



Multicenter trial of an internal joint stabilizer for the elbow



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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.

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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

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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

Table I Characteristics of operated-on patients*

Variable	Outcome
	(N = 26)
Age, mean (SD), y	57 (18)
Gender, No. (%)	
Male	12 (46)
Female	14 (54)
Side dominance, No. (%)	
Left	1 (3.9)
Right	24 (92)
Left and right	1 (3.85)
Fracture type, No. (%)	
Radial head	16 (62)
Coronoid	14 (54)
Olecranon	1 (3.9)
Distal humeral	1 (3.9)
Injury pattern, No. (%)	
Terrible triad	12 (46)
Monteggia	1 (3.9)
Elbow dislocation with	
Radial head fracture	3 (12)
Coronoid fracture	2 (7.7)
Unstable elbow dislocation	1 (3.9)
Chronic elbow dislocation >3 wks	6 (23)
Posterolateral instability†	1 (3.9)
Reduction status, No. (%)	
Dislocated	19 (73)
Subluxated	7 (27)
No. of operations before index, No. (%)	
0	19 (73)
1	5 (19)
2	1 (3.9)
3	1 (3.9)

SD, standard deviation.

* All 26 patients had elbow dislocation at some point.

† The patient had 2 prior operations for lateral ulnar collateral ligament reconstruction.

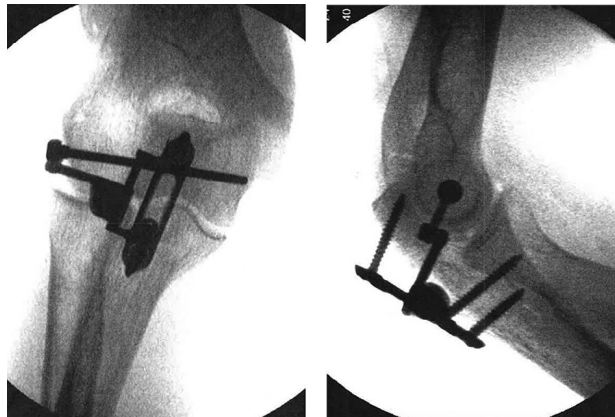


Figure 1 Intraoperative anteroposterior and lateral radiograph of the patient after stabilization surgery with the internal joint stabilizer of the elbow.

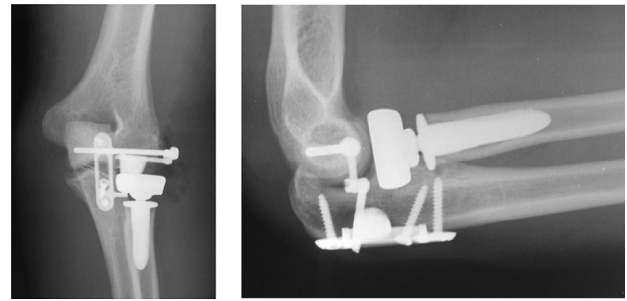


Figure 2 Anteroposterior and lateral radiograph of the patient after stabilization surgery with the internal joint stabilizer of the elbow.

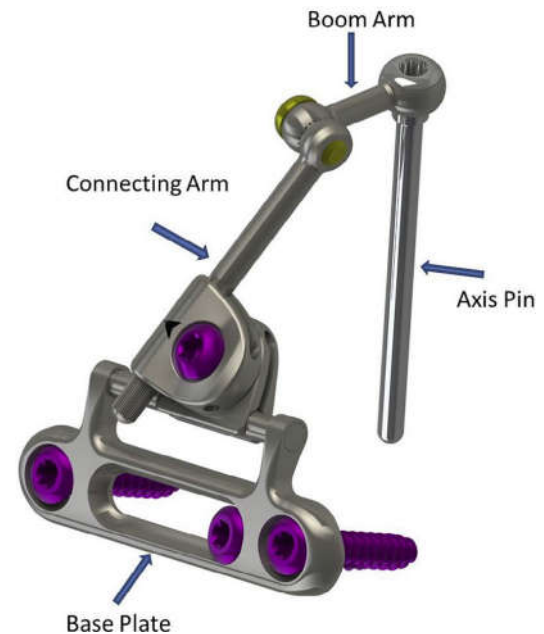


Figure 3 Depiction of the internal joint stabilizer of the elbow shows different components.

implantation, at the time of implantation, immediately before implant removal, and the final evaluation at 24 to 26 weeks after removal.

At the first return after the initial operation, bulky dressings were removed, and patients were prescribed physical therapy and taught active self-assisted elbow, forearm, and wrist exercises.

Outcomes

At the final evaluation 6 months after removal of the IJS-E, we evaluated (1) the Broberg-Morrey Functional Score¹; (2) any subluxation or dislocation while the IJS-E was in place or after removal; (3) DASH questionnaire score³; and (4) adverse events during implantation and after removal of the device.

Results

The elbow remained concentrically reduced in 23 of 24 patients. One patient with a coronoid fracture involving 50%

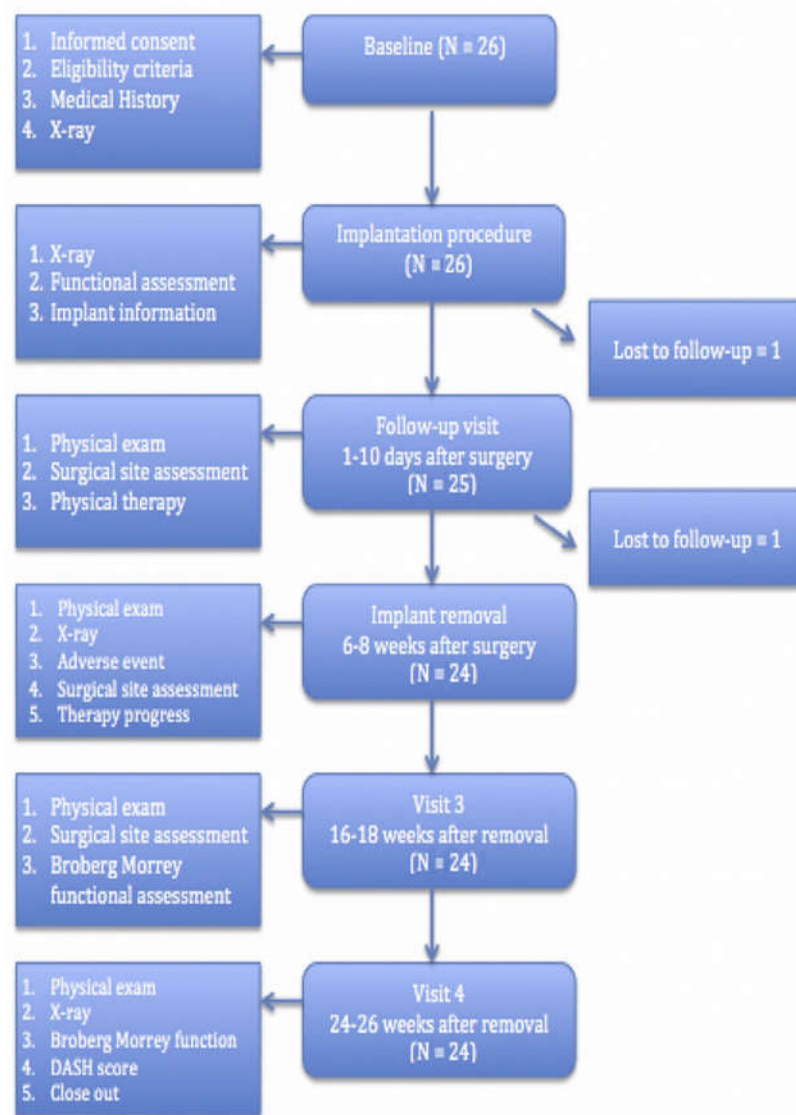


Figure 4 The flowchart shows the study visits with intended evaluations per visit. *DASH*, Disabilities of Arm, Shoulder and Hand.

of the coronoid height had subluxation at final evaluation believed to be caused by the coronoid deficiency.

The final mean arc of elbow flexion and extension 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 Functional Score were 93 and 97, representing good and excellent functional outcome, respectively. An excellent Broberg-Morrey Functional Score was noted in more than half of the patients (14 excellent, 8 good, 1 fair, and 1 poor). The patient who had a fair rating experienced mild pain, mild loss of strength, and limited flexion, with no instability. The patient with a poor rating had insufficient coronoid and experienced subluxation after the IJS-E was removed (Table II).

The mean DASH score for the 24 patients was 16 (range, 0-68; SD, 18), and 13 (54%) had DASH scores between 0 and 10. Only 2 patients had DASH scores above 50: the patient

with coronoid deficiency and a patient who had a factor V Leiden clotting disorder and a deep vein thrombosis 2 weeks after the implantation procedure, which limited exercises.

A transient nerve palsy (median and ulnar neurapraxia) occurred in 1 patient with an elbow that was dislocated for more than 3 months and extensive pre-existing anterior heterotopic ossification. One patient presented with an apparent inflammatory process at the time of explant and was treated prophylactically with antibiotics. Cultures were negative for infection, and the patient had no further problems (Table III).

Discussion

The primary goal of surgery for traumatic elbow instability is to achieve a stable concentric alignment with functional motion. We studied the effectiveness of the IJS-E in helping

Table II Broberg-Morrey Functional Rating Subscales

Broberg-Morrey Subscale	No (%)	Mean	Standard deviation	Minimum	Maximum
(N = 24)					
Motion value		24	3.3	16	27
Flexion, °		131	13	110	155
Flexion contracture, °		12	11	(-10)	35
Motion value		13	1.2	9	13
Pronation, °		76	12	45	95
Supination, °		76	16	45	102
Strength value		19	4.3	0	20
Normal strength	21 (88)				
Mild loss	2 (8)				
Severe loss	1 (4)				
Stability value		4.8	1	0	5
Normal stability	23 (96)				
Severe loss	1 (4)				
Pain value		33	4.5	15	35
No pain	20 (83)				
Mild pain	3 (13)				
Moderate pain	1 (4)				
Total Functional Rating*		93	12	44	100
Excellent	14 (58)				
Good	8 (34)				
Fair	1 (4)				
Poor	1 (4)				

* Broberg-Morrey categorical rating: excellent (95-100), good (80-94), fair (60-79), poor (≤ 60).

Table III Adverse events in 24 patients

Event	Study visit				Total
	Post-op	Explant	Visit 3	Visit 4	
	1-10 d	6-8 wks	16-18 wks	24-26 wks	
	(n = 25)	(n = 24)	(n = 21)	(n = 16)	
Implant related					
Implant displacement/loosening	0	0	0	0	0
Sterile inflammatory reaction	0	1	0	0	1
Nonunion	0	0	0	0	0
Infection	0	0	0	0	0
Surgery related					
Median and ulnar nerve palsy	1	0	0	0	1
Malreduction	0	1	0	0	1

to achieve these goals. Most patients achieved good or excellent elbow function, with stability, good range of motion, good strength, and little to no pain. Complications consisted of 1 patient with an elbow that experienced ongoing subluxation, and 2 patients with heterotopic ossification (both injury-related and pre-existing, not device related), 1 of which developed transient median and ulnar nerve palsies. Another patient presented with questionable infection, was treated with oral antibiotics, and had no ongoing problems.

Our results should be considered in the light of several limitations. This was a single-arm study with no control group

because elbow instability is uncommon. Two patients were lost to follow-up, and to our knowledge, the device in these patients was not removed. The device is meant to be temporary, and we do not know the effects of long-term implantation. Problems that may develop after that time are arthrosis and ulnar neuropathy that were not assessed in our study after the final follow-up. The indications for use of the device are heterogeneous and somewhat subjective, making it difficult to compare our results with prior studies.

The mean arc of flexion (119°) and forearm rotation (151°) are comparable with prior studies. Orbay and Mijares⁸ achieved

Table IV The results of internal and external hinge fixators

Study	Y	Cases	Device	Mean follow-up (mo)	Flexion extension arc (°)	Pronation supination arc (°)	Pain	Inability/malalignment			Broberg-Morrey score	Broberg-Morrey rating			Pin problem	Nerve injury	
								No or slight	Moderate	Severe		Poor	Fair	Good			Excellent
First author		(No.)		(mo)	(°)	(°)											
Our study	2015	24	IJS-E	8-12	119	152	23	1	0	1	93	1	1	8	14	0	0
Iordens ⁶	2015	27	HEF	12	120	160	6	90	7	.
Hopf ⁴	2015	26	HEF	52	146	167	8	93	0	0	8	18	1	0
Orbay ⁸	2014	10	Hinged internal Steinmann pin	32	115	139	0	0	0
Ring ¹⁰	2014	19	HEF	31	94	115	1	90	1	1	11	6	7	2
Wang ¹⁵	2014	46	HEF	24	126	140	3	91	2	1	15	27	.	7
Sørensen ¹⁴	2011	20	HEF	44	95	52	1	74	4	4	7	2	5	2
Zilkens ¹⁷	2009	24	HEF	11	85	122	0	5	0
Yu ¹⁶	2007	20	HEF	25	93	96	15	4	1	2	75	4	5	5	6	3	0
Papandrea ⁹	2007	21	HEF	60	95	118	12	5	2	8	1	2
Ring ¹¹	2004	13	HEF	57	99	122	2	84	0	3	4	6	5	.
Ruch ¹³	2001	8	HEF	18	97	128	1	1
Fox ³	2000	11	HEF	29	96	...	8	0	3	4	5	2
McKee ⁷	1998	16	HEF	23	105	151	11	4	1	1	84	1	3	10	2	2	1

HEF, hinged external fixator; IJS-E, internal joint stabilizer for the elbow.

mean arcs of flexion and rotation of 115° and 139°, respectively, using a shaped Steinmann pin as an internal hinge. The results of hinged external fixator showed a range of flexion arc from 75° to 146° and rotation arc from 52° to 167°^{3,4,6,9,11,13-17} (Table IV).

No IJS-E patients in the present study experienced a recurrent dislocation, and 1 patient had persistent subluxation. The rate of dislocation or subluxation, or both, of the IJS-E study population was 4% among patients who completed the study. Notably, the patient who experienced a recurrent subluxation presented with 50% loss of coronoid height (the limit of the inclusion criteria). This patient had a Broberg-Morrey score of 44, representing a poor outcome.

In comparison, Ring et al¹⁰ reported 1 residual subluxation in 19 patients treated with hinged external fixation (5%) and no residual instability in 10 patients treated with cross pin fixation with cast immobilization. McKee et al⁷ reported 1 recurrent subluxation among 16 patients (6%) in whom hinge external fixator was used as an adjunct to treat traumatic elbow instability. In a series of 10 patients treated with an internal hinged device fashioned by shaping a Steinmann pin, Orbay and Mijares⁸ reported no recurrent or residual instability. In this case, the Steinmann pin offered internal support similar to the IJS-E but relied on the surgeon's craftsmanship to create a stabilizing internal pin configuration. Other studies reported a range of 0% to 30% recurrent subluxation or malalignment after treatment of persistent instability with a hinged external fixator^{3,4,6,9,11,13-17} (Table IV). If instability rates are compared between the IJS-E and published data on other devices, it can be concluded that the IJS-E is at least as effective as the external fixator at achieving elbow stability.

In the present study, 2 patients (8%) had heterotopic ossification restricting motion. The heterotopic ossification was present in both patients at the time of implant surgery. In comparison, Hopf et al⁴ recently reported heterotopic ossification in 16 of the 22 patients (73%) treated with a hinged external fixator. The rate of nerve injury was as high as 15% using hinged external fixation.^{2,4,6,9,11,13-17}

One IJS-E patient appeared to have an inflammatory reaction at the time of explant and was treated prophylactically with antibiotics, but cultures were negative for infection. Importantly, the IJS-E provided stability to the elbow and allowed this patient to achieve a full recovery, with a final Broberg-Morrey rating of 99 (representing an excellent outcome) and no recurrence of inflammation. Similarly, there was a prominent implant in the series of stabilization with shaped Steinmann pins,⁸ but the other adverse events noted with shaped Steinmann pins were not likely device related (deep infection, wound hematoma, and heterotopic ossification). In contrast, external fixation has a notable rate of pin track infection, pin breakage, pin loosening, or bone insufficiency fracture through the site of pin insertion. (Table IV). By comparison, the IJS-E significantly reduces the incidence of pin problems (infection, breakage, bone fracture, nerve injury).

Conclusion

As assessed by the Broberg-Morrey categoric rating (motion, strength, stability, and pain), the IJS-E is at least as effective as an external fixator at maintaining concentric elbow reduction. The IJS-E can help maintain concentric reduction while allowing functional motion in the early postoperative period. Although the IJS-E and the external fixator both require a second procedure to remove the device, the IJS-E seems less cumbersome for the surgeon and the patient. Moreover, complications of external fixation, such as pin problems (infection, breakage, bone fracture, and nerve injury), are avoided with the IJS-E. Traumatic elbow instability remains a difficult entity to treat, but with thoughtful treatment strategies, the IJS-E is a useful and safe adjunctive treatment option.

Disclaimer

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