

**Non-operative Treatment, Outcome Measurements and  
Characteristics of Patients with  
Traumatic Anterior Shoulder Dislocation**

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**'I alone cannot change the world,  
but I can cast a stone across the waters to create many ripples.'**

*Mother Teresa*

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## List of papers

This dissertation is based on the following five papers, referred to by their Roman numerals:

### ***Paper I***

Henrik Eshoj, Sten Rasmussen, Lars Henrik Frich, Inge Hvass, Robin Christensen, Steen Lund Jensen, Jens Søndergaard, Karen Søgaaard, Birgit Juul-Kristensen

A neuromuscular exercise programme versus standard care for patients with traumatic anterior shoulder instability: Protocol for a randomised controlled trial (the SINEX trial).

*In manuscript.*

### ***Paper II***

Henrik Eshoj, Klaus Bak, Lars Blønd, Birgit Juul-Kristensen

Translation, adaptation and measurement properties of an electronic version of the Danish Western Ontario Shoulder Instability Index (WOSI).

*Submitted to BMJ Open, September 2016.*

### ***Paper III***

Henrik Eshoj, Kim Gordon Ingwersen, Camilla Marie Larsen, Birgitte Hougs Kjær, Birgit Juul-Kristensen

Inter-examiner reliability of clinical shoulder instability tests.

*Submitted to Journal of the American Physical Therapy Association (APTA), September 2016.*

### ***Paper IV***

Henrik Eshoj, Birgit Juul-Kristensen, Rene Jørgensen, Karen Søgaaard

Reproducibility and validity of the Nintendo Wii Balance Board for measuring shoulder sensorimotor control in prone lying.

*Submitted to Gait and Posture, September 2016.*

### ***Paper V***

Henrik Eshoj, Sten Rasmussen, Lars Henrik Frich, Steen Lund Jensen, Karen Søgaaard, Birgit Juul-Kristensen

Traumatic anterior shoulder dislocation – are there differences between primary and recurrent events in relation to subjective and objective outcome measures - a cross-sectional study.

*In manuscript.*

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Study design	Henrik Eshoj, Sten Rasmussen, Lars Henrik Frich, Inge Hvass, Robin Christensen, Steen Lund Jensen, Jens Søndergaard, Karen Søgaard, Birgit Juul-Kristensen
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## Abbreviations

<b>CCC</b>	Concordance Correlation Coefficient
<b>CI</b>	Confidence Intervals
<b>CMS</b>	Constant Murley shoulder Score
<b>COPL</b>	Centre of Pressure path Length
<b>DASH</b>	Disability of Arm, Shoulder and Hand
<b>GJH</b>	Generalized Joint Hypermobility
<b>GPE</b>	Global Perceived Effect
<b>ICC</b>	Intra-class Correlation Coefficient
<b>iMVC</b>	isometric Maximal Voluntary Contraction
<b>JPS</b>	Joint Position Sense
<b>LOA</b>	Limits of Agreement
<b>MDC</b>	Minimal Detectable Change
<b>MSK</b>	Musculoskeletal
<b>NPRS</b>	Numeric Pain Rating Scale
<b>NWBB</b>	Nintendo Wii Balance Board
<b>OSS</b>	Oxford Shoulder Score
<b>PABAK</b>	Prevalence-And-Bias-Adjust-Kappa
<b>PROM</b>	Patient Reported Outcome Measurement
<b>PSFS</b>	Patient Specific Functioning Scale
<b>QoL</b>	Quality of Life
<b>RC</b>	Rotator Cuff
<b>RCT</b>	Randomized Controlled Clinical Trial
<b>ROM</b>	Range of Movement
<b>SD</b>	Standard Deviation
<b>SEM</b>	Standard Error of Measurement
<b>SINEX</b>	Shoulder Instability Neuromuscular Exercise
<b>TASD</b>	Traumatic Anterior Shoulder dislocation
<b>TSK</b>	Tampa Scale of Kinesiophobia
<b>VAS</b>	Visual Analogue Scale
<b>WOSI</b>	Western Ontario Shoulder Instability

## **Definitions**

### ***Chronic shoulder instability***

Subluxations of the shoulder possibly releasing a quick, sharp feeling of pain, and that something feels loose in the shoulder during movements. Symptoms may vary and fluctuate from activity to activity

### ***Closed kinetic chain***

Exercise with distal segment (foot/hand) fixed, and remains fixed during an exercise.

### ***Open kinetic chain***

Exercise where the distal segment (foot/hand) is free to move during an exercise.

### ***Neuromuscular control***

The unconsciousness trained response of a muscle to a signal regarding dynamic joint stability

### ***Primary shoulder dislocation***

A first-time shoulder dislocation defined as total separation of the humeral head relative to the glenoid fossa

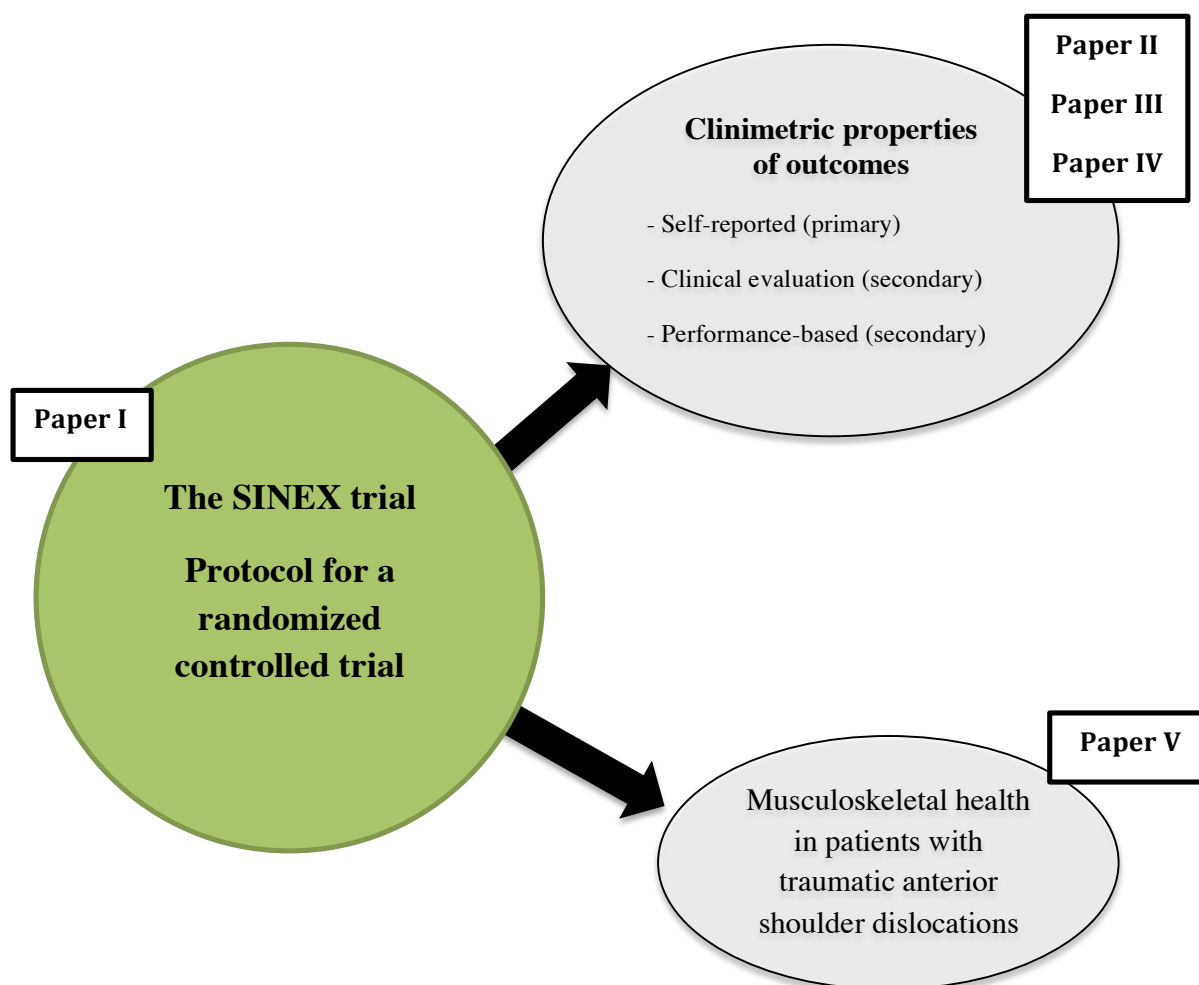
### ***Recurrent shoulder dislocation***

When the shoulder repeatedly dislocates following a primary shoulder dislocation

## Thesis at a glance

This thesis comprises five studies with different perspectives within non-operative treatment, outcome measurements and characteristics of patients with traumatic anterior shoulder dislocation.

The focal point of this thesis was a study protocol describing the design of a randomized controlled trial (RCT) evaluating the efficacy of a 12-week structured ‘Shoulder Instability Neuromuscular Exercise’ (SINEX) programme versus 12-weeks of self-managed training-based shoulder exercise programme (“standard care”) in patients with traumatic (primary and recurrent) anterior shoulder dislocation (the SINEX trial, paper I). To validate outcomes in the SINEX trial, three methodological studies (paper II, III and IV), nested within the study protocol, were performed to determine the clinimetric properties of the primary (paper II) and secondary (Paper III and IV) outcomes used. Lastly, differences in musculoskeletal health among patients with primary and repeated shoulder dislocations were examined by utilizing baseline data from patients included in the SINEX trial up until August 2016. However, recruitment for the RCT is still ongoing, thus, all results of this trial cannot be included in this thesis.



**Paper I – A protocol for a randomized controlled clinical trial on two non-operative physical therapy treatments for patients with traumatic anterior shoulder dislocations (The SINEX trial)**

Method: Randomised, assessor-blinded, controlled multi-centre trial allocated to either 12 weeks of physiotherapist-supervised Shoulder Instability Neuromuscular Exercise (SINEX) programme or self-managed shoulder exercise programme (standard care).

Subjects: 80 patients with traumatic anterior shoulder dislocation aged 18-39 years

Conclusion/interpretation: Based on the protocol the recruitment of patients has started and the RCT study is currently ongoing. The results of the SINEX trial will shed light on the effects of non-operative treatment for patients with primary and recurrent shoulder dislocations as well as provide support for future guidelines on non-surgical treatment.

**Paper II – Is an electronic version of the Danish Western Ontario Shoulder Instability Index questionnaire reliable and valid for use in Denmark?**

Method: Translation of the Western Ontario Shoulder Instability Index (WOSI) questionnaire into Danish and evaluation of reliability and validity of an electronic version of the Danish WOSI.

Subjects: 63 subjects with shoulder instability.

Conclusion: A Danish version of the WOSI was established and found to be easily administered electronically with excellent test-retest reliability along with highly satisfactory concurrent and construct validity. WOSI is now validated in Sweden, Norway and Denmark, which allows for collaboration projects within Scandinavian shoulder instability patients.

**Paper III – What are the reliability of six clinical shoulder instability tests?**

Method: Inter-examiner reliability study of six clinical tests (apprehension, relocation, surprise, load-and-shift, sulcus sign, and Gagey) for evaluation of glenohumeral joint pathology.

Subjects: 40 subjects (13 patients with shoulder instability).

Conclusion: Four of six tests (apprehension, surprise, load-and-shift, and Gagey) were reliable for clinical use. Further investigation on the performance and interpretation of the relocation and sulcus sign tests is needed.

**Paper IV – Is assessment of shoulder sensorimotor control using a Nintendo Wii Balance Board reproducible and valid when compared with a laboratory force platform (used as the gold standard)?**

Method: Test-retest reproducibility study of a prone lying test position for measuring shoulder sensorimotor control using a Nintendo Wii Balance Board (NWBB), and testing of concurrent validity of the NWBB through systematic and simultaneous loading of the NWBB and force platform with increasing deadweights ranging from 5-90 kg.

Subjects: 71 subjects (34 patients with mixed shoulder symptoms).

Conclusion: The prone lying, shoulder sensorimotor control test using a NWBB was highly reproducible. The concurrent validity of the NWBB was poor compared with a force platform, limiting the use of NWBB for prone lying measurements.

**Paper V – Do patients with primary dislocations have better musculoskeletal health than patients with recurrent shoulder dislocations?**

Method: A cross-sectional study utilizing baseline data of patient-reported, clinical and performance-based outcomes from patients included in the SINEX trial.

Patients: 48 patients (30 patients with primary and 18 patients with recurrent shoulder dislocations, respectively).

Conclusion: Patients with primary shoulder dislocation do not present better musculoskeletal health than patients with recurrent shoulder dislocations. Though, both groups present with equal and high severity of shoulder instability, affected by psychological factors and poor shoulder-related quality of life. Hence, optimum treatment strategies need further improvements, also for those with primary dislocation.

## Summary

Musculoskeletal (MSK) complaints are frequent and affect people worldwide. Shoulder-related disorders are in top three of all MSK disorders constituting a socioeconomic burden that is quite excessive. One costly and significant problem is a traumatic anterior shoulder dislocation (TASD), which is a common injury among young athletic active individuals. Following TASD, patients are often affected physiologically and mentally, reducing shoulder-related Quality of Life (QoL). The risk for repeated dislocations is relatively high following TASD due to structural changes in the stabilising structures of the shoulder. Re-dislocations may further compromise shoulder function. First line treatment of TASD is recommended to be non-operative, though, patients do not necessarily receive treatment today. Currently, there is no evidence-based exercise programme to prescribe and the quantity and quality of existing studies investigating non-operative treatment for this patient group is low. In MSK disorders of other body regions, neuromuscular exercise has shown great potential in improving functional capacities and QoL. E.g., neuromuscular exercise has shown to be as equally effective as early surgical reconstruction in patients with traumatic anterior cruciate ligament injuries, which is highly comparable with TASD on injury mechanism (traumatic origin, high impact), age (late teens to mid-thirties), post-traumatic symptoms (pain, instability, loss of mechanical stability), besides reduction in physical and social function. Thus, use of neuromuscular exercises in the rehabilitation of patients with TASD seems evident. Such programme including neuromuscular exercises, though, has not yet been developed and tested scientifically on the shoulder.

The aim of this thesis was to evaluate the efficacy and safety of 12 weeks of physiotherapist-supervised neuromuscular shoulder exercise programme versus 12 weeks of self-managed shoulder exercise programme (standard care) for patients aged 18-39 years with traumatic (primary and recurrent) anterior shoulder dislocations. Nested within that study, we aimed at reporting on the methodological quality of the outcomes used in the SINEX trial besides reporting on MSK health in patients with TASD.

A protocol for a randomized controlled trial (the SINEX trial) investigating non-operative treatment effects in patients with TASD was developed (study I). Embedded in the protocol, a physiotherapist-supervised neuromuscular shoulder exercise programme was developed and described in detail according to current pathophysiological evidence and clinical experience.

Additionally, the Western Ontario Shoulder Instability Index (WOSI) questionnaire, used as primary outcome in the SINEX trial, was translated into Danish according to international guidelines and found to be highly reliable and valid for evaluation of shoulder instability patients (study II). Further, patients included in the SINEX trial were evaluated for objective shoulder pathology with the use of three clinical anterior shoulder instability tests (apprehension, relocation and surprise). Evaluation of inter-examiner reliability of these tests, in addition to three shoulder laxity tests (load-and-shift, sulcus sign and Gagey) was performed resulting in acceptable reliability for all tests, except for relocation and sulcus sign found not to be reliable (study III). To evaluate performance-based shoulder function in

patients included in the SINEX trial, a Nintendo Wii Balance Board (NWBB) was used to assess shoulder sensorimotor control in a prone lying test position. Likewise, this method was investigated for clinimetric properties resulting in high reproducibility, but poor validity, especially at low loads (study IV). Finally, to test for differences in patient characteristics of patients included in the SINEX trial according to injury status (primary versus recurrent shoulder dislocations) subjective and objective outcome measures was reported. The findings were that primary shoulder dislocation patients do not present better musculoskeletal health than patients with recurrent shoulder dislocations. However, both groups present with equal and high severity of shoulder instability, are affected by psychological factors and have poor shoulder-related QoL (study V).

## Resumé (Danish)

Muskuloskeletale (MSK) lidelser er hyppige og påvirker mennesker i hele verden. Skulder lidelser indplaceres i top tre over alle MSK lidelser og udgør derfor en ganske betragtelig samfundsøkonomisk byrde. Et økonomisk og stort problem blandt unge aktive mennesker er en traumatisk skade, hvor skulderen ryger ud af led. Efter en sådan skade påvirkes patienterne ofte fysiologisk og mentalt, med efterfølgende reduceret skulder-relateret livskvalitet. Som følge af den alvorlige skade, er der stor risiko for at skulderen går ud af led igen som følge af strukturelle ændringer i de stabiliserende skulder strukturer. Dette kan yderligere forværre tilstanden i skulderen. I første omgang anbefales ikke-operativ behandling til disse patienter. Dog modtager disse patienter nødvendigvis ikke noget behandlingstilbud i dag. For nuværende er der ingen evidensbaseret træningsprogrammer at tilbyde og mængden og kvaliteten af eksisterende studier på området er meget lav.

Neuromuskulær træning har vist sig at have et stort potentiale for at forbedre funktionelle egenskaber og livskvalitet hos personer med MSK lidelser i andre kropsregioner. Eksempelvis, så har neuromuskulær træning vist sig at være lige så effektiv som tidlig kirurgisk indsats overfor patienter med traumatisk skade på det forreste korsbånd i knæet, hvilket er meget sammenlignelig med skulder ude af led ifht. skadesmekanisme (traumatisk skade, stor energi), alder (sene teenageår til midten af tredive), posttraumatiske symptomer (smerte, løshed, tab af mekanisk stabilitet), foruden reduktion i fysisk og social funktion. Derfor virker det oplagt, at anvende neuromuskulære øvelser i rehabiliteringen af patienter der har haft skulderen ude af led. Et sådant program, indeholdende neuromuskulære øvelser er dog endnu ikke blevet udviklet og testet videnskabeligt på skulderen.

Formålet med denne afhandling er således at evaluere effekten og gennemførligheden af 12 ugers fysioterapeutisk superviseret neuromuskulær skulder træning overfor 12 ugers selvstyret skulder hjemmetrænings program (standardbehandling) for patienter i alderen 18-39 år med en skulder der har været ude af led (én eller flere gange). Vi ønskede samtidig at undersøge kvaliteten af de målemetoder der blev anvendt i studiet og yderligere at rapportere om der var forskel i MSK sundhed hos patienter med en først-gangs skulder ude af led ifht. patienter der har oplevet dette ske flere gange.

Til at undersøge dette, blev der udviklet en protokol til et randomiseret kontrolleret forsøg (SINEX studiet) som skulle undersøge ikke-operative behandlingseffekter hos patienter med traumatiske skader der har afledt at skulderen gik ud af led (studie I). I forbindelse med protokollen blev der udviklet og detaljeret gjort rede for et fysioterapeutisk superviseret neuromuskulært skulder træningsprogram baseret på nuværende viden omkring patofysiologiske ændringer ifbm. at skulderen har været ude af led samt input fra klinisk erfaringer.

Spørgeskemaet Western Ontario Shoulder Instability Index (WOSI), anvendt som primær effektmål i SINEX studiet, blev oversat til dansk i henhold til internationale retningslinjer. WOSI viste sig at være både reliabel og valid ifht evaluering af skulderinstabilitets patienter (studie II).



Patienter inkluderet i SINEX studiet blev evalueret for objektiv skulder patologi vha. tre kliniske skulderinstabilitets tests (apprehension, relocation og surprise). Disse tre tests, i tillæg til tre yderligere tests til undersøgelse af skulder løshed (load-og-shift, sulcus sign og Gagey), blev undersøgt for inter tester reliabilitet. Dette resulterede i acceptabel reliabilitet for alle tests, på nær relocation og sulcus sign som havde dårlig reliabilitet (studie III). En Nintendo Wii Balance Board (NWBB) blev anvendt til at evaluere performance-baseret skulder funktion hos de patienter der blev inkluderet i SINEX studiet ved at måle deres sensomotoriske skulder kontrol i en maveliggende test position. Denne metode blev ligeledes undersøgt for måleegenskaber, hvilket resulterede i høj reproducerbarhed, men dårlig validitet, især under lave belastninger (studie IV). Endelig, afrapportering af subjektive og objektive patientkarakteristika af patienter med skulderen ude af led en gang overfor dem med flere gange blev foretaget. Undersøgelsen fandt ikke belæg for at sige, at der var forskel på de to grupper. Men begge grupper havde store problemer med skulderfunktion, var påvirket psykologisk og havde dårlig skulder-relateret livskvalitet.

## **Introduction**

### **Musculoskeletal injuries - a global burden of disease**

Musculoskeletal (MSK) complaints are frequent and one of the most disabling conditions affecting Quality of Life (QoL) in people all over the world [1]. An MSK condition covers many different aspects, but common to all is the presence of pain and functional impairments to joints, muscles, ligaments and/or tendons [2]. MSK disorders may start early due to athletic injuries or later in life as a consequence of degenerative conditions. The lifetime prevalence of shoulder problems in the general population is reported to range between 30-50% [3] placing shoulder-related dysfunction and pain in top three of all MSK disorders [4]. As a consequence, shoulder MSK disorders constitute a socioeconomic burden that is quite excessive and constantly increasing [5]. Hence, attention on accurate diagnosis and cost-effective treatments are vital to improve MSK health and QoL in individuals affected by shoulder-related dysfunctions.

Specifically for athletic injuries, 8-13% of all MSK complaints derive from the shoulder [6]. One common shoulder injury is the traumatic anterior shoulder dislocation (TASD) that accounts for up to 50% of all joint dislocations in emergency departments [7]. Choosing the right treatment regimen is challenging to health professionals due to the fact that the natural course of shoulder instability following a TASD is far from complete/well understood [8]. Often, patients and health professionals are left with no other options than to take a 'wait-and-see-approach', which may have fatal consequences for some. Though, the number of patients affected by this is not yet known. Thus, further research is needed to establish evidence-based guidelines for management and treatment of this patient group.

### **Traumatic anterior shoulder dislocation**

#### ***Definition***

A traumatic shoulder dislocation is often caused by a high impact injury resulting in a displaced humeral head outside the glenoid fossa [9, 10]. The injury mechanism is typically due to a direct external force to, or falls on, an extended arm with the shoulder forced into hyperabduction and external rotation [10]. A total shoulder dislocation is defined as a complete separation of the humeral head from the glenoid surface, whereas a subluxation is regarded as a symptomatic separation without total displacement [11]. Dislocations may occur in either one (anterior, posterior, inferior) or more directions (multidirectional) [12-15]. Anterior dislocations accounts for up to 96% of all cases [9].

## ***Epidemiology***

Joint dislocations most frequently involve the shoulder [16], though, only few studies have reported on the incidence and prevalence rates. Nonetheless, most of the available evidence is derived from Scandinavian countries most likely due to mandatory registration of patients and their diagnoses within primary care in the Nordic countries. The incidence rates for primary TASD in the general population of Denmark (DK), Sweden (S) and Norway (N), have been reported to range between 12.3 [17], 23.9 [18] and 26.2 [19] per 100.000 person-years, respectively, with data extracted from emergency departments in Aarhus (Dk), Malmø (S) and Oslo (N). The two former cities are almost equal in size (300.000 citizens each), as opposed to Oslo, representing the largest of the three cities, with approximately 600.000 citizens. In line with these numbers, the annual incidence (per 100.000 persons) of TASDs presenting to emergency departments in the United States is 23.9 [20]. Overall, it seems that there has been an increased incidence rate of TASD over the last three-four decades possibly reflecting an increase in physical activity and sports participation. Finally, the lifetime prevalence of TASD in the general population is reported to be 1.7% with data derived from a prospective large-scaled multi-centre cohort study, initiated in Sweden for more than 40 years ago, including over 250 patients with a primary TASD [21].

## **Risk factors for sustaining traumatic anterior shoulder dislocations**

### ***Age***

TASD usually affects young adults (late teens to mid-thirties) or elderly at retirement age. The first peak relate to high levels athletic activities increasing the risk for sports-related shoulder dislocations whereas the second relate to the elderly who tend to have poor balance late in life increasing the risk of falling [20]. Furthermore, patients sustaining a TASD below the age of 40 are 13 times more likely to experience repeated shoulder dislocations [22].

### ***Sex***

The male to female ratio reported by Hovelius et al. (1982) was approximately 3:1, which very well reflects the findings of studies also reporting higher risk rates for males as opposed to females in people aged 40 years and younger [17-20, 22]. The skewed male to female ratio is hypothesized to be due the preponderance of male participants in contact sports [22].

### ***Joint laxity***

Shoulder laxity and generalized joint hypermobility (GJH) have been shown to be a risk factor for TASD [23-25]. Additionally, shoulder laxity and GJH have shown to increase the likelihood for

developing repeated dislocations and/or recurrent symptomatic shoulder instability following a primary T ASD by a factor of 2.7 [22, 26].

### **Anatomy and biomechanics of the shoulder**

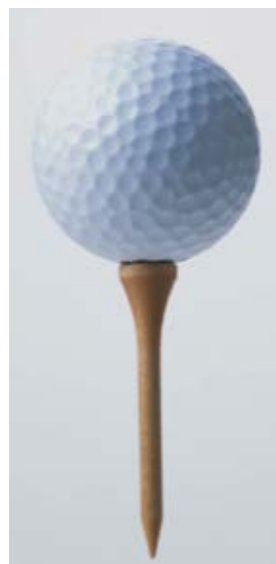
The shoulder is one of the most complex joints in the human body with up to 17 muscles and four articulations involved in stabilizing and moving this joint [27].

Anatomically, the shoulder is a ball and socket joint with highly limited osseous congruence between the humeral head and glenoid fossa [28] (Figure 1).

The advantage of this construction is an enormous degree of movement freedom that is widely used during both simple daily tasks and more complex movements during specific sports. The downside of being the most mobile joint of all, however, is the increased risk of injuries [29].

Unlike the lower extremity, the shoulder and upper extremity are not supported by weight-bearing forces, and, is thus highly dependent on the static and dynamic stabilizing tissue. The static stabilizers include the glenoid labrum, ligaments and capsule whereas the dynamic stabilizers refer to the muscles surrounding the glenohumeral and scapula thoracic joints. The labrum is a fibrocartilaginous stabilizer attached to the rim of the glenoid fossa providing stability for the shoulder through the following mechanisms; it extends the surface area of the small fossa, it increases the depth of the socket, it provides a fibrocartilaginous ring to which the glenohumeral ligaments attach and, finally, it has a “suction-cup” effect for maintaining intra-articular pressure [30]. The glenoid fossa is a small and pear-shaped surface located at the upper, lateral border of the scapula and serves as a basis for the humeral head throughout any movement of the upper extremity. Other important static stabilizers include the shoulder capsule and its three glenohumeral ligaments embedded within the capsule [27].

The dynamic stabilizers can be separated into locally and globally stabilisers. The locally stabilizing muscles, the rotator cuff (RC), act together through coordinated contractions to draw and center the humeral head into the glenoid fossa to maintain its axis of rotation during shoulder movements. Hence, an important RC function is the deep stabilization of the glenohumeral joint through force-couple activity similar to that of transversus abdominis (lower back) and vastus medialis (knee) [31, 32]. The RC consists of four muscles; subscapularis (internal rotator, anteriorly positioned), infraspinatus/teres minor (external rotators, posteriorly positioned) and supraspinatus (abductor, superiorly positioned) that all emanate from the scapula. The position and movement of the scapula is therefore of equal



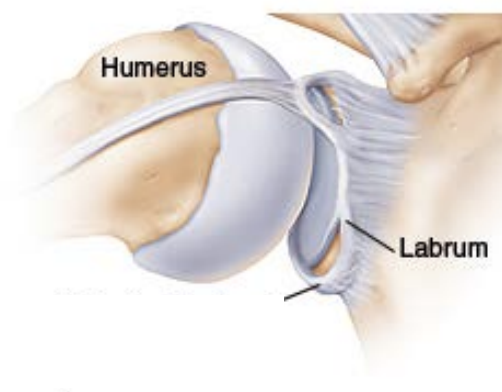
**Figure 1.** Shoulder joint anatomy - mobility versus stability.

importance in order to provide stability for the humeral head and the function of the RC muscles during movement [33, 34]. The prime movers and stabilisers responsible for scapular function are the upper, middle and lower parts of trapezius as well as serratus anterior. Despite the gross biomechanical complexity, it is generally accepted that the normal scapular movement during shoulder flexion is posterior tilt in combination with upward and external rotation [34].

## **Pathophysiologic changes following traumatic anterior shoulder dislocation**

### ***Structural changes***

The most frequently encountered pathology following a TASD is detachment of the antero-inferior labral-ligamentous tissue leading to a Bankart lesion. The shoulder may be further deteriorated by avulsion of the antero-inferior glenoid (Bony Bankart) or by bony defects to the humeral head (Hill Sachs fracture) [35, 36] (Figure 2).



**Figure 2.** Detachment of the anterior capsulolabral stabilising complex

### ***Scapular function***

Few studies have been performed on scapular position, function and muscle activity in patients with anterior shoulder instability. However, one study demonstrated a downward rotated scapula at rest [37], whereas contrast findings have been found during shoulder elevation in the scapular plane. A review, compiling the results from several studies demonstrated decreased, respectively increased scapular upward and internal rotation [34]. The contradicting findings may be due to different measurement techniques (two plane x-ray, 3-D kinematic, topography) and patient groups (atraumatic instability, anterior instability warranted for surgery besides multi-directional instability), respectively. Regarding scapular muscle activity and recruitment patterns, shoulder instability patients present with varying muscle activity compared to healthy subjects. Also, muscle recruitment timing has displayed non-normal patterns, but a conclusive statement is not possible [38]. Thus, although not clear, shoulder instability patients present with scapular dysfunctions when compared with healthy, unimpaired shoulders.

### ***Rotator cuff***

Altered co-activation and muscle recruitment of the RC muscles during simple upper extremity elevation tasks have been found in patients with generalized ligamentous laxity

[39] and symptomatic [37, 40-42] glenohumeral instability. Also, isokinetic internal and external rotator strength has shown to be weakened in patients with TASDs [26, 43, 44].

### ***Sensorimotor control and proprioception***

Due to the absence of glenohumeral osseous stability and structural joint changes following a TASD a large amount of functional stability is required [45]. Functional stability is achieved through activity of the dynamic stabilizers mediated by the sensorimotor system, which is composed of afferent (proprioceptive information) and efferent (neuromuscular control) systems [29]. Signals from these systems are integrated within the central nervous system and translated into coordinated shoulder movements by activation of dynamic stabiliser and movers [28, 46]. Hence, injuries resulting in insufficient neuromuscular control may have large consequences due to decreased centralization of the humeral head within the glenoid. Thus, lack of neuromuscular shoulder control may result in excessive translation of the glenohumeral head potentially increasing injury risks, inflammatory responses, and reflexive inhibition of the dynamic stabilisers [29]. In patients with shoulder instability, global neuromuscular control [47] and proprioceptive function [28, 48-55] seem to be negatively affected. These deficits may contribute to the continuation of shoulder instability symptoms and, partly, explain the relative high rates of recurrent shoulder dislocations.

### **Post-traumatic consequences of sustaining a traumatic anterior shoulder dislocation**

A TASD may have considerable impact on the level of sports participation, social activity and shoulder-related QoL [56-58]. There is a high probability for experiencing recurrent dislocations and/or development of chronic shoulder instability following a primary TASD, with a mean risk rate estimated to range between 39% and 67% [20, 59].

Progression in joint deterioration is expected in recurrent shoulder dislocations and, thus contributing to further development of chronic instability [10]. Frequently, patients are affected both physically and mentally [60-62]. It may be anticipated that patients with recurrent instability/events of dislocation exhibit more severe and/or complex symptoms (physical as well as mental) than those with a primary dislocation. However, the evidence to support this anticipation is limited as the natural course of shoulder instability symptoms from primary to recurrent events is far from understood [8].

Physical symptoms refer to ongoing or fluctuant pain and/or instability from the shoulder whereas mental affections refer to distrust in shoulder function and a fear of re-injury during movement [63]. Hence, a large proportion of these patients will not be able to return to pre-injury levels of physical function thereby affecting patients QoL [64]. Furthermore, post-traumatic mental distress, such as fear of movement and re-injury conditions, may keep the patients from returning to the desired level of sport [64].

## **Management and treatment of traumatic anterior shoulder dislocations**

### ***Closed reduction and immobilization***

Traditionally, the shoulder is manually repositioned with a closed reduction procedure at the emergency departments followed by a period of immobilization with the shoulder in adduction and internal rotation, supported by a sling. Recent studies have investigated whether immobilization in a position with the shoulder in abduction and external rotation is a better option for optimizing tissue healing and minimizing risk of recurrence [65], but with no additive effect of the more advanced external rotation position [66]. Also, the duration of immobilization has gained some interest. Studies have shown that shoulder immobilization for more than one week is of no further benefit for reducing the risk of experiencing recurrent shoulder dislocations and/or return to pre-injury levels of sports activity [67-69]. Another study suggests that immobilization is not needed at all [70]. Hence, current practice should be moving towards early mobilization and restoration of neuromuscular function.

### ***Treatment paths (non-operative and operative)***

Currently, there is no evidence-based exercise programme to prescribe for patients with TASDs [10]. Also, the quantity and quality of studies investigating non-operative treatment for this patient group is low [71]. Previously, only three randomized controlled trials have been conducted investigating the effect of non-operative (shoulder rehabilitation) versus operative treatment (arthroscopic or open Bankart procedures in addition to shoulder rehabilitation) in patients with primary T ASD [72-74]. Overall, the findings were that the additive effect of early operative reconstruction of the anterior capsulolabral complex is superior to a strategy of non-operative treatment in reducing re-dislocation rates. Though, the exercise programmes are poorly described and they consist mostly of post-operative principles. Hence, the non-operative treated patients in these RCTs may have been undertreated and intensive non-operative exercise programmes are lacking [75]. Finally, varying methodological issues exist anticipated to bias the findings of these RCTs [71]. Systematic reviews advocate for initial stabilizing surgery in young, highly athletic active male patients with a primary T ASD [76, 77]. This is in spite of concern, that early surgery will expose some patients for unnecessary surgery-related complications and add to society treatment costs [78]. For other T ASD patient groups (e.g. aged 25-40 years, non-professional athletes, primary or recurrent dislocations), though, the evidence for optimal treatment (operative as well as non-operative) is limited [77]. This is further reflected by current practice, with large variations in the management of both primary and recurrent T ASD patients [79].

In MSK disorders of other body regions, neuromuscular exercise has shown great potential in reducing joint pain, besides improving functional capacities and QoL [80-84]. More specifically, neuromuscular exercise has shown to be as equally effective as early surgical reconstruction in e.g. patients with traumatic anterior cruciate ligament injuries, which is highly comparable with T ASD on injury mechanism (traumatic origin, high impact), age (late teens to mid-thirties), post-traumatic symptoms (pain, instability, loss of mechanical stability), besides reduction in physical and social function [83]. Hence, use of neuromuscular exercises in post-traumatic rehabilitation of

patients with T ASD seems evident due to loss of mechanical stability [85], and potential impaired proprioceptive function [47, 55]. To our knowledge, such programme of neuromuscular exercises for increasing sensorimotor control and compensatory functional stability has not yet been developed and tested scientifically on the shoulder [86].

### **Neuromuscular exercise**

The aim of neuromuscular training is to improve sensorimotor control and achieve compensatory functional stability through controlled movements [80, 87]. Facilitation of the neuromuscular system is achieved through muscular co-activation, proprioceptive stimulation through joint position sense training, besides balance, strength and plyometric exercises. Also, special attention to movement quality rather than quantity is given. Finally, the level of training and load during exercise is matched and adjusted to the capability of the individual patient [80].

For shoulder instability, current clinical knowledge suggests incorporation of RC strength exercises, optimization of scapular function, focus on overhead shoulder sports specific activities, activation of muscle chains from the lower to the upper extremity and facilitation of core muscles [33, 88-90].

### **Treatment effect measures in patients with shoulder instability**

Shoulder stabilization surgery has proven to be effective for preventing recurrent shoulder dislocation [91] and, with arthroscopic Bankart repair as the most commonly performed procedure [92]. Although some patients continue to experience recurrent dislocations, surgical stabilization seems to improve shoulder-related QoL [93]. Whether the shoulder re-dislocate may therefore seem as an optimal primary outcome for evaluating failure or success of a given intervention. Still, even though patients seem to achieve an objective shoulder function close to 100% following surgical stabilisation, not everybody succeed in returning to their pre-injury sport [64]. Thus, it seems important also to include patient reported outcomes in addition to objective clinical and performance-based measurements in patients with T ASDs.

### ***Patient Reported Outcome Measures***

The most frequently recommended Patient Reported Outcome Measurement (PROM) for evaluating treatment effects in shoulder instability patients is The Western Ontario Shoulder Instability Index (WOSI) questionnaire [94]. WOSI is an important outcome tool due to its capability of capturing changes in shoulder-related QoL during activity, comprising such as the "feeling of slipping" and "being unable to trust the shoulder" [95, 96]. WOSI has been



translated into various languages according to international guidelines, and validated for measurement properties nation wise [95-100]. In Denmark, though, WOSI exists only in an unpublished version with no descriptive information on translation procedures and cross-cultural measurement properties.

### ***Objective clinical evaluations***

Clinical tests for diagnosing shoulder instability are commonly performed by use of shoulder pain and instability provoking/relieving tests, supplemented by shoulder laxity tests with reference to normal standards (healthy shoulders) [101, 102]. The former tests usually include the anterior instability tests apprehension, relocation and surprise with the latter laxity tests predominantly consisting of the load-and-shift, sulcus sign and Gagey tests [27, 103, 104]. The laxity tests aim to determine how loose the stabilising glenohumeral ligaments and shoulder capsule are.

Only few studies, however, have investigated the reliability of these tests, showing large variations of reliability [105-107], and with limited methodological quality, hampering interpretation and comparison with other studies.

### ***Objective performance-based evaluations***

To evaluate objective performance-based shoulder function, clinicians may use traditional isometric strength measurements and/or functional performance tests. Muscle strength is important during daily activities, as is functional performance, relying mostly on neuromuscular systems. In contrast to, e.g., strength measurements, there is a lack of simple, reliable and valid methods for measuring shoulder neuromuscular control [108]. Efficient neuromuscular control of the shoulder is important throughout any movement with the upper extremity, however, most important at end range such as in overhead positions [29, 109]. Current methods for measuring neuromuscular control mainly involves time-consuming and expensive equipment (e.g. isokinetic dynamometers and motion-tracking systems) [108], thus, not suited for clinical practice.

One way to address shoulder neuromuscular control is to measure shoulder Joint Position Sense (JPS) in open kinetic chains mimicking activities of daily living. A simple and cheap method has recently been described using a laser pointer and a target scale developed to calculate joint position errors from patients asked to actively reproduce different shoulder angles in flexion while blindfolded [108].

Another way to evaluate shoulder neuromuscular control is stabilometric measurement by use of a laboratory force platform with subjects positioned in prone lying [110]. However, force platforms are also expensive and not suited for field settings such as clinical practice. Hence,

the low-cost and clinically feasible Nintendo Wii Balance Board (NWBB) has been suggested and found to be a reliable and valid substitute, though only investigated for assessment of standing sensorimotor control [111-114]. Nevertheless, the use of NWBB as scientific and clinical measurement tool has been widely discussed due to presence of relative high levels of background noise [115, 116].

## **Aims of this thesis**

The overall aim of this thesis was to report the study design of a randomized controlled trial (the SINEX trial) designed to investigate non-operative treatment effects in patients with traumatic anterior shoulder dislocations and to report the methodological quality of the various outcomes used in the SINEX trial besides to report shoulder function of patients with traumatic anterior shoulder dislocation.

*The specific aims of the individual papers were:*

- I.** To develop a protocol for an assessor-blinded randomized controlled multi-centre trial (the SINEX trial) investigating the efficacy and safety of 12 weeks of supervised neuromuscular shoulder exercise programme versus 12 weeks of self-managed shoulder exercise programme (standard care) for patients aged 18-39 years with traumatic (primary and recurrent) anterior shoulder dislocations.
- II.** To linguistically translate and cross-culturally validate, and adapt the Western Ontario Shoulder Instability Index (WOSI) questionnaire for use in Denmark and, further, to determine the reliability and validity of the Danish WOSI version.
- III.** To determine the inter-examiner reliability of clinical shoulder instability tests for diagnosing glenohumeral joint pathology in subjects with and without self-reported symptomatic shoulder instability.
- IV.** To determine test-retest reproducibility of the Nintendo Wii Balance Board (NWBB) for measuring shoulder sensorimotor control in a prone lying, upper limb weight-bearing position in subjects with and without self-reported shoulder trouble. Besides that, to test the concurrent validity of the NWBB when compared with a force platform used as the gold standard.
- V.** To test for differences between traumatic primary anterior shoulder dislocations versus recurrent anterior shoulder dislocations in subjective and objective outcome measures.

## **Material and methods**

Due to the different study designs and varying methodological procedures, required to explore the aims of this thesis, each paper is described separately. Included patients/subjects were recruited separately for each study. Identical methods and procedures used across papers are described once and individually referred to the specific paper by the Roman numerals (I-V). An overview of the individual designs and subjects included in each of the five papers is provided in Table 1.

**Table 1.** Overview of the five papers

<b>Papers</b>	<b>Design</b>	<b>Subjects (n)</b>
<b>I</b>	A neuromuscular exercise programme versus standard care for patients with traumatic anterior shoulder instability: Protocol for a randomised controlled trial.	-
<b>II</b>	Translation, reliability and validity of an electronic version of the Danish Western Ontario Shoulder Instability Index (WOSI).	63
<b>III</b>	Inter-examiner reliability of clinical shoulder instability tests	40
<b>IV</b>	Reproducibility and validity of the Nintendo Wii Balance Board for measuring shoulder sensorimotor control in prone lying.	71
<b>V</b>	Cross-sectional study reporting the characteristics of patients with primary and recurrent shoulder dislocations	48

## **Ethics**

### ***Paper I and V***

Patients included in the SINEX trial (paper I and V) were informed about the randomized design with allocation to one of two treatment arms and they all signed an informed consent form prior to inclusion. Patients received a treatment of either an anticipated equivalent, or one superior to what they would have received if they had not participated in the study. Additionally, it was not expected that the risk of sustaining another shoulder dislocation from participating in this study would be any higher than from regular daily activities. The SINEX trial met the criteria and principles of the Declaration of Helsinki [117] and has been approved by the local Ethics Committee for the Region of Southern Denmark (project ID: S-20140093). The SINEX trial is registered at Clinicaltrials.gov (NCT-02371928).

## Paper II, III and IV

The three methodological studies, nested within the SINEX trial, were all exempted for notification to the Health Research Study Board due to the non-invasive/-non-treating study designs. Though, patients were provided with detailed information about the study objectives before enrolment, and written informed consent was obtained.

## Study design

### Paper I

A multi-centre (three sites), stratified (primary or recurrent shoulder dislocation) randomized, and controlled, assessor-blinded superiority trial, with a two-group parallel design (Figure 3) was initiated to investigate the efficacy and safety of 12 weeks of a physiotherapist-supervised neuromuscular exercise programme versus self-managed shoulder exercise programme for patients with traumatic anterior shoulder dislocations.

The primary endpoint is shoulder-related Quality of Life assessed by the Western Ontario Shoulder Instability Index (WOSI) questionnaire evaluated 12 weeks after enrolment (Figure 3).

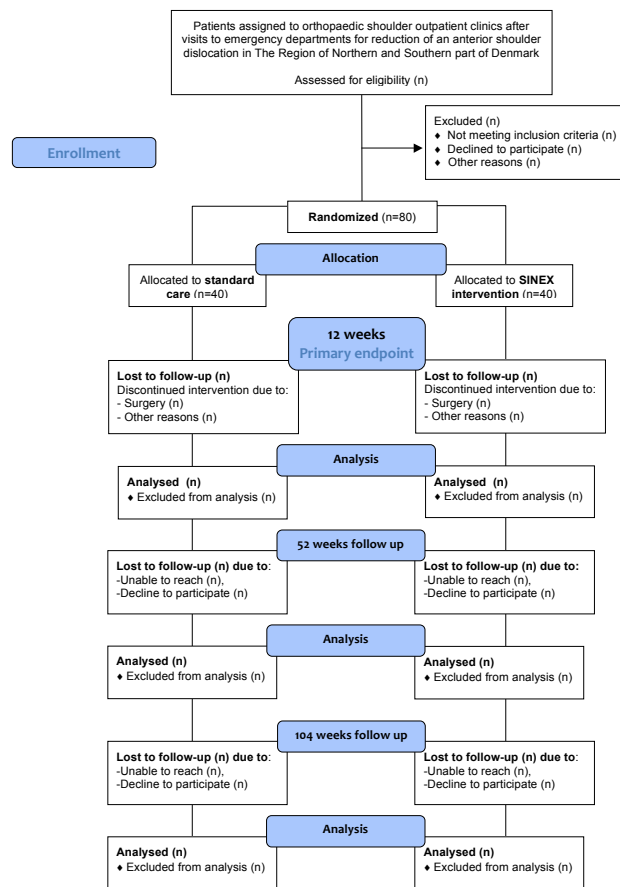
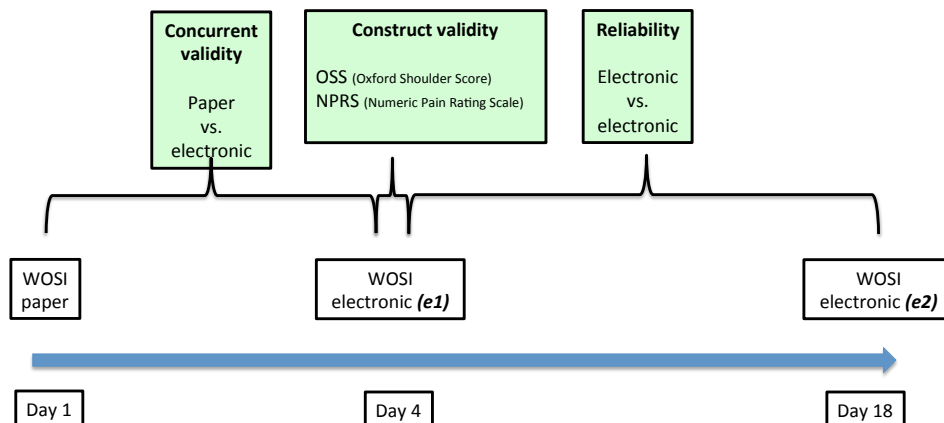


Figure 3. Flowchart of the SINEX trial.

### Paper II

The WOSI questionnaire was linguistically and cross-culturally translated and adapted for use in Denmark according to standardized guidelines.

Subsequently, a prospective longitudinal design examined the test-retest reproducibility and validity of the Danish WOSI questionnaire (Figure 4).

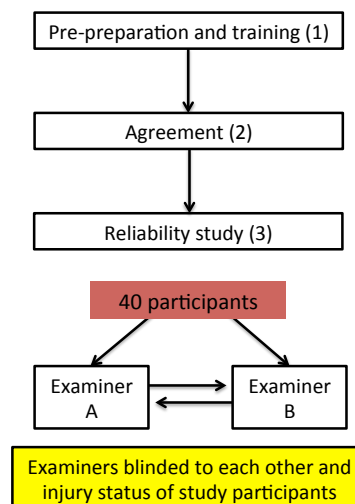


**Figure 4.** Longitudinal design used for examination of reliability and validity of WOSI.

**Paper III**

A standardized protocol was used to determine the inter-examiner reliability of clinical shoulder instability tests.

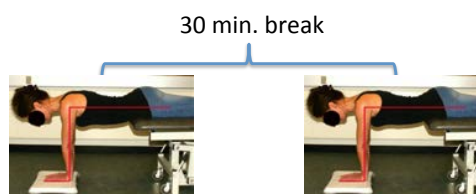
The protocol consisted of three phases distributed as follows: (1) pre-preparation and training of clinical tests, (2) agreement phase, and (3) the actual reliability study (Figure 5).



**Figure 5.** Flowchart of training, agreement phase and reliability study.

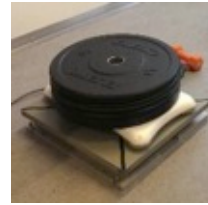
**Paper IV**

A test-retest design evaluated reproducibility of a NWBB for measuring prone lying shoulder sensorimotor control (Figure 6).



**Figure 6.** Test-retest reproducibility design

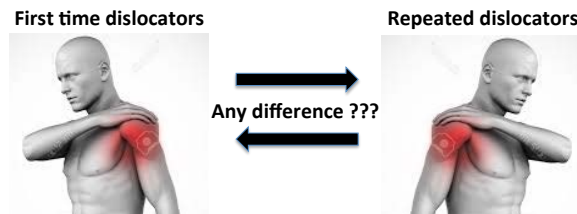
Concurrent validity was evaluated by comparing levels of background noise in a NWBB and a laboratory force platform by systematic loading of both platforms with increasing deadweight's (Figure 7).



**Figure 7.** Setup for the deadweight experiment for determining concurrent validity of the NWBB.

### *Paper V*

A cross-sectional study design was used to test for differences in self-reported musculoskeletal health, clinical tests and performance-based outcome according to injury status (primary versus repeated dislocations) of patients included in the SINEX trial (paper I) (Figure 8).



**Figure 8.** Cross-sectional study design

## Subjects and settings

### *Paper I and V*

The cross-sectional study (paper V) is based on baseline data from shoulder instability patients included in the SINEX trial (paper I). Hence, eligibility criteria for paper V followed that of paper I. Patients were recruited from three shoulder outpatient clinics of orthopedic departments at the Region of Northern Denmark (Aalborg University Hospital, Farsoe and Aalborg) and Southern Denmark (South-West Jutland Hospital, Esbjerg and Odense University Hospital, Odense).

Eligible criteria for the SINEX trial (paper I) were men and women between the ages 18-39 years old with primary or recurrent shoulder dislocations due to at least one traumatic event.

Specific inclusion criteria were; at least one x-ray verified traumatic anterior shoulder dislocation, besides self-reported shoulder trouble (mental or physical) within the latest week affecting the ability to fully participate in sports/leisure activities and/or work.

Patients were excluded if in need for surgery (decided by orthopaedic surgeons), prior surgery in the affected shoulder, more than five anterior shoulder dislocations, suspected competing diagnosis, neurological deficits in neck and shoulder muscles, pregnancy, inadequacy in written and spoken Danish and if they were unwilling or unable to attend 12 weeks of supervised physical therapy (Table 2).

Inclusion	
1.	Age between 18-39
2.	Minimum one radiographic verified anterior shoulder dislocation
3.	Self-reported shoulder trouble (physical and/or emotionally) within the latest week
Exclusion criteria	
1.	In need of surgery (humeral fracture and/or bony Bankart)
2.	Prior surgery in affected shoulder
3.	>5 anterior shoulder dislocations
4.	Suspected competing diagnosis
5.	Sensory and motor deficits in neck and shoulder
6.	Pregnancy
7.	Inadequacy in written and spoken Danish
8.	Not willing or able to attend 12 weeks of supervised therapy

**Table 2.** Eligibility criteria for the SINEX trial

### *Paper II*

Subjects were recruited from shoulder outpatient clinics at hospitals located in the South (South-West Jutland Hospital, Esbjerg and University Hospital Odense) and East (Sports Clinic, Aleris-Hamlet Parken, Copenhagen besides Zealand University Hospital, Department of Orthopaedic Surgery, Køge) Denmark Region. Also, patients were recruited through local advertisements.

Eligible subjects were men and women with the following inclusion criteria; minimum age of 18 years, current symptomatic self-reported shoulder instability due to traumatic dislocations (primary or recurrent), non-traumatic (any subluxation events), pre- or post-surgical conditions (Bankart lesions warranted for or already reconstructed).



### ***Paper III***

Subjects were separately recruited from Metropolitan University College, Copenhagen, and Bispebjerg Hospital, Copenhagen.

Men and women between ages 18-60 years old willing to participate were asked the following two questions:

*‘Do you have a sense of shoulder instability?’* and *‘Have you ever had a shoulder injury?’*

Subjects answering yes to at least one of the above questions were invited for a clinical pre-screening and included as a “shoulder instable” subject, if at least one out of six clinical shoulder instability tests (apprehension, relocation, surprise, load-and-shift, sulcus sign or Gagey) was positive. Subjects answering no to both questions were included as “shoulder healthy” subjects. Patients were excluded in case of prior shoulder surgery.

### ***Paper IV***

Subjects were separately recruited through advertising for participation in a research project at municipal rehabilitation centres, shoulder outpatient clinics, private physiotherapy clinics, and personal network in the Region of Southern Denmark.

Eligibility criteria were men and women, between the ages aged 18-50 years old, capable of reading and understanding Danish, besides being able to lie prone with the upper body supported by extended elbows. Subjects were specifically included as either cases (shoulder trouble) or controls (no shoulder trouble) (according to the following criteria:

Inclusion criteria for cases were self-reported, current shoulder symptoms/pathology (pain and/or discomfort) in one or both shoulders. Inclusion criteria for controls were no current shoulder symptoms/pathology/trouble or shoulder-related pain not exceeding more than 20mm on a VAS.

Patients were excluded if presenting with a max active shoulder flexion below 90 degrees and/or acute shoulder injury/pain exceeding 80mm on VAS. Furthermore, due to the test position used in this paper, subjects with self-reported trouble or documented pathology in trunk, back, elbows and wrist, besides neurological or rheumatologic disorders were excluded.

An overview of demographic data and shoulder conditions for all subjects included in this thesis is provided in Table 3.

**Table 3.** Characteristics of patients and subjects included in this thesis (paper II-V)

<b>Paper</b>	<b>Patients (n, % males)</b>	<b>Mean age, SD</b>	<b>Mean height, SD</b>	<b>Mean weight, SD</b>	<b>Symptoms (n)</b>
<b>II</b>	63 (64)	35 (12)	179.9 (9.1)	84.8 (17.6)	Instability (63)
<b>III</b>	40 (28)	29 (8)	173.7 (8.3)	72.9 (18.1)	Instability/healthy (13/27)
<b>IV</b>	71 (55)	36 (8)	175.0 (10.0)	80.2 (15.3)	Mixed/healthy (34/37)
<b>V</b>	48 (71)	26 (6)	181.1 (7.3)	83.5 (18.4)	Instability (48)

## **Procedures**

### *Paper I*

#### *Randomization*

Baseline measurements are performed before patients are randomly assigned to either of the treatment arms with a 1:1 allocation per centre, stratified according to injury status (primary versus recurrent shoulder dislocation). A computer generated list of random numbers (1:1) has been prepared and packed at each trial site into sequentially numbered, opaque, concealed envelopes, stating which group every single individual is randomized to. At each trial site, envelopes are stored in a closed room and managed by one single research assistant.

#### *Blinding*

The primary investigator and one research assistant performs all outcome measurements. Both assessors are blinded according to treatment allocation and have no involvement in the treatment. To keep study hypothesis secret, patients are thoroughly informed (written and orally) that the optimal choice of treatment is truly unknown [118]. Also, patients are encouraged not to uncover their treatment assignment until all follow-up measurements are collected. Finally, statistical analyses will be performed blinded according to group allocation and results will be interpreted prior to disclosing/revealing group allocation.

#### *Interventions*

Prior to patient enrolment, physical therapists have attended two training sessions on how to administer the two intervention protocols. Further, all physical therapists practiced the exercise sessions on a pilot patient for at least two weeks before being allowed to startup study subjects. For quality assurance, physiotherapists are instructed to continuously encourage patients receiving physical therapist-supervised neuromuscular exercise programme versus to attend at least seven

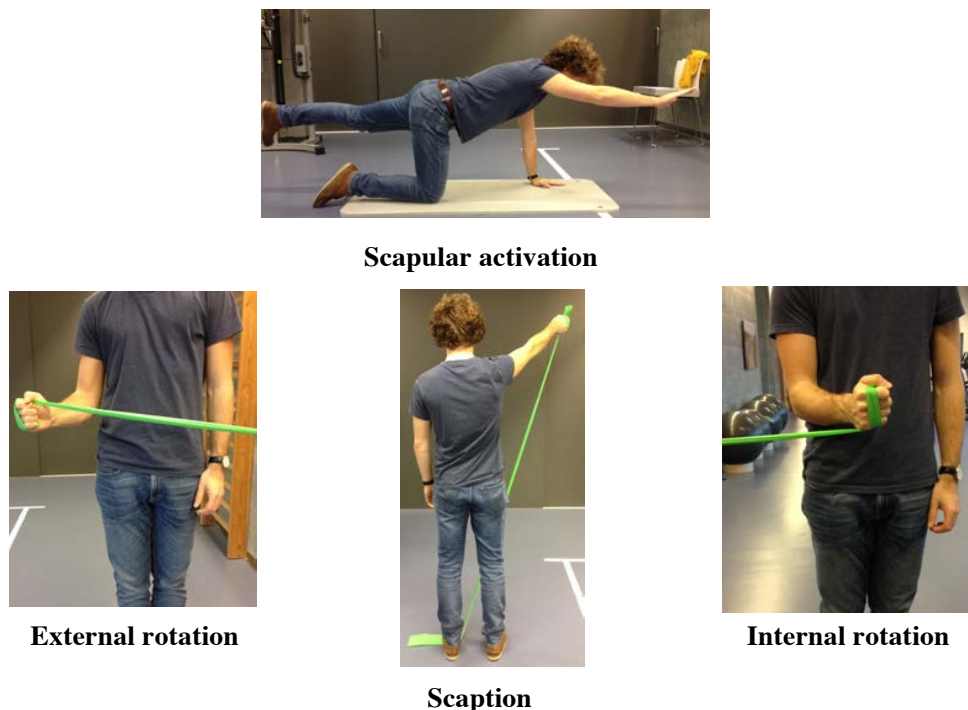
supervised sessions within the 12-weeks intervention period. Physiotherapists are allowed to contact primary investigator regarding any exercise-based challenges that they may have, though, without revealing treatment allocation of individual patients.

Both groups receive 12 weeks of active shoulder exercise treatment and information on correct ergonomic posture besides range of motion and/or stretching exercises of shoulder muscles if needed. Patients are asked not to seek other treatment during the 12-week intervention period. Also patients are asked to fill out a home-based exercise diary. Patients experiencing additional dislocations or worsening of shoulder symptoms during the intervention period are referred to an orthopaedic surgeon who decides whether participation in the study can continue or not.

### *Self-managed training-based shoulder exercise programme (Control)*

Patients allocated to standard care receive one introductory supervised physiotherapy session. Standard care consists of active exercises for the rotator cuff and scapular muscles as depicted below (Figure 9). Patients are instructed to perform the exercises three times weekly with 10x2 repetitions for each exercise. After six weeks of training each patient receive a phone call from an unblinded physical therapist to ensure progression and compliance with the exercises, in addition to patient-initiated shoulder-related communication. Patients allocated to standard care are regarded as compliant with the intervention of a completion of a minimum of two-thirds (66%) of the planned home training.

**Figure 9.** Self-managed, training-based shoulder exercise programme (Control)



*Physiotherapist-supervised neuromuscular shoulder exercise programme (Intervention)*

An overview of the content, concept and structure of the neuromuscular exercise programme (SINEX) is provided in Table 4 and 5.











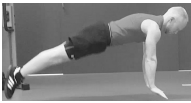



In brief, patients allocated to the SINEX programme receive 12 weeks of individually physical therapist-supervised exercise specifically targeting the glenohumeral and scapular muscles. Moreover, functional kinetic chain exercises are incorporated to progress to more advanced shoulder function levels.

The SINEX programme is individually tailored using a standardized framework consisting of seven exercises. Each exercise includes seven levels (A-G) of difficulty, ranging from basic to elite level. Patients are advised to perform each exercise at home as follows; exercises at basic level (A-E) seven days a week and exercises at elite levels (F-G) three times a week.

Patients are provided with online access to instructions and video recordings of each exercise and the accompanying levels of progression through the physical therapy site [www.digifys.com](http://www.digifys.com). Patients are encouraged to challenge themselves and, if possibly, progress to levels of higher difficulty during the home-based exercise sessions. Performance quality of each exercise is then provided from physical therapists at the supervised sessions.

A full description of the exercise programme, including structure, content, progression guidelines and overall concept is provided in paper I (supplementary material (Appendix B)).

**Table 4.** Overview of the seven exercises in the SINEX programme with examples of basic and elite level performances.

		EXERCISE						
		1	2	3	4	5	6	7
		Scapular setting and control	Glenohumeral setting and control Internal rotation	Glenohumeral setting and control External rotation	Glenohumeral muscle co-contraction	Dynamic glenohumeral muscle stability	Glenohumeral proprioception (exercise ball)	Glenohumeral proprioception (laser pointer)
Basic level								
	Elite level							

**Table 5.** Concept, structure and content of the SINEX program

<b>Exercise focus</b>	<ul style="list-style-type: none"> <li>1) Scapula setting and control</li> <li>2) Glenohumeral setting and control (during internal glenohumeral rotation)</li> <li>3) Glenohumeral setting and control (during external glenohumeral rotation)</li> <li>4) Glenohumeral muscle co-contraction</li> <li>5) Dynamic glenohumeral muscle stability</li> <li>6) Glenohumeral proprioception (use of an exercise ball)</li> <li>7) Glenohumeral proprioception (use of a laser pointer)</li> </ul>
<b>Determination of exercise level</b>	<ul style="list-style-type: none"> <li>- Physical therapist demonstrates the exercise</li> <li>- Patient performs the exercise</li> <li>- Physical therapist evaluates exercise performance and quality until an appropriate level is found</li> </ul>
<b>Criteria for progression</b>	<p>Satisfactory neuromuscular control (which determines progression of exercises) is defined as follows:</p> <ul style="list-style-type: none"> <li>- Exercise performed as described</li> <li>- Load and repetitions achieved</li> <li>- Symptoms &lt; 5 (on the pain and instability symptom-scale, ranging from 0-10, 10 being worst)</li> <li>- No need for visual, verbal or tactile feedback (from physical therapist, mirrors, etc.)</li> <li>- Movement quality throughout (No compensating strategies)</li> </ul>
<b>Exercise adjustments</b>	<p>If criteria for progression are accomplished at one exercise level, but the next level causes symptoms &gt;5 on the pain and instability symptom-scale, one of two options may be used:</p> <ul style="list-style-type: none"> <li>-1) Patient continues at the exercise level where criteria for progression is obtained, but is challenged by minimizing base of body support and/or exercise with eyes closed</li> <li>-2) Patient progress to the exercise level that could not be performed according to symptoms, but the exercise is adjusted so that it can be accomplished according to the pain and instability symptom-scale and with satisfactory movement quality.</li> </ul> <p>For further progression, any adjusted exercises must be performed as originally described with satisfactory neuromuscular control</p>
<b>Exercise difficulty</b>	
- Basic (A-E)	<ul style="list-style-type: none"> <li>Low load (2x20-25 repetition-maximum (RM))</li> <li>Large base of body support</li> <li>Focus on local muscular activity (quality before quantity)</li> <li>Movement speed during exercise equal to counts of 1-2-3-3-2-1</li> </ul>
- Elite (F-G)	<ul style="list-style-type: none"> <li>High load (2x8-12 RM)</li> <li>Minimal base of body support</li> <li>Focus on local and global muscular activity (core, functional movements, muscle chains)</li> <li>Movement speed during exercise adjusted to individual capabilities</li> </ul>
<b>Exercise frequency</b>	
- Basic level (A-E)	Every day
- Elite level (F-G)	Three times a week
<b>Supervised sessions</b>	<ul style="list-style-type: none"> <li>1-2 supervisions per week in the first two weeks</li> <li>1 supervision per week for the remaining ten weeks</li> </ul> <p>The amount of supervisions will be based upon individual capabilities and movement qualities during the supervised sessions</p>
<b>General instruction and add-on's</b>	<ul style="list-style-type: none"> <li>Avoidance of slouched position and protracted shoulders in general</li> <li>Shoulder range of motion exercises and/or stretching of neck muscles if needed</li> </ul>

## ***Paper II, III and IV***

### *Cross-cultural translation and adaptation (paper II)*

The validated Swedish version of WOSI [95] was used for translation, since Sweden is both linguistic and cross-culturally more similar to Denmark than e.g. Canada, where the original version was developed [98]. International guidelines for translation and adaptation were followed, including independent forward and backward translations, besides adaptive testing of the final Danish version [119]. Merging of the previous Danish translated version from Canadian and the new Danish translated version from Swedish was performed to develop only one Danish WOSI version (Further details concerning the translation and adaptation process can be found in paper II).

### *Test-retest reliability (paper II, III, IV)*

For test-retest reliability of the Danish WOSI (paper II), symptomatic “shoulder instable” subjects completed an electronic version twice within a 14-day period. Only subjects with self-reported “*largely unchanged*” shoulder symptoms within the 14-day period were included in the analysis, which is essential when evaluating reliability. 14 days was considered long enough for subjects not to be able to recall any of their previous responses, but also potentially short enough to remain stable in terms of symptoms, which is essential when evaluating reliability.<sup>28</sup>

For the electronic version of WOSI a VAS score with an electronic moveable “slider” was developed (Figure 10).

**Figure 10.** Electronic WOSI with moveable slider acting through finger touch or traditional computer (Danish version, item one)



For the inter-examiner reliability study of clinical shoulder instability tests (paper III), a test protocol for each of the clinical tests (apprehension, relocation, surprise, load-and-shift, sulcus sign and Gagey) was thoroughly described. Subsequently, all clinical tests were rehearsed by two examiners (A and B) on 10 subjects to reach uniformity and mutual agreement of testing procedures and interpretation of the clinical tests before proceeding to the agreement phase two and the actual study phase. In the agreement phase, examiner A and B examined a group of “shoulder instable”

and “shoulder healthy” subjects, mutually blinded to the health status of the subjects and each other’s test results. According to the recommendations for performing reliability studies, a cutoff of at least 80%, for an overall between-examiner agreement on the six clinical tests was required before proceeding to the actual study phase [120].

For the test-retest reproducibility study of the NWBB for measuring prone lying shoulder sensorimotor control (paper IV) a test protocol was thoroughly described (phase one). Subsequently, the test protocol was tested and rehearsed on subjects with and without shoulder trouble to achieve experience and consistency in managing the protocol (phase two) before proceeding to the actual study phase.

#### *Concurrent validity (paper II and IV)*

To establish concurrent validity of the Danish WOSI (paper II), comparison of a traditional pen and paper WOSI version and an electronic WOSI version were performed completed by symptomatic “shoulder instable” subjects within a short three-day interval. As previously described, only subjects with a stable shoulder condition within the three-day interval were included in the analysis.

To establish concurrent validity of the NWBB (paper IV) background noise from NWBB and a laboratory force platform was compared. The NWBB was placed on top of the force platform and systematically loaded with increasing deadweight’s. Noise bias was recorded simultaneously preloaded with a deadweight of 5 kilo (kg), which was increased to 10 kg, and then stepwise increased with 1 kg until the reach of 50 kg. From 50 kg, deadweight’s were increased by a stepwise increase of 5 kilo until a final deadweight of 90 kg. In total, 50 measurements were obtained of the increasing, with three measurements of each. The force platform was nullified every time a new deadweight was added.

#### *Construct validity (paper II)*

To examine construct validity, symptomatic “shoulder instable” subjects completed the Danish WOSI questionnaire in addition to shoulder pain within the latest 24 hours (as measured with a 0-10 NPRS, 10 being worst) [121] and the validated version of the Danish Oxford Shoulder Score (OSS)[122].

#### *Paper V*

Baseline data on demographic and descriptive characteristics, patient-reported questionnaires besides objective clinical and performance-based outcomes obtained from patients included in the SINEX trial (paper I) were utilized and statistically analysed.



## Outcomes

An overview of outcomes measurements obtained in paper I-V is presented in Table 6.

**Table 6.** Included outcome measures in papers I-V

Outcomes		Paper				
		I	II	III	IV	V
<b>Socio-demographic</b>	Male/female	*	*	*	*	*
	Age	*	*	*	*	*
	Height	*	*	*	*	*
	Weight	*	*	*	*	*
	Education	*				*
	Employment	*	*			*
	Physical activity (Hours/week)	*		*		*
	Dominant arm (Right/left)	*	*			*
	Injured arm (Right/left)	*	*			*
<b>Patient-reported</b>	Western Ontario Shoulder Instability Index (WOSI)	*	*	*	*	*
	Tampa Scale of Kinesiophobia (TSK)	*				*
	EQ-VAS	*				*
	Pain Specific Function Scale (PSFS)	*				
	Global perceived effect (GPE)	*				
	Oxford Shoulder Score (OSS)		*			*
	Disability of Arm, Shoulder and Hand (DASH)				*	*
	Pain intensities (NPRS/VAS)	*	*	*	*	*
<b>Clinical evaluation</b>	Generalized Joint Hypermobility (Beightons criteria)	*				*
	Apprehension, relocation, surprise (anterior instability tests)	*		*		*
	Load-and-shift, sulcus sign, Gagey (shoulder laxity tests)			*		
<b>Performance-based</b>	Constant Murley shoulder Score (CMS total)	*				*
	Shoulder Range of Motion (CMS-ROM)	*				*
	Shoulder strength (CMS-iMVC)	*				*
	Shoulder Joint Position Sense (JPS)	*				*
	Shoulder sensorimotor control	*			*	

*NPRS* Numeric Pain Rating Scale; *VAS* Visual Analogue Scale; *ROM* Range of Motion; *iMVC* Isometric Maximal Voluntary Contraction

### *Patient-reported*

Patient-reported outcomes included the following questionnaires: Western Ontario Shoulder Instability Index (WOSI), Tampa Scale of Kinesiophobia (TSK), EuroQoL (EQ-5D), Patient Specific Function Scale (PSFS), Global Perceived Effect (GPE), Oxford Shoulder Score (OSS) and Disability of the Arm, Shoulder and Hand (DASH) besides Numeric Pain Rating Scale/Visual Analogue Scale (NRPS/VAS).

*WOSI* (paper I-V) is designed to measure health-related QoL in patients with shoulder instability and covers four domains: Physical symptoms (10 items), Sport, recreation and work (4 items), Life-style (4 items) and Emotions (3 items). Each item is scored on a VAS ranging from 0-100, 0

representing worst score. Hence, total score ranges within 0-2100 [98]. Change in WOSI is the primary outcome in the SINEX trial (paper I).

*TSK* (paper I and V) is designed to measure “fear of movement and re-injury” in patients with pain and/or musculoskeletal disorders [123]. TSK includes 17 items individually scored on a four-point Likert scale (1=strongly disagree, 4=, strongly agree). A total score is calculated after inversion of items 4, 8, 12 and 16. The summed score ranges from 17-68, 68 representing poorest score. A TSK score of 37 or more has been established as the cut-off for a high score [124]. TSK is reported in paper V.

*EuroQoL* (EQ-5D) (paper I and V) consists of a descriptive system and a visual analogue scale (EQ VAS). The descriptive system comprises five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) scored on a five-point Likert scale (1=no trouble, 5=worst trouble). The EQ VAS measures health-related QoL and is scored on a numeric range scale ranging from 0 to 100, 0=lowest health-related QoL [125]. The EQ-5D descriptive system is used for cost-effective analysis, but will not be reported until the 12 months follow-up in the SINEX trial (paper I) has been completed. EQ VAS is reported in paper V.

*PSFS* (paper I) measures self-reported shoulder function, from before to after having completed an intervention and scored on a numeric range scale from 0-10 (10=no trouble) [126]. PSFS scores are obtained at baseline in the SINEX trial (paper I). Baseline PSFS scores will not be reported in this thesis, since it comprises individually-rated important activities used to measure individual treatment effects at follow up.

*GPE* (paper I) measures self-rated global perceived impression of recovery evaluated after completing an intervention. GPE is rated on a seven-point Likert scale (1=very much worse, 7=very much improved). GPE scores are obtained only at the 3-months follow-up in the SINEX trial (paper I) and cannot be presented in this thesis [127].

*OSS* (paper II) measures treatment effects in patients with shoulder disorders. OSS consists of 12 items, individually scored with the use of five-point Likert scale (1=best, 5=worst). A total score ranges within 12-60, 60 representing worst [122]. OSS has shown to be reliable, valid and sensitive to changes [57]. OSS was used to determine construct validity of the Danish WOSI.

*DASH* (paper IV) measures symptoms and physical function of the upper extremity. DASH consists of a primary dimension (30 items) and two optional sub-dimensions (4 items each). Each item is scored on a five-point Likert scale and calculated as a cumulative DASH score ranging from 0 to 100, 100 representing extreme disability [128]. The DASH score was used for descriptive purpose of study subjects in paper IV.

*NPRS/VAS* (paper I-V) measures pain by use of either numeric (paper I-II and V) or visual scales (paper IV), respectively. Scales ranges from 0-10, 10= worst imaginable pain [129]. NPRS/VAS is reported in paper II-IV.

**Objective clinical evaluations**

To evaluate generalized joint hypermobility (GJH) (paper I and V) Beighton’s criteria was used with scores ranging from 0-9, 9 representing a high degree of GJH [130]. A score <4 was regarded as no GJH.

Tests for GJH include: forward bending while standing with legs straight placing both palms on the ground (one point), bilateral elbow hyperextension (one point per side), bilateral tests for knee hyperextension (one point per side), bilateral tests of the fifth finger and whether it can be backwards bended beyond 90 degrees (one point per side) and bilateral tests of each thumb whether it can touch the forearm when bent backwards (one point per side).

Beighton’s criteria have shown to be reliable [131].

Shoulder instability was evaluated with six clinical tests (Table 7).

Three tests evaluated anterior shoulder instability (apprehension, relocation and surprise) (paper I, III and V) and three tests evaluated shoulder laxity (load-and-Shift, sulcus sign and Gagey) (paper III) [27, 103-107].

Apprehension	
Relocation	
Surprise	
Anterior test	
Posterior test	
Load-and-shift	
Sulcus sign	
Gagey	

**Table 7.** Clinical tests for evaluation of shoulder instability.

**Performance-based**

*Combined patient-reported and objective shoulder function (paper I and V)*

The total Constant Murley Shoulder Score (CMS) evaluates subjective and objective shoulder function. Total CMS is rated from 0-100, 100 representing best [132].

### *Shoulder Range of Movement (paper V)*

Shoulder range of movement (ROM) was measured according to the protocol for assessing ROM in the CMS (CMS-ROM) [132] (Figure 11).

CMS-ROM is a combined score of shoulder internal, external, flexion and abduction ROM ranging from 0-40, 40 representing full ROM.



**Figure 11.** Measurement of shoulder abduction range of motion

### *Shoulder Strength (paper V)*

Shoulder strength was performed according to the CMS protocol for assessing Isometric Maximal Voluntary Contraction (CMS-iMVC) [132]. CMS-iMVC was obtained with the use of an Isoforce dynamometer (kilo) with subjects standing, 90 degrees of shoulder abduction, full extension of the elbow and hand in pronation (Figure 12). Three repetitions for the injured and non-injured shoulder were obtained, performed in random order beginning with the non-injured shoulder. If the third iMVC was more than 5% larger than any of the prior, it was repeated, up to five times in all [132].



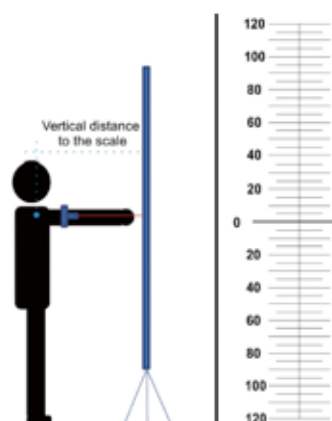
**Figure 12.** Measurement of isometric MVC strength

### *Shoulder Joint Position Sense (paper I and V)*

This test evaluated shoulder proprioception in ranges of  $60 \pm 10$  degrees of shoulder flexion and abduction, according to the protocol by Vafadar et al. (2016) (Figure 13).

A laser attached at the elbow pointing towards a target scale was used to examine shoulder JPS.

Subjects were blindfolded, standing on two legs with arms resting alongside the body and then instructed to flex/abduct their shoulder (thumbs pointing upwards).



**Figure 13.** Laser pointer JPS measurement. With permission from Vafadar et. al, 2016.

Subjects were verbally stopped when the laser dot reached within pre-calculated angles of shoulder flexion/abduction.

The examiner counted to three, noted the position of the laser dot at the target scale and told subjects to bring back their arm to neutral and immediately reproduce the shoulder position.

Patients were instructed to inform the examiner verbally when they felt the previous position was reached. Flexion and abduction tests were repeated three times each. Though, only the middle test (second round) was used for analysis. The difference from the reference point to the re-position point was calculated thereby representing the shoulder JPS function/error. By using simple trigonometry and backward calculations the specific shoulder joint angles were calculated. This method has previously shown to be reliable for measuring shoulder JPS in shoulder flexion [108].

#### *Shoulder sensorimotor control (paper I and IV)*

This test evaluated shoulder sensorimotor control (paper I) and was tested for reproducibility in paper IV.

Subjects were placed in a prone lying, upper limb weight-bearing position with the lower limbs resting on a table supported from the anterior superior iliac spines and down to the feet with shoulders and wrists positioned in 90 degrees of flexion and extension, respectively. Three test positions were performed: 1) Two Arms, eyes closed (Two-Arms), 2) One Arm, Non-Dominant or Non-Injured (One-Arm, non-dom/non-inj) and 3) One Arm, Dominant or Injured (One-Arm, dom/inj). The dominant arm was defined as the preferred arm for throwing a ball. Subjects were to stay as steady as possible during testing. Each test lasted 30 seconds, followed by 30 seconds pause and with each test repeated three times (three trials of each test). The primary outcome in paper IV was Centre of Pressure path Length (COPL) measured in centimeter (cm) [110, 112], defined as the total length of vertical line displacements from the centre of mass [133]. COPL was calculated as the mean of three successful COPL values in each of the three prone lying sway tests.

### **Sample size**

#### *Paper I*

The sample size of the SINEX trial (paper I) was based on the primary outcome, the WOSI questionnaire. The power and sample size calculation was based on the differences in WOSI change score between the two intervention groups from baseline to the 12 weeks follow up. With a mean baseline WOSI score expected to be 1100 points and a common standard deviation assumed to be 320 [97], a sample size of 35 subjects per group was required to detect a statistical significant difference of 250 WOSI points (significance level of 0.05, two-sided, with 90% power). To account

for possible barriers, non-compliant patients and subjects' lost-to-follow-up, it was decided to enrol a minimum of 80 participants (40:40).

### ***Paper II***

The sample size determined appropriate for assessing reliability in health questionnaires followed previous recommendations [134]. Hence, a convenient sample of minimum 50 subjects was determined to be the minimum required number of study subjects

### ***Paper III and IV***

As recommended for performing reliability studies of clinical tests and performance-based methods a sample size of at least 40 subjects was used [120].

### ***Paper V***

A total of 48 patients, out of the 80 patients (about 60%) that will be recruited for the SINEX trial (paper I), are included in the cross-sectional study (paper V). The primary and recurrent shoulder dislocation group consisted of 30 and 18 patients, respectively.

### **Statistical methods, analysis and interpretation (paper II-V)**

Descriptive data in this thesis are presented as absolute or mean values with standard deviations (SD). Data were tested for normal distribution by visual inspection of histograms, QQ-plots Shapiro-Wilk's and Kolmogorov-Smirnoff tests. To test for group differences student t-tests were used for normally distributed data, whereas for non-parametric continuous data Mann-Whitney U-test was used. For categorical outcomes Chi Square and Fischer's Exact test was used.

Statistical analyses were performed using SPSS software (SPSS Inc, Chicago, Illinois), except for the Bland Altman plots in paper IV, which were computed in STATA version 13, StataCorp LP.

Significance level was set at  $p < 0.05$ , except for paper V with significance level set at  $p < 0.01$  to minimize risk of mass significance. An overview of the statistical methods used in paper I-V is provided in Table 8.

**Paper II and IV**

Intra-class Correlation Coefficients (ICC) and Concurrent Correlation Coefficients (CCC) were interpreted as follows: <0.40=poor, 0.40 to 0.70=fair to good and >0.75=excellent [135]. Standard Error of Measurements (SEM) and Minimal Detectable Changes (MDC) were calculated and presented as absolute values and percentages of maximal obtainable scores [136]. A Pearson’s Product Moments Correlation Coefficient (r) > 0.7 was defined as satisfactory [137].

**Paper III**

Observed and expected agreements were presented along with prevalence [120] and bias [138] indexes. Cohen’s kappa (k) with 95% confidence intervals (CI) and Prevalence-Adjusted-Bias-Adjusted-Kappa (PABAK) calculation was interpreted as follows: 0.00-0.20 (Slight); 0.21-0.40 (Fair); 0.41-0.60 (Moderate); 0.61-0.80 (Substantial) and 0.81-1.00 (Almost perfect) [139]. Also, proportions of specific agreements on positive and negative test ratings for both examiners were presented [140].

**Table 7.** Statistical methods used in paper I-V

Statistical methods	Paper				
	I	II	III	IV	V
Descriptive		*	*	*	*
Sample size calculation	*				*
Mann-Whitney U-test					*
Student’s t-test		*	*	*	*
Fischer’s exact test					*
Chi-square test					*
McNemar’s test		*			*
Cohen’s kappa			*		
PABAK			*		
Pearson’s Product Moment Correlation Coefficient		*		*	*
Intra-class Correlation Coefficients (two-way random)		*			
Intra-class Correlation Coefficients (two-way mixed)				*	
Concurrent Correlation Coefficients		*		*	
Bland Altman plots		*		*	

**PABAK** Prevalence-Adjusted-Bias-Adjusted-Kappa

## **Summary of results**

In total, 222 individuals (66% males, mean age 32 SD9) have contributed to the findings of the current thesis. 158 of the 222 subjects had a shoulder disorder distributed as follows; 101 of the subjects had one or more anterior shoulder dislocations (paper II and V); 13 subjects had self-reported shoulder instability (paper III) and 34 had mixed self-reported shoulder symptoms (8 of these where shoulder instability) (paper IV).

### ***Paper I***

This paper describes the design of an RCT investigating the efficacy and safety of neuromuscular exercise programme versus standard care for patients with TASP. Additionally, the rationale for and development of a standardized and individualized neuromuscular shoulder exercise programme for patients with TASP, based on current pathophysiological evidence and clinical experience, was described.

The primary outcome, the WOSI questionnaire, was successfully translated and adapted with final approval of a Danish version obtained January 2015 by one of the co-authors (S. Griffin, personal communication) of the original WOSI version [98]. Patient recruitment in the SINEX trial began March 2015.

### ***Paper II***

#### ***Reliability***

The reliability of the Danish WOSI was high with an ICC of 0.97 (95% CI 0.95-0.99) for the total WOSI score and between 0.93 and 0.96 (95% CI 0.87-0.98) for the individual domains. For the total WOSI score SEM and MDC were low corresponding to only 5% and 13%, respectively (Table 8). No tendency for funnel effects or signs of bias was found in the Bland Altman plots (not shown).

#### ***Concurrent validity***

The concurrent validity between a traditional pen and paper versus electronic WOSI version was excellent with a CCC of 0.96 (95% CI 0.91-0.98) and between 0.89-0.96 (95% CI 0.78-0.98) for the total and individual WOSI domains, respectively (not shown in table).



### Construct validity

The construct validity of the Danish WOSI was high with correlations equal to 0.85 and 0.74, respectively. The individual domains of WOSI and NPRS resulted in correlations of 0.64 to 0.84 (not shown in table).

**Table 8.** Test-retest reliability of the Danish Western Ontario Shoulder Instability (WOSI) questionnaire (electronic versions) completed within a 14-day interval (n=42)

	Mean Diff. ± SD	95% LOA	SEM (%)	MDC (%)	ICC (95% CI)
<b>Domains</b>					
Physical symptoms (0-1000)	13.5 (81.1)	-145.5; 172.5	57.4 (6)	159.0 (16)	0.95 (0.91-0.97)
Sports, recreation, work (0-400)	12.7 (49.6)	-84.5; 109.9	35.1 (9)	97.8 (25)	0.93 (0.87-0.96)
Lifestyle (0-400)	1.9 (35.8)	-68.3; 72.1	25.3 (6)	70.2 (18)	0.96 (0.93-0.98)
Emotions (0-300)	7.1 (39.1)	-69.5; 83.7	27.7 (9)	76.6 (26)	0.94 (0.89-0.97)
<b>WOSI total score (0-2100)</b>	<b>31.4 (139.9)</b>	<b>-242.3; 305.6</b>	<b>98.9 (5)</b>	<b>274.2 (13)</b>	<b>0.97 (0.95-0.99)</b>

*SD* Standard Deviation; *e (1)* first electronic completion; *e (2)* second electronic completion; *Diff.* Difference; *LOA* Limits Of Agreement; *SEM* Standard Error of Measurements; *MDC* Minimal Detectable Change; *ICC* Intra-class Correlation Coefficient; *CI* Confidence Interval

### Paper III

Low prevalence of positive tests was found in four (relocation, load-and-shift, sulcus sign and Gagey) out of six tests resulting in unbalanced 2x2 contingency tables justifying the use of PABAK (Table 9).

**Table 9.** 2x2 contingency tables with absolute findings from examiner (Ex) A and B

<b>Apprehension</b>	<b>Ex A</b>		<b>Relocation</b>	<b>Ex A</b>		<b>Surprise</b>	<b>Ex A</b>				
	Yes	No		Yes	No		Yes	No			
<b>Ex B</b>	Yes	14	4	<b>Ex B</b>	Yes	6	2	<b>Ex B</b>	Yes	14	4
	No	3	19		No	8	24		No	3	19
<b>Load and Shift</b>	<b>Ex A</b>		<b>Sulcus</b>	<b>Ex A</b>		<b>Gagey</b>	<b>Ex A</b>				
	Yes	No		Yes	No		Yes	No			
<b>Ex B</b>	Yes	1	0	<b>Ex B</b>	Yes	7	1	<b>Ex B</b>	Yes	8	3
	No	2	37		No	9	23		No	1	28

Relative and adjusted reliability of each test is shown in Figure 14. Red, yellow and green colour indicates fair, moderate and substantial to almost perfect agreement between examiners, respectively.

Relative unadjusted agreement between examiners was highest for apprehension, surprise and Gagey resulting in substantial reliability.

PABAK improved kappa values mostly for the relocation, load-and-shift, sulcus sign and Gagey tests now ranging between moderate to almost perfect reliability (Figure 14).

Prevalence and bias indexes ranged from 0.05-0.44 (lowest for load-and-shift, relocation and sulcus; 0.05, 0.28 and 0.30) and 0.03-0.20 (highest for relocation and sulcus; 0.15 and 0.20), respectively and significant between-examiner differences were found for relocation and sulcus sign tests ( $p=0.021$ ) (not shown in tables).

Clinical tests	Kappa	Adjusted kappa
Apprehension	0.65	0.65
Relocation	0.39	0.50
Surprise	0.65	0.65
Load and Shift	0.48	0.90
Sulcus sign	0.43	0.50
Gagey	0.73	0.80

**Figure 14.** Findings of inter-examiner reliability of clinical shoulder instability tests. Red, yellow and green colour indicates fair, moderate and substantial to almost perfect reliability

Absolute inter-examiner reliability was highest for negative test findings for all six tests, whereas proportions of positive test findings were high only for apprehension, surprise and Gagey tests.

## ***Paper IV***

### ***Reproducibility***

Test-retest reproducibility of the NWBB was excellent including narrow confidence intervals besides low SEM and MDC, corresponding to 3-12% of the total mean sway measurements (Table 10).

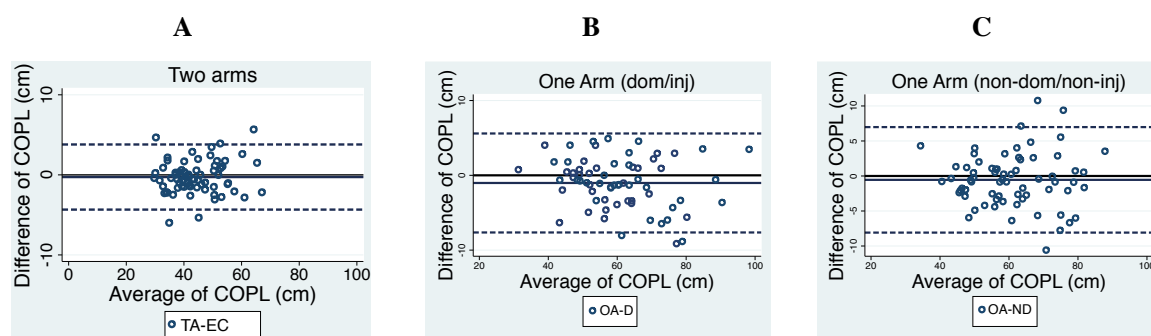
Systematic bias was found in the One-Arm, dom/inj test ( $p<0.05$ , not shown in tables) and tendencies towards funnel effects in both one-arm tests (Figure 15, B and C).

**Table 10.** Test-retest reproducibility of Centre Of Pressure path Lengths (COPL) between test session one and two for controls and cases (n=68)

Controls/cases	Mean diff* (SD)	ICC (95% CI)	LOA	SEM (%)	MDC (%)
Two-Arm	-0.27 (2.08)	0.97 (0.96; 0.98)	-4.34; 3.80	1.47 (3.32)	4.07 (9.20)
OA, non-dom/non-inj	-0.55 (3.84)	0.95 (0.92; 0.97)	-8.09; 6.98	2.72 (4.47)	7.53 (12.4)
OA, dom/inj	-1.02 (3.38)	0.97 (0.95; 0.98)	-7.64; 5.59	2.39 (3.95)	6.62 (10.9)

\* Mean difference between test-session one and two; **OA** One Arm **SD** Standard Deviation **ICC** Intraclass Correlation Coefficients; **LOA** Limits of agreement; **SEM** Standard Error of Measurement; **MDC** Minimal Detectable Change; **non-dom/non-inj**; non-dominant/non-injured; **dom/inj** dominant/injured

**Figure 15.** Bland Altman plots with 95% Limits of Agreement (LOA) for A) Two Arms, Eyes-closed (Two arms), B) One arm dominant/injured (One arm, dom/inj) and C) One arm non-dominant/non-injured (One arm, non-dom/non-inj)



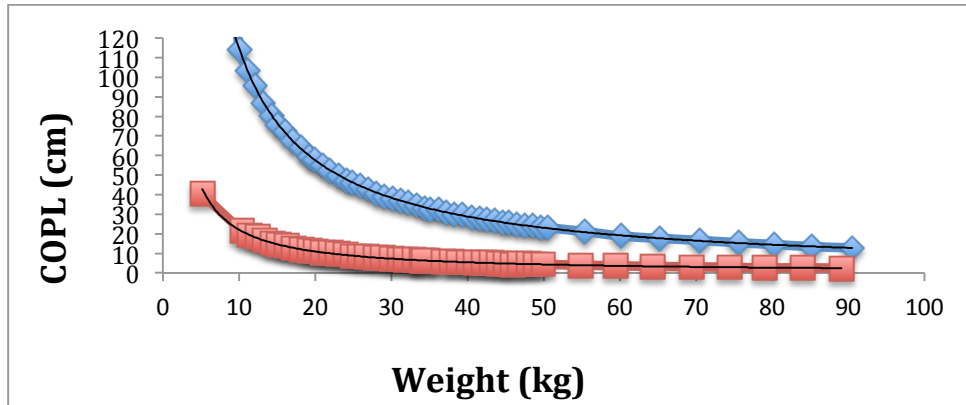
**COPL** Centre Of Pressure path Length

### Validity

The linear correlation between NWBB and force platform was almost perfect ( $r=0.995$ ) (not shown). In contrast, though, the CCC was low (0.17 (95% CI 0.12-0.22)) indicating poor validity. This was further reflected by constantly larger NWBB noise especially at loads below 50 kg (Figure 16).

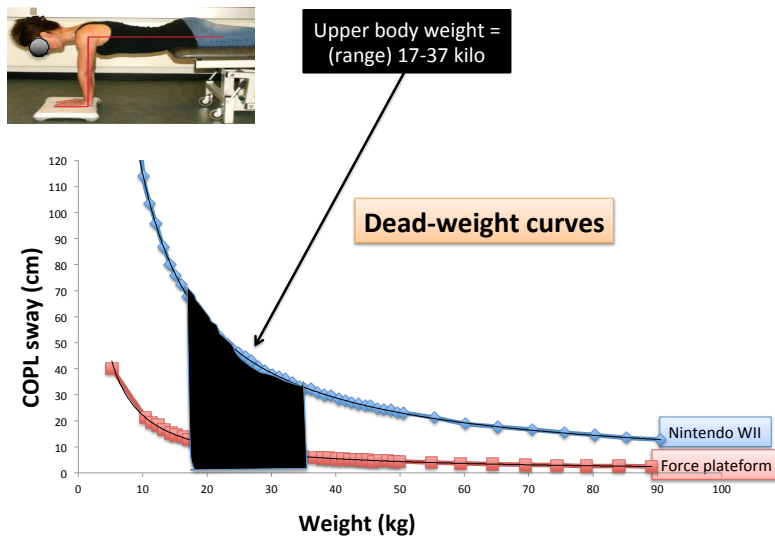
The mean upper body weight during the prone lying tests ranged between 17 and 37 kilo (Figure 17).

**Figure 16.** Deadweight noise sensitivity curves for NWBB (blue) and AMTI Force Platform (red).



COPL Centre Of Pressure path Length

**Figure 17.** Upper body-weight during prone lying and deadweight noise sensitivity curves for NWBB (blue) and force platform (red).



## *Paper V*

Overall, no difference in musculoskeletal health between patients with primary and recurrent dislocations was found.

With a mean age of 26 (SD 6) and an overweight of males (43 out of 58 corresponding to 90%) no statistical between-group differences were found. In the recurrent group, though, 10 patients (56%) reported long-term shoulder symptoms following their primary T ASD, and 11 patients (61%) in the recurrent group reported not to have had any shoulder treatment following their primary T ASD. Finally, 39% in the recurrent group were not physically active prior to the current repeated dislocation compared to 13% in the group sustaining their first ever dislocation (not shown in table).

Mean shoulder and health related QoL, as measured with WOSI and EQ-VAS, was 1078.0 (SD 384.8) (0-2100, 0=best) and 75.3 (SD 17.4) (0-100, 100=best), respectively. Mean TSK score was 40.2 (SD 6.4) (17-68, 17=best) with 21 (70%) and 14 patients (78%) scoring above 37, being the cut-off for a high TSK score, in the primary and recurrent groups, respectively. A larger frequency of patients with GJH was found in the recurrent group, however, without obtaining the required statistical significance level ( $p=0.02$ ). All patients had positive apprehension test, whereas relocation and surprise were positive in 83-90% of all patients. No between-group difference was found in the performance-based outcomes (Table 11).

**Table 11.** Patient reported, objective clinical and performance-based outcomes in patients with traumatic anterior shoulder dislocation according to injury status (primary vs. recurrent)

<b>Outcomes</b>	<b>Primary (n=30)</b>	<b>Recurrent (n=18)</b>	<b>P-value</b>
<b>Patient reported (Mean, SD)</b>			
WOSI total (0-2100)	1098.4 (364.4)	1057.5 (405.2)	0.72
-Physical symptoms 1 (0-1000)	387.6 (183.1)	393.4 (207.7)	0.96
-Sport function (0-400)	252.7 (97.4)	235.8 (70.3)	0.53
-Lifestyle (0-400)	239.3 (81.0)	224.5 (105.1)	0.59
-Emotions (0-300)	218.8 (69.4)	203.8 (67.9)	0.39
TSK (17-68)	39.7 (5.3)	40.7 (7.4)	0.59
- $\geq 37$ , yes (%)	21 (70)	14 (78)	0.74
EQ VAS (0-100)	72.8 (17.1)	77.7 (17.8)	0.27
NPRS (Latest 24 hours) (0-10)	3.5 (2.1)	3.1 (2.3)	0.43
<b>Clinical tests</b>			
GJH (0-9, positive $\geq 4$ , yes (%))	1 (<1)	5 (28)	0.02
Clinical tests <sup>a</sup> (positive, yes, (%))			
-Apprehension	30 (100)	17 (100)	-
-Relocation	27 (90)	14 (82)	0.65
-Surprise	25 (83)	15 (88)	1.00
<b>Performance-based (Mean, SD)</b>			
CMS-total <sup>a</sup> (combined score, 0-100)	64.0 (23.4)	69.4 (20.2)	0.88
CMS-ROM (combined score, 0-40)	28.3 (8.6)	30.7 (9.0)	0.38
CMS-iMVC (kg)			
-Injured shoulder	7.1 (3.7)	8.4 (3.9)	0.29
-Non-injured shoulder	12.3 (3.2)	10.6 (2.7)	0.09
Shoulder JPS <sup>a</sup> (°, AE)			
-Flexion	4.0 (5.4)	3.9 (4.6)	0.94
-Abduction	4.7 (4.6)	5.6 (4.7)	0.52

*SD* Standard deviation; *WOSI* Western Ontario Shoulder Instability Index; *TSK* Tampa Scale of Kinesiophobia; *EQ VAS* Euroqol Visual Analogue Scale; *NPRS* Numeric Pain Rating Scale; *GJH* Generalized Joint Hypermobility; *CMS* Constant Murley shoulder Score; *ROM* Range of Motion *JPS* Joint Position Sense; *iMVC* isometric Maximal Voluntary Contraction; ° degrees; *AE* absolute error; - No statistics computed

## **General discussion**

### **Main findings**

According to the protocol of the SINEX trial, recruitment of patients is initiated and currently ongoing with expected termination June 2017. A Danish WOSI was established and tested electronically for reliability and validity with satisfactory results. Clinical testing for shoulder instability showed relative high reliability for apprehension, surprise, load-and-shift, and Gagey, but not for relocation and sulcus sign. Findings based on the relocation test in paper V should therefore be interpreted with caution. The ability of tests to evaluate individual changes in health status over time was more reliable in ruling out, rather than ruling in shoulder instability. Measurement of prone lying, shoulder sensorimotor control with a NWBB was highly reproducible, but concurrent validity was poor, especially at low loads as in the prone lying. Finally, injury status (primary or recurrent) was not decisive for higher or lower MSK health, but both groups present with equal and high severity of shoulder instability, highly affected by psychological factors and poor shoulder-related QoL. Hence, optimum treatment strategies need further improvements, supporting the rationale for and content of the SINEX trial (paper I) including both primary and recurrent T ASD patients.

### **Discussion of the findings within this thesis**

#### ***The Western Ontario Shoulder Instability Index (paper II)***

With regard to WOSI, a Danish version was successfully linguistically and cross-culturally adapted. Test-retest reliability of the Danish WOSI was similar to other European countries [95-97, 99, 100] and to that of the original WOSI [98]. All studies, except for the French had excellent [141] reliability indicating that WOSI is highly reliable and useful for comparison on a group level [142]. The lower reliability obtained in the French version [141] may be due to patients receiving physical therapy treatment while participating in the reliability study, thereby introducing potential bias due to non-stable shoulder conditions between test and retests. The current study found lower SEM and MDC values than in the Dutch and Norwegian versions [99, 100], but higher than in the Italian version [97]. The reason may be the varying length of test-retest periods and different inclusion criteria [97]. Differences could also be due to the various ways of calculating SEM [136]. Since patient reported outcomes usually are not influenced by objective measurements (e.g. performance bias from clinicians), we used the SEM consistency.

Consistency between completions of traditional pen and paper WOSI versions and an electronic version was satisfactory. This was in line with previous results reporting on consistencies between electronic and paper completed VAS scores [143, 144]. Though, previous studies have used a Pearson Product-Moment Correlation ( $r$ ) to evaluate consistency, whereas the current study used a concordance correlation coefficient taking into account any systematic errors that may exist [145]. Also, the current construct validity of the electronic Danish WOSI was satisfactory when compared with NPRS and OSS. To our knowledge, construct validity between WOSI and OSS has not

previously been tested hampering comparison with other studies. Though, the construct validity was in line with previous studies comparing WOSI with other self-reported shoulder questionnaires or pain measures, such as DASH [128], CMS [146] and Rowe score [95].

### ***Apprehension, relocation and surprise tests (paper III)***

Apprehension and surprise tests were substantially, and equally, reliable. In line with this, another study also found equal reliability for apprehension and surprise, although lower than in the current study [106]. The reason for the present higher reliability may be due to the inclusion of both “shoulder instable” and “shoulder healthy” subjects, as opposed to the previous study including only “shoulder instable”. Hence, subject variation was increased in the current study, known to affect reliability positively [120]. Finally, PABAK calculation did not affect reliability further for apprehension and surprise due to nearly optimal prevalence’s (close to 0.50) and low bias, as illustrated by the 2x2 contingency tables. With regard to the relocation test, reliability was only fair in the current study, which is in line with a previous also using apprehension and/or pain as criterion for a positive test [106]. This may indicate that examiners have difficulty in interpreting test findings of positive and negative character. Additionally, the current 2x2 contingency table for the relocation test indicates low prevalence of positive tests and, significant inter-examiner bias reflected by disagreement between examiners on 10 subjects out of 40. Hence, PABAK calculation had little influence on improving reliability for relocation. The reason for the inter-examiner bias observed may be due to potential variability in the posteriorly force produced to relocate the glenohumeral head. In relation to absolute reliability, indicating the ability of tests to evaluate individual changes in health status over time, reliability was high for apprehension and surprise, but low for relocation in terms of ruling shoulder instability in. This was further supported by the high agreement on negative findings only.

### ***Load-and-shift, sulcus sign and Gagey tests (paper III)***

Load-and-shift and sulcus sign tests present with relatively low reliability, while Gagey was substantially reliable. In both tests, poor prevalence was found in addition to significant bias for sulcus sign. PABAK resulted in considerable improved reliability for load-and-shift, but not for sulcus sign. The reason is highest likely due to the inter-examiner variation in the performance and/or interpretation of the sulcus sign test. Few studies have investigated reliability for load-and-shift and sulcus sign, using varying statistics (kappa vs. ICC). One study, using ICC statistics, showed almost excellent reliability for load-and-shift [105], but had limited subject-variation since only few patients had positive laxity tests. In relation to sulcus sign, the current reliability was slightly lower than in previous studies [105, 106]. Difference in patient positions during testing, lying versus sitting (as in the current study) and scoring systems by which laxity was graded with, may explain the variance in reliability. The reason for the substantial reliability of Gagey may be the addition of a mirror in front of subjects, to visually improve the evaluation of the shoulder abduction angle. No other studies have reported on the reliability of Gagey. Absolute reliability for ruling out shoulder laxity was high for all three tests, but for ruling in shoulder laxity only Gagey had high reliability.



### ***Nintendo Wii Balance Board (Paper IV)***

NWBB had excellent reproducibility for measuring shoulder sensorimotor control in a prone lying, upper limb weight bearing test position. Although higher in the current study, reliability was also satisfactory in a similar study measuring stability in the upper extremity [47]. However, the previous study used a laboratory force platform (Win-Posturo, Médicaptureurs SA, France) as opposed to the current NWBB, which may limit direct comparison of reliability. Though, several additional discrepancies exist between the two studies possibly explaining the reason for not obtaining equal reliability. We used a study population with mixed shoulder symptoms and more males and a larger mean body weight as opposed to healthy and fewer males in the previous study. Secondly, the test protocol differed slightly on test positions and repetitions, with the current three different positions (three repetitions, fixed order), versus four different test positions (two repetitions, random order). Finally, for statistics, a fixed model was used in the current study as opposed to random model in the previous study for calculating ICC and, with random models known to produce lower reliability [147].

Validity of the NWBB, however, was poor when compared with a laboratory force platform due to higher noise sensitivity in NWBB. Especially at loads below 40 kilo corresponding to sway measures (COPL) of 44-61 centimeter solely related to background noise. Hence, reliability measures of prone lying, shoulder sensorimotor control with a NWBB may largely be attributed to equipment noise, and may therefore not be applicable under certain low-load circumstances, as the current mean upper body weight during testing ranged between 17 and 37 kg.

Surprisingly, acceptable validity of the NWBB, when compared with a laboratory force platform, was found in a previous study using different standing balance tasks for children. The mean weight of the children was approximately 44.1 kg (SD 10.3) and may potentially be the minimum acceptable valid weight for using NWBBs. Though, the longer lever arm while standing, as opposed to prone lying, may increase the conditions for larger sway measures and may be some of the reasons for the higher validity of NWBB on children [111]. Though, studies on adults have shown equal high validity when comparing NWBB and force platforms [112]. Hence, whether center of pressure displacements (sway measures) from "living moving subjects" are contained in or added to the noise sensitivity is unknown and, whether this plays a role in the sway measurements obtained with the NWBB is to be further investigated. Unless preloaded with a minimum of 45-50 kg (to minimize background noise) NWBB seems not to be valid, thus, cannot be recommended for clinical use.

### ***Musculoskeletal health (paper V)***

The present equal group status with poor shoulder-related QoL and general health scores on the current patients with shoulder dislocations (measured until know) were in line with previous studies [97, 100, 141], and also, when compared with shoulder impingement patients awaiting shoulder surgery due to long-standing symptoms [148]. Moreover, fear of re-injury and movements was relatively high among the current patients. Moreover, for some patients it may be defined as serious conditions [124] indicating a large impact on fear-related physiological and emotional conditions in patients with T ASD. For the specific condition, GJH, this was found in every third of the recurrent

dislocation patients as opposed to only one patient totally among the primary dislocation patients, which is in line with previous studies [22-25]. For the remaining clinical tests, tests for anterior shoulder instability were also largely positive possibly indicating some joint arthropathy to be present. Though, findings related to the relocation test should be interpreted with caution according to the reliability of this test, as described above (paper III).

For the performance-based outcomes, corresponding to CMS, ROM, strength and JPS no between-group differences were found. The current mean values for CMS, however, were markedly better than for patients with shoulder impingement (69 vs. 45) [148], which may reflect the limited appropriateness of using CMS (sum score) in shoulder instability. CMS lack elements directed towards the disbelieve in shoulder function and the fluctuant shoulder instability symptoms [149]. Maximal strength of the injured shoulder was not affected, and even higher than that of shoulder healthy subjects [150], presumably due to the current higher distribution of males (90% vs. 42%) as well as variations in test performance. Also here, the appropriateness of using maximum strength tests in shoulder instability patients can be questioned, since it may not reflect true shoulder function, since shoulder instability patients may be more affected by sub-maximal tasks [26]. Finally, the present findings on JPS (open kinetic chain tests) were in line with a previous study on healthy subjects [108], and seems therefore not to be affected in the low range of shoulder flexion in this group of T ASD patients. Whether this also accounts for high range shoulder flexion JPS measurements is unknown, as this was not measured due to poor reliability in high range shoulder flexion [108]. Whether the present JPS measurements represent true proprioceptive function in this patient group needs to be further investigated for other movements.

## **Methodological considerations**

### ***Study designs***

This thesis is based on study designs with varying levels of evidence [151]. The SINEX trial, presented in paper I, was designed to meet the key demands typical of an RCT considered to be high level of evidence. It was planned to be as methodologically rigorous as possible according to guidelines for protocols of clinical trials and CONSORT Statement for reporting RCTs [118, 152]. Yet, we did not succeed in recruiting the estimated number of patients needed for adequate power in the SINEX trial within the timeframe of this thesis. The reason may be use of strict inclusion and exclusion criteria. Another reason may be that some patients do not attend the scheduled routine check at the participating shoulder units 4-6 weeks following a T ASD and is therefore not screened. Though, patient recruitment is a challenge in most RCTs [153]. Paper II, III and IV were based on clinimetric study designs regarded to be low level of evidence. Finally, paper V was a cross-sectional design, carried out at one time point and limited with regards to infer causality. However, cross-sectional designs are valuable in finding associations that can be further investigated by other high level designs, e.g. RCTs [154, 155].

### ***Patients***

Patients included in this thesis were recruited from either orthopedic departments or through patient initiated contact. Inclusion for the SINEX trial was restricted to patients with T ASD between the

age of 18 and 39 years old, which is in contrast to other studies including patients younger than 18 years [72-74]. Though, incidence rates and risk for recurrent dislocations are somewhat higher in the younger patients [156]. Hence, to avoid another stratification (related to age), further limiting the power of the current study, we choose an age limit of 18. T ASD patients older than 39 years were not included due to a high risk of risk of associated shoulder injuries (e.g. rotator cuff tears, axillary and nerve damages besides serious fractures) [157]. Furthermore, a maximum number of five anterior shoulder dislocations were defined as the cut-off for inclusion in the SINEX trial (paper I). This was a rather pragmatic choice since little is known about non-operative treatment potentials for patients with recurrent shoulder dislocations in general and, furthermore, that it is anticipated that most patients with five dislocations or more have been surgically stabilised already.

To improve recruitment strategies of patients for the methodological papers (II, III and IV) inclusion criteria were kept relatively wide. Generalizability of the findings of paper II was high due to patients being recruited from several regions in DK and with various shoulder instability symptoms.

The patient initiated recruitment for paper III may have influenced on the reliability of the clinical tests since advertising recruitment of patients with self-reported shoulder instability may not be as severely affected as patients with more established conditions (such as T ASDs, multi-directional instability or GJH). Still, though, the current “shoulder instable” subjects present with significantly worse shoulder-related QoL as measured with the total WOSI score when compared with the “shoulder healthy” individuals included in paper III. Also, a pragmatic setup was used to recruit participants for paper IV since we expected it to be rather difficult to recruit “real” patients for a pure methodical study. Yet, we succeeded in recruiting two groups (shoulder healthy and shoulder affected) that differed significantly in terms of self-reported DASH and WOSI, with the “shoulder affected” group scoring significantly worse.

## ***Outcomes***

### ***Patient-reported***

Based on the included patients in the SINEX trial (paper I) until now, the mean value of WOSI is 1083, SD 378. Thus, the eligibility criteria used in the SINEX trial (paper I) seem to include patients with values close to the anticipated baseline value of 1100 WOSI points and an SD of 320, as used a priori for sample size calculation. Fear of re-injury and movement is assessed with the TSK questionnaire (paper I and V). To our knowledge, TSK has not previously been used in patients with shoulder dislocations. Though, TSK is not region-specific and has previously been found to be appropriate for use in patients with shoulder pain [123]. Thus, the present findings with regard to psychological factors seem valid.

### ***Objective clinical evaluations***

Currently, there is no consensus on whether or not pain should be regarded as a diagnostic criterion, along with apprehension sign, when evaluating anterior shoulder instability. In favour of using pain as diagnostic criterion is the anticipation that shoulder instability may lead to painful shoulder impingement and repetitive microtrauma [109, 158, 159]. In contrast, demonstration of

apprehension, rather than pain, has shown to be a better predictor of anterior shoulder instability [107, 160]. Moreover, following a primary T ASD, a positive apprehension test, defined as muscular resistance or apprehension during testing, has proven to be a useful test to predict patients at higher or lower risk for experiencing recurrent dislocations [161]. Nevertheless, the cause of pain during performance of these tests has not yet been established and, whatever the cause, some shoulder joint pathology may presumably be present and, further supported if symptoms cannot be replicated in the contralateral shoulder. Though, further investigations are needed to unravel this diagnostic challenge. With regard to load-and-shift, the current study only rated the direction with most laxity, whereas previous studies rated laxity separately for anterior and posterior directions, increasing possibilities for discrepancy in inter-examiner agreements [105, 106]. Finally, for the sulcus sign test, the current study tested subjects in sitting, as opposed to previous study with subjects lying. The reason for this was that inferior glenohumeral translation is suggested to be easier to obtain and interpret in sitting [162].

### ***Performance-based***

Despite its frequent use for orthopaedic shoulder patients [163], CMS is not recommended as outcome tool for shoulder instability patients [149]. However, the present study (paper V) further presented data from ROM and strength separately for the injured shoulder, due to the standardization of these methods [132].

### **Interventions**

One study has previously succeeded in managing patients with T ASD with non-operative rehabilitation. During 1979 and 1982, 20 patients from the United States Naval Academy that sustained a T ASD were treated with a specific shoulder rehabilitation programme consisting of progressive strengthening of the rotator cuff muscles for approximately 12 weeks. The average age of patients was 19 years and time to follow-up was on average three years. The findings were that fifteen out of 20 patients (75%) did not re-dislocate their shoulder and returned to sport within an average of three months [164]. Specific, supervised and adequate progressive shoulder rehabilitation therefore seems evident following a T ASD. Though, this has not yet been documented in high-level studies, underlining the need for the SINEX trial (paper I).

### ***Physiotherapist-supervised Shoulder Instability Neuromuscular Exercise programme (SINEX)***

Complex exercise programme are optimally evaluated in RCTs and include detailed description of development processes and specific content of the exercise programme used [165].

The SINEX programme is based upon biomechanical and neuromuscular principles adapted from lower limb studies [80]. Furthermore, knowledge on pathophysiological changes following T ASD in addition to expert opinions, input from physiotherapists with theoretical and practical knowledge of neuromuscular training and previously described programmes formed the basis of the SINEX programme [28, 31-33, 46, 49, 81-83, 88, 90, 148, 166-170].

Transfer of neuromuscular exercise principles from MSK disorders in the lower extremities to the shoulder may seem controversial due to difference in physiological and biomechanical aspects. Obviously, the greatest difference is the lack of weight-bearing load in the upper extremity, as opposed to the standing, walking and landing actions in the lower extremities. Weight-bearing actions promotes joint stability and facilitates muscular co-contractions and proprioception. For this reason, many shoulder rehabilitation programmes contain upper limb weight bearing exercises [171]. Also, exercises to improve neuromuscular control and functional stability in patients with knee injuries are frequently incorporated and based largely on movement quality rather than quantity (e.g. alignment exercises and stability during single-leg-hop) [81, 172]. Likewise, movement quality of the scapula [33] and glenohumeral joint [32, 167] is of equally importance in shoulder rehabilitation. Consequently, it seems reasonable to believe that shoulder instability patients are likely also to benefit from neuromuscular principles and adapted theories from experiences with non-operative treatment of lower extremity MSK disorders.

### ***The self-managed training-based shoulder exercise programme***

This exercise programme was developed as the lowest denominator for a standard care programme, and was accepted by all partners (participating orthopaedics and physiotherapists). To improve retention in the study of the non-supervised exercise group we decided also to call/contact patient's midway (performed by an unblinded physiotherapist) to ensure progression and compliance with the exercises.

## **Strengths and limitations**

### ***Paper I***

Blinding of patients and physiotherapists involved in the SINEX trial (paper I) is not possible, with only testers being blinded. Exclusion of patients with no self-reported shoulder trouble (physically and/or emotionally) may be a limitation since some of these patients may develop recurrent dislocations and/or chronic symptomatic shoulder instability later on. However, this was chosen to avoid floor effect in the primary outcome at the three months follow-up. The strengths of the SINEX trial are the rigorous inclusion criteria aiming at a homogenous patient group. Moreover, the standardised, individualised and physiotherapist-supervised neuromuscular shoulder exercise programme developed for accommodating all types of T ASD patients (e.g. those with severe instability and pain and those in need of more sports-specific exercises) with exercises progressed from very basic to high levels of difficulty, respectively, is another strength.

### ***Paper II***

The use of the Swedish WOSI for translation, instead of the original Canadian version, may limit the validity of the Danish version, due to loss of important linguistic and cross-cultural aspects between Canada and Denmark. Secondly, a relative large proportion of patients were excluded from the reliability study due to non-stable shoulder conditions. The reason may be the relatively long test-retest reliability period of 14 days and that symptoms of shoulder instability may be fluctuant. Further, responsiveness of the Danish WOSI version was not investigated, which is another

limitation. Strengths of the study were the use of standardized guidelines for translating and adapting questionnaires across countries. Further, generalizability was high due to recruitment of patients from hospitals located in different geographic regions in Denmark. Finally, the use of electronic and online questionnaires resulted in no missing data nor any technically incorrectly completed items (e.g. as can be the case with self-administered paper questionnaires).

### ***Paper III***

A potential carry-over effect from one to the other examiner may have been present possibly explaining parts of the significant inter-examiner bias found in the relocation and sulcus sign tests. Random testing may have avoided this. Also, test protocols for the relocation and sulcus sign tests may have been insufficiently described and trained, even though a lot of effort was put into this part. Further, we did not succeed in obtaining a 50:50 distribution of subjects classified as “shoulder instable” or “shoulder healthy”. This may reflect the limitations on patient reported recruitment. The strength of the study is use of a three-phased protocol for performing reliability studies [120]. To control for low prevalence we used PABAK in addition to transparent presentation of the current findings, with the latter being a significant strength of the study

### ***Paper IV***

The order of the tests, by which the prone lying measurements were performed, was not randomized possibly introducing learning and fatigue effects possibly reflected by the somewhat skewed Bland Altman plots in the one-arm tests. Concurrent validity was measured with deadweights only. Hence, whether validity is also poor with the use of “true living subjects” with natural postural sways needs further investigation. Moreover, COPL was the only outcome measured and it is unknown whether other sway measures (e.g. COP area or velocity, anterior-posterior/medial-lateral displacements, respectively) would be less sensitive to deadweight noise.

A strength of the study was the use a strict protocol for reliability studies including thorough training of managing the test protocol before proceeding to the study phase with the rigorous design resulting in excellent reproducibility. Another strength was use of the same NWBB since a previous study has indicated that NWBBs holds higher inter than intra-device variability [173]. Additionally, the continuously adding of a large range of deadweights with three repetitions of each trial to assess noise sensitivity simultaneously from a NWBB and a force platform was another strength.

### ***Paper V***

A clear limitation is the preliminary small sample size limiting the statistical power of the findings. However, to avoid mass significance the significance level was defined to be below 0.01. The use of baseline data from an RCT, with use of strict inclusion and exclusion criteria, may limit the generalizability of the findings due to selected inclusion of patients. A strength is the use of electronic collection of demographic and patient-reported outcomes resulting in no missing data. With only two examiners, thoroughly trained in all test procedures, assessment variability was kept

to a minimum. Finally, with patients included from hospitals located in the Southern, Western and Northern part of Denmark, external validity is anticipated to be high.

### **Ethical considerations**

#### ***Paper I and V***

Patients are informed about the randomized design with allocation to either of the two treatment arms. Patients are kept blinded for any of the study hypotheses, which can be justified since patients are treated with either an anticipated equivalent, or superior, treatment to what they would have received if they did not participate in the study. Both patient groups are expected to benefit from participation in the study due to the active shoulder rehabilitation programmes in both treatment arms. Furthermore, the risk of sustaining another shoulder dislocation from participating in this study is not expected to be any higher than from regular daily activities. It is not anticipated that participation will cause any serious adverse events or harms.

#### ***Paper II, III and IV***

All of these studies were non-invasive/non-intervention studies and, therefore, the risk for adverse events or harms was little to almost none. Nevertheless, patients were informed about each of the study objectives and signed a written consent before participation. For safety reasons, though, subjects were excluded from further participation if the prone lying test position caused pain intensities  $\geq 8$  on a VAS after completing the first test rounds.

### **Deviations from the original study protocol for the SINEX trial**

According to Clinicaltrials.gov registrations there has been changes of inclusion criteria for the SINEX trial (paper I). Initially, patients needed to be positive on at least two out of three clinical tests for anterior shoulder instability (apprehension, relocation and surprise). However, the number of patients needed to screen [174], to actually include patients, were relatively high due to large proportion of negative findings with the three clinical tests. Thus, these tests were omitted from the eligibility criteria to broaden the inclusion criteria. This deviation was accepted by the Ethical committee and further registered in the study record for the SINEX trial at Clinicaltrials.gov. Though, clinical tests were still performed to evaluate treatment effect measures in those with positive tests SINEX trial (paper I)

## **Conclusions**

The following conclusions can be drawn from the current thesis:

- I.** A protocol for a randomized controlled trial (the SINEX trial) investigating non-operative treatment effects in patients with traumatic anterior shoulder dislocations has been developed. Embedded in the protocol, a standardised physiotherapist-supervised neuromuscular shoulder instability exercise programme was developed and described in detail according to current pathophysiological evidence and clinical experience. Recruitment of patients has started and is currently ongoing.
  
- II.** An electronic Danish version of the WOSI was established and found to be highly reliable and valid for evaluation of shoulder instability patients.
  
- III.** Four of six tests (apprehension, surprise, load-and-shift, and Gagey) were reliable for clinical use in patients with self-reported symptomatic shoulder instability. Relocation and sulcus sign were found not to be reliable.
  
- IV.** The NWBB used in prone lying test positions was highly reproducible, but compared with a force platform concurrent validity was poor, especially at low loads.
  
- V.** Patients with a primary shoulder dislocation do not present better musculoskeletal health than patients with recurrent shoulder dislocations. Though, both groups present with equal and high severity of shoulder instability, are affected by psychological factors and have poor shoulder-related QoL.



## **Clinical implications and future perspectives**

Sufficiently powered, good quality, and well-reported randomised controlled trials are needed in order to establish evidence-based treatment. The results of the SINEX trial will shed light on the effect of non-operative treatment for patients with primary and recurrent anterior shoulder dislocations and provide foundation for non-operative national treatment guidelines. Further, evidence-based findings of the SINEX trial may optimize shared decision-making processes (between physicians and patients) in clinical practice, when patients seek orthopaedic and/or physiotherapy treatment for a primary or recurrent anteriorly dislocated shoulder.

Based on previous and current findings, we suggest incorporation of the patient-reported questionnaires WOSI and TSK in the evaluation of patients, whether primary or recurrent, with a traumatic anterior shoulder dislocation. Furthermore, we encourage physicians to clinically screen for generalized joint hypermobility (by use of Beighton's criteria) and anterior shoulder instability (by use of the apprehension test).

This may lead to early detection of those in need for post-traumatic treatment and may decrease the risk for re-dislocation, improve shoulder related quality of life and delay the need for surgical intervention.

### **Suggested screening tool based on previous and current findings:**

- WOSI questionnaire                      Quickly performed, reliable and valid (study II), electronically manageable, and valuable for identifying patients with poor shoulder-related quality of life
- TSK questionnaire                        Quickly performed, electronically manageable, and valuable for identifying patients emotionally affected due to fear of re-injury
- Beighton's criteria                         Quickly performed, reliable clinical tests [131], and valuable for identifying patients with an increased risk of recurrence
- Apprehension test                         Quickly performed, reliable clinical test (study III), and valuable for identifying patients with an increased risk of recurrence [161]

Future studies should focus on how to identify patients with anterior shoulder dislocations in need for early post-traumatic treatment. Furthermore, validation of or elaboration on the suggested screening tool may be of high importance.

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## ***Paper I-V***

## *Paper I*