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ORIGINAL STUDY

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The use of the internal joint stabiliser for elbow instability Report of two cases and systematic review

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The management of elbow fracture-dislocations is challenging. The internal joint stabiliser (IJS) (Skeletal Dynamics, Miami, FL) has been advocated as an alternative to traditional techniques. This article shares our initial clinical experience and provide a systematic review analysing the ability of the IJS to maintain radiographic joint reduction and the associated complication profile. Two cases of elbow fracture-dislocations treated at our centre using the IJS are presented. A systematic review of the literature was conducted using the online databases Medline, Scopus and EMBASE. Clinical studies reporting the maintenance of joint reduction after the use of IJS in patients with acute or chronic elbow instability were included. The two cases reported remained radiographically concentric at 6 months follow up without complications. 5 studies met the inclusion criteria and were included in the systematic review (total n=65). Only two patients across the studies had ongoing radiological instability (3%) and both were associated with coronoid insufficiency. The mean flexion-extension arc ranged from 106° to 135° and pronation-supination arc ranged from 138° to 151°. The mean DASH scores ranged from 16 to 37.3 and the mean Broberg and Morrey Functional score from 68.2 to 93. Complication rates in the case series ranged from 21% to 40%, the commonest complications were heterotopic ossification, neuropathy and infections.

Initial reports into the use of the Internal Joint Stabiliser for elbow instability have shown a low incidence of residual radiological joint incongruency.

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INTRODUCTION

The elbow is the second most commonly dislocated large joint after that of the shoulder with a reported annual incidence of 13 per 100,000 of the population *(1)*. Elbow dislocations are classified as simple or complex *(2)*; simple dislocations occur without fractures and complex dislocations are associated with fractures of the radial head,

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olecranon, or coronoid process. The radial head and coronoid process are considered to be important bony stabilisers and the presence of concomitant fractures is associated with poorer functional results *(3)*. Terrible triad elbow injuries refer to a dislocation, radial head fracture and coronoid fracture. It is often accompanied by collateral injuries (lateral collateral ligament and medical collateral ligament) and have been associated with 20% recurrent instability even after surgical fixation *(4)*. Late-presenting, unreduced dislocations of the elbow commonly have a non-functional range of movement and provide a further surgical challenge *(5, 6)* due to retraction of the triceps muscles and collateral ligaments *(7, 8)*.

The primary goal of surgery is to achieve a stable and reduced joint with a functional range of motion. Surgical management involves a combination of open reduction and internal fixation of fractures and ligamentous repair and/or reconstruction *(9)* with avoidance of post-operative immobilisation. However complex fracture-dislocations, especially if the dislocation was neglected or chronic, can remain unstable even after such surgical intervention *(10, 11)*. In this situation additional stabilisation is generally required. Options to achieve this include plaster, trans-articular pinning, rigid external fixator and hinge fixator, however each is associated with significant associated pitfalls and complications. Plaster holding the elbow in flexion may not provide sufficient restraint to maintain congruent stability and risks profound joint stiffness *(12, 13)*. Trans-articular pinning has the potential to damage the articular surface and external fixators have a high prevalence of pin track infection, risk nerve injury and provides a challenge in correctly aligning the axis of ulnohumeral rotation *(10, 13-15)*.

The internal joint stabiliser (IJS) (Skeletal Dynamics, Miami, FL) has recently been advocated as an alternative surgical technique to provide this additional joint stability. This implant is placed under the soft tissues and aims to provide maintenance of concentric joint reduction while allowing for immediate postoperative range of motion, example radiographs are provided in the two clinical cases within the report (Figure 1 and 2). The IJS has the potential advantages of reducing pin tract infections, allowing early range of motion and utilising a short moment arm making reproduction of axis of ulnohumeral rotation easier. However, the success of the implant in terms of maintaining a concentric joint reduction, preventing stiffness and complications remains uncertain. This article aims to share our initial clinical experience and provide a systematic review analysing the ability of the IJS to maintain radiographic joint reduction in both acute and chronic instability cases whilst analysing the resultant range of motion and associated complication profile.

MATERIAL AND METHODS

The IJS has been utilised in the management of two cases of elbow fracture/dislocations at our centre over the last one year. These two cases were identified prospectively and were seen post-operatively at 2 weeks, 6 weeks, 4 months and 6 months by the operating surgical team. Radiographs were taken and range of motion was measured using a goniometer at 6 months. Removal of the implant was suggested at 4 months but was left to patient choice.

A systematic review of the literature was conducted in accordance with the PRISMA guidelines *(16)* using the online databases Medline, Scopus and EMBASE. The review was registered on the PROSPERO database (CRD42020187670). The searches were performed independently by two authors on the 19th of May 2020 and repeated on the 22nd of May 2020 to ensure accuracy. Search terms included 'Internal Joint Stabiliser' and 'Elbow dislocation.' Any discrepancies were resolved through discussion between these two authors, with the senior author resolving any residual differences.

The eligibility criteria were clinical studies published in the English language that reported on patients managed surgically for acute or chronic elbow instability. The use of the IJS implant was mandatory for inclusion in addition to any concomitant surgical procedures. The studies were required to report an evaluation of radiographic joint congruency during follow up for inclusion. Only primary research was considered for review with any abstracts, comments, review, biomechanical and technique articles excluded. The clinical studies were appraised independently by two authors and quality

assessment of non-randomised studies was completed using the Methodological index for non-randomised studies (MINORS) tool *(17)* MINORS is a validated scoring tool for non-randomised studies. Each of the 8 items in the MINORS criteria relevant to case series were given a score of 0, 1, or 2, with maximum score of 16 (Table I).

Patients are positioned in the supine position with the extremity on a hand table. A standardised approach to allow for repair of relevant injured structures is then carried out. If after repair of

Table I. — Methodological items for non-randomized studies (MINORS) Score

	Orbay et al. *(18)*	Orbay et al. *(19)*	Sochol et al. *(20)*	Paster-nacket al. *(22)*
A clearly stated aim: the question addressed should be precise and relevant in the light of available literature	2	2	2	2
Inclusion of consecutive patients: all patients potentially fit for inclusion (satisfying the criteria for inclusion) have been included in the study during the study period (no exclusion or details about the reasons for exclusion)	2	1	1	1
Prospective collection of data: data were collected according to a protocol established before the beginning of the study	0	2	0	0
Endpoints appropriate to the aim of the study: unambiguous explanation of the criteria used to evaluate the main outcome which should be in accordance with the question addressed by the study. Also, the endpoints should be assessed on an intention-to-treat basis.	1	2	2	2
Unbiased assessment of the study endpoint: blind evaluation of objective endpoints and double-blind evaluation of subjective endpoints. Otherwise the reasons for not blinding should be stated	0	1	1	1
Follow-up period appropriate to the aim of the study: the follow-up should be sufficiently long to allow the assessment of the main endpoint and possible adverse events	2	2	2	2
Loss to follow up less than 5%: all patients should be included in the follow up. Otherwise, the proportion lost to follow up should not exceed the proportion experiencing the major endpoint	2	1	2	2
Prospective calculation of the study size: information of the size of detectable difference of interest with a calculation of 95% confidence interval, according to the expected incidence of the outcome event, and information about the level for statistical significance and estimates of power when comparing the outcomes	N/A	N/A	N/A	N/A
An adequate control group: having a gold standard diagnostic test or therapeutic intervention recognized as the optimal intervention according to the available published data	N/A	N/A	N/A	N/A
Contemporary groups: control and studied group should be managed during the same time period (no historical comparison)	N/A	N/A	N/A	N/A
Baseline equivalence of groups: the groups should be similar regarding the criteria other than the studied endpoints. Absence of confounding factors that could bias the interpretation of the results	N/A	N/A	N/A	N/A
Adequate statistical analyses: whether the statistics were in accordance with the type of study with calculation of confidence intervals or relative risk	0	2	0	2
Total	9	13	10	12

The items are scored 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). The global ideal score being 16 for non-comparative studies.

these structures the elbow remained unstable then the IJS is utilised.

The centre of rotation of the capitellum is marked and a guide wire placed horizontal to the joint from lateral to medial up until the medial cortex under fluoroscopy (Figure 3). A jig of three sizes is available that is inserted and hooked around the trochlea to help guide wire position. This step is a key step and time should be taken to obtain a true lateral radiograph before wire insertion to ensure that the centre of rotation is identified. The wire depth is measured and a cannulated drilled passed over the wire. The baseplate is positioned on the posterior aspect of the olecranon, three screws are used to secure the baseplate onto the olecranon. The axis pin is inserted through the eyelet of the proximal connecting rod and into the hole drilled into the humerus. The elbow is reduced and the IJS locked by tightening the screws on the connecting arm. Fluoroscopy is used to confirm correct positioning and concentric elbow reduction. Example intra-operative images are provided in Figures 1 and 2.

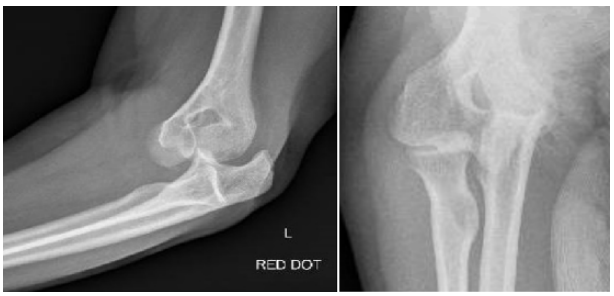

Figure 1a. — Case 1 pre-operative radiographs demonstrating elbow dislocation.

Figure 1b. — Case 1 pre-operative radiographs demonstrating elbow subluxation at four weeks following injury.

Figure 1c. — Case 1 post-operative radiographs of the Internal Joint Stabiliser.

Figure 2a. — Case 2 pre-operative radiographs demonstrating elbow dislocation and subsequent reduction.

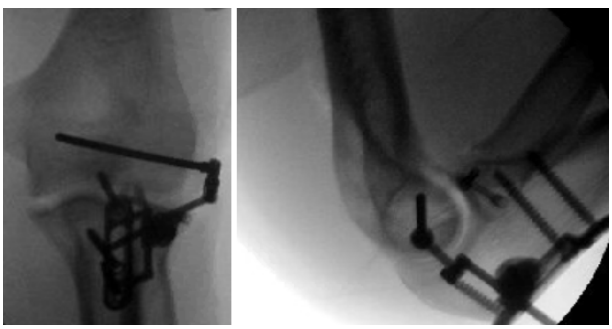

Figure 2b. — Case 2 intra-operative radiographs of the Internal Joint Stabiliser.

RESULTS

Case One

A 51 year old female suffered an isolated fracture dislocation of her left elbow after tripping up a step. The injury was closed, neurovascularly intact and was reduced in the Emergency Department (see Figure 1a). Initially a CT scan demonstrated a tip of coronoid fracture and likely LUCL injury with small avulsion of the lateral epicondyle. This was treated in plaster for 2 weeks but a further radiograph at 4 weeks demonstrated subluxation of the elbow (see Figure 1b) and was referred to the elbow surgeons at our centre. An MRI scan was then performed which demonstrated a small coronoid fracture, medial collateral ligament injury and lateral collateral ligament injury with associated avulsion of the common extensor origin. The patient underwent an open repair of the lateral ulnar collateral ligament through a Kocher's approach. However, given the persistent instability on table beyond 30° of extension and the delayed presentation the IJS was employed to protect the repair and ensure early active motion was possible. Follow up radiographs at 6 months demonstrated concentric reduction (Figure 1c). Flexion-extension arc at this stage was 20-140° and pronation-supination 150°. The patient chose not to have this implant removed and no complications were observed.

Case Two

A 33 year old male suffered an isolated fracture dislocation of his right elbow after falling from his bicycle. The injury was closed, neurovascularly intact and was reduced in the Emergency Department (see Figure 2a). Initially a CT scan demonstrated a comminuted radial head fracture and coronoid tip fracture. The patient underwent surgery 5 days after injury which involved fixation of the radial head using headless screws and lateral ulnar collateral ligament repair through a Kocher's approach. Following this fixation, screening of the elbow demonstrated instability before the final 30° of extension and therefore the IJS was applied (Figure 2b) to allow early active motion without splintage. Follow up radiographs at 4 months demonstrated concentric reduction and at this stage patient chose to have the IJS implant removed (Figure 2c). Flexion-extension arc at this stage was 40-125° and pronation-supination 130°. No additional complication to the stiffness described were observed.

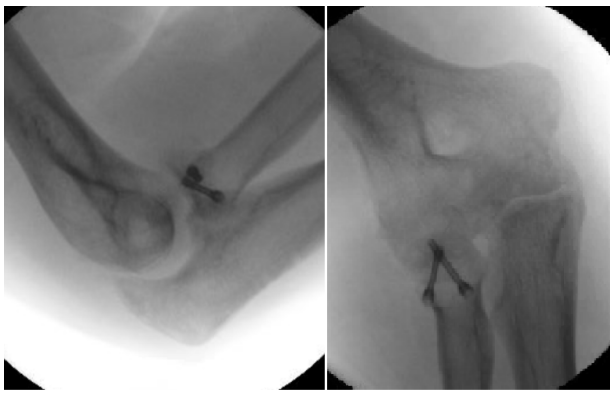

Figure 3. — Guide wire passed parallel to joint on AP and at centre of rotation on lateral before replacing with axis pin.

The search strategy is illustrated in Figure 3 and identified 222 studies for consideration. After application of inclusion criteria 5 studies were deemed eligible for inclusion (total n=65) *(18-21)*. Orbay et al. *(19)* reported a multicenter prospective series, three further studies were retrospective case series *(18, 20, 22)* and the Schneider et al. reported a case report *(21)*. Two of the five included studies were from Orbay et al. *(18, 19)*, however these two case series did not overlap, and the patients included in each were different. The first was a retrospective case series of patients treated between June 2008 and November 2009 *(18)* and the second was a multicentre prospective case series of patients treated between August 2013 and July 2014 *(20)*. Study characteristics are summarised in Table II, range of motion (ROM) and functional outcome scores in Table III and maintenance of joint reduction, complications and revision rates in Table IV.

All five studies reported the rate of maintenance of radiological reduction during follow up and the mean incidence of joint incongruence was 3%, see Table IV. Two case series and the case report demonstrated no cases of joint incongruence in a total of 34 patients with a mean of between

Table II. — Summary of studies

Study	Study Design	Population	Intervention (s)	Mean Follow up	Outcome
Orbay et al. 2014 n=10	Retrospective case series	43 years (9-67) 60% male 1) Acute terrible triad (n=3) 2) Persistent simple dislocation (n=1) 3) Medial facet coronoid fracture (n=1) 4) Instability after release of chronic elbow stiffness (n=5)	Acute injuries repaired Chronic cases no repair performed All IJS removed (mean 7 weeks)	32 month (14-59)	Radiographic alignment ROM Complications
Orbay et al. 2017 n=24	Multicentre prospective case series	57 years +/- 18 46% male 1) Terrible triad (n=12) 2) Monteggia (n=1) 3) Coronoid fracture (n=2) 4) Radial head fracture (n=2) 5) Unstable simple dislocation (n=1) 6) Chronic dislocation >3 weeks (n=6)	Acute injuries repaired If persistent instability then IJS IJS removed between 6-8 weeks	6 months	Radiographic alignment ROM BMFS DASH Complications
Sochol et al. 2019 n=20	Retrospective case series	43.3 years (17-74) 65% male 1) Acute terrible triad (n=8) 2) Acute monteggia (n=1) 3) Failed surgical fixation of acute dislocation (n=8) 4) Failed non-operatively managed dislocations (n=3)	Acute injuries repaired If persistent instability then IJS Indomethacin 2 weeks Planned MUA then arthroscopic release if stiff at 12 weeks performed in 50%	11.3 months (2-25)	Radiographic alignment ROM DASH MEPS Complications Revisions
Schneider et al., 2019 n=1	Case report	22 years Female Ehlers-Danlos syndrome with recurrent instability	MCL and LUCL reconstruction IJS subsequently removed at 6 months	12 months	Radiographic alignment ROM
Pasternack et al. 2020 n=10	Retrospective case series	50.8 years +/- 12.8 Male 40% 1) Terrible triad (n=6) 2) Lateral condyle/capitellum fracture (n=1) 3) Chronic elbow dislocation (n=1) 4) Acute simple (n=2)	Acute injuries repaired If persistent instability then IJS IJS removed between 6-10 weeks	14.4 months (range 4 to 28)	Radiographic alignment ROM BMFS DASH Revision surgery

Table III. — Concise details of ROM and functional outcome scores

Study	Range of Motion	Functional Outcome Scores
Orbay et al. 2014 *(18)* n=10	Flexion arc 115 Pronation-supination arc 138	Not reported
Orbay et al. 2017 *(19)* n=24	Flexion arc 119 +/- 18 Pronation-supination arc 151 +/- 24	Mean BMFS 93 Mean DASH 16+/-18
Sochol et al. 2019 *(20)* n=20	Flexion arc 124.3 +/-14.9	Mean Dash 85.3 pre-op to 37.3 post-op Mean MEPS 12.2 pre-op to 82.5 post-op
Schneider et al., 2019 *(21)* n=1	Flexion arc 135	Not reported
Pasternack et al. 2020 *(22)* n=10	Flexion arc 106 +/-33 Pronation-supination arc 141 +/- 23	Mean DASH 28.7 +/- 19.2 Mean BMFS 68.2 +/- 25.4

Table IV. — Concise details of maintenance of reduction, complications and revision surgery

Study	Further Dislocation or Subluxation	Complications	Revision Surgery
Orbay et al. 2014 *(18)* n=10	No further dislocation or subluxation	Overall complications 40% • Haematoma 10% • Heterotopic ossification 10% • Deep infection 10% • Ulna pain 10%	Further surgery 40% • Washout 20% • Early removal of implant 10% • Arthrolysis 10% Implants removed routinely
Orbay et al. 2017 *(18)* n=24	Ongoing subluxation 4%	Overall complications 21% • Ongoing subluxation 4% • Transient nerve palsy 4% • Heterotopic ossification 8% • Infection 4%	No revisions Implants removed routinely
Sochol et al. 2019 *(20)* n=20	No further dislocation or subluxation	Overall complications 30% • Ulna neuropathy 20% • Implant fracture 5% • Infection 5%	Removal of implant in 30% • Patient choice 20% • Implant breakage 5% • Infection 5% Implants removed routinely
Schneider et al., 2019 *(21)* n=1	No further dislocation or subluxation	0%	0%
Pasternack et al. 2020 *(22)* n=10	Ongoing subluxation 10%	Overall complications 40% • Ongoing subluxation 10% • OA 10% • Ulna neuropathy 20%	Further surgery 40% • Elbow arthroplasty for OA 10% • MCL reconstruction 10% • Ulna neuropathy 20% Implants removed routinely

12 and 32 months follow up *(18, 20, 21)*. The final two case series reported one case each where joint congruency was lost during follow up *(19, 22)*. Orbay et al. *(19)* reported that one case (4%) was found to have radiological subluxation at 6 months but at the time of injury had suffered a coronoid fracture involving 50% of the coronoid and the authors felt that coronoid deficiency was

the cause of recurrent instability. Pasternack et al. *(22)* reported that one case (10%) had recurrent elbow instability during follow up and the authors felt this was due to coronoid insufficiency. This patient was a 60-year-old female who had suffered a terrible triad injury and had undergone coronoid open reduction and internal fixation, radial head arthroplasty and lateral ulnar collateral ligament repair at initial surgery.

The overall complication rates varied in the case series from 21% to 40%, see Table IV. Orbay et al. 2017 *(19)* reported the largest series with an overall complication rate of 21% which included heterotopic ossification (8%), transient ulnar nerve palsy (4%), loss of joint congruency (4%) and superficial infection (4%). Pasternack et al. *(22)* reported the highest complication rates (40%) with the commonest complications being infections, heterotopic ossifications and neuropathies.

The overall revision rate varied from 0% to 40% in the case series, see Table IV. In the largest series Orbay et al. 2017 *(19)* reported no revisions above the routine removal of implants. Pasternack et al. *(22)* reported revision surgery in 40% of patients in addition to routine removal of the IJS implant; revisions in this group were elbow arthroplasty for osteoarthritis in 10%, medial collateral reconstruction for persistent instability 10% and cubital tunnel release in 20%.

Three authors routinely removed the IJS implant in all patients between 6 weeks and 6 months *(18, 19, 22)*. Sochol et al. *(20)* did not routinely remove the IJS implant and reported that 30% of patients required removal of implants with the majority of these due to patient choice (20%) and the remainder due to infection (5%) and implant breakage (5%).

All studies reported the resultant mean flexion-extension arc which varied from 106° to 135° and three case series reported the mean pronation-supination arc and this varied from 138° to 151° *(18, 19, 22)*. Three case series reported functional outcome scores; the mean DASH scores ranged from 16 to 37.3 *(19, 20, 22)* and the mean Broberg and Morrey Functional score (BMFS) ranged from 68.2 to 93 *(19, 22)*. Further details are provided in Table III.

DISCUSSION

The most important finding of the present review was that the use of the IJS resulted in a high rate of maintenance of joint congruency during follow up. Only two of the four case series reported any cases of recurrent radiological instability with the overall rate across this review being 2 cases in the 65 patients (3%). The two cases from our centre also had maintenance of joint congruency during their short follow up. This figure appears comparable to alternative surgical techniques. Cramer et al. and Ring et al. published series of patients treated with trans-articular fixation with wires or screws and reported no cases of recurrent radiological instability but their series including only 11 and 17 patients respectively *(23, 24)*. Studies assessing the hinged external fixators have reported residual radiological instability rates ranging from 3% to 14% *(10, 23, 25-27)*. Potentially any increase in joint incongruence after use of the hinged external fixators may be secondary to the longer lever arm associated with this device which may magnify any error in identifying the ulnohumeral centre of rotation.

In the two cases of recurrent radiological instability using IJS in this review, both patients had suffered a coronoid fracture and had the IJS removed routinely. Both sets of authors suggested in their paper that coronoid insufficiency was the likely reason for recurrent instability. The importance of coronoid fractures as a significant risk for recurrent instability has been shown in both cadaveric and clinical studies *(4, 28)*. If coronoid fractures are large, such as Morrey classification *(29)* Type 3 fractures which involve more than 50% of the coronoid, or the coronoid fracture includes the medial collateral ligament attachment, such as O'Driscoll classification *(30)* Type 2 fractures, then the risk of recurrent elbow instability is higher. These two cases raise the concern that the IJS in isolation is insufficient to provide stability if a significant coronoid fracture (>50% height) is present. Therefore, this finding suggests elbow instability with an associated significant coronoid fracture cannot be adequately treated with the IJS alone and coronoid fixation or reconstruction is also required.

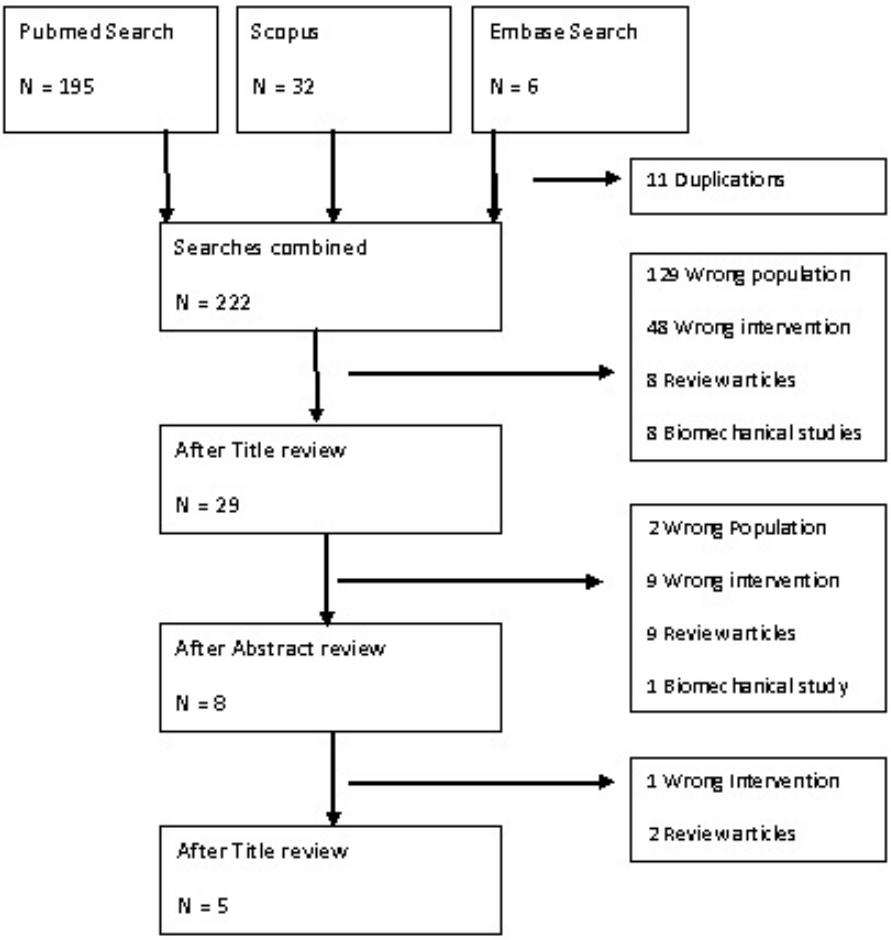

Figure 4. — Flow diagram of review process.

The complication rates in the included case series were relatively high and ranged from 21% to 40%. A comparably high complication rate has previously been reported after the use of hinged external fixators (37.5% to 50%) *(10, 13, 14, 23, 26)* and transarticular fixation (9% to 23%) in this patient cohort *(23, 24)*. In the authors small experience, 1 of the 2 patients reported developed moderate stiffness at their 6 months follow up. One potential advantage of the IJS implant is the reduction of infection and pin tract complications associated with hinged external fixators and transarticular pins. The infection rate in this IJS case series ranged from 0% to 10% with an overall infection rate of 4.6% across all studies. However, this figure appears to be lower than that associated with hinged external fixator infection rates in the previous literature. Cheung et al. reported on 100 consecutive patients undergoing hinged external fixators and reported 18% of their patient developed pin site complications in the form of infection, loosening or fracture *(14)*. McKee et al. similarly reported a pin tract infection rate of 12.5% and broken pin rate of 6.3% after use of hinged external fixators *(10)*. The infection rate associated with transarticular fixation was reported as 9% to 12% and the rate of broken metalwork was 0 and 6% *(23, 24)*. Overall, the literature currently lacks any studies directly comparing complication rates with these techniques which limit the ability to draw firm conclusions on preference on implant based on complication rate.

Most authors removed the implant routinely post-operatively between 6 weeks and 6 months. Sochol et al. *(20)* only removed the implant in 30% of cases

when it caused clinical concerns with 5% due to implant breakage, however given the follow up in this study ranged from only 12 to 30 months further breakages may occur later. The authors feel that theoretically, unless the centre of rotation is perfectly identified, that metal failure and fatigue of the IJS implant is likely to occur eventually. Therefore, in our practice, we aim to remove the implants in patients where the risk of secondary procedures is acceptable. Despite this, in our small clinical experience, one patient chose to avoid removal of the implant as she was delighted with her outcome despite appropriate counselling. However, this patient is only 8 months post-surgery and the long-term sequelae of retaining implants remains uncertain.

The use of the IJS implant allows early movement of the elbow joint with the aim to reduce the risk of stiffness. The mean flexion-extension arc (106° to 135°) and the mean pronation-supination arc (138° to 151°) were higher in this systematic review than those achieved using either a hinged external fixator 81° to 112° and 96° to 151° respectively *(10, 13, 26, 26, 31)* and using trans-articular fixation 99° to 102° and 142° respectively *(23, 24)*. However, the lack of comparative studies limits the ability of this review to draw a firm conclusion. A possible explanation for any improved ROM achieved using the IJS is the shorter lever arm of the implant when compared to the hinged external fixators. A challenging step when applying either an IJS or a hinged external fixator is the identification of the central axis of ulnohumeral rotation, however the longer lever arm of the external fixator will magnify any error in defining the central axis and therefore potentially reduce the possible range of motion. The use of transarticular fixation aims to limit any initial joint motion initially and a degree of subsequent joint stiffness is to be expected and may explain the lower arc of motion achieved with this technique than after the IJS.

Limitations of this systematic review are acknowledged. The included studies provide only level IV and V evidence with common weaknesses being the low study numbers, the low patient numbers, relatively short follow up and the lack of comparative groups. Two of the four studies originated from one of the designing surgeons and these results may not be reproducible at other centres *(18, 19)*. Table IV illustrates the appraisal of the case series studies against the MINORS criteria with scores ranging from 9 to 13 which demonstrate additional study limitations. Heterogeneity of the underlying cause for instability (which in broad terms included acute injuries, failed fixations and chronic injuries), the concomitant surgical procedures performed (e.g. radial head fixations, radial head replacements, coronoid fixation, lateral or medial ligament repair and reconstruction) and the outcomes reported restricted direct comparison of results between the studies.

CONCLUSION

Initial reports into the use of the Internal Joint Stabiliser for elbow instability have shown a low incidence of residual radiological joint incongruency. However, the complication rate associated with the procedure is relatively high. Further robust independent comparative studies are required to confirm these findings and compare these outcomes with other surgical techniques.

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