

Long-term, Prospective, Multicenter Study of Isolated Bankart Repair for a Patient Selection Method Based on the Instability Severity Index Score

Hervé Thomazeau,^{*} MD, Prof, Tristan Langlais,[†] MD, Alexandre Hardy,[‡] MD, Jonathan Curado,[§] MD, Olivier Herisson,^{||} MD, Jordane Mouton,[¶] MD, Christophe Charousset,[#] MD, Olivier Courage,^{**} MD, French Arthroscopy Society, and Geoffroy Nourissat,^{††‡‡} MD, PhD
Investigation performed at Rennes University, Clinical Research Unit, Rennes, France

Background: An isolated arthroscopic Bankart repair carries a high mid- and long-term risk of recurring instability. Preoperative patient selection based on the Instability Severity Index Score should improve outcomes.

Purpose: To report the overall long-term recurrence rate for isolated Bankart repair, investigate the predictive factors for recurrence, analyze time to recurrence, and determine a quantitative cutoff point for recurrence in terms of Instability Severity Index Score.

Study Design: Cohort study; Level of evidence, 2.

Methods: This was a prospective multicenter study. Inclusion criteria were recurring anterior instability and an Instability Severity Index Score of 4 or less. Of the 125 patients included, 20 patients had a score of 0, 31 patients scored 1, 29 patients scored 2, 34 patients scored 3, and 11 patients scored 4. All centers used the same arthroscopic technique and rehabilitation protocol. Follow-up data were collected at 3, 6, 12, and 24 months and 3 and 9 years. The primary endpoint was recurrence of instability (total or partial dislocation). The statistical analysis was performed by use of the software package SAS 9.4.

Results: We initially identified 328 patients, of whom 125 patients were prospectively included. The main reason for excluding the 202 patients was the presence of bony lesions, which carry 2 points each in the Instability Severity Index Score (humeral head notch and/or glenoid lesion visible on standard radiographs). Of the 125 eligible patients, 73% were athletes and 22.5% competitors; 16% were lost at the last follow-up. At the endpoint, 23% had experienced a recurrence after a mean interval of 35 months (range, 5.5-103 months). No statistical differences were found between patients with and without bony lesions in the overall group of 125 patients or in the subgroup with an Instability Severity Index Score of 3 or 4 points ($P = .4$). According to univariate analysis, the only predictive factor for recurrence was age less than 20 years at the time of surgery, with a 42% rate of recurrence in this group ($P = .03$). Multivariate analysis showed that the Instability Severity Index Score was the only predictive factor with a quantitative cutoff point (namely, a score of ≤ 2 points) that was statistically associated with a decreased long term recurrence rate ($P = .02$). The recurrence rate was 10% for a preoperative Instability Severity Index Score of 2 or less compared with 35.6% for a score of 3 or 4. The survival curves demonstrated no new dislocations after year 4 for patients with an Instability Severity Index Score of up to 2 points.

Conclusion: In a preselected population, mainly without bony lesions, the Instability Severity Index Score cutoff value that provides an acceptable recurrence rate at 9 years after isolated Bankart repair is 2 out of 10.

Keywords: Bankart; Instability Severity Index Score; long-term follow-up

Stabilization with an arthroscopic Bankart repair is the most widely used technique for correcting chronic instability of the shoulder. However, the literature reports a 20% to 50% risk of recurrence long-term.⁹ To reduce this rate

of failure, Balg and Boileau³ introduced the Instability Severity Index Score as a way of improving patient selection. This score was developed based on a retrospective analysis of risk factors for the failure of isolated arthroscopic Bankart repair. The score uses age, degree of sports participation, type of sport, laxity, and bone criteria assessed via standard AP radiograph (Figure 1). The highest possible score is 10 points. The higher the score, the greater the risk of recurrence after stabilization of the shoulder with an isolated Bankart repair (Figure 1). The main aim of this

Age <20 Years	2 points
Sport: competitor	2 points
Sport: contact or overhead-forced	1 point
Ligamentous laxity (inf or ant) passive external rotation >85° points	
Hill-Sachs notch > X-rays in ext rotation points	2
Glenoid bone loss > on standard X-rays points	2
Total	10 points

Figure 1. The Instability Severity Index Score as described by Balg and Boileau³ in 2007. To be included in the present study, patients had to have a score of 4 points or less.

multicenter study was to prospectively validate this score by including only patients with recurrent instability of the shoulder and an Instability Severity Index Score of ≤ 4 out of 10. We hypothesized that this selection process would achieve a recurrence rate of no greater than 5%.¹¹ A score of 4 or less was chosen to include patients with risk of recurrence, because Balg and Boileau³ recommended isolated Bankart repair for an Instability Severity Index Score of 3 or less, although theirs was a retrospective study. The secondary aims of this study were to report the overall long-term (9-year) recurrence rate following an isolated Bankart arthroscopy, to investigate predictive factors for recurrence, to analyze the time to recurrence, and to determine an Instability Severity Index Score cutoff for recurrence.

METHODS

Between October 2007 and October 2008, after institutional review board (reference 09-7) approval was granted, 11 centers were recruited to take part in this multicenter study. The 11 centers specialized in shoulder sports surgery with experienced surgeons. Of the 328 patients undergoing surgery for instability of the shoulder during this period, 125 met the chosen inclusion criteria:

1. Instability Severity Index Score of 4 or less.
2. Identical surgical technique, comprising at least 3 screw anchors and 4 sutures on the anterior and inferior side.
3. No secondary surgical procedure (eg, remplissage, posterior-inferior fixation).
4. Immobilization for at least 4 weeks.

Clinical follow-up data were obtained from the patients at 3 months, 6 months, 1 year, 2 years, 3 years, and 9 years. The criteria for failure of the surgical technique were true dislocation or subluxation after surgery. At the time of surgery, 15% of patients were younger than 20 years ($n = 19$), 21% were between 20 and 25 years ($n = 26$), 20% were between 26 and 30 years ($n = 25$), and 44% were older than 30 years ($n = 55$).

The statistical analysis was performed at the Epidemiology and Public Health Department of Rennes Teaching Hospital (Rennes, France). Qualitative variables were compared between the groups through use of either a chi-square test or Fisher exact test, depending on the validity conditions. Quantitative variables were compared between the groups by use of either a Student test or Wilcoxon-Mann-Whitney test, depending on the validity conditions. Explanatory factors of recurrence were studied via logistic regression, and time to recurrence was modeled with a Kaplan-Meier curve. Time to recurrence based on preoperative Instability Severity Index Score (≤ 2 vs > 2) was also modeled with 2 Kaplan-Meier curves, which were compared by use of the log-rank test. The statistical analyses were performed with the software package SAS v 9.4 (SAS Institute).

RESULTS

Of the initial population of 328 patients who had an arthroscopic Bankart repair, 202 were excluded either because they did not meet the inclusion criteria or because their Instability Severity Index Score was greater than 4. In most cases, a high score was the result of bony lesions detectable on standard radiographs according to the scoring procedure for the Instability Severity Index Score (Table 1). Between October 2007 and October 2008, 125 patients were included; their mean age was 30.2 years (range, 16.5-59.6 years; median, 28.5 years). Of the 125 patients included, 20 had an Instability Severity Index Score of 0, 31 patients scored 1, 29 patients scored 2, 34

††Address correspondence to Geoffroy Nourissat, MD, PhD, Groupe Ramsay Generale de Santé, 67 rue de Romainville, 75019 Paris, France (email: gnourissat@wanadoo.fr).

*Centre Hospitalier Universitaire, Rennes, France.

†iULS, Hôpital Pasteur 2, Nice, France.

‡APHP, Hôpital Ambroise Paré, Boulogne Billancourt, France.

§Centre Hospitalier Universitaire, Caen, France.

||APHP, Hôpital Saint Antoine, Paris, France.

*Centre Hospitalier Universitaire, Rouen, France.

#Iopac, Paris, France.

**Hôpital de l'Estuaire, le Havre, France.

††Groupe Ramsay Generale de Santé, Clinique Maussins Nollet, Paris, France.

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TABLE 1
Differences in Bony Lesions Between Included and Excluded Patients^a

	Included (n = 125)	Excluded (n = 202)
Humeral notch	18.5	57.2
Glenoid lesion	5.6	38.5

^aDifferences in bony lesions were defined by the Instability Severity Index Score radiological scoring system. The included patients had a score of 4 points or less; the excluded patients had a score of more than 4 points. Values are expressed as percentages of patients.

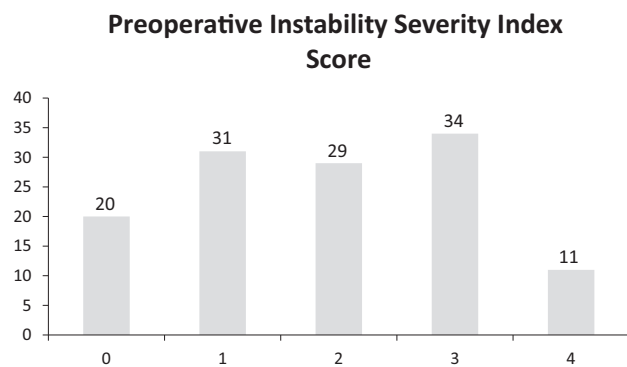


Figure 2. Diagram of the 125 included patients according to Instability Severity Index Score: 20 patients had a score of 0, 31 patients had a score of 1, 29 patients had a score of 2, 34 patients had a score of 3, and 11 patients had a score of 4.

patients scored 3, and 11 patients scored 4 (Figure 2). The rate of loss to follow-up was 9.2% at 3 years and 16% at 9 years. The patients who were lost to follow-up did not differ epidemiologically from the patients who completed the study. The instability recurrence rate was 12% at 3 years and 23% at 9 years (ie, 23 of the 105 patients were still in the study at this point). Of the recurrences, 12 were caused by a traumatic event, 10 were caused by a nontraumatic event, and 1 case was unspecified. The types of recurrence were 12 total dislocations and 11 partial dislocations.

Preoperative Instability Severity Index Score was a significant predictive factor of recurrence at 9 years. When this score was greater than 2, the relative risk of recurrence was 3.547 ($P = .0191$; 95% CI, 1.230-10.230) compared with that in patients with a score of 2 or less. The recurrence rate was 10% for a preoperative Instability Severity Index Score of 2 or less versus 35.6% for a score of 3 or 4 (Table 2). Mean time to recurrence, as determined with Kaplan-Meier curves, was 35 months, with a median of 28 months (Figure 3). The first 10% of recurrences occurred at 2 years. For patients with an Instability Severity Index Score of 2 or less, the rate of recurrence was 10% at 9 years; however, this rate had leveled out after 4 years and no patient had a recurrence after this point. In contrast, when the Instability Severity Index Score was

TABLE 2
Recurrence Rates Related to Preoperative Instability Severity Index Score^a

	0, 1, and 2 points	3 and 4 points
Recurrence rate ($P = .0005$)	10%	35.6%

^aRates are expressed as percentages. The highest possible Instability Severity Index Score is 10 points.

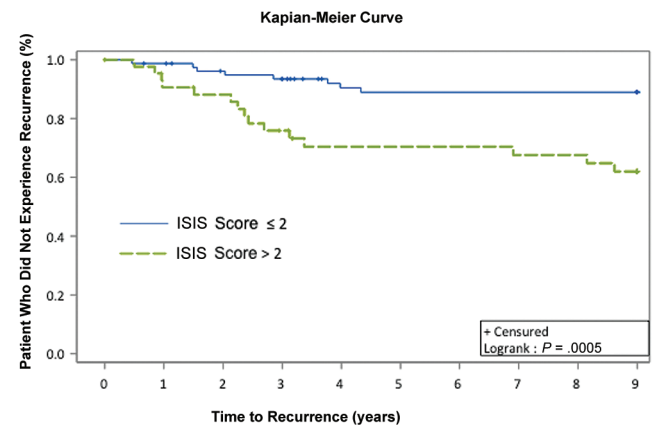


Figure 3. Kaplan-Meier curve for time to recurrence. Note the second break at 7 years of follow-up for the group of patients with a preoperative Instability Severity Index Score (ISIS) of more than 2.

greater than 2, the recurrence rate was 35.6% at 9 years, due to a second step-up in the rate for this group from the seventh year (Figure 3).

The univariate analysis revealed age less than 20 years at the time of surgery as the only predictive factor for failure ($P < .003$). Patients younger than 20 years at the time of surgery had a failure rate of 42%, compared with 16% in the 20- to 40-year-old group and 10% in the over-40 group. Multivariate analysis showed that the Instability Severity Index Score was the only predictive factor with a quantitative cutoff point (namely, ≤ 2) that was associated with decreased long-term recurrence rate ($P = .02$) (Figure 3). The study did not identify any statistical differences between patients with and without bony lesions, either in the overall group of 125 patients or in the subgroup of patients with an Instability Severity Index Score of 3 or 4 ($P = .04$).

DISCUSSION

The goal of this study was to validate the ability to reduce the recurrence rate after Bankart repair by using the Instability Severity Index Score as a preoperative selection tool. This tool was created by Balg and Boileau³ on the basis of retrospective data. Rouleau et al¹⁰ demonstrated that this scoring system is a reliable parameter for

TABLE 3
Studies of Arthroscopic Bankart Repair With a Minimum of 10 Years of Follow-up

Study	No. of Shoulders	Loss to Follow-up, %	Mean Follow-up, y (range)	Recurrence Rate, %
Flinkkilä et al ⁵	167	19	12.2 (10-16)	30
Zimmermann et al ¹⁴	271	38	12.2	13
Aboalata et al ¹	143	37	13.3	18.2
Zaffagnini et al ¹³	49	28	13.7 (10-17)	12.5
Kavaja et al ⁶	81	14	13 (11-15)	22
Privitera et al ⁸	20	12	13.5 (10.75-17.5)	25
Castagna et al ⁴	31	12	10.9 (9.8-14.3)	22
van der Linde et al ¹²	68	2	9 (8-10)	35
Total	830	30 (n = 252)	12.2	22.2

preoperative patient assessments. Phadnis et al⁷ retrospectively confirmed the validity of this scoring system, but with a short-term follow-up, and identified the major criteria to be bony lesions and age less than 21 years at the time of surgery. Interestingly, those authors recommended a cutoff of a maximum 4 points on the Instability Severity Index Score to allow Bankart, the same value we have chosen. The current study is the only prospective study with long-term follow-up, and the Instability Severity Index Score appears to have been an excellent tool to analyze our data. It now seems that other criteria such as age and bony lesions are sufficient to indicate procedures other than isolated anterior Bankart repair. This was the first long-term prospective study of isolated Bankart arthroscopic repair using the Instability Severity Index Score as a criterion for initial patient selection. We hypothesized that an Instability Severity Index Score of 4 or less was required for a long-term recurrence rate comparable with that achieved with open repair techniques or the Latarjet procedure (ie, around 5%).² A limitation of this study was the small population size, which, despite a high rate of follow-up at 9 years, made it impossible to draw conclusions for most of the components of the Instability Severity Index Score taken individually (eg, type of sport, laxity). In addition, patients were selected with a maximum Instability Severity Index Score of 4 points, meaning it was not possible to study patients with more severe bony lesions, in particular, a combination of a glenoid and humeral lesion, which is usually sufficient to surpass the threshold of 4 points. Finally, the required surgical technique was a 3 o'clock to 6 o'clock anterior labral repair without any other procedure.

This study found that the cutoff point was 2 points and that the preoperative Instability Severity Index Score had to be 2 or less to achieve a 9-year failure rate of 10%. Within this population with a score of 4 points or less, we found no statistical evidence for the influence of bony lesions, even though they had a higher rate of recurrence without statistical evidence ($P = .4$).

Published data are lacking regarding long-term outcomes of arthroscopic Bankart repair. We found that 8 studies had a follow-up of 9 years or longer; however, all of these were retrospective studies with a low level of proof and an

overall rate of loss to follow-up of 30% (range, 3%-47%) (Table 3).^{1,4-6,8,10,12-14} The pooled results of these studies give an average follow-up of 12 years (range, 10-16 years), an average age at time of surgery of 28.5 years, and an overall rate of recurrence of 22.2% (range, 12.5%-35%).

Most of the recurrences happened early, in the first 2 years in 40% of cases and after 5 years in 28.5% of cases, with an average time to recurrence of 3.8 years. In total, 62% of patients were able to resume their sporting activities and 17% of patients required revision surgery. The authors differ in terms of the risk factors to which they attribute this overall recurrence rate. Flinkkilä et al⁵ believe that age less than 20 years is the primary cause of failure. Aboalata et al¹ consider this age to be just one of the main risk factors. Aboalata et al¹ also highlighted the importance of insufficient rehabilitation (<6 months) and a high number of preoperative dislocations. Castagna et al⁴ identified contact sport as the main cause of failure, and van der Linde et al¹² believe that humeral lesions and insufficient repair with fewer than 3 sutures anchors were predictive of failure.

CONCLUSION

This long-term prospective study demonstrated an overall recurrence rate of 23% after isolated Bankart repair in a selected population, mainly patients without bony lesions. The recurrence rate was acceptable when the Instability Severity Index Score was 2 points or less, with 10% recurrence, but remained as high as 35.6% for 3- and 4-point values, with a second decrease of the results at the seventh year for those 2 groups. The overall main predictive factor was age less than 20 years at time of surgery, more than the Instability Severity Index Score itself.

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REFERENCES

1. Aboalata M, Plath JE, Seppel G, Juretzko J, Vogt S, Imhoff AB. Results of arthroscopic Bankart repair for anterior-inferior shoulder instability at 13-year follow-up. *Am J Sports Med.* 2017;45(4):782-787.
2. Allain J, Goutallier D, Glorion C. Long-term results of the Latarjet procedure for the treatment of anterior instability of the shoulder. *J Bone Joint Surg Am.* 1998;80:841-852.
3. Balg F, Boileau P. The Instability Severity Index Score: a simple pre-operative score to select patients for arthroscopic or open shoulder stabilisation. *J Bone Joint Surg Br.* 2007;89(11):1470-1477.
4. Castagna A, Markopoulos N, Conti M, Delle Rose G, Papadakou E, Garofalo R. Arthroscopic Bankart suture-anchor repair: radiological and clinical outcome at minimum 10 years of follow-up. *Am J Sports Med.* 2010;38(10):2012-2016.
5. Flinkkilä T, Knape R, Sirniö K, Ohtonen P, Leppilahti J. Long-term results of arthroscopic Bankart repair: minimum 10 years of follow-up. *Knee Surg Sports Traumatol Arthrosc.* 2018;26(1):94-99.
6. Kavaja L, Pajarinen J, Sinisaari L, et al. Arthritis of glenohumeral joint after arthroscopic Bankart repair: a long-term follow-up of 13 years. *J Shoulder Elbow Surg.* 2012;21(3):350-355.
7. Phadnis J, Arnold C, Elmorsy A, Flannery M. Utility of the Instability Severity Index Score in predicting failure after arthroscopic anterior stabilization of the shoulder. *Am J Sports Med.* 2015;43(8):1983-1988.
8. Privitera DM, Bisson LJ, Marzo JM. Minimum 10-year follow-up of arthroscopic intra-articular Bankart repair using bioabsorbable tacks. *Am J Sports Med.* 2012;40(1):100-107.
9. Rollick NC, Ono Y, Kurji HM, et al. Long-term outcomes of the Bankart and Latarjet repairs: a systematic review. *Open Access J Sports Med.* 2017;8:97-105.
10. Rouleau DM, Hébert-Davies J, Djahangiri A, Godbout V, Pelet S, Balg F. Validation of the Instability Shoulder Index Score in a multicenter reliability study in 114 consecutive cases. *Am J Sports Med.* 2013;41(2):278-282.
11. Thomazeau H, Courage O, Barth J, et al; French Arthroscopy Society. Can we improve the indication for Bankart arthroscopic repair? A preliminary clinical study using the ISIS score. *Orthop Traumatol Surg Res.* 2010;96(8)(suppl):S77-S83.
12. van der Linde JA, van Kampen DA, Terwee CB, Dijkman LM, Kleinjan G, Willems WJ. Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up. *Am J Sports Med.* 2011;39(11):2396-2403.
13. Zaffagnini S, Marcheggiani Muccioli GM, Giordano G, et al. Long-term outcomes after repair of recurrent post-traumatic anterior shoulder instability: comparison of arthroscopic transglenoid suture and open Bankart reconstruction. *Knee Surg Sports Traumatol Arthrosc.* 2012;20(5):816-821.
14. Zimmermann SM, Scheyerer MJ, Farshad M, Catanzaro S, Rahm S, Gerber C. Long-term restoration of anterior shoulder stability: a retrospective analysis of arthroscopic Bankart repair versus open Latarjet procedure. *J Bone Joint Surg Am.* 2016;98(23):1954-1961.