EVALUATING SHOULDER INSTABILITY TREATMENT

Just Alexander van der Linde

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"Evaluating shoulder instability treatment."
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van der Linde JA, van Kampen DA, van Beers LWAH, van Deurzen DFP, Terwee, CB, Willems WJ. Validation of the Oxford Shoulder Instability Score (OSIS) in Dutch and the assessment of its smallest detectable change. *J Orthop Surg Res.* 2015;17;10:146.

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van der Linde JA, van Kampen DA, Terwee CB, Dijksman LM, Kleinjan G, Willems WJ. Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up. *Am J Sports Med.* 2011;39:2396-403

van der Linde JA, van Wijngaarden R, van Somford MP, van Deurzen DFP, van den Bekerom MPJ. The Bristow-Latarjet procedure, a historical note on a technique in comeback. *Knee Surg Sports Traumatol Arthrosc.* 2016;24:470-478.

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Brand H, **van der Linde JA**, Vaes P, Van Deurzen DFP, van den Bekerom MPJ. Rehabilitation following arthroscopic soft tissue repair in patients with anterior shoulder instability; what is the evidence? A systematic review. *Submitted for journal publication.*

Voor mijn ouders

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CHAPTER 1

Introduction, Aims and Outline of this thesis

SHOULDER INSTABILITY

The treatment of shoulder instability is based upon experiences that date back to approximately 4500 to 5000 years ago. The first commonly accepted description of a shoulder dislocation is found on papyrus described in ancient Egypt (3000-2500 B.C.); it depicts a worker who performs a maneuver that resembles an attempted reduction as presented in figure 1.[3,16] Hippocrates first described the surgical treatment in detail (around 400 B.C.); selectively burning the axilla with a red-hot iron to enhance stabilizing scar tissue, which was then followed by immobilization.[13,35] The willingness to suffer such a painful procedure may reflect the fact that shoulder instability with its recurrent character has a huge impact on the patients' well being.

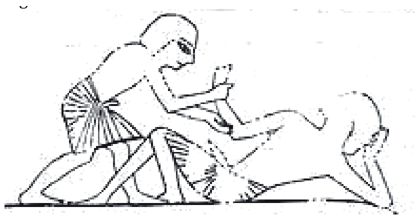

Figure 1

Shoulder instability is a very difficult problem for patients. Due to structural changes in the shoulder joint, a first and often traumatic shoulder dislocation can prelude recurrent episodes of instability. Not only does each episode of instability cause pain, discomfort and insecurity regarding one's shoulder, it could also lead to degenerative changes in the shoulder joint in up to 20% of the patients after 10 years and 56% of the patients after 25 years when treated nonoperative.[14,38] Degenerative changes on the long term might cause pain. Moreover, shoulder instability could also be troublesome in other perspectives, such as the impact on work with subsequent societal costs and the impact on sports participation.

Both the increasing life expectancy and the current global economic conditions cause the public debate to focus on societal costs and cost-effectiveness of therapies. Recurrent episodes of shoulder instability most frequently affect young and active patients[26,28,56], with considerable socioeconomic impact. After each episode of shoulder instability, a patient could have difficulty working, especially when required to perform physically demanding tasks. Recurrent episodes of instability could thus have a considerable effect on time away from work. One aim of this thesis is to estimate productivity losses following conservative treatment of shoulder instability in the Netherlands. In this study we also evaluated direct costs resulting from primary and secondary care. A previous study, based on a Markov model, suggests that surgery is hypothetically more cost-effective compared to the nonoperative treatment[6,23], but absenteeism (i.e. work leave) and presenteeism (i.e. less productive while attending work because of sickness) were not included in this model.

As *Mens sana in corpore sano* reflects the thought that physical exercise is essential for physical and mental well-being, sports participation and physical exercise can countervail the hectic work and social life that characterizes our society. This also pertains to Winston Churchill, Prime Minister of the United Kingdom from 1940 to 1945 and from 1951 to 1955, who had shoulder instability to his right shoulder. With his right shoulder, Churchill avoids the maneuver that he demonstrates with his left shoulder on photo 1.; the combined abduction and exorotation that will typically cause apprehension for recurrent instability. Whereas his shoulder instability forced Churchill to quit tennis,[54] he kept playing polo while wearing a leather harness that strapped his right elbow to his torso as depicted on photo 2.[53]

Depending on the type of sport and on the level of sports participation, shoulder instability can thus force patients to end their activities, either temporarily or definitively. This also accounts for most patients who participate in contact or collision sports, as they have a two to three times increased risk to develop recurrent instability, compared to non-contact athletes.[40,55]

Photo 1

Photo 2

MEASUREMENT INSTRUMENTS TO EVALUATE TREATMENT STRATEGIES

The goal of treatment for shoulder instability is to prevent recurrent episodes of instability and to provide patients with a normal shoulder function. To evaluate which treatment strategy is preferred, adequate measurement instruments are required.

Recurrent instability is a very clear outcome parameter to define treatment failure.[50]

However functional limitations could be more indicative of success or failure from the patient's perspective. Theoretically, a surgical procedure might be designated successful when no recurrent instability occurs. However, the stabilizing technique might compromise the shoulder function, its range of motion, or cause complications[51] that impair the patients functional abilities and limit satisfaction. Functional limitations can be assessed using Patient Reported Outcome Measures (PROMs). These are often questionnaires that specifically reflect the patient's perspective without influence by others.[39]
Using PROMs in clinical practice facilitates shared decision-making and, when the PROMs are standardized, the results can potentially be used as benchmarks to compare results of treatment strategies, doctors or centers. From a practical perspective, PROMs have the advantage that patients can complete them at home or in the waiting room of the outpatient clinic. Completion at home facilitates the patients' willingness to participate in long-term follow-up studies, resulting in a more complete understanding and insight in the long-term results. This especially accounts for a population with relatively young patients who might move or migrate.

Patients who have migrated might be more willing to complete a questionnaire at home compared to a hospital visit.

PROMs contain multiple items or questions that reflect different domains of self-rated health (e.g. work, life style, and mental and physical components). Some PROMs are designed to address the patients' general health status (e.g. Short Form 36 (SF-36)), others to address a specific domain such as the shoulder (e.g. the Simple Shoulder Test (SST)) or a certain condition such as shoulder instability (e.g. the Western Ontario Shoulder Instability Index (WOSI)).

Like each measurement instrument, PROMs hold possible uncertainties and its scores should be interpreted in respect to its measurement properties. Measurement properties include reliability, including internal consistency, reliability and measurement error, validity, including content validity, structural validity, construct validity and cross-cultural validity, and responsiveness.[34]

PROMs should be validated in the designated language and patient population. Standards to guide validation of PROMs were developed by the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) group.[32,33] The

Western Ontario Shoulder Instability Index (WOSI) and the Oxford Shoulder Instability Score (OSIS, also referred to as OIS) are most commonly used to evaluate patients with shoulder instability. One of the aims is to validate the WOSI and the OSIS in Dutch and to evaluate their measurement properties.

It is important to realize that a statically significant change in PROM score does not necessarily represent a clinical improvement perceived by the patient. For example, an increased score of 5 points on a fictive scale of 0-100 might be statistically significant, whereas a minimum 15 points might be required on the same scale for patients to perceive an actual benefit. This minimal improvement, needed to reflect a relevant change for patients is referred to as the Minimal Important Change (MIC).[8] Change in scores should thus be interpreted in respect to the MIC. One of the aims is to determine the MIC for the WOSI and the OSIS.

SURGICAL TREATMENT STRATEGIES OF SHOULDER INSTABILITY

Although the shoulder complex encompasses multiple joints, shoulder instability traditionally refers to the glenohumeral joint. With a global incidence varying from 23.1 to 56.3 per 100,000 person-years[26,28,36,56] and an incidence of 37/100.000 in the Netherlands[47], shoulder instability is commonly seen in orthopaedic clinics.

Ninety five percent of the shoulder dislocations are directed anterior-inferiorly. Less frequent (2-4%) but notorious to be initially missed[20] are posterior dislocations,[30,45] often caused by a direct trauma or by strong muscle contraction as a result of an (epileptic) insult or electrocution.[9,44,49]

Several techniques for closed reduction of the dislocated shoulder have been proposed, predominantly variations on classic techniques as first described by Kocher[22,48], Milch[31], Stimson[46] and Bosley[5] using traction, leverage, scapular manipulation and their combinations.[42] Recently a technique that uses deep massage to the trapezius, the deltoid and the biceps sequentially, while keeping the arm fully abducted with the elbow flexed has been argued to be successful.[7]

Traditionally reduction of the dislocated shoulder is followed by immobilization and physiotherapy to strengthen shoulder muscles and regain the range of motion. It is unclear whether immobilization in external rotation would cause better coaptation of the labrum and improve healing of the labral avulsion, reducing the risk of recurrence.[12,17-19,27,10,52]

Because 17-96% of the patients who are treated nonoperative experience recurrent instability[15,21,43], surgical treatment is often required. Surgical techniques can be broadly divided between soft a tissue repair (e.g. the Bankart repair) and bony reconstruction (e.g the Bristow or Latarjet procedure). The optimal surgical treatment remains debated and depends on several patient characteristics, including age, sports participation, physical work and the presence of bony lesions. Although the peak incidence of shoulder instability is around the age of 20-30, children under 18 years old can also encounter shoulder instability. Because the optimal treatment for patients aged 18 years or younger is yet unknown a systematic review and quantitative synthesis of the literature will be performed to address this issue.

A soft tissue repair or Bankart repair[1] is argued to give satisfactory results in the adolescent patient population, if stability-compromising major bony defects are absent. This procedure was initially performed open, with transglenoid sutures to reattach the avulsed capsulolabral complex to the glenoid rim. The sutures were later replaced by tacks and finally by suture-anchors, while the procedure has evolved from an open to an arthroscopic procedure nowadays. Arthroscopic surgery decreases the risk of stiff scar tissue, which could result in an impaired range of motion, it enables faster surgery, improves cosmetics, and finally causes less postoperative pain. However, surgical treatment should lead to a solid and long lasting effect. The results following the arthroscopic soft tissue repair using suture anchors after eight to ten years will be assessed.

Long term follow-up studies demonstrate a relatively high number of patients with recurrent instability following the arthroscopic soft tissue repair. Moreover, improving diagnostic imaging, which also becomes more easily accessible, leads to better knowledge regarding the pathophysiology of shoulder instability, including the influence of bony defects (e.g. the off and on-track lesions). Both help to better assess the individual risk of surgical failure and seem to cause a shift in the Netherlands towards primary bony reconstructions instead of an attempted soft tissue repair.

Bony reconstructions provide better stability, but are associated with more frequent and more serious complications, including shoulder stiffness, bony non-union, screw migration and bending or breakage, neurological injury and potentially more osteoarthritis over time.[2,12,29]

Subsequent adaptations have been made to the initial procedure, with the intention to improve the results and to decrease the complication risk. Most recently, this resulted in the introduction of an arthroscopically assisted procedure.[4,24,25,37] Knowledge regarding subsequent adaptations and modifications of the treatment in the past including its argumentation are important to enable future improvement. An overview that emphasizes on the original procedures as well as its subsequent adaptations will be presented.

Both the soft tissue repair as well as the bony reconstruction generally provides a high rate of return to activities among patients treated for shoulder instability.[11,24,41] However, bony reconstructions generally offer better stability compared to soft tissue repairs, especially when considerable bony defects are present. A bony reconstruction might thus be preferred when patients intend to resume high risk activities such as: overhead activities and contact or collision sports. Due to their predisposing activities it is unclear whether patients who participate in collision sports (collision athletes) will benefit from surgical treatment as much as the sedentary population or noncollision athletes, regarding recurrent instability. We will address this issue with two systematic reviews; one to compare the redislocation rate between collision athletes and noncollision athletes following a bony reconstruction, the other following a soft tissue repair.

The optimal postoperative rehabilitation program following the arthroscopic soft tissue repair remains unclear. Authors describe various programs, which differ in respect to length and position of immobilization, the start of exercises to regain range of motion and strength and the time to resume sport activities. A systematic review will be presented that evaluates the available evidence for rehabilitation programs following the soft tissue repair.

Shoulder instability has a huge impact on both the patients' well being, as well as on our society. The objective of this thesis is to enhance the knowledge on shoulder instability and its treatment.

AIMS OF THIS THESIS

The general aim of this thesis is to enhance knowledge about shoulder instability from both a patient and societal perspective. To give insight in the societal relevance of this condition (part I), to assess the measurement properties and interpretation of instruments that enable the evaluation of treatment strategies (part II) and to evaluate different aspects of surgical treatment strategies for shoulder instability (part III).

The following specific aims were defined:

Part I Societal impact of shoulder instability

Aim I To estimate productivity losses following the conservative treatment of shoulder instability.

Aim II To estimate the healthcare utilization following the conservative treatment of shoulder instability.
Aim III To assess the development of coping strategies in shoulder instability.

Part II Measurement instruments to evaluate treatment of shoulder instability

Aim IV To translate and validate the WOSI and OSIS for the Dutch population and to assess their measurement properties.
Aim V To evaluate the responsiveness of the WOSI and OSIS.
Aim VI To assess the Minimal Important Change of the WOSI and OSIS.

Part III Surgical treatment strategies for shoulder instability

Aim VII To compare the outcome of surgical and nonoperative treatment in patients up to 18 years of age with traumatic shoulder instability.
Aim VIII To evaluate the results eight to ten years after the arthroscopic stabilization using suture anchors for traumatic recurrent anterior instability.
Aim IX To provide a historical overview regarding subsequent technical modifications for the Bristow-Latarjet procedure.
Aim X To assess if collision athletes have an increased risk to develop recurrent instability compared to noncollision athletes, after a bony reconstruction and after a soft tissue repair.
Aim XI To evaluate the evidence for postoperative rehabilitation protocols following a soft tissue repair.

OUTLINE OF THIS THESIS

Part I aims to describe the societal impact of shoulder instability. *Chapter 2* estimates productivity losses and direct costs of healthcare utilization following the conservative treatment of shoulder instability. Patients are asked whether (consecutive) episodes of shoulder instability have limited them to participate in work, either resulting in absenteeism or presenteeism. Patients also specify their healthcare utilization following each episode of shoulder instability, both regarding primary as well as secondary care. As a result, the mean productivity losses and healthcare expenses following the first, the second and the third or following episodes of shoulder instability are estimated. Moreover, the influence of patient characteristics on productivity losses or healthcare utilization will be assessed. Finally, it will be assessed whether the mean societal costs decrease following consecutive episodes of shoulder instability, which could indicate the development of coping strategies.

Part II aims to evaluate the quality of outcome measurement instruments that can be used to evaluate the treatment of shoulder instability. In *chapter* 3 and *chapter 4*, the WOSI and OSIS are translated and validated in Dutch. Both PROMs are specifically designed to assess shoulder function in patients who experience shoulder instability. Their measurement properties, including the internal consistency, the test-retest reliability, the measurement error, and their validity and responsiveness are also assessed *(chapter 3 and 4)*. *Chapter 5* determines the minimal improvement in WOSI and OSIS score, which is required to reflect a relevant change for the patient (MIC).

Part III aims to describe and evaluate surgical treatment strategies for shoulder instability. In an attempt to assess the optimal treatment strategy for shoulder instability in patients up to 18 years old, in *chapter 6* the literature is summarized that compares the operative versus nonoperative treatment. In *chapter 7* a cohort of patients is evaluated eight to ten years after an arthroscopic soft tissue repair to assess the long-term functional results and recurrent instability. C*hapter 8* provides a historical overview of bony reconstructions for shoulder instability, including a detailed description of the original procedures and subsequent adaptations that aim to improve the results and to decrease specific complications.

Despite the fact that a bony reconstruction provides better stability compared to a soft tissue repair, patients who participate in high risk activities might still have an increased risk for recurrent dislocation. In *chapter 9* and *chapter 10* the literature is summarized to assess if patients who participate in contact or collision sports have an increased risk to suffer from recurrent instability compared to noncollision athletes and the sedentary population following a bony reconstruction *(chapter 9)* and following a soft tissue repair *(chapter 10)*.

Finally, rehabilitation protocols for arthroscopic soft tissue repairs frequently differ in the literature. Part III closes with *chapter 11* in which the literature is summarized to assess the available evidence on the effectiveness of different rehabilitation strategies.

REFERENCES

1. Bankart AS. Recurrent or habitual dislocation of the shoulder joint. *BMJ.* 1923;2:1132-1133.
2. Bhatia DN, DasGupta B. Surgical treatment of significant glenoid bone defects and associated humeral avulsions of glenohumeral ligament (HAGL) lesions in anterior shoulder instability. *Knee Surg Sports Traumatol Arthrosc.* 2013;21:1603-1609.
3. Blomstedt P. Orthopedic surgery in ancient Egypt. *Acta Orthop.* 2014;85:670-676.
4. Boileau P, Thelu CE, Mercier N et al. Arthroscopic Bristow-Latarjet combined with bankart repair restores shoulder stability in patients with glenoid bone loss. *Clin Orthop Relat Res.* 2014;472:2413-2424.
5. Bosley R.C. MJC. Scapula manipulation for reduction of anterior dislocations: a new procedure. *AAOS.* 1979.
6. Crall TS, Bishop JA, Guttman D et al. Cost-effectiveness analysis of primary arthroscopic stabilization versus non-operative treatment for first-time anterior glenohumeral dislocations. *Arthroscopy.* 2012;28:1755-1765.
7. Cunningham N. A new drug free technique for reducing anterior shoulder dislocations. *Emerg Med.*2003;15:521-524.
8. de Vet HC, Terwee CB, Mokkink LB et al. Measurement in Medicine. Cambridge University Press, 2011.
9. Elliott DS. Brain tumour presenting as a dislocated shoulder. *J Bone Joint Surg Br.* 1990;72:925.
10. Finestone A, Milgrom C, Radeva-Petrova DR et al. Bracing in external rotation for traumatic anterior dislocation of the shoulder. *J Bone Joint Surg Br.* 2009;91:918-921.
11. Gerometta A, Rosso C, Klouche S et al. Arthroscopic Bankart shoulder stabilization in athletes: return to sports and functional outcomes. *Knee Surg Sports Traumatol Arthrosc.* 2014, Apr 22. [Epub ahead of print].
12. Griesser MJ, Harris JD, McCoy BW et al. Complications and re-operations after Bristow-Latarjet shoulder stabilization: a systematic review. *J Shoulder Elbow Surg.* 2013;22:286-292.
13. Hippocrates: work of Hippocrates with an English Translation. London: William Heinemann, 1927.
14. Hovelius L, Saeboe M. Neer Award 2008: Arthropathy after primary anterior shoulder dislocation--223 shoulders prospectively followed up for twenty-five years. *J Shoulder Elbow Surg.* 2009;18:339-347.
15. Hovelius L, Olofsson A, Sandstrom B et al. Nonoperative treatment of primary anterior shoulder dislocation in patients forty years of age and younger. A prospective twenty-five-year follow-up. *J Bone Joint Surg Am.* 2008;90:945-952.
16. Hussein MK. Kocher's method is 3,000 years old. *J Bone Joint Surg Br.* 1968;50:669-671.
17. Itoi E, Hatakeyama Y, Kido T et al. A new method of immobilization after traumatic anterior dislocation of the shoulder: a preliminary study. *J Shoulder Elbow Surg.* 2003;12:413-415.
18. Itoi E, Hatakeyama Y, Sato T et al. Immobilization in external rotation after shoulder dislocation reduces the risk of recurrence. A randomized controlled trial. *J Bone Joint Surg Am.* 2007;89:2124-2131.
19. Itoi E, Sashi R, Minagawa H et al. Position of immobilization after dislocation of the glenohumeral joint. A study with use of magnetic resonance imaging. *J Bone Joint Surg Am.* 2001;83-A:661-667.
20. Jacobs RC, Meredyth NA, Michelson JD. Posterior shoulder dislocations. *BMJ.* 2015;350:h75.
21. Kirkley A, Griffin S, Richards C et al. Prospective randomized clinical trial comparing the effectiveness of immediate arthroscopic stabilization versus immobilization and rehabilitation in first traumatic anterior dislocations of the shoulder. *Arthroscopy.* 1999;15:507-514.
22. Kocher T. Eine neue Reductionsmethode für Schulterverrenkung. *Berlin Klin.* 1870;7:101-105.
23. Koffijberg H. Regarding: "Operative versus nonoperative treatment after primary traumatic anterior glenohumeral dislocation: expected-value decision analysis": appropriate assessment of uncertainty. *J Shoulder Elbow Surg.* 2012;21:e21-e23.
24. Lafosse L, Boyle S. Arthroscopic Latarjet procedure. *J Shoulder Elbow Surg.* 2010;19:2-12.
25. Lafosse L, Lejeune E, Bouchard A et al. The arthroscopic Latarjet procedure for the treatment of anterior shoulder instability. *Arthroscopy* .2007;23:1242-1245.
26. Leroux T, Wasserstein D, Veillette C et al. Epidemiology of primary anterior shoulder dislocation requiring closed reduction in Ontario, Canada. *Am J Sports Med.* 2014;42:442-450.
27. Liavaag S, Stiris MG, Lindland ES et al. Do Bankart lesions heal better in shoulders immobilized in external rotation? *Acta Orthop.* 2009;80:579-584.
28. Liavaag S, Svenningsen S, Reikeras O et al. The epidemiology of shoulder dislocations in Oslo. *Scand J Med Sci Sports.* 2011;21:e334-e340.
29. Longo UG, Loppini M, Rizzello G et al. Latarjet, Bristow, and Eden-Hybinette Procedures for Anterior Shoulder Dislocation: Systematic Review and Quantitative Synthesis of the Literature. *Arthroscopy.* 2014;30:1184-211

30. McLaughlin HL. Posterior dislocation of the shoulder. *J Bone Joint Surg Am.* 1952;24 A:584-90.
31. Milch H. The treatment of recent dislocations and fracture-dislocations of the shoulder. *J Bone Joint Surg Am.* 1949;31A:173-80.
32. Mokkink LB, Terwee CB, Knol DL et al. The COSMIN checklist for evaluating the methodological quality of studies on measurement properties: a clarification of its content. *BMC Med Res Methodol.* 2010;10:22.
33. Mokkink LB, Terwee CB, Patrick DL et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res.* 2010;19:539-549.
34. Mokkink LB, Terwee CB, Patrick DL et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol.* 2010;63:737-745.
35. Mosely H.F. Recurrent Dislocations of the Shoulder. 1961. Montreal, McGill University Press.
36. Nordqvist A, Petersson CJ. Incidence and causes of shoulder girdle injuries in an urban population. *J Shoulder Elbow Surg.* 1995;4:107-112.
37. Nourissat G, Nedellec G, O'Sullivan NA et al. Mini-open arthroscopically assisted Bristow-Latarjet procedure for the treatment of patients with anterior shoulder instability: a cadaver study. *Arthroscopy.* 2006;22:1113-1118.
38. Ogawa K, Yoshida A, Ikegami H. Osteoarthritis in shoulders with traumatic anterior instability: preoperative survey using radiography and computed tomography. *J Shoulder Elbow Surg.* 2006;15:23-29.
39. Patrick DL, Burke LB, Powers JH et al. Patient-reported outcomes to support medical product labeling claims: FDA perspective. *Value Health.* 2007;10 Suppl 2:S125-S137.
40. Petrera M, Dwyer T, Tsuji MR et al. Outcomes of arthroscopic Bankart repair in collision versus noncollision athletes. *Orthopedics.* 2013;36:e621-e626.
41. Plath JE, Feucht MJ, Saier T et al. Sporting Activity After Arthroscopic Bankart Repair for Chronic Glenohumeral Instability. *Arthroscopy.* 2015;31(10):1996-2003.
42. Riebel GD, McCabe JB. Anterior shoulder dislocation: a review of reduction techniques. *Am J Emerg Med.* 1991;9:180-188.
43. Roberts SB, Beattie N, McNiven ND et al. The natural history of primary anterior dislocation of the glenohumeral joint in adolescence. *Bone Joint J.* 2015;97-B:520-526.
44. Robinson CM, Seah M, Akhtar MA. The epidemiology, risk of recurrence, and functional outcome after an acute traumatic posterior dislocation of the shoulder. *J Bone Joint Surg Am.* 2011;93:1605-1613.
45. Rowe CR. Prognosis in dislocations of the shoulder. *J Bone Joint Surg Am.* 1956;38-A:957-977.
46. Stimson L.A. An easy method of reducing dislocations of the shoulder and hip. *Med Record.* 1900;57:357.
47. te Slaa RL. Incidence of acute shoulder dislocation. In: The acute first-time anterior shoulder dislocation (AFASD), p 59-70. Amsterdam, 2003.
48. Thakur AJ, Narayan R. Painless reduction of shoulder dislocation by Kocher's method. *J Bone Joint Surg Br.* 1990;72:524.
49. Thangarajah T, Lambert S. The management of recurrent shoulder instability in patients with epilepsy: a 15-year experience. *J Shoulder Elbow Surg.* 2015;24:1723-1727.
50. van der Linde JA, van Kampen DA, Willems JW. How should we define failure after surgical shoulder stabilization? *Arthroscopy.* 2013;29:1602.
51. van der Linde JA, van WR, Somford MP et al. The Bristow-Latarjet procedure, a historical note on a technique in comeback. *Knee Surg Sports Traumatol Arthrosc.* 2016 Feb;24:470-478.
52. Whelan D. Immobilization in an external or internal rotation brace did not differ in preventing recurrent shoulder dislocation. *J Bone Joint Surg Am.* 2010;92:1262.
53. William Manchaster. The Last Lion: Winston Spencer Churchill: Visions of Glory, 1874-1932. Boston: Little, Brown & Co., 1983.
54. Winston Spencer Churchill. A Roving Commission: My Early Life. London: Thornton Butterworth, 1934.
55. Yamamoto N, Kijima H, Nagamoto H et al. Outcome of Bankart repair in contact versus non-contact athletes. *Orthop Traumatol Surg Res.* 2015;101:415-419.
56. Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am.* 2010;92:542-549.

PART I

Societal impact of shoulder instability

CHAPTER 2

Estimation of societal costs following nonoperative treatment of shoulder instability in the Netherlands

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ABSTRACT

Introduction

Shoulder instability occurs commonly and is associated with decreased functioning. Therefore, the associated costs are of interest to clinicians, researchers and policy makers.

Objective

1) To estimate productivity losses (resulting from absenteeism, presenteeism and the inability to perform unpaid work) and healthcare expenses following the nonoperative treatment of shoulder instability; 2) to identify patient characteristics that influence societal costs and 3) to assess the development of coping strategies.

Methods and materials

One hundred and thirty-two patients completed a questionnaire regarding production losses and healthcare utilization following their consecutive episodes of shoulder instability. Productivity losses were calculated using the friction cost approach. Healthcare utilization was valued using Dutch standard costs. ANOVA-test was used to assess which patient characteristics are related to productivity losses and healthcare expenses.

Societal costs of consecutive episodes of shoulder instability were assessed using multilevel analyses. Bootstrapping was used to estimate statistical uncertainty.

Results

Mean productivity losses are € 3110 € 1866 and € 1543 and mean healthcare expenses are € 3759, € 3267 and € 2424 per patient per dislocation for the first, second and third dislocation, respectively. Productivity losses are significantly higher when patients have other chronic disorders (p 0.02).

Productivity losses decrease significantly between the first and second (mean difference - € 1969, 95% CI= -3680 to -939) and between the first and third dislocation (mean difference - € 2298, 95% CI= -4092 to -1288).

Conclusion

Nonoperative treatment of shoulder instability has substantial societal costs. Productivity losses are higher if patients have other disorders. The decrease in costs for subsequent dislocations may indicate that patients develop coping strategies.

INTRODUCTION

Shoulder instability is a form of musculoskeletal pathology with an incidence varying from 23.1 to 56.3 per 100,000 person-years.[10, 11, 18] Shoulder instability generally affects young and active patients.[11, 18] Nonoperative treatment, including immobilization and physiotherapy, is a widely accepted initial treatment for shoulder instability. Recurrent instability after nonoperative treatment is described to be 17-96%, with younger patients having a higher risk.[6, 7, 12] Each consecutive episode of instability is likely to decrease the patients' level of physical activity temporarily. Given the high recurrence rate following nonoperative treatment and the fact that predominantly young and active patients are affected, the societal costs (i.e. productivity losses and healthcare costs) associated with shoulder instability could be substantial. Productivity losses result from absenteeism (i.e. sick leave), presenteeism (i.e. attending work while sick) and the inability to perform unpaid work

In other orthopaedic fields, several cost-of-illness studies were performed.[1, 13, 14, 16] These studies have shown that absenteeism, work leave and disability represent the vast majority (> 90%) of societal costs associated with these orthopaedic disorders.[1, 13, 14, 16] Moreover, the Dutch cost-of-illness study recently estimated that on the treatment of back and neck problems for example 673 million was spent in the year 2003.[13]

The first aim of this study was to estimate productivity losses, due to the inability to perform paid and unpaid work and to estimate the direct costs as a result of healthcare utilization following nonoperative treatment for shoulder instability. Second, we assessed which patient characteristics significantly influence productivity losses or healthcare utilization. Finally, development of coping strategies is assessed, by comparing healthcare expenses and productivity losses between consecutive series of shoulder instability.

METHODS AND MATERIALS

Patients

This observational study was conducted in 2 hospitals in the Netherlands; the Onze Lieve Vrouwe Gasthuis (OLVG) in Amsterdam and the Waterlandziekenhuis (WLZ) in Purmerend. Ethical approval was provided by the ethical commission of both hospitals. We aimed to include at least 125 patients, similar to other studies in the same field.[1, 14]

All consecutive patients that visited the emergency room or the outpatient clinic because of a shoulder dislocation were eligible for inclusion. At the OLVG, patients were included between January 1st and August 1st 2015, at the Waterlandziekenhuis patients were included between April 1st and August 1st 2015. Patients were initially selected on their treatment code in the hospital's database; their files were double checked for the correct diagnosis. Patients were contacted by an orthopaedic surgeon either at the outpatient clinic or by telephone. Study information was provided and written informed consent was obtained when patients agreed to participate. Questionnaires were completed online (no missing data allowed) or on a paper version where missing data were completed by telephone.

Patients were eligible to participate when they had a history of either subjective or observed shoulder instability, both primary and recurrent, including all directions of instability that was treated nonoperative. Patients that suffered recurrent shoulder dislocations despite a history of surgical stabilization were also included. Excluded from this study are patients that did not speak Dutch, multi-trauma patients, patients with pre-existing severe disabilities (e.g. hemi-paresis, frontal dementia) or patients with documented non-compliance to nonoperative therapy.

Questionnaire

Patients completed a 25-item questionnaire on paper or on Internet, or were interviewed by telephone. This questionnaire was based on the TiC-P questionnaire which is a widely used questionnaire to estimate health care utilization and production losses by self-report from patients with mental health problems in the Dutch health care setting.[2]

The first part of this questionnaire included questions on the specific complaints associated with the shoulder instability. The second part of the questionnaire assessed whether patients participate regularly in sports activities and have chronic comorbid disorders, what the patients' highest attained educational level is and what the patients' primary occupation during the day is (paid work, student, no paid work, retired). The final part of the questionnaire assessed absenteeism and presenteeism from paid and unpaid work, as well as which healthcare services were used by the patient due to shoulder instability. Healthcare services that were assessed included visits to the emergency department, the general practitioner, the company doctor, the outpatient clinic, the physical therapist, the manual therapist, the mensendieck therapist the cesar therapist or other therapists. Presence of comorbid disorders was assessed based on a list of 27 chronic disorders used by the Dutch Central Office of Statistics.[5, 17]

We aimed to have an interval of approximately 2-4 months between the most recent shoulder dislocation and the completion of the questionnaire. This approach enables patients to remember their limitations and healthcare utilization reliably, while on the other hand this period of time is likely to encompass the bulk of productivity losses and healthcare utilization in the first phase after an episode of shoulder instability.

Costs

All costs were calculated for the year 2015. Productivity losses from paid work were valued using the friction cost approach using average lost productivity costs per hour stratified for age and gender in the Netherlands.[4] The friction period used was 160 days. Productivity losses from unpaid work were valued using a shadow price which is based on the hourly wage of a legally employed cleaner. Use of healthcare services was valued using Dutch standard costs.[4]

Patient characteristics

Patient characteristics that are assessed are the level of education (low/middle/high), the presence of other chronic disorders, the type of work (physical/ non-physical/ half physical and half non-physical) and the fact whether the dominant side is affected.

Statistical analysis

Cost estimates are described using mean and standard deviation (SD) in different categories (primary care, secondary care, lost productivity). Although costs generally are not normally distributed, estimates of the mean (SD) costs allow decision makers to easily estimate budget impact, and, therefore, are considered more useful to decision makers than estimates of the median (IQR).

ANOVA analyses were performed to assess which patient characteristics were associated with total societal costs, and healthcare and lost productivity costs separately. Bootstrapping was used to estimate statistical uncertainty, 95% CI are presented. IBM SPSS Statistics, version 22 was used.

The presence of coping strategies was assessed in multilevel analyses using STATA, version 12 in a subgroup of patients who experienced at least 3 episodes of shoulder instability. Bootstrapping was used to estimate statistical uncertainty. A p-value of <0.05 is interpreted as statistically significant.

RESULTS

Patients

Figure 1 illustrates the flowchart of the included patients. There were 233 potentially eligible patients at the OLVG and 12 at the Waterlandziekenhuis. Eighty-one patients were unable to participate (25 tourists, 40 patients could not be contacted, 16 were excluded based on the exclusion criteria), 32 patients were unwilling to participate. Thus, a total of 132 patients completed the questionnaire.

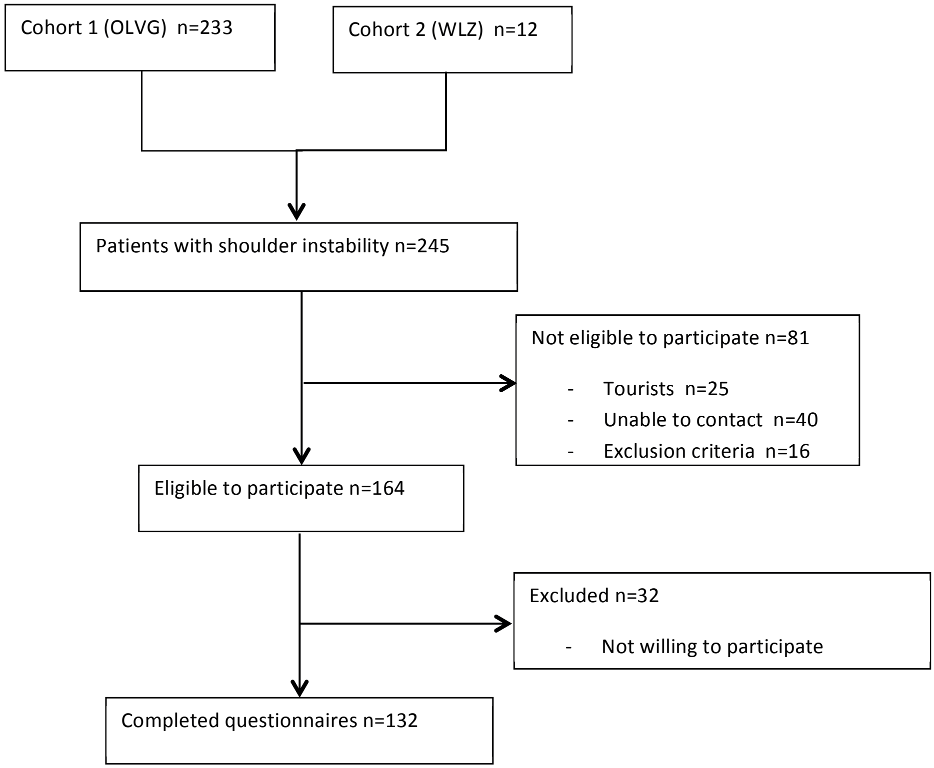

Figure 1. Flowchart of all patients.
OLVG = Onze Lieve Vrouwe Gasthuis, Amsterdam, the Netherlands.
WLZ = Waterlandziekenhuis, Purmerend, the Netherlands.

Demographic data of participating patients are summarized in Table 1. Twenty-two patients experienced only subluxations. The interval between the most recent episode of shoulder instability and completion of the questionnaire was not normally distributed; the median is 43 (IQR: 18-90) days.

Productivity losses including unpaid work

At the time of their first dislocation 59 patients were employed. The mean (SD) number of days missed, as reported by patients with absenteeism was 8.1 (16.7) days. Patients that reported presenteeism missed 11.8 (18.7) days. Results are presented similarly for the second and third dislocation. Table 2 shows that the number of days of absenteeism and presenteeism from paid work after the second and third shoulder dislocation is lower than after the first dislocation. For absenteeism from unpaid work this trend is less clear.

Table 1. Demographic data.

Total number of patients	Number	Percentage
	132	(100 %)
Age in years (mean SD)		
- at the time of completion	36 (16)	
- when the shoulder first dislocated	30 (16)	
Gender (m)	95	(72%)
Dominant side		
- Right	122	(92%)
- Left	6	(5%)
- Both sides equally	4	(3%)
Dominant side is affected side (y)	82	(62%)
Highest level of education *		
- Low	11	(8%)
- Middle	30	(23%)
- High	90	(69%)
Work at the time of completion		
- Employed	101	(77%)
- Unemployed	3	(2%)
- School/ study	9	(7%)
- Retired	12	(9%)
- Other **	7	(5%)
Work days *		
- 5 to 7 days/wk	59	(59%)
- 4 days	19	(19%)
- 3 days	7	(7%)
- 2 days	10	(10%)
- 1 day	5	(5%)
Type of work		
- Physical	31	(31%)
- Non-physical	41	(40%)
- 50/50 (non)-physical	29	(29%)
Other chronic disorders (y)	57	(43%)
Number of dislocations (incl. subluxations)		
- 1 dislocation	49	(37%)
- 2 dislocations	9	(7%)
- 3 or more dislocations	74	(56%)
Patients with only subluxations (1 or more)	22	(17%)
Patients after failed surgery	17	(13%)

* One patient missing

** Including unfit to work (3), housewife (3) and gap year (1).

Table 2. Estimation of costs based on productivity losses and healthcare utilization per dislocation.

Productivity losses (€) after the patients':	1st dislocation~			2nd dislocation~			3rd or following dislocations~		
	N	Missed time^	Costs ‡	N	Missed time ^	Costs ‡	N	Missed time ^	Costs ‡
total number of patients	132			83			74		
with paid work	59			41			39		
- missed days due to absenteeism		8.1 (16.7)	3350 (5395)		3.1 (7.5)	1882 (4074)		3.0 (6.1)	1458 (3067)
- missed days due to presenteeism		11.8 (18.7)			5.9 (13.9)			3.4 (7.2)	
- missed hrs. of unpaid work	93	12.3 (22.0)	1256 (4130)	63	3.9 (9.5)	372 (922)	60	13.0 (63.8)	386 (938)
Total prod losses	130		**3110(8313)**	79		**1866(6192)**	70		**1543(4816)**
Health care utilization after the patients'									
	1st shoulder dislocation~			2nd shoulder dislocation~			3rd or following shoulder dislocations~		
- use of ambulance	36			12			11		
Visits to:		No. ¤			No. ¤			No. ¤	
- emergency department §	92	1.0		36	1.0		38	1.0	
- general practitioner	46	1.5		24	1.6		33	2.4	
- company doctor	8	3.1		4	3.3		6	1.5	
- outpatient clinic *	77	1.6		29	1.6		50	1.8	
- physical therapist	61	9.5		24	10.7		31	5.6	
- manual therapist	7	4.6		2	4.0		4	63	
- mensendieck therapist	1	3.0		1	3.0		0	0	
- cesar therapist	0	0		0	0		2	5.5	
- other therapist	3	2.7		1	2.0		3	1.7	
Total health care expenses (€)			**3759 (20049)**			**3267 (20098)**			**2424 (16013)**
Overall costs (€) **per patient per dislocation**			**6914 (21448)**			**5284 (21306)**			**4061 (16997)**

~ dislocations include full dislocations and subluxations.
^ mean (SD) number of missed days or hours per patient per dislocation. This number includes patients with and without absenteeism or presenteeism.
‡ mean (SD) costs in euro's (€) per patient per dislocation. This number includes patients with and without absenteeism or presenteeism.
* only outpatient visits because of the shoulder dislocation (e.g. to the orthopedic, neurology or radiology department).
§ one or more visits.
¤ mean number of visits per patient per dislocation.

Mean productivity losses per patient per dislocation (including patients without work) are € 3110 (SD 8313), € 1866 (SD 6192) and € 1543 (SD 4816) respectively, reported by 130, 79 and 70 patients.

Healthcare utilization

One hundred thirty-one patients completed questions regarding healthcare utilization; the associated costs are summarized in Table 2. Following the first dislocation, 92 patients (70%) visited the emergency department once.

Seventy-seven patients (59%) visited the outpatient clinic once or twice and 61 patients (47%) visited a physiotherapist, with a mean number of 10 visits per patient. The company doctor and manual therapist were visited less; by 8 and 7 patients respectively.

The mean (SD) health care expenses are € 3759 (SD 20049), € 3267 (20098) and € 2424 (16013) after the first, the second, the third and following episode of shoulder instability, respectively.

Societal costs

The mean (SD) societal costs per patient were € 6914 (21448), € 5284 (21306) and € 4061 (16997) for the first, second and third dislocation, respectively.

Factors associated with costs

Factors potentially associated with costs in patients with shoulder instability are summarized in Table 3. Patients with other (chronic) disorders had significantly higher productivity losses than patients without comorbid disorders (p 0.02). Other factors were not associated with lost productivity costs, healthcare costs or societal costs.

Cost differences between subsequent dislocations

A subgroup of 74 patients (56%) experienced at least 3 dislocations. Mean productivity losses and mean health care utilization per patient per dislocation are summarized in Figure 2. Productivity losses decreased significantly between the first and second dislocation (mean difference - € 1969, 95% CI= -3680 to -939) and between the first and third dislocation (mean difference - € 2298, 95% CI= -4092 to -1288). There were no statistically significant differences in healthcare costs between subsequent dislocations.

Table 3. Covariates that influence healthcare utilization and productivity losses in patients with paid work.

Covariates	Healthcare utilization				Productivity losses			
		Costs (€)^				Costs (€)^		
	N	Mean	(SD)	p	N	Mean	(SD)	p
Dominant side affected *								
- Yes	82	4790	(24205)	0.45	19	4018	(7683)	0.60
- No	50	2068	(1007)		36	3184	(3911)	
Work type								
- No work	23	6568	(28722)	0.72	NA	NA	NA	
- Physical work	32	1872	(7080)		14	2637	(2713)	0.06
- Desk work	45	2203	(10611)		26	2302	(3225)	
- Half physical/desk	32	5816	(29761)		15	6281	(8812)	
Level of education *								
- Low	11	425	(321)	0.81	1	3243	NA	0.99
- Middle	30	6536	(25938)		18	3489	(4425)	
- High	90	3283	(19184)		36	3470	(6032)	
Other (chronic) disorders								
- Yes	57	3740	(18907)	0.99	18	5835	(7663)	**0.02**
- No	75	3773	(21001)		37	2323	(3571)	
Gender								
- Male	95	4976	(23552)	0.27	44	2949	(4170)	0.16
- Female	37	635	(559)		11	5567	(8936)	

ANOVA analyses (calculated with bootstrapping) regarding healthcare costs and productivity losses at the time of their first dislocation.
* one patient missing
** two patients missing
^ mean (SD) costs per patient per dislocation
NA = not applicable

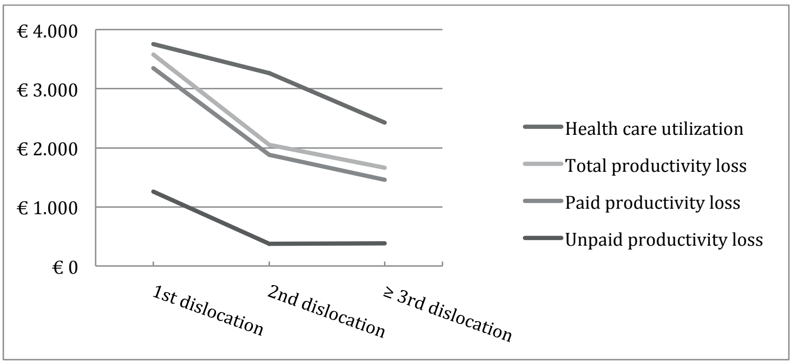

Figure 2. Lost productivity costs and healthcare costs per patient per subsequent dislocation.

DISCUSSION

The aim of this study was to estimate societal costs following nonoperative treatment for shoulder instability. So far, little is known about this.

Our results show that societal costs following nonoperative treatment for shoulder instability are substantial. The costs per dislocation however, tend to decrease with each subsequent dislocation.

Kraus et al. previously described that the mean incapacity to work after surgical treatment for shoulder instability is 2.73 months (equals 54.6 workdays with 20 workdays each month).[9] In this study, the number of workdays lost is substantially lower. This may be explained by the fact that all patients in this study were treated nonoperative.

Kraus et al. identified workload as a factor that influences productivity losses,[9] but did not assess comorbidity. We found that productivity losses are significantly higher when patients have other (chronic) disorders. One explanation might be that the dislocating shoulder is the final factor that causes the inability to work. Another explanation might be that these patients are more familiar with sick leave and have less moral difficulty to call in sick. Other factors were not statistically significant associated with costs of productivity losses or healthcare utilization

Our data shows that costs of healthcare utilization and productivity losses decrease following consecutive shoulder dislocations. This may be explained by the fact that patients use experience and knowledge from previous dislocations to cope with consecutive dislocations. Patients might restart exercises previously provided by their physiotherapist and be able to engage alternative activities until their shoulder function improves.

Crall et al. previously studied the cost effectiveness of various treatments for first time shoulder dislocations. Using a Markov model and a willingness-to-pay threshold of $25,000 per quality-adjusted life-year, primary arthroscopic stabilization was considered cost-effective as compared to nonoperative treatment of shoulder instability.[3,8] This model included costs resulting from surgery, closed reduction, capsular release, incisional drainage, antibiotics, CT-scans, MRI-scans, MR-arthrography and physical therapy,[3] but costs as a result from productivity losses were not included. Considering the importance of lost productivity costs in patients with shoulder instability as shown by this study, this can be considered a limitation of this particular study.

A strength of this study is the fact that productivity losses as well as healthcare expenses are addressed. Because the nonoperative treatment (visits to the physiotherapist, immobilization y/n and its length) was not standardized, this study represents the routine daily practice in the Netherlands.

However, the observational, retrospective design of the study has also some limitations. First, there could be selection bias; some patients might seek medical attention sooner than others. This may lead to overestimation of the societal costs. Selection bias could also occur because specific patients might be eligible to have early surgical treatment, based on their sports ambition, physical workload or own preferences.

Second, specific diagnostic tests (e.g. MRI- or CT-scans) are not included in the costs estimates in this study. This might give an underestimation of the total costs resulting from healthcare utilization due to a shoulder dislocation.

Third, the median interval between the most recent episode of shoulder instability and the questionnaire completion was 43 (IQR: 18-90) days. Because the physiotherapy treatment for shoulder instability might take longer, this could lead to an underestimation of the healthcare expenses.

Finally, limitation is that this cohort includes patients with observed shoulder dislocations as well as 22 patients (17%) with subluxations only. Although subluxations are for some patients the initial reason to seek medical attention, this leads to a mixed population.(15) Because patients that experienced only subluxations have lower mean societal costs compared to the group as a whole (€ 1747 compared to € 6914), this could lead to an underestimation of the healthcare expenses.

Earlier in this discussion we hypothesized that the decreased costs associated with subsequent shoulder dislocations are a result from coping by the patient. However, another explanation could be that a first shoulder dislocation causes more damage to the shoulder anatomy compared to following dislocations, leading to more pain and relatively more healthcare utilization and greater disability resulting in increased work absenteeism.

The social security system in the Netherlands obligates employers to pay at least 70% of the employees' salary in case of sick leave during at least 107 weeks. Employees are thus likely to resume work, only if they are actually able to. Although this could result in an accurate reflection of sick leave following shoulder instability, sick leave may vary betweend countries according to their social security systems.

Future research should focus on differences in the shoulder function following consecutive episodes of shoulder instability in patients that are treated nonoperative. When the shoulder function is equally affected each time, then a decrease in societal costs is more likely the result of coping strategy development.

Societal costs of shoulder instability inform clinicians, researchers and policy makers and could be taken into consideration when treating patients with shoulder instability. However, although societal costs decrease with subsequent shoulder dislocations, this does not necessarily imply that patients have less discomfort or pain following consecutive episodes of shoulder instability. The treatment for shoulder instability should thus always include the patients' specific characteristics and desires.

CONCLUSION

In the nonoperative treatment of shoulder instability, the societal mean costs per patient per dislocation were estimated to be € 6914 € 5284 and € 4061 for the first, second and third dislocation, respectively. The presence of other (chronic) disorders significantly increases productivity losses. Costs associated with productivity losses decrease significantly during following subsequent episodes of shoulder instability, this could be due to the development of coping strategies.

REFERENCES

1. Boonen A, Brinkhuizen T, Landewe R, et al. Impact of ankylosing spondylitis on sick leave, presenteeism and unpaid productivity, and estimation of the societal cost. *Ann Rheum Dis*. 2010;69:1123-1128.
2. Bouwmans C, De JK, Timman R, et al. Feasibility, reliability and validity of a questionnaire on healthcare consumption and productivity loss in patients with a psychiatric disorder (TiC-P). *BMC Health Serv Res*. 2013;13:217.
3. Crall TS, Bishop JA, Guttman D, et al. Cost-effectiveness analysis of primary arthroscopic stabilization versus nonoperative treatment for first-time anterior glenohumeral dislocations. *Arthroscopy*. 2012;28:1755-1765.
4. Hakkaart-van Roijen L., Tan S.S. BCAM. Handleiding voor kostenonderzoek, methoden en standaard kostprijzen voor economische evaluaties in de gezondheidszorg. College voor zorgverzekering (CVZ). Geactualiseerde versie 2010. [Dutch manual for costing in economic evaluations]. Diemen, the Netherlands: 2011
5. Hakkaart-van Roijen L., van Straten A., Donker M., et al. Handleiding. Trimbos/iMTA questionnaire for costs associated with psychiatric illness (TiC-P).[Guideline for the Trimbos/iMTA questionnaire for costs associated with psychiatric illness (TiC-P)]. Rotterdam, the Netherlands: 2002
6. Hovelius L, Olofsson A, Sandstrom B, et al. Nonoperative treatment of primary anterior shoulder dislocation in patients forty years of age and younger. a prospective twenty-five-year follow-up. *J Bone Joint Surg Am.* 2008;90:945-952.
7. Kirkley A, Griffin S, Richards C, et al. Prospective randomized clinical trial comparing the effectiveness of immediate arthroscopic stabilization versus immobilization and rehabilitation in first traumatic anterior dislocations of the shoulder. *Arthroscopy* 1999;15:507-514.
8. Koffijberg H. Regarding: ".Operative versus nonoperative treatment after primary traumatic anterior glenohumeral dislocation: expected-value decision analysis": appropriate assessment of uncertainty. *J Shoulder Elbow Surg.* 2012;21:e21-e23.
9. Kraus TM, Freude T, Fiedler S, et al. Incapacity of work after arthroscopic Bankart repair. *Arch Orthop Trauma Surg*. 2015;10: 1429-1436.
10. Leroux T, Wasserstein D, Veillette C, et al. Epidemiology of primary anterior shoulder dislocation requiring closed reduction in Ontario, Canada. *Am J Sports Med*. 2014;42:442-450.
11. Liavaag S, Svenningsen S, Reikeras O, et al. The epidemiology of shoulder dislocations in Oslo. *Scand J Med Sci Sports.* 2011;21:e334-e340.
12. Roberts SB, Beattie N, McNiven ND, et al. The natural history of primary anterior dislocation of the glenohumeral joint in adolescence. *Bone Joint J*. 2015;97-B:520-526.
13. Slobbe L.C.J., Kommer G.J., Smit J.M., et al. Kosten van ziekten in Nederland 2003. Zorg voor euro's. (Costs of illness in the Netherlands 2003) . Rijswijk, the Netherlands. RIVM rapport 270751010, 2006
14. Spaetgens B, Wijnands JM, van DC, et al. Cost of illness and determinants of costs among patients with gout. *J Rheumatol*. 2015;42:335-344.
15. van der Linde JA, van Kampen DA, Willems JW. How should we define failure after surgical shoulder stabilization? *Arthroscopy.* 2013;29:1602.
16. van Tulder MW, Koes BW, Bouter LM. A cost-of-illness study of back pain in the Netherlands. *Pain.* 1995;62:233-240.
17. van RL, Essink-Bot ML, Koopmanschap MA, et al. Labor and health status in economic evaluation of health care. The Health and Labor Questionnaire. *Int J Technol Assess Health Care*. 1996;12:405-415.
18. Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am*. 2010;92:542-549.

PART II

Measurement instruments to evaluate treatment of shoulder instability

CHAPTER 3

Measurement properties of the Western Ontario Shoulder Instability Index (WOSI) in Dutch patients with shoulder instability

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ABSTRACT

Introduction

The Western Ontario Shoulder Instability index (WOSI) is a patient-reported outcome measure for patients with shoulder instability.

Objective

The purpose of this study was to validate the WOSI in Dutch by evaluating the structural validity, internal consistency, measurement error, reliability, and construct validity. Floor and ceiling effects were also addressed.

Methods and materials

Two cohorts were recruited, including a total of 138 patients with shoulder instability. Confirmatory factor analysis was used to assess the structural validity and Cronbach' s α to assess internal consistency. The measurement error was calculated as the Smallest Detectable Change (SDC). Reliability (test-retest) was estimated in a subgroup of 99 patients that completed the re-test after a mean of 13 days (5-30 days). Reliability was calculated with the Intraclass Correlation Coefficient (ICC). Construct validity was evaluated by comparing the WOSI with the Oxford Shoulder Instability Score (OSIS), the Simple Shoulder Test (SST), the Oxford Shoulder Score (OSS), the Disability of the Arm, Shoulder, and Hand assessment (DASH), and the Short Form-36 (SF-36). Measurement properties were evaluated for both the total WOSI score, as well as its four domains.

Results

Factor analysis could not confirm the 4 domains. Best results were found for a one-factor model. Internal consistency was good, with a Cronbach's α ranging from 0.93 to 0.96. The reliability was excellent (ICC 0.88 - 0.92 for all subscales). The measurement error (SDC) was 23.0% for the WOSI total, ranging from 23% to 28% for the subscales (on a scale of 0 -100). Regarding the construct validity, 76% of the results were in accordance with the hypotheses, including a high correlation with the OSIS (0.82) and the DASH (0.81) assessments. No floor or ceiling effects were found.

Conclusion

The Dutch version of the WOSI showed good reliability and validity in a cohort of patients with shoulder instability, although the factor structure remains unclear.

INTRODUCTION

With an incidence up to 49/100.000 each year, shoulder instability is commonly seen in an orthopaedic clinic [34,42], generally affecting young and active patients.[28,51]
Treatment in shoulder instability aims to provide a stable shoulder, to enable them to perform overhead activities and to return to previous (sports) activities. Results of the treatment of shoulder instability are evaluated with both objective and subjective outcome measures. Objective measures include redislocations and range of motion. Subjective measures include questionnaires with regard to shoulder function and are commonly referred to as patient-reported outcomes measures (PROMs).

PROMs are designed to reflect the patient's subjective function, addressing subdomains such as sports, work, and emotional well-being. They enable the practitioner to detect functional changes in a standardized way. PROMs have become increasingly important in assessing patient's health status [37] and can focus on general health, a physical domain or body part (e.g., the shoulder), or a certain condition or disease (e.g., instability).[50]

Several PROMs have been developed over time to evaluate shoulder instability. The Western Ontario Shoulder Instability Index (WOSI) is a well-designed, thoroughly evaluated questionnaire that has proved to be reliable, valid, and sensitive to changes that are of clinical importance to Canadian patients with shoulder instability[26], leading to international acceptance. The WOSI has been proven useful as outcome measure in several clinical studies [1,2,36] and has been translated and validated in Italian, German, Swedish and Japanese.[6,11,19,20,40] Translation and validation of PROMs allows comparison of national and international study results.[3,18,26,32,49]

The aim of this study was to translate and validate the WOSI for a Dutch population of patients with shoulder instability. We evaluated its measurement properties according to the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines.[49]

METHODS AND MATERIALS

Translation procedure

The WOSI was independently translated into Dutch by an official translator (Metamorfose Translations, Utrecht, the Netherlands) and three medically educated translators whose native language was Dutch.[3,8,12,49]

When they reached consensus, this version (version 1, or V1) was completed with the help of 20 patients with shoulder instability, who noted whether the questions were applicable to their daily activities. Another 13 patients, who were previously treated for shoulder instability, were asked to complete the Dutch version of the WOSI at home to assess the comprehensibility of the questions. A few linguistic adjustments were made accordingly (V2). These 33 patients were excluded from our final analysis. This WOSI version was translated back into English by another official translator (Vertaalbureau Oattes, Amsterdam, the Netherlands) and by a native English

speaker without a medical background. Both were blinded to the original version and focused on the linguistic aspects. Their versions were compared with the original text. Subsequently, the researchers composed a final version (V3), taking into account all discrepancies.

Patients and procedures for assessing measurement properties

Two cohorts of patients with shoulder instability were recruited to assess reliability and validity. We planned to include at least 100 patients, which is considered excellent for assessing measurement properties.[45,49] The first cohort included 75 patients with shoulder instability who visited our outpatient clinic between December 2009 and December 2011. The second cohort included 79 patients with shoulder instability who visited the emergency department or the outpatient clinic between December 2012 and May 2013. All patients were recruited at the Onze Lieve Vrouwe Gasthuis, Amsterdam, the Netherlands.

Inclusion criteria were age 16 years or older and any form of glenohumeral instability (anterior, posterior, multidirectional) as diagnosed by one of our doctors. Exclusion criteria were an inability to master the Dutch language and a large glenoid fracture or proximal humeral fracture, such as a displaced fracture of the greater tuberosity. Hill-Sachs and bony Bankart lesions were included. Patients who underwent treatment or follow-up at another clinic were excluded to avoid the inconvenience of a double follow-up.

All patients were assigned a study number and received a web-based questionnaire to be completed at home. All answers were required prior to submission. Patients lacking Internet access received an identical paper version. Missing items were completed by telephone. Patients were asked to complete the questionnaire twice at an interval of 5 to 30 days, which was considered long enough to forget prior answers and short enough to assume an unchanged shoulder condition. Both versions were either web-based or on paper.

The local ethics committee (METC from the Onze Lieve Vrouwe Gasthuis) approved the study and written informed consent was obtained from all patients.

Patient Reported Outcome Measurements

Western Ontario Shoulder Instability index (WOSI)

The WOSI is a disease-specific PROM developed by Kirkley et al. in 1998 according to the methodology described by Kirschner and Guyatt.[27] It was designed to be used as primary outcome measure in clinical trials that evaluated treatments for patients with shoulder instability.[26] The 21-item questionnaire consists of four domains, referring to physical symptoms, sport/recreation/work function, lifestyle function, and emotional function. Originally responses are given on a 100-mm visual analogue scale, ranging from no complaints (0 mm) to severe complaints (100 mm). We created a web-based version in which patients can choose a score from 0 to 10. Items were summarized in four domain sub scores as a total score, ranging from 0 to 2100, where 0 indicated no limitations in shoulder-related quality of life and 2100 indicated extreme limitations. The score could also be expressed as a percentage of normal shoulder function, where a score of 2100 reflected 0% of normal function and a score of 0 reflected 100%.[25] The WOSI was originally validated against the Disabilities of the Arm, Shoulder, and Hand (DASH) assessment and the University of California-Los Angeles (UCLA) shoulder rating scale, with correlations of 0.77 and 0.65, respectively.

Validation instruments

The following instruments were used to assess the construct validity of the WOSI.

Oxford Shoulder Instability Score (OSIS)

The OSIS is a disease-specific PROM developed by Dawson et al. to assess treatment for shoulder instability.[8]

It was originally validated against the Rowe and Constant scores, with correlations of 0.51 and 0.56, respectively. The internal consistency (Cronbach's α) was 0.92. The reliability was 0.97, calculated with Pearson's correlation coefficient.[8] The OSIS is currently being translated and validated in Dutch in our institution. Unpublished results show good internal consistency, reliability and construct validity.

Simple Shoulder Test (SST)

The Simple Shoulder Test (SST) is a body-part-specific PROM that was developed by Matsen and Lippitt et al.[30] It was intended to measure functional limitations of the affected shoulder in patients with common shoulder problems, including rotator cuff tears, degenerative osteoarthritis, and instability.[30] It was validated against the American Shoulder and Elbow Surgeons (ASES) survey with a correlation of 0.81. It has recently been validated in Dutch language, showing high reliability (interclass correlation coefficient (ICC) 0.92) and high internal consistency (Cronbach's α 0.78).[17,47]

Oxford Shoulder Score (OSS)

The Oxford Shoulder Score (OSS) is a body-part-specific PROM, developed in 1996 by Dawson et al.[7] It was developed for patients with general shoulder complaints.

The OSS was originally validated against the Constant shoulder score and the Short Form-36 (SF-36) subscales, with correlations of -0.74 and -0.66, respectively (the highest correlation was with the SF-36 Pain subscale). It has later been validated in Danish [14], Korean [38], Turkish [46], Italian [33], German [22], and Dutch. It had a high reliability (ICC 0.98) and high internal consistency (Cronbach's α 0.92).[5]

Disability of the Arm, Shoulder and Hand (DASH) assessment

The Disability of the Arm, Shoulder and Hand (DASH) assessment is a body-part-specific PROM, developed in 1996 by the American Association of Orthopaedic Surgeons (AAOS), to measure physical function and symptoms in patients with musculoskeletal disorders caused by any condition in any joint in the upper extremity.

The DASH was shown to be reliable, valid, and responsive for patients with shoulder disabilities.[10] It was validated by Beaton et al. in 2001.[4,23] The DASH was validated in English against the Shoulder Pain and Disability Index (SPADI), and correlations with the pain and function subscales were 0.82 and 0.88, respectively. It was also validated in Dutch for patients with disorders of the upper limb. It had a high internal consistency (Cronbach's α 0.95) and reliability (Pearson correlation coefficient of 0.98).[48]

Short form 36 Health Survey, version 1 (SF-36)

The Short form 36 Health Survey (SF-36) is the most widely used PROM for assessing general health.[15] It has eight domains: Physical function, Social function, role limitations caused by physical problems (Role physical), role limitations caused by emotional problems (Role emotional), General mental health, Vitality, Bodily pain, and Perception of general health.[39]

The SF-36 was translated and validated in a Dutch general population.[11] Previous studies have also validated the SF-36 specifically for shoulder complaints.[16,35]

Assessment of measurement properties

Structural validity and internal consistency

Items of PROMs that are being summarized into one score (either a subscale or total score) should measure the same construct. Structural validity is defined as the degree to which the scores of an instrument are an adequate reflection of the dimensionality (i.e. expected number of subscales) of the construct to be measured.[32]

Thus, in case of the WOSI, do questions within the subscales measure the same construct (i.e. physical symptoms, sport/recreation/work function, lifestyle function or emotional function)? Likewise, do questions from different subscales measure different constructs?

Structural validity was assessed by confirmatory factor analyses (CFA) using baseline measurements. We expected four factors— one for each of the WOSI domains. Factor loadings represent the correlation between the items in the questionnaire and the factors (the underlying dimensions). We examined factor loadings and model fit with CFA for categorical items, performed in Mplus (modeling program) using the method of weighted least squares with mean and variance adjustment.

Factor loadings are generally considered to be meaningful when they exceed 0.30 or 0.40.[13] We considered factor loadings of at least 0.50 appropriate. The Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), and the Root Mean Square Error of Approximation (RMSEA) were used as measures for model fit. A CFI and TLI of > 0.95 and a RMSEA of < 0.05 were considered as adequate fit. For a moderate fit, values > 0.90 and < 0.08 were used.[21] Because the model didn't fit well (see Results), additional exploratory factor analyses were performed with SPSS software, using the Varimax rotation.

Internal consistency is defined by COSMIN as the degree of interrelatedness among the items.[32] Items may ask similar questions in slightly different ways for reliably capturing the respondent's opinion or level of function.[7] The internal consistency of the WOSI was assessed by calculating Cronbach's α for each subscale. Cronbach's α is preferably ≥ 0.70.[43]

Measurement error and reliability

The measurement error is the systematic and random error of a patient's score that is not attributed to true changes in the patient's condition.[32]

When a patient's score changes within the range of the measurement error, it is unclear whether the change is an effect of the therapy or should be attributed to a measurement error.

Measurement error can be expressed as the standard deviation of repeated measurements in a single patient, which is referred to as the standard error of measurement (SEM). The SEM was calculated from the square root of the variance between the measurements and the error variance of the ICC. Subsequently, the SEM can be transformed into the smallest detectable change ($SDC = 1.96 * \sqrt{2} * SEM$), which can be used to interpret change scores in individual patients over time. It represents the minimum change a patient must show to ensure that the observed change is real and not a measurement error.[9]

Reliability is defined as the proportion of the total variance in the measurements that is due to true differences between patients.[32] Reliability is calculated using the ICC with a two-way mixed-effects model for absolute agreement. The ICC ranges from 0 (poor reliability) to 1 (patients with unchanged health status whose answers would be the same on two occasions). Scores ≥ 0.70 are considered adequate.[43]

Construct validity

Construct validity refers to the degree to which scores are consistent with hypotheses regarding relations with other instruments measuring similar constructs. In this study, the condition-specific WOSI was compared with the OSIS, measuring a similar disease-specific construct (shoulder instability); the SST, OSS, and DASH, assessing a similar body-specific domain (shoulder); and several subscales of the original version of SF-36, measuring general health status. The hypotheses were based on clinical experience, knowledge of several PROMs, and consensus among the study investigators. Our hypotheses are presented in Table 1.

Expected correlation between the WOSI and the OSIS was ≥ 0.70. Between the WOSI and the SST, OSS, and DASH assessment it was ≥ 0.60. The highest correlation was expected between two PROMs assessing the same disease-specific construct (WOSI and OSIS, both measuring limitations caused by shoulder instability).

Each WOSI domain was expected to have the highest correlation with its comparable SF-36 domain: WOSI Physical symptoms and SF-36 Bodily pain; WOSI Sport/ recreation/ work and SF-36 Role functioning; WOSI Lifestyle and SF-36 Social functioning; WOSI Emotional function and SF-36 Mental health. These four correlations were also expected to be at least 0.40.

In total, 79 correlations (or comparisons between correlations) were evaluated. Construct validity was considered good when at least 75% of the results were in accordance with our hypotheses.[44]

Table 1. Pre-determined hypotheses for testing validity of the Dutch version of WOSI; expected and observed correlations.

	Expected correlations	Observed correlations
1. WOSI and OSIS	≥ 0.7	0.82
2. WOSI and SST	≥ -0.6	- 0.66
3. WOSI and OSS	≥ 0.6	0.79
4. WOSI and DASH	≥ 0.6	0.81
5. Correlation between WOSI and OSIS, both measuring a disease-specific construct should be at least 0.1 higher compared to all other correlations.		
6. Correlation between similar WOSI and SF-36 domains should be higher compared to dissimilar domains.		
7. Correlation between similar WOSI and SF-36 domains should be ≥ 0.4.		

Correlations were calculated using the total WOSI score.

Floor and ceiling effects

Floor and ceiling effects occur when more than 15% of patients achieve the lowest or highest possible score, respectively.[31] When patients already have the highest or lowest possible score before intervention, it is impossible to measure further improvement or deterioration.

When we take the SDC into account we should consider floor and ceiling effects more broadly. If a score is close to one of the extremes, and the distance between the initial score and the extreme is smaller than the SDC, a change beyond the measurement error cannot be measured. For this reason, we also assessed how many scores were observed within the SDC range from both extremes.

Statistical analyses

Statistical analyses were performed using SPSS software, version 18.0.0 and MPlus.

RESULTS

Translation process

Forward translation of the WOSI into Dutch (V1) did not impose any problems. No difficulties occurred with the patients completing the questionnaire under supervision or at home. Their answers were not used in the subsequent validation process. Translating the WOSI backward also did not impose any problems. The Dutch version is presented in Appendix 1.

Patients

A total of 154 patients with shoulder instability were recruited, among whom 138 patients (90%) completed the WOSI. Because retesting was initiated after the first 21 patients had been included, 117 were asked to complete the WOSI twice. Fifteen patients were either not able or not willing to participate in the retest. Of the remaining 102 patients, three were excluded because they exceeded the 30-day interval. In total, 99 (64%) completed a retest. A flowchart is presented in Figure 1.

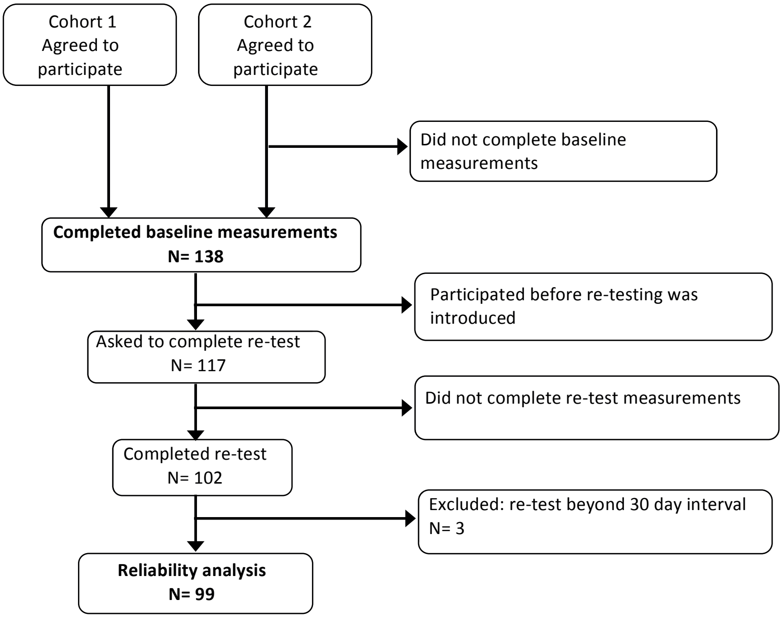

Figure 1. Flowchart of selection of patients that participated in the study.

Table 2. Demographic data and mean (SD) data from the OSIS, SST, OSS and DASH at baseline and re-test.

		Baseline assessment	Reliability cohort
		138	99
mean age yrs (SD)		32 (12)	32 (14)
gender (male vs female)		98 (71%) vs 40 (29%)	66 (67%) vs 33 (33%)
dislocated shoulder			
right		72 (53%)	54 (55%)
left		59 (43%)	40 (40%)
both		6 (4%)	5 (5%)
dominant side dislocated		72 (53%)	53 (54%)
date first dislocation			
<1 month		8 (6%)	8 (8%)
1 - 6 months		21 (15%)	17 (17%)
>6 months – 2 years		40 (29%)	25 (25%)
>2 years		67 (49%)	49 (50%)
OSIS	(0 – 48)*	27.3 (9.1)	27.6 (9.7) ¶
SST	(0 – 12)*	8.8 (3.1)	8.8 (3.2) ¶
OSS	(48 – 0)*	23.7 (7.8)	22.8 (8.3) ¶
DASH	(100 – 0)*	22.2 (16.7)	22.7 (18.3) ¶

* ranges reflect most impaired to least impaired function.
¶ No significant change in either shoulder function (OSIS, SST, OSS, DASH) or general health (SF-36) was observed at retest compared to baseline.

The mean time between completion of the first and second questionnaires was 13 days (5– 30 days). Sixteen patients completed their first questionnaire on paper followed by a web-based retest; four patients completed both questionnaires on paper. Table 2 shows the patients' demographic data and the mean scores of all PROMs at baseline and at retesting. The mean age at baseline was 32 years. Men were affected more frequently than women. Both sides of the shoulder were equally affected. All patients had suffered anterior dislocations. As measured with the OSIS, OSS, SST, and DASH evaluations, there was no significant change in shoulder function at baseline and retesting.

Structural validity and internal consistency

The expected four-factor model did not fit well: CFI 0.869, TLI 0.850, RMSEA 0.104. Subsequently, three-factor, two-factor, and one-factor models were tested by exploratory factor analyses (Table 3). The best interpretable results were found with only one factor, although confirmative testing of this one-factor model in CFA showed worse fit

Table 3. Exploratory factor analysis.

question	3-factor			2-factor		1-factor
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 1
1	,302	,402	**,662**	**,743**	,357	**,779**
2	,145	,375	**,761**	**,830**	,192	**,725**
3	,396	**,604**	,417	**,625**	**,531**	**,818**
4	,339	**,546**	**,523**	**,693**	,449	**,809**
5	,125	**,653**	,296	**,571**	,300	**,617**
6	,152	**,560**	,470	**,671**	,281	**,675**
7	,028	,375	**,706**	**,793**	,086	**,624**
8	,407	**,665**	,230	,494	**,577**	**,757**
9	,323	**,704**	,297	**,579**	**,504**	**,766**
10	,374	**,648**	,332	**,576**	**,531**	**,783**
11	**,659**	,451	,299	,423	**,740**	**,822**
12	**,608**	,469	,396	**,520**	**,690**	**,855**
13	**,694**	**,533**	,075	,269	**,819**	**,767**
14	,375	,147	**,738**	**,674**	,338	**,717**
15	**,582**	,378	,185	,295	**,654**	**,670**
16	**,535**	,020	**,578**	,458	,463	**,652**
17	**,624**	,402	,156	,279	**,704**	**,693**
18	,204	,277	**,732**	**,749**	,219	**,686**
19	**,753**	,327	,113	,192	**,805**	**,703**
20	**,792**	,051	,173	,102	**,749**	**,600**
21	**,738**	,155	,364	,323	**,715**	**,733**
scores ≥ 0.50	9	8	7	12	12	21

Factor loadings ≥ 0.50 are appropriate (bold). Best results are with the 1-factor model in which all questions score at least 0.50.

(CFI 0.800, TLI 0.778, RMSEA 0.127) than the original four-factor model.

Internal consistency was analyzed using baseline measurements for all 138 patients. For the WOSI domains, Cronbach's α was 0.93 for emotional function, 0.94 for physical symptoms and lifestyle function, and 0.95 for sports/ recreation/work. For the WOSI total, Cronbach's α was 0.96.

Measurement error

For the total WOSI score, the SEM was 8.3%, resulting in an SDC of 23.0%. This indicates that a patient has to change 23.0 points on a scale from 0 to 100 to detect an actual change in shoulder function (that cannot be attributed to measurement error). For the

Table 4. Test-retest reliability (ICC) and the standard error of measurement (SEM) for the WOSI.

N=99	Mean (SD)			SEM	ICC (95% CI)
	Baseline	Re-test	Change		
WOSI					
total	971 (482)	959 (509)	-12.1 (199.5)	174	0.92 (0.88-0.95)
total as %	46.0 (22.3)	45.7(24,2)	- 0.6 (9.5)	8.3	0.92 (0.88-0.95)
Domain as %					
physical	60.2 (24.0)	60.6(24.7)	0.4(11.2)	8.3	0.90 (0.85 – 0.93)
sp/rec/wrk	47.7 (27.8)	49.6(28.5)	1.9(12.7)	9.4	0.90 (0.85 – 0.93)
lifestyle	56.5 (24.3)	55.8(25.4)	- 0.7(12.3)	8.8	0.88 (0.83 - 0.92)
emotion	36.8 (27.5)	37,8(30.2)	1.0(14.4)	10.1	0.88 (0.82 - 0,92)

Scores are presented for the total WOSI score (ranging from 0 - 2100), for the total WOSI score expressed as percentage (ranging 1 – 100) as well as for all WOSI subdomains.

Table 5. Floor and ceiling effects and the smallest detectable change (SDC) for the WOSI.

N=138	Absolute Floor	Absolute Ceiling	SDC	SDC- range from		% of patients scoring within SDC -range	
WOSI				Floor	Ceiling	Floor	Ceiling
total	No	No	23.0	0-23	77-100	17%	5%
Domain							
physical	No	No	23.1	0-23.1	76.9-100	3%	26%
sp/rec/wrk	No	No	26.0	0-26	74.0-100	23%	20%
lifestyle	No	No	24.4	0-24.4	74.6-100	9%	25%
emotion	No	No	28.1	0-28.1	71.9-100	41%	10%

From left to right are presented; absolute floor and ceiling scores. The smallest detectable change (SDC) with its ranges, and the percentage of scores that fell within the SDC-range for both extremes. Scores are presented for the total WOSI score and all WOSI subdomains.

domains, the SEM varied from 8.3% to 10.1%, resulting in a SDC ranging from 23.1% to 28.1%. Scores are presented in Tables 4 and 5.

Reliability

The WOSI test and retest scores are shown in Table 4. The mean WOSI total score at baseline was 971 (46.0%). The mean total WOSI retest score was 959 (45.7%). For the four domains, scores expressed as a percentage ranged from 60.2% to 82.6% at baseline and from 37.8% to 60.6% at retest.

Regarding the WOSI total, the ICC (95% CI) was 0.92 (0.88– 0.95), indicating excellent reliability. For the WOSI domains, the ICC ranged from 0.88 (0.82– 0.92) to 0.90 (0.85–0.93).

Construct validity

Correlations are summarized in Table 1. The correlation between the instability-specific WOSI and OSIS was 0.82 (≥ 0.70 expected). The correlations between the WOSI and the shoulder-specific SST, OSS, and DASH were − 0.66, 0.79, and 0.81, respectively (≥ 0.60 expected).

The correlations between both the total WOSI score and WOSI domains and the SF-36 domains are presented in Table 6. The correlation between the WOSI and OSIS was at least 0.10 higher than all other correlations, except the correlation between the total WOSI score and SF-36 Bodily pain (0.76) and between the WOSI Physical functioning domain and SF-36 Bodily pain (both 0.76).

Correlations between similar WOSI and SF-36 domains were highest, as expected, except for WOSI Emotional function (0.27). Three of four correlations between similar WOSI

Table 6. Observed correlations between the WOSI domains and SF-36 domains.

	WOSI total	physical	sp/rec/work	lifestyle	emotions
SF-36					
PF	-0.69	0.63	0.71	0.66	0.46
RF	-0.60	0.56	**0.60**	0.54	0.40
RE	-0.48	0.44	0.42	0.46	0.37
MH	-0.28	0.23	0.23	0.30	**0.27**
V	-0.39	0.35	0.31	0.45	0.31
SF	-0.51	0.46	0.51	**0.46**	0.39
BP	-0.76	**0.76**	0.71	0.67	0.46
GH	-0.36	0.35	0.28	0.35	0.27

Expected correlations ≥ 0.4 between similar domains are expressed in bold.
PF= Physical Functioning, SF= Social Functioning, GH= General Health, V= Vitality, MH=Mental Health, RE= Role Emotional, RF= Role Functional, BP= Bodily Pain.

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Table 7. Measurement properties of the WOSI as presented in the original article and subsequent validation studies.

Study	N	Internal consitency	ICC (interval)	Construct validity		SEM and SDC	Floor/ ceiling	MIC	SRM & ES
Kirkley et al. 2001	Total: 300 Not specified	N = 33 item reduction	N = 51 0,494 (2wks) 0.911 (3mnts)	N=47 (baseline) DASH UCLA Constant Rowe ASES SF12 physical SF-12 mental ROM	 0.768 0.649 0.590 0.609 0.553 0.656 0.115 0.394	NA	NA	NA	SRM 0.931
Salomonsson et al. 2009	Total: 99 22 surgery 32 partly surgery 45 healthy	N = 22 α = 0.89	N = 32 0.94 (2 mnts)	N = 22 VAS function EQ-5D N = 32 Rowe	 0.80 0.44 0.59	NA	Not found	NA	N = 22 SRM 1.40 ES 1.67
Hatta et al. 2011	Total: 85 Not specified	N = 85 α = 0.84	N = 59 0.91 (2wks)	N = 85 Quick DASH Rowe SF-36 Physical funct Social funct General health Mental health Vitality Role emotional Role functional Bodily pain	 0.63 0.42 0.36 0.10 0.27 0.26 0.28 0.16 0.26 0.34	NA	NA	NA	NA

Table 7. Measurement properties of the WOSI as presented in the original article and subsequent validation studies. (continued)

Study	N	Internal consitency	ICC (interval)	Construct validity		SEM and SDC	Floor/ ceiling	MIC	SRM & ES
Hofstaetter et al. 2009	Total: 86 24 surgery 25 partly surgery 37 healthy	N = 24 α = 0.92	N = 25 0.92 (24-72 hr)	Rowe UCLA Constanst SF-36 Physical funct Social functl General health Mental health Vitality Role emotional Role functional Bodily pain	0.627 0.609 0.590 0.44 0.32 0.34 0.38 0.33 0.32 0.39 0.56	NA	High ceiling in healthy shoulders	NA	NA
Drerup et al. 2010	Total: 30	N = 29 α = 0.89	N = 29 0.87	ASES	0,58	NA	Not found	NA	NA
Cacchio et al. 2012	Total: 64	N = 64 α = 0.93	N = 64 0.95 (3 days) N = 20 0.92 (14 wks)	DASH SF-36	0.79 0.11	SEM 71 SDC 196	Not found	400	N = 39 SRM 1.94 ES 1.47

Measurement properties include the Internal consistency (Cronbach's α), the Intraclass Correlation Coefficient (ICC), the Construct validity (Pearsons correlation coefficient), the Standard Error of Measurement (SEM) and Smallest Detectable Change (SDC), Floor- and ceiling effects, the Minimal Important Change (MIC) and Sensitivity to change (Standardized Response Mean (SRM) and Effect Size (ES)). NA means Not Assessed.

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and SF-36 domains were at least 0.40. In total, 76% of the results were in accordance with the hypotheses.

Floor and ceiling effects

Floor and ceiling effects are presented in Table 5. No floor or ceiling effects were found. When considering the SDC, however, more than 15% of the scores in two subdomains were within the SDC from the lowest possible score (23% and 41%), and more than 15% of the scores in three subdomains were within the SDC from the highest possible score (20%, 25%, 26%).

DISCUSSION

International adoption and validation of measurement instruments helps us to exchange results globally in a standardized way, thereby enabling international evaluation to optimize treatment strategies. Regarding shoulder instability, the WOSI is the most thoroughly studied PROM to evaluate shoulder functioning in patients with shoulder instability. It has officially been validated in five other languages since its development in English. Measurement properties of the original WOSI and subsequent validation studies are summarized in Table 7.

Translating the WOSI into Dutch did not incur difficulties and resulted in a well-translated and comprehensive Dutch version.

Regarding the structural validity, we were unable to confirm the validity of the four domains of the WOSI. An exploratory factor analysis suggested a one-factor model, but this model fit even worse. The factor structure and the value of the four domains of the WOSI therefore remain unclear. Apparently, there is no clear distinction between the questions about symptoms, physical functioning, and emotional aspects. Also, when reading the questions, there is a lack of face validity of the four dimensions. For example, questions about fear of falling or sleeping are included in the lifestyle subscale, which may actually measure emotional aspects and symptoms, respectively. Also one may wonder whether a question about 'feel the need to protect your arm during activities' refers to functioning or emotional aspects. The subscales should therefore be used with caution.

A high Cronbach's α of 0.96 for the total WOSI score and 0.93– 0.95 for the subscales were found, which exceeded those in previous validation studies (ranging from 0.84 to 0.93). Compared with other Dutch-validated PROMs, Cronbach's α of the WOSI was higher than that of the SST (0.78), OSS (0.92), or DASH (0.95).[5,47,48] However, Cronbach's α of the WOSI total score was highly affected by the large number of items.

This study is the second one to report on measurement errors of the WOSI. Cacchio et al.[6] reported an SEM of 71 and an SDC of 196 in 64 patients. We found much higher SEM and SDC values (174 and 483, respectively), indicating that a patient has to improve at least 23% of the total score (483/2100 possible points) to ensure an improvement beyond measurement error. It should be noted that the SDC refers to the measurement error in one changed score in one individual patient. When measuring change in a group of patients (as in a study), the measurement error of the mean change score is much lower (in fact, SDC/√ n).

With an ICC of 0.92 for the total WOSI score and 0.88– 0.90 for the subscales, the reliability of the Dutch version is considered very good. Including 99 patients in our test– retest analysis, our population was larger than populations described in previous validation studies (25– 64 patients).

Our study is most similar to those performed by Kirkley, et al.[19] and Hatta, et al.[26] regarding both the length of the test– retest interval (both 2 weeks) and the size of the patient population (51 and 59 patients, respectively). These studies reported ICCs of 0.94 and 0.91, respectively, for the WOSI total score.

Studies performed by Salomonsson et al.[6], Hofstaetter, et al.[20] and Cacchio et al.[40] all had smaller patient populations (32, 25, and 30, respectively) and differed in their treatment-free test– retest interval. Hofstaetter et al. and Cacchio et al. used a test– retest interval of 24– 72 h and 3 days or 14 weeks, respectively. Salomonsson et al. used an interval of 2 and 3 months, respectively. These studies nevertheless present comparable ICCs for the total WOSI score, varying from 0.91 to 0.95. Only Drerup, et al.[11] reported a lower ICC (0.87), without defining either its test– retest interval or patient population.

To assess the construct validity, Kirkley et al. calculated correlations with the DASH, the UCLA shoulder rating scale, the Constant score, the Rowe rating scale, ASES, and SF-12. The original Rowe and Constant scores are not PROMs but observer-based measurement instruments, and the Constant score is considered not applicable to shoulder instability.[24,29] We used only PROMs for the Dutch validation. Because the SST and OSS are validated in Dutch, and because preliminary results of the Dutch OSIS validation are good, we decided to use these instruments instead of the UCLA shoulder rating scale and ASES. It should be noted, however, that the WOSI is validated against the OSIS, and the OSIS is validated against the WOSI. Unfortunately, there is no gold standard or other validated PROM for shoulder instability that could be used to assess construct validity. Therefore, we chose this method but also included other instruments. The high correlation between WOSI and OSIS (0.82) means that the two questionnaires are measuring the same construct, but it does not guarantee that both instruments are valid.

With 76% of our predetermined hypothesis being confirmed, construct validity was considered good. Despite the fact that few questions of the DASH assessment and WOSI overlap, a high correlation was observed (0.81). Both the original article [26] and studies using WOSI translations in Japanese and Italian also found a higher correlation with the DASH and Quick DASH than with other outcome measures (0.77, 0.63, and 0.79, respectively).

Regarding the total WOSI score, no floor or ceiling effects were found, as also described by McHorney.[31] When the SDC (23.0%) is taken into account, however, a total of 23 scores (17%) were within the SDC from the lowest possible score. No real deterioration beyond measurement error could be detected in these patients.

A strong aspect of this study is our large population of patients with shoulder instability and without missing values regarding the PROM questions. Although needed to perform this study, a weak aspect might be the total number of questions posed to our patients. Completing six questionnaires at once requires considerable time and concentration, during which patients might lose their focus. Another weak point is the fact that we used a preliminary version of the Dutch OSIS to validate the WOSI. Official translation and validation is a subject of future, yet unpublished studies in our institution.

Future studies should focus on determining the responsiveness and the minimum important changes (MIC) needed in the WOSI. This information can be used to determine whether observed changes are important to patients and to determine the number of patients who achieve a change greater than the MIC (e.g., responders in an intervention study). The numbers of responders can then be compared between groups in clinical trials.[41]

CONCLUSION

The Dutch version of the WOSI showed good reliability and construct validity in a cohort of patients with shoulder instability, but the factor structure remains unclear.

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REFERENCES

1. Ahmed I, Ashton F, Robinson CM. Arthroscopic Bankart repair and capsular shift for recurrent anterior shoulder instability: functional outcomes and identification of risk factors for recurrence. *J Bone Joint Surg Am.* 2012;94:1308-1315.
2. Bak K, Fogh K. Reconstruction of the chronic anterior unstable sternoclavicular joint using a tendon autograft: medium-term to long-term follow-up results. *J Shoulder Elbow Surg.* 2013:
3. Beaton DE, Bombardier C, Guillemin F et al. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine (Phila Pa 1976).* 2000;25:3186-3191.
4. Beaton DE, Katz JN, Fossel AH et al. Measuring the whole or the parts? Validity, reliability, and responsiveness of the Disabilities of the Arm, Shoulder and Hand outcome measure in different regions of the upper extremity. *J Hand Ther.* 2001;14:128-146.
5. Berendes T, Pilot P, Willems J et al. Validation of the Dutch version of the Oxford Shoulder Score. *J Shoulder Elbow Surg.* 2010;19:829-836.
6. Cacchio A, Paoloni M, Griffin SH et al. Cross-cultural adaptation and measurement properties of an Italian version of the Western Ontario Shoulder Instability Index (WOSI). *J Orthop Sports Phys Ther.* 2012;42:559-567.
7. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about shoulder surgery. *J Bone Joint Surg Br.* 1996;78:593-600.
8. Dawson J, Fitzpatrick R, Carr A. The assessment of shoulder instability. The development and validation of a questionnaire. *J Bone Joint Surg Br.* 1999;81:420-426.
9. de Vet HC, Terwee CB, Knol DL et al. When to use agreement versus reliability measures. *J Clin Epidemiol.* 2006;59:1033-1039.
10. Desai AS, Dramis A, Hearnden AJ. Critical appraisal of subjective outcome measures used in the assessment of shoulder disability. *Ann R Coll Surg Engl.* 2010;92:9-13.
11. Drerup S, Angst F, Griffin S et al. Western Ontario shoulder instability index (WOSI): translation and cross-cultural adaptation for use by German speakers. *Orthopade.* 2010;39:711-718.
12. Floor S, Overbeke AJ. Questionnaires on the quality of life in other than the Dutch language used in the Nederlands Tijdschrift voor Geneeskunde (Dutch Journal of Medicine): the translation procedure and arguments for the choice of the questionnaire. *Ned Tijdschr Geneeskd.* 2006;150:1724-1727.
13. Floyd FJ, Widaman KF. Factor analysis in the development and refinement of clinical assessment instruments. *Psychological Assessment.* 1995;7:286-299.
14. Frich LH, Noergaard PM, Brorson S. Validation of the Danish version of Oxford Shoulder Score. *Dan Med Bull.* 2011;58:A4335.
15. Garratt A, Schmidt L, Mackintosh A et al. Quality of life measurement: bibliographic study of patient assessed health outcome measures. *BMJ.* 2002;324:1417.
16. Gartsman GM, Brinker MR, Khan M et al. Self-assessment of general health status in patients with five common shoulder conditions. *J Shoulder Elbow Surg.* 1998;7:228-237.
17. Godfrey J, Hamman R, Lowenstein S et al. Reliability, validity, and responsiveness of the simple shoulder test: psychometric properties by age and injury type. *J Shoulder Elbow Surg.* 2007;16:260-267.
18. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *J Clin Epidemiol.* 1993;46:1417-1432.
19. Hatta T, Shinozaki N, Omi R et al. Reliability and validity of the Western Ontario Shoulder Instability Index (WOSI) in the Japanese population. *J Orthop Sci.* 2011;16:732-736.
20. Hofstaetter JG, Hanslik-Schnabel B, Hofstaetter SG et al. Cross-cultural adaptation and validation of the German version of the Western Ontario Shoulder Instability index. *Arch Orthop Trauma Surg.* 2010;130:787-796.
21. Hu LT, Bentler PM. Cut-off criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Structural Equation Modeling.* 1999;6:1-55.
22. Huber W, Hofstaetter JG, Hanslik-Schnabel B et al. The German version of the Oxford Shoulder Score--cross-cultural adaptation and validation. *Arch Orthop Trauma Surg.* 2004;124:531-536.
23. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). *Am J Ind Med.* 1996;29:602-608.
24. Jensen KU, Bongaerts G, Bruhn R et al. Not all Rowe scores are the same! Which Rowe score do you use? *J Shoulder Elbow Surg.* 2009;18:511-514.
25. Kirkley A, Griffin S, Dainty K. Scoring systems for the functional assessment of the shoulder. *Arthroscopy.* 2003;19:1109-1120.
26. Kirkley A, Griffin S, McLintock H et al. The development and evaluation of a disease-specific quality of life

measurement tool for shoulder instability. The Western Ontario Shoulder Instability Index (WOSI). *Am J Sports Med.* 1998;26:764-772.

27. Kirshner B, Guyatt G. A methodological framework for assessing health indices. *J Chronic Dis.* 1985;38:27-36.
28. Liavaag S, Svenningsen S, Reikeras O et al. The epidemiology of shoulder dislocations in Oslo. *Scand J Med Sci Sports.* 2011;21:e334-e340.
29. Lillkrona U. How should we use the Constant Score?--A commentary. *J Shoulder Elbow Surg.* 2008;17:362-363.
30. Lippitt SB, Harryman DT II, Matsen FA III. A practical tool for evaluating function: the Simple Shoulder Test. In: Matsen FA III, Fu FH, Hawkins RJ, eds. The Shoulder: A Balance of Mobility and Stability. Rosemont, Illinois: The American Academy of Orthopaedic Surgeons; 1993:545-559.
31. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? *Qual Life Res.* 1995;4:293-307.
32. Mokkink LB, Terwee CB, Patrick DL et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res.* 2010;19:539-549.
33. Murena L, Vulcano E, D'Angelo F et al. Italian cross-cultural adaptation and validation of the Oxford Shoulder Score. *J Shoulder Elbow Surg.* 2010;19:335-341.
34. Nordqvist A, Petersson CJ. Incidence and causes of shoulder girdle injuries in an urban population. *J Shoulder Elbow Surg.* 1995;4:107-112
35. Ostor AJ, Richards CA, Prevost AT et al. Diagnosis and relation to general health of shoulder disorders presenting to primary care. *Rheumatology. (Oxford).* 2005;44:800-805.
36. Park MJ, Garcia G, Malhotra A et al. The evaluation of arthroscopic remplissage by high-resolution magnetic resonance imaging. *Am J Sports Med.* 2012;40:2331-2336.
37. Poolman RW, Swiontkowski MF, Fairbank JC et al. Outcome instruments: rationale for their use. *J Bone Joint Surg Am.* 2009;91 Suppl 3:41-49.
38. Roh YH, Noh JH, Kim W et al. Cross-cultural adaptation and validation of the Korean version of the Oxford shoulder score. *Arch Orthop Trauma Surg.* 2012;132:93-99.
39. Salaffi F, De Angelis R, Stancati A et al. Health-related quality of life in multiple musculoskeletal conditions: a cross-sectional population based epidemiological study. II. The MAPPING study. *Clin Exp Rheumatol.* 2005;23:829-839.
40. Salomonsson B, Ahlstrom S, Dalen N et al. The Western Ontario Shoulder Instability Index (WOSI): validity, reliability, and responsiveness retested with a Swedish translation. *Acta Orthop.* 2009;80:233-238.
41. Schunemann HJ, Akl EA, Guyatt GH. Interpreting the results of patient reported outcome measures in clinical trials: the clinician's perspective. *Health Qual Life Outcomes.* 2006;4:62.
42. Simonet WT, Melton LJ, III, Cofield RH et al. Incidence of anterior shoulder dislocation in Olmsted County, Minnesota. *Clin Orthop Relat Res.* 1984;186-191.
43. Snyder CF, Aaronson NK, Choucair AK et al. Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations. *Qual Life Res*. 2012;21:1305-1314.
44. Terwee CB, Bot SD, de Boer MR et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol.* 2007;60:34-42.
45. Terwee CB, Mokkink LB, Knol DL et al. Rating the methodological quality in systematic reviews of studies on measurement properties: a scoring system for the COSMIN checklist. *Qual Life Res.* 2012;21:651-657.
46. Tugay U, Tugay N, Gelecek N et al. Oxford Shoulder Score: cross-cultural adaptation and validation of the Turkish version. *Arch Orthop Trauma Surg.* 2011;131:687-694.
47. van Kampen DA, van Beers LW, Scholtes VA et al. Validation of the Dutch version of the Simple Shoulder Test. *J Shoulder Elbow Surg.* 2012;21:808-814.
48. Veehof MM, Sleegers EJ, van Veldhoven NH et al. Psychometric qualities of the Dutch language version of the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH-DLV). *J Hand Ther.* 2002;15:347-354.
49. Wild D, Grove A, Martin M et al. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. *Value Health.* 2005;8:94-104.
50. Wright RW, Baumgarten KM. Shoulder outcomes measures. *J Am Acad Orthop Surg.* 2010;18:436-444.
51. Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am.* 2010;92:542-549.

CHAPTER 4

Validation of the Oxford Shoulder Instability Score (OSIS) in Dutch and the assessment of its smallest detectable change

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ABSTRACT

Introduction

The Oxford Shoulder Instability Score (OSIS) is a short, self-reported outcome measurement for patients with shoulder instability.

Objective

In this study the OSIS was validated in Dutch by testing the internal consistency, reliability, measurement error, validity and the floor and ceiling effects and its Smallest Detectable Change (SDC) was calculated.

Methods and materials

A total of 138 patients were included. Internal consistency was calculated with Cronbach's α. Reliability (test-retest) was calculated with the intraclass correlation coefficient (ICC). The measurement error was calculated (SEM), and the SDC was estimated in a subgroup of 99 patients that completed the re-test after a mean of 13 days (5-30 days). Construct validity was evaluated by comparing the OSIS with the Western Ontario Shoulder Instability index (WOSI), the Simple Shoulder Test (SST), the Oxford Shoulder Score (OSS), the Disability of the Arm, Shoulder, and Hand assessment (DASH), and the Short Form-36 (SF-36).

Results

Internal consistency was good, with a Cronbach's α of 0.88. The reliability was excellent, with an ICC of 0.87. The SEM was 3.3 and the SDC was 9 points (on a scale of 0-48). Regarding the construct validity, 80% of the results were in accordance with the hypotheses, including a high correlation (0.82) with the WOSI. No floor or ceiling effects were found.

Conclusion

The Dutch version of the OSIS showed good reliability and validity in a cohort of patients with shoulder instability.

INTRODUCTION

Shoulder instability is common in orthopaedic practice; it generally affects young, active patients.[26,27,51]

Research and evaluation of therapies for shoulder instability should focus both on objectively verifiable outcomes, such as the range of motion and redislocations, and on subjective functioning. A variety of patient-reported outcome measures (PROM) exist, some of which are specifically designed to reflect the patient's subjective assessment of function. They enable the practitioner to detect functional changes in a standardized format. Because patients and doctors do not always agree on functional outcome after therapeutic interventions[22], PROMs have become increasingly important in assessing patient health status.[50] They can focus on general health; a physical domain or body part, such as the shoulder; or a specific condition or disease, such as instabilit.[21,34,50]

The Oxford Shoulder Instability Score (OSIS) is a comprehensive questionnaire including 12 questions to assess shoulder instability. With a Cronbach's α of 0.92, a Pearson correlation coefficient of 0.97 and measurement error of 5.7, the OSIS has proven to be valid and reliable, making it clinically important in patients with shoulder instability.[6] The OSIS was proven to be a useful outcome measure in several clinical studies [40;41;45], but it has not been translated and validated in languages other than English.

Translation and validation of internationally used PROMs will lead to culturally equivalent instruments and allow direct comparisons of national and international study results.[1,16,49] The aim of this study was to translate and validate the OSIS for the Dutch population and to evaluate its measurement properties according to the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) guidelines.[31]

METHODS AND MATERIALS

Translation procedure

After we obtained the official licence for the original English version, the OSIS was independently translated into Dutch by three native Dutch-speaking, medically educated translators. When they reached a consensus, a professional translator and a native English speaker (without a medical background) independently translated the version back into English; both were blinded to the first version and emphasized specifically on the linguistic aspects. Finally, the latter version was compared to the original text, composing a pre-final version. All items were agreed to be relevant for this patient population, and taken together, the items represented a comprehensive measurement of shoulder instability.

The pre-final version was checked for cross-cultural differences. It was subsequently completed by 13 patients with shoulder instability that were asked independently to assess the comprehensibility of all questions. These patients were not included in our final analysis.

Patients and procedures

To assess the reliability and validity of the OSIS in the Dutch population, 154 patients with shoulder instability were recruited. Institutional approval was obtained by the local ethics committee; Institutional Review Board (IRB): METC, OLVG Hospital, Amsterdam, the Netherlands. Written informed consent was obtained from all participants.

We planned to include at least 100 patients, which is considered excellent for assessing measurement properties.[31,43] A total of 154 patients with shoulder instability were included; all were diagnosed by one of the doctors in the outpatient clinic or the emergency department.

Patients were eligible to participate when they were 16 years or older and had been diagnosed with shoulder instability, based on their history and clinical examination. All patients were included on the ER or outpatient department of a hospital in Amsterdam. Exclusion criteria were an inability to master the Dutch language, a fracture in the glenoid, or a fracture in the humeral head. Hill-Sachs lesions and bony Bankart lesions were included. Tourists and temporary inhabitants of Amsterdam that were followed up in another clinic were also excluded, to avoid patient burden as a result of double follow-up.

All patients were assigned a study number and received either a web-based questionnaire, or alternatively, an identical paper questionnaire to complete at home. The order of administration was fixed. The web-based version required answers to all questions prior to submission. Missing values in paper submissions were completed in an interview by telephone.

Patients were asked to complete the questionnaire twice, without intervention. Both times, the questionnaire was either web-based or on paper. The repeated questionnaire was completed after a maximum interval of 5 to 30 days; this interval was considered long enough to forget prior answers, and short enough to assume an unchanged shoulder condition.[9,47]

Patient Reported Outcome Measurements

Oxford Shoulder Instability Score (OSIS)

The OSIS is a disease-specific PROM that was developed by Dawson et al. in 1999 in the United Kingdom for assessing the outcome of treatment for shoulder instability.[6]

This 12-item questionnaire contained 5 response categories for each question. In the original scoring system, answers were scored from 1 to 5 points, and summarized to a total score that ranged from 12 (least impaired) to 60 (most impaired). The scoring system was revised in 2009, in accordance with the revised scoring for the Oxford Shoulder Score (OSS), which originated in the same institute.[7] In the revised scoring system, answers were scored from 0 to 4, and the score was reversed; thus, the total score ranged from 0 (most impaired) to 48 (least impaired). We presented the results in terms of the new scoring system.

4

The OSIS was originally validated in 92 patients with shoulder instability that against the Rowe and Constant scores, with correlations of 0.51 and 0.56, respectively. The internal consistency (Cronbach's α) was 0.92. The reliability was 0.97, calculated with a Pearson correlation coefficient. The measurement error was 5.7 points, calculated with the Bland and Altman method. No intraclass correlation coefficient (ICC) was calculated.[6] To date, no cross-cultural validation has been conducted.

Validation instruments

The following instruments were solely used to assess the construct validity of the OSIS. No other data is used from these additional questionnaires. All instruments have been validated in Dutch, with good to excellent reliability and internal consistency.[15,46,47,3,48]

Western Ontario Shoulder Instability index (WOSI)

The WOSI is a disease-specific PROM for assessing the outcome of treatment for shoulder instability.[24,25] Responses to the 21-item questionnaire were summarized in a total score, ranging from 0 or 0% (no limitations) to 2100 or 100% (extreme limitations).

It has been validated in Italian, German, Swedish, Japanese and Dutch.[4,11,17,18,3,46] The Dutch version was validated using the same dataset as was used for the OSIS validation.

Simple Shoulder Test (SST)

The SST is a body-part-specific PROM.[29] It was designed to measure functional limitations of patients with general shoulder complaints. A cumulative score is calculated based on 12 questions (yes/no) and ranges from 0 (poor) to 12 (excellent shoulder function). It was validated against the American Shoulder and Elbow Surgeons (ASES) survey with a correlation of 0.81.[29]

Oxford Shoulder Score (OSS)

The OSS is a body-part-specific PROM. It was developed and validated for patients with general shoulder complaints.[5] Responses to the 12-item questionnaire were summarized to a total score that ranged from 12 (least impaired) to 60 (most impaired). This scoring system was revised in 2009.[7] Currently, answers are scored from 0 to 4, and the summary is reversed; thus, the total score ranges from 0 (most impaired) to 48 (least impaired).

The OSS was originally validated against the Constant shoulder score and the SF-36 subscales.[5] Since that validation, it has been validated in Danish, Korean, Turkish, Italian, German, and Dutch.[3,12,19,32,35,44]

Disability of the Arm, Shoulder, and Hand (DASH) assessment

The DASH assessment is a body-part-specific PROM, designed [20] to measure physical function and symptoms in patients with musculoskeletal disorders from any condition in any joint in the upper extremity.

Responses to the 30-item questionnaire are used to calculate the total score by averaging the item scores, subtracting 1, and multiplying the result by 25. The resulting score ranged from 0 (no disability) to 100 (extreme disability).

The DASH was shown to be reliable, valid, and responsive for patients with shoulder disabilities.[2,10]

Short form 36 Health Survey, version 1 (SF-36)

The SF-36 is a general health PROM that includes 36 questions for assessing the general health of patients with all kinds of disorders. It is the most widely used PROM for assessing general health.[13] It includes eight domains; physical function, social function, role limitations caused by physical problems (role physical), role limitations caused by emotional problems (role emotional), general mental health, vitality, bodily pain, and perception of general health. Each domain has a total score of 0 (extremely poor) to 100 points (no complaint).[36]

The SF-36 was translated and validated in a Dutch general population, with a mean alpha coefficient across all scales and samples of 0.84. Previous studies have also validated the SF-36 specifically for shoulder complaints.[14;33]

Assessments of measurement properties

Internal consistency and factor analysis

Internal consistency tells you to what extend different items within one questionnaire measure the same construct of interest (e.g. shoulder instability). Ideally this score is high, indicating that all items measure the same construct. The internal consistency of the OSIS was assessed by calculating Cronbach's α. For acceptable internal consistency, the Cronbach's α should preferably be ≥ 0.7. Internal consistency can also be addressed using confirmatory factor analysis. See Appendix 3.

Measurement error

Measurement error is the systematic, random error in the construct, which cannot be attributed to true changes in the patient's condition.[31] When a score changes within the range of measurement error, it is not clear whether the change is a true effect of therapy, or whether it should be attributed to measurement error.

Measurement error can be expressed as the standard deviation of repeated measurements in a single patient, referred to as the Standard Error of Measurement (SEM). The SEM was calculated from the square root of the variance between the measurements and the error variance of the ICC. Subsequently, the SEM can be transformed into the Smallest Detectable Change ($SDC=1.96*\sqrt{2}*SEM$). The SDC represents the minimal change that a patient must show to ensure that the observed change is real, and not a measurement error.[39] The SDC is thus calculated; it is not derived from clinical observations following treatment.

Reliability

Since each instrument has a degree of uncertainty due to measurement error, reliability is defined as the degree to which the measurement is free from measurement error.[31] The reliability refers to the proportion of the total variance in the measurements that can be attributed to true differences between patients. Reliability was assessed by calculating the ICC, which was calculated with a 2-way, mixed-effects model for absolute agreement. The mixed-effect model is used because a 'fixed' value (all questions remained unchanged during the whole cohort), is compared to a 'random' value (a cohort of patients was selected from all patients with shoulder instability). Scores ≥ 0.70 are considered adequate.[39]

Construct validity

Construct validity reflects whether the instrument measures what it was designed to measure. In case of shoulder instability, do questions actually measure the typical complaints following shoulder instability (e.g. How much pain do you experience in your shoulder with overhead activities?)? In the absence of a gold standard for comparison, hypotheses are formulated that state the expected correlation between the investigated instrument and similar PROMs. In this study, the condition-specific OSIS was compared with the condition-specific WOSI (instability) and with the body-part-specific SST, OSS, and DASH (shoulder). Finally, it was compared with several subscales of the original version of the SF-36 for measuring general health status. Pre-determined a priori hypotheses are stated in Table 1. These 6 hypotheses lead to a total of 42 correlations (or

Table 1. Pre-determined hypotheses for testing the validity of the Dutch version of OSIS; expected correlations.

	Expected correlations
1. OSIS and WOSI	≥ 0.7
2. OSIS and SST	≥ 0.6
3. OSIS and OSS	≥ 0.6
4. OSIS and DASH	≥ 0.6
5. Correlation between OSIS and body-specific PROMs (SST, OSS, and DASH) should be at least 0.1 higher than that between OSIS and the generic SF-36 subscales	
6. Correlation between OSIS and SF-36 physical function scale should be at least 0.1 higher than the correlations between OSIS and the other SF-36 subscales	

comparisons between correlations). The hypotheses were based on clinical experience, knowledge about several PROMs, and a consensus among the study investigators.

The highest correlation (≥ 0.7) was expected between the two disease-specific PROMs (OSIS and WOSI). High correlations (≥ 0.6) were expected between similar body-part-specific PROMs (OSIS and SST, OSS, and DASH). These correlation coefficients were expected to be at least 0.1 higher than the correlations between the OSIS and the more general subscales of the SF-36. Finally, because the OSIS predominantly measured physical function, we expected the correlation between the OSIS and the SF-36 physical function to be at least 0.1 higher than the correlations between the OSIS and the other SF-36 subscales.

Construct validity was considered good when at least 75% of the results (correlations) were in accordance with our hypotheses.[42]

Floor and ceiling effects

Floor and ceiling effects occur when more than 15% of patients achieve the lowest or highest possible score, respectively.[30] Moreover, when a patient scores close to one of the extremes at baseline, a real change (defined as the SDC) could cross that extreme. Patients that score within the SDC-range from one of the extremes can thus be regarded as being at either their floor- or ceiling too.

Statistical analyses

Statistical analyses were performed with SPSS software, version 18.0.0 (SPSS, Gorinchem, the Netherlands).

RESULTS

No major differences occurred between the OSIS translations into Dutch and back into English, no content- or linguistic-related difficulties were reported. The final version was considered free of cross-cultural inconsistencies; all questions are applicable to the Dutch population. The Dutch version is presented in Appendix 2.

Figure 1 presents the selection of participating patients. One hundred and thirty-eight patients with shoulder instabilities completed the first questionnaire, 99 patients were eligible for the second questionnaire. The shoulder function, presented as the mean and SD scores of the WOSI, SST, OSS and DASH did not differ significantly between the 2 measurements. The demographic data and means PROM scores are summarized in Table 2.

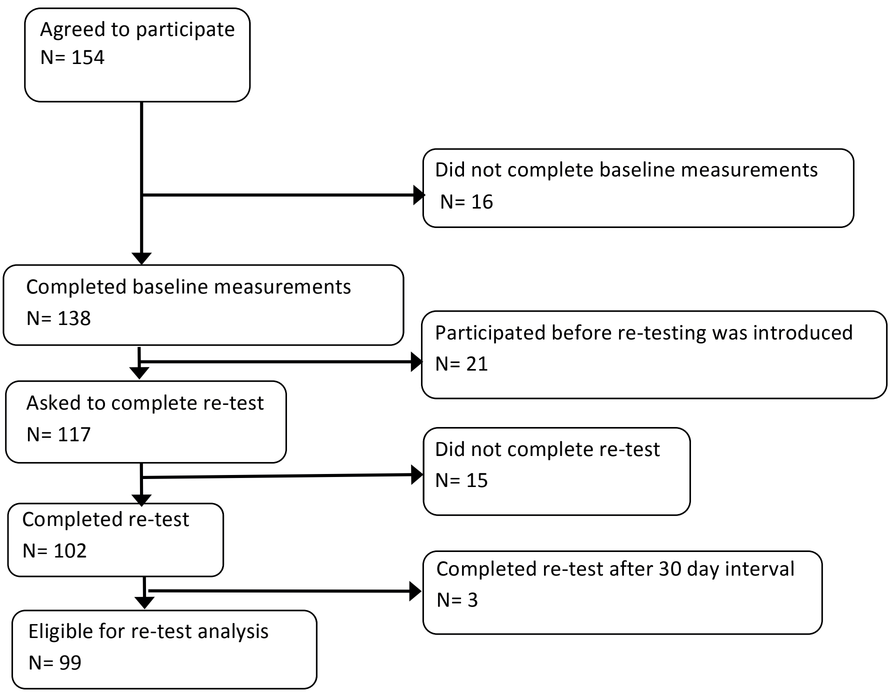

Figure 1. Flowchart of selection of patients that participated in the study.

Table 2. Demographic data of patients completing baseline and the reliability cohort.

	Baseline assessment N (%)	Reliability cohort N (%)
mean age, y (SD)	32 (12)	32 (14)
gender (male)	98 (71%)	66 (66%)
dislocated shoulder		
right	72 (53%)	54 (55%)
left	59 (43%)	40 (40%)
both	6 (4%)	5 (5%)
dominant side dislocated	73 (53%)	53 (54%)
time first dislocation to completion OSIS		
<1 month	8 (6%)	8 (8%)
1 - 6 months	21 (15%)	17 (17%)
>6 months – 2 years	40 (29%)	25 (25%)
>2 years	67 (49%)	49 (50%)
sports-related traumatic instability	71 (54%)	47 (47%)
WOSI (100 – 0)*	46.0 (22.3)	45.7 (24.2) †
SST (0 – 12)*	8.8 (3.1)	8.8 (3.2) †
OSS (48 – 0)*	23.7 (7.8)	22.8 (8.3) †
DASH (100 – 0)*	22.2 (16.7)	22.7 (18.3) †

* ranges reflect most impaired to least impaired function.
† No significant change in shoulder function (WOSI, SST, OSS, DASH) was observed at re-test compared with baseline interval.

Internal consistency and factor analysis

For all 138 patients that completed the OSIS at baseline, the Cronbach's α was 0.88, indicating good internal consistency.

Reliability

The mean time between the completion of the first and second questionnaires was 13 days (5-30). Table 3 presents the scores of the tests and retests and the ICC with a 95% confidence interval (ICC is 0.87 (0.82-0.91). These results indicated excellent reliability.

Measurement error

The SEM was 3.3, which resulted in a SDC of 9.0 points, indicating that a patient has to show a change of 9.0 points to ensure the detection of a true change. This is 19% of the total range.

Construct validity

The observed correlation results are summarized in Table 4. In total, 80% of the results were in accordance with our hypotheses. The hypotheses were confirmed for the cor-

Table 3. Test-retest reliability (ICC), standard error of measurement (SEM) and smallest detectable change (SDC) for the OSIS.

	Baseline Mean (SD)	Re-test Mean (SD)	Change Mean (SD)	SEM	SDC	ICC (95% CI)
New scoring system	27.2 (9.3)	27.6 (9.7)	- 0.4 (4.8)	3.3	9.0	0.87 (0.82-0.91)

Scores are expressed according to the new scoring system. This analysis included 99 patients that completed the baseline and retest evaluations.

Table 4. Observed correlations for testing the validity of the Dutch version of OSIS.

	Observed correlations
1. OSIS and WOSI	0.82
2. OSIS and SST	0.69
3. OSIS and OSS	0.76
4. OSIS and DASH	0.79
5. OSIS and SF-36 subscales:	
Physical function	0.65
General health	0.31
Social function	0.56
Vitality	0.39
Mental health	0.20
Role emotional	0.41
Role functional	0.69
Bodily Pain	0.78

relation between the OSIS and the other instability-specific WOSI (0.82; ≥ 0.7 expected) and the correlations between the OSIS and the shoulder-specific SST, OSS, and DASH (0.69, 0.76, and 0.79 respectively; ≥ 0.6 expected). The hypothesis was partly confirmed for the strength of the correlation between the OSIS and the SF-36 subscales.

Floor and ceiling effects

No patients scored minimum or maximum scores. At most, 12% of patients scored within the SDC-range for the lowest possible score. The results are presented in Table 5.

Table 5. Floor and ceiling effects of the OSIS scoring system.

Scoring system	Absolute floor	Absolute ceiling	SDC	SDC-range from		% of patients scoring within SDC –range from	
				Floor	Ceiling	Floor	Ceiling
New (48-0)*	No	No	9.0	48-39	9-0	12%	4%

* ranges reflect least impaired to most impaired function.
From left to right are presented; the new scoring system with the ranges and the absolute floor and ceiling scores. The smallest detectable change (SDC), and the percentage of scores that fell within the SDC-range for both extremes.

DISCUSSION

There is a growing interest in PROMs for both clinical and research purposes to supplement clinical outcome measures. To our knowledge, this is the first study to validate the OSIS in a foreign language and the first to report the measurement error and evaluate floor- and ceiling effects.

The results show a high internal consistency (Cronbach's α = 0.88); it was only slightly lower than that described in the original article (Cronbach's α = 0.91 at pre treatment [n = 92] and 0.92 at follow-up [n = 64]). Compared to other Dutch-validated PROMs, our Cronbach's α for the OSIS was higher than that of the SST (0.78) and lower than that of the OSS (0.92).[3,47]

Considering the content of the questions, it is clear that the OSIS measures several constructs, such as pain, physical-, social-, and role functioning, frequency of dislocation, and worries.

The reliability was addressed with a test-retest sample in 99 patients with a mean interval of 13 days (5-30) and showed an ICC of 0.88. This was lower than the 0.97 that Dawson et al described after a 24-h interval in 34 patients; nevertheless, 0.88 is considered a very good ICC.

To our knowledge, the measurement error (SDC) of the OSIS has not been reported previously. Our SDC value showed that, to determine a treatment effect, one must find a difference of at least 9 points between two scores from an individual patient to ensure that the difference was not due to measurement error.[8]

To assess the construct validity, Dawson et al calculated correlations with the Rowe and Constant scores. However, the Rowe and Constant scores are not PROMs, but observer-based measurement instruments. Moreover, the Constant score is not considered applicable to shoulder instability.[23,28] Therefore, the construct validity was assessed by calculating correlations with the WOSI, the SST, the OSS, the DASH, and the SF-36 subscales. With 80% of the results in accordance with our hypotheses, the construct validity was considered good. The highest correlation (0.82) was observed between the two instability-specific PROMs (OSIS and the WOSI).

A high correlation was observed with the DASH (0.79), which addresses daily activities more specifically than the OSIS. However, many questions overlapped such as 'putting on a pullover sweater' (DASH) and 'during the last three months, have you had any trouble (or worry) dressing, because of your shoulder?' (OSIS). This similarity might explain the high correlation between the two instruments.

The OSIS was more closely correlated with the SF-36 subscales 'pain' (0.78) and 'role physical' (0.69) than with the subscale 'physical function' (0.65). These correlations were comparable to those described by Dawson et al. This may indicate that, in addition to physical function, the OSIS measures aspects of pain and role limitations due to physical problems.

In previous studies, floor and ceiling effects were not addressed. In this study, no patient had the maximum or minimum score. The estimation of the smallest detectable change indicated that the baseline patient scores should ideally be at least 9 points different from the extremes. That margin would enable detection of improvements and deteriorations that are distinct from measurement errors at follow-up. At most, 12% of patients scored within the SDC-margin; thus, these scores were less than the commonly used cut off of 15%.[30]

A strong aspect of this study was the large size of our patient population without missing values.

Conversely, an unavoidable limitation of this study was the total number of questions posed to the patients. Completing six questionnaires at once requires considerable time and concentration, and patients might have digressed or lost focus. Also, although web-based versions have many advantages over paper versions such as an increased the follow-up ratio and prevention of missing data, validation of digital formats should still be performed. Here the results are expressed according the new scoring system. It is important to be aware of the changed scoring system and we recommend that future studies should specify the scoring system used.

Finally, for future studies, it would be very interesting to determine responsiveness and the minimal important change (MIC) of the OSIS. This information can be used to determine whether the observed change is important to the patient and to calculate the percentage of patients that report changes greater than the MIC (responders) in each arm of a trial. Then, the percentage of responders can be compared between groups.[38]

CONCLUSION

This study found that the Dutch version of the OSIS was a reliable outcome measure in patients with shoulder instability, with a Cronbach's α of 0.87 and an ICC of 0.87. In addition, the construct validity was considered good. Comprising 12 questions, the OSIS is user-friendly and can be easily administered. Furthermore, in the absence of floor or ceiling effects, it is a valuable PROM in clinical practice. Patients need to change at least 9 points to ensure that the difference is not due to measurement error.

REFERENCES

1. Beaton DE, Bombardier C, Guillemin F et al. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine (Phila Pa 1976).* 2000;25:3186-3191.
2. Beaton DE, Katz JN, Fossel AH et al. Measuring the whole or the parts? Validity, reliability, and responsiveness of the Disabilities of the Arm, Shoulder and Hand outcome measure in different regions of the upper extremity. *J Hand Ther.* 2001;14:128-146.
3. Berendes T, Pilot P, Willems J et al. Validation of the Dutch version of the Oxford Shoulder Score. *J Shoulder Elbow Surg.* 2010;19:829-836.
4. Cacchio A, Paoloni M, Griffin SH et al. Cross-cultural adaptation and measurement properties of an Italian version of the Western Ontario Shoulder Instability Index (WOSI). *J Orthop Sports Phys Ther.* 2012;42:559-567.
5. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about shoulder surgery. *J Bone Joint Surg Br.* 1996;78:593-600.
6. Dawson J, Fitzpatrick R, Carr A. The assessment of shoulder instability. The development and validation of a questionnaire. *J Bone Joint Surg Br.* 1999;81:420-426.
7. Dawson J, Rogers K, Fitzpatrick R et al. The Oxford shoulder score revisited. *Arch Orthop Trauma Surg.* 2009;129:119-123.
8. de Vet HC, Terwee CB, Knol DL et al. When to use agreement versus reliability measures. *J Clin Epidemiol.* 2006;59:1033-1039.
9. de Vet HC, Terwee CB, Mokkink LB et al. Measurement in Medicine. Cambridge University Press, 2011.
10. Desai AS, Dramis A, Hearnden AJ. Critical appraisal of subjective outcome measures used in the assessment of shoulder disability. *Ann R Coll Surg Engl.* 2010;92:9-13.
11. Drerup S, Angst F, Griffin S et al. Western Ontario shoulder instability index (WOSI): translation and cross-cultural adaptation for use by German speakers. *Orthopade.* 2010;39:711-718.
12. Frich LH, Noergaard PM, Brorson S. Validation of the Danish version of Oxford Shoulder Score. *Dan Med Bull.* 2011;58:A4335.
13. Garratt A, Schmidt L, Mackintosh A et al. Quality of life measurement: bibliographic study of patient assessed health outcome measures. *BMJ.* 2002;324:1417.
14. Gartsman GM, Brinker MR, Khan M et al. Self-assessment of general health status in patients with five common shoulder conditions. *J Shoulder Elbow Surg.* 1998;7:228-237.
15. Godfrey J, Hamman R, Lowenstein S et al. Reliability, validity, and responsiveness of the simple shoulder test: psychometric properties by age and injury type. *J Shoulder Elbow Surg.* 2007;16:260-267.
16. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *J Clin Epidemiol.* 1993;46:1417-1432.
17. Hatta T, Shinozaki N, Omi R et al. Reliability and validity of the Western Ontario Shoulder Instability Index (WOSI) in the Japanese population. *J Orthop Sci.* 2011;16:732-736.
18. Hofstaetter JG, Hanslik-Schnabel B, Hofstaetter SG et al. Cross-cultural adaptation and validation of the German version of the Western Ontario Shoulder Instability index. *Arch Orthop Trauma Surg.* 2010;130:787-796.
19. Huber W, Hofstaetter JG, Hanslik-Schnabel B et al. The German version of the Oxford Shoulder Score--cross-cultural adaptation and validation. *Arch Orthop Trauma Surg.* 2004;124:531-536.
20. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). *Am J Ind Med.* 1996;29:602-608.
21. Irrgang JJ, Lubowitz JH. Measuring arthroscopic outcome. *Arthroscopy.* 2008;24:718-722.
22. Janse AJ, Gemke RJ, Uiterwaal CS et al. Quality of life: patients and doctors don't always agree: a meta-analysis. *J Clin Epidemiol.* 2004;57:653-661.
23. Jensen KU, Bongaerts G, Bruhn R et al. Not all Rowe scores are the same! Which Rowe score do you use? *J Shoulder Elbow Surg.* 2009;18:511-514.
24. Kirkley A, Griffin S, Dainty K. Scoring systems for the functional assessment of the shoulder. *Arthroscopy.* 2003;19:1109-1120.
25. Kirkley A, Griffin S, McLintock H et al. The development and evaluation of a disease-specific quality of life measurement tool for shoulder instability. The Western Ontario Shoulder Instability Index (WOSI). *Am J Sports Med.* 1998;26:764-772.
26. Leroux T, Wasserstein D, Veillette C et al. Epidemiology of primary anterior shoulder dislocation requiring closed reduction in Ontario, Canada. *Am J Sports Med.* 2014;42:442-450.
27. Liavaag S, Svenningsen S, Reikeras O et al. The epidemiology of shoulder dislocations in Oslo. *Scand J Med Sci Sports.* 2011;21:e334-e340.
28. Lillkrona U. How should we use the Constant Score?--A commentary. *J Shoulder Elbow Surg.* 2008;17:362-363.

29. Lippitt SB, Harryman DT II, Matsen FA III. A practical tool for evaluating function: the Simple Shoulder Test. In: Matsen FA III, Fu FH, Hawkins RJ, eds. The Shoulder: A Balance of Mobility and Stability. Rosemont, Illinois: The American Academy of Orthopaedic Surgeons; 1993:545-559.
30. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? *Qual Life Res.* 1995;4:293-307.
31. Mokkink LB, Terwee CB, Patrick DL et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res.* 2010;19:539-549.
32. Murena L, Vulcano E, D'Angelo F et al. Italian cross-cultural adaptation and validation of the Oxford Shoulder Score. *J Shoulder Elbow Surg.* 2010;19:335-41.
33. Ostor AJ, Richards CA, Prevost AT et al. Diagnosis and relation to general health of shoulder disorders presenting to primary care. *Rheumatology. (Oxford)* 2005;44:800-805.
34. Poolman RW, Swiontkowski MF, Fairbank JC et al. Outcome instruments: rationale for their use. *J Bone Joint Surg Am.* 2009;91 Suppl 3:41-49.
35. Roh YH, Noh JH, Kim W et al. Cross-cultural adaptation and validation of the Korean version of the Oxford shoulder score. *Arch Orthop Trauma Surg.* 2012;132:93-99.
36. Salaffi F, De Angelis R, Stancati A et al. Health-related quality of life in multiple musculoskeletal conditions: a cross-sectional population based epidemiological study. II. The MAPPING study. *Clin Exp Rheumatol.* 2005;23:829-839.
37. Salomonsson B, Ahlstrom S, Dalen N et al. The Western Ontario Shoulder Instability Index (WOSI): validity, reliability, and responsiveness retested with a Swedish translation. *Acta Orthop.* 2009;80:233-238.
38. Schunemann HJ, Akl EA, Guyatt GH. Interpreting the results of patient reported outcome measures in clinical trials: the clinician's perspective. *Health Qual Life Outcomes.* 2006;4:62.
39. Snyder CF, Aaronson NK, Choucair AK et al. Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations. *Qual Life Res.* 2012;21:1305-1314.
40. Steffen V, Hertel R. Rim reconstruction with autogenous iliac crest for anterior glenoid deficiency: forty-three instability cases followed for 5-19 years. *J Shoulder Elbow Surg.* 2013;22:550-559.
41. Tan CK, Guisasola I, Machani B et al. Arthroscopic stabilization of the shoulder: a prospective randomized study of absorbable versus nonabsorbable suture anchors. *Arthroscopy.* 2006;22:716-720.
42. Terwee CB, Bot SD, de Boer MR et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol.* 2007;60:34-42.
43. Terwee CB, Mokkink LB, Knol DL et al. Rating the methodological quality in systematic reviews of studies on measurement properties: a scoring system for the COSMIN checklist. *Qual Life Res.* 2012;21:651-657.
44. Tugay U, Tugay N, Gelecek N et al. Oxford Shoulder Score: cross-cultural adaptation and validation of the Turkish version. *Arch Orthop Trauma Surg.* 2011;131:687-694.
45. van der Linde JA, van Kampen DA, Terwee CB et al. Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up. *Am J Sports Med.* 2011;39:2396-2403.
46. van der Linde JA, Willems WJ, van Kampen DA et al. Measurement properties of the Western Ontario Shoulder Instability index in Dutch patients with shoulder instability. *BMC Musculoskelet Disord.* 2014;15:211.
47. van Kampen DA, van Beers LW, Scholtes VA et al. Validation of the Dutch version of the Simple Shoulder Test. *J Shoulder Elbow Surg.* 2012;21:808-814.
48. Veehof MM, Sleegers EJ, van Veldhoven NH et al. Psychometric qualities of the Dutch language version of the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH-DLV). *J Hand Ther.* 2002;15:347-354.
49. Wild D, Grove A, Martin M et al. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. *Value Health.* 2005;8:94-104.
50. Wright RW, Baumgarten KM. Shoulder outcomes measures. *J Am Acad Orthop Surg.* 2010;18:436-44.
51. Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am.*2010;92:542-549.

CHAPTER 5

The interpretation of PROMs in shoulder instability; when changes become important for the patient

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ABSTRACT

Introduction

Patient Reported Outcome Measurements (PROMs) are widely used to evaluate the outcome of treatment. Considering PROMs for shoulder instability, relevant change from baseline-scores such as the Minimal Important Change (MIC) are lacking.

Objective

The first aim is to evaluate the responsiveness of the Western Ontario Shoulder Instability Index (WOSI) and the Oxford Shoulder Instability Score (OSIS). The second aim is to assess their MIC.

Methods and materials

One hundred six consecutive patients with shoulder instability completed the WOSI and OSIS and the Simple Shoulder Test (SST), the Oxford Shoulder Score (OSS) and the Disability of the Arm, Shoulder, and Hand assessment (DASH) twice; with a 6-month interval (T0 and T1). Responsiveness was addressed by hypothesis testing. Patients rated their functional change on an anchor question at T1. Mean change in scores were calculated and correlated to the functional anchor 'slightly improved' and 'much improved'.

Results

All pre-determined hypotheses regarding the responsiveness were confirmed. Most patients (N=45) scored their shoulder function as 'much improved', with an increase of 22.3 WOSI-points and 12.4 OSIS-points. Only 9 patients scored their shoulder function as 'slightly improved', with an increase of 14.6 WOSI- points and 6.0 OSIS-points.

Conclusion

The responsiveness of the WOSI and OSIS is high. An increase of approximately 12% and 25% of the total WOSI and OSIS scores correspond to a 'slightly improved' and 'much improved' shoulder function respectively. The first is based on 9 patients and should be considered with caution.

INTRODUCTION

Treatment strategies for shoulder instability aim to restore the shoulder function and to prevent recurrent instability.[10,18,26] Evaluation of treatment strategies requires measurement instruments. Redislocations are usually documented, however the presence of redislocations is not the only worthwhile outcome parameter. Patient Reported Outcome Measurements (PROMs) are widely used to assess functional limitations.[13,22] Two PROMs that are specifically designed for the evaluation of functional limitations due to shoulder instability are the Western Ontario Shoulder Instability Index (WOSI) and the Oxford Shoulder Instability Score (OSIS).[5,16] Both have been validated in Dutch language (blinded for review purposes).[27,28]

Responsiveness and the Minimal Important Change (MIC) are central measurement properties of tools to assess treatment outcome. Responsiveness refers to the ability of an instrument to detect a change over time in the construct to be measured and should be high in an instrument that is used to evaluate (functional) changes.[20]

The Minimal Important Change (MIC) is defined as the smallest change in score that patients perceive to be important.[7] The MIC can be regarded as a threshold; any exceeding change score reflects a relevant change for the patient. This will allow better interpretation of the results of treatment.[14]

The first aim of this study is to evaluate the responsiveness of the WOSI and OSIS. The second aim of this study is to assess the MIC of the WOSI and OSIS to assess when change scores of the WOSI and the OSIS are deemed relevant for patients.

METHODS AND MATERIALS

Patient Reported Outcome Measurements

All PROMs are validated for use in the Dutch language (blinded for review purposes).[2,27,28,29,31]

Western Ontario Shoulder Instability index (WOSI)

The WOSI was designed to be used as outcome measure in clinical trials that evaluate treatment for patients with shoulder instability.[16] The instrument consists of 21 items that reflect four domains; physical symptoms (10 items), sport/recreation/work function (4 items), lifestyle function (4 items), and emotional function (3 items). Responses are given on a 100-mm visual analogue scale that ranges from no complaints (0 mm) to severe complaints (100 mm). Items are summarised in a total score that ranges from 0 to 2100, where 0 indicates no limitations and 2100 indicates extreme limitations. The score can also be expressed as a percentage of normal shoulder function, where a score of 2100 reflects 0% of normal function and a score of 0 reflects 100%.[15] The smallest detectable change (SDC) is 23.0 points (on a scale of 0-100).[28]

Oxford Shoulder Instability Score (OSIS)

The OSIS was also designed to assess the outcome of treatment for shoulder instability.[5] The instrument consists of 12 questions; each question has 5 response categories. In the original scoring system, answers were scored from 1 to 5 points, and summarized to a total score that ranged from 12 (least impaired) to 60 (most impaired). Answers are scored from 0 to 4, thus the total score ranges from 0 (most impaired) to 48 (least impaired). The SDC is 9.0 points.[27]

Simple Shoulder Test (SST)

The SST contains 12 items (yes/no) with a total score that ranges from 0-12. It was designed to measure functional limitations in patients with common shoulder problems, including rotator cuff tears, degenerative osteoarthritis, and instability.[17]

Oxford Shoulder Score (OSS)

The OSS was developed for patients with general shoulder complaints.[4] The OSS contains 12 items (each question has 5 response categories) with a total score that ranges from 12-48.

Disability of the Arm, Shoulder, and Hand assessment (DASH)

The DASH was developed to measure physical functions and symptoms in patients with musculoskeletal disorders caused by any condition in any joint of the upper extremity. It contains 30 items (each question has 5 response categories) with a total score that ranges from 100-0.[1,9,12]

Patient population

A cohort of patients was prospectively recruited, between 2009 and 2014. Inclusion criteria were patients aged 18 years or older, and the presence of shoulder instability as diagnosed in the outpatient clinic. Both patients with primary and recurrent shoulder instability were included. Exclusion criteria were large fractures (other than Hill Sachs or bony Bankart lesions), a frozen shoulder, and the inability to understand Dutch language (blinded for review purposes). Ethical committee approval was obtained from the local ethical committee, and written informed consent was obtained from all participants, the rights of subjects were protected.

Measurements

Patients were asked to complete the WOSI and OSIS twice; at baseline (T0) and after 6 months (T1). The only difference between both versions is the addition of an anchor question at T1. Both questionnaires were completed at home using the same medium; either on paper or on the Internet. On the Internet, all questions were required to be completed prior to submission, preventing missing data. On paper, missing answers were verified by telephone. If patients were treated surgically, they completed the T1 questionnaire at approximately 6 months after their surgery. According to international guidelines, a minimum of 50 patients is considered adequate for assessing measurement properties.[24]

External anchor

The anchor question at T1 enquires how much the patients function has changed since baseline.[8] This was formulated as 'How has your shoulder function changed compared to the first time you completed this questionnaire?'. Answers included 7 possibilities varying from 'completely recovered' to 'worse than ever' (Table 1). The anchor question was posed prior to the PROMs to prevent the PROMs from influencing the patient's judgment on functional change.

Table 1. The mean change scores for the WOSI and OSIS according to the functional anchor.

Functional anchor (N=106)	Mean change scores (SD)				
	N	WOSI		OSIS	
Completely recovered	15	23.7	(18.5)	12.7	(8.3)
Much improved	45	**22.3**	(20.4)	**12.4**	(8.1)
Slightly improved	9	14.6	(14.4)	6.0	(7.3)
Unchanged	28	0.1	(11.6)	1.9	(6.1)
Slightly worse	6	0.1	(24.3)	-4.2	(4.1)
Much worse	2	-29.3	(9.8)	-7.5	(5.0)
Worse than ever	0	NA		NA	

NA = not applicable.
WOSI = Western Ontario Shoulder Instability Index, OSIS = the Oxford Shoulder Instability Score.

Responsiveness

Responsiveness is defined as the ability of an instrument to detect change in the construct to be measured. We assessed responsiveness by hypothesis testing. Correlations were calculated between change scores on the shoulder instability specific PROMs (WOSI, OSIS) and change scores on PROMs that have been developed for general shoulder complaints (DASH, OSS, SST). A total of 7 hypotheses were formulated a priori. (Table 2) Responsiveness is considered to be high if less than 25% of the hypothesis is rejected,

Table 2. Expected and observed correlations between change scores.

Correlations between the change scores of the		Expected	Observed
1. WOSI and	OSIS	≥ 0.7	0.77
2. WOSI and	DASH	≥ 0.6	0.75
3. WOSI and	OSS	≥ 0.6	0.68
4. WOSI and	SST	≥ 0.6	0.69
5. OSIS and	DASH	≥ 0.6	0.73
6. OSIS and	OSS	≥ 0.6	0.61
7. OSIS and	SST	≥ 0.6	0.63

The expected correlations between the shoulder instability specific Western Ontario Shoulder Instability Index (WOSI) and the Oxford Shoulder Instability Score (OSIS) were higher, compared to correlations with general shoulder PROMs, such as the Disability of the Arm, Shoulder, and Hand assessment (DASH), the Oxford Shoulder Score (OSS) and the Simple Shoulder Test (SST).

moderate if 25-50% is rejected and poor if more than 50% is rejected. The hypotheses were based on clinical experience, knowledge about several PROMs, and a consensus among the study investigators. A higher correlation was expected between PROMs that are both specifically designed to measure shoulder instability (WOSI and OSIS), compared to the correlation between shoulder instability specific PROMs and PROMs that are designed to measure shoulder function in general (DASH, OSS, SST).

Minimal Important Change

Individual mean scores and standard deviation were calculated for each PROM at T0 and T1. Change from baseline scores from the WOSI and OSIS were calculated by subtracting the score at T1 (6 months) from the score at T0 (baseline) for each patient. To determine the MIC, we initially aimed to use the ROC-method. Although the correlation between the functional anchor and change score was 0.64 and 0.63 for the OSIS and WOSI respectively, no cut-off point could be identified because both curves showed too much overlap. We subsequently decided to calculate the mean change scores of the patients that reported to be 'slightly improved' and the patients that reported to be 'much improved'.

Statistical analysis

Statistical analysis was performed using SPSS (SPSS Inc., version 18).

Mean scores and standard deviations were calculated for each PROM at T0 and T1, from which change scores were inferred. For each category of the anchor, the mean change scores on the WOSI and OSIS were calculated.

Responsiveness was assessed using a two-tailed Pearson correlation coefficient, because the mean change scores were normally distributed.

RESULTS

Descriptive statistics

Of the 138 patients who completed T0, 32 patients were not willing to complete the same questionnaire twice. The demographic characteristics of the remaining 106 patients are presented in Table 3.

Forty nine percent of the patients suffered their first shoulder dislocation more than 2 years before they completed the first questionnaire; no patients suffered their first dislocation within 1 month before completion of the baseline measurement.

Table 3. Demographic characteristics of the study population.

Number of patients	106	
Mean age (SD)	32	(12)
Gender (m)	74	(70%)
Treated surgically after 6 months	38	(36%)
Interval first instability - baseline measurement		
0 – 4 weeks	8	(8%)
1 – 6 months	20	(19%)
6 months – 2 years	26	(25%)
>2 years	51	(49%)

Patient Reported Outcome Measures

Table 4 presents the PROM scores at baseline and after 6 months. All shoulder related PROM scores improved over the 6-month interval.

Table 4. The PROM scores at baseline and after 6 months and the SDC.

PROMs		T0 (baseline)		T1 (6 months)		SDC *
- WOSI	(0 – 100)	54.0	(22.3)	69.4	(21.8)	23.0 (23%) [28]
- OSIS	(0 – 48)	27.3	(9.1)	35.4	(8.9)	9.0 (18%) [27]
- DASH	(100 – 0)	22.2	(16.7)	13.7	(12.7)	16.3 (16%) [30]
- OSS	(0 – 48)	36.3	(7.8)	40.8	(5.6)	6.0 (12%) [30]
- SST	(0 – 12)	8.8	(3.1)	10.0	(2.4)	2.8 (23%) [30]

*The smallest detectable change (SDC) is the smallest change that can be detected beyond the measurement error in individual patients. The Smallest Detectable Change (SDC) of the Western Ontario Shoulder Instability Index (WOSI), the Oxford Shoulder Instability Score (OSIS), the Disability of the Arm, Shoulder, and Hand assessment (DASH), the Oxford Shoulder Score (OSS) and the Simple Shoulder Test (SST) was calculated in previous studies and given in absolute points and as the percentage of the total possible score.

Responsiveness

Table 2 presents the expected and observed correlations between change scores. With the observed correlations exceeding the expected correlations, all hypotheses were confirmed. The responsiveness can be considered high.

Change from baseline scores

According to the external anchor; 69 patients (64%) improved, 28 patients (26%) were unchanged and 8 patients (12%) were worse at follow-up. Table 1 presents the mean change scores for the WOSI and OSIS for each subgroup of patients according to the anchor question. Most patients (N=45) scored their shoulder function as 'much improved' after 6 months. This correlates to a mean improvement of 22.3 points on a scale of 0-100 for the WOSI and 12.4 points on a scale of 0-48 for the OSIS. Twenty-eight patients scored their shoulder function unchanged.

Only 9 patients regarded their shoulder function as 'slightly improved'. This correlates to a mean improvement of 14,6 points on a scale of 0-100 for the WOSI and 6.0 points on a scale of 0-48 for the OSIS. Twenty-eight patients scored their shoulder function unchanged.

No patients indicated their shoulder function to be worse than ever.

DISCUSSION

For evaluation of the shoulder function from the patients' perspective the WOSI and OSIS are widely used for shoulder instability.[18,21,26]

The first aim of this study was to assess the responsiveness of the WOSI and OSIS. All pre-defined hypotheses could be confirmed (100%), indicating high responsiveness. Both the WOSI and OSIS are capable to adequately monitor the change in shoulder function in patients with shoulder instability. Responsiveness of the WOSI was previously assessed by Kirkley, et al.[16], by Salomonsson, et al.[23] and by Cacchio, et al.[3], who determined the Effect Size (ES) and Standard Response Mean (SRM). ES and SRM are, however, measures that reflect the magnitude of change scores, not the validity of change scores. Therefore, we prefer responsiveness assessment by hypotheses testing.

The second aim of this study was to assess the MIC with the anchor-based approach. The MIC score depends on the choice of anchor and on the anchor's definition of important change.[7] Initially we tried to estimate the MIC using the ROC-method. Despite a correlation of 0.64 and 0.63 between the anchor and change scores for the OSIS and WOSI respectively, both curves overlapped considerably and therefor no cut-off point could be identified.

One explanation could be that patients have answered the external anchor as it relates to their present shoulder function rather than their improvement in shoulder function. Another possibility is that our patient population is too small. This is a common problem when trying to determine the MIC, because the MIC methods use scores from subgroups.

We subsequently decided to calculate the mean change scores for all patients within each category of the functional anchor, which is a common technique in the orthopaedic literature.[11]

In this patient population, the 'much improved' group has an increase of approximately 25% (14,6 points on a scale of 0-100 for the WOSI, 6.0 points on a scale of 0-48 for the OSIS), the 'slightly improved' group has an increase of approximately 12% of the total score (14,6 and 6.0 points respectively). This is based however on the change scores of just 9 patients.

Change scores should be interpreted in relation to the instrument's measurement error [19,30] and in relation to the smallest change that can be detected beyond the measurement error in individual patients, the Smallest Detectable Change (SDC).[6] Ideally, the measurement error should be smaller then the MIC of the same instrument to be 95% sure that a change in an individual patient as large as the MIC is not due to measurement error.[25]

The SDC was previously calculated as 23.0 points for the WOSI and 9.0 points for the OSIS.[27,28] This means that individual patients should improve at least 23.0 and 9.0 points respectively to ensure that their change is not a result of the measurement error. Regarding the WOSI, patients that reported a 'slightly improved' shoulder function improved 14.6 points on average, not enough to distinguish from the measurement error. Moreover, patients that reported a 'much improved' shoulder function improved 22.3 points on average, which is not enough either to distinguish from the measurement error (difference 0.7 points on scale of 0-100). The interpretation of WOSI change scores in individual patients should therefore be considered with caution. Regarding the OSIS, patients that reported a 'slightly improved' shoulder function improved 6.0 points on average, not enough to distinguish from the measurement error. Patients that reported a 'much improved' shoulder function improved 12.4 points on average, which can be safely distinguished from the SDC (9.0 points)

The OSIS is thus better capable to distinguish a relevant change from the measurement error or SDC.

A strong point is the homogeneity of this patient population, including only patients with shoulder instability. A weak point is the fact that we were unable to determine the MIC using the ROC method. A second weak point is the fact that only 9 patients scored their shoulder function as 'slightly improved'. Based on the author's experience, the 6-month interval was specifically chosen to optimize the number of patients with a 'slightly improved' shoulder function.[30] However many more patients reported either a 'much improved shoulder function' (N=45) or an 'unchanged' shoulder function (N=28) instead. The change scores that reflect patients with a 'slightly improved' shoulder function should therefore be used with caution. A third weak point is the fact that patients were asked to complete 5 PROMs at once to enable hypotheses testing for the responsiveness assessment. This could be a patient burden, which can theoretically cause patients to loose their interest, increasing the measurement error.[30]

CONCLUSION

Both the WOSI and OSIS are capable to adequately monitor change in shoulder function in patients with shoulder instability. A change score of 22.3 (on a scale of 0-100) and 12.4 (on a scale of 0-48) correspond to a 'much improved' shoulder function for the WOSI and OSIS respectively. A change score of 14.6 WOSI-points and 6 OSIS-points corresponds to an 'slightly improved' function respectively. In case of the WOSI, the MIC (22.3 points) falls within the SDC range (23.0 points). We thus recommend the use of the OSIS to evaluate relevant changes in the individual patient with shoulder instability.

REFERENCES

1. Beaton DE, Katz JN, Fossel AH, Wright JG, Tarasuk V, Bombardier C. Measuring the whole or the parts? Validity, reliability, and responsiveness of the Disabilities of the Arm, Shoulder and Hand outcome measure in different regions of the upper extremity. *J Hand Ther.* 2001;14:128-146.
2. Berendes T, Pilot P, Willems J, Verburg H, te SR. Validation of the Dutch version of the Oxford Shoulder Score. *J Shoulder Elbow Surg.* 2010;19:829-836.
3. Cacchio A, Paoloni M, Griffin SH, et al. Cross-cultural adaptation and measurement properties of an Italian version of the Western Ontario Shoulder Instability Index (WOSI). *J Orthop Sports Phys Ther*. 2012;42:559-567.
4. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about shoulder surgery. *J Bone Joint Surg Br.* 1996;78:593-600.
5. Dawson J, Fitzpatrick R, Carr A. The assessment of shoulder instability. The development and validation of a questionnaire. *J Bone Joint Surg Br.* 1999;81:420-426.
6. de Vet HC, Terwee CB, Knol DL, Bouter LM. When to use agreement versus reliability measures. *J Clin Epidemiol*. 2006;59:1033-1039.
7. de Vet HC, Terwee CB, Mokkink LB et al. Measurement in Medicine. Cambridge University Press, 2011.
8. de Vet HC, Terwee CB, Ostelo RW, Beckerman H, Knol DL, Bouter LM. Minimal changes in health status questionnaires: distinction between minimally detectable change and minimally important change. *Health Qual Life Outcomes.* 2006;4:54.
9. Desai AS, Dramis A, Hearnden AJ. Critical appraisal of subjective outcome measures used in the assessment of shoulder disability. *Ann R Coll Surg Engl.* 2010;92:9-13.
10. Franceschi F, Longo UG, Ruzzini L, Rizzello G, Maffulli N, Denaro V. Arthroscopic salvage of failed arthroscopic Bankart repair: a prospective study with a minimum follow-up of 4 years. *Am J Sports Med*. 2008;36:1330-1336.
11. Holmgren T, Oberg B, Adolfsson L, Bjornsson HH, Johansson K. Minimal important changes in the Constant-Murley score in patients with subacromial pain. *J Shoulder Elbow Surg.* 2014;23:1083-1090.
12. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). *Am J Ind Med*. 1996;29:602-608.
13. Janse AJ, Gemke RJ, Uiterwaal CS, van der Tweel I, Kimpen JL, Sinnema G. Quality of life: patients and doctors don't always agree: a meta-analysis. *J Clin Epidemiol.* 2004;57:653-661.
14. Judge A, Arden NK, Kiran A, et al. Interpretation of patient-reported outcomes for hip and knee replacement surgery: identification of thresholds associated with satisfaction with surgery. *J Bone Joint Surg Br.* 2012;94:412-418.
15. Kirkley A, Griffin S, Dainty K. Scoring systems for the functional assessment of the shoulder. *Arthroscopy.* 2003;19:1109-1120.
16. Kirkley A, Griffin S, McLintock H, Ng L. The development and evaluation of a disease-specific quality of life measurement tool for shoulder instability. The Western Ontario Shoulder Instability Index (WOSI). *Am J Sports Med*. 1998;26:764-772.
17. Lippitt SB, Harryman DT II, Matsen FA III. A practical tool for evaluating function: the Simple Shoulder Test. In: Matsen FA III, Fu FH, Hawkins RJ, eds. The Shoulder: A Balance of Mobility and Stability. Rosemont, Illinois: The American Academy of Orthopaedic Surgeons; 1993:545-559.
18. Mohtadi NG, Chan DS, Hollinshead RM, et al. A randomized clinical trial comparing open and arthroscopic stabilization for recurrent traumatic anterior shoulder instability: two-year follow-up with disease-specific quality-of-life outcomes. *J Bone Joint Surg Am*. 2014;96:353-360.
19. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res*. 2010;19:539-549.
20. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol*. 2010;63:737-745.
21. Provencher MT, McCormick F, Dewing C, McIntire S, Solomon D. A prospective analysis of 179 type 2 superior labrum anterior and posterior repairs: outcomes and factors associated with success and failure. *Am J Sports Med*. 2013;41:880-886.
22. Rouleau DM, Faber K, MacDermid JC. Systematic review of patient-administered shoulder functional scores on instability. *J Shoulder Elbow Surg.* 2010;19:1121-1128.
23. Salomonsson B, Ahlstrom S, Dalen N, Lillkrona U. The Western Ontario Shoulder Instability Index (WOSI): validity, reliability, and responsiveness retested with a Swedish translation. *Acta Orthop*. 2009;80:233-238.

24. Terwee CB, Mokkink LB, Knol DL, Ostelo RW, Bouter LM, de Vet HC. Rating the methodological quality in systematic reviews of studies on measurement properties: a scoring system for the COSMIN checklist. *Qual Life Res*. 2012;21:651-657.
25. Terwee CB, Roorda LD, Knol DL, De Boer MR, de Vet HC. Linking measurement error to minimal important change of patient-reported outcomes. *J Clin Epidemiol.* 2009;62:1062-1067.
26. van der Linde JA, van Kampen DA, Terwee CB, Dijksman LM, Kleinjan G, Willems WJ. Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up. *Am J Sports Med.* 2011;39:2396-2403.
27. van der Linde JA, van Kampen DA, van Beers LWAH, van Deurzen DFP, Terwee CB, Willems WJ. The Oxford Shoulder Instability Score; validation in Dutch and first time assessment of its smallest detectable change. *J Orthop Surg Res*. 2015; 10:146.
28. van der Linde JA, Willems WJ, van Kampen DA, van Beers LW, van Deurzen DF, Terwee CB. Measurement properties of the Western Ontario Shoulder Instability Index in Dutch patients with shoulder instability. *BMC Musculoskelet Disord.* 2014;15:211.
29. van Kampen DA, van Beers LW, Scholtes VA, Terwee CB, Willems WJ. Validation of the Dutch version of the Simple Shoulder Test. *J Shoulder Elbow Surg*. 2012;21:808-814.
30. van Kampen DA, Willems WJ, van Beers LW, Castelein RM, Scholtes VA, Terwee CB. Determination and comparison of the smallest detectable change (SDC) and the minimal important change (MIC) of four-shoulder patient-reported outcome measures (PROMs). *J Orthop Surg Res*. 2013;8:40.
31. Veehof MM, Sleegers EJ, van Veldhoven NH, Schuurman AH, van Meeteren NL. Psychometric qualities of the Dutch language version of the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH-DLV). *J Hand Ther*. 2002;15:347-354.

PART III

Surgical treatment strategies for shoulder instability

CHAPTER 6

Traumatic shoulder instability in patients up to 18 years old, operative versus nonoperative treatment?

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Adapted from: Surgical Versus Nonoperative Treatment in Patients up to 18 Years Old With Traumatic Shoulder Instability: A Systematic Review and Quantitative Synthesis of the Literature.

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ABSTRACT

Objective

To compare the outcome of surgical and nonoperative treatment in patients aged 18 years or younger with traumatic shoulder instability.

Methods and materials

A systematic review according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines was performed. A complete search of PubMed, Medline, Cochrane, CINAHL, Embase, and Google Scholar databases was performed using various combinations of the keywords "shoulder," "instability," "glenohumeral instability," "pediatric," "adolescent," "skeletally immature," "young," "open physis," "children," "management," "treatment," "surgical," "stabilization," and "recurrence." There was no time restriction.

Results

Fifteen articles met our inclusion criteria, including a total of 693 patients with 705 shoulders aged 18 years or younger. Of 411 shoulders, 293 (71.3%) treated with a nonoperative approach experienced a redislocation compared with 55 of 314 shoulders (17.5%) that received surgical treatment. The results of the quantitative synthesis showed that the recurrence rate was significantly lower in the surgical group compared with the nonoperative group.

Conclusion

The recurrence rate is lower in patients undergoing surgical treatment. Further studies are necessary to clarify several points in the treatment of skeletally immature patients with traumatic shoulder instability.

INTRODUCTION

Shoulder dislocations in the skeletally immature population are relatively unusual.[17,19-21] In growing and skeletally immature patients, physes are open and shoulder trauma more commonly results in a proximal humeral physical or metaphyseal fracture than a dislocation.[15] Therefore, shoulder dislocations are more frequent in adolescents than in pediatric atients.[17,19-21] Less than 2% of all shoulder dislocations occur in patients younger than 10.[1,2,5,12,26,29] Younger patients at the time of their first traumatic shoulder dislocation are considered to have an increased risk of recurrent instability compared with older patients.[17]

The choice of surgical versus nonoperative treatment of primary shoulder dislocation and the appropriate timing for surgical intervention in young patients remain debated.[12] Because most of the available studies refer to skeletally mature adolescents, there is no evidence for the optimal treatment of skeletally immature patients.[14] Some authors proposed that the choice of the treatment of acute anterior shoulder dislocation in skeletally immature patients should be decided on the basis of the patient's age, type of sport, and concomitant pathology.[3,23]

Even though the nonoperative approach has been considered the treatment of choice, recent pieces of evidence suggest that surgery could be the best option to avoid risk of recurrence.[7,11] The current literature lacks to provide shoulder surgeons with a guide on how to treat young patients with a shoulder dislocation, and treatment of these patients remains a challenge.

Our hypothesis is that patients aged 18 years and younger, who receive surgical treatment, will have a decreased redislocation rate. The aim of this systematic review is to compare the outcome of surgical and nonoperative treatment in patients up to 18 years of age with traumatic shoulder instability.

METHODS AND MATERIALS

A systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. The search algorithm according to these guidelines is shown in Figure 1.

The search was performed on April 30, 2015, including the following databases: Medline, Google Scholar, EMBASE, and Ovid. Various combinations of the following keywords were used: "shoulder," "instability," "glenohumeral instability," "pediatric," "adolescent," "skeletally immature," "young," "open physes," "children," "management," "treatment," "surgical," "stabilization," "recurrence." There was no time restriction. Given the linguistic

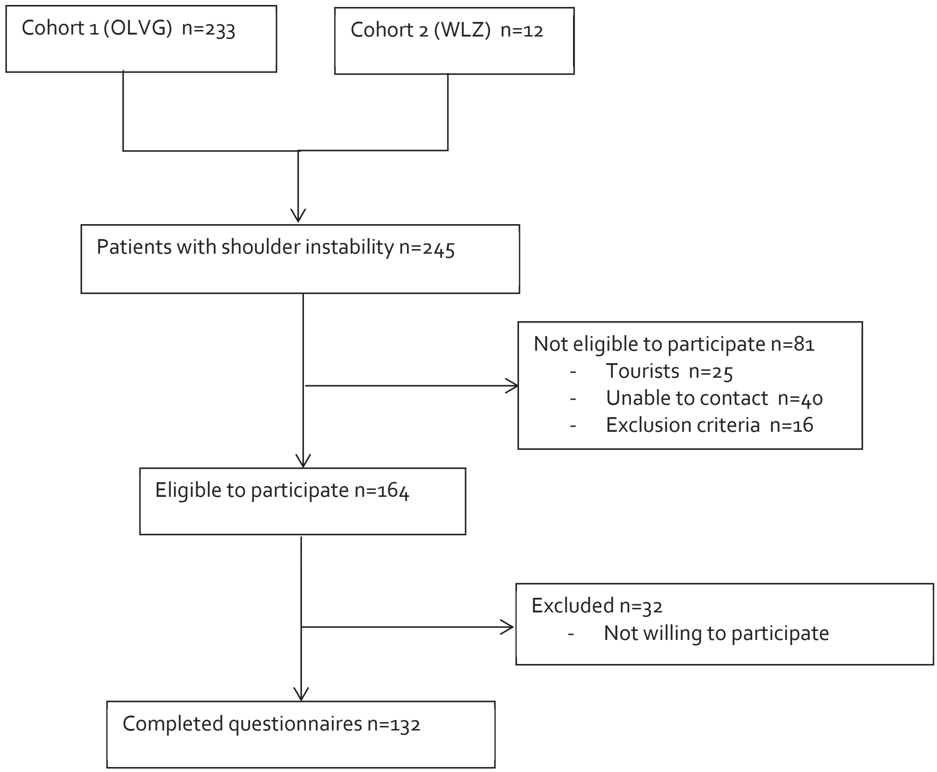

Figure 1. The search algorithm according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

capabilities of the authors, articles in English, French, Spanish, German, Dutch, or Italian were included.

All journals and all relevant articles were analyzed. First, all articles were screened for relevance by title and abstract, excluding articles without an abstract. A cross-reference search of the selected articles was performed to obtain other relevant articles.

Inclusion criteria were the treatment of shoulder instability in children and adolescents up to 18 years including all instability patterns (anterior, posterior, and multidirectional) due to traumatic shoulder dislocation. Exclusion criteria were articles with no age specified, articles regarding patients aged 19 or older, or articles regarding patient populations in which the range exceeded 18 years (e.g., 10-30 years).

Furthermore, articles reporting on patients with voluntary dislocations or atraumatic dislocations, as well as patients who have dislocations due to neurological or neuromuscular disease (i.e., Marfa disease, Ehlers-Danlos syndrome, and Moebius syndrome), or patients with a familial history of connective tissue pathology were excluded. Articles lacking treatment or follow-up were also excluded. According to the Oxford center for

Evidence-Based Medicine, only level I to IV articles were included in our study. Literature reviews, case reports, studies on animals, cadavers, or in vitro, biomechanical reports, technical notes, letters to editors, and instructional course were excluded.

Finally, to avoid bias, the selected articles, the relative list of references, and the articles excluded from the study were reviewed, assessed, and discussed by all authors. The following data were independently extracted by all investigators: demographics, diagnosis including type of imaging, treatment strategy, recurrence of instability, return to sports, and length of follow-up. Because other factors, such as assessment of bony defects, and complications were only incidentally described, we did not include these in our review.[16,18]

Quality Assessment

To assess the quality of the articles, the Coleman Methodology Score (CMS) was performed, which assesses methodology based on 10 criteria, leading to a total score between 0 and 100. A score of 100 indicates that the study largely avoids chance, various biases, and confounding factors. The CMS is based on 10 subsections derived from the subsections of the CONSORT statement (for randomized controlled trials) that are modified to allow for a reproducible and relevant systematic review of surgical versus nonoperative treatment of shoulder instability in young patients. Each study was assessed by two reviewers (U.G.L. and M.L.) independently and in duplicate using the Modified CMS; disagreement was resolved by discussion.

Moreover, each study was also assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, which offers the possibility to assess the overall quality of a study.

Quantitative Synthesis

We performed a quantitative synthesis of the literature to compare surgical and nonoperative treatments. Moreover, a quantitative synthesis was performed to compare internal and external rotations for immobilization in patients undergoing nonoperative treatment. We used Review Manager (RevMan, version 5 for Windows; Cochrane Information Management System) to calculate the magnitude of the treatment effect. We calculated an I^2 index as a measure of heterogeneity for the main analysis. An I^2 value represents the percentage of the total variation across studies, caused by heterogeneity rather than by chance. We considered a low I^2 value as 25% or lower and a high I^2 value as 75% or higher. Categorical variable data were reported as frequency with percentage. Continuous variable data were reported as mean value with a range between minimum and maximum values. In all studies, $P < .5$ was considered statistically significant.

RESULTS

The literature search and cross-referencing resulted in 100 articles; 80 were excluded because they did not meet the inclusion criteria, and 5 articles provided insufficient data. Finally, 15 articles regarding the treatment of shoulder instability in patients up to 18 years old were included.[3,5-7,10-14,22,24,26-29] The Modified CMS and the extracted data from these articles are summarized in Table 1.

The GRADE assessment of each article is summarized in Table 2. The overall quality of evidence was very low in eight studies, low in six studies, and moderate in one study.

Demographics

A total of 693 patients with 705 shoulders were included according to our criteria. Detailed demographics are reported in Table 1. Regarding skeletally immature patients, only two articles report an age limit of 14 years maximum,[5,12] four articles report an age limit of 16 years maximum,[14,22,24,29] and the remaining articles report an age limit of 18 years.[3,6,7,10,11,13,26-28]

Management

In 3 of 15 articles, all patients received surgical treatment,[2,12,28] 6 articles described nonoperative treatment,[5,6,22,26,27,29] and 6 articles described both surgical and nonoperative treatment.[7,10,11,13,14,24] Table 3 summarizes the nonoperative and surgical treatment strategies, including the total number of patients that were treated accordingly. Both nonoperative treatment strategies and surgical treatment strategies differ considerably between the included articles.

Recurrent Instability

Of 411 shoulders, 293 (71.3%) that were treated nonoperatively experienced a redislocation compared with 55 of 314 shoulders (17.5%) treated surgically.

Quantitative Synthesis

A quantitative synthesis including articles that compared surgical and nonoperative treatment was performed.[7,11] The results showed that the rate of recurrence was statistically significantly lower in the surgical group than in the nonoperative group (odds ratio, 0.06; 95% confidence interval, 0.02 to 0.17; $P < .00001$). A very low heterogeneity (I^2 = 0%) across the study results was found.

Table 1: Data extracted from the included articles.

Authors	Study design (LoE)	N° patients (shoulders)	Age (y)	Diagnosis	Surgical treatment	Nonoperative treatment	Recurrence	Coleman score	FU (y)
Castagna et al.[13] 2012	Retrospective cohort study (IV)	65 (65)	16 (13-18)	Traumatic anterior dislocation (53) Anterior subluxation (12)	Arthroscopic capsulolabral repair followed by 4-wk sling immobilization: 15° abduction and 15° external rotation (65)		21% (14)	62	5.2
Cordischi et al.[7] 2009	Retrospective cohort study (III)	14 (14)	12 (10-13)	Traumatic anterior dislocation		4-wk sling immobilization NWB followed by physiotherapy (14)	21,4%(3)	36	5.6
Deitch et al[20] 2003	Retrospective cohort study (III)	32 (32)	(11-18)	Traumatic anterior dislocation		1- to 8-wk immobilization (32)	75% (24)	39	4
Gigis et al.[15] 2014	Prospective comparative study (II)	65 (65)	16.7 (15-18)	Traumatic anterior dislocation				65	3
					Arthroscopic Bankart repair, followed by 3-wk sling immobilization and 5-wk physiotherapy (38)		13.1% (5)		

Table 1: Data extracted from the included articles. (continued)

Authors	Study design (LoE)	N° patients (shoulders)	Age (y)	Diagnosis	Surgical treatment	Nonoperative treatment	Recurrence	Coleman score	FU (y)
						3-wk sling immobilization and 5-wk physiotherapy (27)	70.3%(19)		
Jones et al.[21] 2007	Retrospective cohort study (III)	30 (32)*	15.4 (11-18)	Traumatic anterior dislocation (24) Anterior subluxation (6)				40	2
					Arthroscopic Bankart repair, followed by 4-wk sling adduction and internal rotation and exercises. (16)		12,5%(2)		
						Sling immobilization some in adduction and internal rotation, others in external rotation (14)	100%(14)		

Table 1: Data extracted from the included articles. (continued)

Authors	Study design (LoE)	N° patients (shoulders)	Age (y)	Diagnosis	Surgical treatment	Nonoperative treatment	Recurrence	Coleman score	FU (y)
Khan et al.[16] 2014	Retrospective cohort study (III)	23 (25) (nonoperative group) 26 (28) (Surgical group)	13.7 (nonoperative group) 14.1 (Surgical group)	Traumatic anterior dislocation				65	8.3 (Nonoperative group) 9.7 (Surgical group)
					open Latarjet (28)		7% (2)		
						Manipulative reduction and immobilization in an arm sling in internal rotation for 3 to 4 wk and, subsequently, shoulder rehabilitation for 6 to 8 wk on a daily basis (25)	56% (14)		
Kraus et al.[9] 2010	Retrospective cohort study (III)	7 (7)	11 (5-14)	Traumatic anterior dislocation		Not specified (1)	100%(1)	28	2
					Arthroscopic Bankart repair (5) Open Bankart repair (1)		0% (0)		

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Table 1: Data extracted from the included articles. (continued)

Authors	Study design (LoE)	N° patients (shoulders)	Age (y)	Diagnosis	Surgical treatment	Nonoperative treatment	Recurrence	Coleman score	FU (y)
Lampert et al.[22] 2003	Retrospective cohort study (III)	54 (54)	14.5 (4-18)	Traumatic anterior dislocation				43	1
			≥14		Open- or arthroscopic Bankart repair (14)	2-to 3-wk Gilchrist bandage (28)	surg: 14% (2) cons: 96% (27)		
			≤14			2- to 3-wk Gilchrist bandage (12)	0%		
Lawton et al. [12] 2002	Retrospective cohort study (III)	55 (59)§	14.3	Traumatic anterior dislocation	Bankart repairs with capsular shift (11), Bristow (5), Putti-Platt procedures (3), capsular shift (3), Bankart repair alone (1), arthroscopic anterior Bankart repair with capsular tightening (1), not specified (2)	Physical therapy (33)	surg: 4% (1) cons: 15% (5)	49	8.5

Table 1: Data extracted from the included articles. (continued)

Authors	Study design (LoE)	N° patients (shoulders)	Age (y)	Diagnosis	Surgical treatment	Nonoperative treatment	Recurrence	Coleman score	FU (y)
Marans et al.[23] 1992	Retrospective cohort study (III)	21 (21)	12.7 (4-16)	Traumatic anterior dislocation		No immobilization (9) 4-wk sling or Velpeau dressing (2) 6-wk sling or Velpeau dressing (10)	100% (21)	36	6.5
Ochs et al.[24] 2005	Retrospective cohort study (III)	32 (33)	< 16	Traumatic anterior dislocation (31) Traumatic post dislocation (2)		3-wk immobilization and physiotherapy (33)	94% (31)	32	5
			< 15			Nonoperative (8)	50% (4)		
			> 15		Open stabilization (16) Arthroscopic (6)		38% (8)		
Postacchini et al.[10] 2000	Retrospective cohort study (III)	28 (28)	15.5 (12-17)	Traumatic anterior dislocation		4-wk immobilization in adduction and internal-rotation (28)		42	7.1
			≥14				92% (23)		
			<13				33% (1)		

Table 1: Data extracted from the included articles. (continued)

Authors	Study design (LoE)	N° patients (shoulders)	Age (y)	Diagnosis	Surgical treatment	Nonoperative treatment	Recurrence	Coleman score	FU (y)
Shymon et al.[25] 2015	Retrospective cohort study (III)	99 (99)	16.5 (Open) 17 (Arthroscopy)	Traumatic anterior dislocation				55	
					Open Bankart (28)		14% (4)		5.5
					Arthroscopic Bankart Repair (71)		24% (17)		2.4
Roberts [26] 2015	Prospective cohort study (II)	133 (133)	16.3 (13-18)	Traumatic anterior dislocation				70	37.5 months
						1-wk immobilization in adduction and internal-rotation (133)	76.7% (102)		
Wagner et Lyne[26] 1983	Retrospective cohort study (III)	9 (10)	13.4 (12-16)	Traumatic anterior dislocation		4-wk Velpeau dressing and 2-wk sling (10)	80%(8)	30	6

FU, follow-up; LoE, level of evidence; wk, week

* One patient (2 shoulders) was excluded Jones et al [21] due to familial joint hyperlaxity syndrome.

§ eleven shoulders were excluded from Lawton et al [12] due to voluntary dislocations.

Table 2. Quality assessment of the included articles, based on the GRADE Methodology.

	Quality assessment							Summary of findings	
Authors	No. of participants (Mean Follow-up)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Publication bias	Event rates (%) with surgery	Event rates (%) with nonoperative treatment
Castagna[13] 2012	65 (5.2 yr)	Serious*	Not serious	Not serious	Not serious	None	ØOOO VERY LOW	14/65 (21.5%)	-
Cordischi[7] 2009	14 (5.6 yr)	Serious*	Not serious	Not serious	Not serious	None	ØOOO VERY LOW	-	3/14 (21.4%)
Deitch[20] 2003	32 (4 yr)	Serious*	Not serious	Not serious	Not serious	Strong association	ØØOO LOW	-	24/32 (75%)
Gigis[15] 2014	65 (3 yr)	Serious*	Not serious	Not serious	Not serious	Strong association	ØØOO LOW	5/38 (13.2%)	19/27 (70.4%)
Jones[21] 2007	30 (2 yr)	Serious*	Serious‡	Not serious	Not serious	None	ØOOO VERY LOW	2/16 (12.5%)	3/14 (21.4%)
Khan[16] 2014	53 (8.3 yr-nonoperative) (9.7 yr-surgery)	Serious*	Not serious	Not serious	Not serious	Strong association	ØØOO LOW	2/28 (7.1%)	14/25 (56%)
Kraus[9] 2010	6 (2 yr)	Serious*	Serious¥	Not serious	Not serious	None	ØOOO VERY LOW	0/1 (0.0%)	0/5 (0.0%)
Lampert[22] 2003	42 (1 yr)	Serious*	Not serious	Not serious	Not serious	Strong association	ØØOO LOW	2/14 (14.3%)	27/28 (96.4%)
Lawton[12] 2002	53 (8.5 yr)	Serious*	Serious¥	Not serious	Not serious	None	ØOOO VERY LOW	0/24 (0.0%)	1/29 (3.4%)
Marans[23] 1992	21 (6.5 yr)	Serious*	Serious‡	Not serious	Not serious	Very strong association	ØØOO LOW	-	21/21 (100%)
Ochs[24] 2005	54 (5 yr)	Serious*	Serious¥	Not serious	Not serious	Strong association	ØOOO VERY LOW	8/22 (36.4%)	30/32 (93.8%)

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Table 2. Quality assessment of the included articles, based on the GRADE Methodology. (continued)

		Quality assessment						Summary of findings	
Postacchini[10] 2000	28 (7.1 yr)	Not serious	Not serious	Not serious	Not serious	Strong association	ØØØO MODERATE	-	24/28 (85.7%)
Shymon[25] 2015	99 (2.4 yr- a'sopic Bankart) (5.5 yr-open Bankart)	Serious*	Serious¥	Not serious	Not serious	None	ØOOO VERY LOW	21/99 (21.2%)	-
Roberts[26] 2015	133 (37.5 mo)	Serious*	Not serious	Not serious	Not serious	Strong association	ØØOO LOW	-	102/133 (76.7%)
Wagner et Lyne[26] 1983	9 (6 yr)	Serious*	Serious‡	Not serious	Not serious	Strong association	ØOOO VERY LOW	-	7/9 (77.8%)

* No independent observer mentioned.
‡Inconstant immobilization in conservative group; different methods used.
¥ Inconsistent surgical treatment; different methods used.

Table 3. summarizes the nonoperative and surgical treatment strategies

Surgical treatment	No. Shoulders	References
Arthroscopic Bankart repair	199	Kraus, Ochs, Shymon, Castanga, Jones, Gigis
Open Bankart repair	46	Kraus, Lawton, Shymon, Ochs
Open Bankart repair with capsular shift	11	Lawton
Arthroscopic- or open Bankart repair	14	Lampert
Arthroscopic soft tissue repair (capsular tightening or shrinkage)	2	Lawton, Ochs
Open soft tissue repair (Putti-Platt, capsular shift, Max-Lange procedure)	7	Lawton Ochs
Open Bristow or Latarjet procedure	33	Khan, Lawton
Not specified	2	Lawton
Total no. of shoulders treated surgical	314	
Nonoperative treatment		
No immbilization	9	Marans
Physiotherapy	33	Lawton
Immobilisation		
1 wk in AD + IR, followed by PT	133	Roberts
1-8 wk (sling)	32	Deitch
2-3 wk (Gilchrist)	40	Lampert
3 wk (Gilchrist)+ PT	33	Ochs
3 wk + 5wk PT	27	Gigis
3-4 wk IR + 6-8 wk daily rehabilitation	25	Khan
4 wk (sling) + PT	14	Crodischi
4 wk (Valpeau)	2	Marans
4 wk in AD + IR	28	Postachini
4 wk (Valpeau) + 2wk (sling)	10	Wagner
6 wk (Valpeau)	10	Marans
Brief immobilization; in AD + IR or ER	14	Jones
Not specified	1	Kraus
Total no. of shoulders treated nonoperative	411	

AD, adduction; IR, internal rotation; ER, external rotation; PT, physiotherapy.

DISCUSSION

The most important finding of the present study was that the rate of recurrence in patients up to 18 years of age with shoulder traumatic instability was statistically significantly lower in the surgical group (17.5%) when compared with the nonoperative group (71.3%), as shown by our quantitative synthesis.[7,11]

The articles included in the quantitative synthesis used two different surgical techniques to be compared with the nonoperative treatment. In the study from Khan et al.,[11] a Latarjet procedure was used, whereas Gigis et al.[7] performed an arthroscopic stabilization. Even though these two techniques are different, the reported outcome was similar. The mean age of the patients undergoing surgery was 14.1[11] and 16.8[7] years, respectively.

Age is as an important risk factor for redislocation. Some authors[13,23,26] divided their patients into two groups, including patients younger or older than 14 years. Previously, Li and Ochs have proposed therapeutic algorithms for the treatment of shoulder instability in skeletally immature patients. Li et al.[15] emphasized age as a risk factor older vs. younger than 14 years) and type of dislocation (first time vs. recurrent instability). Ochs et al.[24] propose therapeutic decisions to be based on the age limit of 15 years or a full-grown glenoid on MRI, when the initial nonoperative treatment with 3-week Gilchrist bandage and physiotherapy has failed.

In this review, only Cordischi et al.[5] and Kraus et al.[12] report results of treatment in patients aged 14 years maximum, insufficient to draw conclusions regarding the treatment of skeletally immature patients. The remaining articles either included patients up to 16 years or up to 18 years; however, girls might be skeletally mature by the age of 15 and boys by 16.

Traditionally, the treatment of shoulder dislocation in skeletally immature patients was nonoperative, including immobilization, physiotherapy, and restricted activities.[2,8] However, the nonoperative treatment strategies were considerably different among the included studies.

The importance of surgical treatment is, however, emphasized by four studies.[7,10,13,23] Gigis et al.[7] compared arthroscopic Bankart repairs with immobilization for 3 weeks, followed by 5 weeks of physiotherapy, and reported that, in skeletally immature patients, nonoperative treatment after a first traumatic dislocation leads to a significantly higher and unacceptable high failure rate compared with early arthroscopic stabilization.[7] Regarding the high recurrence rate after nonoperative treatment (96%), Lampert et al.[13] recommend an arthroscopic stabilization of the glenohumeral joint in patients aged 14 years and older. Immobilization is recommended in younger patients, who are reported to have a very low redislocation rate.

Ochs et al.[24] focused on 32 patients with a mean age of 14.5 years, treated with immobilization in internal rotation for 3 weeks followed by physiotherapy. With a recurrence rate of 94%, they subsequently treated their patients individually based on age (older and/or your than 15 years), the number of redislocation, the type of injury, and sports participation, particularly if they participate in contact sports, overhead sports, or snowboarding and skiing.

These patients were treated with open or arthroscopic stabilization.

Kraus et al.[12] suggested recurrent dislocations or persistent instability as a criterion for surgical treatment. Because these patients have proven to be susceptible for recurrent dislocation, arthroscopic stabilization is a reasonable surgical option in this population.[3,8,12,24,25]

Sports participation is an important issue in the treatment of shoulder instability; it is mentioned as an important risk factor for shoulder dislocation,[3,4,8,10] whereas return to sports was a secondary outcome in some studies.[3,7,10,22,24] With 71% to 93% of the patients returning to sports after surgical treatment compared with 50% to 56% after nonoperative treatment, surgical treatment might be superior to enable patients to return to sports.[7,24]

Because shoulder instability in the pediatric population is relatively rare, there are unfortunately some limits to this review. First, patient populations have a wide age range, which makes results difficult to interpret. Second, they included articles mix categories: athletes and not active patients, first episode shoulder dislocation, and subluxation involving inevitably different recurrence rates. Third, treatment strategies differ making comparison between results difficult. Because one study for example immobilizes using Gilchrist bandage, other authors might use a sling or immobilization in external rotation, with different recurrence rates.[9] Finally, methodological assessment with the GRADE methodology and Modified CMS revealed very low quality in eight of the included studies, low quality in six studies, and moderate quality in only one study.

CONCLUSION

The rate of recurrence is lower in patients undergoing surgical treatment. Further studies are necessary to clarify several points of the treatment of skeletally immature patients with traumatic shoulder instability.

REFERENCES

1. Bishop JY, Flatow EL. Pediatric shoulder trauma. *Clin Orthop Relat Res.* 2005;41-48.
2. Bottoni CR, Smith EL, Berkowitz MJ et al. Arthroscopic versus open shoulder stabilization for recurrent anterior instability: a prospective randomized clinical trial. *Am J Sports Med.* 2006;34:1730-1737.
3. Castagna A, Delle RG, Borroni M et al. Arthroscopic stabilization of the shoulder in adolescent athletes participating in overhead or contact sports. *Arthroscopy.* 2012;28:309-315.
4. Cil A, Kocher MS. Treatment of pediatric shoulder instability. *J Pediatr Orthop.*2010;30:S3-S6.
5. Cordischi K, Li X, Busconi B. Intermediate outcomes after primary traumatic anterior shoulder dislocation in skeletally immature patients aged 10 to 13 years. *Orthopedics.* 2009;32.
6. Deitch J, Mehlman CT, Foad SL et al. Traumatic anterior shoulder dislocation in adolescents. *Am J Sports Med.* 2003;31:758-763.
7. Gigis I, Heikenfeld R, Kapinas A et al. Arthroscopic versus conservative treatment of first anterior dislocation of the shoulder in adolescents. *J Pediatr Orthop.* 2014;34:421-425.
8. Good CR, MacGillivray JD. Traumatic shoulder dislocation in the adolescent athlete: advances in surgical treatment. *Curr Opin Pediatr.* 2005;17:25-29.
9. Itoi E, Hatakeyama Y, Sato T et al. Immobilization in external rotation after shoulder dislocation reduces the risk of recurrence. A randomized controlled trial. *J Bone Joint Surg Am.* 2007;89:2124-2131.
10. Jones KJ, Wiesel B, Ganley TJ et al. Functional outcomes of early arthroscopic bankart repair in adolescents aged 11 to 18 years. *J Pediatr Orthop.* 2007;27:209-213.
11. Khan A, Samba A, Pereira B et al. Anterior dislocation of the shoulder in skeletally immature patients: comparison between non-operative treatment versus open Latarjet's procedure. *Bone Joint J.* 2014;96-B:354-359.
12. Kraus R, Pavlidis T, Dongowski N et al. Children and adolescents with posttraumatic shoulder instability benefit from arthroscopic stabilization. *Eur J Pediatr Surg.* 2010;20:253-256.
13. Lampert C, Baumgartner G, Slongo T et al. Traumatic shoulder dislocation in children and adolescents. *Eur J Trauma* 2003;29:375-378.
14. Lawton RL, Choudhury S, Mansat P et al. Pediatric shoulder instability: presentation, findings, treatment, and outcomes. *J Pediatr Orthop.* 2002;22:52-61.
15. Li X, Ma R, Nielsen NM et al. Management of shoulder instability in the skeletally immature patient. *J Am Acad Orthop Surg.* 2013;21:529-537.
16. Longo UG, Loppini M, Rizzello G et al. Remplissage, humeral osteochondral grafts, weber osteotomy, and shoulder arthroplasty for the management of humeral bone defects in shoulder instability: systematic review and quantitative synthesis of the literature. *Arthroscopy.* 2014;30:1650-1666.
17. Longo UG, Loppini M, Rizzello G et al. Management of primary acute anterior shoulder dislocation: systematic review and quantitative synthesis of the literature. *Arthroscopy.* 2014;30:506-522.
18. Longo UG, Loppini M, Rizzello G et al. Glenoid and humeral head bone loss in traumatic anterior glenohumeral instability: a systematic review. *Knee Surg Sports Traumatol Arthrosc.* 2014;22:392-414.
19. Maffulli N, Longo UG, Gougoulias N et al. Long-term health outcomes of youth sports injuries. *Br J Sports Med.* 2010;44:21-25.
20. Maffulli N, Longo UG, Spiezia F et al. Sports injuries in young athletes: long-term outcome and prevention strategies. *Phys Sportsmed.* 2010;38:29-34.
21. Maffulli N, Longo UG, Spiezia F et al. Aetiology and prevention of injuries in elite young athletes. *Med Sport Sci.* 2011;56:187-200.
22. Marans HJ, Angel KR, Schemitsch EH et al. The fate of traumatic anterior dislocation of the shoulder in children. *J.Bone Joint Surg Am.* 1992;74:1242-1244.
23. Mazzocca AD, Cote MP, Solovyova O et al. Traumatic shoulder instability involving anterior, inferior, and posterior labral injury: a prospective clinical evaluation of arthroscopic repair of 270 degrees labral tears. *Am J Sports Med.* 2011;39:1687-1696.
24. Ochs BG, Rickert M, Schmelzer-Schmied N et al. Post-traumatic shoulder instability in adolescence. *Orthopade.* 2005;34:152-158.
25. Owens BD, DeBerardino TM, Nelson BJ et al. Long-term follow-up of acute arthroscopic Bankart repair for initial anterior shoulder dislocations in young athletes. *Am J Sports Med.* 2009;37:669-673.
26. Postacchini F, Gumina S, Cinotti G. Anterior shoulder dislocation in adolescents. *J Shoulder Elbow Surg.* 2000;9:470-474.
27. Roberts SB, Beattie N, McNiven ND et al. The natural history of primary anterior dislocation of the glenohumeral joint in adolescence. *Bone Joint J.* 2015;97-B:520-526.

28. Shymon SJ, Roocroft J, Edmonds EW. Traumatic anterior instability of the pediatric shoulder: a comparison of arthroscopic and open bankart repairs. *J Pediatr Orthop*. 2015;35:1-6.

29. Wagner KT, Jr., Lyne ED. Adolescent traumatic dislocations of the shoulder with open epiphyses. *J Pediatr Orthop*. 1983;3:61-62.

6

CHAPTER 7

Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up

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ABSTRACT

Introduction

Arthroscopic stabilization using suture anchors is widely used to restore stability after anterior shoulder dislocations and is associated with low recurrence rates in short-term follow-up studies.

Objective

To evaluate the long-term follow-up after arthroscopic stabilization for traumatic recurrent anterior instability using suture anchors with emphasis on both redislocations and subjective shoulder function.

Methods and materials

We included 67 consecutive patients with 70 affected shoulders. After 8 to 10 years, patients were asked to report the presence and course of their redislocations. Subjective shoulder function was addressed using the Oxford Instability Score (OIS), the Western Ontario Shoulder Instability Index (WOSI), and the Simple Shoulder Test (SST). Patients rated their health status using the Short Form-36 (SF-36).

Results

Sixty-five patients with 68 affected shoulders (97%) were evaluated for follow-up; 35% reported a redislocation. Median shoulder function scores were 16 of 12 to 60, 22 of 0 to 210, and 12 of 0 to 12 for the OIS, WOSI, and SST, respectively. There was a significant difference in subjective function between patients with and without recurrent instability, respectively, 16 versus 24 for the OIS (p 0.004), and 16 versus 47 for the WOSI (p 0.05). We found a trend for an inverse relationship between the number of suture anchors and recurrent instability, with 2 having a higher recurrence rate than 3 or more (p 0.06). Another trend was found with the presence of a Hill-Sachs defect slightly increasing the risk of a redislocation (p 0.07).

Conclusion

With a follow-up of 97%, about one third of the stabilized shoulders experienced at least one redislocation after 8 to 10 years. The presence of a Hill-Sachs defect and the use of less than 3 suture anchors might increase the chance of a redislocation. Patients without a redislocation have a significantly better shoulder function compared with patients with a redislocation.

INTRODUCTION

Shoulder dislocations have an incidence of 17 to 24 per 100 000 per year[24,45] and are more than 90% directed anteriorly.[13] After an initial dislocation, the labral structures often tear from the bony glenoid to reinsert more inferiomedially. The capsular ligaments stretch, thus widening the joint, often resulting in recurrent dislocations.

Several risk factors for primary dislocation have been identified. Being adolescent or a young adult at the time of initial dislocation is clearly associated with a higher risk of subsequent instability, just as is occupational use of the arm at or above chest level, hyper laxity, and participation in collision sports.[15,40] Although nonoperative therapy, that is, shoulder immobilization and physical therapy, can lead to satisfactory results,[17] it is also reported to be associated with a recurrence rate as high as 57%, which is inversely related to the age of the initial dislocation.[15,18]

Surgical stabilization can be achieved using several techniques such as the open and arthroscopic Bankart procedure at which the labrum is reattached to the glenoid.[2,3] The presence of recurrent instability after the open Bankart procedure varies from 3.5% to 23% after 4 to 6 years postoperatively[39,42] and 10% to 22.6% after the modified Bankart procedure 11 to 29 years postoperatively.[4,25,33]

Open stabilization has long been considered the gold standard for surgical stabilization and is still reported in several reviews to be superior to arthroscopic stabilization.[12,27,31] However, arthroscopic stabilization evolved and shows to have good results too. Arthroscopic advantages include less chance of loss of motion, especially external rotation that could limit the shoulder function, shorter surgery time, improved cosmetics, and less postoperative pain.[14] The most recent arthroscopic technique involves the use of suture anchors and decreases the failure rate when compared with the previous arthroscopic techniques of capsulorrhaphy, transglenoid sutures, and bioabsorbable tacks.[16]

Most studies with this technique show recurrence rates around 10% up to 3.6 years postoperatively.[6,9,16,44] With more extended follow-up, one study in rugby players shows a success rate of .90% 5.9 years postoperatively.[26] Recently, Castagna et al[10] showed a recurrence rate of 23% in 10.9 years after arthroscopic stabilization using suture anchors.

Predisposing factors identified for recurrent dislocation after arthroscopic stabilization include a young age, being male, and having an interval of more than 6 months between the first dislocation and time of surgery.[22,36] Also, both humeral head and glenoidal defects are described as risk factors as well as the number of suture anchors that have been used.[6,44]

Increasing evidence is emerging that patients and doctors do not always agree on functional improvements after therapeutic interventions.[20] The patient's subjective wellbeing is increasingly considered to be important, in addition to objective shoulder scores. This implies the start of using patient-based questionnaires more regularly. To investigate the outcome of a surgical intervention ideally, both system-specific (shoulder) and condition-specific (instability) instruments should be used.[34,35]

The purpose of the present study was to prospectively evaluate the long-term surgical outcomes after arthroscopic shoulder stabilization in patients with traumatic recurrent anterior shoulder instability using absorbable suture anchors with emphasis on both redislocations and subjective shoulder function.

METHODS AND MATERIALS

Design

Institutional approval was obtained from our local ethics committee. Patients signed informed consent forms. We performed an observational prospective case series of 67 consecutive patients with 70 affected shoulders who underwent an arthroscopic stabilization using suture anchors from January 1999 to December 2001, with a mean follow-up of 9 years (range, 8-10 years). This technique was introduced in our hospital in 1997. All patients were operated on by one single senior surgeon.

These patients met the following inclusion criteria: (1) all patients were 18 years or older and had repeated involuntary anterior instability after an initial episode caused by a traumatic event, and patients with atraumatic or multidirectional instability were excluded; (2) arthroscopic repair was performed using absorbable suture anchors; and (3) a consistent postoperative treatment program was followed, which included 6 weeks of immobilization in a sling after which a period of active exercises was started. Sport activities were allowed 4 months postoperatively.

Preoperative evaluation consisted of a detailed history including their level of sports activity and physical workload, and physical examination included Rowe scores (version 1978; 0-25 = poor, 25-50 = fair, 50-75 = good, and 75-100 = excellent) to enable prospective evaluation.[39] We have a heterogeneous population including professional athletes, recreational athletes, and sedentary patients.

Surgical Procedure

Patients received an interscalene block before induction of general anesthesia to diminish postoperative pain. Patients were operated in the lateral decubitus position with traction in 2 directions. For the procedure, we used Rodtag (Smith & Nephew, Andover, Massachusetts) made of polyglycolide/polylactate, 3.7 mm in size with a PDS 2.0. The anchors were applied using a push-in technique and were single loaded.

Three portals were used: the standard posterior portal, the standard anterior portal just above the subscapularis tendon through which the anchors were placed, and one superior portal just anterolateral to the acromion. The first anchor was placed at the 5-o'clock position (right shoulder) or 7-o'clock position (left shoulder), which was sufficient to fix the advanced anteroinferior capsula/labrum complex anterosuperior.

With a suture passer through the anterior portal, a shuttle relay was passed through the labrum and advanced through the superior portal, where one of the strands of the anchor suture was brought as well. With the shuttle relay, the first strand was led through the labrum. The same was repeated with the second strand of the anchor suture. After having led both sutures through the labrum, they were tied, thus achieving a mattress configuration. Capsular plication was performed when the capsule was stretched out.

Postoperative Evaluation

Patients were contacted by telephone and asked for written follow-up using Web-based questionnaires. Our primary outcome is recurrent instability, defined as either a subluxation or a full dislocation. Our secondary outcome is the subjective improvement of shoulder function. The shoulder function was not objectified by physical or radiographic examination.

We conducted a sub analysis addressing the influence of several possible risk factors on redislocation. These risk factors include age, dominance, gender, preoperative shoulder function (Rowe score), the number of dislocations preoperatively, the time to surgery in months, and the number of suture anchors that were used. Also, possible influences of both preoperative overhead and contact sports are assessed, as well as the presence of bony defects on both sides of the shoulder joint.

Because both glenoidal bone loss as well as Hill-Sachs lesions have proven to significantly influence the rate of a redislocation after soft tissue shoulder stabilization, the extent of osseous defects was measured on magnetic resonance imaging (MRI) scans.[7,37] Glenoid defects (compression fracture) were assessed using the Bigliani classification, ranging from an ununited glenoidal fragment attached to the separated labrum (type 1) to a malunited fragment detached from the labrum (type 2) to an anterior glenoidal erosion<25% (type 3A) or >25% (type 3B).[5] Defects on the humeral head (Hill-Sachs lesions) were calculated by taking the MRI slice with the largest observed defect and measuring the size of the defect in relation to the total joint circumference in the same slice, expressed as a percentage.

We used the Oxford Instability Score (OIS),[11] the Western Ontario Shoulder Instability Index (WOSI),[23] and the Dutch version of the Simple Shoulder Test (SST)[28] as validated patient-based questionnaires to evaluate the shoulder function at follow-up. We used the Short Form-36 (SF-36) to assess perceived general health status from our patients compared with the normal Dutch population.[1]

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Statistical Analysis

Analyses were performed using SPSS version 17.0 (Chicago, Illinois). Characteristics of our study population were described using the median and standard deviation (SD) when normally distributed or the interquartile range when nonnormally distributed. The number of redislocations was calculated as a percentage of the examined shoulders. To evaluate the influence of gender, dominance, number of suture anchors, preoperative sports participation, and degree of bone defect on the risk of redislocation (yes/no), we calculated relative risks with 95% confidence intervals. For the categorical and continuous variables of age, Rowe score, months to surgery, and number of preoperative dislocations, we used logistic regression analysis, with redislocation (yes/no) as the dependent variable, and calculated odds ratios with 95% confidence intervals. For the number of preoperative dislocations, we divided our patients into 3 groups: having experienced up to 2, up to 5, and more than 10 preoperative dislocations. The differences in OIS, WOSI, and SST between patients with and without redislocations were evaluated using the Mann-Whitney test. Scores on the SF-36 were compared with reference scores from the Dutch general population (version SF-36-1), adjusted for age and sex.[1] A value of $P < .05$ was considered statistically significant.

RESULTS

Of 67 patients in total, 65 patients with 68 affected shoulders (97%) could be reached for follow-up to evaluate redislocation; 2 patients were lost to follow-up. One patient died 5 years postoperatively without ever having experienced a redislocation.

There were 43 men and 22 women; in 47%, their dominant side was involved. The mean age at time of surgery was 31 years (range, 19-56 years). One patient who reported 2 severe subluxations was included because of the presence of a labral lesion on his MRI arthrography.

The median number of dislocations before surgery was 5 (range, 2-40). The median number of months between the first dislocation and surgery was 51 months (range, 8-479 months). Sixty-five percent of the shoulders were stabilized using 2 suture anchors and 35% using 3 or more suture anchors. Before stabilization, 17 patients (19 shoulders) participated in contact sports, 22 patients (23 shoulders) participated in overhead sports, and 8 patients (9 shoulders) participated in a combination of both.

Recurrent Instability

At follow-up, 8 to 10 years postoperatively, a total of 24 (35%) shoulders had experienced a redislocation. In 10 (15%) shoulders, redislocation took place within the first 2 years

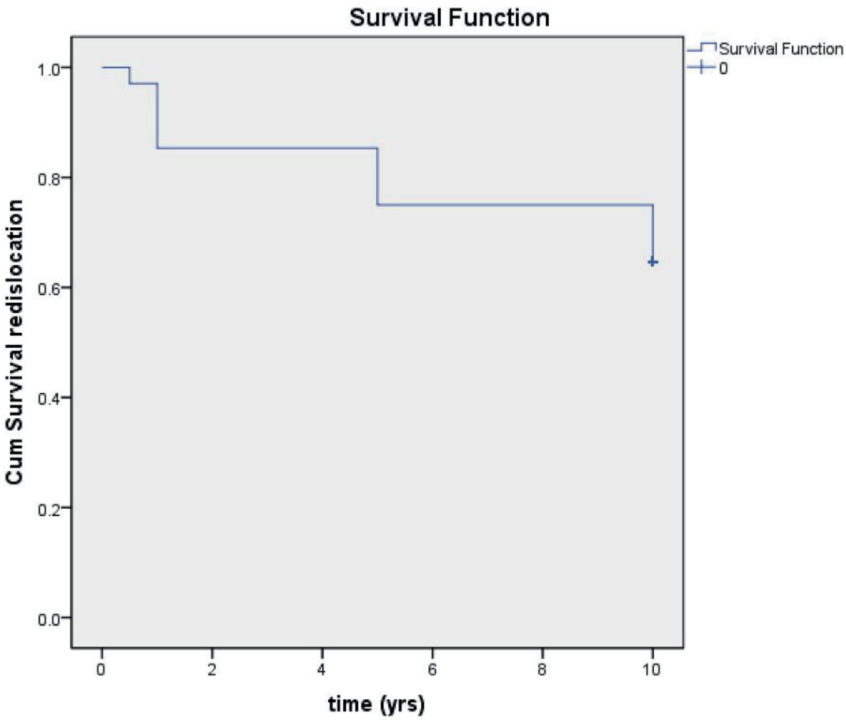

Figure 1. Kaplan-Meier curve of the redislocation rate over time.

postoperatively, another 7 (10%) shoulders redislocated 2 to 5 years postoperatively, and another 7 (10%) experienced a redislocation after more than 5 years (Figure 1).

Of all patients who experienced a redislocation, 18% (12 shoulders) experienced 1 to 2 recurrent dislocations at most, 7% (5 shoulders) experienced 3 to 4 recurrent dislocations, another 7% (5 shoulders) experienced 5 to 10, and 3% (2 shoulders) experienced more than 10 recurrent dislocations. Nine patients (13%) in whom primary stabilization failed underwent a new operation; others were treated nonoperatively or refused a reoperation.

Risk Factors

The results are shown in Table 1. Although not significant, shoulders stabilized with 3 or 4 anchors tended to have a less chance to redislocate than ones stabilized with 2 anchors (p 0.06). No relationship was found between the number of suture anchors and the postoperative period in which a redislocation took place (p 0.48).

No other possible risk factors could be confirmed; being operated on the dominant side was not associated with having an increased risk for experiencing a redislocation (p 0.60), nor was being male (p 0.79). Age (p 0.43) and preoperative Rowe score (p 0.84)

Table 1. Subanalysis for possible risk factors for redislocation.

Variable		N	Re-dislocation %	RR	95% CI	P-value
Gender	Male	43	37	1.16	0.57 – 2.38	0.79
	Female	22	32			
Surgery	Dominant	36	33	0.82	0.43 – 1.57	0.60
	Non dominant	32	37			
Anchors	2	43	44	2.12	0.91 – 4.96	0.06
	3 or more	25	20			
Pre-op dislocations						
	> 2	43	37	1.06	0.52 – 2.17	1.00
	≤ 2	20	35			
	> 5	28	32	0.80	0.41 – 1.58	0.60
	≤ 5	35	40			
	> 10	13	23	0.58	0.20 – 1.65	0.34
	≤ 10	50	40			
			median (range)	OR		
Age (per 10 years older)		68	31 (19-56)	0.77	0.41-1.46	0.43
Rowe-score (per point higher)		64	45 (15-75)	1.00	0.95-1.05	0.84
Months to surgery (per 6 months longer)		61	51 (8-479)	0.96	0.91-1.00	0.09
Number of pre-op dislocations		61	1 (0-4)	1.02	0.61-1.70	0.94

RR, relative risk; CI, confidence interval; OR, odds ratio.

were neither associated to have an increased risk, and also time span to surgery (p 0.09) and the number of preoperative dislocations in general (p 0.23) or up to 2, up to 5, or more than 10 were not associated with an increased risk of experiencing a redislocation (p 1.00, p 0.60, and p 0.34, respectively).

Preoperative Sports Participation

In total, 40 patients (42 shoulders, 62%) participated in either contact sports or overhead sports or both preoperatively. Twenty-five patients (26 shoulders, 38%) either participated in other sports or no sport at all. Preoperative participation in contact sports alone or in both contact and overhead sports simultaneously did not increase the chance of experiencing a redislocation (p 0.57 and p 0.48, respectively). Participation in overhead sports alone, however, seemed to significantly decrease the chance of experiencing a redislocation (p 0.03) (Table 2).

Bony Defects

To assess the effect of bony defects on redislocations, we conducted a sub analysis using 54 MRI scans in which we evaluated both the glenoid and humeral head (Hill-Sachs) (Table 3). In 15 shoulders (28%), the glenoid was intact; in 39 shoulders (72%), the glenoid had some

Table 2. Subanalysis for preoperative sport activities as risk factors for redislocation.

Type of sport		N	Re-dislocation %	RR	95% CI	P-value
Contact	Yes	19	42	1.29	0.66 – 2.50	0.57
	No	49	33			
Overhead	Yes	23	17	0.39	0.15 – 1.01	0.03
	No	45	44			
Both	Yes	9	22	0.60	0.17 – 2.11	0.48
	No	59	37			

RR, relative risk; CI, confidence interval.

Table 3. Subanalysis for bony defects as risk factors for redislocation.

Degree bone defect			N	Re-dislocation %	RR	95% CI	P-value
Glenoid	Type 2	Yes	6	50	1.32	0.55 – 3.20	0.63
		No	48	38			
	Type 3A	Yes	33	39	1.03	0.52 – 2.06	1.0
		No	21	38			
	Any degree	Yes	39	41	1.23	0.55 – 2.76	0.60
		No	15	33			
Hill Sachs	<25%	Yes	43	42	1.56	1.08 – 2.21	0.13
		No	11	27			
	>25%	Yes	3	67	1.79	0.75 – 4.30	0.55
		No	51	37			
	Any degree	Yes	45	44	4.00	0.61 – 26.1	0.07
		No	9	11			

RR, relative risk; CI, confidence interval.

degree of damage, varying from Bigliani type 2 (6 cases) to type 3A (33 cases). When compared with shoulders without a glenoid defect, neither type 2 nor type 3A nor both types combined increased the risk of redislocation (p 0.63, $P = 1.00$, and p 0.60, respectively).

Addressing the humeral head, in 9 shoulders (17%), no Hill-Sachs lesion was identified; in 42 shoulders (78%), a Hill-Sachs lesion comprised less than 25% of the humeral head circumference, and in only 3 shoulders (6%), the Hill-Sachs lesion comprised more than 25%. Although not significant, there might be a relationship between the presence of any degree of Hill-Sachs lesion and the presentation of a redislocation (p 0.07). The lesion's size, however, was of no significant influence, with p 0.13 for lesions <25% and p 0.55 for lesions >25%.

Postoperative Shoulder Function

Our secondary outcome was the subjective shoulder function, evaluated with the above-mentioned questionnaires. This function was not objectified. Although 57 patients (59 shoulders, 84%) were willing to answer the questionnaires, the postoperative function vwas conducted only from those 48 patients (50 shoulders) without a reoperation during follow-up (71%). The characteristics of these scores are summarized in Table 4.

The median scores for both the OIS and the WOSI were low (meaning good function), with 16 of 12 to 60 for the OIS and 22 of 0 to 210 for the WOSI. The scores of patients without a redislocation were significantly better compared with patients with a redislocation. The median SST score was high (meaning good function), with 12 of 0 to 12, and there was no difference between SST scores of patients with or without a redislocation (Table 4).

In the SF-36 score, when corrected for age (16-40 years), only 5 participants scored less in both the physical and mental component compared with the normal Dutch population. Because not all patients were athletes, the SF-36 score was not corrected for this entity, even though athletes might have a higher baseline SF-36 score. When corrected for sex, there were only 3 patients to score less than the norm (Figure 2).

Table 4. Subjective shoulder scores (median and IQR).

Score	No. items	Range	Best	Total	Re-dislocation		P-value
					No (n=35)	Yes (n=15)	
OIS	12	12-60	Lowest	16 (13-24)	16 (13-17)	24 (15-28)	0.004
WOSI	21	0-210	Lowest	22 (11-70)	16 (9-45)	47 (19-75)	0.05
SST	12	0-12	Highest	12 (10-12)	12 (10-12)	12 (11-12)	0.48

Patients with recurrent surgery are excluded. IQR, interquartile range; OIS, Oxford Instability Score; WOSI, Western Ontario Shoulder Instability Index; SST, Simple Shoulder Test.

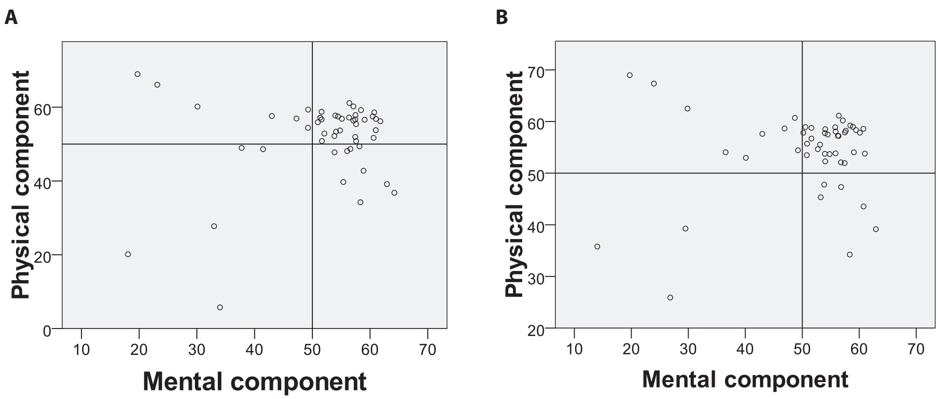

Figure 2. The SF-36 scores corrected for age (16-40 years) (A) and sex (B) compared with the normal Dutch population. The physical and mental scores above 50 correspond to better physical or mental function than the comparison group.

Complications

No infections or other complications occurred in this series.

DISCUSSION

The optimal surgical technique to treat recurrent anterior glenohumeral instability remains a controversial topic, as good results have been shown by both open and arthroscopic stabilization. Although often described to show a lower recurrence rate, the open Bankart procedure can result in a limited range of motion.[21,27]

In our study on the long-term follow-up after arthroscopic stabilizations for traumatic onset of recurrent anterior shoulder instability, redislocation was defined as our primary outcome. Because the subjective questionnaires reflect the experience of the patient, we used strict criteria for redislocation, including both a subluxation and a full dislocation, to avoid possible confusion for the patient. Our results up to 2 years postoperatively resemble previous studies with a 15% failure rate.[6,16,44] However, another 20% of the patients experienced their first redislocation after 2 years, leading to a total 35% of our patients having experienced at least one redislocation 8 to 10 years postoperatively. This is slightly more compared with long-term follow-up studies in open stabilization[4,25,33] and one previous long-term follow-up study in arthroscopic stabilization, which only reached 71% for final follow-up.[10]

No previously identified risk factors could be confirmed in our study. Contrary to previous studies, no significance was found for age as a risk factor.[36,38,43] Because young age has been identified as a risk factor to increase the chance of a redislocation, the relatively high age of our population might positively influence our results. The interval between first dislocation and surgery did not increase the chance of a redislocation. Nor did the number of preoperative dislocations, up to 2, up to 5, or more than 10, influence the chance of having a redislocation. Dominance, gender, and preoperative shoulder function did not influence the chance of having a redislocation either.

As Boileau et al[6] previously described, we also did find, although not significantly, a relationship between the number of suture anchors that were used and the chance of a redislocation. This trend shows that patients stabilized with 3 or more suture anchors have less chance to experience a redislocation than patients stabilized with 2 suture anchors. The fact that 43 shoulders (63%) were stabilized using 2 suture anchors might partly explain the higher recurrence rate in our study compared with previous studies. We did not find any confounding factors between the different risk factors.

We also found, as previously described by Voos et al[44] and Boileau et al,[6] that the presence of a Hill-Sachs defect, although not significantly, increased the redislocation risk. We did not find a relationship between glenoid lesions and redislocations.

Preoperative participation in contact sports, as Ide et al[19] described before, did not influence the redislocation risk. We observed that preoperative participation in overhead sports, however, decreased this risk significantly, although no specific measures were taken in overhead athletes. This is contrary to the findings of Ide et al[19] and Pagnani et al,[32] who previously described no relationship, and to Sachs et al[40] and Calvo et al,[8] who described a significant increased redislocation risk in patients participating in overhead sport activities.

This finding might be because of higher awareness, better muscular control, and better proprioceptive abilities in patients participating in overhead sports compared with their peers who do not share their experiences. Another plausible explanation is that these patients might have diminished their sports intensity or did not return to their preinjury level of shoulder function compared with patients who were not engaged in overhead activity.

To investigate the subjective functional improvement of a surgical intervention ideally, both system (shoulder)– specific and condition (instability)–specific instruments should be used.[34,35] The OIS, WOSI, and SST are designed to do so, including questions addressing sport, work, and daily activities. To objectify the results of our initial procedure, in this sub analysis, we only included patients without a reoperation during follow-up. Based on the good average scores, we conclude that our patients in general are satisfied with their shoulder function.

We furthermore found that only the instability-specific questionnaires (OIS and WOSI) distinguished significantly between patients with and without redislocation, whereas the more general shoulder score (SST) did not. In our opinion, only instability-specific questionnaires should therefore be used in long-term follow-up studies for instability management.

The SF-36 showed that the majority of the patients score above average on both the mental and physical component. With our heterogeneous patient population, we did not correct for the fact that athletes might have a higher baseline SF-36 score.

Because the OIS, WOSI, and SST have only recently been developed and had not yet been validated thoroughly at the time of surgery, we conducted the Rowe score before surgery. The Rowe score is a very commonly used scoring system largely based on the objective shoulder function.

An important advantage of using validated patient-based questionnaires is that patients can be included for final follow-up without visiting the hospital. Especially in this relatively young and highly mobile patient population, it is a very practical way to follow-up on patients.

Although long-term follow-up studies on previous arthroscopic techniques are available,[30,41] to our knowledge, only one previous study has been published on extended follow-up after arthroscopic stabilization using suture anchors in a community-based patient population. This study, however, included only 71% for their final follow-up.[10]

One study with an extended follow-up included only male contact athletes who are likely to be in excellent condition and might not be as representative as our population.[26] Another previous study described the results after open stabilization with suture anchors using the OIS. Eleven years after their initial operation, they have a response rate of 64% and have a mean score of 21.7, with 12% experiencing further dislocations or ongoing symptoms of instability.[29]

Strong points of this study are the 97% long-term follow-up and the presence of an independent observer using validated patient-based questionnaires. A weak point is the fact that 10 years ago, generally 2 to 3 anchors were used, while presently, a large consensus exists to use 3 or more anchors. Another weak point is the fact that, although the used subjective scores are highly valuable, patients were not physically or radiographically evaluated, and instability, shoulder range of motion, or strength is not objectified. The authors, however, argue that a stiff shoulder or an impaired shoulder function will translate in the outcome of the questionnaires. Instability-specific parameters like passive apprehension could therefore not be included in our results.

CONCLUSION

Eight to 10 years postoperatively, about one third of the patients undergoing this type of procedure reported a redislocation. More than half of these occurred for the first time more than 2 years after surgery. We found that the number of anchors used, as well as the presence of a Hill-Sachs defect, tended to be predisposing factors for experiencing a redislocation. Other previously identified predisposing factors for redislocation could not be confirmed. Although all patients in general reported few functional problems, patients without a redislocation have a significantly better subjective shoulder function compared with their peers with a redislocation.

REFERENCES

1. Aaronson NK, Muller M, Cohen PD, et al. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. *J Clin Epidemiol.* 1998;51:1055-1068.
2. Bankart ASB. The pathology and treatment of recurrent dislocation of the shoulder. *Br J Surg.* 1938;26:23-29.
3. Bankart ASB. Recurrent or habitual dislocation of the shoulder joint. *BMJ.* 1923;2:1132-1133.
4. Berendes TD, Wolterbeek R, Pilot P, Verburg H, te Slaa RL. The open modified Bankart procedure: outcome at follow-up of 10 to 15 years. *J Bone Joint Surg Br.* 2007;89:1064-1068.
5. Bigliani LU, Newton PM, Steinmann SP, Connor PM, McIlveen SJ. Glenoid rim lesions associated with recurrent anterior dislocation of the shoulder. *Am J Sports Med.* 1998;26:41-45.
6. Boileau P, Villalba M, Hery JY, Balg F, Ahrens P, Neyton L. Risk factors for recurrence of shoulder instability after arthroscopic Bankart repair. *J Bone Joint Surg Am*. 2006;88:1755-1763.
7. Burkhart SS, De Beer JF, Barth JR, Cresswell T, Roberts C, Richards DP. Results of modified Latarjet reconstruction in patients with anteroinferior instability and significant bone loss. *Arthroscopy.* 2007;23:1033-1041.
8. Calvo E, Granizo JJ, Fernandez-Yruegas D. Criteria for arthroscopic treatment of anterior instability of the shoulder: a prospective study. *J Bone Joint Surg Br*. 2005;87:677-683.
9. Carreira DS, Mazzocca AD, Oryhon J, Brown FM, Hayden JK, Romeo AA. A prospective outcome evaluation of arthroscopic Bankart repairs: minimum 2-year follow-up. *Am J Sports Med.* 2006;34:771-777.
10. Castagna A, Markopoulos N, Conti M, Delle RG, Papadakou E, Garofalo R. Arthroscopic Bankart suture-anchor repair: radiological and clinical outcome at minimum 10 years of follow-up. *Am J Sports Med.* 2010;38:2012-2016.
11. Dawson J, Fitzpatrick R, Carr A. The assessment of shoulder instability: the development and validation of a questionnaire. *J Bone Joint Surg Br.* 1999;81:420-426.
12. Freedman KB, Smith AP, Romeo AA, Cole BJ, Bach BR Jr. Open Bankart repair versus arthroscopic repair with transglenoid sutures or bioabsorbable tacks for recurrent anterior instability of the shoulder: a meta-analysis. *Am J Sports Med.* 2004;32:1520-1527.
13. Goss TP. Anterior glenohumeral instability. *Orthopedics.* 1988;11:87-95.
14. Green MR, Christensen KP. Arthroscopic versus open Bankart procedures: a comparison of early morbidity and complications. *Arthroscopy.* 1993;9:371-374.
15. Handoll HH, Almaiyah MA, Rangan A. Surgical versus non-surgical treatment for acute anterior shoulder dislocation. *Cochrane Database Syst Rev.* 2004;CD004325.
16. Hobby J, Griffin D, Dunbar M, Boileau P. Is arthroscopic surgery for stabilisation of chronic shoulder instability as effective as open surgery? A systematic review and meta-analysis of 62 studies including 3044 arthroscopic operations. *J Bone Joint Surg Br.*2007;89:1188-1196.
17. Hovelius L, Augustini BG, Fredin H, Johansson O, Norlin R, Thorling J. Primary anterior dislocation of the shoulder in young patients: a ten-year prospective study. *J Bone Joint Surg Am.* 1996;78:1677-1684.
18. Hovelius L, Olofsson A, Sandstrom B, et al. Nonoperative treatment of primary anterior shoulder dislocation in patients forty years of age and younger: a prospective twenty-five-year follow-up. *J Bone Joint Surg Am.* 2008;90:945-952.
19. Ide J, Maeda S, Takagi K. Arthroscopic Bankart repair using suture anchors in athletes: patient selection and postoperative sports activity. *Am J Sports Med.* 2004;32:1899-1905.
20. Janse AJ, Gemke RJ, Uiterwaal CS, van der Tweel I, Kimpen JL, Sinnema G. Quality of life: patients and doctors don't always agree: a meta-analysis. *J Clin Epidemiol.* 2004;57:653-661.
21. Karlsson J, Magnusson L, Ejerhed L, Hultenheim I, Lundin O, Kartus J. Comparison of open and arthroscopic stabilization for recurrent shoulder dislocation in patients with a Bankart lesion. *Am J Sports Med.* 2001;29:538-542.
22. Kim SH, Ha KI, Cho YB, Ryu BD, Oh I. Arthroscopic anterior stabilization of the shoulder: two to six-year follow-up. *J Bone Joint Surg Am.* 2003;85:1511-1518.
23. Kirkley A, Griffin S, McLintock H, Ng L. The development and evaluation of a disease-specific quality of life measurement tool for shoulder instability: the Western Ontario Shoulder Instability Index (WOSI). *Am J Sports Med.* 1998;26:764-772.
24. Kroner K, Lind T, Jensen J. The epidemiology of shoulder dislocations. *Arch Orthop Trauma Surg.* 1989;108:288-290.
25. Langford J, Bishop J, Lee E, Flatow E. Outcomes following open repair of Bankart lesions for recurrent, traumatic anterior glenohumeral dislocations. *Orthopedics.* 2006;29:1008-1013.

26. Larrain MV, Montenegro HJ, Mauas DM, Collazo CC, Pavon F. Arthroscopic management of traumatic anterior shoulder instability in collision athletes: analysis of 204 cases with a 4- to 9-year follow-up and results with the suture anchor technique. *Arthroscopy.* 2006;22:1283-1289.
27. Lenters TR, Franta AK, Wolf FM, Leopold SS, Matsen FA III. Arthroscopic compared with open repairs for recurrent anterior shoulder instability: a systematic review and meta-analysis of the literature. J *Bone Joint Surg Am.* 2007;89:244-254.
28. Lippitt SB, Harryman DT II, Matsen FA III. A practical tool for evaluating function: the Simple Shoulder Test. In: Matsen FA III, Fu FH, Hawkins RJ, eds. The Shoulder: A Balance of Mobility and Stability. Rosemont, Illinois: The American Academy of Orthopaedic Surgeons; 1993:545-559.
29. Loughead JM, Williams JR. Outcome following Bankart repair for shoulder instability 1998-2002 using a subjective patient based shoulder questionnaire (Oxford). *Injury.* 2005;36:539-543.
30. Marquardt B, Witt KA, Gotze C, Liem D, Steinbeck J, Potzl W. Longterm results of arthroscopic Bankart repair with a bioabsorbable tack. *Am J Sports Med.* 2006;34:1906-1910.
31. Mohtadi NG, Bitar IJ, Sasyniuk TM, Hollinshead RM, Harper WP. Arthroscopic versus open repair for traumatic anterior shoulder instability: a meta-analysis. *Arthroscopy.* 2005;21:652-658.
32. Pagnani MJ, Warren RF, Altchek DW, Wickiewicz TL, Anderson AF. Arthroscopic shoulder stabilization using transglenoid sutures: a four-year minimum followup. *Am J Sports Med.* 1996;24:459-467.
33. Pelet S, Jolles BM, Farron A. Bankart repair for recurrent anterior glenohumeral instability: results at twenty-nine years' follow-up. *J Shoulder Elbow Surg.* 2006;15:203-207.
34. Plancher KD, Lipnick SL. Analysis of evidence-based medicine for shoulder instability. *Arthroscopy.* 2009;25:897-908.
35. Poolman RW, Swiontkowski MF, Fairbank JC, Schemitsch EH, Sprague S, de Vet HC. Outcome instruments: rationale for their use. *J Bone Joint Surg Am.* 2009;91 Suppl 3:41-49.
36. Porcellini G, Campi F, Pegreffi F, Castagna A, Paladini P. Predisposing factors for recurrent shoulder dislocation after arthroscopic treatment. *J Bone Joint Surg Am.* 2009;91:2537-2542.
37. Purchase J, Wolf EM, Hobgood ER, Pollock ME, Smalley CC. Hill-Sachs "remplissage": an arthroscopic solution for the engaging Hill-Sachs lesion. *Arthroscopy.* 2008;24:723-726.
38. Robinson CM, Howes J, Murdoch H, Will E, Graham C. Functional outcome and risk of recurrent instability after primary traumatic anterior shoulder dislocation in young patients. *J Bone Joint Surg Am.* 2006;88:2326-2336.
39. Rowe CR, Patel D, Southmayd WW. The Bankart procedure: a longterm end-result study. *J Bone Joint Surg Am.* 1978;60:1-16.
40. Sachs RA, Lin D, Stone ML, Paxton E, Kuney M. Can the need for future surgery for acute traumatic anterior shoulder dislocation be predicted? *J Bone Joint Surg Am.* 2007;89:1665-1674.
41. Soderlund T, Mattila VM, Visuri TI, Pihlajamaki HK. Long-term outcome of a transglenoid suture technique for anterior shoulder instability in young adults. *J Bone Joint Surg Br.* 2008;90:189-193.
42. Uhorchak JM, Arciero RA, Huggard D, Taylor DC. Recurrent shoulder instability after open reconstruction in athletes involved in collision and contact sports. *Am J Sports Med.* 2000;28:794-799.
43. Vermeiren J, Handelberg F, Casteleyn PP, Opdecam P. The rate of recurrence of traumatic anterior dislocation of the shoulder: a study of 154 cases and a review of the literature. *Int Orthop.* 1993;17:337-341.
44. Voos JE, Livermore RW, Feeley BT, et al. Prospective evaluation of arthroscopic Bankart repairs for anterior instability. *Am J Sports Med.* 2010;38:302-307.
45. Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am.* 2010;92:542-549.

CHAPTER 8

The Bristow-Latarjet procedure, a historical note on a technique in comeback

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ABSTRACT

The Bristow-Latarjet procedure is a well-known surgical technique designed to treat shoulder instability. In this procedure the coracoid process is transferred to the glenoid rim, to serve as augmentation of an associated bony defect. Because long-term results following a soft tissue repair (Bankart repair) reveal that up to 21% and 33% of the patients might experience recurrent instability and with the advent of the arthroscopic coracoid transfer, there is renewed interest in this procedure to treat shoulder instability. The aim of this study is to provide a historical overview, with emphasis on the original inventors Bristow and Latarjet, the complications and following modifications regarding the surgical approach, the coracoid transfer and the arthroscopic technique.

INTRODUCTION

Recurrent shoulder instability can be associated with bony lesions of both the glenoid and the humeral head.[39] The glenoid erosion (bony Bankart) or impression of the humeral head (Hill Sachs defect) impairs the congruity of the glenohumeral joint, possibly resulting in subsequent shoulder dislocations. Although controversial, bony reconstruction of the glenoid is usually recommended if there is significant bone loss (usually >20% to 25%).[16;27;35;43;45] Defects that are too large to be restored with the coracoid process can be treated with a tricortical iliac crest graft or a distal tibia allograft.[35;43]

The Bristow-Latarjet procedure is a surgical technique that is designed to restore the congruity of the shoulder joint, using the coracoid process as an augmentation of the anteroinferior glenoid rim. The conjoined tendon remains attached to the coracoid process, providing the so-called hammock effect to prevent anterior dislocation with the arm in abduction and exorotation position.[44]

A less invasive surgical technique is the arthroscopic Bankart repair with suture anchors, used to restore soft tissue damage. This technique is associated with a redislocation rate of 8%, although some authors report redislocation rates up to 21 % after 10 years and even 33% when subluxations are counted too.[42] The Bristow-Latarjet procedure on the contrary, has a low redislocation rate, ranging from 0 to 8% [2;12;16;42], but is associated with a history of high complication rates including osteoarthritis, screw breakage, nonunion and stiffness.

Since the original manuscripts, many changes were proposed both in the technical procedure as well as in the name of the procedure (Figure 1). To our knowledge May was the first to combine both procedures naming it the modified Bristow repair in 1970. Others referred to it as the Bristow-Helfet procedure[14], the Bristow-Helfet-May procedure[40] and the Bristow-Latarjet procedure.[15]

The aim of this study is to provide a historical overview, with emphasis on the original inventors Bristow and Latarjet and the complications and modifications regarding the approach, the coracoid process transfer and the arthroscopic technique.

Edward Smith papyrus - approx 3000BC
first documented shoulder dislocation

Hippocrates - approx 440BC
detailed description of shoulder dislocation and relocation technique

Albert - 1898
arthrodesis for shoulder dislocation

Bankart - 1939
Bankart repair (capsular plication and/or labrum repair)

Latarjet - 1954
Latarjet procedure

Helfet - 1958
Bristow procedure

May - 1970
screw fixation coracoid and subscap split

Hovelius - 1983
first mention of the name Bristow-Latarjet for the procedure

Torg - 1987
coracoid over subscap (Bristow-Helfet-May procedure)

Nourissat - 2006
arthroscopically assisted mini open procedure in cadaveric population

Lafosse and Boileau - 2007
arthroscopic procedure

Figure 1. A timeline regarding shoulder instability and the Bristow-Latarjet procedure with its subsequent modifications.

HISTORICAL BACKGROUND

W.R. Bristow

Walter Rowley Bristow (Figure 2) was born at Bexley, Kent, on December 12, 1882. He received his early medical education at St Thomas' Hospital Medical School. He was conspicuous for his athletic skills and became close friends with, among others, Gathorne Girdlestone. After his graduation he started as surgeon at St Thomas' in 1910, where he returned in 1919 after serving as a medical officer in the First world War (WW I) to constitute the orthopaedic department. He was attached to the Middlesex Yeomanry and took part at the Suvla Bay Landing in Gallipoli in WW I. Bristow would attend St Nicholas home for Crippled Children, to treat the bone and joint diseases. Due to his efforts the hospital evolved into an active country hospital that started treating adults as well. During WW II the hospital was used to treat injured servicemen and in 1948 the hospital was renamed Rowley Bristow Hospital, a name it would bear until the hospital closed (Figure 3). Funds from the sale of the land were used to finance the Rowley Bristow Orthopaedic Unit, which opened in 1998 in the then newly built Prince Edward Wing of St Peter's Hospital, Chertsey. In the interbellum Bristow conducted his practice located on 102 Harley Street, which was the scene of bounteous hospitality and well-known dinners, until the Luftwaffe blasted it into ruins in WW II. During WW II he organized the orthopaedic sections of the military hospitals in Great Britain as a Consulting Orthopaedic Surgeon to the army in the rank of Brigadier.

Figure 2. Left to right, Brigadier L. E. J. Whitby, RAMC, Brigadier Rowley W. Bristow, and Maj. Gen. D. C. Monro, Consulting Surgeon, RAMC, at a reception given by Maj. Gen. Paul R. Hawley and consultants, Cheltenham, England, 30 April 1943. (Courtesy of the Office of the Army Surgeon General, Public Affairs, and the Network Enterprise Center, Fort Detrick, Md)

Figure 3. A granite stone commemorates the site of the former Rowley Bristow Orthopaedic Hospital. It reads: " Nearby once stood the world renowned Rowley Bristow Orthopaedic Hospital, which began as a Waifs and Strays' Home 1907 - 1990".

He was known as a great teacher and therefore loved and remembered by his students. One of his aphorisms was "we treat patients, not disease". He married in 1910 and had a son and two daughters. He passed away November 10, 1947.[31]

Bristow never described his shoulder stabilizing technique himself, but he taught it to his students. Some argue that Bristow himself probably never performed the Bristow procedure.[36] One of his students, AJ Helfet, published the technique ten years after Bristow's death and 19 years after learning it from the man whose name it would come to bear.[13]

M. Latarjet

Michel Latarjet was born in 1919. His father, André Latarjet, was a renowned surgeon and became professor of anatomy in Lyon. Together with Léo Testut he wrote a work on the human anatomy. His name and legacy is still remembered in the 'Musée Testut-Latarjet', a museum on anatomy in Lyon.

In 1936 Michel Latarjet became an assistant of anatomy, only to become prosector the next year. He graduated from medical school in 1939. His thesis was on the treatment of bronchiectasis, evolving from his interest in thoracic surgery. During WW II, Michel Latarjet created a mobile group of surgeons and experienced the need for continuous ambulance service to and from the battlefield, for which he was decorated with the 'Croix de guerre' (war cross). In 1942 he became chief of the anatomy department and in 1946 he became professor of anatomy at the age of 33. In 1953 Michel Latarjet started his surgical training. Although he was interested in thoracic surgery, he soon published his paper on the stabilising operation for the traumatically dislocated shoulder (1954). In 1958 he became the head of the thoracic surgery department in the Jules-Courmont hospital in Lyon. He continued publishing on anatomy during his entire career and revised his father's anatomical work in 1949, only to publish his own in 1983. After suffering a cerebrovascular accident with Broca's aphasia, Michel Latarjet passed away in 1999.

THE ORIGINAL PROCEDURE

In 1954 Latarjet presented a technique to treat recurrent shoulder instability, by supporting the anteroinferior glenoid with a bony graft. Simultaneously, orthopaedic surgeon Trillat described an identical technique in the same edition of the same journal.[41] Where Latarjet's technique detached the periost and the subscapular muscle to obtain good visualization of the glenoid, Trillat advised to use an elevator to keep the subscapular muscle aside.

Latarjet refers to a technique described by Mauclaire, Hybinette and Eden. Eden, in 1917, transferred a corticocancellous bone block from the tibia to the scapular neck to act as an extended buttress of the anterior glenoid [9], Speed of Chicago described Eden's technique in the English literature in 1927 and also noted that Phemister had also used Eden's method.[38]

Hybinette in 1932 reported a similar procedure using iliac bone graft.[17] The Eden-Hybinette procedure became especially popular in the Scandinavian countries.[38]

In 1924 Oudard reported a tibial graft interposition to the coracoid process to serve as an anterior strut after plication of the subscapular muscle (Figure 4).[33] Boicev reported an operation very similar to the one described by Latarjet and Helfet in a paper in 1938.[3]

This is modified by Latarjet by removing the 'canopy' coracoid to ease access to the glenoidal lesion, and was previously advised by Morestin (1911) and Bazy (1923) in the treatment for long standing shoulder dislocations.[21]

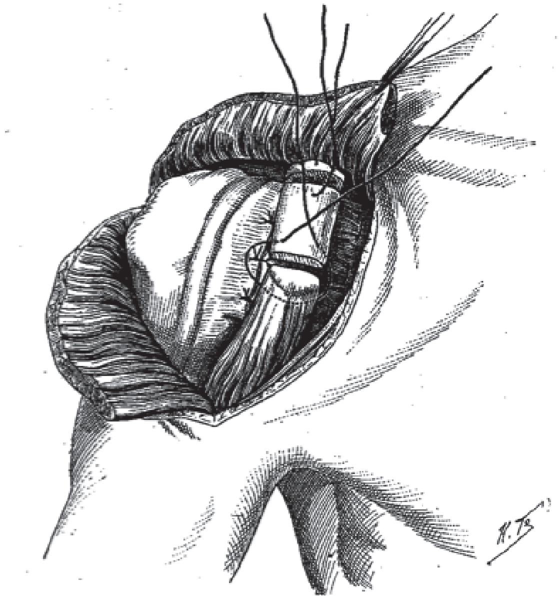

Figure 4. Illustration of the tibial graft interposition to the coracoid process described by Oudard in 1924.

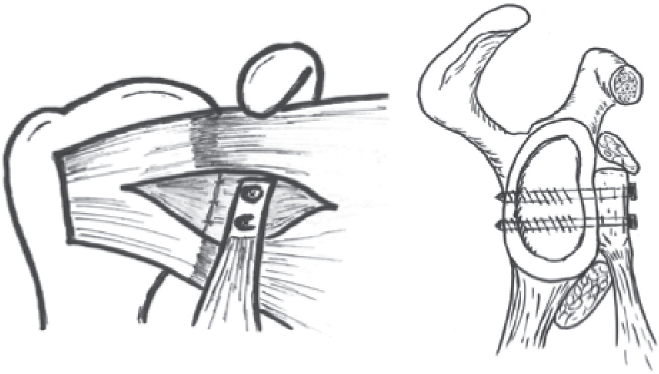

Figure 5. Illustration of the principle of the coracoid transplant described by Latarjet in 1958.

Based on a series of nine patients, a more detailed technical description of the technique was published in 1958.[22;23] In this report he underlined the importance of three technical principles; first, the coracoid serves as an augmentation of the glenoid surface. Second is the secure fixation of the graft to the scapular neck and third is imbrication of the subscapularis, to provide the necessary tension (Figure 5).

Using a deltopectoral approach, the coracoid process is exposed and its tip is (pre)drilled. The coracoid process is cut between the insertions of the coracobrachialis muscle and the insertion of the pectoralis minor muscle.

The arm is placed in external rotation and the anterior glenoid rim is exposed by a vertical incision of the subscapularis tendon near the attachment on the humerus. The subscapularis is peeled of the capsule. Shredded periosteal connective tissue on the anterior glenoid neck is removed. After the scapular neck is prepared with a drill, the coracoid process is pushed against the scapular neck and attached to the scapular neck with a 30 or 35 millimeter screw. The screw should be perpendicular to the anterior surface of the scapular neck, halfway between the top and bottom oblique edges of the glenohumeral surface. The arm is then placed in internal rotation and the subscapular tendon is sutured with sufficient overlap.

In 1958 Helfet (Johannesburg, South Africa), who was trained by Bristow - describes nearly the same technique as Latarjet.[13] The main difference is the way the coracoid process is attached to the glenoid rim. In contrast to Latarjet, Helfet only uses sutures to attach the coracoid process. In his report the subscapular muscle is not sectioned completely; a 2.5 to 3cm (1 to 1.25 inch) vertical slit is made in the middle two-thirds of the musculofibrous junction of the muscle, opening the joint at the same time. On the scapular neck an area of bone about three-quarters of an inch in diameter is exposed by removing periosteal tissue. The bony surface on the scapular neck is prepared using a fine osteotome or gouge. The coracoid process is then passed through the slit in the subscapularis and pressed to the scapula neck by incorporating the conjoint tendon in the sutures approximating the cut edges of the slit in the subscapularis. The conjoined tendon functions as a buttress with the arm abducted and rotated laterally (Figure 6). If the capsule is very voluminous it may be sutured in an overlapping manner.

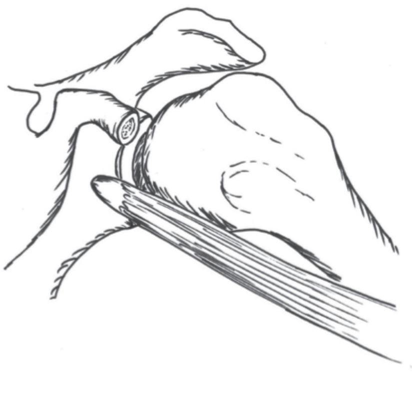

Figure 6. Illustration of the buttressing action of the transplanted bone and tendons with the arm abducted and rotated latterly described by Helfet in 1958.

In 1984 Mackenzie describes communications he had with Helfet regarding the procedure.[28] As a comment on this technique Helfet said: '… the only poor results I saw were in patients in whom the tip of the coracoid process had been screwed on to the scapula. If displacement occurred in the early stages, the bone did not unite because the metal prevented apposition.'.[28]

COMPLICATIONS

Although the first two patients that were described by Latarjet which recovered very quickly and had a painless and unimpaired range of motion after 20 days [21], the overall short term complication rate has been reported to be as high as 25%.[37] A recent systematic review reported an overall complication rate of 15% following open Latarjet procedure in 1018 shoulders.[26] Another systematic review reported a complication rate of 30% in 1904 patients following both open and arthroscopic procedures with a mean follow-up of 6.8 years.[12] Although they have a shorter follow-up, patients treated with an arthroscopic procedure seem to have a lower redislocation and reoperation rate. They also seem to do better in their rehabilitation, although they have a significant greater loss of external rotation at final follow-up. Other complications, such as the rate of coracoid graft nonunion do not differ.[12;26] In both reports, complications were classified as recurrent instability, wound infections and superficial hematoma, screw migration and bending or breakage, bony non-union and nerve injuries (a.o. the musculocutaneous nerve, the axillary nerve and the suprascapular nerve). The most reported complications and their incidence are summarized in Table 1.[12;26]

Rare complications include stiffness and frozen shoulder, keloid formation, humeral fracture during manipulation and axillary artery pseudoaneurysm or laceration, requiring surgical attention. With rates as high as 59% after 14.3 years following an open

Table 1. The most reported complications, with their associated incidence.

Complication	Incidence
Osteoarthritis	6 - 59%
Non-union, migration or osteolysis of the bone block	2 - 30%
Screw migration or breakage	1 - 14 %
Infection	3 - 10%
Nerve injury	3 - 10%
Recurrent dislocation and subluxation	3-6%
Superficial hematoma	3 - 5 %
Other (e.g. frozen shoulder, humeral fracture during manipulation, Keloid formation, stiffness, axillary artery pseudoaneurysm or laceration)	2 %

Latarjet procedure, osteoarthritis of the shoulder joint is the most frequent reported complication [1] and is most likely attributed to an overhanging bone block position. Compared to Bankart repairs however, comparative studies did not find a significant difference.[26] In contrast to this considerable complication rate, the reoperation rate was only 7% and most often (in 35%) related to symptomatic hardware removal.[12]

To decrease the risk of complications, subsequent modifications have been added to the surgical technique.

MODIFICATIONS OF THE SURGICAL TECHNIQUE

Positioning and fixation of the coracoid process

Precise positioning and secure fixation of the coracoid process is important to provide the stabilizing effect of the Bristow-Latarjet procedure, based on an increased anterior-posterior glenoid diameter, the sling effect of the conjoined tendon and the enforcement of the capsule with the coracoacromial ligament.[18] Illustrations by Latarjet (1958) show that the coracoid process is placed with the osteotomised side facing upwards at the anterior rim of the scapular neck. Moreover glenohumeral contact pressure is optimally restored when the coracoid bone block is positioned flush to the glenoid surface.[11]

To optimize external rotation, Mackenzie (1984) suggested to position the coracoid process with the concave side facing towards the humerus and to place the coracoid process antero-inferiorly instead antero-superiorly.[28] In this technique the orientation of the coracoid process is not changed after the osteotomy is performed. Describing the "the congruent arc" technique, De Beer in 2009 advocates to rotate the coracoid process 90 degrees in both the coronal and axial plane, such that the inferior surface of the coracoid graft is flush to the glenoid surface.[8] The purported advantage of the congruent-arc procedure is that the radius of curvature of the inferior coracoid surface matches the radius of curvature of the glenoid rim.[6] Additionally, this method allows treatment of a significantly greater glenoid bone deficiency, as the coracoid is wider than it is thick and glenoid articular surface contact pressures are better restored. By cutting de medial side of the coracoid process obliquely, a greater surface area of coracoid can be attached to the scapular neck.[8]

To minimize non-union, the sutures that were used by Bristow to attach the coracoid process to the scapular neck [13], were replaced by screws. The drill bit diameter increased from 2.8 mm in 1970 and 1976 [24;30], to 3.2 and 4.5mm between 1984 and 2011.[24;28;40;45] Screw lengths range from 1.9 cm[15] to 2.5 cm[29] or were measured in each patient individually [30;40] and all authors describe the lag screw principle.

To our knowledge, the use of two screws to fixate the coracoid process was first described in the book "Surgical Techniques for the shoulder" in 1995.[34]

Nerve injuries

Using two screws also prevents rotation of the coracoid graft. This protects the musculocutaneous nerve which is thought to be possibly tethered by the lateral cord branch of the coracobrachialis muscle, equally to a windlass effect of the conjoint tendon in case of a single screw fixation.[7]

To prevent suprascapular nerve injury, adequate screw positioning is essential.[29] Because the suprascapular nerve runs along the posterior aspect of the scapula, the posterior safe area of the scapular neck is at its greatest when the coracoid graft is fixated with the shoulder in external rotation.[25]

Finally, awareness is required because cadaveric studies show that the musculocutaneous and the axillary nerve have an altered location as a result from the coracoid process transfer itself. The musculocutaneous nerve moves inferior to the anterior glenoid rim and both nerves move medial of their original position. Moreover, both nerves consistently overlap each other after a Latarjet procedure, obscuring the future identification of either nerve. This may cause them to be vulnerable to injury, especially in revision cases.[7;10]

Transecting the subscapular muscle and closing

Optimal placement of the coracoid graft requires adequate exposure of to the glenohumeral joint. Initially Latarjet (1958), Bonnin (1973) and Lombardo (1976) dissected the subscapular muscle completely with a vertical incision and reattached it with sufficient overlap to get the right amount of muscle tension.[5;22] Helfet (1958) only makes a 2,5 to 3cm (1 to 1.25 inch) vertical slit in the middle two-thirds of the musculofibrous junction of the muscle, and closes the capsule overlapping when it is voluminous.

Additional to the vertical slit, May (1970) divides the muscle parallel to its fibers to enable placement of the coracoid graft to the glenoid rim under direct vision (Figure 7).

The coracoid process is osteomised just anterior to the insertion of the pectoralis minor muscle. The incised subscapularis tendon and muscle is split parallel with its fibers.

Torg (1987) places the coracoid segment and conjoint tendon above and over the superior border of the subscapular muscle rather than through its fibers, for three reasons. First, by approaching the glenohumeral joint and contiguous osseous glenoid cavity superior rather than through the subscapularis tendon and muscle gives better exposure thus facilitating accurate and rigid placing of the screw and coracoid segment. Second, utilizing the entire subscapular tendon and muscle increases its strength as anterior-inferior musculotendinous sling or buttress. Third, by directing the osteotomised coracoid segment and conjoint tendon above and over the superior border of the subscapular muscle it simplifies salvage in patients who had a redislocation.[40]

Young (2011) splits the subscapularis in line with its fibers between the superior two-thirds and the inferior one-third. If constitutional hyperlaxity has been noted in the pa-

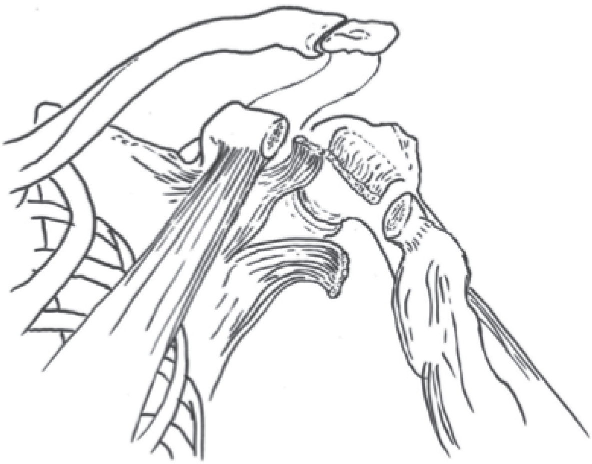

Figure 7. Modification described by May in 1970. The coracoid process is osteomised just anterior to the insertion of the pectoralis minor muscle. The incised subscapularis tendon and muscle is split parallel with its fibers.

tient's preoperative examination, the split is performed in the middle of the subscapular muscle to maximize the effect of the conjoint tendon sling.[45]

Using three suture anchors in the anteroinferior glenoid rim, Bathia performs a capsular repair after the coracoid is placed, rendering an extra articular position of the coracoid process. The stump of the coracoacromial ligament may then be sutured over the capsule for additional augmentation.[2]

Arthroscopic procedure

To enable a more accurate positioning of the coracoid graft, Nourissat was the first to describe an arthroscopically assisted Bristow-Latarjet procedure in a cadaveric study in 2006.[32] One year later, Lafosse and Boileau reported the arthroscopic Bristow-Latarjet procedure.[4;20] Lafosse described a detailed 5-stage all arthroscopic technique concluding that arthroscopic control offers the advantage of more accurate positioning of the coracoid graft.[19;20]

In the first stage exposure is achieved by performing an anterior capsulotomy and the rotator interval is opened to gain access to the coracoid process. The coracoacromial ligament is sectioned at its insertion on the coracoid and the anterior glenoid rim is debrided in preparation for the graft.

The second stage is the exposure of the coracoid. The axillary nerve is identified at the anterior part of the subscapular muscle. The lateral border of the conjoined tendon is debrided and the brachial plexus is identified before section of the pectoralis minor.

A coracoid portal is created midway between the base and tip of the coracoid process. In the third stage two drill holes are made and the osteotomy of the coracoid process is performed. Stage four describes the horizontal split of the subscapular muscle and the coracoid process transfer to the glenoid rim. Before transferring the coracoid process, two cannulated screws are inserted into the drill holes for complete control during graft positioning. In the fifth and final stage the coracoid bone graft is accurately positioned on the glenoid rim. Fixation is performed using cannulated screws.

Postoperative treatment

In the original report by Latarjet (1958) only a brief description for postoperative treatment is provided. Passive range of motion exercises are initiated at the end of the first week and continued until complete return of motion and muscle strength is achieved.

Helfet (1958) provides a collar and cuff sling with a crepe bandage to prevent external rotation during 6 weeks. Static exercises for the deltoid and upper arm muscle are started after a few days. The arm is then taken from the sling and gentle exercises are advised to restore movement and power.[13]

May (1970) uses a Velpeau bandage to immobilize the shoulder and maintain humeral internal rotation. The bandage is maintained for 4 weeks and then gentle active and passive range of motion exercises are started.[30] Mackenzie (1984) immobilized his patients for 6 weeks using a sling. After this period mobilization is started and sport participation is allowed until 4 months after the operation.[28]

To prevent stiffness, Bonnin (1973) encourages his patients to get up as soon as possible with a sling for 1 week, after which pendulum shoulder movements are started. Active physiotherapy is started as soon as the patient feels comfortable, most of the time from the end of the first week, followed by full range of motion exercises after 4-6 weeks. Full range of motion is reached by the end of 3 months.

Torg (1987) advises a postoperative management consisting of 5 phases: the first is complete immobilization for 2 weeks, the second is limited range-of-motion exercises for 4 weeks, the third is full range-of-motion and limited isotonic exercises 4 weeks, the fourth is active assisted range-of-motion and variable-resistance isotonic exercises for 4-8 weeks and then return to activities.[40]

Young (2011) also provides a detailed description for postoperative care. His patients are instructed to wear a simple sling for 15 days. Rehabilitation with self- mobilization in elevation and external rotation is allowed from day 3. After 15 days, usual activities of daily living are allowed and self-mobilization in elevation and external rotation is continued. At 1 month, patients are allowed to progressively resume athletic conditioning (e.g., Fogging, cycling, and swimming), without any specific strengthening exercises for the upper limbs. Progressive return to sporting activities, including contact sports, is allowed at 3 months after clinical and radiographic evaluation confirms satisfactory consolidation of the coracoid graft.[45]

CONCLUSION

The Bristow-Latarjet procedure is a well-known surgical technique designed to treat shoulder instability and gained attention is the past decades. Since its introduction by Latarjet in 1954 and Helfets "Bristow repair" in 1958 many technical changes and improvements have been made. Historical knowledge of the evolution of the procedure is important for further improvement of a surgical technique.

REFERENCES

1. Allain J, Goutallier D, Glorion C. Long-term results of the Latarjet procedure for the treatment of anterior instability of the shoulder. *J Bone Joint Surg Am.*1998;80:841-852.
2. Bhatia S, Frank RM, Ghodadra NS et al. The outcomes and surgical techniques of the latarjet procedure. *Arthroscopy.* 2014;30:227-235.
3. Boicev B. Solla lussazione abituale della spalla. *Chir Org Mov.* 1938;23.
4. Boileau P, Bicknell RT, El Fegoun AB et al. Arthroscopic Bristow procedure for anterior instability in shoulders with a stretched or deficient capsule: the "belt-and-suspenders" operative technique and preliminary results. *Arthroscopy.* 2007;23:593-601.
5. Bonnin JG. Transplantation of the coracoid tip: a definitive operation for recurrent anterior dislocation of the shoulder. *Proc R Soc Med.* 1973;66:755-758.
6. Boons HW, Giles JW, Elkinson I et al. Classic versus congruent coracoid positioning during the Latarjet procedure: an in vitro biomechanical comparison. *Arthroscopy.* 2013;29:309-16.
7. Burkhead WZj. Musculocutaneous and axillary nerve position after coracoid graft transfer. *Surgery of the shoulder.* St. Louis: Mosby-Year, 1990:152-155.
8. De Beer JMM, Burkhart SSM, Roberts CPMB et al. The Congruent-Arc Latarjet. *Tech Shoulder Elb Surg.* 2009;10:62-67.
9. Eden R. Zur Operation der habituellen Schulterluxation unter Mitteilung, eines neuen Verfahrens bei abriss am inneren Pfannenrand. *Dtsch Z Chir.* 1918;144-269.
10. Freehill MT, Srikumaran U, Archer KR et al. The Latarjet coracoid process transfer procedure: alterations in the neurovascular structures. *J Shoulder Elbow Surg.* 2013;22:695-700.
11. Ghodadra N, Gupta A, Romeo AA et al. Normalization of glenohumeral articular contact pressures after Latarjet or iliac crest bone-grafting. *J Bone Joint Surg Am.*2010;92:1478-1489.
12. Griesser MJ, Harris JD, McCoy BW et al. Complications and re-operations after Bristow-Latarjet shoulder stabilization: a systematic review. *J Shoulder Elbow Surg.* 2013;22:286-292.
13. Helfet AJ. Coracoid transplantation for recurring dislocation of the shoulder. *J Bone Joint Surg Br.* 1958;40-B:198-202.
14. Hill JA, Lombardo SJ, Kerlan RK et al. The modification Bristow-Helfet procedure for recurrent anterior shoulder subluxations and dislocations. *Am J Sports Med.* 1981;9:283-287.
15. Hovelius L, Akermark C, Albrektsson B et al. Bristow-Latarjet procedure for recurrent anterior dislocation of the shoulder. A 25 year follow-up study on the results of 112 cases. *Acta Orthop Scand.* 1983;54:284-290.
16. Hovelius L, Sandstrom B, Olofsson A et al. The effect of capsular repair, bone block healing, and position on the results of the Bristow-Latarjet procedure (study III): long-term follow-up in 319 shoulders. *J Shoulder Elbow Surg.* 2012;21:647-660.
17. Hybinette S. De la transplatation d'un fragment osseux pour remedier aux luxations recivantes de l'epaule; constatations et resultats operatiores. *Acta Orthop Scand.* 1932;71:411-445.
18. Kraus TM, Graveleau N, Bohu Y et al. Coracoid graft positioning in the Latarjet procedure. *Knee Surg Sports Traumatol Arthrosc.* 2013; Sep 8. [Epub ahead of print]
19. Lafosse L, Boyle S. Arthroscopic Latarjet procedure. *J Shoulder Elbow Surg.* 2010;19:2-12.
20. Lafosse L, Lejeune E, Bouchard A et al. The arthroscopic Latarjet procedure for the treatment of anterior shoulder instability. *Arthroscopy.* 2007;23:1242-1245.
21. Latarjet M. Treatment of recurrent dislocation of the shoulder. *Lyon Chir.* 1954;49:994-997.
22. Latarjet M. Technique of coracoid preglenoid arthroereisis in the treatment of recurrent dislocation of the shoulder. *Lyon Chir.* 1958;54:604-607.
23. Latarjet M, Ricard R, Ludin P. The pre-glenoid stop screw for coracoid screwing in the treatment of recurring dislocations of the shoulder. *Mem Acad Chir (Paris).* 1961;87:457-460.
24. Lombardo SJ, Kerlan RK, Jobe FW et al. The modified Bristow procedure for recurrent dislocation of the shoulder. *J Bone Joint Surg Am.*1976;58:256-261.
25. Longo UG, Forriol F, Loppini M et al. The safe zone for avoiding suprascapular nerve injury in bone block procedures for shoulder instability. A cadaveric study. *Knee Surg Sports Traumatol Arthrosc.* 2015 May;23:1506-1510.
26. Longo UG, Loppini M, Rizzello G et al. Latarjet, Bristow, and Eden-Hybinette Procedures for Anterior Shoulder Dislocation: Systematic Review and Quantitative Synthesis of the Literature. *Arthroscopy.* 2014;30:1184-211
27. Longo UG, Rizzello G, Locher J et al. Bone loss in patients with posterior gleno-humeral instability: a systematic review. *Knee Surg Sports Traumatol Arthrosc.* 2014, Jul 24. [Epub ahead of print]
28. Mackenzie DB. Treatment of recurrent anterior shoulder dislocation by the modified Bristow-Helfet procedure. *S Afr Med J.* 1984;66:436.

29. Maquieira GJ, Gerber C, Schneeberger AG. Suprascapular nerve palsy after the Latarjet procedure. *J Shoulder Elbow Surg.* 2007;16:e13-e15.
30. May VR, Jr. A modified Bristow operation for anterior recurrent dislocation of the shoulder. *J Bone Joint Surg Am*. 1970;52:1010-1016.
31. Mostofi SB. Who's who in Orthopedics.Springer, 2005:39.
32. Nourissat G, Nedellec G, O'Sullivan NA et al. Mini-open arthroscopically assisted Bristow-Latarjet procedure for the treatment of patients with anterior shoulder instability: a cadaver study. *Arthroscopy.* 2006;22:1113-1118.
33. Oudard P. La luxation recidivante de l'epaule (variete anter-interne) procede aperatoire. *J Chir.* 1924;23:13-25.
34. Piccin e. *Surgical Techniques for the shoulder*. 1995:70-71.
35. Provencher MT, Ghodadra N, LeClere L et al. Anatomic osteochondral glenoid reconstruction for recurrent glenohumeral instability with glenoid deficiency using a distal tibia allograft. *Arthroscopy.* 2009;25:446-452.
36. Rockwood C. Fractures and dislocations of the shoulder. *Fractures in adults.* Philadelphia: JB Lippincott, 1983:722-859.
37. Shah AA, Butler RB, Romanowski J et al. Short-term complications of the Latarjet procedure. *J Bone Joint Surg Am*. 2012;94:495-501.
38. Speed K. *Fractures and Dislocations.* Philadelphia: Lea and Febiger, 1942.
39. Sugaya H, Moriishi J, Dohi M et al. Glenoid rim morphology in recurrent anterior glenohumeral instability. *J Bone Joint Surg Am*. 2003;85-A:878-884.
40. Torg JS, Balduini FC, Bonci C et al. A modified Bristow-Helfet-May procedure for recurrent dislocation and subluxation of the shoulder. Report of two hundred and twelve cases. *J Bone Joint Surg Am*. 1987;69:904-913.
41. Trillat A. Treatment of recurrent dislocation of the shoulder; technical considerations. *Lyon Chir.* 1954;49:986-993.
42. van der Linde JA, van Kampen DA, Terwee CB et al. Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up. *Am J Sports Med.* 2011;39:2396-2403.
43. Warner JJ, Gill TJ, O'hollerhan JD et al. Anatomical glenoid reconstruction for recurrent anterior glenohumeral instability with glenoid deficiency using an autogenous tricortical iliac crest bone graft. *Am J Sports Med.* 2006;34:205-212.
44. Yamamoto N, Muraki T, An KN et al. The stabilizing mechanism of the Latarjet procedure: a cadaveric study. *J Bone Joint Surg Am.* 2013;95:1390-1397.
45. Young AA, Maia R, Berhouet J et al. Open Latarjet procedure for management of bone loss in anterior instability of the glenohumeral joint. *J Shoulder Elbow Surg.* 2011;20:S61-S69.

Chapter 9

A systematic review on redislocations after the Bristow-Latarjet procedure, collision athletes at higher risk?

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ABSTRACT

Objective

To assess (1) the absolute risk for redislocations in collision athletes after a Bristow-Latarjet procedure, and (2) to compare the redislocation risk between collision athletes and noncollision athletes after a Bristow-Latarjet procedure.

Methods and materials

A systematic review of English, French, Portuguese and Dutch articles was conducted in PubMed and EMBASE on January 9th 2015. Search terms were synonyms of Bristow-Latarjet, shoulder and dislocation. Studies concerning any Bristow-Latarjet like procedure due to glenohumeral instability and mentioning redislocation rates in collision athletes were included. Studies with a follow-up period less than 2 years, or studies in which the absolute risk could not be calculated with certainty were excluded. The included articles were critically appraised, and data were extracted for analysis by predefined data sheets by 2 independent authors.

Results

After the literature search 263 studies were screened for title and abstract, 80 were full-text screened, 16 were critically appraised, and 11 met criteria for data extraction. The reported absolute risk for a redislocation after a Bristow-Latarjet procedure varies from 0 – 15.8% for collision athletes, compared to 0 – 4.3% for noncollision athletes. The absolute risk difference disfavored collision athletes in three studies (5.9, 5.9 and 15.8%), was equal in two studies, favored collision athletes in three studies (-0.5, -0.7, and -1.3%), and was not assessable in three studies.

Conclusion

Based on limited evidence, collision athletes do not tend to have an increased redislocation rate compared to noncollision athletes or general population after a Bristow-Latarjet procedure.

INTRODUCTION

Approximately 50% of all major joint dislocations affect the shoulder, most frequently (95-97%) resulting in an anterior shoulder dislocation (ASD).[34-37,42] A higher incidence has been demonstrated in collision athletes (CA), and may lead to a decreased level of sport activities.[32] Traditionally, primary dislocations are treated with immobilization followed by physiotherapy with satisfactory results,[18,25] although they are associated with recurrence rates up to 57%;[11,19] recurrence rates for collision athletes tend to be slightly higher.[11] Indications for acute surgical treatment include irreducible dislocations, displaced greater tuberosity fractures, and Bankart fractures with glenohumeral instability.[9] Indications for delayed surgical treatment include redislocations, activity limitations, and presence of significant bone loss.[9,26,27] As 90% of patients with ASD have a Bankart lesion, redislocations may be often treated with an (arthroscopic) Bankart repair.[40] After a Bankart repair, sports levels remain unchanged or get better in 82.6 % of the athletes,[15] although 8 to 10 years after surgery redislocations have been reported in up to 35% of the patients.[40]

Risk factors significantly associated with the recurrence of instability after a primary arthroscopic Bankart repair include young age, male gender, the number of preoperative dislocations, and participation in competitive sports.[33]

The Bristow-Latarjet procedure and its modifications have proved to be successful in achieving glenohumeral stability with redislocation rates varying from 0 - 8%.[6] Complications after a Bristow-Latarjet procedure include wound infections, shoulder stiffness, screw migration, bending or breakage, bony non-union, neurological injury and wound infection and osteoarthritis.[24] It is generally accepted that CA may have an increased risk of developing redislocations after Bristow-Latarjet like procedures,[28] even though this has been not generally proved.

Therefore, we assessed (1) the risk for CA to develop a redislocation after a Bristow-Latarjet procedure, and (2) we compared the redislocation risk between CA and non-CA after a Bristow-Latarjet procedure.

METHODS AND MATERIALS

Protocol

This systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines with a PRISMA checklist and algorithm.[23]

Literature search & study selection

A literature search was performed in PubMed and EMBASE on January 9^{th} 2015 (Appendix 4). The search was not limited for year of publication. Titles and abstracts were screened following predetermined in –and exclusion criteria to select relevant studies. Inclusion criteria were: studies concerning surgical glenoid articular arc reconstruction (i.e. any Bristow-Latarjet like procedure) due to glenohumeral instability and studies mentioning redislocation rates in CA. Exclusion criteria were case reports, (systematic) reviews, meta-analyses, animal/cadaver/in vitro studies, biomechanical reports, letters to editors and instructional courses. Arthroscopic procedures were excluded because a preliminary literature search revealed no mid- to long-term outcomes in collision athletes regarding this relatively recent modification.

Subsequently, remaining articles were full-text screened to assess applicability. All cross-references from reviews and included studies were screened for potential relevant studies not identified by the initial literature search.

Assessment of methodological quality

All included studies were critically appraised and rated for applicability by predefined criteria. To determine relevance, studies were scored on domain, determinant and outcome. Validity was scored by assessing the study design, selection bias and information bias. Relevance, study design, loss to follow-up, follow-up period and analysis were considered the most important factors. Additionally, we used the Coleman Methodology Score (CMS) as an objective tool to assess the overall quality of the studies (Table 1).[2] The CMS assesses the methodological quality of a study based on 10 criteria that are summarized to a total score. A maximum score of 100 points indicates that the study largely avoids chance, various biases, and confounding factors. The final score can be defined as excellent (85-100 points), good (70-84 points), fair (50-69 points), and poor (< 50 points).[2] The Coleman criteria were adjusted to make them reproducible and relevant for our systematic review.

A number of actions were applied to minimize the risk of bias. To maximize study homogeneity, articles mentioning a follow-up period less than 2 years were excluded as previous studies have shown that redislocation rates consistently increase up to 10 years after surgical treatment.[40] Studies for which the absolute risk could not be calculated with certainty were excluded for further analysis. Two authors independently performed the study selection, assessment of methodological quality and data extraction by predefined data charts. Any disagreements between the reviewers during the entire study process were resolved by discussion.

Table 1. Coleman Methodology Score

A	Only one score to be given for each of the 7 sections		
1.	Study size – number of	< 20	0
		20-50	4
		51-100	7
		>100	10
2.	Mean follow-up	< 12 months	0
		12-36 months	4
		37-60 months	7
		> 61 months	10
3.	Surgical or conservative approach	Different approach used and outcome not reported separately	0
		Different approaches used and outcomes reported separately	7
		Single approach used	10
4.	Type of study	Retrospective cohort study	0
		Prospective cohort study	10
		Randomized controlled trial	15
5.	Description of indications/ diagnosis	Described without % specified	0
		Described with % specified	5
6.	Description of surgical or conservative technique	Inadequate (not stated, unclear)	0
		Fair (technique only stated)	5
		Adequate (technique stated, details of surgical or conservative procedure given)	10
7.	Description of postoperative rehabilitation	Described	5
		Not described	0
B	Scores may be given for each option in each of the 3 sections if applicable		
1.	Outcome criteria	Outcome measures clearly defined	2
		Timing of outcome assessment clearly stated	2
		Used of outcome criteria that has reported reliability	3
		General health measure included	3
2.	Procedure of assessing outcomes	Participants recruited	5
		Investigator independent of surgeon	4
		Written assessment	3
		Completion of assessment by patients themselves with minimal investigator assistance	3
3.	Description of subject selection process	Selection criteria reported and unbiased	5
		Recruitment rate reported > 90%	5
		Recruitment rate reported = 90%	0

9

Data extraction

The following variables were extracted from the included studies: number of included patients and shoulders operated on; number of CA; number of non-CA; number of redislocations in CA and non-CA and average follow-up time regarding redislocations. If athletes were not clearly described as collision athletes, we defined them as contact/ collision or limited contact/ impact sports as described by the American Academy of Pediatrics Committee on Sports Medicine (Table 2).[3]

Table 2. sports as described by the American Academy of Pediatrics Committee on Sports Medicine

		Noncontact		
Contact/collision	**Limited contact/ Impact**	**Strenuous**	**Moderate strenuous**	**Nonstrenuous**
Boxing	Baseball	Aerobic dancing	Badminton	Archery
Field hockey	Basketball	Crew	Curling	Golf
Football	Bicycling	Fencing	Table tennis	Riflery
Ice hockey	Diving	Field		
Lacrosse	Field	Discus		
Martial arts	High jump	Javelin		
Rodeo	Pole vault	Shot put		
Soccer	Gymnastics	Running		
Wrestling	Horseback riding	Swimming		
Rugby	Skating	Tennis		
	Ice	Track		
	Roller	Weight lifting		
	Skiing			
	Cross-country			
	Downhill			
	Water			
	Softball			
	Squash, handball			
	Volleyball			

This classification was designed by the American Academy of Pediatrics Committee on Sports Medicine to assist practitioners in deciding whether athletes should be allowed to participate in particular sports. In this guideline, sports are divided in their degree of strenuousness and probability on collision. Further on, these groups were assessed in light of common medical and surgical conditions to determine whether participation would create a substantial risk of injury.

Statistical analysis

The CMR score is presented individually with total scores as well as in total for all critically appraised studies with a median and interquartile range (IQR). In all studies, a p-value < 0.05 was considered as statistically significant. Statistical analysis was performed using Stata 13.0 (StataCorp LP, College Station, TX, USA).

The absolute risk for all patients, CA and non-CA was calculated from the extracted data. When available, the number of concerning shoulders was used for absolute risk calculation. The Fisher's exact test was used to analyze the redislocation difference between CA and non-CA. The absolute risk difference per study was calculated by subtracting the absolute risk for non-CA from the absolute risk of CA. If specific analyses were reported on collision athletes in relation to redislocations in included articles, these were described.

RESULTS

Study selection

The initial search resulted in 263 articles, of which 80 satisfied inclusion and exclusion criteria (Figure 1). After full-text screening, 66 articles were excluded: 32 were not eligible for data extraction as they did not mention the number of collision athletes and/or redislocation rates in collision athletes, 34 articles were unavailable or non-exact duplicates. The cross-reference check in 14 eligible articles resulted in 2 additional inclusions.

Critical appraisal

Sixteen articles were included and critically appraised (Table 3).[1,4,5,7,8,10,12,13,16,17,21,22,29-31,41] The median CMS score in the studies that were included for data extraction was 60 points (range 43 to 63) showing that the median quality of the included studies was fair. No statistically significant difference was found between mean values of CMS calculated by the 2 independent authors (NRP and JL).

Five studies were excluded for data extraction, because they had a poor follow-up and/or unclear data for calculation of the absolute risk for CA.[10,13,16,17,22]

Study population

When pooled, a total of 809 patients was treated with a Bristow-Latarjet like procedure, with a minimum follow-up of 2 years; 499 (62%) were CA, and 310 (38%) were non-CA. Study populations varied from 27 – 126 included patients with follow-up periods between 24.3-240 months, of which 18.3 – 100% were CA throughout the studies (Table 4).

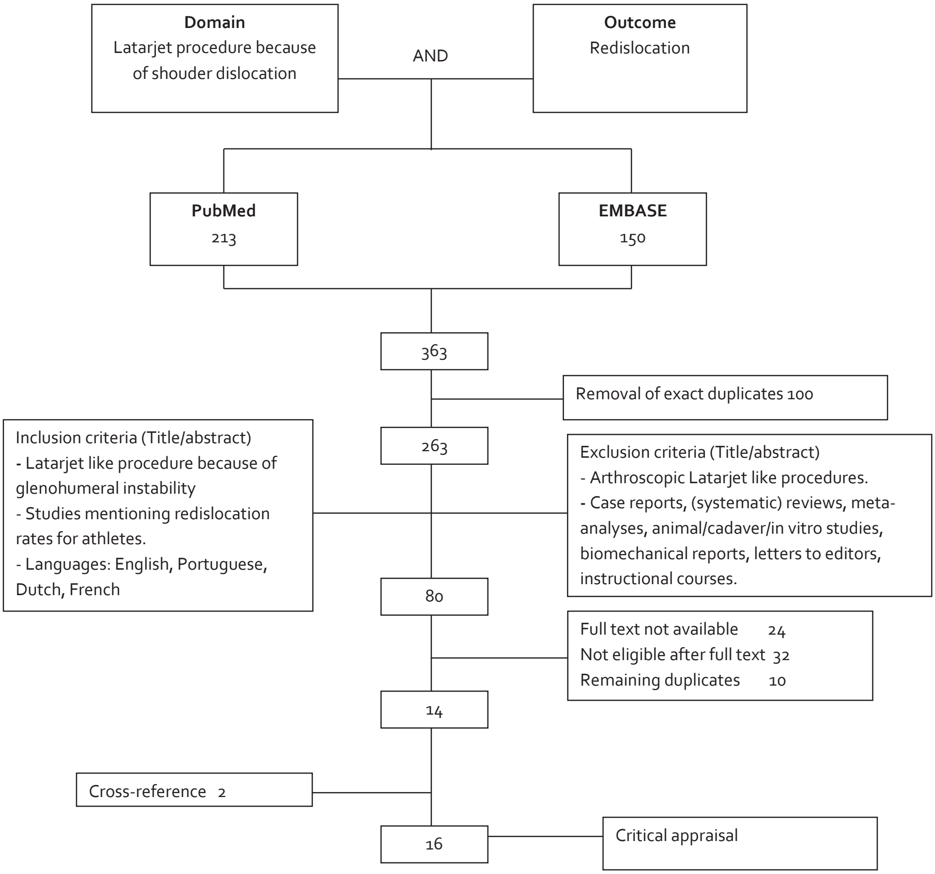

Figure 1. Flow chart of study selection.
This figure represents the flow chart of the study selection in chronologic order: (1) identification of the literature, (2) screening of the 263 identified articles, (3) assessing eligibility by full-text screening of 80 articles to result in (4) the 16 included articles that underwent critical appraisal.

Redislocations

The overall redislocation risk for patients among included studies was 2.7% (22/809); 3.2% (16/499) of the CA suffered of a redislocation, whereas 1.9% (6/310) of non-CA had a redislocation (p 0.375). The absolute risk that was reported for CA to have a redislocation varied from 0 – 15.8%,[1,4,5,7,8,12,21,29-31,41] compared to 0 – 4.3% for non-CA.[1,4,5,7,12,21,41]

The difference in absolute risk was described as increased disfavoring collision athletes in three studies (5.9, 5.9 and 15.8%),[5,12,29] equal in two studies,[1,41] decreased in three studies (-0.5, -0.7 and -1.3%),[8,30,31] and not assessable in three studies.[4,7,21]

Table 3. Critical appraisal, studies listed alphabetically.

Studies (1st author)		Relevance			Validity								
					Selection bias				Information bias				
	Year of publication	Domain	Determinant	Outcome	Design	Loss to follow-up (LTFU)	Missing data	Standardization of determinant (SD)	Standardization of outcome (SO)	Blinding of the exposure status (BES)	Follow-up	Analysis	Modified Coleman score
Allain	1998	+	+	+	-	-	-	+	-	-	+	+	61
Banas	1993	+/-	+/-	+	-	+	-	+	+	+	+	+	63
Bessiere	2012	+	+	+	-	+	+	+	+	+	+	+	62
Burkhart	2007	+/-	+	+	-	+	-	+	-	-	+/-	+	62
Cerciello	2012	+	+	+	-	-	-	+	-	+	+	+	44
Di Giacomo	2011	+	+	+	+	+	-	+	-	-	-	+	64
Doursounian	2009	+/-	+	+	+	-	-	+	-	+	+/-	+	62
Edouard	2011	+	+/-	+	+	+	-	+	-	-	-	+/-	69
Halley	1975	+/-	+	+	-	-	-	+	-	-	-	+	35
Hill	1981	+/-	+	+	-	-	-	+	-	-	+/-	+/-	32
Hovelius	2004	+	+	+	+	+	+	+	-	-	+	+	59
Kenesi	1990	+	+	+	-	-	-	+	-	-	+/-	+/-	45
Mizuno	2014	+	+	+	-	-	-	+	-	-	+	+	59
Neyton	2007	+/-	+	+	-	-	-	+	-	-	+	+	57
Neyton	2012	+	+	+	-	-	-	+	-	-	+	+	57
Yamashita	2002	+/-[a]	+/-	+	-	-	-	+	-	-	+/-	+	60

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[a] Bankart procedure followed by a Bristow procedure

Domain: (+) Patients treated by a Bristow-Latarjet procedure for anterior glenohumeral instability; (+/-) Patients treated by a modified Bristow-Latarjet procedure for anterior glenohumeral instability; (-) Other.

Determinant: (+) Stated as CA in article, or type of athletes specifically mentioned; (+/-) Recreational athletes, mixed athlete population or CA group not well defined; (-) Nothing mentioned on athletes.

Outcome: (+) Redislocations after surgical procedure mentioned for athletes; (-) Redislocation rates for athletes not separately mentioned or other outcome used instead

Design: (+) Prospective study design; (-) Retrospective study design

LTFU: (+) < 10%; (+/-) 10 – 15%; (-) > 15% or not reported

Missing data: (+) < 10%; (+/-) 10 – 15%; (-) > 15% or not reported

SD: (+) Definition for athletes is given; (-) Definition for athletes not reported

SO: (+) Definition of redislocation is given; (-) Definition of redislocation is not reported or standardized

BES: (+) Blinding for athletes status when diagnosing redislocation; (-) Blinding not performed or not described

Follow-up: (+) > 5 years follow-up for redislocation rates; (+/-) 2 – 5 years follow-up for redislocation rates; (-) < 2 year or not mentioned

Analysis: (+) Absolute risk/AUC available or may be calculated; (+/-) Absolute risk/AUC may be calculated, though questionable; (-) Absolute risk/AUC unavailable or cannot be calculated.

Table 4. Results, studies listed alphabetically.

Study	Included patients (Shoulders)	CA	Non-CA	Redislocation rate CA	Redislocation rate non-CA	AR for CA	AR for non-CA	RD	Follow-up
1st author	n (n)	n	n	n	n	%	%	%	Months
Allain	56 (58)	50	8	0	0	0	0	0	171.6
Banas	78 (86)	60*	26*	2	1	3.3	3.8	-0.5	103
Bessiere	51 (51)	38	13	6	0	15.8	0	15.8**	66
Burkhart	102	55	47	2	2	3.6	4.3	-0.7	52
Cerciello	46 (51)	51	0	1	NA	2.0	NA	NA	85
Doursounian	27	17*	10*	1	0	5.9	0	5.9	24.3
Hovelius	113 (118)	70	48	2	2	2.9	4.2	- 1.3	180
Mizuno	60 (68)	13*	55*	1	1	7.7	1.8	5.9	240
Neyton	79 (85)	85	0	1	NA	1.2	NA	NA	75
Neyton	34 (37)	37	0	0	NA	0	NA	NA	144
Yamashita	126	23*	103*	0	0	0	0	0	41

* Number of patients as number of shoulders was not (clearly) stated in the article
**Univariate analysis p = 0.31 NB: subluxation was also scored as a recurrence
CA Collision athletes
Non-CA Non collision athletes
AR Absolute risk
RD Risk difference (AR of CA minus AR of non-CA)
NA Not available (information is unavailable for this measurement)

DISCUSSION

Redislocation rates after Bristow-Latarjet like procedures vary between 0 to 8%.[6] It is thought that CA may have an increased risk to develop redislocations because of their high demanding activities; rugby players for example have more than 200 tackles per game, with peak shoulder forces up to 2000N (equivalent of 204 kilograms of force).[14,39] With this systematic review we found that the redislocations risk for CA is 3.2%, and that the prevalence varies between 0 to 15.8% among eleven studies mentioning CA. Absolute risk differences among 8 studies were balanced, and overall no difference in redislocations were found between CA and non-CA (p 0.375). Furthermore, one study performed a univariate analysis of risk factors of recurrence after a Latarjet procedure, showing no association between contact or forced overhead sports and redislocation (RD = 15.8%, p 0.31).[5] Moreover, this was the only study exceeding the 0 – 8% redislocation rate of the general population.[6] This suggested that CA were not at higher risk compared to non-CA; nevertheless, higher numbers might have revealed significantly more redislocations for CA.

To our knowledge, no other reviews focusing on redislocations for CA after a Bristow-Latarjet procedure are available. The findings in this review suggest that CA do not have a higher risk compared to non-CA to develop redislocations after a Bristow-Latarjet procedure. There are several plausible explanations for these findings: CA might have better proprioception than non-CA therefore being more conscious of joint movements -and limitations after surgery; after surgery CA will probably be accompanied more strictly by their physiotherapist and be more compliant during rehabilitation than non-CA, because there is more at stake; a number of CA might never have attended their sports at the level prior to the injury giving a decreased risk of redislocation exposure.

One of the drawbacks of bony reconstructions has been the increased risk to develop postoperative osteoarthritis; these have shown to occur in up to 49% after 15 years.[20] The alternative, i.e. the Bankart repair, has shown to have a risk of 69% to develop osteoarthritis 13 years after surgery.

The results in this review should be interpreted carefully, as they are accompanied by certain limitations. Firstly, only three studies were scored as relatively highly relevant and no studies were scored with a good or excellent CMS. Secondly, a universally accepted classification for athletes which have an increased risk of developing an ASD is lacking and, therefore, it should be mentioned that definitions for CA may be different between studies, especially when details are not provided in the original articles. Furthermore, some articles mention the number of redislocations for all treated shoulders and do not specify whether patients have bilateral procedures. Moreover, because the included articles were chosen to determine redislocation rates in CA, redislocation rates for non-CA may not represent accurate literature rates. Finally, due to the small number of non-CA in the included studies, the absolute risk difference in several studies should be interpreted with caution.

CONCLUSION

Based on the available limited evidence, the redislocation rate in CA following a bony reconstruction is 3.2%, compared to 1.9% for non-CA (p 0.375). Therefore CA do not seem to have a greater risk at developing redislocations after such procedures, when compared to non-CA. These findings can be used to educate future patients and aid surgical decision-making. Furthermore, when considering treatment for a young CA, one should keep in mind that the redislocation rate without surgical stabilization for young patients is estimated to be as high as 50-90%.[38]

REFERENCES

1. Allain J, Goutallier D, Glorion C. Long-term results of the Latarjet procedure for the treatment of anterior instability of the shoulder. *J Bone Joint Surg Am.* 1998;80:841-852.
2. Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med.* 2001;134:663-694.
3. American Academy of Pediatrics Committee on Sports Medicine: Recommendations for participation in competitive sports. *Pediatrics.* 1988;81:737-739.
4. Banas MP, Dalldorf PG, Sebastianelli WJ, DeHaven KE. Long-term followup of the modified Bristow procedure. *Am J Sports Med.* 1993;21:666-671.
5. Bessiere C, Trojani C, Pelegri C, Carles M, Boileau P. Coracoid bone block versus arthroscopic Bankart repair: a comparative paired study with 5-year follow-up. *Orthopedics Traum Surgery Res*. 2013;99:123-130.
6. Bhatia S, Frank RM, Ghodadra NS, Hsu AR, Romeo AA, Bach BR, Jr. et al. The outcomes and surgical techniques of the latarjet procedure. *Arthroscopy.* 2014;30:227-235.
7. Burkhart SS, De Beer JF, Barth JR, Cresswell T, Roberts C, Richards DP. Results of modified Latarjet reconstruction in patients with anteroinferior instability and significant bone loss. *Arthroscopy.* 2007;23:1033-1041.
8. Cerciello S, Edwards TB, Walch G. Chronic anterior glenohumeral instability in soccer players: results for a series of 28 shoulders treated with the Latarjet procedure. *J Orth Traum*. 2012;13:197-202.
9. Cleeman E, Flatow EL. Shoulder dislocations in the young patient. *Orthop clinics of N America.* 2000;31:217-229.
10. Di Giacomo G, Costantini A, de Gasperis N, De Vita A, Lin BK, Francone M et al. Coracoid graft osteolysis after the Latarjet procedure for anteroinferior shoulder instability: a computed tomography scan study of twenty-six patients. *J Shoulder Elbow Surg.* 2011;20:989-995.
11. Dickens JF, Owens BD, Cameron KL, Kilcoyne K, Allred CD, Svoboda SJ et al. Return to play and recurrent instability after in-season anterior shoulder instability: a prospective multicenter study. *Am J Sports Med.* 2014;42:2842-2850.
12. Doursounian L, Debet-Mejean A, Chetboun A, Nourissat G. Bristow-Latarjet procedure with specific instrumentation: study of 34 cases. *Int Orthopaedics.* 2009;33:1031-1036.
13. Edouard P, Beguin L, Degache F, Fayolle-Minon I, Farizon F, Calmels P. Recovery of rotators strength after Latarjet surgery. *Int J Sports Med.* 2012;33:749-755.
14. Fuller CW, Brooks JH, Cancea RJ, Hall J, Kemp SP. Contact events in rugby union and their propensity to cause injury. *Br J Sports Med.* 2007;41:862-867; discussion 867.
15. Gerometta A, Rosso C, Klouche S, Hardy P. Arthroscopic Bankart shoulder stabilization in athletes: return to sports and functional outcomes. *Knee Surg Sports Traumatol Arthrosc.* 2014, Apr 22. [Epub ahead of print]
16. Halley DK, Olix ML. A review of the Bristow operation for recurrent anterior shoulder dislocation in athletes. *Clin Orthop Relat Res.* 1975:175-179.
17. Hill JA, Lombardo SJ, Kerlan RK, Jobe FW, Carter VS, Shields CL, Jr. et al. The modification Bristow-Helfet procedure for recurrent anterior shoulder subluxations and dislocations. *Am J Sports Med.* 1981;9:283-287.
18. Hovelius L, Augustini BG, Fredin H, Johansson O, Norlin R, Thorling J. Primary anterior dislocation of the shoulder in young patients. A ten-year prospective study. *J Bone Joint Surg Am.* 1996;78:1677-1684.
19. Hovelius L, Olofsson A, Sandstrom B, Augustini BG, Krantz L, Fredin H et al. Nonoperative treatment of primary anterior shoulder dislocation in patients forty years of age and younger. a prospective twenty-five-year follow-up. *J Bone Joint Surg Am.* 2008;90:945-952.
20. Hovelius L, Sandstrom B, Saebo M. One hundred eighteen Bristow-Latarjet repairs for recurrent anterior dislocation of the shoulder prospectively followed for fifteen years: study II-the evolution of dislocation arthropathy. *J Shoulder Elbow Surg.* 2006;15:279-289.
21. Hovelius L, Sandstrom B, Sundgren K, Saebo M. One hundred eighteen Bristow-Latarjet repairs for recurrent anterior dislocation of the shoulder prospectively followed for fifteen years: study I--clinical results. *J Shoulder Elbow Surg.* 2004;13:509-516.
22. Kenesi C, Grelier JL. Surgical treatment of anterior instability of the shoulder using an anteglenoid stop. *Chirurgie.* 1990;116:609-612; discussion 613.
23. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin epidemiol.* 2009;62:e1-34.
24. Longo UG, Loppini M, Rizzello G, Ciuffreda M, Maffulli N, Denaro V. Latarjet, Bristow, and Eden-Hybinette procedures for anterior shoulder dislocation: systematic review and quantitative synthesis of the literature. *Arthroscopy.* 2014;30:1184-1211.
25. Longo UG, Loppini M, Rizzello G, Ciuffreda M, Maffulli N, Denaro V. Management of primary acute anterior

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shoulder dislocation: systematic review and quantitative synthesis of the literature. *Arthroscopy.* 2014;30:506-522.

26. Longo UG, Loppini M, Rizzello G, Romeo G, Huijsmans PE, Denaro V. Glenoid and humeral head bone loss in traumatic anterior glenohumeral instability: a systematic review. *Knee Surg Sports Traumatol Arthrosc.* 2014;22:392-414.
27. Longo UG, Rizzello G, Locher J, Salvatore G, Florio P, Maffulli N et al. Bone loss in patients with posterior gleno-humeral instability: a systematic review. *Knee Surg Sports Traumatol Arthrosc.* 2014, Jul 24. [Epub ahead of print]
28. Maffulli N, Longo UG, Gougoulias N, Caine D, Denaro V. Sport injuries: a review of outcomes. *Br Med Bull.* 2011;97:47-80.
29. Mizuno N, Denard PJ, Raiss P, Melis B, Walch G. Long-term results of the Latarjet procedure for anterior instability of the shoulder. *J Shoulder Elbow Surg.* 2014;23:1691-1699.
30. Neyton L DE, Jouve F, Nove-Josserand L, Walch G. Chronic anterior glenohumeral instability in rugbyplayer. Series of 85 Latarjet procedures with medium follow-up of seven years. *J Traumatologie du Sport.* 2007;24:122-127.
31. Neyton L, Young A, Dawidziak B, Visona E, Hager JP, Fournier Y et al. Surgical treatment of anterior instability in rugby union players: clinical and radiographic results of the Latarjet-Patte procedure with minimum 5-year follow-up. *J Shoulder Elbow Surg.* 2012;21:1721-1727.
32. Owens BD, Agel J, Mountcastle SB, Cameron KL, Nelson BJ. Incidence of glenohumeral instability in collegiate athletics. *Am J Sports Med.* 2009;37:1750-1754.
33. Randelli P, Ragone V, Carminati S, Cabitza P. Risk factors for recurrence after Bankart repair a systematic review. *Knee Surg Sports Traumatol Arthrosc.* 2012;20:2129-2138.
34. Schaider J SR. Shoulder injuries. In: Wolfson AB HG, Hendry PL, et al editor. Clinical Practice of Emergency Medicine. Philadelphia Lippincott Williams & Wilkins; 2005. p. 1033.
35. Simon RR SS, Koenigsknecht SJ. Emergency Orthopedics: The Extremities. New York; 2006.
36. Simonet WT, Melton LJ, 3rd, Cofield RH, Ilstrup DM. Incidence of anterior shoulder dislocation in Olmsted County, Minnesota. *Clin Orth Relat Res.* 1984:186-191.
37. Sineff SS RE. Shoulder joint dislocation reduction. In: Reichman EF SR, editor. Emergency Medicine Procedures. New York: McGraw-Hill; 2004. p. 593.
38. te Slaa RL, Wijffels MP, Brand R, Marti RK. The prognosis following acute primary glenohumeral dislocation. *J Bone Joint Surg Br.* 2004;86:58-64.
39. Usman J, McIntosh AS, Frechede B. An investigation of shoulder forces in active shoulder tackles in rugby union football. *J Sci Med Sport.* 2011;14:547-552.
40. van der Linde JA, van Kampen DA, Terwee CB, Dijksman LM, Kleinjan G, Willems WJ. Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up. *Am J Sports Med.* 2011;39:2396-2403.
41. Yamashita T, Okamura K, Hotta T, Wada T, Aoki M, Ishii S. Good clinical outcome of combined Bankart-Bristow procedure for recurrent shoulder instability: 126 patients followed for 2-6 years. *Acta Orthop Scand.* 2002;73:553-557.
42. Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am.* 2010;92:542-549.

Chapter 10

Analyzing risk of redislocations after a Bankart procedure in collision athletes

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ABSTRACT

Objective

To determine the redislocation risk for collision athletes after an arthroscopic Bankart repair and to compare the redislocation rate between collision athletes and noncollision athletes after an arthroscopic Bankart repair.

Methods and materials

A PubMed and EMBASE query was performed, screening all relevant literature of arthroscopic Bankart procedures mentioning redislocation rates in collision athletes. Studies with a follow-up less than 2 years, or lacking information on redislocation rates in collision athletes, were excluded. We used the modified Coleman Methodology Score to assess the quality of included studies. Finally, the data in all the studies were combined and analysed.

Results

1012 studies were screened on title and abstract, of which 111 studies were screened full-text and finally 20 studies were included. Four studies reported on collision athletes only, whereas sixteen compared collision to noncollision athletes. Fourteen studies reported increased redislocation rates for collision athletes in comparison to noncollision athletes (absolute risk difference [ARD] varying from 0.4 to 28.6%), whereas two studies reported decreased rates (ARD -6%; -2.4%). A combined analysis revealed that collision athletes have an increased AR of 10.17% to develop post-operative instability in comparison to noncollision athletes (p-value 0.001).

Conclusion

Collision athletes have an increased risk for redislocations in comparison to noncollision athletes following an arthroscopic Bankart repair.

INTRODUCTION

Shoulder dislocations account for 50% of major joint dislocations, and are most commonly directed antero-inferiorly.[40–43,49] Primary treatment for shoulder dislocations including immobilization and physiotherapy has satisfactory results[18,26] although recurrence rates are reported up to 57%.[12,19] Furthermore, redislocation rates are slightly higher –up to 1.67 times– in collision athletes, resulting in impaired sport performances.[12,33,39]

Surgical treatment is indicated when conservative treatment fails or the redislocation risk is substantial. A surgeon has to choose between soft tissue repair (arthroscopic Bankart repair) or a bony reconstruction (e.g. Bristow-Latarjet procedure). When the bony congruity of the glenoid is impaired, the bony reconstruction is indicated. In this procedure the joint surface area is increased by transferring the coracoid process and its muscles to the anterior glenoid.[10,28,29]

An arthroscopic Bankart repair provides less limited range of motion, shorter duration of surgery, decreased postoperative pain symptoms, and improved cosmetic results.[15,25] Moreover the risk of shoulder stiffness, wound infections, bony non-union, screw migration and bending or breakage, osteoarthritis and neurological injury is lower with the arthroscopic Bankart repair.[4,15,25,27] However, redislocation rates are considerably higher after a Bankart repair (3.4 – 35%)[14,37] when compared to an open procedure (0–8%).[4]

Risk factors to develop recurrent instability after a primary arthroscopic Bankart repair include younger age (<22 years), male gender, participation in competitive sports and an increased number of preoperative dislocations.[37] To our knowledge, it is still unclear whether collision athletes have a higher risk compared to noncollision athletes to develop recurrent instability after an arthroscopic Bankart repair: some studies report a higher redislocation rate, while other studies report a comparable redislocation rate for collision athletes. For this reason it is important to obtain pooled data about the redislocation rates for collision as well as noncollision athletes.

Therefore the aim of this study is to determine (1) the redislocation rate for collision athletes after an arthroscopic Bankart repair, and (2) to compare the redislocation rate between collision athletes and noncollision athletes.

METHODS AND MATERIALS

Protocol

This systematic review was performed according to the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) using the PRISMA checklist and algorithm.[23]

Literature search & study selection

A literature search was run in PubMed and EMBASE on June 1st 2015; no limitations were set for the year of publication (Appendix A). Titles and abstracts were screened based on predetermined inclusion and exclusion criteria (Table 1). Studies observing redislocation rates for collision athletes after undergoing an arthroscopic Bankart repair were included. All biomechanical studies, case reports, letters to editors, instructional courses, systematic reviews, cadaver/in vitro studies, studies with a follow-up shorter than 2 years and wherein the absolute risk could not be calculated with certainty were excluded. Associated lesions like Hills-Sachs and Humeral avulsion of the glenohumeral ligament (HAGL) were not excluded. A recurrent dislocation was also no criterion for exclusion. Studies satisfying for inclusion were full-text screened to assess applicability. References from included studies were screened to identify studies missed by the initial search.

Table 1. Inclusion and exclusion criteria.

Inclusion	Exclusion
Arthroscopic Bankart repair	Follow-up < 2 years
Postoperative instability	Studies wherein the absolute risk could not be calculated with certainty
Collision athletes	animal/cadaver/in vitro studies
	biomechanical reports
	case reports
	(systematic) reviews and meta analyses
	letters to editors
	instructional courses

Type of operation

A Bankart repair is indicated when the labrum is torn and bony lesions of the glenohumeral joint are insignificant. During this arthroscopic procedure the labrum and joint ligaments are repaired usually using sutures and/or anchors.

Assessment of methodological quality

The methodological quality of included studies was evaluated with the Coleman Methodology Score.[2] The total number of points refers to a poor (0-50 points), fair (50-69 points), good (70-84 points), or excellent (85-100 points) quality of the study.[2] We modified the Coleman Methodology Score to make it applicable for our systematic review (Table 2).

The two primary authors selected studies, assessed methodological quality, and extracted data independently. Disagreements were resolved by discussion.

Table 2. Modified Coleman Score.

A	Only one score to be given for each of the 7 sections		
1.	Study size – number of	< 20	0
		20-50	4
		51-100	7
		>100	10
2.	Mean follow-up	< 12 months	0
		12-36 months	4
		37-60 months	7
		> 61 months	10
3.	Surgical or conservative approach	Different approach used and outcome not reported separately	0
		Different approaches used and outcomes reported separately	7
		Single approach used	10
4.	Type of study	Retrospective cohort study	0
		Prospective cohort study	10
		Randomized controlled trial	15
5.	Description of indications/ diagnosis	Described without % specified	0
		Described with % specified	5
6.	Description of surgical or conservative technique	Inadequate (not stated, unclear)	0
		Fair (technique only stated)	5
		Adequate (technique stated, details of surgical or conservative procedure given)	10
7.	Description of postoperative rehabilitation	Described	5
		Not described	0
B	Scores may be given for each option in each of the 3 sections if applicable		
1.	Outcome criteria	Outcome measures clearly defined	2
		Timing of outcome assessment clearly stated	2
		Used of outcome criteria that has reported reliability	3
		General health measure included	3
2.	Procedure of assessing outcomes	Participants recruited	5
		Investigator independent of surgeon	4
		Written assessment	3
		Completion of assessment by patients themselves with minimal investigator assistance	3
3.	Description of subject selection process	Selection criteria reported and unbiased	5
		Recruitment rate reported > 90%	5
		Recruitment rate reported = 90%	0

Data extraction

From each study the year of publication, the number of patients and shoulders operated on, the number of collision athletes and noncollision athletes, the number of redislocations in collision athletes and noncollision athletes, the rate of athletes returning to sports, the accompanying lesions and the average follow-up was recorded.

As definitions for collision athletes differ between included studies, we applied the criteria described by Allain et al.[1] to define collision athletes (Table 3). Herein the sports are defined as collision/noncollision sports based on the impact on the shoulders. Although judo, karate, wrestling and ice hockey are not considered as collision sports in Allain et al. we categorized these sports as collision sports due to the high collision rate. If the sport was mentioned as a collision sport without further specification we considered it a collision sport. When the specific sport was not mentioned in the list we accounted it to the sport with the same impact mechanism on the shoulder (for example American Football and Rugby). The patients participating in the military academy were considered collision athletes due to the sports participated in the military course consisting of collision sports. We used the sport with the highest impact as leading to categorize the type of impact on the shoulder.

Table 3. Sports classification.

Group 1 (non-impact)	Group 2 (high impact/collision)	Group 3 (overhead + hitting)	Group 4 (overhead hitting and sudden stops)
Rowing Fencing Swimming The breaststroke Skin diving Gymnastics Langlauf	Martial arts (with exception of Judo and Karate) Riding a bicycle or motorcycle Motocross Soccer Rugby (with exception of hooking) Water skiing Downhill skiing, parachuting and equitation	Climbing Weight lifting Shot putting Swimming the crawl or Butterfly stroke Pole vaulting Figure skating Canoeing Pitching a ball Golf Field hockey Tennis	Basketball Handball Volleyball Kayaking Goal keeping Water polo Rugby hooking Judo Karate Wrestling Hang gliding Wind surfing Diving Ice hockey Acrobatic dancing Gymnastics performed either on the ground or on an apparatus

This table summarizes the groups of sports described by Allain et al.[1] The sports are divided in four groups according to the manner it affects the shoulder. The groups consist of non-impact sports, high impact/collision sports, overhead sports with hitting movements and sports with overhead hitting movements and sudden stops.

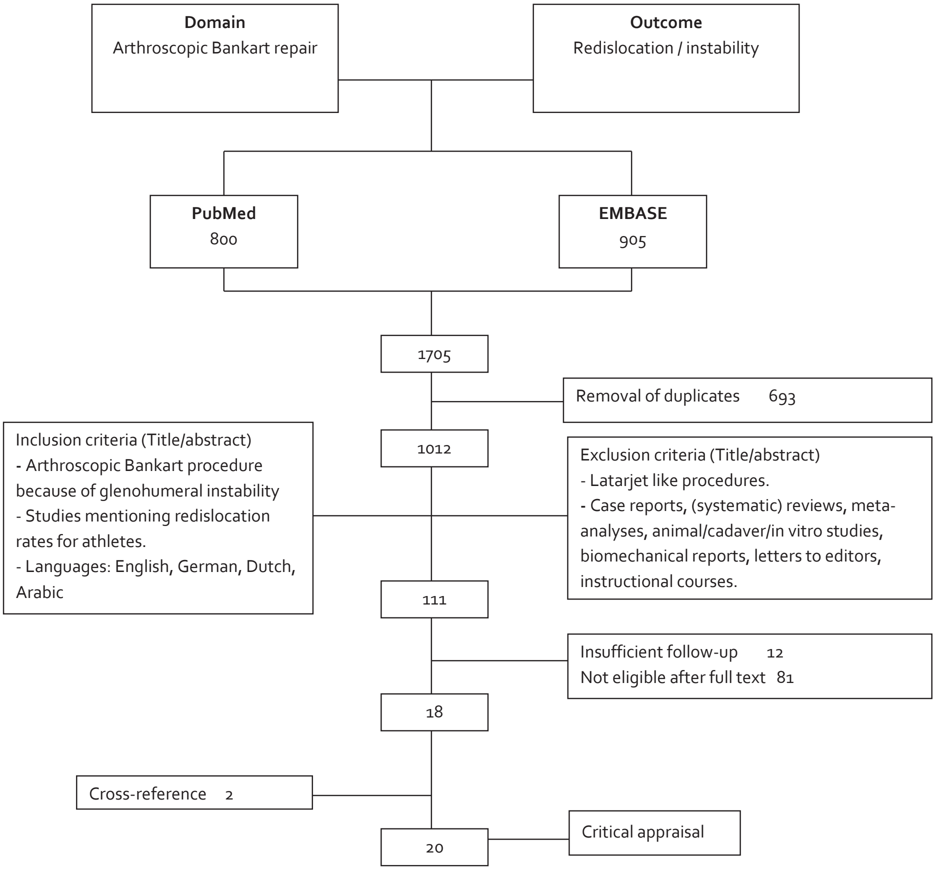

Figure 1. A flowchart of the study selection.

A redislocation or recurrent instability was defined as a either radiographic dislocation or clinical signs of instability (for example a positive apprehension test).

The absolute risk (AR) for collision athletes and noncollision athletes was acquired by calculating the percentage of redislocations. If a patient had bilateral shoulder dislocations, and both were treated with surgical stabilization, they were considered as two separate observations. Subsequently, the absolute risk difference (ARD) was obtained by subtracting the absolute risk of noncollision athletes from the absolute risk for collision athletes. The relative risk ratio (RR) was calculated by dividing the absolute risk of collision athletes by the absolute risk for noncollision athletes.

Statistical analysis

The Coleman Methodology Score for all studies combined is presented with a median and interquartile range (IQR). We used the Fisher's exact test to measure the difference

Table 4. Coleman analysis.

Article (reference)	PART A							PART B			Mean Modified Coleman Score
	Patients (n)	Mean FU	Surgical/ conservative	Diagnostic certainty	Type of study	Description of treatments	Postoperative rehabilitation	Outcome criteria	Procedure for assessing outcomes	Description of subjects	
Pangani[35]	37	67,2	+	+	retrospective	+	-	1,3	3,4	1,2	60
Petrera[36]	43	27,6	+	-	retrospective	+	+	1,3	2,3	1,2	58
Stein[45]	47	24-32	+	-	prospective	+	+	1,2,3	3,4	1,2	74
Levy[22]	37	36	+	-	prospective	+	+	3	2,3	1,2	68
Larrain[21]	160	70,8	+/-	-	retrospective	+	+	1, 3	3	2	55
Carreira[7]	57	46	+	+	prospective	+	+	1, 3	3	1,3	72
Rhee[38]	56	72	+/-	+	retrospective	+	+	1,3	3	3	52
Sugaya[46]	43	34	+	+	prospective	+	+	1,3	3	1,2	74
Mazzocca[30]	18	37	+	+	prospective	+	+	1,2,3	3	2	67
Mishra[31]	42	>24	+	+	prospective	+	+	1,3	-	1	66
Owens[34]	49	140,4	+	-	prospective	+/-	-	1,3	3,4	1	63
Speer[44]	52	42	+	-	retrospective	+	+	1,3	2	1,3	53
O'Neill[32]	41	52	+	-	prospective	+	+	3	1	1,2	72
Hayashida[17]	82	40	+	-	retrospective	+	+	3	3	1,2	58
Castagna[8]	31	130,8	+	-	retrospective	+	+	3	2,3	1,3	54
Balg[3]	134	31,2	+	+	prospective	+	+	3	3	1,2	75
Thal[47]	72	24-84	+	+	retrospective	+	+	3	1,3	1,2	65
Ide[20]	55	42	+	+	prospective	+	+	3	1,2,3	1,2	84
Cole[11]	59	52	+/-	+	prospective	+	+	3	1,2,3	1,2	81
Cho[9]	29	62.1	+	+	prospective	+	+	1,2,3	1,3	1	79
						Total Score					66,5

Surgical/conservative: (+) Single approach used (+/-) Different approaches used and outcomes reported separately (-) Different approach used and outcome not reported separately

Diagnostic certainty: (+) Described (-) Not described

Description of treatments: (+) Adequate, technique stated and necessary details of that type of procedure given (+/-) Fair, technique only stated without elaboration (-) Inadequate, not stated, or unclear

Postoperative rehabilitation: (+) Described (-) Not described

Outcome criteria: (1) Outcome measures clearly defined (2) Timing of outcome assessment clearly stated (3) Used of outcome criteria that has reported reliability (4) General health measure included

Procedure for assessing outcomes: (1) Participants recruited (2) Investigator independent of surgeon (3) Written assessment (4) Completion of assessment by patients themselves with minimal investigator assistance

Description of subjects: (1) Selection criteria reported and unbiased (2) Recruitment rate reported > 90% (3) Recruitment rate reported = 90%

Table 5. Summary of results.

Article (reference)	Year of publication	Included patients (n)	Collision athletes (n)	Non-collision athletes (n)	Redislocations in collision athletes (n)	Redislocations in noncollision athletes (n)	Absolute risk for collision athletes (%)	Absolute risk for non-collision athletes (%)	Risk difference (%)	Follow-up (mnts)	Level of evidence	p-value
Pangani[35]	1996	37 *	13	13	4	1	30,8	7,7	23,1	>48	2C	0.321
Petrera[36]	2013	43	23	20	2	0	8,7	0	8,7	>24	2C	0.491
Stein[45]	2011	47	13	34	3	2	23	5,9	17,1	24-32	2C	0.121
Levy[22]	2007	37*	17	12	1	1	5,9	8,3	-2.4	27-87	2C	1.000
Larrain[21]	2006	160	160	NA	12	NA	7,5	NA	NA	47-107	2C	NA
Carreira[7]	2006	57*	16	27	2	5**	12,5	18,5**	-6**	24-108	2C	0.695
Rhee[38]	2006	56***	16	NA	4	NA	25	NA	NA	30-136	2C	NA
Sugaya[46]	2005	43*	30	8	2	0	6,7	0	6,7	24-54	2C	1.000
Mazzocca[30]	2005	18	18	NA	2	NA	11,1	NA	NA	24-66	2C	NA
Mishra[31]	2001	42	14	28	2	2	14,3	7,1	7,2	>24	2C	0.590
Owens[34]	2001	39	39	0	15	NA	38,5	NA	NA	24-60	2C	NA
Speer[44]	1996	52*	26	13	4	0	15,4	0	15,4	24-60	2C	0.281
O'Neill[32]	1999	41	17	24	2	0	11,7	0	11,7	25-84	2C	0.166
Hayashida[17]	1998	82	24	58	7	8	29	14	15	24-70	2C	0.123
Castagna[8] ***	2010	31*	21	7	6	1	28,6	14,3	14,3	117-171,6	2C	0.639
Balg[3]	2007	134	80*****	51	14	5**	17,5	9,8**	7,7**	24-52	2C	0.310
Thal[47] ****	2007	72	42	30	3	2	7,1	6,7	0,4	24-84	2C	1.000
Ide[20]	2004	55	21	34	2	2	9,5	5,9	3,6	25-72	2C	0.632
Cole[11] ***	2000	59	21	16	6	0	28,6	0	28,6	27-72	2C	0.027
Cho[9]	2006	29	17	12	4	1	23,5	8,3	15,2	25-117	2C	0.370

* Not all included patients were athletes
** Mixed for non-collision athletes and non-athletes
*** Mixed open and arthroscopic group
**** Contact athletes, not mentioned which contact sports

in redislocation rates between collision and noncollision athletes per study, and for the studies combined. A p-value less than 0.05 was considered statistically significant in all studies.

RESULTS

Study selection

After screening 1012 titles and abstracts, 111 articles met inclusion criteria and were full-text screened; 93 studies were excluded because these were not eligible (81 studies), unavailable from our sources, or had insufficient follow-up (12 studies) (Figure 1). Cross-referencing resulted in 2 additional study, giving a total of 20 included studies.

Critical appraisal

The mean modified Coleman score was 66.5 (ranging from 52-74), indicating a "fair" overall quality of included studies (Table 4); twelve studies were ranked as "fair"[8,17,21,22,30,31,34–36,38,44,47] and eight studies were ranked as "good".[3,7,9,11,20,32,45,46]

Study Characteristics

Study populations varied from 18 to 160 patients, from which the rate of collision athletes varied from 28.1-100% and of noncollision athletes from 0-72.3% (Table 5). Follow-up varied between 24 and 140 months. Three articles compared time to redislocation between collision and noncollision athletes.[8,31,47] The mean time to redislocation in the three studies combined was 7 months for noncollision athletes and 31,3 months for collision athletes. However, only a small number of redislocations occurred in these studies (12 for collision athletes and 4 for noncollision athletes).

Table 6. Practiced sports and percentages of athletes returning to sports.

Article	Practiced sports (n)	Return to sports
Pangani[35]	4 contact sports; 2 swimming; 7 throwing athletes; 3 recreational racquet sports; 1 professional golfer	-
Petrera[36]	13 hockey; 4 American Football; 3 rugby; 1 soccer; 1 martial arts; 4 basketball; 4 baseball; 3 golf; 2 tennis; 2 weight lifting; 2 swimming; 1 badminton; 1 volleyball; 1 skiing; 1 running	72.7% of CA and 80.9% of NCA returned to pre-injury level
Stein[45]	12 soccer; 1 American football; 5 fitness; 2 mountain biking; 1 horseback riding; 1 tabletop soccer; 1 dancing; 5 bodybuilding; 3 goalkeeper; 3 tennis; 2 basketball; 2 volleyball; 2 badminton; 1 underwater rugby; 2 handball; 4 martial arts	-

Table 6. Practiced sports and percentages of athletes returning to sports. (continued)

Article	Practiced sports (n)	Return to sports
Levy[22]	9 overhead (swimming, cricket, or tennis); 17 collision (rugby, soccer, or skiing)	100% of CA and 90% of non-CA returned to sports. 86% of CA and 50% of NCA returned to pre-injury level
Larrain[21]	All did rugby (160)	100% of acute injuries and 84.3% of recurrent injuries returned to sports
Carreira[7]	11 football; 5 basketball; 2 baseball; 2 skiing/ snowboarding; 2 soccer; 2 rollerblading; 10 other	-
Rhee[38]	13 Judo; 7 wrestling; 13 ice hockey; 13 American football. After arthroscopic surgery 4 Judo; 3 wrestling; 4 ice hockey; 5 American football	25% returned to pre-injury level; 68.75% returned to sports with minimal restriction; 6.2% dislocated while sporting
Sugaya[46]	Not specified, only contact/overhead mentioned	84% returned to pre-injury level; 11% with minimal restriction; 5% dislocated while sporting
Mazzocca[30]	13 football; 5 wrestling or soccer	100% returned to sports
Mishra[31]	14 high level contact or collision, from these 4 division 1 football. Specific sport not mentioned	90.4% returned to sports
Owens[34]	All were in the military college	100% returned to sports on pre-injury level, all were collision athletes
Speer[44]	26 football, hockey, wrestling or rugby; 13 baseball, softball, swimming or tennis	85% returned to collision sports
O'Neill[32]	17 football	98% returned to sports; 94,1% returned to collision sports
Hayashida[17]	24 American football, rugby or judo	-
Castagna[8]	21 contact sports, specific sport not mentioned	71% returned to sports
Balg[3]	No specific sport mentioned	-
Thal[47]	42 involved in contact or collision sports, no specific sport mentioned	-
Ide[20]	8 rugby; 6 judo; 5 soccer; 2 wrestling; 11 baseball; 4 softball; 4 handball; 2 volleyball; 2 basketball; 1 badminton; 1 goalkeeping; 2sprinting; 2 cross-country; 2 gymnastics; 1 rowing; 1 golf; 1 bowling	80% returned without limitations; 18.2% with limitations; 1.8% could not return to sports
Cole[11]	21 contact sports; no specific sport mentioned	-
Cho [9]	4 judo, 3 wrestling, 2 ice hockey, 1 American football, 4 soccer, 6 baseball, 3 basketball, 2 volleyball, 1 skiing, 2 Taekwondo and 1 heavy gymnastics	27.6% returned to pre-injury level; 37.9% near return to the preinjury activity level; 20.7% return to the preinjury activity with a moderate limitation; 10.4% return to the preinjury activity with a severe limitation; 3.4% inability to return to the preinjury activity with discomfort during daily activities

CA= collision athletes
NCA= non-collision athletes

Table 7. Associated injuries.

Article	Percentage of patients with a lesion
Pangani[35]	97% Hill-Sachs lesions; 3% Bankart lesion
Petrera[36]	100% Bankart lesion; all patients with a Hill-Sachs lesion or >25% bone loss were excluded
Stein[45]	All bony defects were excluded
Levy[22]	Not mentioned
Larrain[21]	All patients with a Hill-Sachs lesion, HAGL, capsular laxity or >25% bone loss were excluded
Carreira[7]	Not mentioned
Rhee[38]	All patients had a Hill-Sachs lesion; 57% classic Bankart; 2% HAGL; 4% ALPSA; 23% bony Bankart
Sugaya[46]	51% >25% bone loss
Mazzocca[30]	5,6% Hill-Sachs
Mishra[31]	All had Bankart lesions; 28,6% Hill-Sachs lesions of 80-100%; all patients with HAGL lesions, complete rotator cuff tears and SLAP lesions were excluded
Owens[34]	Not mentioned
Speer[44]	46% Hill-Sachs; 27% anterior abnormality of the glenoid
O'Neill[32]	44% Hill-Sachs, 7.3% osseous Bankart, 2.4% loose body
Hayashida[17]	9% labral detachment with a well-developed glenohumeral ligament; 21% labral detachment with a poorly-developed glenohumeral ligament; 27% ligamentous tear with labral disruption
Castagna[8]	All had a Hill-Sachs lesion and a capsulolabral lesion
Balg [3]	84% Hill-Sachs; 35.2% SLAP
Thal[47]	All had a Hill-Sachs lesion; 27.8% SLAP
Ide[20]	65% Hill-Sachs; 22% bony Bankart lesion
Cole[11]	All had a Bankart lesion; 44% Hill-Sachs
Cho[9]	100% Hill-Sachs, 90% classic Bankart lesions, 10% non-classic Bankart (bony defect <25% of anteroinferior glenoid), 44,8% SLAP lesion, 17,2% fibrillation of the supraspinatus

HAGL= humeral avulsion of the glenohumeral ligament
ALPSA = anterior labroligamentous periosteal sleeve avulsion
SLAP = superior labral tear from anterior to posterior

Four studies reported on collision athletes alone,[21,30,34,38] whereas sixteen compared collision to noncollision athletes,[3,7–9,11,17,20,22,31,32,35,36,44–47] of which 3 studies considered patients who did not practice any sport as noncollision athletes (table 5).[3,7,22]

Return to sports

Twelve studies reported the return to sports rate (Table 6),[8,20–22,30–32,34,36,38,44,46] from which three studies compared the return to sports rate between collision and noncollision athletes.[22,32,36] Two showed a slightly lower chance for collision athletes to return to sports (ARD of 8.2% and 3.9%),[32,36] and one showed a higher chance for collision athletes to return to sports as well as practicing the sports on the pre-injury level (ARD of 10% to return to sports and 36% to return to pre-injury level).[22] If these three studies are combined there is no difference in return to sports between collision athletes (87.5%) and noncollision athletes (89.5%) (p=0.78).

Associated injuries

Accompanying lesions are reported in all studies except in three.[7,22,34] However, based on the available data it is not possible to assess whether associated injuries occur more frequently in collision athletes (Table 7).

Redislocation rates

The reported redislocation rates for collision athletes vary from 5.9% to 38.5% compared to 0% to 18.5% for noncollision athletes (Table 5). In five studies none of the noncollision athletes experienced a redislocation.[11,32,36,44,46]

Only one study reported a statistically significant difference between collision and noncollision athletes, with a 28.6% higher redislocation risk for collision athletes.[11] Thirteen other studies reported a higher redislocation rate for collision athletes, but the difference between groups did not reach statistical significance (ARD ranging from 0.4 to 23.1%).[3,8,9,17,20,31,32,35,36,44–47] Two studies reported a higher redislocation rate in noncollision athletes (ARD -6%; -2.4%) but this difference was not statistically significant either.[7,22]

When combining all studies, excluding those with uncertainties regarding the amount of collision and noncollision athletes,[3,7,8,11,47] collision athletes have an increased risk of 10.2% (17.3% for collision athletes compared to 7.2% for noncollision athletes) to develop a redislocation after a Bankart repair. (Table 8) The relative risk ratio was 2.43, indicating that collision athletes have a 2.43 higher risk of developing a redislocation (*p*=0.001).

Table 8. Cross-table of meta-analysis.

		Redislocation	No redislocation	Total	Redislocation rate (%)
Population	Collision Athletes	66	382	448	17.28
	Noncollision Athletes	17	239	256	7.11
	Total	83	621	704	24.39

DISCUSSION

This systematic review assesses the redislocation rate for collision athletes compared to noncollision athletes after an arthroscopic Bankart repair. Based on 20 included studies the redislocation rate for collision athletes ranges between 5.9% and 38.5%. A meta-analysis showes that the redislocation rate for collision athletes was significantly higher compared to noncollision athletes (absolute risk difference 10.17%, relative risk ratio 2.43, p = 0.001).

There are certain limitations to this study. First, the overall methodological quality of the studies was "fair", only seven studies have a "good" methodological quality.[3,7,9,20,32,45,47] In 13 out of 14 articles that report a higher risk for collision athletes to develop a redislocation, the differences were not statistically significant (p-value > 0,05).[3,7–9,17,20,31,32,35,36,44–47] This could be due to the fact that the analysed studies included not enough patients to reach statistical significance.

Furthermore, the overall heterogeneity of the included studies was high due to several reasons. First of all, despite similarities in the surgical procedures, differences were also observed (i.e. the use of bio-absorbable knots or non-bio-absorbable knots and anchors or sutures). Differences between surgical techniques could influence the surgical outcome and, at least partly, explain the differences in redislocation rates between studies. [24] Finally, the definition of redislocations was not clearly defined in all the studies; it was unclear whether a positive apprehension test or a subluxation was considered as a redislocation.

The limitations mentioned for individual studies illustrate the value of this meta-analysis, as it raises the statistical power by combining the groups that are compared and excluding studies with possible inaccurate data or confounding variables.

The increased redislocation rate in collision athletes could be attributed to several factors. First, when collision athletes restart sports participation, they are likely to expose their shoulder to greater forces compared to noncollision athletes For example, rugby players have a peak shoulder force of approximately 2000N measured during a tackle [48] and approximately 221 tackle events per game.[13]

Second, the magnitude of the collision effect in collision athletes could result in a higher risk for serious concomitant injuries such as a Hill-Sachs lesion or a Humeral Avulsion Glenohumeral Ligament (HAGL) lesion.[5,6] Possibly, these concomitant injuries are insufficiently addressed, which could result in more persistent or recurrent instability.

When informing patients about an arthroscopic soft-tissue (arthroscopic Bankart repair) or an open bony reconstruction (for example a Bristow or Latarjet procedure), one must consider the advantages and disadvantages of both techniques. Although collision athletes seem to have an increased redislocation risk following a Bankart procedure, its advantages are a relatively easier operation with less chance of a decreased range of motion (especially external rotation), shorter surgery time, improved cosmetics and less postoperative pain.[15]

A previous study performed in our department shows that collision athletes have no statistical significant increased risk for recurrent instability after a bony reconstruction, compared to noncollision athletes. The bony reconstruction however holds certain disadvantages including shoulder stiffness, wound infections, bony non-union, screw migration and bending or breakage, osteoarthritis and neurological injury. [4,15,27]

The treatment of shoulder instability remains challenging, especially in the athletic population. The increased risk for collision athletes to suffer from recurrent instability after a Bankart repair can provide additional support to the practitioner when informing the patient regarding surgery. Although previous studies suggest similar return to sport rates after a soft tissue repair or a bony reconstruction[16], the bony reconstruction yields a higher complication risk. Therefore, risks and benefits have to be evaluated with the individual patient while choosing the preferred surgical procedure.

CONCLUSION

Based on limited evidence collision athletes tend to have an increased risk to develop a redislocation after an arthroscopic Bankart repair, compared to noncollision athletes (absolute risk difference 10.2%, relative risk ratio 2.43, $p = 0.001$).

This higher redislocation risk should be included when choosing the preferred surgical procedure.

REFERENCES

1. Allain J, Goutallier D, Glorion C. Long-term results of the Latarjet procedure for the treatment of anterior instability of the shoulder. *J Bone Joint Surg Am*. 1998;80:841–852.
2. Altman DG, Schulz KF, Moher D, Egger M, Davidoff F, Elbourne D. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med*. 2001;134:663–694.
3. Balg F, Boileau P. The instability severity index score. A simple pre-operative score to select patients for arthroscopic or open shoulder stabilisation. *J Bone Joint Surg Br*. 2007;89:1470–1477.
4. Bhatia S, Frank RM, Ghodadra NS, Hsu AR, Romeo AA, Bach BR, et al. The outcomes and surgical techniques of the Latarjet procedure. *Arthroscopy*. 2014;30:227–235.
5. Bokor DJ, Conboy VB, Olson C. Anterior instability of the glenohumeral joint with humeral avulsion of the glenohumeral ligament. {A} review of 41 cases. *J Bone Joint Surg Br*. 1999;81:93–96.
6. Burkhart SS, Beer JF de. Traumatic glenohumeral bone defects and their relationship to failure of arthroscopic Bankart repairs: significance of the inverted-pear glenoid and the humeral engaging Hill-Sachs lesion. *Arthroscopy*. 2000;16:677–694.
7. Carreira DS, Mazzocca AD, Oryhon J, Brown FM, Hayden JK, Romeo A a. A prospective outcome evaluation of arthroscopic Bankart repairs: minimum 2-year follow-up. *Am J Sports Med*. 2006;34:771–777.
8. Castagna A, Markopoulos N, Conti M, Rose GD, Papadakou E, Garofalo R. Arthroscopic bankart suture-anchor repair: radiological and clinical outcome at minimum 10 years of follow-up. *Am J Sports Med*. 2010;38:2012–2016.
9. Cho NS, Hwang JC, Rhee YG. Arthroscopic Stabilization in Anterior Shoulder Instability: Collision Athletes Versus Noncollision Athletes. *Arthroscopy*. 2006;22:947–953.
10. Cleeman E, Flatow EL. Shoulder dislocations in the young patient. *Orthop Clin North Am*. 2000;31:217–229.
11. Cole BJ, L'Insalata J, Irrgang J, Warner JJ. Comparison of arthroscopic and open anterior shoulder stabilization. A two to six-year follow-up study. *J Bone Joint Surg Am*. 2000;82-A:1108–1114.
12. Dickens JF, Owens BD, Cameron KL, Kilcoyne K, Allred CD, Svoboda SJ, et al. Return to play and recurrent instability after in-season anterior shoulder instability: a prospective multicenter study. *Am J Sports Med*. 2014;42:2842–50.
13. Fuller CW, Brooks JHM, Cancea RJ, Hall J, Kemp SPT. Contact events in rugby union and their propensity to cause injury. *Br J Sports Med*. 2007;41:862–867; discussion 867.
14. Gerometta A, Rosso C, Klouche S, Hardy P. Arthroscopic Bankart shoulder stabilization in athletes: return to sports and functional outcomes. *Knee Surg Sports Traumatol Arthrosc*. 2014, April 22. [Epub ahead of print]
15. Griesser MJ, Harris JD, McCoy BW, Hussain WM, Jones MH, Bishop JY, et al. Complications and re-operations after Bristow-Latarjet shoulder stabilization: A systematic review. *J Shoulder Elbow Surg*. 2013;22:286–292.
16. Harris JD, Gupta AK, Mall NA, Abrams GD, McCormick FM, Cole BJ, et al. Long-term outcomes after bankart shoulder stabilization. *Arthroscopy*. 2013;29:920–933.
17. Hayashida K, Yoneda M, Nakagawa S, Okamura K, Fukushima S. Arthroscopic Bankart suture repair for traumatic anterior shoulder instability: Analysis of the causes of a recurrence. *Arthroscopy*. 1998;14:295–301.
18. Hovelius L, Augustini BG, Fredin H, Johansson O, Norlin R, Thorling J. Primary anterior dislocation of the shoulder in young patients: A ten- year prospective study. *J Bone Joint Surg Am*. 1996;78:1677–1684.
19. Hovelius L, Olofsson A, Sandström B, Augustini B-G, Krantz L, Fredin H, et al. Nonoperative treatment of primary anterior shoulder dislocation in patients forty years of age and younger. a prospective twenty-five-year follow-up. *J Bone Joint Surg Am*. 2008;90:945–952.
20. Ide J, Maeda S, Takagi K. Arthroscopic Bankart Repair Using Suture Anchors in Athletes: Patient Selection and Postoperative Sports Activity. *Am J Sports Med*. 2004;32:1899–1905.
21. Larrain MV, Montenegro HJ, Mauas DM, Collazo CC, Pavón F. Arthroscopic Management of Traumatic Anterior Shoulder Instability in Collision Athletes: Analysis of 204 Cases With a 4- to 9-Year Follow-Up and Results With the Suture Anchor Technique. *Arthroscopy*. 2006;22:1283–1289.
22. Levy O, Matthews T, Even T. The "Purse-String" Technique: An Arthroscopic Technique for Stabilization of Anteroinferior Instability of the Shoulder With Early and Medium-Term Results. *Arthroscopy*. 2007;23:57–64.
23. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Ioannidis JP a, Clarke M, et al. The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions. *Ann Intern Med*. 2009;151:W65–W94.

24. van der Linde J a., van Kampen D a., Terwee CB, Dijksman LM, KleinJan G, Willems WJ. Long-term Results After Arthroscopic Shoulder Stabilization Using Suture Anchors: An 8- to 10-Year Follow-up. *Am J Sports Med. 2*011;39:2396–2403.
25. van der Linde JA, van Wijngaarden R, Somford MP, van Deurzen DFP, van Den Bekerom MPJ. The Bristow–Latarjet procedure, a historical note on a technique in comeback. *Knee Surg Sports Traumatol Arthrosc.* 2016;24:470-478.
26. Longo UG, Loppini M, Rizzello G, Ciuffreda M, Maffulli N, Denaro V. Management of primary acute anterior shoulder dislocation: Systematic review and quantitative synthesis of the literature. *Arthroscopy.* 2014;30:506–522.
27. Longo UG, Loppini M, Rizzello G, Ciuffreda M, Maffulli N, Denaro V. Latarjet, Bristow, and Eden-Hybinette Procedures for Anterior Shoulder Dislocation: Systematic Review and Quantitative Synthesis of the Literature. *Arthroscopy.* 2014;30:1184-1211
28. Longo UG, Loppini M, Rizzello G, Romeo G, Huijsmans PE, Denaro V. Glenoid and humeral head bone loss in traumatic anterior glenohumeral instability: A systematic review. *Knee Surg Sports Traumatol Arthrosc.* 2014;22:392–414.
29. Longo UG, Rizzello G, Locher J, Salvatore G, Florio P, Maffulli N, et al. Bone loss in patients with posterior gleno-humeral instability: a systematic review. *Knee Surg Sports Traumatol Arthrosc.* 2016;24:612-617.
30. Mazzocca AD, Brown FM, Carreira DS, Hayden J, Romeo A a. Arthroscopic anterior shoulder stabilization of collision and contact athletes. *Am J Sports Med.* 2005;33:52–60.
31. Mishra DK, Fanton GS. Two-year outcome of arthroscopic bankart repair and electrothermal-assisted capsulorrhaphy for recurrent traumatic anterior shoulder instability. *Arthroscopy.* 2001;17:844–849.
32. O'Neill DB. Arthroscopic Bankart repair of anterior detachments of the glenoid labrum. A prospective study. *J Bone Joint Surg Am.* 1999;81:1357–1366.
33. Owens BD, Agel J, Mountcastle SB, Cameron KL, Nelson BJ. Incidence of glenohumeral instability in collegiate athletics. *Am J Sports Med.* 2009;37:1750–1754.
34. Owens BD, DeBerardino TM, Nelson BJ, Thurman J, Cameron KL, Taylor DC, et al. Long-term follow-up of acute arthroscopic Bankart repair for initial anterior shoulder dislocations in young athletes. *Am J Sports Med.* 2009;37:669–673.
35. Pagnani MJ, Warren RF, Altchek DW, Wickiewicz TL, Anderson AF. Arthroscopic shoulder stabilization using transglenoid sutures. A four-year minimum followup. *Am J Sports Med.* 1996;24:459–467.
36. Petrera M, Dwyer T, Tsuji MRS, Theodoropoulos JS. Outcomes of arthroscopic Bankart repair in collision versus noncollision athletes. *Orthopedics.* 2013;36:e621–626.
37. Randelli P, Ragone V, Carminati S, Cabitza P. Risk factors for recurrence after Bankart repair a systematic review. *Knee Surg Sports Traumatol Arthrosc.* 2012;20:2129–2138.
38. Rhee YG, Ha JH, Cho NS. Anterior shoulder stabilization in collision athletes: arthroscopic versus open Bankart repair. *Am J Sports Med.* 2006;34:979–985.
39. Sachs RA, Lin D, Stone M Lou, Paxton E, Kuney M. Can the need for future surgery for acute traumatic anterior shoulder dislocation be predicted? *J Bone Joint Surg Am.* 2007;89:1665–1674.
40. Schaider JSR. Shoulder injuries. In: Clinical Practice of Emergency Medicine. Philadelphia Lippincott Williams & Wilkins; 2005. p. 1033.
41. Simon RRSS, Koenigsknecht SJ. Emergency Orthopedics: The Extremities. New York: 2006.
42. Simonet WT, Melton LJ, Cofield RH, Ilstrup DM. Incidence of anterior shoulder dislocation in Olmsted County, Minnesota. *Clin Orthop Relat Res.* 1984;1984:186–191.
43. Sineff SSRE. Shoulder joint dislocation reduction. In: Reichman EFSR, editor. Emergency Medicine Procedures. New-York: McGraw-Hill; 2004. p. 593.
44. Speer KP, Warren RF, Pagnani M, Warner JJ. An arthroscopic technique for anterior stabilization of the shoulder with a bioabsorbable tack. *J Bone Joint Surg Am.* 1996;78:1801–1807.
45. Stein T, Linke RD, Buckup J, Efe T, von Eisenhart-Rothe R, Hoffmann R, et al. Shoulder Sport-Specific Impairments After Arthroscopic Bankart Repair: A Prospective Longitudinal Assessment. *Am J Sports Med.* 2011;39:2404–2414.
46. Sugaya H, Moriishi J, Kanisawa I, Tsuchiya A. Arthroscopic osseous Bankart repair for chronic recurrent traumatic anterior glenohumeral instability. *J Bone Joint Surg Am.* 2005;87:1752–1760.
47. Thal R, Nofziger M, Bridges M, Kim JJ. Arthroscopic Bankart Repair Using Knotless or BioKnotless Suture Anchors: 2- to 7-Year Results. *Arthroscopy.* 2007;23:367–375.
48. Usman J, McIntosh AS, Fréchède B. An investigation of shoulder forces in active shoulder tackles in rugby union football. *J Sci Med Sport.* 2011;14:547–552.
49. Zacchilli M a, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am.* 2010;92:542–549.

Chapter 11

Rehabilitation following arthroscopic soft tissue repair in patients with anterior shoulder instability; what is the evidence?

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ABSTRACT

Objective

The aim of this study is to evaluate the evidence regarding rehabilitation following antero-inferior capsulolabral soft tissue repair in patients with anterior shoulder instability.

Methods and materials

A literature search was conducted including MedLine (Pubmed), Embase, PEDro and the Cochrane Database for related articles that compared different rehabilitation protocols. Inclusion criteria were patients with a mean age of 18-65 years, with primary or recurrent traumatic anterior shoulder instability, treated with an arthroscopic soft tissue repair, and a clear description of the rehabilitation program following surgery. Exclusion criteria were the presence of multidirectional, posterior or voluntary instability and concomitant injuries such as a bony Bankart lesion, a humeral avulsion of the glenohumeral ligament (HAGL) or rotator cuff pathology during surgery.

A second search was performed by hand to evaluate the current practice in rehabilitation protocols described in the recent leading literature. Eligible articles were published between January 1st 2010 and December 31st 2014 in the four orthopaedic journals with the highest Impact Factor. In- and exclusion criteria were identical for the second search, but no comparison between different rehabilitation protocols was required.

The American Society of Shoulder and Elbow Therapists' Consensus (ASSET) guideline was assessed with the AGREE II tool.

Results

The initial search resulted in 902 articles. After screening title and abstract only 2 studies met the inclusion criteria. The second search resulted in 6 articles, which emphasize the differences between current rehabilitation protocols (immobilization time, technique, range of motion, strength exercises and return to overhead activities and throwing sports).

Our average score of the ASSET guideline was 49%.

Conclusion

Based on clinical studies, there is insufficient evidence to suggest one rehabilitation protocol over another to treat patients after an arthroscopic soft tissue repair for shoulder instability. Although based on limited evidence, the ASSET guideline (2010) is applicable.

INTRODUCTION

The antero-inferior capsulolabral repair (Bankart procedure) and variants are techniques to repair the capsulolabral complex in order to restore the stability of the shoulder joint.[1] In the last decades of the previous century it has evolved from an open, to a fully arthroscopic procedure.[2,3] Subsequently different rehabilitation protocols have been described,[4-10] but despite surgical development with, recurrent instability still occurs.

Generally the operated shoulder is initially immobilized, followed by physiotherapy to regain strength and range of motion. The immobilization technique, duration and position in which the shoulder is immobilized remain controversial.

Regarding the immobilization technique, it is argued that patients who sustained a shoulder dislocation should initially be immobilised in external rotation, because both MRI and cadaveric analysis suggest that this position enables coaptation of the Bankart lesion, which may minimise the risk of recurrent shoulder instability.[11,12] It is unknown whether the same rationale accounts for postoperative patients. With regard to duration, postoperative treatment regimens include shoulder immobilization for 2.9 weeks on average[.13]

In 2010, the American Society of Shoulder and Elbow Therapists (ASSET) published a consensus rehabilitation guideline for patients with antero-inferior capsulolabral repair. This consensus was based on basic science and best evidence, combined with expert opinions.[14] The introduction of the consensus-derived ASSET rehabilitation guideline into routine care is however not associated with an improved clinical outcome or a reduction in costs.[15]

The aim of this study is to evaluate the evidence regarding the postoperative rehabilitation protocol and to compare different rehabilitation protocols for patients treated with an arthroscopic antero-inferior capsulolabral repair.

METHODS AND MATERIALS

Literature search

An initial literature search was performed on December 1st 2014 in collaboration with a medical librarian from the Cochrane group. Search terms are summarized in Table 1. Both Medline (Pubmed), EMBASE and PEDro were searched. There was no limitation concerning year of publication. Only articles written in English, German and Dutch were included. Duplicates were removed and 2 authors screened titles and abstracts independently. Inclusion and exclusion criteria are summarized in Table 2. Inclusion criteria were studies including patients with a mean age between 18 and 65 years, with primary or recurrent traumatic anterior shoulder instability, treated with an arthroscopic soft tissue

Table 1. Search strategy for initial literature search based on PICO*.

	Citations Medline	Citations Embase	Total citations	Total exclusion	Total inclusion
1. Glenohumeral	3774	4494			
2. Shoulder dislocation	4846	5185			
3. Bankart	992	1173			
4. Shoulder instability	1250	1634			
5. Shoulder luxation	74	112			
6. Shoulder (joint)	14.723	27.480			
7. 1 or 2 or 3 or 4 or 5 or 6	19.195	33.860			
8. Arthroscopy	20.563	20.128			
9. Arthroscopic surgery	1507	6417			
Bankart repair	328	401			
8 or 9 or 10	20.941	24.800			
7 and 11	2989	3044			
Rehabilitation	263.582	239.492			
Physical therapy	47.015	17.408			
Physiotherapy	19.302	57.370			
Manual therapy	2034	1749			
Physical therapy modalities	27.259	310			
Postoperative care	53.849	69.602			
Musculoskeletal manipulations	856	28.997**			
Muscle training	1376	4822			
Exercise	235.659	224.089			
Immobilization	39.003	58.792			
(Joint) mobilization	40.695	573			
13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23	632.567	640.431			
1 and 24	536	540			
Total citations 2 databases			1076		
Excluded based on title and abstract	511	535		1046	
Excluded based on missing original data				14	
Excluded based on full text				14	
Included citations					2
Added background information (articles)					14
Added background information (other)					1

* *P*atient: postoperative adult patient (mean age 18-65 years old) following a stabilizing procedure after primary or recurrent anterior shoulder dislocation ; *I*ntervention: rehabilitation protocols ; *C*omparison: the American Society of Shoulder and Elbow Therapists' Consensus Rehabilitation Guideline for arthroscopic anterior capsulolabral repair of the shoulder; *O*utcome: evidence-based yes/no.

** Manipulative medicine

Table 2. Inclusion and exclusion criteria for initial literature search.

Inclusion criteria:	- Mean age patient group 18-65 years old - Primary or recurrent traumatic anterior instability (shoulder dislocation) - Arthroscopic stabilizing procedure - (Focus on) rehabilitation program
Exclusion criteria:	- Children or adolescent patients - Multidirectional/posterior/voluntary instability with or without Bankart lesion - Bony Bankart lesion, HAGL*, SLAP** lesion, rotator cuff tear(s)

* Humeral Avulsion Glenohumeral Ligament
** Superior Labrum Anterior Posterior

repair and a clear description of the rehabilitation program following surgery. Exclusion criteria were patients with a mean age <18 years, with multidirectional, posterior or voluntary instability, and/or concomitant injuries such as a humeral avulsion of the glenohumeral ligament (HAGL), a superior labrum anterior-posterior (SLAP) lesion or a rotator cuff tear (Table 2). Expert opinions and instructional courses were also excluded, as were reviews due to the fact that the initial goal was to find articles containing original data. Eligible articles were analysed in full text to evaluate methodological quality and level of evidence (LoE) independently by two authors following the NICE criteria (National Institute for Health and Clinical Excellence; 2009). For LoE assessment, the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence was used (OCEBM Levels of Evidence Working Group; 2011). Disagreement was dissolved either by discussion, or a third author would decide. Finally cross-references were screened for potentially relevant studies.

Additional literature search

Because the initial search resulted in only a minimal number of studies, a second search was performed by hand to evaluate the current practice in rehabilitation protocols in the recent leading literature. The search terms were: arthroscopic AND Bankart AND repair AND rehabilitation, for each journal. Four orthopaedic journals with the highest impact factor (IF) were searched by hand for eligible articles between January 1st 2010 and 31st of December 2014. The four journals of interest in the field of this study are the American Journal of Sports Medicine (IF 4,699), the Journal of Bone and Joint Surgery America (IF 4,663), Physical Therapy (IF 3,245) and Arthroscopy (IF 3,191). The same in- and exclusion criteria were applicable to this second search, but no comparison between rehabilitation protocols was required and an extra inclusion criterion was added in the form of LoE I or II. This resulted in six studies.

ASSET guideline assessment

Finally the existing ASSET guideline was reviewed for methodological quality with the AGREE II tool from Cochrane (dcc.cochrane.org). This tool was created for health care- and other providers to assess guidelines before implementation. It contains 23 items on 6 domains (subject and goal, involvement of stakeholders, methodology, clarity and presentation, application and independency); each item is scored on a 7-point Likert scale (1 is the minimum score, 7 the maximum score). Subscores are calculated for each domain in percentages, using the following formula:

$$\frac{\text{obtained score} - \text{minimum possible score}}{\text{maximum possible score} - \text{minimum possible score}} * 100 =$$

Maximum possible score = 7 x number of items x number of critics
Minimum possible score = 1 x number of items x number of critics

Finally there are two global scoring items (general quality and recommendation) to determine the overall quality of the complete guideline. The general quality is scored by one item, taking all prior domains into consideration.

There are no fixed criteria to distinguish between guidelines with 'high' or 'low' quality, its value is determined by the user of the AGREE II tool within the context of the assessed guideline. The percentages scored on average should thus be interpreted carefully. At least two, but preferably four authors should review the guideline before calculating the average score on each domain. It is advised to set a time frame in which the guideline should be revised, regarding changing insights from on-going studies.

The guideline was evaluated using the AGREE II tool (2009) by two authors independently.

RESULTS

Literature search

After removal of duplicates, the initial search in Pubmed and Embase resulted in 902 articles; the PEDro search did not result in additional articles. Exclusion of 872 articles based on title and abstract, resulted in 30 articles (Figure 1). Fourteen articles were excluded because of absence of original data. Of the remaining 16 articles, 3 were excluded due to poor or lacking description of the rehabilitation protocol. The remaining 13 articles met our inclusion criteria, yet only 2 compare different compared postoperative rehabilitation protocols.[16,17] Cross-referencing of the included articles and the ASSET guideline resulted in three additional articles. One of these articles was excluded because the procedure was an open Bankart repair; the other two articles were excluded

Table 3. Studies from initial literature search comparing rehabilitation protocols.

Author and year	Surgical procedure	Rehabilitation	Imm. method & position	Outcome measurement	Results emphasizing rehabilitation
Kim 2003[16]	Mini-Revo screws (Linvatec) with a No. 2 Ethibond suture were used. Capsular sutures were created about 1 cm inferior to the anchors at or below the level of the glenoid surface. Knot-tying with a Shuttle Relay to obtain an arthroscopic sliding knot.	Conv.: 3wk immob, from 3wk pendulum, 4wk IR strength, 6wk ER ROM + strength, 9wk rot. cuff strength Acc.: 0-2wk sling night only, 0-6wk pendulum, PROM, AROM, isotonic strength, 6-9wk ROM, dynamic strength	Conv.: Sling with pillow spacer, max 20° abduction and 40° internal rotation. No ROM exercises during immobilization period.	Pain scores, ROM, recurrence, return to activity, satisfaction scores, ASES, Rowe, UCLA.	Pain: acc. group had less pain than conv. group after 6wks (p 0.013) ROM: Final follow-up (31mth): Acc. group faster in resuming 90% of final range of ER than conv. group (p<0.001), time to resume 90% of final level of activity was shorter in acc. group than in conv. group (p<0.001). Difference in patient satisfaction is statistically significant (p<0.001) where acc. group is satisfied and conv. group is dissatisfied. No recurrences in either group, 2 patients from each group had positive apprehension at follow-up.
Merk 1996[17]	3-point knot technique with transglenoid sutures. Not tied over infraspinatus fascia but directly on scapula and intra-articular on the ventral side of the glenoid.	Conv.: 3wk immob Acc.: 1-2wk immob	Gilchrist bandage, no exact information about position. CPM exercises max 40° anteversion and 70° abduction from postoperative day 1.	Rowe, CMS	Acc. group has lower Rowe score at follow-up (15,4mth) poor statistical analysis was described. 2 patients with combined SLAP/ Bankart repair in acc. group reported apprehension at follow-up. Conv. group scored highest on all score criteria. There was no recurrence and ROM was not significantly different in both groups.

Conv: conventional group, Acc: accelerated group, IR: internal rotation, ER: external rotation, ROM: range of motion, PROM: passive range of motion, AROM: active range of motion, CPM: continuous passive motion (device), ASES: American Shoulder and Elbow Surgeons shoulder score, UCLA: University of California-Los Angeles shoulder scale, CMS: Constant-Murley Score

Table 4. Methodological quality of the two initial included clinical trials.

Author and year	Study design	Materials & methods	Conclusion	Meth. quality	LoE
Kim 2003[16]	RCT	Compared the clinical results of early motion versus conventional immobilization after arthroscopic Bankart repair in a selected patient population. 62 patients were randomised into a conventional rehabilitation group and an accelerated rehabilitation group and were followed up after 31 months.	Early mobilization of the operated shoulder after arthroscopic Bankart repair does not increase the recurrence rate in a selected group of patients. Although the final outcomes are approximately the same for both groups, the accelerated rehabilitation program promotes functional recovery and reduces postoperative pain, which allows patients an early return to desired activities.	+	II
Merk 1996[17]	RCT	38 arthroscopic refixations of the glenoid labrum as described by Habermeyer (21). Patients were randomized in two groups: 3 weeks immobilization or 1-2 weeks immobilization postoperatively. Physiotherapy started the day after the operation using CPM.	Postoperative management following arthroscopic repair of labral tears should include immobilization of the operated shoulder for 3 weeks and an early start of passive-motion exercises.	±	III

RCT: randomised clinical trial, LoE: Level of Evidence

Table 5. Rehabilitation characteristics from recent articles in high impact journals.

Author & year	Surgical technique	Rehabilitation	Imm. method&position	Outcome measurement
Elmlund, 2009[22]	Bio-absorbable tacks	4 wks immob. with free forward flexion and IR, free ROM in all directions and strengthening exercises, throwing and contact sports from 6 months	Sling, position not specified	Early CRP response, clinical and radiographic long-term results
Hantes, 2009[23]	Suture anchors	3 wks immob., AAROM 3-6 wks, rotator cuff strengthening 6 wks, full ER from 12 wks on, return to sports 6 months	Sling, IR and 20° abduction	CMS, Rowe, VAS, recurrence
Monteiro, 2008[24]	Suture anchors with absorbable or non-absorbable sutures	3 wks immob., PROM 3-5 wks, AAROM + strengthening from 5 wks on, return to sports 5 months	Sling, position not specified	Rowe, ASOSS
Netto, 2012[25]	Suture anchors, open or arthroscopic	4 wks immob., 1-4 wks PROM, AROM from 4 wks on + PT, return to sports 6 months	Sling, position not specified	DASH, UCLA, Rowe, ROM
Nourissat, 2011[26]	Suture anchors with or without remplissage	6 wks immob., PROM 3-6 wks, active mobilisation starts 6 wks	Sling, elbow to waist	ROM, WD
Mohtadi, 2014[27]	Suture anchors, open or arthroscopic	4 wks immob., 4-6 wks pendulum + AAROM, isometric rotator cuff + scapular strengthening, 6 wks-3 months AROM + isotonic strength, 3-6 months strength, propriocepsis, ROM and return to sports	Immobilizer, position not specified	WOSI, ASES, ROM, recurrence

AAROM: assisted active range of motion, CRP: C-reactive protein, VAS: visual analogue scale, ASOSS: athletic shoulder outcome scoring system, DASH: disabilities of the arm, shoulder and hand, WD: Walch-Duplay WOSI: Western Ontario Shoulder Instability Index.

due to poor or lacking description of rehabilitation protocols. The results are summarized and highlighted in Table 3 and Table 4.

Additional literature search

The second search resulted in 6 recently published, LoE I or II articles. Studies are summarized in Table 5.

ASSET guideline assessment

The ASSET guideline was assessed using the AGREE II tool, this resulted in a total score of 49%. An overview of this score and its calculation is presented in Table 6.

Table 6. AGREE II scores.

Domain	Item	Score	Total
Subject and goal	1.	7	
	2.	6	
	3.	4	78%
Involvement of stakeholders	4.	6	
	5.	3	
	6.	7	72%
Methodology	7.	5	
	8.	5	
	9.	2	
	10.	3	
	11.	6	
	12.	4	
	13.	2	
	14.	3	46%
Clarity and presentation	15.	4	
	16.	5	
	17.	6	67%
Application	18.	3	
	19.	4	
	20.	1	
	21.	1	29%
Independancy	22.	1	
	23.	1	0%
Average			49%

Scores: 1 = don't agree at all, 7 = totally agree

AGREE Next Steps Consortium. Appraisal of Guidelines for Research & Evaluation (AGREE) II Instrument. www.agreetrust.org May 2009

Table 7. Brief version of rehabilitation protocols for standard care group and guideline group*.

Phase	Standard care	ASSET guideline
Phase 1 (POW 0–6)	Initial PROM and AAROM exercises, daily exercises for elbow and wrist, external rotation in adduction to neutral. Late phase included (AROM) as prescribed by the surgeon.	Goals: Protect the anatomic repair. Educate patient in postoperative restrictions. Minimize pain and inflammatory response. Ensure adequate scapular function. Interventions and activities: Absolute immobilization in a sling. ROM of uninvolved joints. Shoulder strength through isometrics. Patient education: Explain nature of the surgery and importance of compliance with the regime. ROM exercises: Following absolute immobilization as prescribed by the surgeon. Pendulum exercises, AAROM exercises to achieve ROM goals. Staged ROM goals week 3: PFE 90°, PER at 20° abduction 10º–30º, PER at 90º contraindicated, AFE NA. Staged ROM goals week 6: PFE 135°, PER at 20° abduction 35°–50°, PER at 90° abduction 45°, AFE 115°.
Phase two (POW 6–12)	Gradually obtaining full ROM in week 12. Progress in scapula stabilizing exercises and strength exercises, with elastics and dumbbells.	Goals: Achieve ROM goals. Begin to increase strength and endurance. Increase functional activities. Interventions to avoid: Stretching beyond set goals, heavy lifting, plyometrics, push-ups, military presses. ROM exercises: Gentle joint mobilization if ROM is less than ROM goals. Strength exercises: Scapula and core. Rotator cuff and scapula stabilization exercises with high repetitions (30–50 reps) at low resistance (1–2 kg). Set ROM goals week 9: PFE 155°, PER at 20° abduction 50°–65°, PER at 90° abduction 75°, AFE 145°. Set ROM goals week 12: PFE WNL, PER at 20° abduction WNL, PER at 90° WNL, AFE WNL.
Phase three (POW 12–24)	Tailored strength and AROM exercises according to the patients' demands in work and sports.	Goals: Normalize strength, endurance and neuromuscular control. No activity- specific training until patient has nearly full ROM and strength. ROM: Joint mobilization as needed. Strength: Early phase: (15–25 repetitions), biceps, triceps, shrugs, rows adducted shoulder, overhead dumbbell press, push up. Intermediate phase: bench-press, rows elevated shoulder, overhead military press, pectoralis major flyers, dead lift, power cleans. Avoid: Dips and latissimus pull down, bar behind head. Plyometric exercises if patient have plyometric challenges instituted from week 16. RTW, RTS: Clearance from physician. No complaints of pain. No or minimal sensation of instability with activities. Adequate strength and endurance.

* Both groups received home training programmes according to the phase and their individual needs. AAROM: active assisted range of motion, AFE: active forward elevation, AROM: active range of motion, NA: not applicable, PER: passive external rotation, PFE: passive forward elevation, POW: weeks postoperative, ROM: range of motion, RTS: return to sport, RTW: return to work, WNL: within normal limits.

DISCUSSION

The aim of this review was to evaluate the clinical evidence for the rehabilitation protocol following arthroscopic soft tissue repair for antero-inferior shoulder instability. Based on our literature search only 2 comparative studies address this issue. The first study (Merk et al., 1996[17]) randomized 38 patients to compare an accelerated rehabilitation protocol (1 or 2 weeks immobilisation, n=18) to their conventional rehabilitation protocol (3 weeks immobilisation, n=20) followed by a device for early passive motion exercises, in patients treated with the 3-point knot technique; a modification of the transglenoid suture repair described by Morgan and Bodenstab.[18] In this study significantly lower Rowe-scores ($p<0,05$) were obtained in the accelerated group compared to the conventional protocol. Constant & Murley scores (CMS) were similar for both groups. In the accelerated group, patients with an isolated classic Bankart lesion or SLAP-lesion were immobilized for 1 week, patients with extensive labral damage or combined Bankart/SLAP lesion were immobilised for 2 weeks.

This study includes several weak points. First of all, despite randomization, there is inconsistency in the accelerated treatment arm; 5 out of 18 patients received a prolonged immobilization, based on their more extensive pathology. These patients were however considered the same as patients with 1-week immobilization. Second, the CMS is frequently used to evaluate degenerative shoulder pathology and patients with rotator cuff pathology, other measurement instruments may be better capable to evaluate the shoulder function in patients with instability.[19] Although Patient Reported Outcome Measurements (PROMs) are a practical tool to evaluate shoulder function, objective results such as range of motion were not reported.

Moreover, although statistical analysis has been performed to demonstrate significant differences in outcomes between patients with accelerated and normal immobilisation, no attention was given to the improvement per group between pre-operative and post-operative measurements. Finally, nowadays the technique of transglenoid sutures that was used in this study is largely replaced by the use of suture anchors.

The second study (Kim et al, 2003[16]) compares 3 weeks immobilization with accelerated rehabilitation (no immobilization and range of motion exercises from the first postoperative day) after an arthroscopic Bankart repair using suture anchors. This study was performed in patients with a classic Bankart lesion who participated in sports for less than 5 hours per week. Both the patient and observer were blinded; patients were blinded by agreeing not to know which of the two rehabilitation programs was new, clinical assessment was performed by one doctor who was unaware of the study protocol. Results were evaluated with pain scores, range of motion (ROM), return to activities, patient satisfaction and three different shoulder specific scores at follow-up: the American Shoulder and Elbow Surgeons Shoulder index (ASES), the rating system of the University of California at Los Angeles (UCLA) and the Rowe score. Statistical analysis based on a power analysis and sample size calculation revealed no difference.

No significant difference was found between the conventional and accelerated rehabilitation group, indicating that immobilization might not be required and early controlled motion in patients is safe and promotes shoulder function as well as it decreases morbidity after 31 months.

The current practice in rehabilitation protocols, described in journals with a high impact factor are summarized in Table 5. Including 4 journals over 5 years, only 6 studies published their rehabilitation protocol in detail. Although all studies describe an initial period of immobilization, it ranges from 3 to 6 weeks, either using a standard sling (5 studies) or an immobilizer (1 study). Some authors allow ROM and/or strength exercises during immobilization, others start either passive range of motion (PROM), or active range of motion (AROM) exercises after immobilization. External rotation (ER) either starts on day 1, or is strictly forbidden for up to 4 weeks. Return to overhead activities, sports activities and throwing sports ranges from 3 months to 6 months. **C**onsecutive phases of rehabilitation following immobilization differ significantly.

The authors of the ASSET guideline state that there is a paucity of randomized controlled trials (RCT's) comparing rehabilitation protocols.[14] The guideline suggests immobilization during 4 weeks with a standard sling, together with PROM exercises from 0 to 6 weeks. From 6 to 12 weeks AROM exercises and rotator cuff strengthening is started and from 12 to 24 weeks, strength and endurance exercises are enhanced that eventually lead to return to activities such as work and sports, including overhead activities.[14]

Although a score of 49% on methodological quality might not seem high, the ASSET guideline for rehabilitation following arthroscopic anteroinferior capsulolabral repair of the shoulder is the most up to date guideline available.

In a mixed retrospective and prospective study, Damkjaer et al. (2014) compared the ASSET rehabilitation guideline with a standard rehabilitation protocol. He found no significant differences in patient outcomes in terms of ROM and costs. An overview of both protocols is presented in Table 7.

In other fields of Orthopaedic Surgery, rehabilitation protocols have been subject of interest, leading to innovative and evidence-based rehabilitation protocols.[20] This review illustrates that little evidence is available for the rehabilitation protocol following arthroscopic soft tissue repair in anteroinferior shoulder instability. More research is required to address this topic to optimize rehabilitation protocols.

CONCLUSION

Little evidence is available to suggest one postoperative rehabilitation protocol over another. Although based on limited evidence, the ASSET guideline (2010) is applicable.

REFERENCES

1. Bankart AS. Recurrent or habitual disolcation of the shoulder-joint. *BMJ*. 1923;2:1132-1133.
2. Owens BD, Harrast JJ, Hurwitz SR, Thompson TL, Wolf JM. Surgical trends in Bankart repair: an analysis of data from the American Board of Orthopaedic Surgery certification examination. *Am J Sports Med.* 2011;39:1865-1869.
3. Zhang AL, Montgomery SR, Ngo SS, Hame SL, Wang JC, Gamradt SC. Arthroscopic versus open shoulder stabilization: current practice patterns in the United States. *Arthroscopy*. 2014;30:436-443.
4. Gibson JC. (iii) Rehabilitation after shoulder instability surgery. *Current Orthopaedics*. 2004;18:197-209.
5. Leggin BG, Sheridan S, Eckenrode BJ. Rehabilitation after surgical management of the thrower's shoulder. *Sports Med Arthrosc.* 2012;20:49-55.
6. Lervick GN. Shoulder rehabilitation in glenohumeral instability. *Current Orthopaedic Practice*. 2013;24:79-83.
7. Paulos LE, Rosenberg TD, Beck CL. Postsurgical care for arthroscopic surgery of the knee and shoulder. *Orthop Clin North Am.* 1988;19:715-723.
8. Perez VE. Rehabilitation After Instability Surgery. *Operative Techniques in Orthopaedics.* 2008;18:79-83.
9. Rubin BD, Kibler WB. Fundamental principles of shoulder rehabilitation: conservative to postoperative management. *Arthroscopy*. 2002;18(9 Suppl 2):29-39.
10. Wilk KE, Reinold MM, Andrews JR. Postoperative treatment principles in the throwing athlete. *Sports Med Arthrosc Rev.* 2001;9(1):69-95.
11. Itoi E, Hatakeyama Y, Sato T, Kido T, Minagawa H, Yamamoto N, et al. Immobilization in external rotation after shoulder dislocation reduces the risk of recurrence. A randomized controlled trial. *J Bone Joint Surg Am.* 2007;89:2124-2131.
12. Schofer MD, Diehl A, Theisen C, Timmesfeld N, Heyse TJ, Fuchs-Winkelmann S, et al. Anterior shoulder instability--the current situation. *Z Orthop Unfall.* 2010;148:83-89.
13. Jerosch J, Drescher H, Steinbeck J, Lewejohann B. Current concepts in treatment of the unstable shoulder. Results of a countrywide survey. *Unfallchirurg.* 1994;97:64-68.
14. Gaunt BW, Shaffer MA, Sauers EL, Michener LA, McCluskey GM, Thigpen C. The American Society of Shoulder and Elbow Therapists' consensus rehabilitation guideline for arthroscopic anterior capsulolabral repair of the shoulder. *J Orthop Sports Phys Ther.* 2010;40:155-168.
15. Damkjaer L, Petersen T, Juul-Kristensen B. Is the American Society of Shoulder and Elbow Therapists' rehabilitation guideline better than standard care when applied to Bankart-operated patients? A controlled study. Clin Rehabil. 2015;29:154-164
16. Kim SH, Ha KI, Jung MW, Lim MS, Kim YM, Park JH. Accelerated rehabilitation after arthroscopic Bankart repair for selected cases: a prospective randomized clinical study. *Arthroscopy.* 2003;19:722-731.
17. Merk H, Pap G, Machner A, Nebelung W. Arthroscopic repair of the glenoid labrum using the 3-point knot technique. Early results with consideration to different postoperative immobilization time periods. *Z Orthop Ihre Grenzgeb.* 1996;134:546-552.
18. Morgan CD, Bodenstab AB. Arthroscopic Bankart suture repair: technique and early results. *Arthroscopy.* 1987;3:111-122.
19. Slobogean GP, Slobogean BL. Measuring shoulder injury function: common scales and checklists. *Injury.* 2011;42:248-252.
20. van Grinsven S, van Cingel RE, Holla CJ, van Loon CJ. Evidence-based rehabilitation following anterior cruciate ligament reconstruction. *Knee Surg Sports Traumatol Arthrosc.* 2010;18:1128-144.
21. Habermeyer P, Wiedemann E. Rational therapy of shoulder instability in athletes. *Chirurg.* 1989;60:765-773.
22. Elmlund AO, Kartus J, Rostgard-Christensen L, Sernert N, Magnusson L, Ejerhed L. A 7-year prospective, randomized, clinical, and radiographic study after arthroscopic Bankart reconstruction using 2 different types of absorbable tack. *Am J Sports Med*. 2009;37:1930-1937.
23. Hantes ME, Venouziou AI, Liantsis AK, Dailiana ZH, Malizos KN. Arthroscopic repair for chronic anterior shoulder instability: a comparative study between patients with Bankart lesions and patients with combined Bankart and superior labral anterior posterior lesions. *Am J Sports Med.* 2009;37:1093-1098.
24. Monteiro GC, Ejnisman B, Andreoli CV, de Castro Pochini A, Cohen M. Absorbable versus nonabsorbable sutures for the arthroscopic treatment of anterior shoulder instability in athletes: a prospective randomized study. *Arthroscopy.* 2008;24:697-703.
25. Archetti Netto N, Tamaoki MJ, Lenza M, dos Santos JB, Matsumoto MH, Faloppa F, et al. Treatment of Bankart lesions in traumatic anterior instability of the shoulder: a randomized controlled trial comparing arthroscopy and open techniques. *Arthroscopy.* 2012;28:900-908.
26. Nourissat G, Kilinc AS, Werther JR, Doursounian L. A prospective, comparative, radiological, and clinical study of the influence of the "remplissage" procedure on shoul-

der range of motion after stabilization by arthroscopic Bankart repair. *Am J Sports Med.* 2011;39:2147-2152.

27. Mohtadi NG, Chan DS, Hollinshead RM, Boorman RS, Hiemstra LA, Lo IK, et al. A randomized clinical trial comparing open and arthroscopic stabilization for recurrent traumatic anterior shoulder instability: two-year follow-up with disease-specific quality-of-life outcomes. *J Bone Joint Surg Am.* 2014;96:353-360.

Chapter 12

Summary, Answers to the questions, Discussion and Implications

SUMMARY AND ANSWERS TO THE QUESTIONS

Part I Societal impact of shoulder instability (chapter 2)

The societal costs for the conservative treatment of shoulder instability are substantial. We determined that the mean societal costs per patient per dislocation following non-operative treatment were € 6914, € 5284 and € 4061 for the first, second and third or following dislocation, respectively.

Societal costs include both productivity losses as well as healthcare expenses. Productivity losses result from absenteeism, presenteeism and the inability to perform unpaid work. Health care expenses include transportation by ambulance, visits to the hospital and visits to the physiotherapist.

The mean *productivity losses* per patient per dislocation (including patients with and without work) were € 3110, € 1866 and € 1543 for the first, second and third or consecutive dislocation respectively. **(Aim I)** Productivity losses were significantly higher in patients with other (chronic) disorders compared to patients without comorbid disorders (p 0.02). Other factors, such as the physical work load, the fact whether the dominant side was affected, the level of education or the patients gender did not influence productivity losses or healthcare utilization. Productivity losses are significantly lower after the second dislocation (mean difference - € 1969, 95% CI= -3680 to -939) and after the third dislocation (mean difference - € 2298, 95% CI= -4092 to -1288) compared to the first dislocation. **(Aim III)** One explanation could be that patients use their knowledge and expertise regarding the reduction and rehabilitation from previous episodes to cope with following episodes of shoulder instability. Patients for example might choose to reduce their dislocated shoulder themselves, which could result in less transportation by ambulance (15% of the patients used an ambulance following their second or third dislocation, compared to 27% following their first dislocation). Patients might also choose to restart physiotherapy exercises themselves, that were provided previously (the mean number of visits to the physiotherapist was approximately 5 after the third or following dislocation, compared to 10 after the first or second dislocation).

The mean costs associated with *health care utilization* are estimated € 3759, € 3267 and € 2424 after the first, the second and the third or following episode of shoulder instability. **(Aim II)** This includes transportation by ambulance, visits to the emergency department, the general practitioner, the outpatient clinic, the company doctor and the physiotherapist.

Part II Measurement instruments to evaluate treatment of

shoulder instability (chapter 3 - 5)

To evaluate the effect of treatment strategies, adequate measurement instruments are required. Both the Western Ontario Shoulder Instability Index (WOSI) and the Oxford Shoulder Instability Score (OSIS) are commonly used Patient Reported Outcome Measures (PROMs) for patients with shoulder instability. We translated and validated the WOSI and the OSIS in Dutch according to the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines. We validated both PROMs in a homogeneous population of patients with shoulder instability. The Internal consistency, the reliability, the measurement error expressed as the Smallest Detectable Change (SDC), the presence of floor- and ceiling effects, the construct validity and the responsiveness were assessed.

Regarding the WOSI, the Internal consistency was good, with a Cronbach's α ranging from 0.93 to 0.96 for all four subdomains. The reliability (test-retest) was excellent, with an ICC ranging from 0.88 to 0.92 for all subdomains. The SDC was 23 points on a scale of 0 -100 for the WOSI total, ranging from 23 to 28 for the subdomains. There were no floor- and ceiling effects. Regarding the construct validity 76% of the results were in accordance with the hypotheses, including a high correlation (0.82) with the Oxford Shoulder Instability Score and the Disability of the Arm, Shoulder and Hand assessment (0.81). Finally, the responsiveness was high. **(Aim IV)**

Regarding the OSIS, the Internal consistency was good, with a Cronbach's α of 0.88. The reliability was excellent, with an ICC of 0.87. The SDC was 9.0 on a scale of 0 -48. There were no floor- and ceiling effects. Regarding the construct validity 80% of the results were in accordance with the hypotheses, including a high correlation (0.82) with the WOSI. Finally, the responsiveness was high. **(Aim IV)**

When patients improve following an intervention, it is useful to know how to interpret these changed scores. In other words, when does a change in scores reflect an improvement that is clinically relevant for the patient? We calculated that an increase of approximately 12% (14.6 WOSI-points on a scale of 0-100 and 6 OSIS-points on a scale of 0-48) corresponds to a 'slightly improved' shoulder function. The 'slightly improved' An increase of approximately 25% (22.3 WOSI-points and 12.4 OSIS-points) corresponds to a 'much improved' shoulder function **(Aim VI)**.

PART III Surgical treatment strategies for shoulder instability (chapter 6 - 12)

To evaluate the optimal treatment in patients up to 18 years of age, we performed an evaluation of the literature comparing the redislocation rate in patients receiving operative and nonoperative treatment. All journals and all relevant articles were analyzed that discussed the treatment of shoulder instability in children and adolescents up to 18 years, including all instability patterns due to traumatic shoulder dislocation. Patients with atraumatic shoulder instability or patients with a dislocation due to neurological or neuromuscular disease or patients with a familial history of connective tissue pathology were excluded. According to the Oxford center for Evidence-Based Medicine, only level I to IV articles were included in our study. In total 293 of 411 shoulders (71,3%) that were treated nonoperative experienced a redislocation compared to 55 of 314 shoulders (17.5%) treated surgically. **(Aim VII)**

If surgical intervention is required, the arthroscopic Bankart repair is a soft tissue reconstruction that is commonly accepted as the initial surgical treatment. Nowadays, suture anchors are widely used for refixation of the capsulolabral complex to the glenoid rim in this procedure. The stabilizing effect of a surgical intervention should be long lasting. We evaluated the long-term results after the arthroscopic Bankart repair using suture anchors, with emphasis on both the redislocation risk as well as the shoulder function. With a follow-up including 97% of all patients we found that approximately 35% of the patients experienced recurrent shoulder instability, within 8-10 years postoperative. When about one third of the stabilized shoulders experiences at least one recurrent shoulder dislocation within this period, this should be considered high. Patients were more at risk when 1 or 2 anchors were used compared to 3 or 4 anchors, or in the presence of a Hill Sachs defect. The shoulder function was evaluated with PROMs, including the WOSI and the OSIS. The overall median scores at follow-up were high; 44 points for the OSIS (on a scale from 0-48) and 90 points for the WOSI (on a scale from 0-100), meaning good function. Only the WOSI and OSIS which are condition specific (instability) PROMs demonstrated a statistically significant difference in scores between patients with and without recurrent instability. The Simple Shoulder Test (SST), a PROM designed to measure a domain (the shoulder) could not demonstrate this difference. **(Aim VIII)**

The relatively high risk of recurrent instability, together with improving knowledge regarding the negative effect of bony defects on recurrent instability led to an increased popularity of bony reconstructions. This procedure is often referred to as the Bristow or Latarjet (Bristow-Latarjet) procedure, and is usually performed open instead of arthroscopically. Although various techniques have been described, most commonly the coracoid process is transferred from its origin to the eroded glenoid rim. When fixed to the rim, the graft restores the bony congruity of the glenohumeral joint. Moreover, the attached conjoined tendon will now serve as an anterior hammock for the humeral head when the arm is abducted.[54] Although the procedure offers a superior stabilizing effect compared to an arthroscopic soft tissue reconstruction, it is more extensive and has a higher complication risk. We provided a historical overview regarding the surgeons Walter Rowley Bristow and Michel Latarjet, including their original procedures and the subsequent adaptations that were developed to reduce the complication risk. Adaptations were categorized in the surgical approach, the graft positioning and fixation, the avoidance of nerve injuries and the introduction of arthroscopic techniques. **(Aim IX)**

To investigate if a bony reconstruction, such as the Bristow-Latarjet procedure, protects athletes that participate in collision sports from recurrent instability, we performed a systematic review of the literature. All journals and all relevant articles that evaluated any type of bony reconstructions in athletes were analyzed, with the exception of case-reports, systematic reviews, meta analyses, animal studies, biomechanical reports, letters to editors and instructional courses. Studies with a follow-up period of less than 2 years, or studies in which the absolute risk of recurrent instability could not be calculated with certainty were excluded. All studies were critically reviewed, based on among others their design, the lost to follow-up and follow-up period, the missing data and the analysis. Moreover, the quality of all included studies was assessed with the modified Coleman Score (CMS).

Based on 11 studies, the reported absolute risk for recurrent instability after a bony reconstruction varies between 0 – 15.8% for collision athletes, compared to 0 – 4.3% for noncollision athletes. Eight studies directly compare collision to noncollision athletes; 2 studies show no difference, 3 studies show a small decreased risk (-0.7 to -1.3%) for collision athletes and 3 studies show an increased risk (5.9 to 15.8%) for collision athletes. However, even the authors that described an increased risk of 15.8%, did not show a statistically significant difference (p 0.31).[5] Based on this evidence, we conclude that collision athletes might have a slight, but not statistically significant increased risk for recurrent instability compared to noncollision athletes after a bony reconstruction. **(Aim X)**

A bony reconstruction is associated with a considerable risk for complications.[19,20,31] Therefore, we assessed if collision athletes would benefit as much as noncollision athletes from a soft tissue reconstruction. For this purpose a systematic review of the literature was performed with the similar exclusion criteria compared to the previous study. Twenty studies were included: 4 studies reported on collision athletes only, 16 studies compared collision to noncollision athletes. Regarding the latter, 14 studies reported an increased redislocation rate for collision athletes compared to noncollision athletes (absolute risk difference varying from 0.4 to 28.6%), whereas two studies reported decreased rates (absolute risk difference of -6% and -2.4%). A combined analysis revealed that collision athletes have a statistically significant (p 0.001) increased risk of 10.1% (17.3% compared to 7.2%) to develop recurrent instability compared to noncollision athletes. **(Aim X)**

Finally, we evaluated the evidence regarding the postoperative rehabilitation protocols following the arthroscopic soft tissue reconstruction in a systematic review. The search includes all studies that compare different rehabilitation protocols. Inclusion criteria were patients with a mean age of 18-65 years, with primary or recurrent traumatic anterior shoulder instability, treated with an arthroscopic soft tissue repair, and a clear description of the rehabilitation program following surgery. Studies regarding multidirectional, posterior or voluntary instability and concomitant injuries such as a bony Bankart lesion, a humeral avulsion of the glenohumeral ligament (HAGL) or rotator cuff pathology during surgery were excluded.

Only 2 studies have compared rehabilitation protocols. One study from 1996 compares 1 or 2 weeks postoperative immobilization (accelerated) to 3 weeks immobilization (standard): patients in the accelerated group performed worse after 15 months, measured with the ROWE score. The second study from 2003 compares direct range of motion exercises without immobilization (accelerated) to 3 weeks of immobilization (standard): patients in the accelerated group were more satisfied after 31 months. They experienced less pain after 6 weeks and regained external rotation and their level of activity faster.

This implies that little evidence is available to suggest one rehabilitation protocol over another. Nevertheless, the American Society of Shoulder and Elbow Therapists' (ASSET) Consensus formulated the ASSET guideline in 2010, which is based on basic science and the best available evidence, combined with expert opinions. A second search was performed to evaluate the current best practice in rehabilitation protocols in the recent and leading literature. The four Orthopaedic Journals with the highest impact factor (American Journal of Sports Medicine, the Journal of Bone and Joint Surgery America, Physical Therapy and Arthroscopy) were searched by hand for eligible articles between January 1st 2010 and 31st 85 of December 2014, based on the search terms 'arthroscopic' AND 'Bankart' AND 'repair' AND 'rehabilitation'. This resulted in 6 recent studies. All describe an initial period of immobilization, ranging from 3 to 6 weeks. Some authors allowed ROM and/or strength exercises during immobilization, while others start either passive range of motion (PROM), or active range of motion (AROM) exercises after immobilization. External rotation (ER) either started on day 1, or was strictly forbidden for up to 4 weeks. Returning to overhead activities, sport activities and throwing sports ranged from 3 to 6 months. Consecutive phases of rehabilitation following immobilization differed significantly. These considerable differences and the lack of evidence illustrate the opportunity for future research to identify the optimal postoperative rehabilitation protocol. **(Aim XI)**

DISCUSSION

Shoulder instability has a considerable impact on a patients' daily life. It can cause acute pain and continuous insecurity regarding someone's shoulder.

A traumatic shoulder dislocation can prelude recurrent episodes of instability, due to structural changes in the shoulder joint. Not only does each episode of instability cause pain and insecurity, it can also influence sports participation and work. This especially accounts for those who participate in contact or collision sports, as they have a two to three times increased risk to develop recurrent instability, compared to noncollision athletes.[20,33,53]

In 2015, members of the Dutch Orthopaedic Society (Nederlandse Orthopaedische Vereniging) choose to prioritize research regarding the optimal treatment for first time shoulder dislocations, in order to improve value based patient care in their daily practice.[2] This illustrates the fact that the optimal treatment strategy for individual patients remains a challenge.

Variation in today's practice was assessed by an international survey performed in 2014 that was completed by 197 attendants from 46 countries at an international meeting. It reveals that surgeons perform surgery in 51% of the patients that they treat, and use 25% (median, range 10-85%) of glenoid bone loss as a cut off for when to perform a bony repair.[51]

Because the optimal treatment strategy for shoulder instability depends on several factors, the optimal treatment strategy is difficult to address with a single answer. Factors that should be taken into consideration include patient (skeletal) age, the presence and the degree of bony defects, the type of work and sports participation, cosmetics and the patients' preferences.

This thesis was performed to enhance knowledge regarding shoulder instability and its optimal surgical treatment strategy. To evaluate the societal impact of shoulder instability, we first aimed to estimate the societal costs when shoulder instability is treated nonoperative. Second, we aimed to validate and analyze measurement instruments that are used to evaluate the effect of treatment strategies. Finally, we aimed to evaluate the results of surgical treatment for specific patient populations.

Part I The societal costs of treatment for shoulder instability

The current global economic conditions and the increasing life expectancy cause the public debate to focus on societal costs of diseases, physical impairment and their therapies. In this perspective, we aimed to estimate the societal costs for the nonoperative treatment of shoulder instability. This could enable a comparison between the operative and nonoperative treatment based on the productivity losses and in-hospital costs.

In *chapter 2* we found that patients who are treated nonoperative experience approximately 20 days of work loss (8 days absenteeism and 12 days presenteeism), much less compared to 80 days (2.73 months) of work loss when patients are treated surgically (not specified for absenteeism or presenteeism). [29] From the perspective of productivity losses, initial nonoperative treatment is arguable.

However, a direct economic comparison between surgical and nonoperative treatment is difficult because multiple factors should be taken into consideration, some of which are different between countries, cities and hospitals. The costs of healthcare utilization vary as well. The following comparison is based on the available and current knowledge and the local situation at the Onze Lieve Vrouwe Gasthuis (OLVG) in Amsterdam in 2015. The in-hospital costs for the nonoperative treatment of shoulder instability (including 1 visit to the emergency department, a pre- and post-reduction X-ray, 2 visits to the outpatient clinic and a MRI-scan) are on average € 597, compared to € 2627 and € 4448 on average when a patient is treated with surgery in daycare or stays overnight. The latter includes an identical work-up as the nonoperative treatment. It should be noted that the out of hospital medical costs, such as transportation by ambulance, visits to the general practitioner, the company doctor, the physiotherapist, the manual therapist, etc. lack for the surgical treatment and can thus not be taken into account in this comparison. Moreover, when shoulder instability is treated nonoperative both healthcare utilization and productivity losses are lower after the second and after the third dislocation compared to the first dislocation. It is unknown what these costs are for patients who have been treated surgically.

With our current knowledge and from a solely economic perspective, including in-hospital healthcare utilization and productivity losses, the nonoperative treatment of shoulder instability would be superior to the surgical treatment. This comparison is however based on incomplete data, because out-of-hospital healthcare (e.g. visits to the physical therapist) has not been taken into account for patients who are treated surgically. However, based on a theoretical Markov model including several scenarios, one previous study calculated that primary arthroscopic stabilization would be superior to the nonoperative treatment from a cost-effective perspective for patients with a fist-time anterior shoulder dislocation.[11,28]

Although it is informative to know the economic impact of treatment strategies, economic conditions and costs can change over time. Moreover, as is stated by the Dutch oath of Hippocrates 'I prioritize the patients' wellbeing and I will respect his opinion' ('ik stel het belang van de patiënt voorop en eerbiedig zijn opvattingen')[55], we should strive for the best clinical outcome for our patients.

Part II Evaluation of measurement instruments to evaluate shoulder instability

To evaluate which treatment strategy is best for our patients, adequate measurement instruments are required.

Because the aim of our treatment is to obtain a stable shoulder without compromising its function, stability and function are often evaluated as primary outcome parameters. Evaluation of the *stability* can be done with a single question; 'did you experience recurrent instability, yes or no?'. However, evaluation of the shoulder *function* requires more extensive instruments. The shoulder function can be assessed by 1) physical examination including the range of motion and muscle strength, or 2) with clinician-based outcome scores that are completed by the doctor, such as the Constant-Murley (CM) score, or 3) with Patient Reported Outcome Measurements (PROMs). The latter have gained recognition as they reflect the patients' perception of functioning in daily life without interpretation by someone else. This is important, as doctors and patients don't always agree, while the patients' experience and opinion should be central. This makes PROMs a potentially suitable instrument for the evaluation of the shoulder function. PROMs are increasingly used in clinical practice and research; one recent example is the implementation of PROMs in the national register of shoulder implants (LROI) in 2015.[1]

At least twenty-five scales, both PROMs as well as clinician-based are used to evaluate the general shoulder function.[39] PROMs can focus on general health, a physical domain or body part (e.g. the shoulder), or a specific condition or disease (e.g. instability). Only three PROMs are completely self-administered and specifically designed to for patients with shoulder instability. These are the Western Ontario Shoulder Instability Index (WOSI)[27], the Oxford Shoulder Instability Score (OSIS)[12] and the Melbourne Instability Shoulder Score (MISS).[50] The WOSI and OSIS are most frequently used in the literature, the WOSI was previously validated in Italian[6], German[15,23], Swedish[41] and Japanese.[22]

Before measurement instruments can be safely used in the Dutch population, they should be translated and validated in their target patient population. In *chapter 3 and 4* we translated and validated the WOSI and OSIS in Dutch and assessed their measurement properties in patients with shoulder instability. We found that both PROMs have good internal consistency, excellent reliability (test-retest), good construct validity and have high responsiveness. Neither one has floor- or ceiling effects.

To interpret change in scores of PROMs, it is important to know the thresholds that reflect a clinical relevant change, also known as the Minimal Important Change (MIC). In *chapter 5* we described that the MIC for the WOSI is 22 points (on a scale of 0 to 100) and the MIC for the OSIS is 12 points (on a scale of 0 to 48).

Change in scores should be interpreted in relation to the smallest change that can be detected beyond the measurement error in individual patients, the Smallest Detectable Change (SDC).[13,48] Ideally, the measurement error (SDC) should be smaller than the MIC of the same instrument to be 95% sure that a change in an individual patient as large as the MIC is not due to measurement error.[43]

We calculated that the SDC is 23.0 points for the WOSI and 9.0 points for the OSIS.[45,47] This means that individual patients should improve at least 23.0 and 9.0 points respectively to ensure (with 95% confidence) that their change is not a result of the measurement error. Regarding the WOSI, patients that noted a 'slightly improved' shoulder function improved 14.6 points on average: not enough to distinguish from the measurement error. Moreover, patients that noted a 'much improved' shoulder function improved 22.3 points on average: not enough either to distinguish from the measurement error (although it is a very small difference of 0.7 points (23.0 – 22.3) on scale of 0-100). The interpretation of changed scores in the WOSI in individual patients should therefore be considered with caution. Regarding the OSIS, patients that reported a 'slightly improved' shoulder function improved 6.0 points on average: not enough to distinguish from the measurement error. Patients that reported a 'much improved' shoulder function improved 12.4 points on average, which can be distinguished from the SDC (9.0 points). The OSIS is thus better capable to distinguish a relevant change from the measurement error in individual patients.

Based on our findings, we conclude that both the WOSI and OSIS are suitable PROMs for evaluation of the shoulder function in Dutch patients with shoulder instability. The WOSI has the advantage that it has been validated in other languages, which indicates that it is more widely accepted. However, the WOSI has the disadvantage to include 21 questions and thus potentially burdens the patient more, especially when combined with other PROMs. Moreover, because a 'much improved' shoulder function (22.3 points change on average) cannot be distinguished from the measurement error with 95% confidence, it should be used with caution in individual patients. The OSIS' advantage is that it contains less questions and that a 'much improved' shoulder function (9.0 points change on average) can be distinguished well from the smallest detectable change. The OSIS was not designed to cover subdomains and was not validated in other languages, which makes it less useful for comparison in international studies.

An interesting development in the field of PROMs is the introduction of the Patient Reported Outcome Measurement Information System (PROMIS) in 2004, which aims to improve quality and limit the patients' burden as a result of testing. PROMIS is a dynamic computerized database of questions, developed with financial support of the US National Institutes of Health (NIH).[8] These are item banks that contain a large number of questions measuring a particular construct such as physical functioning, based on existing questionnaires. Item banks form the basis for computer adaptive testing (CAT), where after an initial first question, the computer selects questions, based on answers to previous questions. With this efficient and patient-friendly way of measuring, patients need to complete only 5-7 questions to get a reliable score, instead of 20-30 questions with traditional questionnaires.

Because PROMIS is a generic system (i.e. not designed for a specific condition, such as instability) it can be used for all patients with shoulder complaints.

The fact that PROMIS is user friendly and the fact that it can be used for multiple shoulder conditions make it a valuable instrument for the future evaluation. However, before PROMIS can be implemented into our daily practice, these item banks should be validated and compared to current PROMs for patients with all types of shoulder problems, including shoulder instability.

Part III Surgical treatment strategies for shoulder instability

Nowadays, surgical techniques can be generally subdivided into soft tissue repairs that restore the capsulolabral defect (often referred to as the Bankart repair) and bony reconstructions that restore the glenoid erosion (often referred to as the Bristow, Latarjet or Bristow-Latarjet technique).

The Bristow-Latarjet procedure refers to a surgical technique that was simultaneously described by Walter Rowley Bristow and Michel Latarjet in 1954. Although this technique is often referred to as the Bristow-Latarjet procedure, the original procedures differ. The slightly different technique results in different biomechanical effects as was observed in a recent biomechanical cadaveric study. In the setting of substantial glenoid osseous deficiency, however, the Latarjet reconstruction is superior to the Bristow procedure in its ability to restore joint stability. Therefore, in terms of its biomechanical efficacy, some authors argue that the Latarjet procedure may be preferred.[17] Since their first description, ongoing insight and the introduction of new instruments and implants have facilitated adaptations to the original procedure that ought to improve the outcome or reduce the risk of complications. Modifications have been suggested to the approach (e.g. a horizontal, vertical, combined or no split of the subscapular tendon), the graft positioning and fixation (e.g. the congruent arc), the avoidance of nerve injuries (e.g. 2 screw fixation to prevent graft rotation that could injure the musculocutaneous nerve) and finally the introduction of arthroscopic techniques. We would recommend surgeons to be familiar with the subsequent modifications and use experiences from the past for their clinical practice and future improvement.

Treatment can be tailored to the patients' individual situation and preferences. Like the adult population with shoulder instability, pediatric patients can be treated operative or nonoperative. Several studies report a high rate of recurrent instability following nonoperative treatment.[29,30,37,38] And while some studies report satisfactory results following surgical treatment[7,26], a survival rate of only 49% is observed within 5 years postoperative.[42] To evaluate the optimal treatment strategy for patients aged 18 years or younger with shoulder instability, we compared the surgical and nonoperative treatment. Based on 15 level I to IV studies, we found that 71,3% (293 of 411 shoulders) of the shoulders that were treated nonoperative experienced recurrent instability, compared to 17.5% (55 of 314 shoulders) that were treated surgically.

Taking into account the limitations to this study (e.g. the wide range of age in the patient populations, comparison of different forms of surgical and nonoperative techniques and variation in methodological quality), we conclude that surgical treatment in young patients provides superior results compared to nonoperative treatment regarding recurrent instability. When treating patients up to 18 years old with shoulder instability, this should be taken into consideration.

A more recent analysis regarding 5 of the same articles [10,14,30,32,37] concluded that male children aged 14 years and over had the greatest risk of recurrent shoulder instability following a first-time shoulder dislocation.

Surgical treatment should ideally have a long lasting effect. For this reason, we evaluated the long-term results (i.e. 8 to 10 years) after the arthroscopic Bankart repair with suture anchors, a technique that is commonly used. We found that as much as 35% of the patients experienced recurrent instability within 10 years postoperatively, including patients who require closed reduction, as well as patients with 'subjective instability' or 'subluxations'. Subluxations refer to the sense of instability while the shoulder spontaneously pops back. We argue that subluxations are an outcome parameter that is equally important for patients.[46] When only 'true dislocations' are counted as failures, the recurrence rate for patients who are treated with an arthroscopic anchor repair varies between 6% to 25%, in the literature.[9,21] Moreover, ongoing modifications of the surgical technique[3,18] and the introduction of new instruments and implants might have an effect on the long-term results. Although not statistically significant, we found that patients who have been operated with 2 anchors compared to 3 or 4 anchors (p 0.06) and patients with a Hill-Sachs defect (p 0.07) tend to have an increased risk to experience recurrent instability. Based on this study, we advise to carefully evaluate bony defects, and to consider using 3 anchors minimum when treating patients with an arthroscopic Bankart repair. One study that reports successful stabilization with only 1 anchor had a follow-up of only 4 years.[52] Another study identified the use of more anchors as a risk factor for osteoarthritis 13 years postoperatively; however, the same study also identified a higher number of preoperative dislocations as risk factor. The latter could induce cartilaginous damage and deteriorate the glenoidal rim, thus requiring more anchors for its repair.[36]

Despite the degenerative changes, the clinical results as measured with the Constant score are excellent.

Moreover, considering the natural course of dislocation arthropathy (up to 56% after 25 years following nonoperative treatment[24]), the soft tissue repair neither seems to expose patients to an increased risk, nor to protect against joint degeneration.[36]

Rugby players are collision athletes and are high demanding regarding their shoulder. With a peak shoulder force of approximately 2000N measured during a tackle[44] and approximately 221 tackle events per game[16], they are presumably at higher risk to develop recurrent instability compared to noncollision athletes. Contrary to ballet dancers who might benefit best from a stabilizing procedure that least compromises their range of motion, collision athletes presumably benefit most from a procedure that offers the best results regarding recurrent instability. We evaluated whether collision athletes can continue their sport safely after a bony reconstruction, without an increased risk of recurrent instability. Based on 11 studies, the reported absolute risk for recurrent instability after a bony reconstruction varies between 0 to 15.8% for collision athletes, compared to 0 to 4.3% for noncollision athletes. Eight studies directly compare collision to noncollision athletes; 2 studies show no difference, 3 studies show a small decreased risk (-0.7 to -1.3%) for collision athletes and 3 studies show an increased risk (5.9 to 15.8%) for collision athletes. However, even the authors that described an increased risk of 15.8%, did not show a statistically significant difference (p 0.31).[5] Based on this evidence, we conclude that collision athletes might have a slight, but not statistically significant increased risk for recurrent instability compared to noncollision athletes after a bony reconstruction.

Because the downside of bony reconstructions is their increased risk for complications, such as screw migration or breakage, bony nonunion, graft absorption and a potential higher risk of osteoarthritis on the long term, we performed a similar review of the literature to asses recurrent instability following a Bankart repair. Twenty studies were included: 4 studies reported on collision athletes only, 16 studies compared collision to noncollision athletes. Regarding the latter, 14 studies reported an increased redislocation rate for collision athletes compared to noncollision athletes (absolute risk difference varying from 0.4 to 28.6%), whereas two studies reported decreased rates (absolute risk difference of -6% and -2.4%). A combined analysis revealed that collision athletes have a statistically significant (p 0.001) increased risk of 10.1% (17.3% compared to 7.2%) to develop recurrent instability compared to noncollision athletes.

When treating collision athletes for shoulder instability, we would recommend doctors to consider the increased risk for recurrent instability after a soft tissue repair; a bony reconstruction provides more stability.[31] Although it was long thought that bony reconstructions have the highest risk (6% to 59%) to develop osteoarthritis[19,31], the risk of osteoarthritis following an arthroscopic soft tissue repair with suture anchors is reported 26% after 7.3 years[21] and op to 69% after 13 years.[35]

Whereas we only identified the presence of a Hill Sachs defect, the number of anchors was used during the surgical repair and the participation in collision sports as risk factors for recurrent instability, the Instability Severity Index Score (ISIS) score is nowadays widely used as a prognostic tool to predict recurrent instability after an arthroscopic Bankart repair.[4] The score is based on the age at surgery (≤20 years vs. >20 years), the level of sports participations (competitive vs. recreational), the type of sport (contact/forced abduction and external rotation vs. other) clinical examination (hyperlaxity vs. no hyperlaxity), the presence of Hill-Sachs lesion (yes vs. no) and the presence of glenoid contour loss (yes vs. no), which can be measured on 3D-CT or MRI.[25] The combined score could predict the risk of recurrent postoperative instability; initially a score of ≤ 6 points equals an acceptable recurrence risk of 10% after an arthroscopic soft tissue repair, whereas a score of > 6 points equals an unacceptable recurrence risk of 70% and should be advised to undergo a bony reconstruction (i.e. Latarjet procedure). The ISIS score has been proven to be reliable with an ICC of 0.933.[40] More recently it was suggested to adjust the threshold to a combined score of 4; with a 70% risk of failure if the ISIS was ≥4, as opposed to a 4% risk of failure if the ISIS was <4.[34] Based on these findings, the ISIS score could be used as a guideline when considering an arthroscopic soft tissue repair versus a bony reconstruction.

Arguably one of the most important phases in the surgical treatment of instability is the postoperative rehabilitation. In orthopaedic surgery, the ultimate goal of rehabilitation is often to return to the preinjury level of performance, including motion and strength. In other orthopaedic fields, such as ligamentous reconstructions of the knee, several studies focus on the optimal rehabilitation process. Since many different rehabilitation protocols are described for the shoulder instability, we tried to identify the evidence on which these strategies are based. Although the shoulder, compared to the knee, is a non weight-bearing joint that can be easily immobilized, we were surprised to find that only 2 studies have compared rehabilitation protocols. The lack of evidence leads to a wide range of rehabilitation protocols that was published in high impact journals. With a hand search based the terms 'arthroscopic', 'Bankart', 'repair' and 'rehabilitation' we identified 6 studies that were published between 2010 and 2014 in the orthopaedic journals with the highest impact factor. All studies describe different rehabilitation protocols. Whereas all describe an initial period of immobilization, the immobilization ranges from 3 to 6 weeks. Some authors allow ROM and/or strength exercises during immobilization, others start either passive range of motion (PROM), or active range of motion exercises after immobilization. External rotation (ER) either starts on day 1, or is strictly forbidden for up to 4 weeks. Return to overhead activities, sports activities and throwing sports ranges from 3 months to 6 months. The considerable differences illustrate the need for future research to identify the optimal rehabilitation strategy, following the presently used stabilizing surgical techniques.

In 2010 the American Society of Shoulder and Elbow Therapists' (ASSET) Consensus formulated the ASSET guideline, which is based on basic science and the best available evidence, combined with expert opinions. This guideline (2010) is based on the available evidence and experiences from doctors as well as physiotherapists and is currently the most up to date guideline available. Until more evidence regarding the postoperative rehabilitation protocol is available, this guideline could be a practical tool.

IMPLICATIONS FOR CLINICAL PRACTICE

- Both the Dutch WOSI and OSIS are suitable PROMs for research purposes to analyze the treatment effect in the Dutch population with shoulder instability.
- Only a change beyond 6 OSIS-points (on a scale of 0-48) and 14.6 WOSI-points (on a scale of 0-100) can be designated as a relevant change for patients.
- Patients undergoing an arthroscopic soft tissue repair should be informed regarding a risk of recurrent instability up to 35% after 10 years.
- Surgical treatment in patients aged 18 years or younger provides superior results compared to conservative treatment regarding recurrent instability.

RECOMMENDATIONS FOR FUTURE STUDIES

- To validate PROMIS for shoulder specific conditions, including shoulder instability.
- To perform a randomized controlled trial to compare optimal postoperative rehabilitation protocol after shoulder stabilizing surgery.
- To perform prospective cohort studies comparing treatment strategies in specific populations, which can lead to personalized shoulder care.

REFERENCES

1. Advies Werkgroep Schouder Elleboog - PROM Schouder-prothesiologie - besluitvormend ALV NOV. 6-2-2015.
2. Agena Zorgevaluatie The Netherlandse; *Op weg naar Value Based Patiëntenzorg*. Nederlandse Orthopaedische Vereniging (NOV), 2015.
3. Alexander S, Wallace AL. The "flying swan" technique: a novel method for anterior labral repair using a tensioned suture bridge. *Arthrosc Tech.* 2014;3:e119-e122.
4. Balg F, Boileau P. The instability severity index score. A simple pre-operative score to select patients for arthroscopic or open shoulder stabilisation. *J Bone Joint Surg Br.* 2007;89:1470-1477.
5. Bessiere C, Trojani C, Pelegri C et al. Coracoid bone block versus arthroscopic Bankart repair: a comparative paired study with 5-year follow-up. *Orthop Traumatol Surg Res.* 2013;99:123-130.
6. Cacchio A, Paoloni M, Griffin SH et al. Cross-cultural adaptation and measurement properties of an Italian version of the Western Ontario Shoulder Instability Index (WOSI). *J Orthop Sports Phys Ther.* 2012;42:559-567.
7. Castagna A, Delle RG, Borroni M et al. Arthroscopic stabilization of the shoulder in adolescent athletes participating in overhead or contact sports. *Arthroscopy.* 2012;28:309-315.
8. Cella D, Gershon R, Lai JS et al. The future of outcomes measurement: item banking, tailored short-forms, and computerized adaptive assessment. *Qual Life Res.* 2007;16 Suppl 1:133-141.
9. Chapus V, Rochcongar G, Pineau V et al. Ten-year follow-up of acute arthroscopic Bankart repair for initial anterior shoulder dislocation in young patients. *Orthop Traumatol Surg Res.* 2015;101:889-893.
10. Cordischi K, Li X, Busconi B. Intermediate outcomes after primary traumatic anterior shoulder dislocation in skeletally immature patients aged 10 to 13 years. *Orthopedics.* 2009;32.
11. Crall TS, Bishop JA, Guttman D et al. Cost-effectiveness analysis of primary arthroscopic stabilization versus non-operative treatment for first-time anterior glenohumeral dislocations. *Arthroscopy.* 2012;28:1755-1765.
12. Dawson J, Fitzpatrick R, Carr A. The assessment of shoulder instability. The development and validation of a questionnaire. *J Bone Joint Surg Br.* 1999;81:420-426.
13. de Vet HC, Terwee CB, Knol DL et al. When to use agreement versus reliability measures. *J Clin Epidemiol.* 2006;59:1033-1039.
14. Deitch J, Mehlman CT, Foad SL et al. Traumatic anterior shoulder dislocation in adolescents. *Am J Sports Med.* 2003;31:758-763.
15. Drerup S, Angst F, Griffin S et al. Western Ontario shoulder instability index (WOSI): translation and cross-cultural adaptation for use by German speakers. *Orthopade.* 2010;39:711-718.
16. Fuller CW, Brooks JH, Cancea RJ et al. Contact events in rugby union and their propensity to cause injury. *Br J Sports Med.* 2007;41:862-867.
17. Giles JW, Degen RM, Johnson JA et al. The Bristow and Latarjet procedures: why these techniques should not be considered synonymous. *J Bone Joint Surg Am.* 2014;96:1340-1348.
18. Giles JW, Puskas GJ, Welsh MF et al. Suture anchor fixation of bony Bankart fractures: comparison of single-point with double-point "suture bridge" technique. *Am J Sports Med.* 2013;41:2624-2631.
19. Griesser MJ, Harris JD, McCoy BW et al. Complications and re-operations after Bristow-Latarjet shoulder stabilization: a systematic review. *J Shoulder Elbow Surg.* 2013;22:286-292.
20. Harris JD, Romeo AA. Arthroscopic management of the contact athlete. *Clin Sports Med.* 2013;32:709-730.
21. Harris JD, Gupta AK, Mall NA et al. Long-term outcomes after Bankart shoulder stabilization. *Arthroscopy.* 2013;29:920-933.
22. Hatta T, Shinozaki N, Omi R et al. Reliability and validity of the Western Ontario Shoulder Instability Index (WOSI) in the Japanese population. *J Orthop Sci.* 2011;16:732-736.
23. Hofstaetter JG, Hanslik-Schnabel B, Hofstaetter SG et al. Cross-cultural adaptation and validation of the German version of the Western Ontario Shoulder Instability index. *Arch Orthop Trauma Surg.* 2010;130:787-796.
24. Hovelius L, Saeboe M. Neer Award 2008: Arthropathy after primary anterior shoulder dislocation--223 shoulders prospectively followed up for twenty-five years. *J Shoulder Elbow Surg.* 2009;18:339-347.
25. Huijsmans PE, Haen PS, Kidd M et al. Quantification of a glenoid defect with three-dimensional computed tomography and magnetic resonance imaging: a cadaveric study. *J Shoulder Elbow Surg.* 2007;16:803-809.
26. Jones KJ, Wiesel B, Ganley TJ et al. Functional outcomes of early arthroscopic bankart repair in adolescents aged 11 to 18 years. *J Pediatr Orthop.* 2007;27:209-213.
27. Kirkley A, Griffin S, McLintock H et al. The development and evaluation of a disease-specific quality of life measurement tool for shoulder instability. The Western

Ontario Shoulder Instability Index (WOSI). *Am J Sports Med* .1998;26:764-772.
28. Koffijberg H. Regarding: "Operative versus nonoperative treatment after primary traumatic anterior glenohumeral dislocation: expected-value decision analysis": appropriate assessment of uncertainty. *J Shoulder Elbow Surg.* 2012;21:e21-e23.
29. Kraus TM, Freude T, Fiedler S et al. Incapacity of work after arthroscopic Bankart repair. *Arch Orthop Trauma Surg.* 2015;135(10):1429-1436.
30. Lampert C, Baumgartner G, Slongo T et al. Traumatic shoulder dislocation in children and adolescents. *Eur J Trauma.* 2003;29:375-378.
31. Longo UG, Loppini M, Rizzello G et al. Latarjet, Bristow, and Eden-Hybinette Procedures for Anterior Shoulder Dislocation: Systematic Review and Quantitative Synthesis of the Literature. *Arthroscopy.* 2014;30:1184-1211
32. Marans HJ, Angel KR, Schemitsch EH et al. The fate of traumatic anterior dislocation of the shoulder in children. *J Bone Joint Surg Am.* 1992;74:1242-1244.
33. Petrera M, Dwyer T, Tsuji MR et al. Outcomes of arthroscopic Bankart repair in collision versus noncollision athletes. *Orthopedics.* 2013;36:e621-e626.
34. Phadnis J, Arnold C, Elmorsy A et al. Utility of the Instability Severity Index Score in Predicting Failure After Arthroscopic Anterior Stabilization of the Shoulder. *Am J Sports Med.* 2015;43:1983-1988.
35. Plath JE, Aboalata M, Seppel G et al. Prevalence of and Risk Factors for Dislocation Arthropathy: Radiological Long-term Outcome of Arthroscopic Bankart Repair in 100 Shoulders at an Average 13-Year Follow-up. *Am J Sports Med.* 2015;43:1084-1090.
36. Plath JE, Feucht MJ, Saier T et al. Sporting Activity After Arthroscopic Bankart Repair for Chronic Glenohumeral Instability. *Arthroscopy.* 2015;31:1996-2003.
37. Postacchini F, Gumina S, Cinotti G. Anterior shoulder dislocation in adolescents. *J Shoulder Elbow Surg.* 2000;9:470-474.
38. Roberts SB, Beattie N, McNiven ND et al. The natural history of primary anterior dislocation of the glenohumeral joint in adolescence. *Bone Joint J.* 2015;97-B:520-526.
39. Rouleau DM, Faber K, MacDermid JC. Systematic review of patient-administered shoulder functional scores on instability. *J Shoulder Elbow Surg.* 2010;19:1121-1128.
40. Rouleau DM, Hebert-Davies J, Djahangiri A et al. Validation of the instability shoulder index score in a multicenter reliability study in 114 consecutive cases. *Am J Sports Med.* 2013;41:278-282.
41. Salomonsson B, Ahlstrom S, Dalen N et al. The Western Ontario Shoulder Instability Index (WOSI): validity, reliability, and responsiveness retested with a Swedish translation. *Acta Orthop.* 2009;80:233-238.
42. Shymon SJ, Roocroft J, Edmonds EW. Traumatic anterior instability of the pediatric shoulder: a comparison of arthroscopic and open bankart repairs. *J Pediatr Orthop.* 2015;35:1-6.
43. Terwee CB, Roorda LD, Knol DL et al. Linking measurement error to minimal important change of patient-reported outcomes. *J Clin Epidemiol.* 2009;62:1062-1067.
44. Usman J, McIntosh AS, Frechede B. An investigation of shoulder forces in active shoulder tackles in rugby union football. *J Sci Med Sport.* 2011;14:547-552.
45. van der Linde JA, van Kampen DA, van Beers LWAH et al. The Oxford Shoulder Instability Score; validation in Dutch and first time assessment of its smallest detectable change. *J Orthop Surg Res.* 2015;10:146.
46. van der Linde JA, van Kampen DA, Willems JW. How should we define failure after surgical shoulder stabilization? *Arthroscopy.* 2013;29:1602.
47. van der Linde JA, Willems WJ, van Kampen DA et al. Measurement properties of the Western Ontario Shoulder Instability Index in Dutch patients with shoulder instability. *BMC Musculoskelet Disord.* 2014;15:211.
48. van Kampen DA, Willems WJ, van Beers LW et al. Determination and comparison of the smallest detectable change (SDC) and the minimal important change (MIC) of four-shoulder patient-reported outcome measures (PROMs). *J Orthop Surg Res* 2013;8:40.
49. Wagner KT, Jr., Lyne ED. Adolescent traumatic dislocations of the shoulder with open epiphyses. *J Pediatr Orthop.* 1983;3:61-62.
50. Watson L, Story I, Dalziel R et al. A new clinical outcome measure of glenohumeral joint instability: the MISS questionnaire. *J Shoulder Elbow Surg.* 2005;14:22-30.
51. Weel H. et al. International survey and surgeon's preferences in diagnostic work-up towards treatment of anterior shoulder instability. Accepted for publication in *Arch Orthop Trauma Surg*, 2016.
52. Witney-Lagen C, Perera N, Rubin S et al. Fewer anchors achieves successful arthroscopic shoulder stabilization surgery: 114 patients with 4 years of follow-up. *J Shoulder Elbow Surg.* 2014;23:382-387.
53. Yamamoto N, Kijima H, Nagamoto H et al. Outcome of Bankart repair in contact versus non-contact athletes. *Orthop Traumatol Surg Res.* 2015;101:415-419.
54. Yamamoto N, Muraki T, An KN et al. The stabilizing mechanism of the Latarjet procedure: a cadaveric study. *J Bone Joint Surg Am.* 2013;95:1390-1397.
55. Nederlandse artseneed. Houten: Drukkerij Badoux, 2003.

Appendices

APPENDIX 1.

THE WESTERN ONTARIO SHOULDER INSTABILITY INDEX (WOSI) IN DUTCH.

Aanwijzingen voor de patiënt

In de onderdelen A, B, C en D wordt u verzocht vragen te beantwoorden in het onderstaande vragenformulier. Beantwoord iedere vraag door op de horizontale lijn een schuine streep ("/") te plaatsen.

LET OP: Voorbeeld

1. Als u aan het linker uiteinde van de lijn een schuine streep ("/") plaatst, geeft u aan dat u geen pijn heeft.

geen pijn /____/ *extreme pijn*

2. Als u aan het rechteruiteinde van de lijn een schuine streep ("/") plaatst, geeft u aan dat u extreme pijn heeft.

geen pijn /____/ *extreme pijn*

3. Houd ook rekening met het volgende:

hoe verder u de schuine streep naar rechts plaatst ("/"), hoe sterker u het betreffende symptoom ervaart.

hoe verder u de schuine streep naar links plaatst ("/"), hoe minder u het betreffende symptoom ervaart.

plaats de schuine streep ("/") s.v.p. niet buiten de streepjes die de uiteinden van de lijn aangeven.

In deze vragenlijst wordt u verzocht aan te geven in hoeverre u een bepaald symptoom de afgelopen week hebt ervaren in verband met uw problematische schouder. Als u niet weet om welke schouder het gaat of als niet alles duidelijk is, wordt u verzocht navraag te doen voordat u de vragenlijst invult.

Als u om welke reden dan ook een vraag niet goed begrijpt, lees dan de toelichting aan het eind van de vragenlijst. Plaats vervolgens de schuine streep ("/") op de juiste plek op de horizontale lijn.

Als een bepaalde vraag niet op u van toepassing is of als het betreffende symptoom zich de afgelopen week niet heeft voorgedaan, probeert u de vraag dan te beantwoorden op basis van een zo goed mogelijke schatting. U mag de vraag niet overslaan.

ONDERDEEL A: FYSIEKE SYMPTOMEN

Aanwijzingen voor patiënten

De onderstaande vragen hebben betrekking op de fysieke symptomen die u ervaart als gevolg van uw schouderprobleem. In alle gevallen verzoeken wij u uw antwoord te baseren op de intensiteit van de symptomen van de afgelopen week (door op de juiste plek op de horizontale lijn een schuine streep "/" te plaatsen).

1. Hoeveel pijn heeft u aan uw schouder als u activiteiten verricht waarbij u uw arm boven uw hoofd moet verheffen?

geen pijn /____/ *extreme pijn*

2. Hoeveel last hebt u van een pijnlijke of kloppende schouder?

geen pijn/kloppen /____/ *extreme pijn/ kloppen*

3. Hoeveel last hebt u van een zwakke of verzwakte schouder?

geen zwakte /____/ *extreme zwakte*

4. Hoeveel last hebt u van een vermoeide of krachteloze schouder?

geen vermoeidheid /____/ *extreme vermoeidheid*

5. Hoeveel last hebt u van klikken, kraken of knakken in uw schouder?

geen klikken /____/ *extreem klikken*

6. Hoeveel last hebt u van stijfheid in uw schouder?

geen stijfheid /____/ *extreme stijfheid*

7. Hoeveel last hebt u van pijn in de nekspieren in verband met uw schouder?

geen last /____/ *extreme last*

8. Hoeveel last hebt u van een instabiele of los zittende schouder?

geen instabiliteit /____/ *extreme instabiliteit*

9. In hoeverre compenseert u uw schouderprobleem door andere spieren te gebruiken?

in het geheel niet /____/ *in extreme mate*

10. In hoeverre is de beweeglijkheid van uw schouder beperkt?

niet beperkt /____/ *extreem beperkt*

ONDERDEEL B: SPORT/RECREATIE/WERK

Aanwijzingen voor patiënten

Het onderstaande gedeelte gaat over de mate waarin uw schouderprobleem de afgelopen week een rol heeft gespeeld bij het sporten, in uw vrijetijdsbesteding of op het werk.

Beantwoord iedere vraag door op de juiste plek op de horizontale lijn een schuine streep ("/") te plaatsen.

11. In hoeverre werd u door uw schouderprobleem beperkt bij het verrichten van sportieve of recreatieve activiteiten?

niet beperkt /____/ *extreem beperkt*

12. In hoeverre werd u door uw schouder gehinderd bij het verrichten van de specifieke activiteiten die voor uw werk of sport nodig zijn? (Als uw schouderprobleem zowel uw werk als sportieve activiteiten beïnvloedt, beantwoord de vraag dan voor de activiteit waarbij die invloed het grootst is.)

niet gehinderd /____/ *extreem gehinderd*

13. In hoeverre bent u geneigd uw arm tijdens activiteiten te beschermen?

in het geheel niet /____/ *in extreme mate*

14. Hoeveel moeite hebt u met het optillen van zware voorwerpen onder uw schouderhoogte?

geen moeite /____/ *extreme moeite*

ONDERDEEL C: LEVENSSTIJL

Aanwijzingen voor patiënten

Het volgende gedeelte gaat over de mate waarin uw schouderprobleem uw levensstijl heeft beïnvloed of veranderd. Ook hier wordt u verzocht iedere vraag voor de afgelopen week te beantwoorden, door op de juiste plek op de horizontale lijn een schuine streep (/) te plaatsen.

15. In hoeverre bent u bang om op uw schouder te vallen?

geen angst /____/ *extreme angst*

16. In hoeverre hebt u moeite om in conditie te blijven?

geen moeite /____/ *extreme moeite*

17. In hoeverre kost het u moeite te stoeien e.d. met familie of vrienden?

geen moeite /____/ *extreme moeite*

18. In hoeverre leidt uw schouderprobleem ook tot een slaapprobleem?

geen slaapprobleem /____/ *extreem slaapprobleem*

ONDERDEEL D: EMOTIES

Aanwijzingen voor patiënten

In de onderstaande vragen wordt u verzocht aan te geven hoe u zich in verband met uw schouderprobleem de afgelopen week hebt gevoeld. Beantwoord iedere vraag door op de juiste plek op de horizontale lijn een schuine streep ("/") te plaatsen.

19. In hoeverre bent u zich bewust van uw schouder?

niet bewust /____/ *extreem bewust*

20. In hoeverre maakt u zich zorgen dat uw schouderprobleem verergert?

niet bezorgd /____/ *extreem bezorgd*

21. In hoeverre raakt u gefrustreerd door uw schouderprobleem?

niet gefrustreerd /____/ *extreem gefrustreerd*

TOELICHTING OP DE VRAGEN IN DE WESTERN ONTARIO SHOULDER INSTABILITY INDEX (WOSI)

ONDERDEEL A: FYSIEKE SYMPTOMEN

Vraag 1.
Heeft betrekking op iedere activiteit waarbij u uw arm boven schouderniveau moet verheffen, zoals borden in een keukenkastje zetten, uw haar op orde brengen, borstcrawl in het zwembad, het plafond schilderen, een bal gooien in een bovenhandse worp enz.

Vraag 2.
Heeft betrekking op een doffe pijn op de achtergrond, in tegenstelling tot een plotselinge stekende pijn.

Vraag 3.
Heeft betrekking op het gebrek aan kracht als u uw arm gebruikt om een handeling te verrichten.

Vraag 4.
Heeft betrekking op de mate waarin uw schouder bij inspanning vermoeid raakt.

Vraag 5.
Heeft betrekking op de geluiden die zich in uw schouder voordoen als u hem gebruikt.

Vraag 6.
Heeft betrekking op het gevoel van stroefheid in het schoudergewricht; een veel voorkomend verschijnsel bij het opstaan, na inspanning of juist na een periode van rust. Deze vraag gaat niet over beperkte beweeglijkheid.

Vraag 7.
Heeft betrekking op spanning, pijn of kramp in uw nekspieren die het gevolg lijkt te zijn van uw schouderprobleem.

Vraag 8.
Heeft betrekking op het gevoel dat uw schouder half los zit, volledig uit de kom is geraakt, naar onderen glijdt of in allerlei richtingen verschuift.

Vraag 9.
Heeft betrekking op het gebruik van arm- of nekspieren bij bewegingen of handelingen, ter compensatie van uw schouderprobleem.

Vraag 10.
Heeft betrekking op het gebrek aan beweeglijkheid van uw schouder in verschillende richtingen.

Onderdeel B: Sport/Recreatie/Werk

Vraag 11.
Heeft betrekking op de mate waarin uw schouder het sporten of recreëren belemmert of geheel onmogelijk maakt.

Vraag 12.
Heeft betrekking op de moeite die u hebt bij het verrichten van handelingen die voor werk, sport of recreatie noodzakelijk zijn.

Vraag 13.
Heeft betrekking op het bewust of onbewust beschermen van uw arm door hem dicht tegen uw lichaam aan te houden, af te schermen of in een beugel te dragen.

Vraag 14.
Deze vraag gaat niet over het boven uw hoofd tillen van voorwerpen, maar over het optillen van zware objecten onder schouderniveau, zoals een tas met boodschappen, apparatuur op het werk, boeken of een bowlingbal.

Onderdeel C: Levensstijl

Vraag 15.
Heeft betrekking op de angst die u hebt om op uw schouder te vallen of, aan die zijde, op uw uitgestrekte hand terecht te komen.

Vraag 16.
Heeft betrekking op uw conditie voordat u een schouderprobleem kreeg. Houd hierbij rekening met uw cardiovasculaire conditie en met de kracht en spanning in uw spieren.

Vraag 17.
Heeft betrekking op ruwe of speelse activiteiten die u normaal gesproken onderneemt met familie of vrienden.

Vraag 18.
Heeft betrekking op de mate waarin u, als gevolg van uw schouderprobleem, uw slaaphouding hebt moeten aanpassen, ’s nachts wakker wordt, moeite hebt bij het inslapen of vermoeid bent bij het opstaan.

Onderdeel D: Emoties

Vraag 19.
Heeft betrekking op de mate waarin u zich bewust bent van uw schouder of bij iedere activiteit eerst aan uw schouder denkt.

Vraag 20.
Heeft betrekking op de mate waarin u zich zorgen maakt dat uw schouderprobleem niet afneemt, maar stabiel blijft of zelfs erger wordt.

Vraag 21.
Heeft betrekking op de frustratie die u voelt omdat u dingen die u eerst wel kon doen, of die u wilt doen, nu vanwege uw schouder niet meer kunt doen.

APPENDIX 2.

The Oxford Shoulder Instability Score (OSIS) in Dutch.

1. Hoe vaak is de schouder gedurende de laatste 6 maanden uit de kom of bijna uit de kom geschoten?

❑ Niet
❑ 1 of 2 keer in de afgelopen 6 maanden
❑ 1 of 2 keer per maand
❑ 1 of 2 keer per week
❑ meer dan 2 keer per week

2. Heeft u de afgelopen drie maanden bij het aankleden last gehad van (of u zorgen gemaakt vanwege) uw schouder?

❑ helemaal geen last
❑ weinig last
❑ matig last
❑ veel last
❑ onmogelijk te doen

3. Als u gedurende de laatste 3 maanden pijn had, hoe zou u de pijn beschrijven?

❑ geen pijn
❑ lichte pijn
❑ matige pijn
❑ ernstige pijn
❑ ondraaglijke pijn

4. In hoeverre heeft het probleem met uw schouder u de afgelopen drie maanden belemmerd in uw gewone werkzaamheden?

❑ helemaal niet
❑ een klein beetje
❑ matig
❑ in grote mate
❑ totaal

5. Heeft u gedurende de laatste 3 maanden activiteiten vermeden omdat u bang was, dat de schouder dan uit de kom zou schieten?

❑ niets vermeden
❑ af en toe

❑ soms
❑ meestal
❑ bijna alle activiteiten vermeden

6. Heeft het probleem met uw schouder u de afgelopen drie maanden belet dingen te doen die belangrijk voor u zijn?
❑ helemaal niet
❑ heel soms
❑ sommige dagen
❑ de meeste dagen of meer dan één activiteit
❑ elke dag of veel activiteiten

7. In hoeverre heeft het probleem met uw schouder u de afgelopen drie maanden belemmerd in uw sociale leven?
❑ helemaal niet
❑ heel soms
❑ sommige dagen
❑ de meeste dagen
❑ iedere dag

8. In hoeverre heeft het probleem met uw schouder u de afgelopen vier weken belemmerd in sport of hobbies?
❑ helemaal niet
❑ een beetje/ wel eens
❑ af en toe
❑ meestal
❑ altijd

9. Hoe vaak is uw schouder in beeld geweest of hoe vaak heeft u aan de schouder gedacht gedurende de laatste 4 weken?
❑ nooit, alleen als er iemand naar vraagt
❑ wel eens
❑ sommige dagen
❑ de meeste dagen
❑ iedere dag

10. In hoeverre heeft het probleem met uw schouder u de afgelopen vier weken belemmerd in het optillen van zware voorwerpen?
❑ nooit

❏ wel eens
❏ sommige dagen
❏ de meeste dagen
❏ iedere dag

11. Als u kijkt naar de afgelopen vier weken, hoe zou u dan de pijn beschrijven die u doorgaans in uw schouder had?
❏ geen
❏ erg licht
❏ licht
❏ gemiddeld
❏ heftig

12. Heeft u de afgelopen vier weken 's nachts in bed bepaalde slaaphoudingen vermeden vanwege uw schouder?
❏ nee
❏ maar 1 of 2 nachten
❏ sommige nachten
❏ de meeste nachten
❏ iedere nacht

APPENDIX 3.

CONFIRMATORY FACTOR ANALYSIS TO ADDRESS INTERNAL CONSISTENCY.

Methods

Factor loadings represent the correlation between the items in the questionnaire and the factors (the underlying dimensions, such as work or lifestyle). Factor loadings are generally considered to be meaningful when they exceed 0.30 or 0.40.1 We considered factor loadings of at least 0.50 appropriate. The Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), and the Root Mean Square Error of Approximation (RMSEA) were used as measures for model fit. A CFI and TLI of > 0.95 and a RMSEA of < 0.05 were considered as adequate fit. For a moderate fit, values > 0.90 and < 0.08 were used. Because the model didn't fit well (see results section), an additional exploratory factor analysis was performed in SPSS, using Varimax rotation.

Analogous to Pearson's r, the squared factor loading is the percent of variance in that indicator variable explained by the factor.

Confirmatory factor analysis for categorical items was performed in Mplus using the method of weighted least squares with mean and variance adjustment (WLSMV). We examined factor loadings and model fit.

Results

Factor loadings are presented in Table 1. A one-factor model fitted the data not good (CFI was 0.901, TLI was 0.879 and RMSEA was 0.147), suggesting multiple contributing

Table 1. Factor loadings of the OSIS. Estimate and standard error (SE).

Question	Estimate	SE
1	0.255	0.071
2	0.736	0.039
3	0.592	0.051
4	0.822	0.029
5	0.756	0.037
6	0.823	0.029
7	0.714	0.047
8	0.736	0.041
9	0.605	0.067
10	0.760	0.038
11	0.727	0.038
12	0.612	0.059

factors. Item 1 had a low factor loading of 0.255 and was removed to evaluate the effect on the model. No other items were removed. Removing item 1 did not improve the model (CFI 0.898, TLI 0.873, RMSEA 0.162). An exploratory factor analysis resulted in a three-factor model, explaining 63.6% of the variance, with items 2,3,4 and 7 loading on the first factor, items 8 through 12 loading on the second factor and items 1,5 and 6 loading on the third factor. This model was not clearly interpretable. A 2-factor model was also considered (explaining 55,0% of the variation), but this did not lead to a clearly interpretable model, with multiple items loading on both factors.

Discussion

This is the first study that evaluated the dimensionality of the OSIS, dimensionality or factor loadings were not addressed in the original paper. Because the one-factor model did not fit the data good, the scale is not uni-dimensional. Summary scores should therefore be interpreted with caution. Especially when interpreting change scores because changes can be due to different changes in any of these constructs. A change of 10 points in one patient may therefore not be comparable to a change of 10 points in another patient.

Reference

Hu LT, Bentler PM. Cut-off criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Structural Equation Modelling.* 1999;6:1-55.

APPENDIX 4.

SYNTAX USED FOR SEARCH ENGINES.

PubMed search

((((((Bristow-Latarjet[Title/Abstract]) OR Bristow[Title/Abstract]) OR Latarjet[Title/Abstract]) OR Coracoid glenoid fixation[Title/Abstract]) OR Anterior glenoid reconstruction[Title/Abstract]) OR Glenoid articular arc reconstruction[Title/Abstract]) AND ((((((((Shoulder[Title/Abstract]) OR Glenohumeral[Title/Abstract]) OR Articulatio spheriodea[Title/Abstract]) OR Articulatio humeri[Title/Abstract]) OR Socket joint[Title/Abstract]) OR Spheroid joint[Title/Abstract]) OR Cotyloid joint[Title/Abstract]) OR Enarthrodial joint[Title/Abstract]) AND ((((((((((Dislocat*[Title/Abstract]) OR Displac*[Title/Abstract]) OR Disarticulat*[Title/Abstract]) OR Disjoin*[Title/Abstract]) OR Disjunct*[Title/Abstract]) OR Redislocat*[Title/Abstract]) OR Luxat*[Title/Abstract]) OR Misplace*[Title/Abstract]) OR Instab*[Title/Abstract]) AND (((((((((((Redislocat*[Title/Abstract]) OR Recur*[Title/Abstract]) OR Dislocat*[Title/Abstract]) OR Displac*[Title/Abstract]) OR Disarticulat*[Title/Abstract]) OR Disjoin*[Title/Abstract]) OR Disjunct*[Title/Abstract]) OR Redislocat*[Title/Abstract]) OR Luxat*[Title/Abstract]) OR Misplace*[Title/Abstract]) OR Instab*[Title/Abstract])

EMBASE search

('Bristow-Latarjet':ab,ti OR Bristow:ab,ti OR Latarjet:ab,ti OR 'Coracoid glenoid fixation':ab,ti OR 'Anterior glenoid reconstruction':ab,ti OR 'Glenoid articular arc reconstruction':ab,ti) AND (Shoulder:ab,ti OR Glenohumeral:ab,ti OR 'Articulatio spheriodea':ab,ti OR 'Articulatio humeri':ab,ti OR 'Socket joint':ab,ti OR 'Spheroid joint':ab,ti OR 'Cotyloid joint':ab,ti OR 'Enarthrodial joint':ab,ti) AND (Dislocation:ab,ti OR Dislocated:ab,ti OR Dislocate:ab,ti OR Displaced:ab,ti OR Displace:ab,ti OR Disarticulated:ab,ti OR Disarticulation:ab,ti OR Disjoined:ab,ti OR Disjoin:ab,ti OR Disjunction:ab,ti OR Disjuncted:ab,ti OR Disjunct:ab,ti OR Redislocation:ab,ti OR Redislocated:ab,ti OR Redislocate:ab,ti OR Luxate:ab,ti OR Luxated:ab,ti OR Luxation:ab,ti OR Misplaced:ab,ti OR Misplace:ab,ti OR Instabile:ab,ti OR Instabilisation:ab,ti OR Instabilization:ab,ti) AND (Redislocation:ab,ti OR Redislocated:ab,ti OR Redislocate:ab,ti OR Recur:ab,ti OR Recurred:ab,ti OR Recurrent:ab,ti OR Recurrence:ab,ti OR Dislocation:ab,ti OR Dislocated:ab,ti OR Dislocate:ab,ti OR Displaced:ab,ti OR Displace:ab,ti OR Disarticulated:ab,ti OR Disarticulation:ab,ti OR Disjoined:ab,ti OR Disjoin:ab,ti OR Disjunction:ab,ti OR Disjuncted:ab,ti OR Disjunct:ab,ti OR Redislocation:ab,ti OR Redislocated:ab,ti OR Redislocate:ab,ti OR Luxate:ab,ti OR Luxated:ab,ti OR Luxation:ab,ti OR Misplaced:ab,ti OR Misplace:ab,ti OR Instabile:ab,ti OR Instabilisation:ab,ti OR I

APPENDIX 5.

SYNTAX USED FOR SEARCH ENGINES.

Pubmed search

Bankart AND ((((((((Shoulder[Title/Abstract]) OR Glenohumeral[Title/Abstract]) OR Articulatio spheriodea[Title/Abstract]) OR Articulatio humeri[Title/Abstract]) OR Socket joint[Title/Abstract]) OR Spheroid joint[Title/Abstract]) OR Cotyloid joint[Title/Abstract]) OR Enarthrodial joint[Title/Abstract]) AND (((((((((Dislocat*[Title/Abstract]) OR Displac*[Title/Abstract]) OR Disarticulat*[Title/Abstract]) OR Disjoin*[Title/Abstract]) OR Disjunct*[Title/Abstract]) OR Redislocat*[Title/Abstract]) OR Luxat*[Title/Abstract]) OR Misplace*[Title/Abstract]) OR Instab*[Title/Abstract]) AND (((((((((((Redislocat*[Title/Abstract]) OR Recur*[Title/Abstract]) OR Dislocat*[Title/Abstract]) OR Displac*[Title/Abstract]) OR Disarticulat*[Title/Abstract]) OR Disjoin*[Title/Abstract]) OR Disjunct*[Title/Abstract]) OR Redislocat*[Title/Abstract]) OR Luxat*[Title/Abstract]) OR Misplace*[Title/Abstract]) OR Instab*[Title/Abstract])

EMBASE search

Bankart and (Shoulder or Glenohumeral or Articulatio spheriodea or Articulatio humeri or Socket joint or Spheroid joint or Cotyloid joint or Enarthrodial joint) and (Dislocat* or Displac* or Disarticulat* or Disjoin* or Disjunct* or Redislocat* or Luxat* or Misplace* or Instab*) and (Redislocat* or Recur* or Dislocat* or Displac* or Disarticulat* or Disjoin* or Disjunct* or Redislocat* or Luxat* or Misplace* or Instab*)).ti,ab.

List of abbreviations

95% CI	95% confidence interval
AAROM	Assisted active range of motion
AD	Adduction
AFE	Active forward elevation
ALPSA	Anterior labroligamentous periosteal sleeve avulsion
ANOVA	Analysis of variance
AR	Absolute risk
ARD	Absolute risk difference
AROM	Active range of motion
ASES	American Shoulder and Elbow Surgeons (shoulder score)
ASOSS	Athletic Shoulder Outcome Scoring System
ASSET	American Society of Shoulder and Elbow Therapists
ASD	Anterior shoulder dislocation
BP	Bodily pain
BES	Blinding of the exposure status
CA	Collision athletes
CFA	Confirmatory factor analyses
CFI	Comparative fit index
CI	Confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CM	Constant-Murley
CMS	Coleman Methodology Score
COSMIN	Consensus-based Standards for the Selection of Health Measurement Instruments
CPM	Continuous passive motion (device)
CT	Computer tomography
DASH	Disabilities of the Arm, Shoulder and Hand assessment
EQ-5D	EuroQoL - 5 Dimensions
ER	External rotation
ES	Effect size
FU	Follow-up
GH	General health
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HAGL	Humeral avulsion of the glenohumeral ligament
ICC	Intraclass correlation coefficient
IF	Impact factor
IQR	Interquartile range
IR	Internal rotation
IRB	Institutional review board

LoE	Level of Evidence
LTFU	Loss to follow-up
ME	Measurement error
METC	Medisch Ethische Commissie
MH	Mental health
MIC	Minimal important change
MRI	Magnetic resonance imaging
NA	Not applicable
NCA	Non-collision athletes
NICE	National Institute for Health and Clinical Excellence
NSST	Nederlandse Simple Schouder Test
NWB	Non weight bearing
Non-CA	Noncollision athletes
OA	Osteoarthritis
OLVG	Onze Lieve Vrouwe Gasthuis
OIS	Oxford Instability Score
OR	Odds ratio
OSIS	Oxford Shoulder Instability Score
OSS	Oxford Shoulder Score
p	Level of statistical significance
PICO	Patient Intervention Control Outcome
PER	Passive external rotation
PF	Physical functioning
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRO	Patient reported outcome
PROM	Patient reported outcome measurement
PROM	Passive range of motion
PT	Physiotherapy
RCT	Randomized controlled trial
RD	Risk difference (absolute risk of one minus absolute risk of the other)
RE	Role emotional
RF	Role functional
RMSEA	Root mean square error of approximation
ROC	Receiver operating curve
ROM	Range of motion
RR	Relative risk
RTS	Return to sport
RTW	Return to work
SD	Standard deviation

SDC	Smallest detectable change
SEM	standard error of measurement
SF	Social functioning
SF-36	Short Form (36) Health Survey
SLAP	Superior labral tear from anterior to posterior
SO	Standardization of outcome
SRM	Standardized response mean
SST	Simple Shoulder Test
TiC-P	Trimbos/iMTA questionnaire for costs associated with psychiatric illness
TLI	Tucker-Lewis Index
UCLA	University of California-Los Angeles (shoulder scale)
V	Vitality
WD	Walch-Duplay
WLZ	Waterlandziekenhuis
WOSI	Western Ontario Shoulder Instability Index
VAS	Visual Analogue Scale

Dutch summary/ Nederlandse samenvatting

INLEIDING

Schouderinstabiliteit is een vervelend probleem voor patiënten. Het uit zich in schouderluxaties (schouder uit de kom) en subluxaties (schouder bijna uit de kom, maar schiet spontaan weer terug). Een eerste schouderluxatie is vaak het gevolg van een trauma en kan structurele veranderingen in het schoudergewricht veroorzaken waardoor (sub) luxaties herhaaldelijk kunnen terugkeren. Elke luxatie veroorzaakt pijn en ongemak, gevolgd door een onzeker gevoel bij het maken van bepaalde bewegingen.

Dit proefschrift heeft tot doel om de kennis over en de behandeling van schouderinstabiliteit te verbeteren.

DEEL I MAATSCHAPPELIJKE KOSTEN VAN SCHOUDERINSTABILITEIT

In *hoofdstuk 2* worden de gemiddelde kosten bestaande uit *productiviteitsverlies* en kosten van *zorggebruik* per patiënt per luxatie na een conservatieve behandeling geschat.

Schouderinstabiliteit treedt het meest op bij actieve personen tussen 20 en 30 jaar, een groep die veelal werkt. Door een schouderluxatie kan een patiënt genoodzaakt zijn om zich ziek te melden, kan een patiënt verminderd productief zijn tijdens zijn werkzaamheden of kan iemand verhinderd zijn om onbetaald werk te verrichten, zoals mantelzorg die dan moet worden uitbesteed. Dit leidt tot productiviteitsverlies. Omdat luxaties vaak recidiveren, vooral bij jonge patiënten wier schouders niet worden geopereerd, kan het ziekteverzuim en dientengevolge het productiviteitsverlies toenemen.

Afgezien daarvan zullen patiënten na iedere schouderluxatie gebruik maken van zorg, zoals vervoer per ambulance, ziekenhuisbezoek, diagnostisch onderzoek, fysiotherapie, etc. waardoor de totale kosten van zorggebruik zullen oplopen.

De totale gemiddelde kosten per patiënt zijn € 6914, € 5284 en € 4061 na respectievelijk de eerste, tweede en derde en volgende luxatie.

Het gemiddelde *productiviteitsverlies* per patiënt per luxatie is € 3110, € 1866 en € 1543 na respectievelijk de eerste, tweede en derde en volgende luxatie. Het productiviteitsverlies is significant hoger bij patiënten die reeds andere (chronische) aandoeningen hebben (p 0.02). Andere factoren, zoals het al dan niet verrichten van fysiek werk, de vraag of de geluxeerde zijde dominant is, het opleidingsniveau of het geslacht van de patiënt hebben geen invloed op het productiviteitsverlies. Het productiviteitsverlies nam significant af na de tweede en na de derde luxatie ten opzichte van het productiviteitsverlies na de eerste luxatie. Het gemiddelde verschil was respectievelijk - € 1969 (95% CI= -3680 tot -939) en - € 2298 (95% CI= -4092 tot -1288).

De gemiddelde kosten van *zorggebruik* nemen eveneens af: € 3759, € 3267 en € 2424 na respectievelijk de eerste, tweede, en derde en volgende luxatie. Mogelijk gebruiken patiënten de door hun opgedane kennis en praktijkervaring bij een volgende luxatie. Zo wordt bijvoorbeeld na een tweede luxatie een kleiner percentage van de patiënten per ambulance vervoerd (15% in plaats van 27% na de eerste luxatie) en neemt het aantal bezoeken aan de fysiotherapeut af (10 bezoeken na de eerste en tweede luxatie, 5 bezoeken na de derde en volgende luxatie).

DEEL II MEETINSTRUMENTEN OM HET EFFECT VAN DE BEHANDELING VOOR SCHOUDERINSTABILITEIT TE METEN

In *hoofdstuk 3* en *hoofdstuk 4* worden meetinstrumenten geanalyseerd, waarmee het effect van een behandeling kan worden geëvalueerd. Twee veelgebruikte meetinstrumenten voor patiënten met schouderinstabiliteit zijn de 'Western Ontario Shoulder Instability Index' (WOSI) en de 'Oxford Shoulder Instability Score' (OSIS). Beide zijn gestandaardiseerde vragenlijsten ofwel 'Patient Reported Outcome Measures' (PROMs). Voordat deze PROMs kunnen worden gebruikt in een ander taalgebied, moeten zij volgens beproefde methodiek worden vertaald en worden gevalideerd voor de beoogde patiëntenpopulatie. In *hoofdstuk 3 en 4* worden deze PROMs vertaald en gevalideerd volgens de 'COnsensus-based Standards for the selection of health Measurement INstruments' (COSMIN) richtlijn. Beide PROMs hebben goede en vergelijkbare meeteigenschappen.

De WOSI heeft een goede interne consistentie (Cronbach's α variërend van 0.93 tot 0.96 voor de 4 subdomeinen), de betrouwbaarheid (test-hertest) is uitstekend (de Intraclass Correlation Coefficient (ICC) varieert van 0.88 tot 0.92 voor de subdomeinen) en de constructvaliditeit is goed (76% van de hypotheses wordt geaccepteerd). De WOSI heeft geen 'floor- of ceiling-' effecten. De 'Smallest Detectable Change' (SDC), zijnde de kleinste verandering die kan worden waargenomen buiten de meetfout bij individuele patiënten, is 23 punten op een schaal van 0 - 100. Ten slotte is ook de responsiviteit hoog.

De OSIS heeft een goede interne consistentie (Cronbach's α van 0.88), de betrouwbaarheid is uitstekend (ICC van 0.87) en de construct validiteit is goed (80% van de hypotheses wordt geaccepteerd). De OSIS heeft geen floor- of ceiling-effecten. De SDC is 9 punten op een schaal van 0 - 48. Ten slotte is ook de responsiviteit hoog. Beide PROMs kunnen dus worden gebruikt om de schouderfunctie van Nederlandse patiënten met schouderinstabiliteit te evalueren.

Het verschil tussen de score vóór en ná een behandeling kan statistisch significant zijn, zonder dat dit voor de patiënt als een relevante verbetering voelt. Bijvoorbeeld: een verbetering van 5 punten op een schaal van 0-100 kan statistisch significant zijn, terwijl een patiënt pas vanaf 15 punten merkt dat zijn schouder daadwerkelijk beter functioneert. In *hoofdstuk* 5 wordt de 'Minimal Important Change' (MIC), zijnde de drempelwaarde vanaf waar een verschil in score klinisch relevant is, bepaald voor de WOSI en de OSIS. Een toename in score van circa 12% (14.6 WOSI-punten op een schaal van 0-100 en 6 OSIS-punten op een schaal van 0-48) correspondeert met een schouderfunctie die 'een beetje is verbeterd'. Een toename in score van circa 25% (22 WOSI-punten op een schaal van 0-100 en 12 OSIS-punten op een schaal van 0-48) correspondeert met een schouderfunctie die 'veel is verbeterd'.

DEEL III OPERATIEVE BEHANDELMOGELIJKHEDEN VOOR SCHOUDERINSTABILITEIT

De operatieve behandeling kan in twee groepen worden verdeeld: een wekedelen operatie (bijvoorbeeld de artroscopische Bankart operatie) en een benige operatie (bijvoorbeeld de Bristow of Latarjet operatie). Bij de wekedelen operatie wordt het afgescheurde complex, bestaande uit de kraakbeenrand (labrum) en het kapsel, met behulp van een anker met hechtdraad terug gehecht op de rand van het kommetje (glenoid). Bij de benige operatie wordt een botblokje (meestal het processus coracoideus met de daaraan vastzittende conjoined tendon) vastgezet tegen de rand van het door luxatie(s) geërodeerde kommetje. Daardoor wordt niet alleen de komvorm hersteld, ook functioneert de conjoined tendon dankzij zijn nieuwe anatomische positie als een 'hangmat' aan de voorzijde van het kommetje als de schouder wordt geabduceerd. Dus daar waar de schouderkop meestal naar anterieur luxeert, wordt deze nu tegengehouden door de hangmat. De keuze van de behandeling wordt bepaald door verschillende patiëntgerelateerde factoren, zoals leeftijd, sportbeoefening en de aanwezigheid van botdefecten in het schoudergewricht. De verschillende aspecten hiervan en de nabehandeling komen in *hoofdstuk 6 tot 11* aan bod.

In *hoofdstuk 6* wordt aan de hand van een literatuurstudie de kans op recidiverende instabiliteit na een operatieve en conservatieve behandeling van traumatische schouderinstabiliteit bij patiënten van 18 jaar en jonger geëvalueerd. Atraumatische luxaties en luxaties als gevolg van een neurologische afwijking of familiaire hyperlaxiteit werden niet meegenomen in deze studie. Van de 411 schouders die conservatief werden behandeld, kregen 293 schouders (71,3%) een recidief, vergeleken met 55 van de 314 schouders (17.5%) die operatief werden behandeld. Bij patiënten van 18 jaar en jonger is de kans op recidiverende instabiliteit na een operatieve behandeling dus kleiner dan na een conservatieve behandeling.

In het algemeen geldt dat als wordt besloten om patiënten operatief te behandelen, een wekedelen operatie (artroscopische Bankart operatie) als minst invasieve operatie vaak de voorkeur heeft, mits de patiëntkarakteristieken (botverlies, leeftijd, sportbeoefening) dat toelaten. Het effect van een operatieve behandeling moet langdurig zijn. In *hoofdstuk 7* worden de langetermijnresultaten van de artroscopische Bankart operatie geëvalueerd, wat betreft de kans op recidiverende instabiliteit en ten aanzien van de schouderfunctie. Met een follow-up percentage van 97% blijkt dat na 8 tot 10 jaar circa 35% van de patiënten een recidief schouderluxatie heeft. Ondanks dit relatief hoge percentage was de gemiddelde schouderfunctie goed: 90 WOSI-punten (op een schaal van 0-100) en 44 OSIS-punten (op een schaal van 0-48). Hoewel het verschil niet statistisch significant is, lijken patiënten die geopereerd worden met 2 ankers in plaats van met 3 of 4 ankers (p 0.06) en patiënten met een Hill-Sachs defect (p 0.07) een verhoogd risico te hebben op recidiverende instabiliteit.

Ook blijkt in *hoofdstuk 7* dat van de gebruikte PROMs, alleen de WOSI en de OSIS (die specifiek zijn ontworpen voor patiënten met schouderinstabiliteit) een statistisch significant verschil in functie kunnen aantonen tussen patiënten met en zonder recidief in tegenstelling tot algemene schouder PROMs.

Het relatief hoge percentage patiënten met recidiverende instabiliteit na een wekedelen operatie en het succesvolle stabiliserende effect van een benige operatie heeft ertoe geleid dat de benige operatie meer en meer wordt gebruikt. Weliswaar leidt de benige operatie leidt tot een betere stabiliteit dan de wekedelen operatie, maar hij is uitgebreider (open in plaats van artroscopisch) en heeft een grotere kans op complicaties. In *hoofdstuk 8* wordt een overzicht gegeven van de ontwikkeling van de benige operatie. Hierin worden de operaties volgens Bristow en Latarjet, die vrijwel gelijktijdig voor het eerst werden beschreven, evenals de reeks aanpassingen die zijn ontwikkeld om de kans op complicaties te verminderen, besproken. De aanpassing zijn gecategoriseerd in de chirurgische benadering, het positioneren en het fixeren van het botblokje, het voorkomen van zenuwletsel en de artroscopische procedure.

In *hoofdstuk 9* wordt in een literatuurstudie onderzocht of een benige operatie even effectief is voor 'collision athletes' als voor overige sporters. De term 'collision athletes' wordt gebruikt om sporters aan te duiden, bij wie de kans dat zij elkaar met grote kracht treffen inherent is aan de sport, zoals bij rugby. Op basis van 11 studies die aan de inclusiecriteria voldoen, kan worden geconcludeerd dat het absolute risico op recidiverende instabiliteit voor collision athletes 0-15.8% is, vergeleken met 0-4.3% voor de overige sporters. In 8 van deze 11 studies worden beide groepen vergeleken: 2 studies tonen geen verschil, 3 studies tonen een licht verminderd risico op een recidief schouderluxatie voor collision athletes (-0.7 tot -1.3%) en 3 studies tonen een toegenomen risico voor collision athletes (5.9 tot 15.8%). Echter, zelfs in de studie waarin collision athletes een verhoogd risico van 15.8% hebben, is dit risico niet statistisch significant (p 0.31). Uitgaande van deze data lijken collision athletes na een benige operatie een licht verhoogd, maar niet statistisch significant risico te hebben op recidiverende instabiliteit vergeleken met overige sporters.

In *hoofdstuk 10* wordt in een vergelijkbare literatuurstudie onderzocht of een wekedelen operatie voor collision athletes ook zou volstaan. Deze operatie is immers minder uitgebreid en heeft een lager risico op complicaties. Er zijn 20 studies waarin dit is onderzocht: 4 studies evalueren stabiliteit bij collision athletes, 16 studies vergelijken stabiliteit tussen collision athletes en overige sporters. In 14 van deze vergelijkende studies blijken collision athletes een hogere kans op recidiverende instabiliteit te hebben (verhoogd risico van 0.4 tot 28.6%), in 2 studies hebben zij juist een lagere kans (-6% and -2.4%). Als de gegevens van de 20 studies worden gecombineerd, blijken collision athletes een statistisch significant hoger risico (p 0.001) van 10.1% (17.3 % vergeleken met 7.2%) te hebben op recidiverende instabiliteit vergeleken met overige sporters.

Met een literatuurstudie worden in *hoofdstuk 11* de verschillende wijzen van nabehandeling na een artroscopische wekedelen operatie onderzocht. Buiten beschouwing gelaten zijn studies over patiënten met posterieure instabiliteit, zelf opgewekte instabiliteit en studies waarbij bijkomend letsel is (zoals een benige Bankart, een 'Humeral Avulsion of the Glenohumeral Ligament' (HAGL) laesie of rotator cuff pathologie). Er blijken slechts 2 studies te zijn gedaan waarin verschillende nabehandelingen met elkaar zijn vergeleken. Een studie (uit 1996) vergelijkt 1 tot 2 weken immobilisatie (18 patiënten) met 3 weken immobilisatie (20 patiënten): een snellere mobilisatie resulteert in een slechtere schouderfunctie (Rowe score) na 15 maanden. De andere studie (uit 2003) vergelijkt 3 weken immobilisatie met direct oefentherapie (beide groepen 31 patiënten). Daaruit blijkt dat patiënten die direct oefentherapie kregen minder pijn hadden na 6 weken en dat zij tevredener waren na 31 maanden: er was sprake van een sneller herstel van de bewegelijkheid (exorotatie) en zij waren eerder op het oude activiteiten niveau. Op basis van deze 2 studies is dus geen reden om de ene nabehandeling boven de andere te verkiezen.

Gebaseerd op deze studies, aangevuld met de mening van experts heeft de 'American Society of Shoulder and Elbow Therapists'(ASSET) in 2010 een richtlijn voor de nabehandeling na een artroscopische Bankart operatie opgesteld. Desalniettemin wordt in de huidige 'best practice' nog steeds een sterk uiteenlopende nabehandeling toegepast.

Zo levert een zoektocht in 4 orthopaedische vakbladen met de hoogste impact factor (American Journal of Sports Medicine, the Journal of Bone and Joint Surgery America, Physical Therapy en Arthroscopy) verschenen tussen januari 2010 en december 2014, 6 studies op over de artroscopische Bankart operatie waarin de nabehandeling zeer uiteen loopt. De initiële immobilisatie varieert van 3 tot 6 weken. Oefentherapie gericht op kracht en/of beweging wordt door sommige auteurs tijdens de immobilisatie periode toegestaan, terwijl anderen dit pas na immobilisatie starten. Externe rotatie wordt soms op de 1^{e} postoperatieve dag gestart, maar door anderen tot 4 weken postoperatief strikt verboden. Ook het toestaan van het hervatten van bovenarmse activiteiten, sport en werpsporten varieert van 3 tot 6 maanden.

Ondanks aanbevelingen op basis van de beschikbare literatuur, blijkt er dus veel variatie in de nabehandeling van een artroscopische wekedelen operatie te zijn.

Papers not included in this thesis

Somford MP**, van der Linde JA,** Wiegerinck JJ, Hoornenborg D, van den Bekerom MPJ, van Deurzen DFP. Eponyms in shoulder stabilizing surgery. *Submitted for journal publication.*

ter Meulen D, van Deurzen DFP, **van der Linde JA**, van den Bekerom MPJ. Chondrotoxic effects of intra articular anesthetics in pediatric shoulders. Letter to the editor. *Pediatr Emerg Care*. 2014;30:675.

van der Linde JA, van Kampen DA, Willems WJ. How should we define failure after surgical shoulder stabilization? Letter to the editor. *Arthroscopy*. 2013;29:1602.

Molthof H, **van der Linde JA**, Leijdekkers V. Vaatletsel als late complicatie van een pertrochantere femurfractuur. *Nederlands Tijdschrift voor Traumatologie.* 2010;5:143-146.

van der Linde JA, Ham SJ, van der Hart CP. Een knieluxatie na minimaal trauma bij morbide obesitas; twee casus. Stabilisatie met een fixateur externe. *Nederlands Tijdschrift voor Traumatologie*. 2010;6:176-179.

O'Byrne PM, **van der Linde JA**, Cockcroft DW, Gauvreau GM, Brannan JD, Fitzgerald M, Watson RM, Milot J, Davis B, O'Connor M, Hart L, Korducki L, Hamilton AL, Boulet LP. Prolonged bronchoprotection against inhaled methacholine by inhaled BI 1744, a long-acting beta(2)-agonist, in patients with mild asthma. *J of Allergy Clin Immunology*. 2009;124:1217-1221.

Presentations

ORAL PRESENTATIONS

2009 van der Linde JA, van Kampen DA, Terwee CB, Dijksman LM, Kleinjan G, Willems WJ. Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up. OLVG Wetenschapsdag, 2009, Amsterdam, The Netherlands.

2010 van der Linde JA, van Kampen DA, Terwee CB, Dijksman LM, Kleinjan G, Willems WJ. Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up. ICSES congres 2010, Edinburgh, Scotland.

2011 van der Linde JA, van Kampen DA, Terwee CB, Dijksman LM, Kleinjan G, Willems WJ. Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up. SECEC/ ESSSE congres 2011, Lyon, France.

2011 van der Linde JA, de Vries LS, Thomeer BJM, van Olden GDJ. Drukverband na fixatie van supracondylaire humerusfracturen bij kinderen. Traumadagen 2011, Amsterdam, The Netherlands.

2011 van der Linde JA, van Kampen DA, Terwee CB, Dijksman LM, Kleinjan G, Willems WJ. Long-term results after arthroscopic shoulder stabilization using suture anchors: an 8- to 10-year follow-up AAOS meeting 2011, San Diego, USA.

2014 van der Linde JA, van Wijngaarden R, Somford MP, van Deurzen DFP, van den Bekerom MPJ. The Bristow–Latarjet procedure, a historical note on a technique in comeback. NVA Masterclass 2014, meeting of the NVA (Nederlandse Vereniging voor Arthroscopie), WSE (Werkgroep Schouder en Elleboog) and BELSS: (Belgian Elbow and Shoulder Society), Hilverenbeek, The Netherlands.

2016 van der Linde JA, Bosmans JE, ter Meulen DP, van Deurzen DFP, van Kampen DA, Saris DBF, van den Bekerom MPJ. De maatschappelijke kosten na de conservatieve behandeling van schouderinstabiliteit. Nederlandse Orthopaedische Vereniging, Voorjaarsvergadering 2016.

POSTER PRESENTATION

2016 van der Linde JA, Bosmans JE, ter Meulen DP, van Kampen DA, van Deurzen DFP, Haverlag R, Saris DBF, van den Bekerom MPJ. Estimation of societal costs following nonoperative treatment of shoulder instability in the Netherlands. ESSKA congres 2016, Barcelona, Spain.

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Curriculum vitae

Just van der Linde was born on May 13th 1983 in Amsterdam, The Netherlands and grew up with 1 older brother. In 2001, he graduated from high school (St. Ignatius Gymnasium, Amsterdam) and started medical school at the Rijksuniversiteit Groningen. During his study, he participated in a research project on asthmatic medication at MacMaster University in Hamilton, Ontario, Canada. After completion of his clinical rotations in Zwolle and Curaçao, he completed his final internship at the department of Orthopaedic surgery at the Onze Lieve Vrouwe Gasthuis (OLVG) in Amsterdam. In 2009, he obtained his medical degree and started as non-training resident at the OLVG, where he started his first study on shoulder instability under supervision of dr. W.J. Willems. He started his surgical training in 2010 at the Meander Medisch Centrum in Amersfoort (head: Dr. A.J. van Overbeeke), followed by his Orthopaedic training 2 years later at the OLVG (head: Dr. R.W. Poolman). At the OLVG he initiated his research project together with dr. D.A. van Kampen, dr. C.B. Terwee (EMGO-VUMC), drs. D.F.P van Deurzen, drs. M.P.J. van den Bekerom and prof. dr. D.B.F. Saris (UMC Utrecht). In October 2014 he continued his Orthopaedic training at the University Medical Center Utrecht (head: Prof. dr. D.B.F. Saris) and returned to the OLVG in October 2015, where he is expected to finish his training in December 2016. In 2014 and 2015 Just was also board member of the Vereniging Orthopaedisch Chirurgische Assistenten (VOCA).

Just lives in Amsterdam with his wife Anna and their sons Max and Feije.