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Original Research

The Internal Joint Stabilizer of the Elbow: A Systematic Review of the Clinical and Biomechanical Evidence

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Purpose: The goal of surgical management for unstable elbow injuries is the restoration of joint concentricity and stability. After internal fixation, concerns may exist regarding instability or durability of the fixation construct. Historically, these scenarios were treated with options such as transarticular pinning or external fixation. Recently, an internal joint stabilizer (IJS) that allows postoperative mobilization was introduced. Our objective was to systematically review the literature to aggregate the clinical and biomechanical evidence for the IJS of the elbow.

Methods: A systematic review of the PubMed and Google Scholar databases was performed, following the PRISMA guidelines. The search results were narrowed from 2015 through 2023 to coincide with the inception of the device being reviewed.

Results: A total of nine retrospective reports on the IJS ($N = 171$) cases at a mean follow-up of 10.8 months were included. The pooled rate of implant failure was 4.4%, and recurrent instability was 4.1%. Additionally, the we included seven case reports and two biomechanical reports.

Conclusions: The aggregate literature describes satisfactory clinical outcomes with low rates of recurrent instability and device failure for the IJS of the elbow. The limited biomechanical investigations conclude efficacy for stability profiles.

Clinical relevance: Across a spectrum of unstable elbow cases, the IJS prevented recurrent instability during the early postoperative period. Notably, the device requires an additional procedure for removal, and the long-term impact of the retained devices is currently unclear.

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Elbow stability is predicated on bony structure and ligamentous integrity. Traumatic injury with ligament disruption or fracture and concomitant ligament disruption can result in an unstable elbow.[1] The goal of surgical management is to restore joint concentricity and stability.[2] Furthermore, the maintenance of a stable joint is critical for withstanding the forces of early mobilization. Stiffness after elbow injury is common and may be exacerbated by an extended period of immobility.[3–5]

After internal fixation of a traumatic injury, elbow instability may persist.[6] Additionally, concerns may exist for the durability of the fixation construct. In these scenarios, the surgeon may choose to stabilize the elbow using a static or dynamic means. Transarticular pinning maintains a stable elbow, but prolonged immobilization may contribute to poor functional outcomes.[6] External fixators are classified into the following two types: those that allow motion and those that preclude motion.

Dynamic external fixators provide stabilization; however, pin tract infections and difficulty in application complicate their use.[7] Static fixators are generally considered to be less complex to apply and have demonstrated similar clinical outcomes compared with hinged fixators.[8] Cheung et al[3] reported minor complications of 15% for hinged external fixation that included pin-related erythema and nonpurulent drainage lasting more than 5 days. Zero nerve injuries were noted to be associated with pin placement, which the authors attributed to the fixators being applied by highly experienced elbow surgeons.

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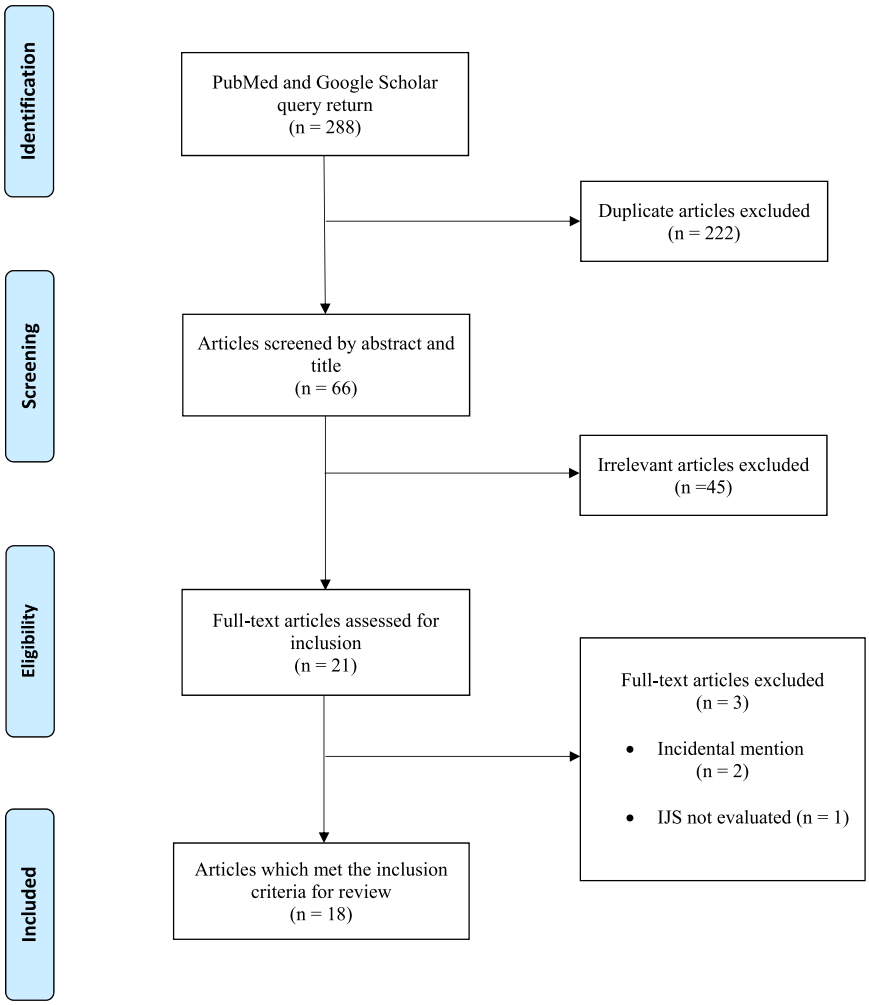

Figure 1. Flowchart displaying the sequence of literature search with exclusion criteria.

Table 1
Retrospective Case Series Reporting Clinical Outcomes on the IJS

Study	N*	Acute Cases	Terrible Triad*	Chronic Cases	Term* f/u	DASH*	MEPS*	Elbow F/E*
Orbay, 2017	26	19	12	7	8	16	—	119°
Sochol, 2018	20	9	8	11	16	37	82	124°
Pasternack, 2020	10	9	6	1	13	28	—	106°
Pardo-Garcia, 2021	5	5	5	0	10	11.7	94	134°
Fene, 2022	17	13	7	4	9	28.4	—	92°
Salazar, 2022	22	21	8	1	12.5	—	—	101°
Sheth, 2022	30	16	20	5	16	24	74	99°
Wynn, 2023	12	12	—	0	6	12	78	105°
London, 2023	29	29	29	0	†6.3	30.3	—	†115°
Total/mean	**171**	**133**	**95**	**29**	**10.8**	**23.4**	**82**	**111°**

DASH, Disabilities of the Arm, Shoulder, and Hand.
* N—sample size, terrible triad injury of the elbow, term of follow-up in mo, Disabilities of the Arm, Shoulder and Hand score, Mayo Elbow Performance Score, elbow flexion-extension arc of motion.
† Median.

Recently, an internal joint stabilizer (IJS) that allows post-operative mobilization was introduced. The initial report by Orbay and Mijares described an intraoperatively constructed Steinmann pin device intended to prevent recurrent instability and allow early motion.[9] This concept evolved into the manufactured IJS for the elbow.

The literature has an increasing body of evidence for the IJS across a spectrum of cases and surgical approaches. Our objective was to systematically review the literature to aggregate the clinical and biomechanical evidence for the IJS of the elbow.

Materials and Methods

A systematic review of the PubMed and Google Scholar databases was performed, following the PRISMA guidelines, on June 12, 2023. The search criteria included terms such as “internal joint

Table 2
Indications for the Use of the IJS as Reported in Retrospective Case Series

Study	Acute Cases*					Chronic Cases*	
	TT	Monteggia	Dislocation	Dislocation w/Fracture	Transolecranon	Instability	Dislocation
Orbay, 2017	12	1	1	5			6
Sochol, 2018	8	1				11	
Pasternack, 2020	6		2				1
Pardo-Garcia, 2021	5						
Fene, 2022	7		1	5		4	
Salazar, 2022	8		1	7	2		1
Sheth, 2022	20		5	2	3		
Wynn, 2023							
London, 2023	29						
Total (%)	**95 (62%)**	**2 (1%)**	**10 (7%)**	**19 (12%)**	**5 (3%)**	**15 (10%)**	**8 (5%)**

* TT—terrible triad injury, Monteggia fracture dislocation, dislocation without fracture, dislocation with associated coronoid or radial head fracture, transolecranon fracture dislocation, chronic as reported by the included articles, indications listed are those which were reported by more than one article, blank cells were not reported.

Table 3
Complications and Removal After the Use of the IJS as Reported in Retrospective Case Series

Study	Recurrent Instability	Device Failure	Device Removal
Orbay, 2017	3.8%	0%	100%
Sochol, 2018	5%	5%†	30%
Pasternack, 2020	10%	0%	90%
Pardo-Garcia, 2021	0%	0%	100%
Fene, 2022	0%	12%*	100%
Salazar, 2022	4.5%	9%*	82%
Sheth, 2022	3.3%	3.3%†	17%
Wynn, 2023	0%	0%	17%
London, 2023	10.3%	10.3%	86%
Mean	**4.1%**	**4.4%**	**69%**

* Includes case(s) of device failure without recurrent instability.
† Includes case(s) of device failure with recurrent instability.

stabilizer," "joint stabilization AND elbow," and "internal stabilizer AND elbow." The search results were narrowed to the time frame between 2015 and 2023 to coincide with the inception of the device being reviewed. Comprehensive exclusions of irrelevant articles including duplicates were performed by two authors. These exclusions pertained to the broad-based topic identified by specific nomenclature. Review articles, conference proceedings, and expert opinions including concept reviews were also excluded. Next, categorical exclusions using title/abstract and full text were performed by two authors.

Eligibility for inclusion

The inclusion criteria specified case reports, retrospective and prospective reports, and biomechanical reports that investigated the manufactured IJS for the elbow (IJS, Skeletal Dynamics, Miami, Florida). Additionally, the references of included articles were screened to ensure a complete capture of relevant articles. Exclusions included articles that did not report outcomes on the IJS or articles that reported on external elbow stabilization.

Data extraction

The following variables were compiled from each included study: sample size, patient demographic information, injury type, time from injury to surgical management, term of follow-up, and clinical outcome metrics including recurrent instability, device failure, device removal, and biomechanical results.

Grouping

Articles were organized according to study type. These groups were as follows: retrospective reports on the IJS (level III/IV evidence), case reports on the IJS (level V evidence), and biomechanical reports on the IJS.

Methodological quality

The Modified Coleman Methodology Score (MCMS), a 90-point scale across two sections with 17 variables, was used to assess reporting quality within the retrospective report group. Section A evaluates the foundational elements of the study with variables including sample size, treatment description, and follow-up interval. Section B evaluates the robust quality of the findings with variables including subject retention and the use of patient-reported outcomes.

Results

The literature search and exclusion criteria leading to the final sample of articles are depicted in Figure 1. In total, 21 articles were assessed by full text; however, three articles were excluded due to incidental mention and lack of outcome data.

IJS retrospective reports

A total of nine retrospective reports on the IJS with a sample of 171 cases and a mean follow-up of 10.8 months were included (Table 1).[10–17] The mean MCMS was 61 (range: 56–67), which indicates a moderate quality of reporting across all groups. Indications are detailed in Table 2, and device-related complications are demonstrated in Table 3. The most common injury pattern for which the IJS was indicated was acute presentation of a terrible triad (53%). Across seven articles, the mean Disabilities of the Arm, Shoulder, and Hand score was 22.4 (range: 11.7–37),[10–15,17] and across four articles, the mean Mayo Elbow Performance Score (MEPS) was 82 (range: 74–94).[13–15,17] All nine articles reported the elbow flexion extension arc for a mean of 111°. The pooled rate of device failure was 4.4% (range: 0% to 12%) with four of the nine reports having zero cases of device failure.[10,11,15,17] The pooled rate of recurrent instability was 4.1% (range: 0% to 10.3%), with three of the nine reports having zero cases of recurrent instability.[12,15,17] The pooled rate of device removal was 69% (range: 17% to 100%) across all retrospective reports.

Table 4
Case Reports Describing Clinical Outcomes on the IJS

Study	Injury	Approach	IJS Position	Outcome/Removal
Schneider, 2019	Recurrent instability in Ehlers-Danlos	Lateral	Lateral	IJS removed at 6 mo and at 1 y no subsequent dislocations
Sheth, 2021	Recurrent instability	Medial	Medial	IJS removed at 8 mo and at 1 y 120° elbow arc of motion
Schultz, 2021	Dislocation	Lateral	Lateral	Maintained concentric reduction
Salazar, 2021	Terrible triad variant with Essex Lopresti	Lateral	Lateral	IJS removed at 3 mo, 125° elbow arc of motion
Gonzalez, 2022*	Chronic dislocation	Posterior	Lateral	—
Salazar, 2022	Chronic dislocation	Lateral	Lateral	IJS removed at 6 wk and at 6 mo 125° elbow arc of motion
Jordan, 2022	Dislocation and coronoid fracture	Lateral	Lateral	IJS not removed at 6 mo 120° elbow arc of motion
	Fracture dislocation	Lateral	Lateral	IJS removed at 4 mo, 85° elbow arc of motion

* Gonzalez et al—technique description.

IJS case reports

A total of seven case reports on the IJS for various indications and surgical approaches exist. Case descriptions and outcomes are shown in Table 4. The IJS is reported for the indications of chronic dislocation,[18,19] Ehlers–Danlos Syndrome recurrent instability,[20] acute dislocations with coronoid fracture,[21] and terrible triad variant with Essex-Lopresti injury.[22] Reports describe the use of the IJS from a medial approach[23] and a posterior approach.[24]

Salazar et al[19] reported the IJS being used for a chronic fixed posterior dislocation with coronoid fracture. Schultz et al[18] reported on the IJS being used for chronic dislocation with gross instability. In a case of terrible triad injury, Jordan et al[21] reported on the IJS with removal of the device 4 months after surgery. Additionally, the same authors reported on the IJS being used in a coronoid fracture elbow dislocation case, but the device was not removed due to the patient's choice. A patient with recurrent elbow dislocation due to Ehlers–Danlos Syndrome was treated with an IJS, as reported by Schneider et al.[20] Salazar et al[22] reported on the IJS being used in a case with Essex-Lopresti injury, terrible triad injury, and distal radius fracture. Sheth et al[23] described the IJS being implanted with a medial approach for terrible triad injury. Gonzalez et al[24] reported the IJS being implanted through a posterior approach to better visualize and address concomitant injury to medial structures.

IJS biomechanical reports

However, two biomechanical reports evaluate the IJS. Reiter et al[25] simulated posteromedial rotatory instability in nine specimens with an O'Driscoll type II coronoid fracture. The results demonstrated no significant differences in stability between a medially placed IJS and a static lateral external fixator, and between the medial IJS and the intact condition. Stenson et al[26] assessed radiographic ulnohumeral congruity in eight specimens under varus stress at 0° and 45° of elbow flexion after a 360° soft tissue release meant to simulate severe injury. Stability was measured using medial and lateral ulnohumeral joint distances and the ulnohumeral opening angle. The results demonstrated no significant differences in stability between the IJS, a static external fixator, and a hinged external fixator.

Discussion

The unstable elbow has consistently been an arduous task for surgeons. Surgical management is intended to provide adequate stability to counter the forces that are generated by early motion. Immobilization provides stability to allow healing but commonly leads to stiffness. Early mobilization mitigates the risk of stiffness but may disrupt a tenuous surgical repair. External devices have accomplished the goals of stability and motion capability, but complications reduce the utility of this option. A temporary internal device was developed to stabilize the elbow, which allows the initiation of motion. The aggregate literature describes satisfactory clinical outcomes and biomechanical efficacy for the IJS. Additionally, case reports have expanded the understanding of case application, device position, and surgical approach for the IJS.

After surgical fixation, the elbow may remain unstable.[6] Application of adjuvant devices, whether internal or external, can provide the requisite stability to reduce the risk of postoperative complications. Recurrent instability has been reported in 20% or more of the cases.[27–29] This complication is challenging and portends chronic dysfunction. The pooled rate of recurrent instability with the IJS was 4.1%. These results are comparable with those of some reports for recurrent instability with hinged external fixators,[7,30] which have been described as technically demanding for the surgeon and cumbersome for the patients.[31,32] The internal stabilization device avoids the complications that commonly arise due to external devices including pin tract infections. Notably, three of the articles that reported a case of recurrent instability described this occurring in the presence of coronoid deficiency.[10,11,14] Sheth et al[14] remarked that cases with large coronoid fragments or coronoid deficiency may require more robust stabilization and alluded to their previous report on a medially placed IJS.

The current literature has two comparative reports on the IJS. Sheth et al[14] reported cases of elbow dislocation or fracture dislocation that were stratified based on the use ($N = 30$) and non-use ($N = 34$) of the IJS. Intraoperative determination for the use of the IJS was based on the presence of instability after the repair or concerning tissue viability, which yielded a tenuous repair. Two cases of recurrent instability in the no IJS group and one case in the IJS group exist, which was due to implant disassembly. The overall findings described similar clinical outcomes for the use of the IJS in unstable elbows compared with the non-use of the IJS in elbows that were deemed stable. Wynn et al[17] reported similar clinical outcomes between the IJS ($N = 12$) and external fixation ($N = 12$), although complications and subsequent interventions were more likely after external fixation. The authors performed a financial analysis and concluded a similar total procedural cost between the IJS and external fixation. Although the implant cost of the IJS was higher, when factoring in the cost of complications and subsequent interventions, the cost of external fixation was higher. Notably, the financial component of device evaluation may substantially vary across geography and institutions.

Terrible triad injuries accounted for 62% of the reported indications for the IJS across the retrospective series. London et al[33] compared clinical outcomes in terrible triad injury between IJS cases that did ($N = 12$) and did not ($N = 17$) require reoperation outside of device removal. Clinical outcomes were superior in cases that did not require reoperation. The most frequent indications for reoperation were heterotopic ossification excision, contracture, and ulnar nerve symptoms. The review by Chen et al[34] reported that reoperation occurred in up to 54% of cases (mean 22%), with the most common indications including stiffness and ulnar nerve symptoms. Tangtiphaiboontana et al[35] reported that heterotopic

ossification occurred in 77% of terrible triad cases with 26% requiring excision. Ostergaard et al[36] reported that 45% of triad cases underwent reoperation at a minimum of one year with stiffness, ulnar neuropathy, and symptomatic hardware being the leading reasons. In totality, reoperation after terrible triad injury may be quite common, which is reasonably attributed to the extent of soft tissue disruption and subsequent pathophysiology.

Terrible triad injuries include lateral collateral ligament disruption, and thus, the IJS is placed laterally. Furthermore, the entirety of the retrospective reports on IJS describes a lateral placement. Recent clinical and biomechanical reports have described a medially placed IJS. Reiter et al[25] reported that medially placed IJS provides comparable stability to the intact joint and a laterally placed external fixator under simulated posteromedial rotatory instability.[25] The authors suggest that a medially placed IJS may provide utility in place of a lateral external fixator, which is often cumbersome to the patient and has the risk of pin-related complications. A case study on terrible triad injury with an anteromedial facet fracture of the coronoid was reported by Sheth et al.[23] The patient was returned to the operating room 6 weeks after the index fixation due to malreduction of the coronoid fragment and instability. An IJS was placed medially due to the pattern of varus posteromedial instability. The IJS was removed 8 months after implantation and at 15 months after surgery, the patients had resumed preinjury levels of activity and had a 120° elbow arc of motion.

The IJS is intended to be a temporary device to provide stability during the healing process. Although there are no manufacturer recommendations for device removal time, the foundational report by Orbay et al[10] described removal of the device between 6 and 8 weeks. Wide variance exists in the subsequent IJS reports for mean device removal time. Fene et al[12] reported 4 months (approximately 16 weeks), Pasternack et al[11] reported 10.5 weeks, Pardo-Garcia et al[15] reported 14 weeks, and Salazar et al[16] reported 4.75 months (approximately 19 weeks). Furthermore, some studies reported removal of the device across a subset of IJS cases. Sochol et al[13] reported 30% removal, and Salazar et al[16] reported 82% removal. The impact of a retained IJS is currently unknown.

We acknowledge the limitations of the current work. Primarily, the quality of the work is dependent on the methodology of the included articles. The mean MCMS was considered moderate by established standards, in part due to the small sample sizes and short terms of follow-up (mean 10.8 months). This is attributable to the recent release of the IJS and the relative infrequency of these injuries, which hinders large sample reporting. Furthermore, the recommendation of device removal can impact patient retention for follow-up. This review is an aggregate of retrospective reports—one of which was the seminal report piloted by the device designer. Thus, no prospective reports and only one report comparing this device with other stabilization options have been performed. The inclusion of case reports was not intended to provide generalizable clinical data but to demonstrate the applicability of the IJS across a variety of unstable elbow cases and surgical approaches. The financial implications of device utilization and device removal were outside the scope of the current work.

Across a spectrum of unstable elbow cases, the IJS prevented recurrent instability during the early postoperative period. The aggregate literature describes satisfactory clinical outcomes with low rates of recurrent instability (4.1%) and device failure (4.4%). In contrast, recurrent instability has been reported in more than 20% of the cases after adjuvant stabilization with external fixators. Notably, the device requires an additional procedure for removal, and the long-term impact of retained devices is currently unclear.

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