# Arthroscopic Bankart repair with remplissage for non-engaging Hill-Sachs lesion in professional collision athletes

Shoulder Elbow

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## Abstract

**Background:** The present study aimed to determine whether arthroscopic remplissage with Bankart repair is an effective treatment for improving outcomes for collision athletes with Bankart and non-engaging Hill-Sachs lesions.

**Methods:** Twenty collision athletes underwent arthroscopic Bankart repair with posterior capsulotenodesis (B&R group) and were evaluated retrospectively, using pre- and postoperative WOSI (Western Ontario Shoulder Instability), EQ-5D (EuroQOL five dimensions), EQ-VAS (EuroQol-visual analogue scale) scores and Subjective Shoulder Value (SSV). The recurrence and re-operation rates were compared to a matched group with isolated arthroscopic Bankart repair (B group).

**Results:** The mean age was 25 years with an mean follow-up of 26 months. All mean scores improved with SSV of 90%. There was a mean deficit in external rotation at the side of  $10^{\circ}$ . One patient was treated with hydrodilatation for frozen shoulder. One patient had residual posterior discomfort but no apprehension in the B&R group compared to 5% persistent apprehension in the B group. In comparison, the recurrence and re-operation rates were 5% and 30% (p = 0.015), 5% and 35% (p = 0.005) in the B&R and B groups, respectively.

**Conclusions:** This combined technique demonstrated good outcomes, with lower recurrence rates in high-risk collision athletes. The slight restriction in external rotation does not significantly affect any clinical outcomes and return to play.

#### **Keywords**

athlete, Bankart repair, non-engaging Hill-Sachs, remplissage, shoulder instability

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# Introduction

The primary treatment for traumatic anterior shoulder dislocation has satisfactory results with shortterm immobilization and physiotherapy,<sup>1,2</sup> although high recurrence rates in some group of patients have been reported.<sup>3–5</sup> The failure rates following surgical Bankart repair are also significantly higher in contact athletes, resulting in impaired sport performances.<sup>3,6–11</sup> Moreover, a recent systematic review and meta-analysis confirmed that the redislocation rate for collision athletes was significantly higher, compared to noncollision athletes, following arthroscopic Bankart repair, ranging between 5.9% and 38.5%.<sup>12</sup>

It is generally accepted that critical anteroinferior glenoid bone loss, comprising 20% to 25% or more of the inferior glenoid diameter, must be addressed by

glenoid bone block procedures, using either a coracoid transfer (Latarjet procedure), iliac crest graft or different allografts.<sup>13</sup> However, there is no clear consensus on how to deal with patients with bipolar lesions, who have varying degrees of bone loss of the glenoid, as well

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as the proximal humerus (Hill-Sachs defects), where soft tissue structures have also undergone plastic deformation both anteriorly and posteriorly, as the result of multiple episodes.

Burkhart and De Beer<sup>14</sup> reported the concept of significant bone defects, either on the humerus or the glenoid, and also described the 'engaging' Hill-Sachs (HS) lesions: this could engage on the anterior glenoid in a position of athletic performances and resulting in failure of the traditional arthroscopic repair. This has also highlighted that the restoration of the soft tissues alone would not be sufficient to stabilize the humeral head.

Wolf and Pollack<sup>15</sup> and Wolf and Arianjam<sup>16</sup> described an arthroscopic technique of HS remplissage associated with Bankart repair. This can provide a filling effect into the engaging humeral head defect, by performing a capsulotenodesis of the infraspinatus. Some studies have already confirmed that simultaneous Bankart repair with the remplissage procedure for engaging HS can provide lower recurrence rates compared to Bankart repair alone.<sup>17–19</sup>

The present study aimed to determine whether arthroscopic remplissage with Bankart repair is an effective treatment for improving outcomes for highrisk collision athletes with Bankart and 'non-engaging' Hill-Sachs lesions.

# **Materials and Methods**

The present study comprises a retrospective analysis of collision athletes who underwent arthroscopic management of combined non-engaging HS and Bankart lesions between 2009 and 2014. The inclusion criteria were: (i) primary or recurrent traumatic anterior instability in professional collision athletes; (ii) Bankart lesion with non-engaging HS defect at dynamic intra-operative assessment; and (iii) no substantial glenoid bone loss (< 20%). Exclusion criteria were: (i) revision surgery; (ii) multidirectional or voluntary instability; (iii) unstable painful shoulder; (iv) no HS lesion; (v) humeral avulsion of the glenohumeral ligament (HAGL) or rotator cuff tear; and (vi) hyperlaxity, psychological conditions or epilepsy. All patients gave their agreement prior to enrolment and the study was approved by our local hospital institutional review board. We identified 22 professional athletes who underwent arthroscopic Bankart repair and remplissage, although one patient was lost to follow-up and another patient was excluded as a result of incomplete data. Twenty patients were available for analysis [arthroscopic Bankart repair with posterior capsulotenodesis (B&R) group] and there were 18 males and two females with a mean age of 25 years (range 15 years to 40 years), operated on from 2012 to 2014, with a mean follow-up of 26 months (24 months to 43 months).

#### Clinical evaluation

All patients were evaluated pre-operatively, at 4 weeks, 8 weeks, 6 months and every year postoperatively. Active range of movements (ROM) were measured pre-operatively and postoperatively, with anterior forward elevation (AFE), external rotation elbow at side (ER1) and at 90° of abduction (ER2), and internal rotation with level of the thumb on the spine (IR1) and at 90° of abduction (IR2). Stability was assessed using the relocation test and the apprehension test, with the arm in the ABER position (abduction and external rotation). Sulcus sign was used to rule out hyperlaxity and O'Brien's test for superior labrum anterior and posterior (SLAP) tears. The recurrence was recorded when patients reported signs of subluxation, one or more frank dislocations, or at least one episode of dead arm syndrome. Objective functional results were evaluated with pre- and postoperative Western Ontario Shoulder Instability (WOSI), EuroOOL five dimensions (EQ-5D), EuroQol-visual analogue scale (EQ-VAS) scores. Subjective results were based on postoperative pain (VASp), instability (VASi), stiffness (VASs) and strength (VASst) for Visual Analogue Scores scale and Subjective Shoulder Value (SSV), ranging from 0% to 100%. Return to play (RTP) and sport level were also documented.

#### Radiographic evaluation

Pre-operatively, plain radiographs (anteroposterior, lateral and axillary views) and a computed tomography scan (with three-dimensional reconstruction) or an arthro-magnetic resonance imaging (MRI) scan were systematically used to assess bone defects and soft tissue injuries. Postoperatively, plain radiographs were performed at each review to follow the radiographic evolution of absorbable anchors used for the Bankart repair and the Hill-Sachs remplissage. Signs of osteolysis around the anchors were carefully analyzed. Glenohumeral osteoarthritis was classified in accordance with the Samilson and Prieto classification.<sup>20</sup>

#### Comparison with matched group

Our database was used to create a control group. After applying the same patient demographics and follow-up period, all imaging studies and operative notes were reviewed to apply our strict criteria. Finally, all patients with incomplete data were excluded and we compared the clinical outcomes (recurrence and re-operation rates, RTP) with a historical group of 20 matched collision athletes (all males) who had undergone isolated Bankart repair (B group) between 2009 and 2013. The mean age was 25 years (range 18 years to 32 years), with a mean follow-up of 29 months

Table	Ι.	Patients'	demographics	of	both	groups.
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	B&R group	B group
Number of patients	20 patients (18 males, 2 females)	20 patients (20 males)
Mean age	25 years (15 years to 40 years)	25 years (18 years to 32 years)
Operated side	12 right, 8 left side (60% dominant)	5 right, 15 left side (45% dominant)
Injury	8 primary, 12 recurrent instability	9 primary, 11 recurrent instability
Pre-operative mean number of instability	subluxation 5.8 (1 to 30), dislocation 1.9 (1 to 7)	subluxation 5.5 (1 to 21), dislocation 2 (1 to 8)
Labral lesions	II Bankart, 9 ALPSA lesion	18 Bankart, 2 ALPSA lesion
Associated lesions	3 associated SLAP lesion	5 associated SLAP lesion
Calandra grades of Hill Sachs defect	13 grade 2, 7 grade 3	15 grade 2, 5 grade 3
Mean time to surgery	7.2 weeks	8.6 weeks
Mean number of anchors	3.9 (2 to 5)	3.1 (2 to 5)
Mean follow-up time	26 months (24 months to 43 months)	29 months (25 months to 47 months)

B&R, Bankart and remplissage; B, Bankart; ALPSA, anterior labroligamentous periosteal sleeve avulsion; SLAP, superior labral anterior posterior tear.

(range 25 months to 47 months). There were no significant differences in the demographic data between the two groups (Table 1).

The statistical analysis was performed using Prism, version 5.0 (GraphPad Software Inc., San Diego, CA, USA). The chi-squared test was used to analyze differences between the categorical data. The level of significance was set at p < 0.05.

# Surgical technique

All procedures were performed by the senior surgeon, with patients in beach-chair position, under an interscalene nerve block with/without intravenous sedation or general anaesthesia. The operated arm was draped freely and the load-and-shift and sulcus sign test were performed in both shoulders, to check translations and general laxities. The 30° arthroscope was inserted into the glenohumeral joint through a standard posterior viewing portal. An anterior working portal was created over the superior edge of the subscapularis tendon as laterally as possible. An 8.5-mm cannula was inserted and a probe introduced to assess the integrity of the labrum. The entire joint was inspected thoroughly to assess the glenoid bone loss (based on the bare spot), to diagnose associated SLAP tears and exclude posterior labral lesions, HAGL lesions, chondral defects or rotator cuff tears. The HS defects were classified

arthroscopically according to Calandra grading<sup>21</sup> (grade I = lesion in the articular surface only; grade bone involvement, II = subchondral and grade III = large defect of the subchondral bone). Intraoperatively, the translation of the glenohumeral joint was assessed dynamically in different positions of arm abduction and external rotation, to determine the presence of the 'engaging' nature of the HS lesion.<sup>14</sup> An additional anterosuperior working portal was created superiorly in the rotator interval, and a 7-mm cannula was inserted. Then, the entire capsulolabral complex was fully mobilized medially, from the base of the anterior glenoid neck. The previously described 'Flying Swan technique'22 was performed for the Bankart repair and capsular shift, using Bioraptor Knotless or SutureFix anchors (Smith & Nephew Endoscopy, Andover, MA, USA). In the historical B-group, the Kinsa (Smith & Nephew Endoscopy, Andover, MA, USA) or the Bioknotless anchors (DePuy-Mitek, Raynham, MA, USA) were used. When present, a SLAP lesion was repaired with one or two additional anchors.

Then, for the remplissage procedure (only B&R group), the arthroscope was switched from posterior to anterior portal and the accessory posterolateral portal was created with a spine needle oriented perpendicular to the HS lesion. A posterior to anterior manual translation of the humeral head enhanced the view and the access to the posterior chamber. A working 7-mm cannula was inserted, the HS lesion was abraded until bleeding surfaces and one double-loaded absorbable Healicoil anchor (Smith & Nephew Endoscopy) was placed in the valley of the defect through transtendinous passage. Then, with the help of a penetrating grasper, superior and inferior mattress sutures were made and tied through the posterior aspect of the capsule and the infraspinatus tendon, creating a posterior capsulotenodesis. Finally, after switching back the arthroscope in the posterior portal, all repairs were checked (the Bankart repair with capsularshift with/ without remplissage).

#### Postoperative care

The rehabilitation was standardized in both groups. The operated arm was placed in a sling, in internal rotation, for 4 weeks, with elevation up to  $90^{\circ}$ , external rotation to neutral position and only isometric exercises were allowed. Then, for another 4 weeks, a progression to full range of movement was initiated, with formal physiotherapy and isokinetic strengthening. After 8 weeks, once the strength was symmetrical and comparable to the other arm, dynamic weights and further conditioning for return to sport were supervised. Contact sports activities were not allowed usually until the third month, or until (i) the operated shoulder was pain-free; (iii) there no apprehension clinically; and (iii) a trial of contact in training was successful.

# Results

# Overall functional results

The mean WOSI, EQ-5D and EQ-VAS scores improved from 41.7% to 86.5%, 0.75 to 0.92 and 72.7 to 84.5, respectively, with SSV of 90% (80 to 100).

Outcome scores were good, with low mean VAS scores for pain [VASp: 0.3 (0 to 1)], instability [VASi: 1.3 (0 to 2)], stiffness [VASs: 1.6 (0 to 3)] and strength [VASstr: 2.3 (0 to 4)]. Comparing active range of movements pre-operatively and at last follow-up, there were no major differences and the deficit in the mean external rotation elbow at side and at 90° of abduction was of 10° (0° to 15°) and 2° (0° to 5°), respectively (p > 0.05) (Table 2).

#### Complications

No iatrogenic postoperative complications were reported. Three patients had initial pain in extreme ROM of the shoulder but only one patient described some persistent posterior discomfort in shoulder rotations beyond the second month after the surgery and the MRI identified no significant abnormalities. Five patients had initial weakness but no final decrease in subjective muscle strength after the second month postoperatively. Five patients had initial stiffness but only one contact athlete had residual pain-free mild stiffness with full AFE, ER1 of 45°, although without affecting sport activities. All of these initial symptoms were commonly associated with recurrent instabilities (68%) and ALPSA (anterior labroligamentous periosteal sleeve avulsion) lesions (64%). Another patient was treated successfully with fluoroscopic-guided intraarticular hydrodilatation and steroid injection for frozen shoulder at 3 months postoperatively. One patient had transient axillary nerve palsy following the initial traumatic dislocation, which fully recovered without any effect on clinical outcomes or RTP.

#### Radiographic analysis

At final follow-up, no patients had signs of osteoarthritis or osteolysis around the anchors.

Table 2. Range of movements.						
ROM	Pre-operative	Postoperative at last follow-up	Mean difference			
AFE (°)	170 (150 to 175)	167 (155 to 170)	3			
ERI (°)	75 (45 to 80)	65 (40 to 70)	10			
ER2 (°)	85 (65 to 90)	83 (60 to 90)	2			
IR2 (°)	75 (60 to 80)	72 (60 to 75)	3			
IRI (level)	Т6	Т7				

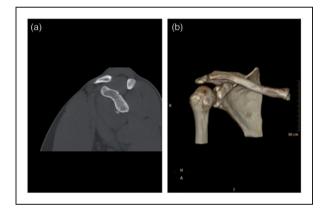
AFE, active forward elevation; ER1, external rotation elbow at side; ER2, external rotation in  $90^{\circ}$  of abduction; IR1, internal rotation determined by the level of the thumb on the spine; IR2, internal rotation in  $90^{\circ}$  of abduction.

#### Table 2. Range of movements.

	B&R group	B group	Þ
Persistent apprehension	0%	5% (one patient)	0.3 (NS)
Recurrence	5% (one patient)	30% (six patients)	0.015
Reoperation	5%; one patient: open corac- oid transfer at 8 months	35%; seven patients:	0.005
		Two arthroscopic revision at 3.5 months and 6 months	
		Four open coracoid transfer at 2 years	
		One interposition arthro- plasty at 3 years for OA	
RTP at same level	100% at the mean of 13 weeks (10 weeks to 18 weeks)	90% at the mean of 13 weeks (10 weeks to 16 weeks)	0.14 (NS)

#### Table 3. Comparative data with matched group.

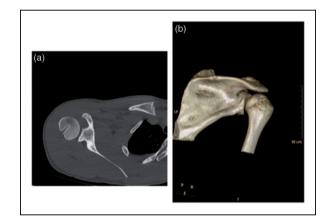
B&R, Bankart and remplissage; B, Bankart; NS, not significant; OA, osteoarthritis; RTP, return to play.



**Figure 1.** (a) Sagittal computed tomography image of the glenoid and (b) three-dimensional reformat reveal another small bony Bankart lesion following a traumatic redislocation in the arthroscopic Bankart repair with posterior capsulotenodesis group.

# Comparison with matched group (recurrence and re-operation rates, as well as RTP)

We have summarized the comparative data in Table 3. There were statistically significant differences in recurrence (p = 0.015) and re-operation (p = 0.005) rates between the B&R and B groups. There was only one patient in B&R group who had a traumatic re-dislocation at 8 months postoperatively, following re-injury when playing rugby at the same level. Three weeks later, he underwent a diagnostic arthroscopy,



**Figure 2.** (a) Axial computed tomography image of the shoulder and (b) three-dimensional reformat show the previous Hill-Sachs remplissage without any sign of re-injury in the same shoulder.

which revealed failure of the anterior reconstruction but intact remplissage and a more medially located new Hill-Sachs lesion (grade 1) (Figures 1 and 2). Open coracoid transfer with the congruent arc technique was performed successfully with RTP again at 10 weeks. Six unstable B group patients (one subluxation, five dislocations) underwent revision surgery without any complication. All of them were stable with no apprehension at final follow-up and successful RTP. One other patient in B group underwent arthroscopic interposition arthroplasty for osteoarthritis 3 years after the stabilization surgery, with moderate success. There was no statistically significant difference in the return to sport activities between the two groups. 100% of patients in the B&R group participated actively in professional contact sport at the same level, whereas only 90% (18) patients of B group managed to return to the same level of collision sport. One patient with persistent apprehension sign but without subluxation or dislocation failed to return to rugby at the same level. Another patient, who sustained a permanent axillary nerve lesion at the time of the primary dislocation, failed to participate in any sport activities postoperatively because this proved to be a career-ending injury.

## Discussion

The results of the present study confirm that arthroscopic Bankart repair alone did not provide the stabilization necessary to prevent further instability in high-risk contact sport patients, even in the case of non-engaging HS lesions.

In a comparative study, Yamamoto et al.<sup>11</sup> reported that the recurrence rate of contact athletes was two times higher in the open repair group and three times higher in the arthroscopic repair group compared to noncontact athletes; however, this was not statistically significant.

The literature also reports<sup>5,10,23</sup> that young male patients, contact athletes and patients who have had several dislocations may be regarded as high-risk populations. These may benefit from bone block procedures or more secure soft tissue reconstructions, the so-called 'arthroscopic plus' procedures, rather than the traditional single-row anterior stabilization technique.

The technically challenging double-row labral repair method has been described in several studies that report satisfactory results and a lower redislocation rate.<sup>24,25</sup> It has also been confirmed, in two cadaveric models,<sup>26,27</sup> that the footprint surface area of the native capsulolabral complex was significantly better re-created with double-row fixation, compared to single-row fixation.

For more robust labral fixation, other arthroscopic techniques have been described to achieve a more uniform load distribution of the entire labrum.<sup>22,28</sup> Although no proven superior clinical outcomes have been published yet, they are possibly more secure compared to classic techniques, in which the labrum is fixed only with 'spot welds' at each anchor. The labral bridge technique uses a LabralTape (Arthrex, Naples, FL) to secure the torn labrum to the glenoid between each suture anchor, for better pressure distribution.<sup>28</sup> We used a similar 'Flying Swan' technique,<sup>22</sup> which also relies on producing a kind of soft tissue seal, with a 'double-mattress suture bridge' medial to the glenoid margin. This augments the buttress effect of the labrum and improves contact and potentially healing

process between the capsulolabral tissue and the bone between the anchors.

Maiotti et al.<sup>29</sup> also reported results of the capsulolabral repair with subscapularis tenodesis augmentation, for patients with small glenoid bone loss and any size of HS lesion. The redislocation rate was 3.4%, with a mean deficit of ER1 of 6° and ER2 of 3°, which is very similar to the clinical results reported in the present study.

Recently Tennent et al.<sup>30</sup> described the technique of arthroscopic conjoint tendon transfer, which can provide a dynamic sling effect additional to the traditional labral repair, for patients without significant anteroinferior glenoid bone loss (<15%).

Burkhart and De Beer<sup>14</sup> reported the concept of significant bone defects either on the humerus or the glenoid and also described the 'engaging' Hill-Sachs lesions. Burkhart and De Beer<sup>14</sup> also highlighted that the onesided restoration of the soft tissues alone with Bankart repair would not be adequate in these cases. The importance of a bipolar fixation in anterior instability with Bankart and HS lesions was emphasized after the concept of glenoid track with 'on-track' and 'off-track' humeral head defects proposed by Yamamoto et al.<sup>31</sup> and then investigated further by Di Giacomo et al.<sup>32</sup>

Filling of the engaging HS lesions with arthroscopic tenodesis of the infraspinatus and the posterior capsule into the defect, as described by Wolf and Pollack,<sup>15</sup> can be performed to prevent recurrent instability. Although the remplissage with Bankart repair procedure has had increasing acceptance, there are still some concerns about postoperative stiffness and especially external rotation loss.<sup>33–35</sup> However, the biomechanical study of Argintar et al.<sup>36</sup> showed that the Bankart repair restored all ER to normal values at 0° and 60° abduction, and the addition of the remplissage procedure did not significantly alter the overall ROM and the anteroposterior translation. In our series, we also found that remplissage is safe and it did not impair the overall ROM or the function of the infraspinatus muscle and the slight restriction in ER1 does not significantly affect any clinical outcomes and RTP in the collision athletes.

The recurrence rate after arthroscopic Bankart repair with remplissage for engaging HS lesions is reported as being less than 10% in the literature.<sup>16,23,33,37</sup> A few other studies<sup>17–19</sup> compared the two procedures (isolated arthroscopic Bankart repair versus remplissage with Bankart repair) for patients with engaging HS lesions, and confirmed lower recurrence rates with the combined technique.

Most studies have focused solely on the management of engaging HS lesions with remplissage but, regardless of the location and the size, all Hill-Sachs lesions, including those classified as 'non-engaging', have to be engaged at least once to be created.<sup>38,39</sup> It is also important to note that the posterior musculotendinous structures may be injured along with the anteroinferior structures and undergo plastic deformation; thus, a traditional one-sided anterior capsulolabral complex repair may not provide the expected results, especially in high-risk athletes. Because quantifying these posterior lesions is difficult, the so-called 'bipolar fixation' with combined arthroscopic Bankart stabilization with remplissage can be useful. Kany et al.<sup>38</sup> reported the results of this bipolar fixation with a recurrence rate of 3.85%, which was used even in the case of no HS lesions when the posterior capsulotenodesis was performed on the bare area of the humeral head. Similarly, the aim of the present study was to investigate whether arthroscopic remplissage with Bankart repair can improve outcomes for 'non-engaging' HS lesions and we also report only 5% of recurrence rate in professional contact athletes. As in a previous study by Park et al.,<sup>40</sup> this may be because, in the case of recurrence, the remplissage still showed almost complete filling of the previous HS defect, even with a failed anterior Bankart repair, which we also confirmed during revision arthroscopy. The redislocation rate was significantly higher in the historical control group (B group), which is likely multifactorial. We tried to eliminate confounding factors (matched groups with the same 'Flying Swan' technique), although other possible reasons are: (i) different levels of surgical experience; (ii) other types of anchors; (iii) no remplissage was performed; and (4) the use of standardized but possibly different rehabilitation protocols.

# Study limitations

There are several limitations to the present study. (i) This was a retrospective analysis not a randomized trial, and the mean follow-up period was relatively short. (ii) The glenoid bone loss was not accurately measured with well-accepted pre-operative imaging methods. (iii) The size of HS lesion was not accurately measured volumetrically with cross-sectional imaging. (iv) Inter-observer variability exists in the dynamic assessment of the engagement of a HS lesion during arthroscopy. (v) Our data were compared with a historical group of patients and different anchors were used for labral fixation, which may have influenced our results.

The present study has several strengths as well. (i) All patients in this series were operated on by a single upper limb surgeon, with the same indication, surgical technique and standardized rehabilitation protocol, thereby reducing the variability of the clinical results. (ii) The arthroscopic evaluation of the glenoid defect based on the bare spot<sup>41</sup> and the Calandra grading<sup>21</sup> of the size of HS defect were systematically performed,

aiming to minimize the potential confounding role of glenoid and humeral bone loss in our interpretation. (iii) We selected an appropriate, comparable historical group of patients, with specific parameters and strict criteria. (iv) Although this limited our ability to obtain large cohort for both groups as similar-sized non-engaging HS lesions were needed to compare and demonstrate the additional role of adding the remplissage procedure to an arthroscopic Bankart repair, in terms of preventing recurrent instability.

# **Conclusions**

The present study has demonstrated an increased prevalence of recurrence with Bankart repair alone and a trend toward improved failure rates with the remplissage procedure for professional collision athletes with Bankart and 'non-engaging' HS lesions in the absence of significant glenoid defects. We consider that the additional remplissage tenodesis plays a crucial role in the increased stability in the case of moderate to large non-engaging HS lesions, and one-sided traditional Bankart repair will not provide the necessary stabilization to prevent failures in high-risk patients possibly as a result of the plastic deformation of posterior structures. In the present study, remplissage was confirmed to be a safe and effective method, without any significant complications affecting professional contact sport activities. Our relatively short-term follow-up does not exclude the occurrence of degenerative changes and other complications in the long-term and future investigations are necessary to further clarify the indication and the pros and cons of the remplissage procedure in anterior shoulder instability.

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#### **Declaration of Conflicting Interests**

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The authors declare that Andrew L. Wallace is acting as a teaching consultant and surgeon mentor for Smith & Nephew, Inc. There are no other conflicts of interest.

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#### **Ethical Review and Patient Consent**

All patients gave their agreement prior to enrolment and the study was approved by the local hospital institutional review board.

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