg 2019;44:161.e1-e7. https://doi.org/10.1016/j.jhsa.2018.05.031
19. Sorensen AK, Sojbjerg JO. Treatment of persistent instability after posterior fracture-dislocation of the elbow: restoring stability and mobility by internal fixation and hinged external fixation. J Shoulder Elbow Surg 2011;20:1300-9. https://doi.org/10.1016/j.jse.2011.06.002
20. Stoneback JW, Owens BD, Sykes J, Athwal GS, Pointer L, Wolf JM. Incidence of elbow dislocations in the United States population. J Bone Joint Surg Am 2012;94:240-5. https://doi.org/10.2106/JBJS.J.01663
21. Tarassoli P, McCann P, Amirfeyz R. Complex instability of the elbow. Injury 2017;48:568-77. https://doi.org/10.1016/j.injury.2013.09.032
22. Wang YX, Huang LX, Ma SH. Surgical treatment of ‘‘terrible triad of the elbow’’: technique and outcome. Orthop Surg 2010;2:141-8. https://doi.org/10.1111/j.1757-7861.2010.00081.x
23. Zhang D, Tarabochia M, Janssen S, Ring D, Chen N. Risk of subluxation or dislocation after operative treatment of terrible triad injuries. J Orthop Trauma 2016;30:660-3. https://doi.org/10.1097/BOT.0000000000000674