Richard O'Connor Award Paper

Prospective Randomized Clinical Trial Comparing the Effectiveness of Immediate Arthroscopic Stabilization Versus Immobilization and Rehabilitation in First Traumatic Anterior Dislocations of the Shoulder

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Summary: Our purpose was to compare the effectiveness of traditional treatment with immediate arthroscopic stabilization in young patients who have sustained a first traumatic anterior dislocation of the shoulder. Forty skeletally mature patients younger than 30 years of age were randomly allocated to immobilization for 3 weeks followed by rehabilitation (group T) or arthroscopic stabilization (within 4 weeks of injury) followed by an identical immobilization and rehabilitation protocol (group S). A blinded research assistant performed all follow-up evaluations. The dominant arm was involved in 35% of subjects. The injury occurred in a sporting event in 70% of subjects. At 24 months, there was a statistically significant difference in the rate of redislocation (T = 47%, S = 15.9%, P = .03). An intention-to-treat analysis comparing disease-specific quality of life using the validated Western Ontario Shoulder Instability (WOSI) index showed statistically significantly better results in the surgically treated group at the 33 months (T = 633.93 *v* S = 287.1, P = .03) and no significant difference in range of motion. At an average 32 months follow-up, a significant reduction in redislocation and improvement in disease-specific quality of life is afforded by early arthroscopic stabilization in patients less than 30 year of age with a first, traumatic, anterior dislocation of the shoulder. **Key Words:** Arthroscopic stabilization—Primary anterior dislocation—Shoulder.

The shoulder dislocates most frequently when the arm is forced into a position of abduction and maximum external rotation. This results in leverage of the humeral head anteriorly out of the joint. Traditional treatment for this injury has included immobilization of the shoulder for a variable period of time, theoretically allowing the soft tissues to heal, and then rehabilitation of the shoulder with range of motion and strengthening exercises before a return to preinjury activities. Unfortunately, the risk of redislocation of the shoulder with this treatment is high in patients who are younger than 30 years of age. The reported rate of redislocation is 17% to 96% with a mean of 67% based on available natural history studies.[1-11] Each time the shoulder redislocates, time is lost from work or sport

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Supported by The Physician's Services Incorporated Foundation of Canada.

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0749-8063/99/1505-2081$3.00/0

and the joint potentially sustains further damage. At some point, patients will choose between cessation of activities or major reconstructive surgery to stabilize the shoulder. With the advent of arthroscopic stabilization procedures, surgeons have questioned whether those patients who are at high risk for recurrent dislocations should undergo an arthroscopic stabilization after the first dislocation.

Only one group has published results of studies comparing traditional treatment with arthroscopic stabilization in this patient population.[10,12] Most recently, Arciero et al.[12] followed two cohorts of young patients who had sustained one anterior dislocation of the shoulder. Those patients who underwent an arthroscopic Bankart repair had a lower rate of redislocation compared with those who pursued a nonoperative program. Because this was a cohort study with the inherent biases of this type of design, we felt it was necessary to design a prospective, randomized clinical trial. This trial would assess not only the risk of redislocation in young patients sustaining a first anterior dislocation of the shoulder but also evaluate their disease-specific quality of life and the effects of treatment on range of motion.

PURPOSE

The purpose of the study was to determine the effectiveness of arthroscopic stabilization in young patients with a first traumatic anterior dislocation of the shoulder. The hypotheses made before undertaking the study were that arthroscopic stabilization would (1) significantly reduce the rate of redislocation, (2) afford patients an improved disease-specific quality of life, and (3) would not significantly decrease range of motion.

METHODS

The study was designed as a prospective, randomized clinical trial. It was single blinded in that all evaluations were performed by a research assistant who was unaware of the treatment group the patient had been assigned to. To achieve this blinding, patients were carefully instructed to wear a t-shirt for all evaluations such that the presence or absence of surgical incisions could not be detected.

Sample Specification

The target population was patients younger than 30 years of age sustaining a first traumatic anterior dislocation of the shoulder. Patients were recruited from the emergency departments and from orthopaedic surgery colleagues in two university centres (The University of Western Ontario and The University of Calgary).

Skeletally mature patients less than 30 years of age who had sustained a first traumatic anterior dislocation as defined by (1) mechanism of abduction, external rotation, (2) sudden pain in the shoulder, and (3) reduction required or radiograph showing anterior dislocation of the shoulder, and who were willing to be available for follow-up, were included in the study. Patient exclusion criteria included associated fracture (except Hill Sachs or Bankart lesion), a history of multidirectional instability or evidence of multidirectional instability of the opposite shoulder, neurovascular compromise of the affected limb, a medical condition making the patient unfit for surgery, and unwillingness to be followed for 5 years.

Sample Size Estimate

The best estimate of rate of redislocation in the traditionally treated group is 67%.[1-11] To determine a clinically relevant decrease in the rate of redislocation, a questionnaire was sent to 10 orthopaedic shoulder surgeons. They were asked what reduction in the rate of redislocation would be necessary with the proposed arthroscopic treatment, given the known complications, for them to adopt this treatment as a routine in their own practice. The mean response was a reduction of 80%. In other words, the new treatment would have to allow a redislocation rate of no more than 15% in order for them to adopt it as their treatment of choice. Therefore, the sample size calculation using the equation for comparing two independent group proportions resulted in an estimate of 20 patients per group.

Stratification

In any clinical trial with small numbers of patients, it is important to stratify the randomization for potential major confounders to avoid inequities between groups.[13] Patient age correlates very closely with the rate of redislocation even within the younger-than-30-years age group itself.[2,4,7,8] Therefore, it was decided to stratify the randomization based on age: (1) 22 years or younger and (2) 23 to 30 years of age. The randomization was also stratified for surgeon to overcome the bias that may be introduced by small differences in surgical technique.

Traditional Therapy (T)

Patients were placed in a shoulder immobilizer for 3 weeks during which time they were allowed to remove it for bathing and mobilizing the elbow and wrist. At 3 weeks after dislocation, they started a physiotherapy program to rehabilitate the shoulder (see Rehabilitation Protocol).

Surgical Treatment (S)

Surgery was performed within 4 weeks of the dislocation in all patients in this group. The patients were allowed to mobilize the shoulder on their own before the surgery to ensure that none of the patients entering surgery had a stiff shoulder, which, in theory, would increase the risk of arthrofibrosis. The surgery was a transglenoid suturing technique and is described briefly below.

Under general anesthetic, the patients were placed supine on a shoulder-positioning device and secured with straps and bolsters. They were then placed in the upright sitting position. The shoulder girdle, arm, and hand were prepped and draped free. A standard posterior portal was established. An anterior portal was then established just above the subscapularis tendon using an inside-out technique. After evaluation of the glenohumeral joint, the Bankart lesion, which was found in all but one patient, was addressed. A rasp/elevator followed by a 4.5-mm full-radius resector was used to completely mobilize the anterior capsulolabral structures from the neck of the glenoid until the subscapularis muscle fibres could be seen. A burr was then used to create a raw bleeding bony surface throughout the length of the Bankart lesion. No. 1 PDS sutures were then placed just beyond the labrum using a Caspari punch. Two parallel-eyed K-wires were drilled 2 mm onto the articular cartilage, one just above the equator and one just below the equator of the glenoid, bringing them out inferiorly and medially on the body of the scapula. Sutures were divided into superior and inferior bundles with 3 or 4 in each bundle, tensioned individually, and then tied one to the other posteriorly over the infraspinatus fascia. This pulled the labrum up onto the anterior edges of the glenoid surface creating a rolled edge and allowing for some degree of superior capsular shift (Fig 1). After surgery, the patients followed a program identical to that of the traditional group in that they were immobilized for a period of 3 weeks and then followed the same rehabilitation protocol, which follows.

Rehabilitation Protocol

This program is briefly outlined below:

Weeks 0 to 3
Immobilization in a sling

Stage I: 4 to 6 weeks
Active assisted ROM
External rotation limited to 20 ^{o} past neutral

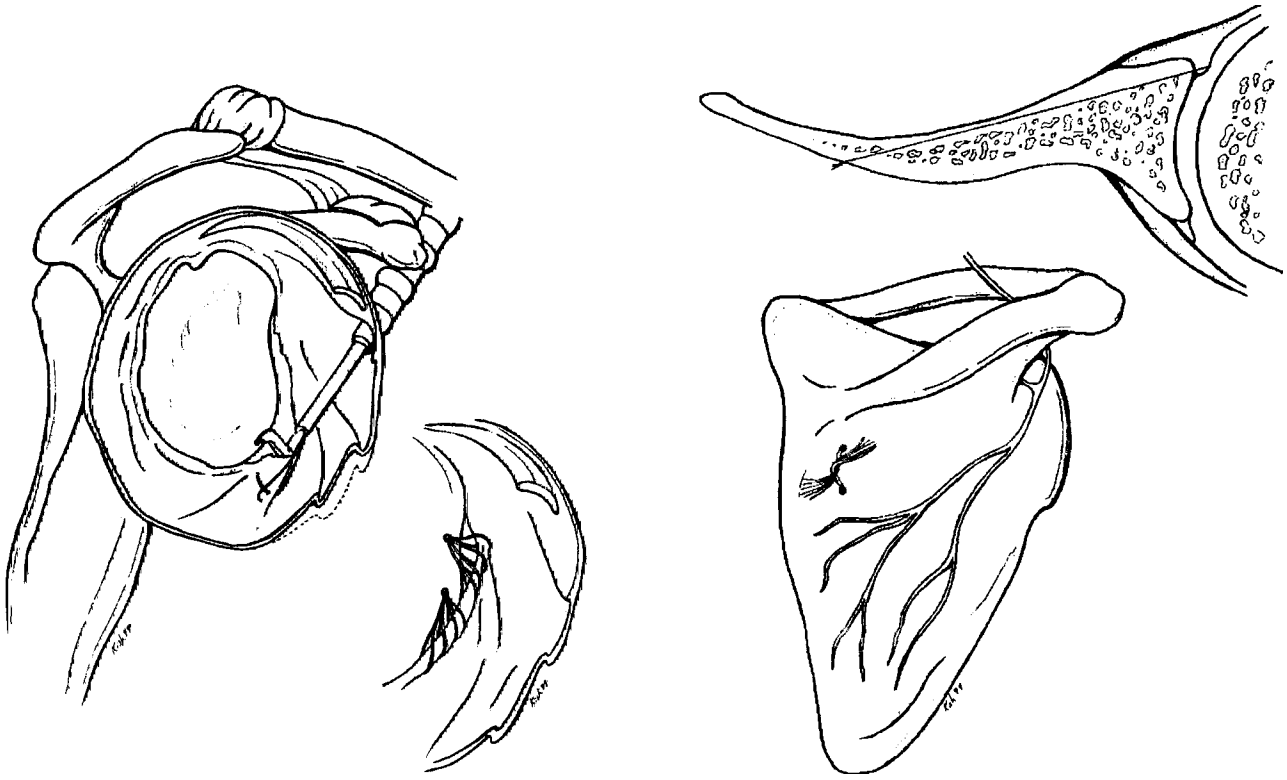

FIGURE 1. Diagram of surgical procedure.

Pendular exercises
Scapular retractions

Stage II: 7 to 8 weeks
Active ROM
Isometric exercises
External rotation limited to 45 ^{o} past neutral
Scapular exercises/retraining

Stage III: 9 to 12 weeks
Active ROM with Terminal Stretch
Isotonics
Scapular strengthening

3 months
Noncontact/nonoverhead sport
Return to work

4 months
Contact sports

RESULTS

Thirty five male and 5 female patients participated in the study, with the average age of study participants being 22.4 years; 35% had dislocated their dominant arm and 70% of the dislocations occurred during sporting activities. The 16 to 22 years-of-age stratum contained 23 patients, 10 in the surgery group and 13 in the traditional group. The 23 to 30 years-of-age stratum contained 17 patients, 9 in the surgery group and 8 in the traditional group. There were no statistically significant differences between groups with respect to age, hand dominance, or the mechanism of the initial event (Table 1).

Surgical Findings

A labral avulsion lesion was found in all patients but 1 undergoing surgery. In that 1 patient, there was a capsular tear that was left alone. In a second patient, there was definite trauma, as evidenced by hemorrhage, to the anterior labrum but with no displacement. This was debrided and sutured to reinforce the traumatized area in an identical fashion to what is described for displaced lesions. All but 1 patient had a Hill Sachs lesion. Otherwise, the articular cartilage on both sides of the joint was normal in all the patients. No patient sustained a tear of the rotator cuff. One patient had an associated type II SLAP lesion that was stabilized with an arthroscopic suture implant.

Study Evaluations

All 19 patients in the surgical group and 19 of the 21 patients in the traditional group have been available for follow-up.

Rate of Redislocation

At a minimum of 24 months follow-up, there was a statistically significant difference in rate of redislocation between the 2 groups (T = 47%, S = 15.9%, P = .03). Three of the 19 patients (15.9%) treated surgically sustained a redislocation. The first was a 17-year-old male defensive back who sustained his first redislocation 10 months after surgery while playing football; he has gone on to have 6 redislocations. At his initial surgery he was found to have a large (11-7 o'clock left shoulder) Bankart lesion. This patient has not opted for further surgery.

The second was a 17-year-old female competitive volleyball, basketball, and badminton player. She had a subluxation episode 8 months after surgery and a redislocation 2 years after surgery while playing volleyball. At her initial surgery, she was found to have a small (3-5 o'clock right shoulder) Bankart lesion, which was not distracted and required minimal surgery to repair the anatomic defect. This patient has not opted for further surgery.

The third patient was a 19-year-old male competitive swimmer whose first dislocation occured while stretching his arms overhead. He started to experience subluxation episodes 7 months after surgery and had a redislocation 3 years after surgery while rolling over in bed. At his initial surgery, he was found to have a large (1-5 o'clock right shoulder) Bankart lesion. This patient did undergo repeat surgery at which time the anterior capsule and labrum was found to be displaced 1-cm medial on the neck of the glenoid. It is interesting to note that this patient's initial injury was also

TABLE 1. *Patient Demographics*

Group	Mean Age P = .62	Gender P = .57	Dominant Arm P = .28	Initial Dislocation				
				Sports	Rough- housing	Fall	Minor Trauma	Other
Traditional	22.75 yr	19 M 2 F	5 Dom 16 Nondom	16	1	2	1	1
Surgery	22.1 yr	16 M 3 F	9 Dom 10 Nondom	12	2	4		1

TABLE 2. *Mechanism of Initial and Subsequent Instability*

Pt. No.	Mechanism of First Dislocation	Mechanism of Redislocation or Subluxation
Traditional group		
1	Diving for a ball in baseball	Redislocated throwing a ball in baseball
2	Playing hockey	Redislocated playing hockey (goalie)
3	Playing roller hockey	Redislocated biking
4	Snowmobiling	Redislocated getting out of bed
5	Playing hockey	Redislocated playing hockey
6	Playing baseball	Redislocated stretching arms overhead
7	Playing football	Redislocated swimming
8	Playing football	Redislocated playing basketball
9	Jolted while holding overhead rail on bus	Redislocated while sleeping
10	Fell downstairs	Subluxed with overhead lifting
11	Skiing	Subluxed shutting van door
Surgical group		
1	Playing football	Redislocated playing football
2	Playing basketball	Redislocated playing volleyball
3	Stretching arms overhead	Redislocated while sleeping
4	Playing football	Subluxed playing hockey
5	Playing baseball	Subluxed taking a slap shot in hockey

minimally traumatic and occurred while stretching his arms behind his back.

In addition, 2 patients in the surgical group have had episodes of subluxation, which they felt warranted further surgery. The first patient, a 17-year-old high school football player had multiple subluxation episodes. At the time of repeat arthroscopy, he was found to have no recurrence of his Bankart lesion and an open capsular shift procedure was performed. One year after the second surgery, he started redislocating while playing hockey. He is scheduled for a third stabilization procedure.

The second patient had 2 episodes of subluxation. At the time of repeat arthroscopic evaluation the shoulder looked normal other than a small Hill Sachs lesion. No further stabilization was undertaken. He continues to play recreational hockey and baseball but has an apprehensive shoulder.

Nine of the 19 traditionally treated patients (47%) sustained a redislocation; 7 of these patients opted for surgical stabilization and all of them were found to have a Bankart lesion. The traditional group also has 2 patients who complain of recurrent subluxations. Neither of these patients has opted for surgical intervention. The mechanism of the first dislocation and redislocation or subluxation is outlined in Table 2. When the redislocation data are evaluated as a time-to-event curve, one can see that the redislocations tend to occur within the first year after the initial event in traditionally treated patients but do not start until about 1 year after surgery in surgically treated patients (Fig 2).

Quality of Life

Disease-specific quality of life was measured using the Western Ontario Shoulder Instability (WOSI) index.[14] This index was developed using a previously described methodology.[15] This index consists of 4 domains: (1) physical symptoms and pain; (2) sport, recreation, and work function; (3) lifestyle and social functioning; and (4) emotional well being. There are a total of 21 items, each with a 100-mm visual analogue scale response. A perfect score on the measurement tool is 0 and the worst possible score is 2,100. This is the only tool that we are aware of that has been

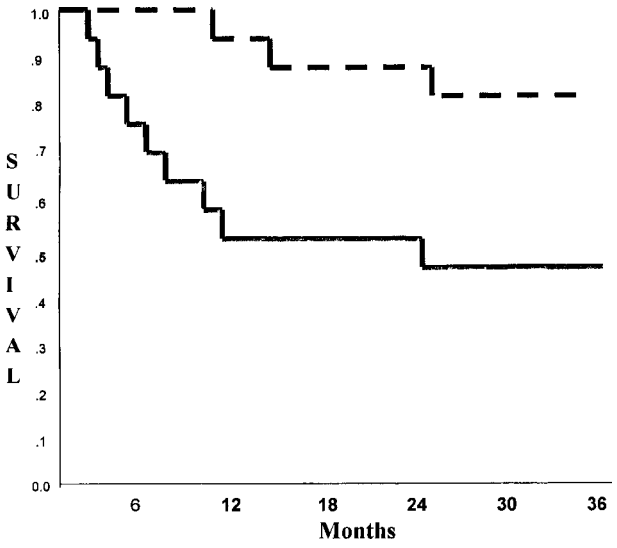

FIGURE 2. Time-to-event curve for time to redislocation. (—) Surgery, (----) traditional, $P = .008$.

validated specifically for use in a population of patients with shoulder instability.

The data for quality of life have been evaluated primarily using an intention-to-treat analysis. In this type of analysis, all the patients in both groups are included in the final analysis regardless of further treatments undergone. For example, 7 of the patients in the traditional group have undergone an arthroscopic stabilization and 3 patients in the surgical group have undergone a second surgical procedure. These patients are included in the analysis because this type of evaluation allows us to answer the bigger question for this population of patients, that is, ''Is it better to immediately stabilize the shoulder or take a wait-and-see approach?''

At a mean follow-up of 33.1 months (36.04 months for the traditional group [range, 21.8 to 54.2 months]; 31.7 months for the surgical group [range, 18.1 to 51.1 months]) there is a statistically significant difference in disease-specific quality of life for the 2 groups ($P = .03$). With a total worst-possible score of 2,100, the traditional group had a mean score of 633.93 (69.8% of normal) and the surgery group had a mean score of 287.01 (86.3% of normal). In other words, the surgery group's total WOSI scores were 16.5% better than the scores of the traditional group. The results of the comparison of the two groups for each of the 4 domains also reaches or approaches statistical significance (see Table 3).

A second way of analyzing the data is with an efficacy analysis. In this type of anaylsis, the latest score of all patients in both groups before any cointerventions, such as stabilization in the traditional group or revision stabilization in the surgery group, are compared. There is a statistically significant difference in disease-specific quality of life for the 2 groups ($P = .05$). With a total worst possible score of 2,100, the traditional group had a mean score of 678.4 (67.69% of normal) and the surgery group had a mean score of 342.6 (83.7% of normal). In other words, the surgery group's total WOSI scores were 16% better than the scores of the traditional group.

TABLE 3. *WOSI Intention-to-Treat Analysis Scores at Average 33.87 Months*

Domains	Traditional (mean ± SD)	Surgery (mean ± SD)	*P* Value
Total (2,100)	633.93 ± 547.25	287.01 ± 290.19	.03
Physical (1,000)	296.82 ± 246.67	160.43 ± 145.9	.06
Sport/Rec/Work (400)	109.27 ± 111.28	34.63 ± 46.89	.02
Lifestyle (400)	111.01 ± 119.66	48.1 ± 62.21	.07
Emotion (300)	116.83 ± 104.2	43.85 ± 65.31	.02

NOTE. The WOSI scores include scores after redislocation.

TABLE 4. *Return to Sport*

WOSI Question	Surgery	Traditional	*P* Value
11	7.95*	27.77*	.05
12	10.81*	30.69*	.05

NOTE. All patients at average follow-up of 2.8 years.
*100-mm VAS scale.

It is important to note that in the group of patients treated traditionally, the scores for those who have never redislocated do not indicate normal function. In fact, the mean WOSI total score for this subgroup at final follow-up was 325.1 indicating a 14.5% deficit in disease-specific quality of life despite no redislocation. This is similar to the results of the surgical group as a whole, which included 3 patients who have redislocated (score, 287.01).

When evaluating sport capabilities specifically, the traditional group had significantly more trouble with sports than the surgical group. Questions 11 and 12 of the WOSI address the issue of return to sport and read:

11. How much has your shoulder limited the amount you can participate in sports or recreational activities?

12. How much has your shoulder affected your ability to perform the specific skills required for your sport?

Table 4 shows that the scores for the traditional group were approximately 20% worse than the scores for the surgically treated group.

Range of Motion

Range of motion was measured using a goniometer in the seated position without stabilization of the scapulothoracic joint. The results are presented as a percentage of the normal side except for internal rotation, which is presented as the mean spine level. There were no statistically significant differences between the 2 groups for any of the range of motion parameters. However, there is a trend for a limitation of external rotation in the surgical group with a mean of 87.03% of the normal side compared with the traditional group with a mean of 99.74% of the normal side (Table 5).

Complications

One patient in the surgical group developed a septic joint postoperatively. This patient was treated with repeat arthroscopy for irrigation and debridement and a course of antibiotics. This patient has had no major long-term problems as a result of this septic joint. It is

TABLE 5. *Range of Motion as a Percentage of the Normal Side*

Test	Traditional (mean ± SD)	Surgery (mean ± SD)	*P* Value
Forward flexion	99.47 ± 5.73	94.91 ± 8.02	.09
External rotation (side)	99.74 ± 23.74	87.03 ± 27.48	.2
External rotation (90°)	96.14 ± 14.53	92.90 ± 24.83	.67
Internal rotation (90°)	94.28 ± 20.39	98.34 ± 16.62	.57
Internal rotation (spine level)*	T5	T6	.11

*Mean spine level.

important to note that no patients in the surgical group developed arthrofibrosis, neurological injury, or wound healing complications. There were no complications in the traditionally treated group.

DISCUSSION

The rate of redislocation of the shoulder in young patients after an initial dislocation has been reported to be as low as 17% in a study by Yoneda et al.[11] in which young patients were immobilized for a period of 5 weeks and participated in a supervised rehabilitation program. Similarly, Aronen and Regan[1] reported a low recurrence rate of only 25% in a very high-risk group of United States Naval Academy midshipmen. In their study, the patients were immobilized for a period of 3 weeks followed by a supervised rehabilitation program. These studies are in contrast to that of Wheeler et al.[10] who reported a 92% redislocation rate in patients at the United States Military Academy despite a similar period of immobilization and rehabilitation program. Based on all the available studies, the best estimate of the rate of redislocation in those patients treated traditionally with immobilization and rehabilitation is approximately 67%.[1,4,6,11,16] For many patients, this represents an unacceptably high risk and in our study we sought to determine whether early arthroscopic intervention could significantly reduce this risk to a more acceptable level of approximately 15%. We also wished to address some deficiencies in previous studies. First of all, most physicians are dealing with a broad patient base rather than a population of military personnel who are likely more compliant and in whom participation in sport and vigorous activity is a mandatory part of their training. Therefore, the results of the excellent studies published by the group at the United States Military Academy and the United States Naval Academy are not necessarily applicable to the general population.

Second, previous studies have used nonrandomized assignment to treatment, making the 2 groups not necessarily comparable. Even if all measurable variables are equal, there are unmeasured characteristics of patients that can affect their outcomes.

Finally, redislocation by itself is not necessarily the most important outcome to the patient. There are many patients who never redislocate but have a persistent feeling of apprehension weakness or pain in the shoulder, which limits their ability to participate in many activities. Therefore, we felt that a very sensitive measurement tool for disease-specific quality of life needed to be used in a study to better assess overall outcome.

Overall, the results of the surgical group in this study fall somewhere in the middle of reported studies for a transglenoid suturing technique procedure.[17-20] The results show that, in this young patient population, the postoperative redislocation rate is suboptimal when compared with published results of open stabilization.[20-23] This may be related to inherent limitations of the procedure (absorbable sutures, fixation over muscle fascia) and/or a relatively early return to sport (4 months postoperatively).

Based on the results of our study, we concur with other reports on the pathology of young patients who have had one traumatic anterior dislocation, and that is that most of the patients will have a Bankart lesion. As well, one can expect a small Hill Sachs lesion and in a small percentage an associated SLAP lesion.[10,12,24,25] With minimal associated capsular redundancy, these lesions are amenable to arthroscopic stabilization.

The time-to-event curves in our study show that the majority of redislocations in traditionally treated patients do occur within 1 year after the initial injury, which is in agreement with other published studies.[1,2,5,7,23] However, it should be noted that recurrent dislocations in surgically treated patients do not start to occur until about 1 year postoperatively, underscoring the need for long-term follow-up studies.

In our patient population, the recurrence rate in the traditionally treated group has been quite low at 47%. There are 2 major factors likely contributing to this low recurrence rate. First, the patients in this study were from the general population and not necessarily involved in very high level sporting activities. Second, the patients all underwent a 3-week period of immobilization followed by a closely supervised rehabilitation program and were not allowed back to full sporting activities until 4 months after their injury.

The study did show a trend toward loss of external rotation in shoulders treated surgically compared with

those treated traditionally. However, this loss may be protective because all shoulders had a Hill Sachs lesion that could engage at the extreme of external rotation.

The most important finding of the study relates to the data on disease-specific quality of life. Patients treated traditionally who have never redislocated do not have ''normal' shoulder function. Our data suggested a mean deficit of approximately 15%. Finally, the intention-to-treat and efficacy analyses showed that patients who have undergone an early arthroscopic stabilization have better disease-specific quality of life than those patients treated with immobilization. This suggests that early intervention may in fact be better than taking a wait-and-see approach. However, longer follow-up is needed to establish the effectiveness of early surgical stabilization over time.

CONCLUSIONS

Arthroscopic stabilization significantly reduces the rate of redislocation in patients younger than 30 years of age who have sustained a first traumatic anterior dislocation of the shoulder without negatively affecting range of motion. More importantly, the 2-year follow-up of these patients suggests that arthroscopic stabilization may afford better disease-specific quality of life than taking a wait-and-see approach.

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