

A Randomized Clinical Trial Comparing Open and Arthroscopic Stabilization for Recurrent Traumatic Anterior Shoulder Instability

Two-Year Follow-up with Disease-Specific Quality-of-Life Outcomes

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Background: The literature comparing open and arthroscopic repair for glenohumeral instability is conflicting. We performed a prospective, expertise-based, randomized clinical trial to compare open shoulder stabilization with arthroscopic shoulder stabilization by measuring quality-of-life outcomes and recurrence rates at two years among patients treated for traumatic anterior shoulder instability.

Methods: Computer-generated, variable-block-size, concealed randomization allocated 196 patients to either the open-repair group (n = 98) or the arthroscopic-repair group (n = 98). An expertise-based randomization design was employed to avoid a differential bias in terms of physician experience. Outcomes were measured at baseline, at three and six months postoperatively, and at one and two years postoperatively with use of the Western Ontario Shoulder Instability Index (WOSI) and the American Shoulder and Elbow Surgeons (ASES) functional outcome scale. Recurrent instability was also analyzed.

Results: There were no significant differences in outcome scores at baseline. At two years, seventy-nine patients in the open group and eighty-three patients in the arthroscopic group were available for follow-up. There was no significant difference in mean WOSI scores between the groups; the mean WOSI score (and standard deviation) for the open group was 85.2 ± 20.4 (95% confidence interval [CI] = 80.5 to 89.8), and for the arthroscopic group, 81.9 ± 19.8 (95% CI = 77.4 to 86.4); $p = 0.31$. There was also no significant difference in mean ASES scores: 91.4 ± 12.7 (95% CI = 88.5 to 94.4) for the open group and 88.2 ± 15.9 (95% CI = 84.6 to 91.8) for the arthroscopic group; $p = 0.17$. Recurrence rates at two years were significantly different: 11% in the open group and 23% in the arthroscopic group ($p = 0.05$). Recurrent instability was more likely in patients with a preoperative Hill-Sachs lesion and in male patients who were twenty-five years old and younger. There was no significant difference in shoulder motion between the groups at two years.

continued

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A commentary by Diane L. Dahm, MD, is linked to the online version of this article at jbjs.org.

Conclusions: There was no difference between open and arthroscopic repair in terms of patient quality of life. Open repair resulted in a significantly lower risk of recurrence. Secondary outcome data from this trial suggest that open surgical repair may be recommended to reduce the risk of recurrent instability in younger male patients with a Hill-Sachs lesion.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Shoulder instability most commonly affects people who are in their late teens to mid-thirties. The resulting disability, time lost from work, and effect on quality of life represent important orthopaedic concerns.

The operative management of traumatic anterior glenohumeral instability has evolved from open to arthroscopic stabilization techniques. However, controversy over the results of open or arthroscopic shoulder stabilization still exists¹⁻⁴. Advocates of arthroscopy cite faster recovery, less postoperative pain, decreased operative time, improved cosmetic appearance, improved range of shoulder motion, and more accurate identification of intra-articular pathology^{1,5,6}. Those favoring open procedures cite superior long-term results with fewer recurrences^{7,8}.

Four meta-analyses have critically evaluated the literature comparing open and arthroscopic repair for traumatic anterior shoulder instability⁹⁻¹². A main concern in those reviews is the lack of patient-based quality-of-life outcome measures. A recently published randomized trial utilized a validated patient-reported outcome measure, the Western Ontario Shoulder Instability Index (WOSI)¹³. This trial showed no difference in WOSI scores when comparing open and arthroscopic repair in military personnel after thirty-two months of follow-up¹⁴. However, the small sample size and limited generalizability to other patient populations may be problematic.

The primary purpose of our study was to address the following question: What is the disease-specific quality-of-life outcome at two years, as measured by the WOSI, for patients who have undergone open repair or arthroscopic repair for recurrent traumatic unidirectional anterior shoulder instability?

Materials and Methods

The University of Calgary Research Ethics Board approved this research. Subject recruitment occurred between 2001 and 2008. This trial is registered on ClinicalTrials.gov, identifier: NCT00251264.

Patient Selection and Randomization

Patients with recurrent traumatic anterior shoulder instability who were referred to one of five fellowship-trained shoulder surgeons at the University of Calgary Sport Medicine Centre were initially seen by the orthopaedic fellow, who confirmed the diagnosis and screened patients for study eligibility (see Appendix). Patients with obvious glenoid fracture or bone loss as seen on standard radiographs were ineligible. For those who were eligible, the fellow and research coordinator obtained informed consent and randomly allocated patients to one of two surgical procedure groups: open repair or arthroscopic repair. Allocation was determined through the use of computer-generated, variable-block-size randomization and consecutively numbered opaque envelopes. Patients met the assigned surgeon, who discussed the repair technique in a typical clinical context, reconfirmed eligibility, and addressed any patient concerns regarding consent and randomization. Two surgeons performed the open repairs (N.G.H.M.

and R.S.B.), and three surgeons performed the arthroscopic repairs (R.M.H., L.A.H., and I.K.Y.L.). To avoid a differential bias in terms of surgical expertise between study groups, the surgeons were matched according to years of experience in performing their preferred procedure (N.G.H.M. and R.M.H., ten years; R.S.B., L.A.H., and I.K.Y.L., two to five years), with the randomization stratified accordingly.

The expertise-based randomization design allowed the surgeons to perform their preferred surgical technique, while enhancing study validity, generalizability, and feasibility¹⁵.

Operative Treatments

All procedures included a standardized examination under general anesthesia to confirm the diagnosis.

Open Repair

Open procedures were performed with the patient in a modified beach-chair position. No diagnostic arthroscopy was performed. A 5-cm deltopectoral incision was made. The conjoined tendon was identified and was retracted medially. The underlying subscapularis tendon was either incised vertically or split horizontally. If required for adequate exposure, the subscapularis split was extended vertically by incising the inferior component of the tendon near its insertion on the lesser tuberosity. The shoulder was entered through a "T"-shaped arthrotomy, which allowed for full exposure of the anterior aspect of the glenoid rim. Shoulder pathology was addressed with suture-anchor repair of any capsulolabral detachment (Bankart lesion) and/or a suture capsular plication of any existing capsular redundancy. The superior aspect of the labrum was not specifically evaluated or addressed surgically.

Arthroscopic Repair

Arthroscopic procedures were performed with the patient in the lateral or beach-chair position. Diagnostic arthroscopy was performed, and intra-articular pathology was identified. Repairs for associated or conjoined superior labral anterior-to-posterior (SLAP) tears were performed at the surgeon's discretion. Labral detachments were repaired with the use of suture-anchor fixation and arthroscopic tying techniques. Capsular redundancy was addressed with arthroscopic suture plication at the surgeon's discretion.

Surgeons in both groups mobilized the capsulolabral tissue as deemed necessary and placed the most inferior suture anchor as close to the six o'clock position as possible. Rotator interval repairs were not done routinely but were left to the discretion of the surgeon.

Postoperative Rehabilitation Protocol

An immobilizer was worn by patients in both treatment arms, and patients in both groups followed identical rehabilitative protocols (see Appendix).

Primary Outcome Measure

The WOSI, a valid and reliable disease-specific quality-of-life outcome measure, was the primary outcome measurement tool¹³. Each question uses a 100-mm visual analog scale response format. For the purposes of this trial, the overall score was converted to a value of 0 to 100, where a higher score represented a better quality of life¹⁴. Patients completed the WOSI at baseline, at three and six months postoperatively, and at one and two years postoperatively.

TABLE 1 Baseline Demographic Characteristics of Included Patients*

Characteristic	Open Group (N = 98)	Arthroscopic Group (N = 98)	P Value
Age (yr)			0.59
Mean and SD	27.8 ± 7.9	27.2 ± 9.0	
Range	16.0-53.7	16.5-59.0	
95% CI	26.2-29.4	25.4-29.0	
Male/female (no. [% female])	80/18 (18%)	80/18 (18%)	1.00
Involved dominant shoulder (no. [%])	45 (46%)	31 (32%)	0.04*
Collision-sport or contact-sport involvement (no. [%])	43 (44%)	55 (56%)	0.09
Mean time (95% CI) from index instability episode to repair (mo)	75 (61-89)	54 (43-64)	0.02*
Dislocations (no. of patients)			N/S†
1 dislocation/multiple subluxations	7	7	
2-10 dislocations	60	56	
>10 dislocations	31	35	
Mean no. of anchors (range)	3 (0 to 4)	3 (1 to 5) without SLAP tear, 4 (2 to 6) with SLAP tear	N/S†

*A significant value. †N/S = not significant.

Secondary Outcome Measures

American Shoulder and Elbow Surgeons (ASES) Scale

The ASES scale, a shoulder-specific functional assessment tool, was used as a secondary outcome measure¹⁶. The score was determined through a patient self-evaluation of pain, instability, and activities of daily living and reported on a scale of 0 to 100, with 100 representing the best possible outcome¹⁶.

Clinical Evaluation

Trained independent research assistants performed all clinical examinations at baseline and at scheduled follow-up evaluations (at three months, six months, one year, and two years postoperatively). A goniometer was used to measure active shoulder range of motion: forward flexion at the maximum arm-trunk angle and external rotation with the arm at the side and at 90° of abduction. Standard preoperative radiographs included an axillary view to document the presence or absence of a Hill-Sachs lesion. Hill-Sachs lesions were not quantified. Complications and recurrent events were documented at each follow-up evaluation. On the basis of a clinical examination and patient history, the surgeon diagnosed recurrent instability and categorized it as a traumatic or atraumatic subluxation or dislocation.

Blinding

Because the open and arthroscopic repairs involved different incisions, it was not possible to blind the patients to the procedure. Because of the expertise-based design of the study, the research assistant performing the clinical examinations was aware of who the treating surgeon was and thus could not be blinded to group allocation.

Sample Size

The sample-size calculation was based on the mean WOSI score (85 of 100; standard deviation [SD] = 20) from a separate sample of 133 patients with traumatic anterior shoulder instability who were followed postoperatively for a minimum of one year. An estimate of change (10% change from the

mean WOSI score) was used to ensure sufficient sample size and power. With the use of a two-sided test, an α value of 0.05, and power of 0.90, the sample size was determined to be eighty-five patients per group. This was inflated to ninety-eight per group to account for an estimated 15% loss to follow-up.

Statistical Methods

The comparability of the two treatment groups was assessed by comparing baseline demographic data. Independent sample t tests were used to compare mean WOSI and ASES scores between groups at two years postoperatively. Adjusted Bonferroni comparisons and repeated-measures analyses of the WOSI and ASES scores were conducted with use of a mixed-model analysis of variance (ANOVA) for treatment group and time of assessment. All patients were analyzed on an "intention-to-treat" basis. A chi-square analysis was used to compare recurrence rates between groups. To assess the independent predictors of recurrence, a logistic regression analysis was performed with use of the "enter" method. Four a priori relevant variables included in the regression analysis were age (twenty-five years or less, or greater than twenty-five years), sex of patient (male or female), Hill-Sachs lesion (yes or no), and type of surgery (open or arthroscopic). Sensitivity analyses were performed to explore the effect of loss to follow-up/withdrawal on WOSI scores and recurrence rates at two years. The sensitivity analysis of WOSI scores used imputation with the respective median two-year WOSI score for each group. The sensitivity analysis of recurrence included assigning all missing values as (1) having a recurrence and (2) not having a recurrence at two years postoperatively. A 5% significance level was used for all analyses.

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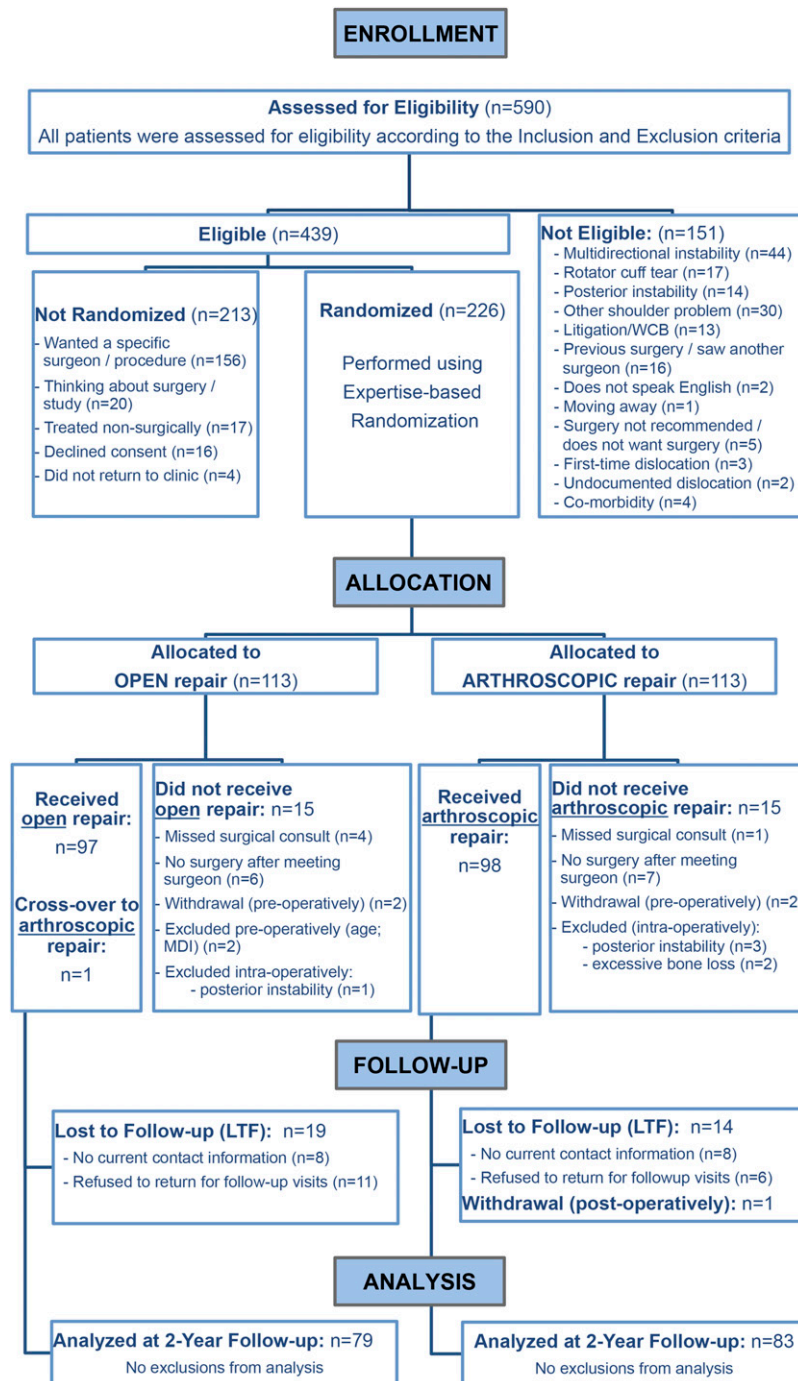


Fig. 1

A CONSORT diagram showing the grouping and flow of patients through the trial. WCB = Workers' Compensation Board; MDI = multidirectional instability.

Results

Detailed information on patient flow through the trial is provided in Figure 1, a CONSORT diagram. A total of 590 patients were screened for eligibility. Of these, 151 were found to be not eligible and 213 eligible patients were not randomized to treatment. Two hundred and twenty-six patients consented to be included and were randomly allocated to either the open or the arthroscopic group prior to meeting their assigned surgeon.

A total of thirty patients (fifteen in each group) did not receive their assigned repair. Six patients (one in the open group and five in the arthroscopic group) were excluded intraoperatively.

Ninety-seven patients in the open group and ninety-eight patients in the arthroscopic group underwent their assigned surgery. One patient randomized to the open group had an arthroscopic repair but was analyzed as part of the open group on an intention-to-treat basis. One patient in the arthroscopic

TABLE II WOSI Scores at Each Follow-up Evaluation

	Baseline	3 Months	6 Months	1 Year	2 Years
Open group					
Mean	41.7	64.6	80.9	86.4	85.2
SD	19.0	20.8	18.9	15.2	20.4
95% CI	37.9-45.5	59.9-69.4	76.6-85.2	82.8-89.9	80.5-89.8
Change in score from baseline	0	22.9	39.2	44.7	43.5
Arthroscopic group					
Mean	40.6	66.8	78.5	81.6	81.9
SD	18.4	18.4	19.4	19.1	19.8
95% CI	36.9-44.3	62.5-71.1	74.0-83.0	77.2-85.9	77.4-86.4
Change in score from baseline	0	26.2	37.9	41.0	41.3
P value	0.69	0.50	0.43	0.10	0.31

group withdrew postoperatively. Nineteen patients in the open group and fourteen patients in the arthroscopic group were lost to follow-up at two years. Seventy-nine patients in the open group and eighty-three patients in the arthroscopic group were available for the two-year follow-up evaluation.

Baseline Characteristics

Baseline characteristics did not differ significantly between groups (Table I), with an exception being the proportion of involved shoulders that were also the patient's dominant shoulder (46% in the open group compared with 32% in the arthroscopic group). One other baseline difference was the length of time from the index instability episode to repair, which was significantly longer for the open group (75 months) than for the arthroscopic group (54 months).

Among patients who were lost to follow-up and/or withdrew, there were no significant differences between groups at baseline. The mean age (and SD) of those lost to follow-up/withdrew was 27.3 ± 7.0 years (95% confidence interval [CI] = 23.9 to 30.7 years) and 23.2 ± 5.7 years (95% CI = 19.9 to 26.5 years) in the open group and the arthroscopic group, respectively ($p = 0.08$).

WOSI Scores

The WOSI scores increased significantly from baseline to two years postoperatively within each treatment group ($p \leq 0.01$). The mean WOSI score at two years for the open group (85.2) was higher than that of the arthroscopic group (81.9) although the difference was not significant ($p = 0.31$) (Table II). The change in WOSI scores at each evaluation did not differ significantly between the groups.

The sensitivity analysis using the imputed median WOSI score for each group (93.2 for the open group and 88.4 for the arthroscopic group) showed no significant difference ($p = 0.15$) between groups at two years.

ASES Scores

The increase in ASES scores at each follow-up evaluation was significant within each group ($p \leq 0.05$) but did not differ significantly between groups (Table III).

Range of Motion

Range-of-motion measurements of the involved shoulder at baseline and at the two-year follow-up evaluation did not differ significantly between groups (see Appendix).

TABLE III ASES Scores at Each Follow-up Evaluation

	Baseline	3 Months	6 Months	1 Year	2 Years
Open group					
Mean	67.3	72.0	87.4	91.9	91.4
SD	18.7	24.4	13.9	11.6	12.7
95% CI	63.5-71.0	66.5-77.5	84.2-90.7	89.1-94.6	88.5-94.4
Arthroscopic group					
Mean	64.0	73.0	84.3	89.5	88.2
SD	21.6	25.4	22.2	12.6	15.9
95% CI	59.6-68.4	67.2-78.8	79.2-89.4	86.6-92.3	84.6-91.8
P value	0.27	0.80	0.30	0.23	0.17

TABLE IV Frequency of Traumatic and Atraumatic Dislocations and Subluxations at the Two-Year Follow-up Evaluation*

Group	No Recurrence	Traumatic		Atraumatic	
		Subluxation	Dislocation	Subluxation	Dislocation
Open (n = 80)	71	2	4	0	3
Arthroscopic (n = 87)	67	1	14	3	2

*One patient in the open group and four patients in the arthroscopic group did not return for the two-year follow-up evaluation. However, these patients provided the necessary information regarding recurrent instability to be included in this table.

Recurrent Instability

At two years, the rate of recurrent instability was significantly lower ($p = 0.05$) in the open group (nine patients, 11%) than in the arthroscopic group (twenty patients, 23%) (Table IV). The mean age of the twenty-nine patients who had recurrent instability was 23.3 ± 6.8 years. Of these patients, twenty-eight (97%), the majority of whom were male, had a Hill-Sachs lesion at the time of their index procedure. The mean two-year WOSI and ASES scores of the patients who had a recurrence were 56.2 ± 26.5 (95% CI = 34.0 to 78.3) and 74.4 ± 19.8 (95% CI = 57.9 to 90.9) in the open group, and 65.0 ± 28.5 (95% CI = 49.2 to 80.8) and 80.1 ± 24.1 (95% CI = 66.7 to 93.4) in the arthroscopic group. None of these differences were significant ($p = 0.48$ for WOSI; $p = 0.57$ for ASES). An exploratory subgroup analysis of those patients twenty-five years of age and younger with a Hill-Sachs lesion showed a recurrence rate of 26% in the open group and 38% in the arthroscopic group. This difference was not significant.

There were no relationships between recurrence and the individual surgeons.

A sensitivity analysis in which all patients who were lost to follow-up/withdrew were assigned as having had recurrent instability resulted in no difference in recurrence rates between treatment arms ($p = 0.53$). However, when all patients who were lost to follow-up/withdrew were assigned as having had no recurrence, a significant difference in recurrence rates between the groups was more evident ($p = 0.03$).

Revision surgery was performed in twelve of the twenty patients in the arthroscopic group and in seven of the nine patients in the open group.

Surgical Data

The difference in mean surgical time (from incision to wound closure) between the two groups was significant: 77 ± 21 minutes for the open group and 61 ± 15 minutes for the arthroscopic group ($p = 0.002$).

In the arthroscopic group, forty-seven (48%) of the ninety-eight patients had an identified SLAP tear. Eight tears were classified as Type 1; thirty-five tears, Type 2; two tears, Type 3; and two tears, Type 4. Thirty-eight of the forty-seven identified SLAP tears were repaired (no Type-1 tears were repaired, and one Type-2 tear was not repaired). The incidence of SLAP tears in the open group was indeterminate and none were directly treated because arthroscopy was not routinely performed.

Complications and Adverse Events

In the open group, three patients experienced temporary nerve dysfunction, which resolved completely. One case involved the median nerve and two involved the ulnar nerve. Two patients had a wound infection, and one patient had a stitch abscess. All three of these complications resolved completely after the patients received oral antibiotic treatment. Three patients fell on the operatively treated shoulder with no consequence. Two patients had an allergic reaction to postoperative anti-inflammatory medication.

In the arthroscopic group, one patient experienced temporary ulnar nerve dysfunction, which resolved uneventfully. One patient fell on the operatively treated shoulder with no consequence. No infections occurred in the arthroscopic group.

Logistic Regression Analysis

The regression analysis demonstrated the following: Male patients had a 3.2-times higher odds (95% CI = 0.7 to 15.0) of experiencing a recurrence; patients who were twenty-five years old and younger had a 3.2-times higher odds (95% CI = 1.3 to 7.8) of experiencing a recurrence; patients with a Hill-Sachs lesion present on radiographs had a 5.0-times higher odds (95% CI = 0.6 to 40.9) of experiencing a recurrence; and patients who had an arthroscopic repair had a 1.6-times higher odds (95% CI = 0.6 to 4.0) of experiencing a recurrence. These four predictors in the logistic regression model together accounted for 17% of the explanation for recurrence, based on a Nagelkerke R square statistic value of 0.168.

Discussion

To our knowledge, this study represents the largest and only expertise-based randomized trial comparing open repair with arthroscopic repair for recurrent anterior shoulder instability. An expertise-based randomization design created an environment whereby surgeons could perform their preferred surgical technique rather than both procedures¹⁵. This design was more representative of the clinical setting than traditional randomization designs because surgeons typically prefer one treatment¹⁷. Furthermore, this design removed the bias in favor of the surgeon's preferred technique, which exists in traditional randomized trials¹⁵. Conversely, Biau and Porcher argued that an expertise-based design creates a differential bias if surgeons in one group are more (or less) experienced than surgeons in the other group¹⁸. In our study, surgeon training

and experience (ranging from two to ten years) were comparable in both groups. The two surgeons (N.G.H.M. and R.M.H.) who contributed the most patients to the trial had ten years of expertise in open and arthroscopic procedures, respectively. The mean arthroscopic surgical time (sixty-one minutes) was comparable with the fifty-nine minutes previously reported¹⁴. However, the times for the open surgical procedures, although significantly greater at a mean of seventy-seven minutes, were considerably less than the 149 minutes reported by Bottoni et al.¹⁴.

At two years, the difference in quality of life between the patients in the two groups was neither significant nor clinically important. The mean WOSI scores in this study (85 for the open group and 82 for the arthroscopic group) were slightly higher than those of the military population (open, 76; arthroscopic, 79) as reported by Bottoni et al.¹⁴.

The current study showed no significant differences in shoulder motion between the open-repair and the arthroscopic-repair group, although the patients who underwent arthroscopic repair had less external rotation at two years compared with baseline. The clinical importance of this finding is questionable. Fabbriani et al. reported a significantly better range of motion in their arthroscopic group compared with that in their open group¹.

In our study, the complication rate was higher in the open group and included transient nerve dysfunction and wound infections, although without any long-term adverse effects. There was a significant difference in recurrence rates, favoring the open group. Our data suggest a particular patient profile that is more likely to experience recurrent instability after surgery: a male, twenty-five years old or younger, who has a Hill-Sachs lesion as seen on radiographs. A recommendation would be to consider open repair for this higher-risk group. However, the regression analysis is limited and only explains 17% of the risk. Recurrence can be explained by involvement in high-risk activities given that the majority of recurrences were traumatic (Table IV). It was not possible to account for activity level because there was no reliable measure of activity exposure. Netto et al. reported no differences between groups in terms of complications and clinical failure rates on the basis of scores of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire¹⁹. They followed forty-two patients and stated that the final differences were not clinically relevant. Their only two failures requiring revision surgery were in the arthroscopic group. Fabbriani et al.¹ and Bottoni et al.¹⁴ reported no recurrent dislocations in either group. However, Bottoni et al. reported a failure rate of 6.9% in their open group and 3.1% in their arthroscopic group¹⁴, with *failure* defined as a second dislocation, recurrent subluxation, or symptoms precluding a return to previous work or unrestricted active military duty¹⁴.

The other difference between the treatment groups in our study was with regard to the repair of SLAP tears. It may be appropriate to assume that the process of randomization resulted in a similar proportion of patients in the open group having SLAP tears¹⁴. While SLAP tears may be asymptomatic in this population, open repair may indirectly provide support to

the superior aspect of the labrum or SLAP repairs may increase the risk of recurrence without benefitting the patient.

The majority of patients in the open group were operated on through a subscapularis split approach. We previously reported on shoulder strength in a subset of patients from this study population; no side-to-side differences in shoulder strength between patients in the open group and patients in the arthroscopic group were shown after a mean duration of follow-up of 14.4 months, suggesting that operating through the subscapularis muscle tendon unit has no impact²⁰.

Limitations

The potential for nonparticipation bias exists, as only 51% of the 439 eligible patients participated. The different demographic and/or patient characteristics between participants and non-participants determines the magnitude and direction of bias, if any²¹. It is reasonable to suggest that the results underestimated the true number of recurrent episodes because the patients who declined were, on average, younger (twenty-five years)²² than those in the randomized trial (twenty-eight years).

There was a difference between the groups with regard to the patients who were lost to follow-up: nineteen in the open group and fourteen in the arthroscopic group, with a mean age of 27.3 years and 23.2 years, respectively. This suggests that, on the basis of age, the missing patients in the open group were more representative of the overall sample, whereas those in the arthroscopic group were more representative of patients who had recurrence. A sensitivity analysis assigning all patients who were lost to follow-up as having had recurrent instability resulted in no difference in recurrence rates between the two treatment groups; conversely, an analysis assigning no recurrence showed a greater statistical difference between the groups.

Other limitations included a lack of quantification of the Hill-Sachs lesions. It was not routine for the surgeons to quantify glenoid bone loss given that computed tomography (CT) scans were not routinely performed and comparison between measurements made during arthroscopic surgery and those made during open surgery has not previously been validated. Sports and recreational activities were documented, with a higher percentage of patients in the arthroscopic arm of the trial having been involved in a collision sport or a contact sport. However, specific sport exposure information was not obtained and, therefore, valid comparisons were not possible between groups. A majority of cases of recurrent instability were traumatic in origin, but a minority resulted from a collision/contact sport.

It is difficult to speculate whether remplissage, advocated for Hill-Sachs lesions, would have changed the results²³. To our knowledge, this technique has not been tested in a randomized trial.

In conclusion, we report no difference in quality-of-life outcome (as measured by the WOSI) for patients with recurrent anterior shoulder dislocation, comparing open with arthroscopic stabilization surgery. The expertise-based randomization design successfully allowed surgeons to perform their preferred surgical technique within the context of randomly assigning patients. Secondary outcome data from this trial suggest that open surgical repair may be recommended to reduce recurrent

instability in younger male patients with a Hill-Sachs lesion as seen on radiographs.

Appendix

eA Tables showing study inclusion and exclusion criteria, the postoperative rehabilitation protocol, and a comparison of range-of-motion measurements between groups at baseline and two years are available with the online version of this article as a data supplement at jbjs.org. ■

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