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SYMPOSIUM: COMPLEX ISSUES IN GLENOHUMERAL INSTABILITY

External Rotation Immobilization for Primary Shoulder Dislocation: A Randomized Controlled Trial

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Abstract

Background The traditional treatment for primary anterior shoulder dislocations has been immobilization in a sling with the arm in a position of adduction and internal rotation. However, recent basic science and clinical data have suggested recurrent instability may be reduced with immobilization in external rotation after primary shoulder dislocation.

Questions/purposes We performed a randomized controlled trial to compare the (1) frequency of recurrent instability and (2) disease-specific quality-of-life scores after treatment of first-time shoulder dislocation using either immobilization in external rotation or immobilization in internal rotation in a group of young patients.

Methods Sixty patients younger than 35 years of age with primary, traumatic, anterior shoulder dislocations were randomized (concealed, computer-generated) to immobilization with either an internal rotation sling (n = 29) or an external rotation brace (n = 31) at a mean of 4 days after closed reduction (range, 1–7 days). Patients with large bony lesions or polytrauma were excluded. The two groups were similar at baseline. Both groups were immobilized for 4 weeks with identical therapy protocols thereafter. Blinded assessments were completed by independent observers for a minimum of 12 months (mean, 25 months; range, 12–43 months). Recurrent instability was defined as a second documented anterior dislocation or multiple episodes of shoulder subluxation severe enough for the patient to request surgical stabilization. Validated disease-specific quality-of-life data (Western Ontario Shoulder Instability index [WOSI], American Shoulder and Elbow Surgeons evaluation [ASES]) were also collected. Ten patients (17%, five from each group) were lost to followup. Reported compliance with immobilization in both groups was excellent (80%).

Results With the numbers available, there was no difference in the rate of recurrent instability between groups:

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This study was conducted at the Fowler Kennedy Sport Medicine Clinic in London, Ontario, Canada, in conjunction with JOINTS Canada (Joint Orthopaedic Initiative for National Trials on the Shoulder Canada).

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10 of 27 patients (37%) with the external rotation brace versus 10 of 25 patients (40%) with the sling redislocated or developed symptomatic recurrent instability (p = 0.41). WOSI scores were not different between groups (p = 0.74) and, although the difference in ASES scores approached statistical significance (p = 0.05), the magnitude of this difference was small and of uncertain clinical importance.
Conclusions Despite previous published findings, our results show immobilization in external rotation did not confer a significant benefit versus sling immobilization in the prevention of recurrent instability after primary anterior shoulder dislocation. Further studies with larger numbers may elucidate whether functional outcomes, compliance, or comfort with immobilization can be improved with this device.
Level of Evidence Level I, therapeutic study. See Instructions for Authors for a complete description of levels of evidence.

Introduction

Shoulder dislocations are common, painful injuries. The glenohumeral joint is a loosely opposed ball-and-socket type of joint and as such is the most commonly dislocated large joint in the body. Zachilli and Owens [11] estimated the incidence rate of shoulder dislocations in the United States as 23.9 per 100,000 person-years, nearly twice the previously reported value. The clinical course of patients after nonsurgical treatment has been extensively investigated, and of particular interest is the relatively high rate of recurrent instability in young patients. Estimates of the recurrence rate in this group have been reported to be anywhere between 17% and 96% [9–11].

After initial reduction of the joint, the traditional treatment for primary shoulder dislocations has been immobilization in a sling with the arm in a position of adduction and internal rotation. A study published by Itoi et al. [2] in 2003 suggested that immobilizing acutely dislocated shoulders in a position of relative external rotation reduced subsequent dislocation rates. Their quasirandomized, prospective trial demonstrated a 0% recurrence rate in 20 patients immobilized in external rotation versus a 30% recurrence rate in 20 patients immobilized in a sling at a mean of 15.5 months followup [2]. A subsequent randomized trial by the same investigators confirmed the benefit of external rotation immobilization in a sample of almost 200 patients (relative risk reduction of 38.2%) [3]. These investigations introduced external rotation immobilization as an alternative to early surgical intervention and a possible means to reduce the high rate of recurrent instability in young patients. In 2011, Liavaag et al. [7] conducted a larger randomized trial comparing external and internal rotation immobilization and showed a recurrence rate of 24.7% (23 of 93) in the internal rotation group and 30.8% (28 of 91) in the external rotation group (p = 0.36) and therefore concluded that immobilization in external rotation did not reduce the rate of recurrence for patients with first-time traumatic anterior shoulder dislocation, contradicting Itoi et al.'s findings.

In light of the disagreement on this important issue, we performed a randomized controlled trial to compare the (1) frequency of recurrent instability and (2) disease-specific quality-of-life scores after treatment of first-time shoulder dislocation using either immobilization in external rotation or immobilization in internal rotation in a group of young, North American patients (clinicaltrial.gov registration # NCT00196560).

Patients and Methods

Study Design and Patients

This study was a prospective, multicenter randomized controlled trial. It was single-blinded in that all evaluations were performed by independent evaluators who were unaware of treatment allocation. Randomization was stratified for age (two strata: patients younger than 23 years and patients between 24 and 35 years old) and study center (three strata: University of Western Ontario, London, Ontario, Canada; University of Toronto, Toronto, Ontario, Canada; University of Calgary, Calgary, Alberta, Canada).

The study population was limited to skeletally mature patients younger than 35 years who had sustained a primary anterior glenohumeral dislocation as defined by a radiographically documented dissociation of the humerus anterior to the glenoid requiring manipulative reduction or a shoulder injury occurring through a mechanism of abduction, external rotation with sudden pain, and deformity requiring manipulative reduction. Patients were recruited from emergency departments and outpatient orthopaedic and primary care clinics at three university centers. Patients were assessed within 7 days of injury by the site study coordinator for eligibility. These assessments included a complete history and physical examination as well as a review of radiographs. We excluded patients with a history of previous instability in the affected shoulder with significant associated fractures of the proximal humerus, glenoid, or scapula (exceptions: Hill-Sachs lesions and/or small bony Bankart lesions [defined as those with $< 25\%$ of glenoid curvature as assessed on CT scan]) or who were unwilling or unable to participate.

Fig. 1 The external rotation immobilization brace is shown. A certified orthopaedic technologist will adjust the brace. Reprinted with permission from DJI, LLC.

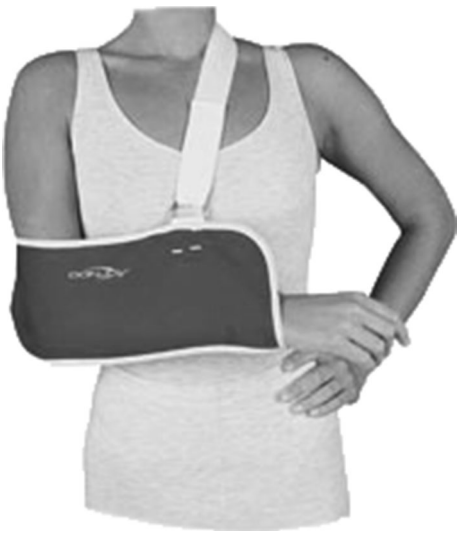

Fig. 2 The traditional sling immobilizer is shown. A certified orthopaedic technologist will adjust the sling. Reprinted with permission from DJI, LLC.

Referred patients meeting the inclusion criteria (further outlined subsequently) were randomly assigned (by computer-generated, permuted block algorithm) to one of two immobilization groups: external rotation brace (experimental group) and internal rotation sling (control group). The randomization sequence was kept concealed by the use of sealed opaque, sequentially numbered envelopes, which were opened only after inclusion criteria were satisfied and informed consent had been obtained.

For the external rotation brace group, the patients were provided with an external rotation shoulder brace to wear for a total of 4 weeks. All patients received an identical brace (DonJoy; DJO, LLC, Vista, CA, USA), which was adjusted by a certified orthopaedic technician to position the injured upper extremity in 90° of elbow flexion, 0° of shoulder abduction and flexion, and 0° to 5° of external rotation at the shoulder (Fig. 1). For the internal rotation sling group, patients were provided with a traditional internal rotation sling to wear for a total of 4 weeks. All patients in the control group received an identical sling (DonJoy; DJO, LLC), which was adjusted by a certified orthopaedic technician to position the injured upper extremity in 90° of elbow flexion, 0° of shoulder abduction and flexion, and 70° to 80° of internal rotation at the shoulder (Fig. 2). Patients in both groups were instructed to wear their respective braces or slings at all times with the exception of brief removal for showering and therapy of the ipsilateral elbow, wrist, and hand. A detailed instruction sheet outlining how to remove the brace/sling, how to maintain position of the arm for the brief periods out of the brace/sling, and how to reapply the brace/sling was given to each patient. This instruction sheet also included general information about how to care for, adjust, and remove the respective devices (in case of emergency). In the event of difficulties, contact information for the study coordinators was also provided.

After the 4-week period of immobilization, all patients began an identical standardized 16-week physical therapy program, which emphasized resolution of pain and swelling as well as restoration of ROM initially followed by a gradual introduction of strengthening exercises and functional rehabilitation. Physical therapy services were provided by outpatient or private practice therapists at the patient's discretion. Every effort was made to keep therapists blinded to patient group allocation.

Outcome Measures

Clinical and functional evaluations took place at regular, prespecified intervals, namely, 4 weeks and 3, 6, 12, 18, and 24 months after dislocation, and were conducted by site coordinators blinded to group allocation. Followup was forecasted from the time of dislocation to equilibrate the effects of any differences between the groups with respect to treatments/events occurring in the period before randomization. All outcomes were analyzed on an intention-to-treat basis and all data were collected by a research coordinator who was blinded to the patient's intervention assignment.

The primary outcome measure was recurrent instability as defined by a documented episode of anterior shoulder dislocation (see inclusion criteria) with radiographic evidence of the same and/or requiring manipulative reduction in a controlled hospital or healthcare setting or multiple episodes of shoulder subluxation, which, in the patient's

opinion, was disabling or symptomatic enough to warrant surgical stabilization. An assessment by an orthopaedic surgeon was mandatory in the case of the recurrent subluxation before categorizing these patients as having had an adverse event. Secondary outcome measures included clinical assessment (ROM, strength) and compliance.

Disease-specific quality-of-life deficits were also assessed using the Western Ontario Shoulder Instability index (WOSI) [5] and the American Shoulder and Elbow Surgeons evaluation form (ASES) [8]. The WOSI has been validated [5] and consists of four domains: (1) physical symptoms and pain; (2) sport, recreation, work, and function; (3) lifestyle and social functioning; and (4) emotional well-being. There are a total of 21 items, each with a 100-mm visual analog scale (VAS) response. The validity, reliability, and responsiveness of the ASES have been previously reported [8]. The patient self-evaluation section of the ASES has 11 items that can be used to generate a score. These are divided into two areas: pain (one item) and function (10 items). The response to the single pain question is marked on a 10-cm VAS, which is divided into 1-cm increments and anchored with verbal descriptors at 0 and 10 cm. The 10 items in the function area of the ASES include activities of daily living such as managing toileting, putting on a coat, etc, as well as more demanding activities such as lifting 10 pounds (4.5 kg) above shoulder height and throwing a ball overhand. Finally, there are two general items: doing usual work and doing usual sport. These are graded on a scale from 0 (unable to do) to 3 (not difficult) [4].

Patients were also asked to keep a diary of brace/sling wear, which included a record of physical therapy attendance. Patient compliance to brace/sling wear was encouraged through weekly telephone calls made by the study coordinator. Compliance was also formally assessed using a questionnaire administered after the 4-week period of immobilization.

Compliance with the brace or sling wear was good with 85% (51 of 60) wearing their respective devices full-time for at least 3 weeks of the 4-week immobilization period. Compliance was similar for both groups: 87% (27 of 31) wore the brace and 83% (24 of 29) wore the sling more than 75% of the immobilization period. No complications were reported with brace or sling wear.

Sample Size

A sample size of 25 patients per group was calculated based on a difference between event rates of 55% in the sling-immobilized group and 15% in the external rotation brace group with alpha set at 0.05 and 80% power. At the initiation of the study, the best estimate in the literature for the recurrent dislocation rate in nonoperatively treated young patients (younger than 30 years) after primary dislocation was approximately 65% [9–11]. In a previous investigation at our institution, the redislocation rate in a group of sling-immobilized patients (demographically similar to those who were to be included in the current trial) was 45% [6]. An intermediate recurrence rate (55%) was forecasted for the sling-treated group (ie, the control event rate) in the current investigation. This estimate was chosen to reflect the fact that, although the previous study group may have been similar with respect to prognostic factors (demographics, age, etc), they were a small, single sample drawn from a larger population, which, based on the literature at the time, had a slightly higher rate of instability. An experimental event rate of 15% was forecasted based on the data pertaining to the external rotation treatment available at the time [7] and the determination that a reduction in the rate of recurrent instability of 40% (55% versus 15%) would be clinically important and likely change treatment decisions. Given these estimates for the proportions of patients with recurrent instability in each group and setting, Type I and II error levels at 0.05 and 0.20, respectively, an estimated requirement of 19 patients per group was obtained. Factoring in a loss to followup of 30% (given a young, relatively transient trauma population), it was estimated that 25 patients were required in each group to demonstrate a clinically important reduction in recurrence rate with immobilization in external rotation.

Statistical Analysis

Data are presented as means ± SDs for continuous variables and number counts (with corresponding proportions or percentages) for categorical data. For between-group comparisons, we used two-sample t-tests for continuous variables and Pearson chi-square tests or Fisher's exact tests (as appropriate) for categorical data. Changes in outcome scores over time within groups were assessed with repeated-measurement analysis of variance. All statistical assessments were two-tailed. A p value of < 0.05 was considered statistically significant. Analyses were performed using SPSS® 18.0 statistical software (SPSS Inc, Chicago, IL, USA).

Results

A total of 60 patients were randomized between September 2003 and March 2008 with 31 patients allocated to the external rotation brace group and 29 patients allocated to the internal rotation sling group. Patient demographics and prognostic variables were similar between groups at baseline (Table 1). Mean patient age was 23 years in both

Table 1. Baseline patient characteristics for the two groups

Characteristic	External rotation brace group (n = 31)	Internal rotation sling group (n = 29)	p value
Age (years)*	23 (16–35)	23 (14–34)	
Sex (male/female) (number of patients)	28/3	27/2	
Affected side (left/right) (number of patients)	17/14	19/10	
Positive ligamentous hypermobility (number of patients)†	6	9	
Time to immobilization (days)‡	4 (3)	4.5 (6)	
Baseline WOSI score (%)§	32.45 (15.40)	32.69 (15.39)	0.96
Baseline ASES score (points)§	38.96 (21.18)	46.13 (23.35)	0.29

* Values are expressed as mean with range in parentheses; †as assessed by the Hospital Del Mar criteria [11]; ‡values are expressed as mean with mode in parentheses; §values are expressed as mean with SD in parentheses; WOSI = Western Ontario Shoulder Instability index; ASES = American Shoulder and Elbow Surgeons evaluation.

Table 2. Results at minimum 12 months' followup

Outcome	External rotation brace group, n = 27 (number, %)	Internal rotation sling group, n = 25 (number, %)	p value
Recurrent dislocation	6 (22)	8 (32)	0.42
Recurrent instability*	10 (37)	10 (40)	0.82
Recurrent instability requiring surgical stabilization	6 (22)	7 (28)	0.63
WOSI score (%)†	87 (14)	84 (21)	0.74
ASES score (points)†	95 (5)	89 (14)	0.05
Mean ROM (°) (index versus opposite)	70 versus 76	76 versus 78	0.15 versus 0.67

* Includes frank recurrent dislocations and subluxations; †values are expressed as mean with SD in parentheses; WOSI = Western Ontario Shoulder Instability index; ASES = American Shoulder and Elbow Surgeons evaluation.

groups (external rotation brace group: range, 16–35 years; internal rotation sling group: range, 14–34 years). There were 28 males and three females in the external rotation brace group and 27 males and two females in the internal rotation sling group. Ligamentous laxity (as assessed by the 10-point Hospital del Mar criteria for Joint Hypermobility [1]) was evident in six of 31 patients in the external rotation brace group and nine of 29 patients in the internal rotation sling group. Ten patients (17%) were lost to followup, five from each group. Quality-of-life data were not available for these patients; however, information regarding recurrence (and surgery) was obtained from the next of kin for two individuals (one from each group). Minimum followup was 12 months (mean, 25 months; range, 12–43 months).

At latest followup, there was no difference in the frequency of recurrent instability between groups (Table 2). In the external rotation brace group, six patients experienced a recurrent dislocation and four patients experienced symptomatic subluxation for an overall rate of instability overall of 37% (10 of 27 patients assessed). In the internal rotation sling group, there were eight patients with frank dislocations and two with symptomatic subluxations for an overall instability rate of 40% (10 of 25 patients assessed; p = 0.41 for the comparison of recurrent instability between groups). Six patients in the experimental group and seven patients in the control group have had (or are scheduled for) stabilization surgery.

WOSI scores were not different between the groups at most recent followup (Table 2). The external rotation brace group demonstrated a mean overall WOSI score of 87% (SD, 13%), whereas the internal rotation sling group demonstrated a nearly identical mean overall WOSI score of 84% (SD, 21%; p = 0.74). The results for the WOSI scores were analyzed using an intention-to-treat principle. An a priori secondary analysis based on a per-protocol approach also was performed, in which preoperative WOSI scores (for those patients who underwent surgery) were considered final end points; likewise, there were no differences between groups on this analysis. The ASES score for activities of daily living favored the group treated in external rotation by a small amount, which was of questionable clinical significance and borderline statistical significance (95 versus 89 points, p = 0.05; Table 2). Patients in the external rotation brace group had a slightly higher mean score at latest followup (95; SD, 5) than the internal rotation sling group (89; SD, 13).

Discussion

After initial reduction of the joint, the traditional treatment for primary shoulder dislocations has been immobilization in a sling with the arm in a position of adduction and internal rotation. However, recent basic science and clinical data have suggested recurrent instability may be reduced with immobilization in external rotation after primary anterior shoulder dislocation. We therefore performed a randomized controlled trial to compare the effectiveness of immobilization in external rotation with that in internal rotation in a group of patients at high risk for recurrent instability. Our investigation did not confirm a benefit with external rotation immobilization for primary anterior shoulder dislocation for a young, North American population in terms of the frequency of recurrent instability or redislocation or in terms of validated disease-specific quality-of-life scores.

The ASES quality-of-life scores at a minimum 12-month followup showed a statistically significant difference between groups in our study. The WOSI, also used in this study as well as others [7], has been shown to be more responsive than other tools for shoulder instability [5] but has not been shown to be statistically significant in any study to date. The significant finding with the ASES may indicate that more specific activities of daily living such as lifting weight above the head, keyboard use, toileting, or washing may be more impacted by immobilization in internal rotation than has previously been appreciated, a potential area of further research.

Limitations of this investigation and the results here include a moderate loss to followup (17%, 10 of 60 patients) and the relatively small sample size. Given that the difference in the observed event rates was much smaller than the projected estimates, a much larger sample would have been required to detect the true difference between the two treatments. Although the estimates were inaccurate (mostly because of an overly favorable projection of the effect of the external rotation brace), the observed rates (and variance thereof) suggest that the true rates are likely similar in magnitude and the difference not clinically significant. Some difficulties were experienced in enrolling eligible patients and ensuring attendance at clinical followup appointments past 6 months after injury; these phenomena are reflective of the young, active, relatively transient university-based North American study population. Moreover, there was no differential loss to followup between groups (five in each group, 17% in the group treated with a sling and 16% in the group treated in external rotation).

The criteria for surgical intervention were not standardized among the various surgeons at geographically different study sites. This resulted in some patients having stabilization procedures for symptomatic subluxation and apprehension versus frank recurrent dislocation. To limit the effect of variations in practice among the various sites, randomization was stratified to study center. The numbers of patients having been deemed to have recurrent instability were equivalent between groups, thereby suggesting any study site or surgeon bias was limited. Another potential limitation with regard to comparability to other studies is that the immobilization device used may not have positioned the arm in a sufficient amount of external rotation. In a pilot investigation at our center (unpublished data), attempts to immobilize patients in greater than 5° of external rotation were poorly tolerated and therefore we believed that a lesser degree would be optimal to maximize compliance for the current study.

We found that recurrent dislocations after primary traumatic shoulder dislocations in young patients remain a common and challenging problem but that immobilization in external rotation does not appear to confer an advantage over the use of a simple sling. Strengths of our study included the investigation of a population at high risk of recurrent instability, a rigorous randomization protocol, and the use of validated disease-specific heath-related quality-of-life measures. Also, ours is the also the only North American study of the efficacy of external rotation for primary shoulder dislocation of which we are aware, a potentially important issue given the possible geographic variations in activity levels, activity types, and overall health of patients.

The results of randomized trials of external rotation immobilization published to date are at odds and provide inconclusive evidence. Itoi et al. were the first to compare an external rotation brace with the standard sling; however, event rates in both the treatment and control groups were surprisingly low (0% and 30%, respectively), possibly reflecting the inclusion of patients of all ages (there were four patients older than 80 years) and those with significant associated fractures. Liavaag et al. [7] reported more fulsome randomization methods and extremely high adherence rates; however, their results did not show that immobilization in external rotation reduced the rate of recurrence for patients with first-time traumatic anterior shoulder dislocation.

Our investigation also did not confirm a benefit with external rotation immobilization in a young population. Along with the trial of Liavaag et al. [7], it does not support the original results of Itoi et al. [2] with regard to a decreased recurrence rate. Although external rotation does not appear to impart a significant benefit over traditional sling immobilization with respect to clinical or functional outcomes, there may be considerations (and further research) to be made regarding patient compliance and quality of life.

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