Traumatic anterior shoulder dislocation: a case study of nonoperative management in a mixed martial arts athlete

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Objective: To present an evidence-informed approach to the nonoperative management of a first-time, traumatic anterior shoulder dislocation.

Clinical Features: A 30-year-old mixed martial arts athlete, with no prior shoulder injuries, presented one day following a first-time, traumatic anterior shoulder dislocation. An eight-week, individualized, intensive, nonoperative rehabilitation program was immediately begun upon presentation.

Intervention and Outcome: Management consisted of immobilization of the shoulder in external rotation and a progressive rehabilitation program aimed at restoring range of motion, strength of the dynamic stabilizers, and proprioception of the shoulder. Eight weeks post-dislocation the patient had regained full range of motion and strength compared to the unaffected limb and apprehension and relocation tests for instability were negative.

Conclusion: This case illustrates successful management of a first-time, traumatic, anterior shoulder dislocation using immobilization in external rotation combined with an intensive rehabilitation program.

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KEY WORDS: shoulder, dislocation, rehabilitation

Objectif : Présenter une approche fondée sur des faits vis-à-vis du traitement non chirurgical d’une première dislocation traumatique de la partie antérieure de l’épaule.

Caractéristiques cliniques : Un athlète d’arts martiaux mixtes de 30 ans, sans blessures antérieures à l’épaule, s’est présenté un jour à la suite d’une première dislocation traumatique de la partie antérieure de l’épaule. Un programme de réadaptation non chirurgical intensif et individualisé de huit semaines a commencé immédiatement après l’examen.

Intervention et résultats : Le traitement consistait en une immobilisation de l’épaule en rotation externe et un programme de réadaptation progressif ayant pour but de rétablir l’amplitude des mouvements, la force des stabilisateurs dynamiques et la proprioception de l’épaule. Huit semaines après la dislocation, le patient a retrouvé toute l’amplitude des mouvements et la force comparativement au membre non touché et les tests d’appréhension et de recentrage étaient négatifs.

Conclusion : Ce cas illustre le traitement réussi d’une première dislocation traumatique de la partie antérieure de l’épaule au moyen de l’immobilisation en rotation externe avec un programme de réadaptation intensif.

(MOTS CLÉS : épaule, dislocation, réadaptation)

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Introduction
The shoulder is the most frequently dislocated joint in the body. Anterior dislocation accounts for 94–98% of shoulder dislocations. The incidence of anterior shoulder dislocation has a bimodal distribution with peaks occurring in the second and sixth decade. Initial traumatic dislocation is most commonly the result of a posterior directed force placed on an abducted and externally rotated shoulder. Less commonly, a dislocation may occur as a result of an anteriorly directed force placed directly on the posterior aspect of the humeral head.

Many complications to anterior shoulder dislocations are reported in the literature. A Bankart lesion, an avulsion of the capsulolabral complex from the glenoid rim, is reported to occur in 80–97% of anterior shoulder dislocations. A Bankart lesion is often referred to as the "essential lesion" in a dislocation as it pulls the labrum away from the glenoid and disrupts the attachment of the inferior glenohumeral ligament (IGHL), greatly reducing anterior stability. A displaced labrum reduces the depth of the glenoid by half, and a lax IGHL has been shown to double glenohumeral translation.

Hill-Sachs lesions are impression fractures of the articular surface of the humeral head that occur as the dislocated humeral head is snapped back against the glenoid rim. They also occur quite frequently, in approximately 80% of anterior dislocations. While these lesions are usually inconsequential, some authors suggest that a defect greater than 30% of the articular surface may contribute to instability. Axillary nerve injury is a potentially serious consequence of dislocation. Damage to the nerve is cited to occur in 5–35% of anterior dislocations and is most likely due to the nerve’s vulnerability as it travels over the subscapularis tendon and inferior to the glenohumeral capsule. Avulsion of the IGHL from its insertion on the humerus, known as humeral avulsion of the glenohumeral ligament (HAGL), is a rare complication of dislocations. The actual incidence of HAGL lesions associated with first-time dislocations is unknown, but they are found in 7–9% of patients with recurrent instability.

The most common complication of anterior shoulder dislocation is recurrence. Research implicates age as the single most important prognostic factor in the development of recurrent anterior dislocations. A patient’s age at the time of initial dislocation is inversely related to the development of recurrence. The literature suggests the recurrence rates of anterior dislocations are quite high in those under twenty ranging from 66–97%, while they are lower in those over forty ranging from 0–21%. Since age is the major prognostic factor in the development of recurrent instability, it therefore has a significant role in clinical management. As the literature suggests the patient in this case was at a reduced risk for recurrent dislocation (based on age), an informed decision was made to manage this case nonoperatively.

The nonoperative management of anterior shoulder dislocations, as reported in the literature, generally consists of immobilization of the shoulder in a sling and a progressive, individualized rehabilitation program including strength and proprioceptive training. This case discusses an unusual mechanism of injury for first-time, traumatic anterior shoulder dislocation as well as nonoperative management using an intensive, individualized program.

Case
A 30-year-old Mixed Martial Arts (MMA) athlete presented one day following a traumatic, anterior shoulder dislocation. Prior to injury, the athlete was participating in Jiu Jitsu training (a form of martial arts which focuses on ground fighting, or grappling, with emphasis on joint locks, chokes, and various forms of submissions) in which he was sparring with his training partner. The object of this exercise is to force the opponent to concede defeat (or “tap out”) with the application of a submission hold. At the time of incident, the patient was in his opponent’s “guard” position whereby the opponent was lying supine with his legs wrapped around the patient’s waist. The opponent forcefully pulled the patient’s left arm into a position of horizontal adduction causing dislocation. The patient described utilizing a self reduction technique to relocate the articulation. The patient had no prior shoulder injuries and this was his first episode of dislocation.

The patient indicated that post-reduction he had immediately begun a program of cryotherapy (10/10/10 protocol several times per day) and was currently taking Ibuprofen. He was instructed to continue this protocol for a period of five days. On examination the patient’s left glenohumeral joint range of motion was globally restricted by approximately 20 degrees (external rotation was not attempted) and painful. Apprehension and relocation tests were positive. Radiographs of his left shoulder were
unremarkable. Following physical examination a treatment program was immediately initiated as follows:

**Week 0–1:**
The initial treatment program consisted of Interferential Current followed by Microcurrent application along the anterior shoulder in a direction parallel to the fibers of the anterior glenohumeral capsule. Interferential Current was set at 120Hz, continuously for pain relief. Microcurrent therapy included settings of 300Hz/300microamps for edema control and 0.3Hz/30microamps for tissue healing. As well, external stretching or mechanical loading is believed to induce the expression of growth factors beneficial to tissue regeneration and repair. During this period the patient’s shoulder was immobilized in a sling in 10–15 degrees of external rotation and he was instructed to remove the sling only when in the shower and performing his prescribed exercises (see figures 1 and 2). In order to maintain this position during sleep, the patient was instructed to position himself on the unaffected side while the affected arm was secured to the torso using tensor bandages. With the elbow flexed to 90 degrees, the weight of the arm was supported on a pillow to maintain a slightly externally rotated position.

Initial rehabilitation focused on addressing scapular stability, maintaining range of motion to prevent stiffening, and maintaining strength in the affected limb using isometric exercises. The patient was instructed on scapular “setting” techniques and was provided with a program consisting of ‘low row,’ ‘robbery’ and ‘lawnmower’ exercises, as described previously. The patient was also instructed to perform isometric exercises into shoulder flexion, extension, abduction, adduction, external rotation, and internal rotation while the shoulder was maintained in a neutral position against the torso. All contractions were to be held for as long as could be tolerated and were performed for three sets each, twice daily. The patient was encouraged to record contraction times in a log and to increase the duration of recorded times on each subsequent occasion when possible.

**Week 1–2:**
During the second week the patient continued his routine as indicated above. In addition, self assisted range of motion exercises (using the asymptomatic limb) were initiated as well as codman sets (several times daily).

**Week 2–3:**
During the third week, Active Release Techniques® soft
tissue treatment was applied to the anterior capsule of the glenohumeral joint as well as the rotator cuff musculature. The intent of this treatment was again to elicit the piezoelectric effect on the soft tissue structures and augment proper tissue healing. Slow and controlled end-range mobilizations were also performed into external rotation (avoiding abduction) for the same purpose. Terminal range isometric exercises in several directions were performed by the patient while the treating practitioner provided resistance. The patient was asked to gradually build up tension as the motion was resisted with counterpressure. The positions were to be held for as long as tolerated. At this time the patient was instructed to perform active range of motion exercises; however, the combined motions of abduction and external rotation were to be avoided. Finally, ‘wall alphabet’ exercises were introduced with daily frequency for three sets to failure.

Week 3–5:
Treatment during this period continued as above with the addition of dynamic strengthening exercises. These exercises included a 61bs medicine ball chest pass on the rebounder, as well as pushups from a kneeling position. Each was performed every other day for three sets to failure. Progression to full pushups was possible during the 4th week. Proprioceptive training was also initiated at this time which included rhythmic stabilization drills (see figures 3 and 4), as well as upper body rocker board balancing.

Week 5–7:
As the patient continued to demonstrate strength gains, a gradual return to weight training was permitted. The patient performed several exercises as tolerated including bench press, reverse grip pull downs, dead-lifts, squats, lunges, and core strengthening (eg. bird-dog, side bridge, abdominal crunch). In addition the difficulty of proprioceptive training was progressed to upper body rocker board balancing with a Swiss ball placed under the pelvis. At that time, isometric exercises were also being performed in an abducted, externally rotated position, as were slow and gradual passive mobilizations.

Week 7–8:
The patient was progressed to plyometric exercises to maximize strength gains and enhance proprioception. Plyometric training is purported to enhance proprioception through repetitive, maximal stimulation of mechanoreceptors as the shoulder is rotated to near end-range motion. Plyometric exercises included ‘stability push-ups’ (see figures 5, 6 and 7), medicine ball throws on the rebounder with the arm in an externally rotated and ab-
Following this eight-week rehabilitation program, the patient was permitted to gradually return to pre-dislocation training. At this time he had regained full range of motion and strength compared to the unaffected limb and apprehension and relocation tests were no longer positive.

Discussion
When determining appropriate management of first-time, traumatic anterior shoulder dislocations, the clinician is faced with two options: operative or nonoperative management. Age at the time of initial dislocation is inversely related to the recurrence rate which has important implications for treatment recommendations. The literature suggests a primary surgical approach to first-time, traumatic anterior dislocations in younger individuals may be warranted. When a comparison is made between operative and nonoperative management, there is a highly statistically significant decrease in frequency of recurrent dislocations for those managed surgically. It is important to realize such conclusions are based on studies where the majority of subjects are young (less than 30), male, and tend to be highly active and/or involved in high risk or contact sports. Currently there is no evidence from randomized controlled trials (RCTs) to infer conclusions for patients that are female, older than 30, or inactive. It appears immediate operative stabilization in patients younger than thirty years may be a prudent approach for young individuals involved in competitive,
contact, or high risk sports although current evidence is not overwhelming.

Unfortunately, the primary outcome measure used in most trials comparing operative and nonoperative management is recurrent dislocation. While functional outcome measures such as the Western Ontario Shoulder Stability Index (WOSI), range of motion, strength or return to sport are logically important measures of successful management, they are seldom used in clinical trials. Interestingly, in one of the few RCTs examining such measures, Kirkley et al (2005) were unable to demonstrate statistically significant difference on WOSI scores at five-year follow-up when comparing arthroscopic surgery and nonoperative management in subjects younger than thirty years. Surgically treated individuals did not rate their shoulders significantly better than those conservatively managed.

Ultimately, the determining factor when contemplating whether to manage a case operatively or nonoperatively is the expectation that risks incurred with one type of management outweigh those incurred by the other. The risks associated with surgical repair for anterior dislocations include infection, nerve damage, decreased range of motion, and pain. The major risks associated with managing a shoulder conservatively is recurrent instability and the additional glenohumeral damage sustained by subsequent dislocations. While risks associated with nonoperative management appear minimal, given the high rate of recurrence, a patient may conclude that the risk of subsequent episodes of instability is unacceptable and elect for early stabilization through surgery.

For patients aged greater than thirty, nonoperative management is suggested to be the initial course of care. A reasonable approach to caring for these patients includes a discussion of any relevant research, an evaluation of current sport or work participation, and elucidation of the
patient’s feelings on management. When warranted, nonoperative management generally consists of immobilization of the shoulder in a sling and a progressive, individualized rehabilitation program including strength and proprioceptive training. Since the literature indicated our patient was at a reduced risk for a recurrent dislocation, the case was managed with an intensive, nonoperative approach using the best available evidence.9,10

Immobilization
Immobilization of the shoulder post-dislocation has been performed for thousands of years. Since the time of Hippocrates, conservative management of these injuries has generally involved immobilization in an internally rotated and adducted position for varying time periods. The pathoanatomical justification for immobilization in such a position is to allow for healing/scarring of the torn capsule and anterior soft tissue structures which should ultimately limit a patient’s range of motion.24 Scarred, shortened soft tissues theoretically hinders a patient’s ability to move their shoulder into the position most often associated with an anterior dislocation: 90 degrees abduction and full external rotation (ER). The evidence base for this type of management is uncertain at best. The majority of large RCTs and literature synthesises on the topic suggest no benefit (no reduction in recurrence rate) to immobilization in a position of glenohumeral internal rotation (IR).8,10,24,25,26

Due to the high rate of Bankart lesions associated with anterior dislocations, authors have recently queried whether immobilization of the shoulder in ER, rather than IR, has the potential to reduce recurrence rates after initial dislocation.3,27,28,29,30 The pathoanatomical justification for immobilization in ER is to tension the subscapularis and anterior soft tissue structures, thereby approximating the Bankart lesion to the glenoid rim. Better coaptation of the capsulolabral tear to the glenoid rim would augment the resistance imparted by IGHL and restore the chock block effect of the labrum, greatly enhancing static stability anteriorly.31 There is preliminary evidence indicating a reduction in recurrent dislocations when immobilized in a position of ER.3,28

Miller et al. (2005) measured contact pressures between the labrum and glenoid as the shoulders of ten cadavers were rotated in an arc from 60 degrees IR to 45 degrees ER. No detectable contact force was measured in internally rotated shoulders, however, the contact force increased significantly as the shoulder moved through neutral to ER and reached maximum contact at 45 degrees ER. Itoi et al. (2001) and Seybold et al. (2008) used Magnetic Resonance Imaging to determine the position of the torn capsulolabral complex in vivo in individuals with acute anterior shoulder dislocations. Axial slices of recently dislocated shoulders revealed shoulder IR resulted in a displaced labrum from the glenoid while ER (at least 10 degrees) approximated the torn labrum to the glenoid.27,30 Seybold et al. (2008) suggested the benefit to immobilization in ER was in part due to the effect the position had on edema in the joint capsule. In a position of IR, edema remained anterior, distending the shoulder capsule. However, in a position of ER the anterior soft tissue structures became taught, shifting edema posterior in the capsule, thereby permitting coaptation of the Bankart lesion to the glenoid.30

A recent randomized trial by Itoi et al. demonstrated immobilization in ER rather than IR may translate into improved clinical results. At two year follow-up, intention-to-treat analysis demonstrated a relative risk reduction of 38.2% for those immobilized in ER compared with the risk associated with the conventional method of immobilization in IR.3 The study’s results suggest that if seven patients are managed with immobilization in ER rather than IR, one recurrent dislocation should be prevented. While the results appear encouraging, this study is not without its limitations. The authors do report a conflict of interest, return to sport numbers were quite low, and clinically important outcome measures such as strength testing or range of motion measurements were not included.

Managing acute, traumatic anterior shoulder dislocations with conventional immobilization in IR is not supported by the available evidence. Due to preliminary evidence suggesting immobilization in ER (at least 10 degrees), as opposed to IR, may be an effective option for reducing recurrent dislocation rates a clinical decision was made to immobilize the patient in this case in this position. The notion does however require further evaluation before adopting immobilization in ER as the standard of care.

Rehabilitation
The shoulder is an inherently unstable joint sacrificing stability for mobility. Stability of the shoulder is provided by its static and dynamic stabilizers. The glenoid fos-
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The shoulder girdle is a complicated system formed by multiple articulations with an intricate network of muscles, tendons, ligaments and other connective tissues. It is important clinicians be able to apply a knowledge of shoulder anatomy and kinematics during rehabilitation to protect structures that have potentially been injured post dislocation. Safe and effective rehabilitation of the shoulder therefore requires an understanding of the anatomical and biomechanical characteristics of the shoulder complex. For example, a common recommendation immediately after an anterior dislocation is to avoid the combined ranges of motion of external rotation and abduction. The purpose of this recommendation is to evade positions with the potential of driving the humeral head anteriorly placing strain on injured tissues and potentially delaying healing. The patient in this case was prohibited from combining these two ranges of motion for the first five weeks of the rehabilitation program.

Obtaining a stable scapular base is another important concept to consider when rehabilitating the shoulder. The scapula is intimately associated with the position of the humeral head during movement and helps maintain balance between the glenohumeral joint and scapulothoracic joint. Exercises focused on the scapular pivoters (primarily the serratus anterior and trapezius) can be started early in the rehabilitation program and were begun immediately upon presentation in this case. Manual resistance of scapular motion, rowing, or push-up pluses are all reasonable exercises to improve scapular stabilization. It is also important to perform exercises in the scapular plane during rehabilitation. This ensures optimal length-tension relationships for the function of the rotator cuff and deltoid musculature and avoids straining soft tissues recently damaged during the dislocation.

The principle objective of rehabilitation is to return the patient to a pain-free condition with a high level of functionality as quickly and safely as possible. Rehabilitation of the shoulder after dislocation aims at enhancing the dynamic muscular restraints of shoulder stability. The evidence base pertaining to rehabilitative exercises in the management of anterior shoulder dislocations is quite poor. A recent Cochrane review was unable to locate RCTs for any aspects of conservative management of anterior shoulder dislocations including rehabilitation.

The literature discussing rehabilitation protocols is primarily expert opinion, therefore, there is a lack of solid evidence from which conclusions can be drawn.

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Restoring normal function of the rotator cuff musculature is also an important goal in the rehabilitation of anterior shoulder dislocations. Re-establishing muscular strength and endurance of these muscles results in reduced strain on the static stabilizers and enhances joint function and stability. There is evidence to suggest altered electromyographic activity of the supraspinatus muscle in individuals with anterior instability when compared to healthy controls. Altered function of the supraspinatus results in superior migration of the humerus, which has been shown to increase susceptibility to dislocation.

The infraspinatus and teres minor control external rotation of the humerus and reduce anterioinferior capsuloligamentous strain. The subscapularis muscle should be a focus in any rehabilitation program as it has been shown to be a main muscular stabilizer in the abducted and externally rotated position (the position in which most dislocations occur). Rehabilitation of the rotator cuff in this case initially began as isometric exercises through manual resistance provided by the practitioner then progressed to dynamic strengthening exercises and eventually plyometric exercise.

A rehabilitation program post-dislocation should be individually tailored to meet a patient’s needs. While the evidence discussing rehabilitation is limited, expert opinion suggests a program should promote safe attainment of range of motion, while strengthening the dynamic stabilizers of the shoulder girdle.

Proprioception

Proprioception is an afferent neural input from the periphery which conveys information regarding joint movement, joint position, and force applied to or present within a
joint. Essentially, during shoulder movements mechanoreceptors within surrounding tissues (joint capsule, ligaments, and muscles) are stimulated through length and tension changes in the tissues. Proprioceptive information from these mechanoreceptors is integrated with other afferent information (vision, vestibular input, etc.) in the motor cortex resulting in either muscle activation or inhibition. The integrated information enables coordinated motor patterns and enhances reflex activity and joint stiffness, all of which influence shoulder joint stability. Given that joint mechanoreceptors clinical anterior instability using somatosensory cortical differences between normal subjects and subjects with damage that occurs with an anterior shoulder dislocation fast enough to adequately protect the shoulder. Tissue latency time may indicate that proprioceptive exercise is not only affects mechanical restraint by stretching and tension changes in the tissues. Proprioceptive information from these mechanoreceptors is integrated with other afferent information (vision, vestibular input, etc.) in the motor cortex resulting in either muscle activation or inhibition. The integrated information enables coordinated motor patterns and enhances reflex activity and joint stiffness, all of which influence shoulder joint stability.44 Deficits in proprioceptive capabilities have been demonstrated in individuals who have previously dislocated their shoulders.42,43

Why do proprioceptive deficits develop after an anterior shoulder dislocation? Tissue lengthening associated with shoulder dislocation is most likely the principal cause. Decreased proprioceptive capabilities in patients with known history of shoulder dislocation have been shown to improve significantly after surgical repair to restore capsular tension when compared to healthy controls.45,46 Tibone et al (1996) demonstrated no significant differences between normal subjects and subjects with clinical anterior instability using somatosensory cortical evoked potentials.47 Given that joint mechanoreceptors were stimulated with electrical rather than mechanical stimulation and subjects demonstrated differing mechanical capsuloligamentous properties, the results imply proprioceptive input pathways remain intact in those with instability. Simply put, mechanoreceptors are not damaged or non-functioning rather they are not being adequately stimulated due to tissue lengthening post-trauma. Interestingly, Tibone et al (1996) also found the latency response time for mechanoreceptors within the shoulders of this population to be approximately 3 msec.47 A short latency time may indicate that proprioceptive exercise is suitable for protecting the shoulder from subsequent injury as reflexive shoulder muscle contractions could be fast enough to adequately protect the shoulder. Tissue damage that occurs with an anterior shoulder dislocation not only affects mechanical restraint by stretching and tearing capsuloligamentous tissues, it also alters proprioceptive input into the central nervous system, potentially predisposing individuals to future episodes of instability.

Given the important role that proprioception plays in shoulder stability and function, it is important for clinicians to become aware of methods currently available to restore these mechanisms altered by injury. Perturbations, closed kinetic chain, and plyometric exercises are a few of the techniques described in the literature.

Naughton et al. (2004) was able to improve proprioception in fifteen subjects with previous anterior dislocations using an upper-body wobbleboard training regimen. Subjects with a Swiss ball placed under their pelvis stabilized themselves with active movements at their shoulders while balancing on a wobbleboard. After one month of training (ten minutes a day, five to six days a week), subjects not only significantly improved discrimination of shoulder movements when compared to healthy controls but also perceived their shoulders to be stronger and more stable.17 During week 3–5 in this case the patient began proprioceptive exercises including rhythmic stabilization drills and upper body rocker board balancing.

Swanik et al. (2002) was able to demonstrate significant improvement in proprioception in subjects trained with plyometric exercise. The internal rotators of twelve female division I swimmers were trained with elastic tubing (progressing to the Pitchback System) two days a week for six consecutive weeks. Subjects in the plyometric group improved significantly in five of six proprioceptive tests when compared to controls.18 It was surmised that plyometric training enhanced proprioception through repetitive, maximal stimulation of mechanoreceptors as the shoulder was rotated to near end-range of motion during the exercises. Plyometric drills were included near the end of the rehabilitation of this case. Medicine ball throws while on the rebounder and plyometric bench press on the Smith machine were instituted in week 7–8 to maximize strength of the shoulder stabilizers and enhance proprioception.

Overall, investigation into the literature correlates proprioceptive deficits and anterior shoulder instability. Anterior dislocation likely results in mechanical laxity that ultimately alters motor control of the dynamic stabilizers, predisposing individuals to further shoulder injury. Proprioception can be improved through perturbations, closed kinetic chain and plyometric exercises in individuals exhibiting deficits. Unfortunately, no prospective studies currently exist from which conclusions can be drawn as to the effects such training has on recurrent dislocation rates. Ultimately, the literature remains unclear whether improving proprioception at the shoulder joint improves overall prognosis.
Conclusion
Anterior dislocation is a common condition encountered by health care practitioners. Age at the time of initial dislocation is inversely related to the recurrence rate and has important implications for treatment recommendations. Except in the younger athlete, where a primary surgical approach to first-time acute anterior dislocations may be warranted, conservative management should be the initial course of treatment.9,10,21,23 Conservative management of anterior shoulder dislocations should consist of immobilization of the shoulder and a rehabilitation program including strength and proprioceptive training. Preliminary evidence suggests immobilization in ER may be an effective option for reducing recurrent dislocation rates.3,27,28,29,30 Individualized, progressive rehabilitation programs aimed at restoring normal range of motion and strength of the dynamic stabilizers of the shoulder are recommended in the literature.16,34 Research suggests proprioception can be improved through perturbations, closed kinetic chain, and plyometric exercises in individuals exhibiting deficits.17,18

To date, despite the high incidence of anterior shoulder dislocations the evidence base regarding conservative management of these injuries remains quite poor. This case demonstrates potential management of a first-time anterior shoulder dislocation using immobilization in ER, combined with an intensive rehabilitation program. Prior to implementing the type of nonoperative management discussed in this case as treatment protocol, further investigation in larger, controlled trials is required.

References