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# Approach to shoulder instability: a randomized, controlled trial

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**Background:** The significant rate of recurrent instability following arthroscopic stabilization surgery points to a need for an evidence-based treatment approach. The instability severity index Score (ISI score) is a point-based algorithm that may be used to assist clinicians in selecting the optimal treatment approach, but its efficacy compared with a traditional treatment algorithm has not been previously validated. The aim was to compare two surgical treatment algorithms: the ISI score and a conventional treatment algorithm (CTA).

**Methods:** This was a prospective, randomized controlled trial involving participants who were randomized to either the ISI score or CTA and were followed for 24 months postrandomization. In the ISI score cohort, patients underwent a Latarjet procedure if they presented with a score >3 points. Those scoring ISI score ≦3 points underwent an arthroscopic Bankart repair. Patients randomized to the CTA group underwent a Latarjet procedure if the glenoid bone loss was > 25%. The primary outcome was the Western Ontario Shoulder Instability Index. Secondary outcomes included the American Shoulder and Elbow Surgeons score as well as recurrence rates between groups.

**Results:** Sixty-three patients were randomized to ISI score (n = 31) or CTA (n = 32). At two years, the Western Ontario Shoulder Instability Index score was similar between groups (ISI score: 84.1 ± 16.9, CTA: 85.7 ± 12.5, $P = .70$). Similarly, no differences were detected in American Shoulder and Elbow Surgeons scores (ISI score: 93.2 ± 16.2, CTA: 92.6 ± 9.9, $P = .89$). Apprehension was reported in 18.5% for the ISI score group and 20% in the CTA group ($P = 1.00$). At a 24-month follow-up, there was no difference in redislocations: one in ISI score group and none in the CTA group ($P = .48$). There were two revision surgeries in the ISI score group and two in the CTA group.

**Conclusion:** This study did not demonstrate any differences in functional outcomes, the incidence of apprehension, or failure rates between the two treatment algorithms at 24-month follow-up.



Recent arthroscopic techniques with modern suture anchors have been shown to decrease the recurrence rates of anterior shoulder instability with success rates between 4 and 17%,[6,37] which approaches the results of open procedures.[7] Bristow-Latarjet surgery has been reported to result in high levels of satisfaction. Banas et al[4] described 97% satisfaction at 8.6 years postoperative. Hovelius et al[19] reported 98% satisfaction at a 15-year follow-up, and Schroder et al[34] reported 70% satisfaction at 24.6 years postoperatively. Recurrence rates for the Latarjet and Bristow procedures are between 0% and 14%.[1,17-19] The amount of glenoid bone loss that requires grafting is debated.

Decision-making in patients with shoulder instability can be challenging and several treatment algorithms have been proposed.[35] The ISI score introduced in 2007 by Balg and Boileau[3] described a recurrence rate following isolated arthroscopic Bankart repair of 5% if the score was three or less and of 70% if the score was more than six. The score included 5 variables as follows: age at surgery, degree of sport participation (preoperative), type of sport (preoperative), shoulder hyperlaxity, Hill-Sachs on true antero-posterior radiograph and glenoid loss of contour on true antero-posterior radiograph at the first consultation. A subsequent publication by Boileau et al[8] used an ISI score threshold of >3 for the Latarjet procedure. Similarly, Phadnis et al[28] identified a 70%

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risk of failure if the ISI score was 4 and more, as opposed to a 4% risk of failure if the ISI score less than 4. Lippini et al similarly found a lower rate of recurrence in a large cohort of patients based on an ISI score of ≦3.[24] The ISI score was validated in a multicenter study by Rouleau et al[33] in 2013 and found no correlation between the ISI score and the Western Ontario Shoulder Instability Index (WOSI) score. Thomazeau et al[36] used the ISI score as a decision-making tool in arthroscopic treatment of chronic anterior shoulder instability. At a mean follow-up of 18 months, only 3.2% had experienced recurrence.

Bigliani et al[6] reported a 12% recurrence rate in patients with glenoid bone loss > 25% and concluded that a 25% glenoid bone loss should be addressed with a Latarjet procedure. A threshold of 25% glenoid bone loss as an indication for glenoid bone grafting with the Latarjet procedure has been recommended in other publications.[23,28,29,34,35] Burkhart and De Beer[11] described the inverted-pear glenoid and recommended against a Bankart repair when present.

According to a CTA, patients with little bone loss may be treated with arthroscopic stabilization, whereas patients with significant glenoid bone loss (>25%) are treated with a Latarjet procedure to address the higher risk of recurrence in this setting.[5,13,21,25]

The aim of this study was to compare patients' disease-specific quality of life at 2 years, as measured by the (WOSI who undergo a stabilization of the shoulder according to the ISI score compared with patients who undergo stabilization using a CTA. We hypothesized that the ISI score algorithm would yield superior quality of life results.

## Methods

### *Study design*

This was a prospective, randomized controlled trial that was undertaken at two institutions. Enrollment took place between 2014 and 2021, and follow-ups were completed by 2024. The protocol was registered with ClinicalTrials.gov (#NCT02060227).The study was approved by the local research ethics boards. Patients were recruited in outpatient specialty clinics at academic tertiary care hospitals. All participants provided informed consent. This was a double-blind study in which both patients and assessors were blinded to the intervention.

### *Inclusion criteria*

Patients were considered eligible for enrollment if they met the following criteria: history of recurrent anterior instability (dislocation or subluxation), including a clinical history of traumatic anterior instability of the shoulder, positive apprehension or relocation tests, whether able to provide consent, and trial of a minimum of three months of nonoperative treatment, including rotator cuff strengthening.

### *Exclusion criteria*

The exclusion criteria were as follows: patients with (1) other concomitant shoulder pathology, including rotator cuff lesions or humeral avulsion of the anteroinferior glenohumeral ligament, (2) acute first-time dislocation, (3) previous ipsilateral shoulder surgery, (3) unstable painful shoulder without true dislocation or subluxation, (4) active worker's compensation claims, (5) active joint or systemic infection, (6) convulsive disorders, (7) collagen diseases and any other conditions that might affect the mobility of the joint (8) major medical illness (life expectancy less than 2 years or unacceptably high operative risk), (9) inability to speak or read English or French, (10) psychiatric illness that precludes informed consent, and (11) unwillingness to be followed for 2 years.

### *Sample size calculation*

In the absence of availability of WOSI data for a cohort of patients treated with the conventional decision-making algorithm, the sample size calculation was based on a WOSI score of 75 and standard deviation of 23 [data from The Ottawa Hospital shoulder database for Bankart repair at 24 months]. Superiority of the intervention (use of ISI score) would be considered a difference of greater than 25% from the expected mean (WOSI of 93). With alpha at 0.05 and power 0.80, the sample size was determined at 26 per group. With a foreseen dropout rate of 20%, the sample was increased to 62 patients on total.

### *Randomization*

Eligible patients who agreed to participate were randomized following verification of eligibility. Treatment allocation used variable permuted blocks. Randomization and allocation to treatment were determined one day prior to the surgery date. Sealed, opaque envelopes were used, and the research coordinator informed the surgeon of the patients' assigned treatment: ISI score or CTA, which in turn determined the surgical procedure. For the purposes of calculating the ISI score, imaging assessment was carried out by the senior surgeons at each respective center (P.M and P.L). Participants and evaluators were blinded to randomization. In the ISI score cohort, patients underwent a Latarjet procedure if they presented with a score >3 points. Those scoring ISI score ≦3 points underwent an arthroscopic Bankart repair. Patients randomized to the CTA group underwent a Latarjet procedure if the glenoid bone loss was > 25%. The estimation of glenoid bone loss was determined utilizing the best-fit circle technique using sagittal oblique images with either magnetic resonance imaging (MRI) or computed tomography (CT) scans using the glenoid arc angle method to determine the area of bone loss.[15,16] Those with <25% glenoid bone loss underwent an arthroscopic Bankart repair.

### *Surgical technique*

All surgical procedures were performed by fellowship-trained shoulder surgeons and under regional anesthesia.

Arthroscopic Bankart repair: A diagnostic arthroscopy was completed, and the presence of any other pathology was documented. A minimum of 3 anchors were used for the labral repair. The suture anchors used were one of two types, Y-Knot all-suture anchors (Conmed Linvatec, Largo, FL, USA) or PopLock knotless anchors (Conmed Linvatec, Largo, FL, USA). The sutures were passed deep to the labrum, and the labrum was repaired to the glenoid rim following standard glenoid neck bone preparation. Surgical times were recorded.

Open Latarjet procedure: A deltopectoral approach was used. The coracoacromial ligament is exposed and incised 1 cm lateral to its coracoid origin. A 2.5 cm coracoid graft allowed use of 2 screws (cannulated Arthrex 3.75mm; Arthrex, Naples, Fl, USA) for fixation to the glenoid neck through a subscapularis-splitting approach. The stump of the coracoacromial ligament was repaired to the capsule with the arm positioned in external rotation (ER).

Patients were discharged home on the day of surgery. The postoperative rehabilitation was supervised by a physiotherapist and was as follows: surgery to 6 weeks: immobilization in a sling with active-assisted forward elevation to 90 degrees with no ER; at 6 weeks, the sling was discontinued with forward

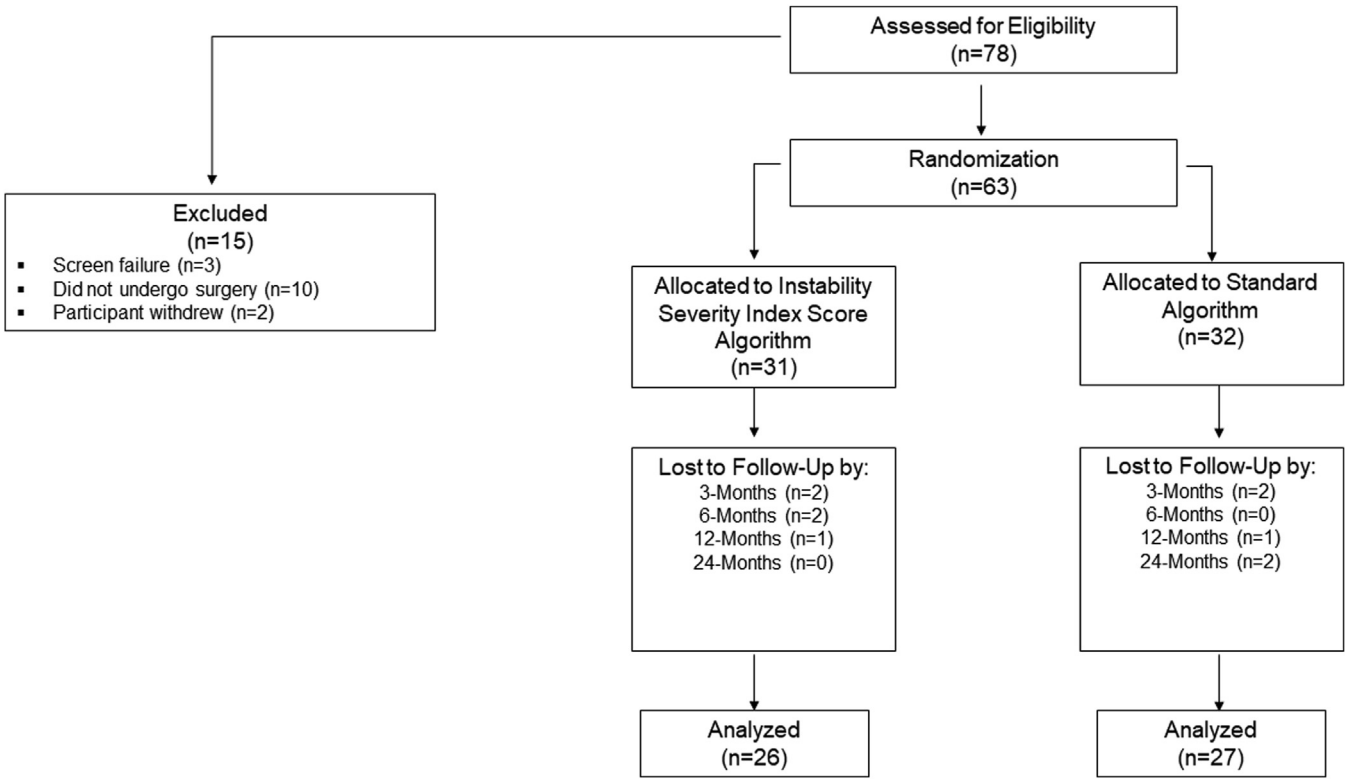


**Figure 1** Consort diagram of study flow.

elevation stretching to 160 degrees; at 12 weeks, strengthening was initiated; and after 6 months, there was full return to activity.

*Outcomes*

The primary outcome was the WOSI score[22] (range 0-100). Secondary outcomes included the ASES score[30] (range 0-100), recurrence rates, and incidence of adverse events. Recurrent instability was defined as a postoperative dislocation or two postoperative subluxations. Shoulder apprehension during physical assessment was also documented. Patient-reported outcome measures were completed preoperatively and by blinded evaluators at 3, 6, 12, and 24 months postoperatively. Adverse events including reoperations were recorded. CT or MRI scans were obtained preoperatively in all patients.

*Statistical analysis*

We reported means with standard deviations for continuous variables and numbers with percentages for categorical variables by groups (ISI score vs standard) and overall. An independent t-test was performed to compare means between groups. All categorical variables were compared between groups using either Chi-square test or Fisher's exact test, where appropriate. We also presented differences with 95% confidence intervals and *P*-values for comparing outcome measures between groups. Multivariable linear regression and logistic regression models were fit with the outcome of WOSI scores at 24 months and apprehension at 24 months, respectively. For all statistical tests, two-tailed tests were used to determine significance at the 5% level. All Analyses were done using SAS version 9.4 for Windows (SAS Institute, Cary, NC, USA).

## Results

*Participants*

Sixty-three participants were randomized to either the ISI score (n = 31) or CTA (n = 32). The mean age was 31.7 years (range 16-62) and 68% (n = 21) of the cohort was male. The flow of patients through the trial is depicted in the consort diagram (Fig. 1). There were no crossovers between groups. There were 5 patients in the ISI score group and 5 in the CTA group who were lost to follow-up by the 24-month final assessment, yielding an 84.1% retention rate. Baseline characteristics were similar between groups (Table I). In the ISI score group, 29% (n = 9) of patients underwent a Latarjet procedure compared with 19% (n = 6) in the CTA group. There were three protocol deviations (2 in the ISI score group and 1 in the CTA group) in which patients were treated with an additional remplissage procedure in addition to their arthroscopic Bankart repair. There was a high degree of concordance between the two treatment algorithms; 27% of patients would have received a different treatment (Latarjet or arthroscopic Bankart repair) if they had had been randomized to the opposite group.

*Functional outcomes*

At 24 months postoperatively, the WOSI score was similar for the ISI score (84.1 ± 16.9) and CTA (85.7 ± 12.5) groups ($P = .70$) (Table II). Similarly, no differences were detected in ASES scores (93.2 ± 16.2 and 92.6 ± 9.9 for the ISI score and CTA groups, respectively, $P = .89$) (Table III). Both groups demonstrated substantial improvement in their WOSI scores from baseline to the two-year follow-up ($P < .0001$).

The apprehension sign was positive in 18.8% for the ISI score group and 20% in the CTA group ($P = 1.00$). There were no

**Table I**
Baseline demographics.

| | ISI score (n = 31) | CTA (n = 32) | Total (n = 63) | *P*-value |
|---|---|---|---|---|
| Age (y): | | | | |
| mean ± SD (range) | 31 ± 9.3 (18.4-50.7) | 32.4 ± 11 (15.8-62.3) | 31.7 ± 10.1 (15.8-62.3) | .752 |
| Sex: | | | | |
| Female | 10 (32%) | 10 (31%) | 20 (32%) | .932 |
| Male | 21 (68%) | 22 (69%) | 43 (68%) | |
| Contact sport | 12 (39%) | 13 (41%) | 25 (40%) | .877 |
| Latarjet performed | 9 (29%) | 6 (19%) | 15 (24%) | .338 |
| Bone loss % (SD) | 15 (9.8) | 18 (9.2) | 16 (9.5) | .21 |

*ISI score*, instability severity index score; *CTA*, conventional treatment algorithm; *SD*, standard deviation.

**Table II**
WOSI scores.

| | ISI score (n = 31) | CTA (n = 32) | Total | *P*-value |
|---|---|---|---|---|
| **Preoperative** mean ± SD (range) | 40.1 ± 15.7 (9.1-78.9) | 41.5 ± 18.5 (1.3-96.2) | 40.8 ± 17 (1.3-96.2) | .752 |
| **3-month** mean ± SD (range) | 50.7 ± 16.8 (15.3-95.2) | 49.4 ± 23.7 (7.4-91.8) | 50.1 ± 20.2 (7.4-95.2) | .833 |
| **6-month** mean ± SD (range) | 78.1 ± 14.1 (45.4-100) | 69.3 ± 22.3 (24.1-97.3) | 73.5 ± 19.1 (24.1-100) | .109 |
| **12-month** mean ± SD (range) | 81.1 ± 20.7 (10.5-100) | 79.1 ± 23.1 (14.1-99) | 80 ± 21.8 (10.5-100) | .757 |
| **24-month** mean ± SD (range) | 84.1 ± 16.9 (40.6-98.9) | 85.7 ± 12.5 (44-98.3) | 84.9 ± 14.7 (40.6-98.9) | .699 |
| **Improvement from baseline** | 43.2 ± 20.1 (2.7-75.6) | 41.6 ± 21.2 (5.7-85.3) | 42.4 ± 20.4 (−5.7 to 85.3) | .783 |
| | $P < .0001$* | $P < .0001$* | | |

*ISI score*, instability severity index score; *CTA*, conventional treatment algorithm; *WOSI*, Western Ontario Shoulder Instability Index; *SD*, standard deviation.
*Within-group difference from baseline to 24-month follow-up.

**Table III**
ASES scores.

| | ISI score (n = 31) | CTA (n = 32) | Total | *P*-value |
|---|---|---|---|---|
| **Preoperative** mean ± SD (range) | 73.4 ± 14.4 (28.3-95) | 71.9 ± 15.1 (26.7-98.3) | 72.7 ± 14.7 (26.7-98.3) | .693 |
| **3-month** mean ± SD (range) | 71.8 ± 14.5 (40-100) | 64.1 ± 18.5 (21.7-88.3) | 68 ± 16.9 (21.7-100) | .125 |
| **6-month** mean ± SD (range) | 89.4 ± 6.2 (76.7-100) | 85.3 ± 16.9 (23.3-100) | 87.3 ± 12.9 (23.3-100) | .2651 |
| **12-month** mean ± SD (range) | 92.6 ± 15 (26.7-100) | 90.2 ± 12.6 (46.7-100) | 91.4 ± 13.8 (26.7-100) | .570 |
| **24-month** mean ± SD (range) | 93.2 ± 16.2 (26.7-100) | 92.6 ± 9.9 (55-100) | 92.9 ± 13.3 (26.7-100) | .891 |
| **Improvement from baseline** | 21.5 ± 14 (−1.7 to 48.3) | 20.5 ± 16.4 (−11.7 to 55) | 21 ± 15 (−11.7 to 55 | .831 |
| | $P < .0001$* | $P < .0001$* | | |

*ISI score*, instability severity index score; *CTA*, conventional treatment algorithm; *ASES*, American Shoulder and Elbow Surgeons; *SD*, standard deviation.
*Within-group difference from baseline to 24 month follow-up.

differences in postoperative shoulder forward flexion or ER in abduction and in adduction at any point during the follow-up (Table IV).

At 24-month follow-up, there was no difference in redislocations between groups (one in ISI score group treated with an arthroscopic stabilization) and none in the CTA group ($P = .48$). There were 2 revisions surgeries in each group. Three of the revisions occurred following Latarjet procedures. Two patients reported postoperative shoulder pain, both of which had graft nonunions; these were revised to distal tibial allografts. The third Latarjet patient was revised two-weeks postoperatively due to graft malposition. One patient had a redislocation following Bankart repair and was revised to a Latarjet procedure.

The multivariable regression analysis did not show any association between the WOSI score at 24 months and group assignment (ISI score vs CTA, $P = .69$), patient age, ($P = .65$), gender ($P = .28$), the type of procedure (Bankart vs. Latarjet, $P = .63$), or the amount of glenoid bone loss ($P = .33$) (Table V). Similarly, there was no association between shoulder apprehension at 24 months and group assignment (ISI score or CTA, $P = .41$), patient age ($P = .15$), gender ($P = .70$), amount of glenoid bone loss ($P = .56$), Hill-Sachs lower edge angle ($P = .25$), or shoulder laxity ($P = .39$) (Table VI).

## Discussion

This trial did not reveal any differences in WOSI and ASES scores at 2-year follow-up between the groups treated based on the ISI score or the CTA. Additionally, no differences were observed in terms of postoperative range of motion, redislocation rate, or postoperative apprehension rate between the two groups at 24 months postop. The hypothesis that the ISI score algorithm would result in better WOSI scores was not supported.

We found no statistical differences between groups at 2 years in the incidence of redislocation. Only a single patient had a redislocation, and there was no difference in the incidence of apprehension between groups. Our expectation of superior outcomes in the ISI score group was based on an anticipated greater number of Latarjet procedures in the ISI score group.[2,20,35,39] We expected this would lead to a lower incidence of postoperative apprehension, a higher incidence of return to sports, and a lower the incidence of recurrence. Although a greater number of Latarjet procedures were carried out in the ISI score group, we found no difference in recurrence rate, postoperative apprehension rate, and functional outcomes between groups. Moreover, we found a postoperative apprehension rate of 18.8% in the ISI score group and 20% in the CTA group (overall 19.4%). This finding is similar to what Rollick et al[31] published, who found a postoperative apprehension rate of 15 to 20% in a systematic review, including 1652 patients who underwent an anterior shoulder stabilization.

Our recurrence rate is also significantly lower than that reported in the literature, with only one redislocation among 63 patients (1.6%). It is noteworthy that there were no redislocation in the CTA group; even though the threshold of bone loss chosen to perform a

**Table IV**
ROM.

| | *ISI score* | CTA | *P*-value |
|---|---|---|---|
| **ROM** | | | |
| **FF 12-month** mean ± SD (range) | 157.8 ± 20.5 (90-180) | 158.3 ± 22.6 (90-180) | .941 |
| **FF 24-month** mean ± SD (range) | 162.2 ± 10.1 (144-180) | 162.8 ± 12.4 (138-180) | .884 |
| **ER ADD 12-month** mean ± SD (range) | 62.9 ± 19.2 (5-90) | 57.9 ± 16.3 (30-85) | .387 |
| **ER ADD 24-month** mean ± SD (range) | 61.8 ± 14.2 (35-85) | 62 ± 21.4 (0-90) | .976 |
| **ER ABD 12-month** mean ± SD (range) | 80.1 ± 13.6 (40-105) | 77.4 ± 16.1 (33-90) | .595 |
| **ER ABD 24-month** mean ± SD (range) | 81.7 ± 6.9 (70-95) | 82.6 ± 6.4 (65-90) | .697 |
| **IR ABD 12-month** mean ± SD (range) | 69.2 ± 14.7 (41-90) | 71.7 ± 16.1 (40-90) | .637 |
| **IR ABD 24-month** mean ± SD (range) | 60.6 ± 17 (38-90) | 68.8 ± 12.6 (46-90) | .114 |

*ISI, score*, instability severity index score; *CTA*, conventional treatment algorithm; *ROM*, range of motion; *FF*, forward flexion; *ER*, external rotation; *ADD*, adduction; *ABD*, abduction; *IR*, internal rotation; *SD*, standard deviation.

**Table V**
Multivariable linear regression analysis: WOSI scores.

| | Regression coefficients | | | P |
|---|---|---|---|---|
| | Estimate | 95% CI | | |
| Group ISI score vs CTA | −2.38 | −11.35 | 6.57 | .59 |
| Age | 0.07 | −0.36 | 0.51 | .72 |
| Gender 1 vs 0 | −5.08 | −14.45 | 4.28 | .28 |
| Procedure B vs L | −3.77 | −15.43 | 7.88 | .51 |
| Glenoid_bone_loss | −0.22 | −0.726 | 0.26 | .35 |

*ISI score*, instability severity index score; *CTA*, conventional treatment algorithm; *95% CI*, 95% confidence interval.

**Table VI**
Multivariable logistic regression analysis: Postoperative Apprehension.

| | Odds ratio | 95% CI | | *P* |
|---|---|---|---|---|
| Group I vs S | 0.37 | 0.03 | 3.90 | .40 |
| Age | 0.89 | 0.76 | 1.04 | .15 |
| Gender 1 vs 0 | 1.62 | 0.13 | 20.04 | .70 |
| Glenoid_bone_loss | 1.04 | 0.90 | 1.19 | .55 |
| LEA | 1.03 | 0.97 | 1.09 | .24 |
| Laxity 1 vs 0 | 3.19 | 0.22 | 44.78 | .38 |

*LEA*, lower edge angle; *95% CI*, 95% confidence interval.

Latarjet procedure was set at 25%, a threshold of bone loss has been called into question by several studies.[12,27,32,38]

Interestingly, none of the factors included in the multivariable regression analysis were associated with the WOSI score or with postoperative apprehension. Young age, ligamentous laxity and larger bone loss on the glenoid and the humerus have been identified as risk factors for postoperative instability and apprehension in the recent literature.[9,14,37] In a systematic review, including 795 shoulders, An et al[2] found that the Latarjet procedure was associated with higher patient-reported outcomes and a lower incidence of postoperative instability. These findings were not supported by our data.

This study has several limitations. The current proposed threshold for addressing glenoid bone loss with grafting is lower than the threshold used in the current trial.[12,27,32,38] It is possible that a different threshold value in the CTA may have yielded different results. In addition, infraspinatus remplissage, an intervention recently demonstrated to be effective,[26] was not included in the CTA. Additionally, 15.9% of patients were lost to follow-up, although the sample size was adjusted to account for this. Two of the five items that comprise the ISI score are related to imaging on plain films. Although the ISI score overall has been shown to have high interobserver reliability,[33] the assessment of glenoid bone loss on plain films has been shown to have moderate reliability.[10] A further possible source of bias may have occurred given that the surgeon would have had access to advanced 3D imaging (CT or MRI scans on all patients. However, given the fact that the score assigned for these two parameters seems distinct (visible Hill-Sachs lesion on the true antero-posterior radiograph in neutral rotation and loss of the sclerotic glenoid line), it seems unlikely that this would have significantly influenced the score. There was a higher than anticipated degree of concordance between the two treatment algorithms. Seventy-three percent of patients would have received the same treatment regardless of the group to which they were randomized. While knowing that significant overlap exists between the two algorithms is useful, this also has a significant impact on the number of patients required to demonstrate a difference and the one which was not accounted for in the sample size calculation. However, given that the differences in clinical outcome scores were very small between the two groups, it seems unlikely that there exists a clinically important difference between the two decision-making approaches. Finally, a longer term follow-up is needed as the recurrence of instability is known to occur beyond two years. It is possible that the higher number of Latarjet procedures in the ISI score group may lead to a lower recurrence rate in the ISI score group in the longer term.

## Conclusion

At a 24-month follow-up, there were no statistically significant differences in functional outcomes, incidence of apprehension, or failure rates following shoulder stabilization between the ISI score and CTA treatment algorithms based on glenoid bone loss. These findings suggest that either treatment algorithm may be used with similar results.

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