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Remplissage yields similar 2-year outcomes, fewer complications, and low recurrence compared to Latarjet across a wide range of preoperative glenoid bone loss

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Title: Remplissage yields similar 2-year outcomes, fewer complications, and low recurrence compared to Latarjet across a wide range of preoperative glenoid bone loss

Running Title: Remplissage vs Latarjet

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ABSTRACT

Purpose:

The purpose of this study was to compare functional outcome, return to sport, satisfaction, postoperative recurrence, and complications in patients undergoing primary arthroscopic Bankart repair with remplissage (ABR) to primary Latarjet.

Methods:

A multicenter retrospective study was performed on patients undergoing primary ABR or open Latarjet between 2013 and 2019 who had minimum 2-year follow-up. Baseline and two-year range of motion (ROM), patient-reported outcomes (PROs: Western Ontario Shoulder Instability Index [WOSI], Single Assessment Numeric Evaluation [SANE], and visual analog scale [VAS] for pain) recurrence, return to sport, satisfaction, and complications were reviewed.

Results:

This study included 258 patients, including 70 ABRs and 188 Latarjet. Baseline demographics, ROM, and PROs were similar. Mean preop glenoid bone loss (GBL) (12.3% +/- 10.9% vs 7.6% +/- 9%; $P<0.001$) and off-track lesions (23% vs 13%; $P=0.046$) were higher in the ABR group while preoperative GBL range was similar (0-42% vs 0-47%). Change in VAS (1.9 vs 0.9; $P=0.019$) and WOSI (1096 vs 805; $P<0.001$) were improved in ABR. Percent achieved MCID was improved in WOSI for ABR and PASS for ABR in SANE, VAS, and WOSI scores. The ABR cohort had worse change in external rotation (ER) (-4° vs $+19^{\circ}$; $P<0.001$). Return to sport amongst overhead and contact athletes favored ABR (91.5% vs 72.7%; $P=0.007$). Satisfaction and recurrent dislocation were similar. Surgical complications were observed in 0% of ABR cases, compared to 5.9% in the Latarjet group.

Conclusion:

Primary ABR resulted in 2-year functional outcomes that were as good or superior to primary Latarjet, with higher return to sport for overhead and contact activities, fewer complications, and

comparably low recurrence rates, even despite greater bipolar bone loss in the ABR cohort.

However, this comes at the expense of decreased external rotation which may be considered in individual patients.

Level of Evidence: Retrospective comparative study, III.

Key Words:

Shoulder instability, Glenohumeral dislocation, Bankart, Remplissage, Latarjet, Glenoid bone loss, Hill-Sachs lesion, On-track, Off-track

Introduction

Anterior glenohumeral instability is the most common form of shoulder instability.^{1,2} It leads to injury to the anteroinferior glenoid and capsulolabral complex (Bankart lesion) along with causing frequent glenoid bone loss (GBL) and Hill-Sachs defects.^{1,3,4} The ideal surgical management for anterior glenohumeral instability, particularly with associated bone loss, remains a subject of debate.

Burkhart, Yamamoto, DiGiacomo and others have advocated for treatment based on glenoid bone loss combined with categorization of on-track and off-track lesions to guide the use of remplissage in the setting of subcritical bone loss.^{5,6,7} While once defined as 25%, the definition of critical bone loss of the glenoid has gradually decreased based on reports that isolated arthroscopic Bankart repair may be suboptimal at ever-decreasing GBL rates.^{3,8,9,10,11} The most common options beyond Bankart repair include the addition of remplissage or Latarjet. Those who favor remplissage often cite the invasiveness and complications of the Latarjet,¹² while Latarjet advocates often tout the triple effect it creates^{13,14,15} as well as the possible decrease in external rotation following remplissage.^{16,17,18,19} Most studies comparing remplissage to Latarjet have focused on patients with off-track lesions and have presented mixed results with regard to ROM and functional outcomes.^{20,21,22,23,24}

The purpose of this study was to compare functional outcome, return to sport, satisfaction, postoperative recurrence, and complications in patients undergoing primary arthroscopic Bankart repair with remplissage (ABR) to primary Latarjet. The hypothesis was that no differences would be noted between the two surgical interventions.

Materials and Methods

A multicenter retrospective review was performed of prospectively collected data between 2013 and 2019. Inclusion criteria included primary surgery for anterior glenohumeral instability managed with either ABR or open Latarjet, and a minimum follow-up of 2 years postoperative. Exclusions included those not entering the outcomes registry, revision surgery, and lack of baseline and postoperative functional outcome data. Glenoid and humeral bone loss were neither stratified nor excluded. All levels of GBL were included in the study. Each patient was independently evaluated by the individual surgeon who obtained history, physical, and imaging data in their own clinical practice and determined the need for surgery without a pre-determined algorithm to guide treatment. Data was collected in a prospective fashion by individual surgeons and later compiled into a unified data collection set for statistical analysis. Institutional review board approval was obtained prior to commencing the study.

Surgical Technique

Surgeries were performed by 4 different surgeons at 4 different institutions. Treatment choice was based on surgeon preference. The four treating surgeons operated in 3 different continents but had completed the same arthroscopic shoulder fellowship representing a similarity in surgical technique.

ABR was performed by 3 of the 4 surgeons (PN, AL, PJD). The technique included three to four anchors for the Bankart repair and two anchors for the remplissage. A mixture of knotted, knotless, and hybrid techniques was utilized based on surgeon preference. During remplissage, care was taken to pass sutures through the tendon and capsule only to avoid muscular damage to

the posterior rotator cuff.²⁵ Postoperatively the shoulder was placed in a sling for six weeks. The sling was then discontinued and ROM and strengthening activities were commenced. Sports, contact or non-contact, were initiated at six months postoperative.

Open Latarjet was performed by all four surgeons (PN, AL, JB, PJD). The patients were placed in the beach chair position and a deltopectoral approach was utilized. The subscapularis was managed with a split in all cases. The coracoid was then transferred to the anterior glenoid with inferior surface flush to the glenoid, and secured with two screws.²⁶ Prior to closure the coracoacromial remnant was sutured to the capsule in an extra-articular fashion. The patient's postoperative rehabilitation and return to sport differed from ABR. The patients were placed in a sling for 2 weeks. The sling was discontinued and ROM and strengthening activities were initiated. Non-contact sports were commenced at six weeks and contact sports began at three months.

Clinical Assessment

Baseline demographics recorded included gender, age, hand dominance, arm involved, and level of activity. Preoperative external rotation (ER) at the side, forward flexion (FF), and internal rotation (IR) to the nearest estimated spinal level were measured by the treating surgeon at each site. Patient-reported outcome measures (PROs) including visual analog scale (VAS) for pain, Western Ontario Shoulder Instability Index (WOSI), and Single Assessment Numeric Evaluation (SANE). Functional outcomes were then reassessed at 2-year follow-up. Final follow-up information also included return to sport, satisfaction, and recurrent instability and complication rates.

Bone Loss Assessment

Bone loss assessment included GBL, the Hill-Sachs lesion depth (HSD), Hill-Sachs interval, and subsequent calculation of on-track or off-track lesions. Assessment was performed by the treating surgeon based on preoperative computed tomography or magnetic resonance imaging scans as previously described^{6,27} and/or intraoperative assessment with a calibrated probe.^{5,6} Advanced imaging was used for glenoid bone loss and glenoid track calculations in 100% of ABR cases and 94.7% of Latarjets, while intra-operative measurements were used for calculations 5.3% (10 cases) of the Latarjets due to lack of availability of preoperative imaging.

Statistical Analysis

To compare baseline characteristics and outcomes between the ABR and Latarjet cohorts, Pearson chi-square tests were used for categorical variables and independent samples T-tests were used for continuous variables. Paired T-tests were performed to compare absolute preoperative and postoperative ROM and PRO scores within groups, as well as relative improvement over time. Continuous variables were presented in terms of the mean and standard deviation (SD), and categorical variables were reported with frequencies and percentages.

Statistical tests were 2-sided with $P < 0.05$ denoting statistical significance.

The minimal clinically important difference (MCID) was determined using a distribution-based method of one-half the SD of the difference between preoperative and postoperative outcome scores. To quantify the outcome threshold scores for achieving patient acceptable symptom state (PASS), patients were asked at the 2-year follow-up if they were satisfied with their current state,

taking into account their activities of daily living, level of pain, and functional impairment. The PASS was determined using a receiver operating characteristic (ROC) curve analysis.

Results

A total of 258 patients met the study criteria and were available for follow-up at an average of 2.5 years postoperative (range 2 to 4.5 years). The cohort included 70 ABRs and 188 Latarjets. Baseline demographics showed similarity in age, gender, athletic participation and preoperative function except for internal rotation which was higher in the ABR group (Table 1). ABR patients were more likely to undergo MRI (78%) and Latarjet patients were more likely to undergo CT (62%). The ABR group had higher preoperative GBL (12.3% +/- 10.9% vs 7.6% +/- 9.0%; $P<0.001$), Hill-Sachs Interval (15.6mm +/- 3.7 vs 13.5mm +/- 3.7; $P=0.003$), Hill-Sachs Depth (8.7mm +/- 3.8 vs 3.9mm +/- 2.6; $P<0.001$), and rate of off-track lesions (22.9% vs 12.8%; $P=0.046$). Glenoid track size was decreased in size for ABR (19.3mm +/- 4.5mm vs 20.7mm +/- 3.2mm; $P=0.024$). Range of preoperative GBL (0-42% vs 0-47%) and interquartile range (3.7-17.9% vs 0-11%) were similar.

Minimum 2-year postoperative PROs were improved in both cohorts. The SANE, VAS, and WOSI scores were all higher for the ABR patients, and the change in these scores was significantly higher for VAS pain and WOSI scores (Table 2, Figure 1). Percent achieved MCID was improved in WOSI (100% vs 93.1%; $P=0.033$) for ABR and percent achieved PASS was improved for ABR in SANE (100% vs 75.5%; $P<0.001$), VAS (91.2% vs 76.7%; $P=.010$), and WOSI (98.5% vs 81.1%; $P<0.001$) scores. (Table 5) With regards to ROM, both groups had

similar improvements in FF and IR, but ABR patients had worse change in ER (-4° vs $+19^{\circ}$, $P<0.001$) (Table 3).

Overall return to sport was similar between the groups, but return to sport among overhead or contact athletes favored ABR (91.5% vs 72.7%; $P=0.007$). There was no difference in satisfaction (95.7% vs 89.7%; $P=0.195$) or recurrent dislocation between groups (1.4% vs 3.2%; $P=0.68$). Of note, return to sport (86%) and satisfaction (87%) data were incomplete amongst the participants. Surgical complications were observed in 0% of the ABR cases, compared to 5.9% in the Latarjet group (Table 4).

Discussion

The primary findings of the current study were that functional outcomes were as good or superior following ABR compared to open Latarjet despite a higher severity of bony lesions in the former. Additionally, return to sport in overhead and contact athletes was higher, recurrence was equivalent, and complications were lower following ABR compared to Latarjet. However, patients in the ABR group had lower postoperative ER compared to the Latarjet group. These findings add to the growing body of evidence noting that primary arthroscopic Bankart repair with remplissage is as effective as Latarjet in reducing recurrence, but has a lower complication compared to Latarjet.

It is well-established that both ABR and Latarjet decrease redislocation rates.^{3,24} In a systematic review of 194 ABRs and 185 Latarjet, for instance, the rates of recurrent instability were 9.8% and 7.0% respectively ($P=0.0004$).²⁴ Similarly, the rate of recurrence in the current study was

equivalent between groups (3.2% vs 1.4%; $P=0.678$). Interestingly, this was despite a higher amount of glenoid bone loss and rate of off-track lesions in the ABR group. MacDonald et al. recently reported a similar 4% ABR dislocation rate in a randomized controlled trial of engaging Hill-Sachs lesions at 26 months. In a matched analysis of collision athletes, Domos et al. reported that recurrence was higher with isolated Bankart repair compared to ABR (30% vs. 5%; $P=0.015$) at a similar 26 months.²⁹ They did not report mean GBL but excluded patients with > 20% GBL. While critical bone loss requiring bony reconstruction has been reported to be as little as 13.5%,³ these findings suggest that there is a role for ABR in patients with moderate GBL. Further study is needed to compare ABR to Latarjet solely in patients with high degrees of bone loss.

Non-instability related complications tend to be increased with Latarjet compared to ABR.^{22,24,30} In the aforementioned systematic review the relative risk for complications following Latarjet was 7.37 times higher compared to ABR with an overall complication rate of 9% vs 1% ($P=0.003$).²⁴ Conversely, Yang et al. specifically evaluated revision non-instability procedures and noted an increase for ABR patients (13.3% vs 4.4%; $P=0.04$) with these procedures mainly including glenohumeral debridement and subacromial decompressions.³⁰ Our study did not note any revision for ABR, but it redemonstrates the preferable ABR complication rate (0% vs 5%; $P=N/A$). Our ABR data is similar to the Lazarides et al. systemic review which reported a complication rate of <1%.⁸ Common complications following Latarjet complications include hematoma, infection, neuropraxia, hardware and healing-related issues.^{12,22,24,26,30} The 5% complication rate in our Latarjet group is similar to Burkhart et al.'s Latarjet series who also reported a 5% complication rate.²⁶ Thus, the Latarjet's inherent invasiveness along with surgical

difficulty and reliance on bony healing are likely what leads to its increased complication rate in comparison to ABR.¹² ROM may differ following ABR compared to Latarjet. In particular, one concern with remplissage is the potential for loss of postoperative ER.^{16,17,18,19} Though reported results have been mixed, increased stiffness may play a part in the low dislocation rates for ABR. In a biomechanical study Degen et al. noted a greater decrease in ER with the arm in abduction following ABR compared to Latarjet (16° vs 34° ; $P=0.043$), but no difference in ER with the arm adducted.²³ Clinically, neither Cho et al. or Yang et al. found significant differences in ER whether abducted or adducted.^{22,30} On the other hand, Bah et al. noted decreased ER in adduction (45° vs 56° ; $P<0.001$) and abduction (63° vs 72° ; $P<0.001$) with ABR compared to Latarjet.²¹ Similarly, in the current study we noted a 4° loss of ER in the ABR group and a 19° gain of ER in the Latarjet group. This should be considered in those requiring complete ER recovery. A recent study evaluating ABR versus Bankart alone noted a 10° ER in abduction deficit at 12 months for ABR, but this was corrected by the 24-month timepoint.²⁸ Interestingly, Yang et al. reported decreased IR with arm in abduction following ABR compared to Latarjet (40° vs 53° ; $P=0.006$).³⁰ In our series, both ABR and Latarjet cohorts gained one level of IR ($P=0.456$), although we did not measure ROM in abduction. Forward flexion was also noted to be similar in our study between the interventions. The heterogeneity noted between the previous studies and ours could be a result of surgical technique, surgical indications, and differences between clinical measurements. Long-term studies are needed to evaluate ROM based on both types of treatment and specifically to evaluate for consequences of loss of ER such posterior rotator cuff atrophy or early onset arthritis

Some studies have reported lower postoperative VAS pain scores following ABR compared to Latarjet, including Bah et al. (1.8 vs 2.8, $P < 0.001$) and Yang et al. (2.4 vs 1.6, $P = 0.041$).^{20,30} However, in a systematic review no statistically significant difference was observed (95% CI, -0.6 to 0.2, $P = 0.3$).¹⁸ Our results favored ABR (-1.9 and -0.9; $P < 0.001$).³¹ In contrast to Nourrissat and al., we did not observe significant postoperative posterior pain in the ABR group.¹⁸ However, this could be explained by our study's retrospective design, our technique, and the possibility that posterior pain following remplissage is a temporary phenomenon and disappears by 2 years postoperative. Yang et al. also reported no difference in postoperative WOSI scores (411 vs 352, $P = 0.164$) or SANE scores (88.4 vs 85.3, $P = 0.111$). Similarly, we did not observe differences in postoperative SANE scores ($P = 0.185$). While our WOSI scores (334.0) were similar to Yang et al. following Latarjet, we observed better scores in the ABR group (62.6) and the difference between our groups was statistically significant ($P < 0.001$).

Few studies have directly compared return to play following ABR compared to Latarjet. In a systemic review of 609 patients Abdul-Rassoul et al. reported an 83.6% rate of return to sport for Latarjet of 83.6% compared to 95.5% for ABR.³² In the current study preoperative participation in overhead or contact sports (68.6% ABR vs 78.7% Latarjet; $P = 0.09$) was similar. Postoperative return to sport was similar overall but higher following ABR in overhead and contact athletes (91.5% vs 72.7%; $P = 0.048$). This is somewhat of a counterintuitive finding as Latarjet is often considered the gold standard for contact athletes. Possible explanations for this include differences in the populations of the 4 surgeons and the difference in how recurrence is prevented between the 2 procedures. It is possible that Latarjet alters glenohumeral kinematics more substantially than ABR. It is also possible that the posterior restraint provided with

remplissage becomes clinically relevant in overhead/contact athletes. Biomechanically it has been demonstrated that ABR can increase stiffness compared to Latarjet.²³ Thus remplissage is not *only* “filling in” the defect, but also repairing/tightening the posterior capsule. This combined with its anterior capsulolabral repair may allow patients to have a more “normal” and natural shoulder that allows them to get back to their activities at the improved rates described above.

Limitations

This study was not without limitation. Our study design was retrospective and treatment choice was based on surgeon preference without a predetermined algorithm which could have led to selection bias. There were likely subtle differences between surgeon clinical assessments and documentation. The assessment of bone loss varied between CT, MRI, and intraoperative assessment. The distribution of MRI and CT use for ABR and Latarjet notably differed and likely affects measurements while also eliciting likely pretest bias for planned surgery.³³ The follow-up was short-term at two years postoperative. It has been demonstrated that recurrence increases with longer term follow-up.³⁴ Our data for return to sport and patient satisfaction were incomplete and attempts to reach out to the participants to complete the data were ineffective. We did not have full data on specific sports being played. Finally, a cost comparison was not practical based on the use of four international sites and therefore we could not assess the value of each procedure.

Conclusion

Primary ABR resulted in 2-year functional outcomes that were as good or superior to primary Latarjet, with higher return to sport for overhead and contact activities, fewer complications, and

284 comparably low recurrence rates, even despite greater bipolar bone loss in the ABR cohort.

285 However, this comes at the expense of decreased external rotation which may need to be

286 considered in individual patients.

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Figure Legends

Figure 1

Graphic illustration of preoperative and postoperative change in patient-reported outcome scores

Table 1. Characteristics of the Study Population

Parameter	All patients	Procedure		<i>P</i>
		Latarjet	Bankart + Remplissage	
Total†	258 (100)	188 (72.9)	70 (27.1)	
Age* (yr)	26.7 ± 9.8	26.8 ± 9.9	26.7 ± 9.3	0.975
Sex†				
Female	41 (15.9)	31 (16.5)	10 (14.3)	0.848
Male	217 (84.1)	157 (83.5)	60 (85.7)	
Participation in overhead or contact sports†	196 (76.0)	148 (78.7)	48 (68.6)	0.090
Glenoid bone loss* (%)	8.9 ± 9.8	7.6 ± 9.0	12.3 ± 10.9	<0.001
Range		0-47%	0-42%	
Interquartile Range		0-11%	3.7-17.9%	
Glenoid Track size (mm)		20.7 ± 3.2	19.3 ± 4.5	0.024
Range (mm)		6.9-25.7	9.4-27.4	
Hill-Sachs size* (mm)				
Interval on axial cut	14.1 ± 6.3	13.5 ± 7.0	15.6 ± 3.7	0.003
Range (mm)		0-30	0-26	
Depth on axial cut	6.3 ± 3.7	3.9 ± 2.6	8.7 ± 3.8	<0.001
Off-track Hill-Sachs lesion†	40 (15.5)	24 (12.8)	16 (22.9)	0.046
Preoperative range of motion*				
Forward flexion (deg)	170 ± 17	171 ± 18	168 ± 15	0.061
External rotation at the side (deg)	65 ± 19	64 ± 20	66 ± 16	0.259
Internal rotation (spinal level)	T9 ± 3	T10 ± 3	T8 ± 2	<0.001
Preoperative patient-reported outcomes*				
SANE	63.2 ± 20.4	62.3 ± 21.5	65.4 ± 17.2	0.137
VAS Pain	2.2 ± 2.2	2.2 ± 2.2	2.2 ± 2.0	0.418
WOSI	1120.3 ± 388.9	1119.7 ± 405.9	1122.1 ± 339.7	0.483

SANE = Single Assessment Numeric Evaluation; VAS = visual analog scale; WOSI = Western Ontario Shoulder Instability Index

*The values are given as the mean and the standard deviation.

†The values are given as the number of patients, with the percentage in parentheses.

Table 2. Minimum 2-Year Postoperative Patient-Reported Outcomes (average follow-up: 2.5 years, range: 2 to 4.5 years)

Outcome*	Latarjet			Bankart + Remplissage		
	Preoperative	Postoperative	Δ	Preoperative	Postoperative	Δ
SANE	62.3 ± 21.5	90.9 ± 12.9	29.5 ± 24.7	65.4 ± 17.2	98.6 ± 3.5	33.5 ± 17.9
<i>P-value within group</i>	-	-	<0.001	-	-	<0.001
<i>P-value between groups</i>	0.137	<0.001	0.185	-	-	-
VAS Pain	2.2 ± 2.2	1.3 ± 2.9	0.9 ± 3.4	2.2 ± 2.0	0.4 ± 0.9	1.9 ± 1.9
<i>P-value within group</i>	-	-	<0.001	-	-	<0.001
<i>P-value between groups</i>	0.418	<0.001	0.019	-	-	-
WOSI	1119.7 ± 405.9	334.0 ± 355.6	805.0 ± 516.5	1122.1 ± 339.7	62.6 ± 214.2	1096.0 ± 340.9
<i>P-value within group</i>	-	-	<0.001	-	-	<0.001
<i>P-value between groups</i>	0.483	<0.001	<0.001	-	-	-

SANE = Single Assessment Numeric Evaluation; VAS = visual analog scale; WOSI = Western Ontario Shoulder Instability Index

*The values are given as the mean and the standard deviation.

Table 3. Minimum 2-Year Postoperative Range of Motion (average follow-up: 2.5 years, range: 2 to 4.5 years)

Range of Motion*	Latarjet			Bankart + Remplissage		
	Preoperative	Postoperative	Δ	Preoperative	Postoperative	Δ
Forward flexion (deg)	171 ± 18	178 ± 10	7 ± 20	168 ± 15	178 ± 10	10 ± 15
<i>P-value within group</i>	-	-	<0.001	-	-	<0.001
<i>P-value between groups</i>	0.061	0.875	0.155	-	-	-
External rotation at the side (deg)	64 ± 20	82 ± 16	19 ± 26	66 ± 16	62 ± 12	- 4 ± 14
<i>P-value within group</i>	-	-	<0.001	-	-	0.012
<i>P-value between groups</i>	0.259	<0.001	<0.001	-	-	-
Internal rotation (spinal level)	T10 ± 3	T9 ± 2	1 ± 4	T8 ± 2	T7 ± 2	1 ± 2
<i>P-value within group</i>	-	-	0.039	-	-	0.017
<i>P-value between groups</i>	<0.001	<0.001	0.456	-	-	-

SANE = Single Assessment Numeric Evaluation; VAS = visual analog scale; WOSI = Western Ontario Shoulder Instability Index

*The values are given as the mean and the standard deviation.

Table 4. MCID and PASS Analysis

Outcome Measure	MCID	MCID, % achieved			PASS	PASS, % achieved		
		Latarjet	Bankart + Remplissage	P		Latarjet	Bankart + Remplissage	P
SANE	11.4	77.6	85.1	0.208	87.5	75.5	100	<0.001
VAS Pain	1.5	48.8	53.8	0.508	1.5	76.7	91.2	0.010
WOSI	244.8	93.1	100	0.033	619.5	81.1	98.5	<0.001

SANE = Single Assessment Numeric Evaluation; VAS = Visual Analog Scale; WOSI = Western Ontario Shoulder Instability Index

SANE = Single Assessment Numeric Evaluation; VAS = Visual Analog Scale; WOSI = Western Ontario Shoulder Instability Index

Table 5. Postoperative Outcomes

Parameter†	Procedure		<i>P</i>
	Latarjet	Bankart + Remplissage	
Overall return to same level of sport^	111 (72.5)	58 (84.1)	0.063
Overhead or contact sports	88 (72.7)	43 (91.5)	0.007
Patient satisfaction*	140 (89.7)	66 (95.7)	0.195
Recurrent dislocation	6 (3.2)	1 (1.4)	0.678
Surgical complication	11 (5.9)	0	NA
Hematoma or infection	2 (1.0)	-	
Painful or loose hardware	6 (3.2)	-	
Neurapraxia	3 (1.6)	-	
†The values are given as the number of patients, with the percentage in parentheses.			
^Data available on 222 patients. *Data available on 225 patients			

