

**RESEARCH ARTICLE**

# Arthroscopic Stabilization of Recurrent Anterior Shoulder Instability Using Two Anchors, One Single-Loaded plus One Double-Loaded; a Prospective Study with Modified Technique

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**Abstract**

**Objectives:** Anterior shoulder instability with minimal glenoid bone loss has several options for Bankart repair. We aimed to evaluate the results of a modified technique using two anchors with double and single loaded suture (three stitches in total) in arthroscopic Bankart surgery.

**Methods:** Thirty-eight patients underwent arthroscopic Bankart surgery and were assessed after an average 40 months follow-up. They underwent two-anchor repairs with single loaded of a high-strength, non-absorbable braided suture and double loaded suture. The participants were assessed preoperatively and postoperatively in terms of range of motion, CONSTANT Scores, and visual analogue scale (VAS). Recurrence of subluxations, dislocations, and other complications were also assessed.

**Results:** The mean follow-up time was 40.1±6.99 months. The mean Constant scores were 80.32±4.81 (95%CI: 78.73-81.90) preoperatively and 94.45±3.71 (95%CI: 93.23-95.67) postoperatively ( $P < 0.001$ ). A significant change was noted for the VAS score from 2.74±0.95 (95%CI: 2.42-3.05) to 0.63±0.75 (95%CI: 0.38-0.88) ( $P < 0.001$ ). Mean preoperative external rotation and forward flexion were also preserved postoperatively ( $P < 0.001$ ). The incidence of nonclinical subluxation was 2/38, 5.3%, however no case of clinical subluxation or re-dislocation was occurred; infection or neurovascular complications have not been observed as well.

**Conclusion:** Using two anchors with single and double loaded arthroscopic suture showed acceptable clinical results for traumatic anterior shoulder instability repair in properly selected patients.

**Level of evidence:** IV

**Keywords:** Anterior shoulder instability, Arthroscopy, Bankart lesion, Suture anchors

**Introduction**

Arthroscopic Bankart repair is commonly used for anterior shoulder instability with minimal bone loss of the glenoid. Different types of surgeries are used for the anterior shoulder instability including open osteotransfer of the coracoid (Latarjet-Bristow procedure), remplissage and arthroscopic Bankart repair.<sup>1,2</sup> Reports of open Bankart repairs have demonstrated high long-term success rates, with re-dislocation rates as low as 5%.<sup>3,4</sup> Though, arthroscopic

Bankart repair has become increasingly popular owing to its earlier postoperative recovery and lower complication rate.<sup>3-8</sup> the effectiveness of arthroscopic Bankart surgery is of great interest to orthopedic researchers and surgeons. Different reports have examined the results of such surgical procedure, including the post-operative range of motion, re-dislocation, pain, and patients' satisfaction. Recognizing the efficacy of arthroscopic Bankart repair is critical for physicians to provide the patients with ideal

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treatment plan. One systematic review surveyed 22 studies involving 1,266 cases and reported a significant decrease in re-dislocation rate after the procedure. This review also showed shoulder function and pain scores improvements after surgery. Similarly, a retrospective study assessed 118 patients and showed satisfactory functional results and low recurrence rate with arthroscopic Bankart repair in long-term manner.<sup>9,10</sup>

Recent literature shows that clinical outcomes are similar between patients undergoing open and arthroscopic repair, but morbidity and complication rates are lower with the arthroscopic approach.<sup>1,11</sup> The clinical outcomes depends on various factors, including the presence of bone defects in the glenoid and humeral head, the extent of injury to the capsulolabral complex, presence of hyperlaxity, patient age, surgical technique, level of athletic activity, and contact or forced overhead sports. To achieve a successful result, the patient must be properly selected for this procedure. The quantity of fixation devices applied in arthroscopic Bankart repair has changed with technical and instrumental improvement.<sup>12-14</sup>

The goal of our article is to assess the outcomes of using minimal anchors for stabilization of recurrent anterior shoulder instability.

## Materials and Methods

### Patients and study design

Fifty-four patients with symptomatic, recurring, and anterior shoulder instability were nominated from February 2016 to February 2021. Sixteen patients were excluded; 38 patients with various activities Table 1-including 26 men (68.4%)-were included in the follow-up.

Study population diagram	
<b>54 patients recruited</b>	
	3cases SLAP(Superior Labrum Anterior-Posterior Tear 2 cases Cuff tear
<b>16 patients excluded</b>	3 Bony Bankart > 15% 4 Extended labral tear 1 HAGLE 1 History of shoulder fracture 2 Cases joint arthropathy
<b>Final 38 patients investigated</b>	

Inclusion criteria: Age 15-40 years, (recurrent) symptomatic anterior-inferior shoulder instability, a capsulo-labral tear between 3-6 of the clock in the right shoulder and 6-9 of the clock in the left shoulder, a glenoid bone loss of below than 15%, and an instability severity index (ISI) score of less than seven. Exclusion criteria: previous shoulder surgery, multidirectional instability, ligamentous hyperlaxity, neuro-muscular dysfunction, voluntary dislocation, off-track lesion, bony Bankart greater than 15%, and magnetic resonance imaging (MRI)-confirmed rotator cuff tears. Demographic data such as the number of patients, age, gender, number of dislocations and subluxations, and time interval between injury (first dislocation) and operation were documented.

Clinical assessments were based on shoulder range of motion (forward flexion, external rotation 1, 2,

apprehension test, VAS, and Constant scores); preoperative and postoperative assessments were performed. Stability was evaluated by the apprehension test. Subluxation was diagnosed either clinically or with a dead-arm syndrome history.<sup>15-18</sup> the diagnosis of re-dislocation was made based on documentation in the patient's records or on the medical history during follow-ups.

Radiographs of the shoulder (antero-posterior, lateral, and axillary views) and MRI were performed in each patient before surgery. These images were assessed for Bankart lesion in glenoid cavity, bony defects in the glenoid cavity and humerus, and other associated injuries. Follow-up was performed at postoperative weeks 2 and 4 and at 3, 6, 12, and 24 months. Shoulder range of motion (external rotation in zero abduction (ER1) and in 90° shoulder abduction (ER2), with 90° elbow flexion and shoulder forward flexion) was measured with a goniometer during physical examination.

### Ethics statement

The study was approved by the local institutional review board of Golestan University of Medical Sciences, Faculty of Medicine. All methods were performed according to the ethical standards of the Declaration of Helsinki. Informed consent was obtained from all subjects. (Ethics Registration ID: IR.GOUMS.REC.1401.586)

### Surgical Technique

All surgeries were performed by the same senior surgeon (SK) using the technique (two anchors-one single-loaded and one double-loaded, i.e., with a total of three stitches) according to the facilities available in our country.

After obtaining informed consent, we performed an arthroscopic shoulder procedure under general anesthesia in the lateral decubitus position, with the affected arm in a traction cuff at 70° abduction and 10° forward flexion. A standard 30° scope was used. First, a standard posterior arthroscopic portal (PP) was stabilized 1.5 cm medial and inferior to the postero-lateral corner of the acromion. An anterior-mid-glenoid portal (AMGP) is then created using an inside-in or outside-in technique, with special care taken to place it as close as possible to the free edge of the superior border of the subscapularis tendon (SSC) for optimal access to the anterior-inferior capsule-labral complex. This AMGP is relatively lateral to achieve a 45° approach angle to the glenoid rim. The presence and size of the Bankart lesion, glenoid bone defect, Hill-Sachs lesion, and quality of the capsular tissue were recorded. The size of the Hill-Sachs lesion and the bony Bankart lesion were assessed with the tip of the probe, and the quality of the capsular lesion was evaluated with grasping forceps.

After a thorough diagnostic evaluation and exclusion of a large Hill-Sachs lesion, capsular tear, and humeral detachment (HAGLE lesion), the capsular-labral detachment is identified; a soft tissue liberator and radiofrequency are used to mobilize the affected area of the anterior labrum from the glenoid. The anterior glenoid was decorticated to ensure a clean and bleeding surface while the capsulo-labral complex was mobilized. Adequate mobilization is achieved when the underlying SSC muscle fibers can be seen. At this point, the capsule-labral tissue is grasped to ensure that it can be displaced medially and superiorly without tension.

A single loaded, non-absorbable sliding suture anchor (FiberTak 1.6mm Arthrex®, Naple, Florida) is inserted through the AMGP on the articular cartilage surface of the glenoid, 1-2 mm from the glenoid edge at the 5:30 position for a right shoulder [Figure 1]. A curved 45° or 60° needle, spectrum hook (CONMED®) from the AMGP vertically penetrate the labrum, 1 to 1.5 cm inferior to the Anchor (typically 6:00 position), depending on the amount of translation and the necessary inferior to superior shift. A number 0 or 1 Prolene or PDS suture is advanced in the hook and used as a shuttle for the suture. The shuttle suture and the fiber wire suture were taken from AMGP. The suture is loaded into the shuttle and returned under the labrum and through the capsule, pulling the shuttle out of the AMGP and tying it with the sliding method. The second anchor is double-loaded - sliding suture and non-sliding ribbon-shaped suture (FiberTak 1.8mm Arthrex®, Naple, Florida) and is inserted at the 4:30 position for the right shoulder. The second stitch is passed through the inferior capsule (at the 5:00 position) where a pinch of the capsule is pierced with the hook to create a pinch-tuck plication and then passed again beneath the labrum, creating a capsulo-labral complex repair with providing additional secure labral fixation with appropriate balancing of the capsule by adding plication and elimination of the capsular redundancy.<sup>19</sup>

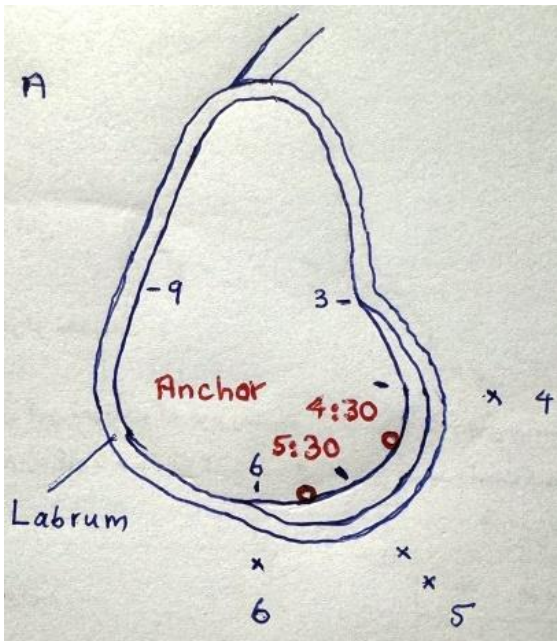


Figure 1. Glenoid surface in right shoulder.anchor sites at the 5; 30 and 4; 30 position (O anchor, X capsular penetration)

The final suture is a fiber wire with a spectrum hook perpendicular through the capsule 1-2 cm lateral to the anchor at the 4:00 position, and the lateral to medial capsular shift occurs [Figure B]. Therefore, the anteroinferior capsulo-labral complex tear can be repaired with these 2 anchors and 3 vertical stitches. At the end of the reconstruction, capsulo-labral complex was shifted superior and medial, restoring the tension at the Inferior

Gleno-Humeral Ligament (IGHL), creating bump at the edge of the articular surface and the humeral head should be centered on the glenoid surface [Figure C]. Finally, repair was assessed by the presence of an arthroscopic drive-through sign, which was not possible in each cases.

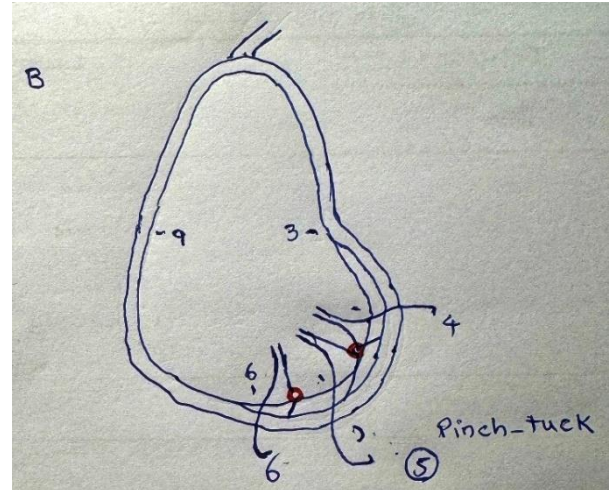


Figure 2. Capsular penetration at 4:00, 5; 00 and 6:00 position

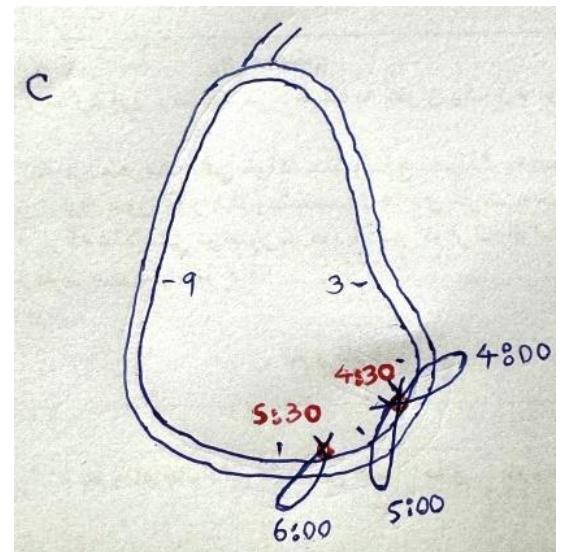


Figure 3. 6:00 position: inferior to superior capsular shift. 5:00 pinch tuck suture. (Shift and plication). 4:00 lateral to medial shift

Patients were kept in a sling for four weeks. Passive motion, flexion, extension, adduction, abduction, and pendulum exercises were started on the first postoperative day and continued at home 3 times daily for 5 minutes. Physical therapy was started at postoperative week 4. External rotation was limited to 0° for 4 weeks and then to 45° by the end of week 6. And then range of movement was allowed in patient's Visual Field. Strengthening exercises were started between weeks 8 and 12.

Patients with subjective apprehension, dyskinesia or limited range of motion received longer rehabilitation

episodes until they were symptom-free. Sports activities were allowed again after six months.

### Statistical analysis

Statistical analysis was conducted in SPSS 16; frequency, percentage, mean, and standard deviation were used to define the data. Chi-square, student t, and ANOVA, Kruskal-Wallis, and Mann-Whitney tests were applied to compare variables, wherever appropriate. The statistical significance level was measured at 0.05.

### Results

A summary of patient characteristics and data is provided in [Table 1]. The mean age of participants was  $23\pm 4.45$  years and ranged from 16-32 years. The mean follow-up time was  $40.1\pm 6.99$  months (range: 24-48 months). The time since the first dislocation to surgery was  $26.89\pm 29.14$  months. Participants' sports activities are shown in [Table 2]. The mean ISI score was  $2.03\pm 1.67$  (95%CI: 1.48-2.57) for the cases. The apprehension test was positive in 35 of 38 cases.

Table 1. Summary of each patient's data

Cases	Age	Sex	Activity and level	Frequency of Dislocation	Subluxation	ISIs	Apprehension	first Dislocation to Surgery(month)	VAS	External rotation 1	External rotation 2	flexion	Constant Score pre op	up(month)	Day to surgery	Postop Subluxed	Revision	Post op VAS	Postop External rotation 1	Postop External rotation 2	Post op flexion	Postop Constant score	Complications
1	26	F	TR	1	+	0	+	60	4	60	70	170	84	48	55	-	-	1	55	70	165	91	none
2	19	M	TP	2	+	4	+	12	2	60	65	175	84	36	70	-	-	0	60	60	170	100	none
3	24	M	BBP	1	-	3	+	2	2	65	60	175	85	48	60	-	-	2	60	60	165	91!	none
4	16	M	BP	2	+	5	+	6	3	65	70	170	85	36	57	-	-	1	65	65	170	92	none
5	23	M	BR	8	+	2	+	60	4	65	65	165	80	48	63	-	-	1	55	60	165	93	none
6	29	M	BR	12	+	4	+	96	3	65	60	165	72	36	58	-	-	0	60	60	160	98	none
7	19	M	VP	2	-	6	+	4	4	65	60	165	83	48	60	-	-	1	60	55	165	94	none
8	18	M	VR	3	-	3	+	6	1	60	60	160	85	36	60	-	-	2	55	60	160	*90	none
9	17	F	SR	2	-	2	+	3	2	65	55	165	85	36	80	-	-	0	65	55	170	97	none
10	22	F	TP	2	+	3	+	4	2	60	60	160	82	48	58	-	-	0	55	60	165	96	none
11	30	M	VR	5	+	0	+	84	4	45	65	165	84	36	68	-	-	1	55	60	170	91	none
12	28	M	BBR	9	+	1	+	84	2	50	65	170	82	48	75	-	-	0	55	60	165	98	none
13	21	M	BBR	4	-	1	+	24	3	55	60	165	82	48	70	-	-	0	60	60	160	100	none
14	19	M	BR	2	+	4	+	6	2	55	60	165	84	36	68	-	-	0	55	55	165	97	none
15	18	M	VR	2	-	2	+	3	2	65	65	170	85	36	55	-	-	0	60	60	165	100	none
16	24	F	TR	5	+	0	+	48	4	60	60	165	80	36	55	-	-	1	60	60	160	93	none
17	27	M	BBR	6	-	1	-	84	2	65	60	165	84	48	80	-	-	0	70	55	165	98	none
18	23	M	BP	2	+	3	+	2	3	65	60	165	85	36	85	-	-	0	65	55	160	100	none
19	32	M	BR	4	-	1	+	36	2	60	60	165	82	48	68	-	-	1	60	60	160	94	none
20	23	M	TR	N	+	0	+	36	2	65	65	170	84	48	70	-	-	0	60	60	170	98	none
21	26	M	KR	12	-	1	-	48	3	60	60	170	85	36	72	-	-	2	65	55	160	90!	none
22	25	M	BBR	5	+	1	+	36	4	65	60	165	85	36	65	-	-	1	65	60	160	92	none
23	28	F	TR	5	+	0	+	48	4	55	50	160	80	24	68	-	-	2	60	55	160	90	none
24	30	M	BBR	N	+	1	+	24	4	60	65	165	82	36	70	-	-	1	55	60	165	94	none
25	32	F	KR	2	+	1	+	24	3	65	60	165	80	48	75	-	-	0	65	60	160	98	none
26	19	F	BBP	1	+	5	+	3	2	65	60	160	82	48	77	1	-	2	60	60	155	88!	none
27	22	M	TR	3	+	0	+	24	3	60	60	160	76	36	80	-	-	1	65	55	160	92	none
28	22	F	TR	N	+	1	+	6	1	65	60	155	75	36	59	-	-	0	60	60	160	95	none
29	26	M	BR	1	+	1	+	6	2	65	65	160	78	36	64	-	-	0	70	60	160	100	none
30	23	F	BBR	3	+	1	+	9	2	65	65	165	75	36	65	-	-	0	65	65	170	94	none
31	18	F	BBR	2	-	4	+	6	2	60	55	160	78	48	57	-	-	0	55	60	160	96	none

Table 1. Continued

32	29	M	BR	2	-	1	+	3	2	65	60	160	82	24	66	-	-	0	65	60	165	95	none
33	20	F	TR	2	+	2	+	6	4	60	55	155	75	36	70	1	-	2	60	60	160	85!	none
34	19	M	VP	3	+	4	+	4	3	65	65	155	75	36	68	-	-	0	60	65	160	94	none
35	19	F	BR	2	+	3	+	3	4	60	55	150	75	36	60	-	-	1	65	60	155	91	none
36	22	M	VP	1	+	2	-	4	2	65	65	155	72	48	60	-	-	0	65	70	160	97	none
37	29	M	FR	12	-	4	+	84	4	60	65	160	65	36	65	-	-	1	55	70	160	92	none
38	24	M	VR	4	+	0	+	24	2	60	55	155	75	48	70	-	-	0	65	60	160	95	none

Table 2. Sport activity of patients

Activities	Frequency	Percent
Professional Boxing (BP)	2	5.3
Recreational Boxing (BR)	7	18.4
Professional Basketball (BBP)	2	5.3
Recreational Basketball (BBR)	7	18.4
Professional Tennis (TP)	2	5.3
Recreational Tennis (TR)	7	18.4
Professional Volleyball (VP)	3	7.9
Recreational Volleyball (VR)	8	21.1
Total	38	100.0

The measured preoperative and postoperative range of motion in terms of external rotation and forward flexion is shown in [Table 3], which shows the relative preservation of range of motion after surgery ( $P < 0.001$ ). At the end of the study period, cases had improved measured scores. There was a significant difference for the Constant Score after

surgery: the mean of the preoperative Constant Score was  $80.32 \pm 4.81$  (95%CI: 78.73-81.90) and for the postoperative one  $94.45 \pm 3.71$  (95%CI: 93.23-95.67) ( $P < 0.001$ ). A significant difference was also observed for the VAS score from  $2.74 \pm 0.95$  (95%CI: 2.42-3.05) to  $0.63 \pm 0.75$  (95%CI: 0.38-0.88) ( $P < 0.001$ ) [Table 3].

Table 3. Measured scores and examinations

	Mean $\pm$ SD <sup>1</sup>	95% Confidence Interval of the Difference		P value
		Lower	Upper	
Pre-operative VAS <sup>2</sup>	2.74 $\pm$ 0.95	2.42	3.05	<0.001
Pre-operative External rotation <sup>1</sup>	61.45 $\pm$ 4.64	59.92	62.97	
Pre-operative External rotation <sup>2</sup>	61.18 $\pm$ 4.26	59.78	62.58	
Pre-operative Forward flexion	163.42 $\pm$ 5.71	161.55	165.30	
Pre-operative Constant score	80.32 $\pm$ 4.81	78.73	81.90	
Post-operative VAS	0.63 $\pm$ 0.75	0.38	0.88	
Post-operative External rotation <sup>1</sup>	60.79 $\pm$ 4.43	59.33	62.25	
Post-operative External rotation <sup>2</sup>	60.13 $\pm$ 3.94	58.84	61.43	
Post-operative Forward flexion	162.76 $\pm$ 4.14	161.40	164.12	
Post-operative Constant score	94.45 $\pm$ 3.71	93.23	95.67	

<sup>1</sup> Standard deviation (SD)

<sup>2</sup> visual analogue scale (VAS)

At follow-up, no clinical instability was observed; considering that only 2/38 (5.3%) had episodes of non-clinical subluxation; re-dislocation was not seen among our cases. In addition, no other complications such as infections,

hematomas, stiffening, and neurovascular impairment were observed in our patients [Table 4].

No statistically significant association between subluxation with duration or number of dislocations was demonstrated

( $P=0.17$ ). The duration of the preoperative instability interval had no significant effect on the subluxation rate ( $P=0.24$ ). A

statistically significant negative correlation was found between age and subluxation rate ( $P=0.032$ ).

**Table 4. The subluxation, re-dislocation, and other complications rate**

	Values (Number, (%))
<b>Post-operative subluxations</b>	2 (5.3%)
<i>Clinical subluxation</i>	0(0%)
<i>Non-clinical subluxation</i>	2(5.3%)
<b>Post-operative re-dislocations</b>	0 (0%)
<b>Complications (infection or neurovascular)</b>	0 (0%)

## Discussion

Techniques and implants have been developed to treat labral tears of the glenoid with better outcomes. Current recommendations consist of using at least three conventional single-loaded anchors in the anteroinferior glenoid to strengthen capsular fixation.<sup>6,20</sup> Given some of the benefits of All-suture anchors over other designs, orthopedic surgeons have preferred an All-suture anchor technique for glenoid labral repair. Consistent with the literature, one of the most important factors determining the treatment outcome is the quantity of used anchors.<sup>21</sup> Previous studies have shown that an increased rate of re-dislocation occurs when two or fewer anchors are used.<sup>20,22-24</sup> In our study, two anchors were used but three vertical stitches. In this method, with first stitch, ensuring that the labrum is well shifted superiorly; the second stitch provides additional secure labral fixation with appropriate balancing of the capsule by adding the plication. Finally, lateral to medial capsular shift occurs with third stitch. However, another study in arthroscopic Bankart repairs showed that stability is not associated with the use of either three versus two double-loaded suture anchors.<sup>25</sup> A previous report compared the results among cases with a labral injury between 2 and 6 o'clock, who received 3 implants, were also compared with those with a labral injury between 3 and 6 o'clock, who received 2 implants, FASTak 2.8-mm suture anchors (FASTak, Arthrex, Naples, Florida). No significant associations were found in the two groups between the Rowe and UCLA scores as outcome indices vs. amount of injury or number of implants.<sup>26</sup> Favourable outcomes have been showed in arthroscopic Bankart repair with the purse-string technique by a single knotless suture. Also, in comparative biomechanical and clinical studies of Bankart repair with double-loaded suture anchors, favourable results were achieved when fewer suture anchors were used.<sup>9,27-29</sup> In addition, there was a report in which two suture anchor applied for labral tear between 3 and 6 o'clock.<sup>26</sup>

The literature indicates that the outcomes of arthroscopic repair of Bankart lesions using anchors with one suture depreciate over time<sup>30</sup>; a previous study by Castagna et al<sup>31</sup> reported a recurrence rate of 23% at a mean follow-up of 10.9 years, and another report by van de Linde et al<sup>32</sup> found a recurrence rate of 35% at a follow-up of 8-10 years, which

was 20% at 2 years. We believe that when two anchors are used, recurrence rates may be lower with increasing follow-up time; however, we did not assess the results in longer follow-up periods. Theoretically, this advantage was demonstrated in a recent biomechanical study that showed that the use of two anchors with double loading had a resistance to failure that was greater than or equal to the use of three anchors with a single thread.<sup>28</sup>

In the patients in the current study, the failure rate was less than 10%, which is comparable to the success rate in previous studies.<sup>33-39</sup> However, a study by Delgrande et al even reported higher failure rate when longer-term follow-ups, e.g. mean 12 years, was considered.<sup>40</sup>

Our results were comparable to those in the literature when evaluated by the mean constant and VAS scores.<sup>41</sup> We achieved results that was considerably superior to that of Kim's study (loss of 7° of external rotation during abduction),<sup>35</sup> which may be due to greater tension on the anterior capsule. The other results achieved in the present study were acceptable compared with those in the literature. Like a previous report, our study showed that postoperative outcomes were not negatively affected by the number of preoperative dislocations, time to surgical treatment, and degree of subluxation observed at preoperative examination during general anesthesia.<sup>42-45</sup>

Overall, the number of preoperative dislocations had no effect on subluxation rates. However, a higher non-clinical subluxation tended to be reported by patients who underwent surgery after more than one dislocation. This may be due to the greater attenuation of the capsulo-ligamentous complex.<sup>5,32,46</sup>

Patient age could be important non-modifiable risk factors for re-instability. The statistically significant negative relationship between age and subluxation was somehow comparable to that described in the literature.<sup>5,46</sup>

We found no significant correlation between the subluxation rate and patient gender. Although previous studies by Szyluk et al and Zhang et al reported that male gender was associated with recurrence,<sup>47,48</sup> Castagna and van der Linde found no significant difference between men and women.<sup>31,32</sup>

A previous study by Tan et al. reported that 6.1% had revision surgery and 26.8% stated residual instability after

surgery;<sup>49</sup> this relatively low rate is somewhat consistent with our results.

We had limitations including a relative small sample size, and that we had no control group so that we could provide comparative results. Further studies with case-control are needed to elucidate the technique outcome for treating recurrent anterior shoulder instability.

### Conclusion

This technique-two anchors and three stitches may prove accessible to arthroscopic surgeons after a relatively short learning curve, making it a less costly alternative for the treatment of anterior shoulder instability in properly selected patients. In addition, the procedure is easy to perform, the operative time would be shorter, and no specific complications have occurred.

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### Authors Contribution:

Saeed Kokly: study conception and design, data collection, and interpretation of results, and manuscript preparation and editing.

Alessandro Castagna: study design, interpretation of results, and manuscript editing.

Ramin Etemadi: data collection, interpretation of results, and manuscript editing.

Seyyed-Mohsen Hosseinienejad: study conception, data collection, analysis and interpretation of results, and manuscript preparation and editing.

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**Declaration of Informed Consent:** There is no information in the submitted manuscript that can be used to identify patients.

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