THE LONG-TERM OUTCOME
OF FROZEN SHOULDER

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ACADEMIC DISSERTATION


Academic dissertation to be publicly discussed, with the permission of the Medical Faculty of the University of Helsinki, in the auditorium of the ORTON Foundation, Tenholantie 10, Helsinki, on Friday 29th May, 2015, at 12 noon.

Helsinki 2015
"It's always about the patient. Always."

Sumant Krishnan, MD, orthopedic surgeon,

in Dallas 2008

With love,

to my parents and Victoria
ABSTRACT

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The long-term outcome of frozen shoulder


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Dissertation

The purpose of the current study was to assess and report the long-term outcome of frozen shoulder. The 234 patients with 257 frozen shoulders were clinically followed up for a mean 9.7 years (range, 2-30). The study includes five peer-reviewed articles. The specific aims of this project were to study: 1) the long-term outcome of the natural course of idiopathic frozen shoulder, 2) the very long-term outcome of manipulation under anesthesia (MUA), 3) the incidence and long-term outcome of postoperative frozen shoulder, 4) any influence of timing on the outcome of MUA, and 5) the long-term outcome of diabetic frozen shoulder.

In general, patients with frozen shoulder recovered spontaneously over a mean duration of 15 months. After 9 year follow-up, 94% of shoulders showed a range of motion (ROM) similar to that of the contralateral, non-affected shoulder; 51% were totally pain-free, and 43% had pain ≤3/10 on the Visual Analogue Scale (VAS). In the long-term follow-up, diabetic patients’ shoulder ROM remained inferior to that of non-diabetic individuals. However, diabetic individuals’ frozen shoulders recovered to the patients’ own contralateral level. The very long-term outcome of manipulation under anesthesia was slightly inferior to the outcome of spontaneous recovery i.e. the natural course. After a mean 23 years follow-up of MUA, 47% of the shoulders had no pain at all. Even though ROM deteriorated between the last two follow-ups (7 vs. 23 years after MUA) the once-manipulated shoulder did reach the ROM level of the contralateral shoulder. Timing of MUA was statistically significantly associated with the outcome after manipulation of the idiopathic frozen shoulder. Optimal timing for MUA may be between 6 and 9 months from the beginning of symptoms. However, this finding may not be clinically significant. Concerning postoperative frozen
shoulder after an open rotator cuff repair (RCR), the incidence was 20%. Compared to patients with no postoperative stiffness in their shoulders, the delay to postoperative healing was 3-6 months. The external rotation resolved first. One year after the surgery, the abduction and the flexion corresponded to that of the control patients’ shoulders. Patient age during RCR and the condition of the biceps tendon were related to the postoperative stiffness.

In conclusion, the long-term outcome of frozen shoulder is good.

Keywords: frozen shoulder, adhesive capsulitis, outcome, long-term, follow-up, diabetic frozen shoulder, postoperative stiff shoulder, postoperative frozen shoulder, timing, manipulation under anesthesia
Summary in Finnish

Dissertation


Väitöskirjatutkimus sisältää viisi osajulkaisua. Tulokset:

I. Jäätyneen olkanivelen luonnollinen kulku


II. Jäätyneen olkanivelen anestesiamanipulaation pitkäaikaistulokset

Tutkimuksessa II seurattiin 15 potilaan 16 jäätynyttä olkaa keskimäärin 23 vuotta anestesiamanipulaation jälkeen seuraavina ajankohtina: 1 kuukausi ennen hoitoa, 0-1 päivää ennen hoitoa sekä keskimäärin 6 päivää, 3 kuukautta, 7 vuotta ja 23 vuotta hoidon jälkeen. Todettiin, että liike parani useimmilla toista olkaa vastaavalle tasolle ja kipu hävisi. Pitkän seuranta-ajan aikana olkanivelen liikerata ehti huonontua mahdollisesti iän vaikutuksesta molemmissa olkapäissä, myös jäätmättömillä puolella. Voitiin todeta, että jäätyneen olkanivelen anestesiamanipulaation jälkeinen tulos säilyy vuosikymmeniä.

III. Olkanivelen kiertäjäkalvosimen avoimen korjausleikkauksen jälkeinen jäykistynyt olkanivel.

Tutkimuksessa III selvitettiin 56 potilaan olkanivelen kiertäjäkalvosimen repeämän avoimen korjausleikkauksen jälkeen jäätyneen olkanivelen toipuminen keskimäärin 8.7 vuoden kuluttua leikkauksesta. Avoimen kiertäjäkalvosimen korjausleikkauksen jälkeinen jäykä olka oli varsin yleinen esiintyen joka viidennellä potilaalla yhteensä 416 leikatusta olasta. Vaiva hidasti leikkausen jälkeistä olan likkeiden palautumista 3-6 kuukaudella. Liikkeet kuitenkin paranivat 6-12 kuukauden aikana valtaosalla potilaista vastaamaan ei-jäätyneiden leikkauspotilaiden
liikelaajuuksia. Korkeampi leikkauksenaikainen ikä sekä hauislihaksen jänteen eheyys liittyivät lisääntyneeseen leikkauksenjalkeiseen jäätymiseen. Tutkimuspotilaiden tuloksia 6 viikkoa, 3 ja 6 kuukautta sekä 1 vuosi leikkauksen jälkeen verrattiin kontrolliryhmän potilaisiin, joilla ei ollut kiértäjäkalvosimen leikkauksen jälkeistä järkyistynyttä olkaniveltä. Olkanivelen keskimääräiset liikeradat potilasryhmissä eivät eronneet enää vuoden kohdalla toisistaan.

IV. Onko anestesiamanipulaation ajankohta yhteydessä hoidon lopputulokseen?

Tutkimuksessa IV seurattiin 57 potilaan 65 manipuloidun jäätyneen olkanivelen tuloksia keskimäärin 6 vuotta ja pyrittiin selvittämään, onko manipulaation suoritusajankohdalla yhteyttä hoidon lopputulokseen. Tilastollisessa analyysissä 6-9 kuukauden kuluessa oireiden alusta suoritettu anestesiamanipulaatio oli yhteydessä parempaan hoidon lopputulokseen kuin muina ajankohtina suoritettu manipulaatio. Kyseisen ryhmän potilailla oli jälkiseurannassa muita paremmat flexio-, ulkokierto-, lepokipu- ja Simple Shoulder Test- arvot.

V. Diabeteksen vaikutus jäätyneen olan paranemiseen


Tämän väitöskirjatutkimuksen vahvuuksina voidaan pitää erittäin pitkiä seuranta-aikoja sekä sitä, että kaikki jäätynyt olkanivel -potilaat on jälkitutkitti klinisesti. Väitöskirja sisältää suurimman tähän mennessä klinisesti tutkitun ja julkaistun aineiston jäätyneen olkanivelen luonnollisesta kulusta ja pisimpään klinisesti tutkitun ja julkaistun jäätyneen olkanivelen anestesiamanipulaation tulosseurannan.

Loppupäätelmänä voidaan todeta, että jäätynyt olkanivel paranee spontaanisti ilman hoitoa lähes kaikilla potilailla. Diabetespotilailla olkanivelen liikerajoitukset jäävät suuremmiksi kuin ei-
diabeetikoilla, mutta näin käy myös diabetespotilaiden terveen olan liikeratojen suhteen. Olkanivelen kiertäjäkalvosimen repeämän avoimen korjauksen jälkeen jäätyyn, jäykkä olkapää on yleinen ilmiö ja viivästyttää olan paranemista usealla kuukaudella, mutta paranee yleensä runsaan puolen vuoden sisällä.

Avainsanat: jäätyyn olkanivel, pitkäaikaistulokset, seurantatutkimus, lopputulos, luonnollinen kulku, anestesiamanipulaatio, leikkauksenjälkeinen jäätyyn olkanivel.
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<td>CS</td>
<td>Constant-Murley Score</td>
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<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
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<td>MUA</td>
<td>Manipulation under anesthesia</td>
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<tr>
<td>NSAID</td>
<td>Non-steroidal anti-inflammatory drug</td>
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<td>p-value</td>
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TIIVISTELMÄ in Finnish

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ORIGINAL PUBLICATIONS
1. INTRODUCTION

A healthy shoulder is the most mobile joint in the human body. One of the most common causes of pain and disability of the shoulder is frozen shoulder. It significantly reduces the range of motion in every direction, thus severely disabling the use of the upper extremity. Frozen shoulder causes aching pain both at rest and during activity, and especially during nighttime. It often causes inability to work and features longstanding pain and deteriorated function.

This thesis deals with the long-term outcome of frozen shoulder. The theme for this retrospective study arose from the possibility to explore a large population of frozen-shoulder patients diagnosed and treated mainly by a single surgeon with a similar protocol, giving the possibility to evaluate its long-term outcome. Although over a thousand articles already exist on frozen shoulder, the outcome still remains controversial (33,34,44,47,51,59,60,63,69,80,82,87,103,147-150,154,159). Only a few studies concentrate on the natural course (20,63,148,159), outcome in diabetic patients’ frozen shoulder (30,80,81), effect of timing for one of the most commonly used treatment methods, manipulation under anesthesia (50,52,136,175), and long-term outcome after manipulation (49,53,75). These, along with the outcome of postoperative frozen shoulder (118,177,199), were the main themes for the thesis.

An American surgeon, Ernest Amory Codman, also referred to as the father of shoulder surgery, claimed that even the most recalcitrant cases of frozen shoulder recover (34). Already in that era, he believed in monitoring the outcome of his patients and used his so-called “end-result cards” with a follow-up time of one year. Now, almost one hundred years later, we sought the end results and the long-term outcome of our unique population of frozen-shoulder patients.
2. REVIEW OF THE LITERATURE

2.1. HISTORY

Nearly one and a half centuries have passed since French pathologist and surgeon Simon-Emmanuel Duplay in 1872 described “péri-arthrite scapula-humérale” (48). He differentiated this mobility-restricting condition of the shoulder from osteoarthritis, and suggested manipulation under anesthesia as a treatment method. Six years later, another French author, Desplats, also wrote on “peri-arthrite scapulo humerale” (42). James J. Putnam was the first to write about it in English. He published his article on “The treatment of a form of painful periarthritis of the shoulder” in The Boston Medical and Surgical Journal in 1882 (142). Among principal symptoms, he listed the inability to raise the arm above the horizontal level, and spontaneous pain, generally worst at night. Putnam also found that “any attempt to move the arm at the scapula-humeral articulation, either by abduction or rotation, causes sharp and severe pain, and is, indeed, nearly or quite impossible.” In 1906, Codman spoke on “subdeltoid bursitis” (32) as did Painter a year later (133), and Klapp in Europe (88). Codman gave the condition its widely used name “frozen shoulder” (32-34). Robert Lippman, in 1943, used the same term (97). Julius Neviaser, in 1945, introduced the term “adhesive capsulitis” and summed up the opinions of previous writers by defining frozen shoulder or adhesive capsulitis as a separate clinical entity (119). Ever since, researchers have tried to explore this entity, first in the fifties (41,98,111,114,165), then later were joined by numerous authors (6,9,10,20,24,30,36,40,44,60,61,63,64,69,78,101,104,112,113,115,121,122,123,125,130,145,146,148,154,178,186-188,208). Frozen shoulder has often been referred to as a mystery or enigma (20,22).

2.2. NOMENCLATURE AND ETYMOLOGY

The multiple names and terms introduced to describe this condition have included “frozen shoulder, adhesive capsulitis, checkrein shoulder, painful stiff shoulder, retractile capsulitis, periarthritis, adherent subacromial bursitis, and Duplay’s disease” (16,109). In Japan, the term “goju-kata” has meant “a 50-year-old-shoulder” (170) referring to the age when it usually strikes.

The first term written down was “periarthritis humeroscapularis”. “Peri”- is a prefix meaning “about”/ “around”; “arthritis” refers to inflammation of a joint. The most used names are frozen
shoulder and adhesive capsulitis. The word *adhesive* is derived from the Latin word *adhaesivus/adhasus* meaning, “clinging, tenacious, sticking fast”. *Capsulitis* is derived from the Latin word *capsula*, or the English word “capsule,” which means a “membranous sac or integument” surrounding the shoulder joint (204), and −“itis” refers to an inflammation. “Retractile” means withdrawn, being drawn back or in, as with the upper extremity held close to the body.

Criticism has arisen towards many of the names. It is obvious that no arthritis is involved and that the primary cause is not in the subacromial bursae (23,24). Even the widely used name “frozen shoulder” has its opponents (21), for the shoulder during the disease is neither cold nor icy. The term “frozen” refers more to the rigidity and stiffness.

### 2.3. NORMAL SHOULDER ANATOMY AND FUNCTION

The shoulder is a synovial joint, meaning that the articulating bones, the head of the humerus and the glenoid (Figure 1), are separated by a fluid-containing joint cavity. The joint capsule (*capsula articularis*) (Figure 2) is a sack-type formation around the joint, reaching from the glenoid to the head of the humerus. The inner surface of the joint capsule is the collagenous *synovium*, the synovial membrane that produces and secretes the *synovia*, a viscous liquid that lubricates the movements of the joint, the articular surfaces (26). The outer surface of the joint capsule is *membrane fibrosa/stratum fibrosum*, a collagenous membrane. The capsule completely covers the joint, but is loose. Normally, the surface area of the capsule is nearly double that of the humeral head (201). The sleeve-type stabilizers of the glenohumeral joint are the rotator cuff musculature, the capsuloligamentous complex, and the long head of the biceps tendon. The rotator cuff surrounding the glenohumeral joint is composed of four muscle tendons, the *supraspinatus*, *infraspinatus*, *subscapularis* and *teres minor* that surround the glenohumeral joint anteriorly, superiorly, and posteriorly. The capsule, the coracohumeral ligament, and the superior, middle, and inferior glenohumeral ligaments comprise the capsuloligamentous complex that also surrounds the glenohumeral joint. The inferior glenohumeral ligament forms a lax double-fold of the capsule forming the inferior or axillary recess (201). The long head of the biceps tendon lies under the coracohumeral ligament (82). The rotator interval is a tissue bridge between the anterior supraspinatus edge and the upper subscapularis border, with the apex located on the biceps sulcus lateral ridge at the margin of the transverse humeral ligament. It is mostly formed by the superior glenohumeral ligament and the coracohumeral ligament (84, 134).
FIGURE 1. Anatomy of the shoulder joint 1.

The whole shoulder girdle complex takes part in the motion of the shoulder (2); glenohumeral joint, acromioclavicular, sternoclavicular, and scapulothoracic articulations. Scapulothoracic and glenohumeral movements occur simultaneously at a ratio of 1:2, with most of the elevation attributed to the glenohumeral joint (201). The abductors include the deltoid, supraspinatus, the long head of the biceps tendon, but also to some extent the infraspinatus. The serratus anterior and trapezius may aid this movement by producing some scapular rotation. The infraspinatus is the strongest external rotator, but also the teres minor and the spinal part of the deltoid perform some rotation. Internal rotation is mainly carried out by the subscapularis, but also to some extent by pectoralis major, the long head of the biceps, the clavicular part of the deltoid, the teres major and also to some degree by the latissimus dorsi (2).

A healthy shoulder joint provides a range of motion beyond any other joint in the human body. It gives us the opportunity to scratch our back, lift dishes up to the upper shelf, and wash both of our armpits. For instance, to reach the perineum, a person needs about 75 to 90° of horizontal abduction, 30 to 45° of abduction, and 90° internal rotation. To wash the opposite shoulder, we need 60 to 90° forward flexion and 60 to 120° horizontal adduction (110).

2.4. ETIOLOGY, PATHOGENESIS, AND PATHOANATOMY IN FROZEN SHOULDER

Differing pathogenesis have been suggested to lie behind frozen shoulder including immunological, biochemical, and endocrinological causes. The main theories include multiregional synovitis with inflammation, scarring, capsuloligamentous complex fibrosis, and contracture. In addition, increased capillary growth and new nerve growth in the capsuloligamentous complex have been described, and this may explain the increased pain response (81). The entire
capsuloligamentous complex may become fibrotic, but specifically the rotator cuff interval and biceps tendon are involved (206). Hand et al took biopsies from resistant frozen-shoulder patients from the rotator interval and the coracohumeral ligament (68). They found fibroblasts, proliferating fibroblasts, and chronic inflammatory cells; mast cells, T cells, B cells and macrophages. They concluded that “the pathology of frozen shoulder includes a chronic inflammatory response with fibroblastic proliferation which may be immunomodulated.” Bulgen et al reported frozen shoulder patients as being significantly more often HLA-B27-positive than were the controls (42% vs. 10%). Their result may support the theory of immunological pathogenesis (19).

According to Bunker, (24) pathology lies behind the fibrous contracture of the rotator interval and coracohumeral ligament of the shoulder. First, new blood vessels emerge in the synovial membrane, especially in the area of the rotator interval. Then, during the stiff stage, the blood-vessel formation decreases, and a thick white scar evolves within the capsule. This results in capsular contracture. Frozen shoulder has been associated with many systemic conditions, including diabetes mellitus, thyroid diseases, and, Dupuytren’s disease (24,160). Bunker also stated that frozen shoulder should perhaps be classified within the group of diseases termed fibromatoses, which includes Dupuytren’s disease. Dupuytren is 8.27 times as common in frozen shoulder patients as in the general population (p<0.001) (24, 168) and occurred in 58% of Bunker’s and 25% of Schaer’s frozen-shoulder patients. Histologically, the predominant cells are fibroblasts and myofibroblasts which lay down a dense collagen matrix, mostly of mature type III and type I within the capsule. The tissue is highly cellular with fibroblasts and contractile myofibroblasts resembling the findings in Dupuytren’s contracture (23,24). Raykha’s findings (147) support Bunker’s theory of a fibrotic disease resembling Dupuytren’s contracture. They found that expression of IGF2 and level of β-catenin were significantly higher in frozen-shoulder patients than in patients with rotator cuff tears. In patients with Dupuytren’s disease, IGF2 and β-catenin are also increased (147). Bunker also found this phenomenon to be related to expression of growth factors, cytokines, and matrix metalloproteinases in frozen shoulder (25).

Julius Neviaser describes adhesions (119). Within a normal capsule there is a loose axillary fold. During frozen shoulder, the capsule thickens with inflammatory infiltrate and subsynovial fibrosis. This obliterates the normal, patulous axillary fold as a result of adhesions and fibrosis of the capsule itself (141). Others findings are that a contracted glenohumeral joint capsule is not associated with
capsular adhesions; some refuse to use the term “adhesions”, however, because these cannot really be seen (43,140). Thus, the basic pathological changes are said to be thickening of the joint capsule and its adherence to the head of the humerus (4,155).

The main abnormalities seen in frozen shoulder patients are synovitis in the anterior superior glenohumeral joint, thickening of the coracohumeral ligament, and periarticular soft-tissue inflammation in the rotator cuff interval. MRI shows a thicker coracohumeral ligament, obliteration of the subcoracoid fat triangle and the axillary recess, variable filling of the biceps tendon sheath, and, surprisingly, no significant thickening of the joint capsule (141). Typical for frozen shoulder are dense collagen fibers, fibroplasia resembling Dupuytren’s, and also thickening and contracture of the capsule, especially anteroinferiorly (102,140,152,207).

Some studies comment on the appearance of frozen shoulder inside the shoulder. “Hot spots” gleaming in a radioisotope scan have been noted (9), or the rotator cuff as being “tender and friable, rather cooked than frozen”. In the early phase of the disease, there is highly vascular, abnormal content arising from the subscapularis bursa and spreading to a variable extent across the rotator interval area. Later on, dense scarring is found in the same area (22). Synovitis is usually found and then thickening and scarring but no adhesions (157). Andersen et al found, during arthroscopy, reduced intra-articular volume, an agglutinated inferior recess and diffuse synovitis in all their frozen-shoulder patients (3). Intra-articularly, first at stage 1, vascular inflammatory synovitis is evident (202); at stage 2, a predominance of red synovium and early adhesion formation; at stage 3, pink synovium and more pronounced adhesion formation; but, at stage 4, synovitis is no longer a predominant feature, and the joint appears white because of the marked capsular adhesions. In cases of frozen shoulder, the range of motion in the shoulder joint declines both actively and passively. The scapulohumeral rhythm changes, and the scapula moves excessively in upward rotation to compensate for the loss of glenohumeral motion (124). Acromion morphology and frozen shoulder have no reported relationship (150). A frozen shoulder has reduced joint volume. The normal volume of a shoulder joint is about 10 to15 ml, but with frozen shoulder only some 3 to 4 ml (9, 22).

The term “postoperative frozen shoulder” has been introduced referring to the postsurgical stiffness after a rotator-cuff repair (106). Stiffness after a fracture has also been called secondary frozen shoulder (68). Secondary frozen shoulder has been defined as that associated with major trauma,
shoulder surgery, cardiovascular disease, and hemiparesis. A discrepancy exists between the extent of trauma and severity of subsequent frozen shoulder (40). The true etiology of frozen shoulder still remains unknown and presumably is multifactorial.

2.5. EPIDEMIOLOGY

Incidence of frozen shoulder in the general population is 2% (4,13,24,81,176,182). The cumulative incidence of frozen shoulder is estimated at 2.4 / 1000 population per year, based on a Dutch general-practice sample (190). A large UK-based primary care study found that frozen shoulder affected 8.2% of men and 10.1% of women of working age (192). In contrast, based on one specialist shoulder surgeon’s hospital care experience, frozen shoulder was estimated to affect only 0.75% of the UK population (23). This inconsistency in estimated prevalence could be explained by the fact that only the most resistant cases are referred to hospitals (67). Difficulty in indicating the true incidence of frozen shoulder can be explained by the vague and insidious nature of the condition; many patients do not seek medical care (75). Frozen-shoulder patients usually are women in their mid-50s (75, 109). Frozen shoulder does not affect the same shoulder twice (75), although, at least one recurrence has been reported (28). Bilateral cases constitute 6% to 50%, some 14% are simultaneously bilateral (201). It has been estimated that the opposite shoulder becomes affected in 6% to 17% of patients within 5 years (109). Incidence of frozen shoulder among diabetes patients has been reported to be as high as 10% to 36%, with prevalence being 10.3% to 22.4%. (4,13). The prevalence of diabetes or prediabetes in patients with frozen shoulder has been estimated to be as high as 71.5% (176). Race does not affect the incidence level (75).

Finland has a population of 5 470 820 (figure of January 10 2014, from Väestörekisterikeskus, the Finnish population register). Those in their thirties hardly ever have frozen shoulder, unless they have diabetes. Elderly patients in their seventies and eighties more frequently suffer from rotator-cuff problems or osteoarthrosis. At the end of 2013, there were 1 486 575 persons in Finland of the age 50-69 years. An incidence of only 2% would mean 29 731 frozen-shoulder patients. When it comes to patients with diabetes, Finland has approximately 500 000 (Diabetesbarometria 2010, Diabetesliitto). Incidence among them by a moderate estimate would be some 10%, amounting to 50 000 frozen-shoulder patients. However, exact numbers are unknown.
2.6. DIAGNOSIS AND DIAGNOSTIC CRITERIA

Diagnosis of frozen shoulder is mainly clinical. Patients present with a typical history of gradual onset of diffuse shoulder pain and progressive decrease in both active and passive ROM. Laboratory tests are unnecessary unless for ruling out rheumatoid arthritis or infections. Radiographs rule out glenohumeral osteoarthrosis. Some studies suggest that frozen-shoulder patients have increased cholesterol and triglyceride levels and even C-reactive protein (201). No other studies have verified these CRP findings. In frozen shoulder, laboratory and radiologic investigations are classically normal (109). Osteopenia, disuse osteoporosis, or calcific tendonitis may appear (197).

The most crucial part in reaching a correct diagnosis is measuring the ROM in both shoulders both actively and passively (31,82). In clinical testing of passive ROM of the glenohumeral joint, it is important to separate the glenohumeral and scapulothoracic movement and stabilize the scapula. The strength of the rotator cuff musculature should always be tested to rule out rotator cuff ruptures. Patients with frozen shoulder do not necessarily have a history of major trauma, but they may relate the beginning of the symptoms to some kind of minor trauma. The proportion of frozen shoulder attributed to minor trauma ranges from 9 to 33%. Patients often complain of pain during an extreme range of motion at the beginning of the symptoms, and nighttime pain causing inability to sleep and inability to lie on the affected shoulder (109).

The classification of frozen shoulder differs somewhat among researchers. Zuckerman et al (180) created a consensus definition in 2011, classifying frozen shoulder into primary (idiopathic) and secondary. In idiopathic frozen shoulder no associated conditions exist, and the underlying etiology is unidentifiable. Secondary frozen shoulder includes three subcategories: systemic, extrinsic and intrinsic. In their classification, secondary “systemic frozen shoulder” would include patients with systemic disorder such as thyroid disease or diabetes mellitus or hypoadrenalism. Secondary extrinsic would include patients with ipsilateral breast surgery, previous cerebrovascular accidents, post-trauma, such as with a previous humeral shaft or clavicle fracture. Secondary intrinsic frozen shoulder would include patients with rotator-cuff disorders or calcific tendonitis. In this study, we have included diabetes patients and patients with thyroid diseases in the category of primary frozen shoulder.
The American Shoulder and Elbow Surgeons (ASES) defines frozen shoulder as: “A condition of varying severity characterized by the gradual development of global limitation of active and passive shoulder motion where radiographic findings other than osteopenia are absent” (179). Varying diagnostic criteria that resemble one another have also been suggested:

- Diercks used the definition of >50% motion restriction of the glenohumeral joint in all directions for a period of 3 months or more (44).
- Lundberg defined primary frozen shoulder in his Supplementum on the Frozen Shoulder in 1969: a) a total elevation in the shoulder joint restricted to 135° or less, b) the restriction of motion localized to the humero-scapular joint, and c) no findings in the case history or in the clinical or radiological examination which could explain the decrease in range of motion; thus post-traumatic conditions, rheumatoid arthritis, osteoarthritis, hemiplegia, and other such more obvious changes, were excluded (102).
- Bulgen’s criteria for the study of natural course and different treatment methods were pain in the shoulder for at least one month with sleep disturbance due to night pain and inability to lie on the affected shoulder. All active and passive shoulder movements restricted, with a reduction in external rotation of at least 50% (20).

We may consider that the onset of frozen shoulder is the beginning of the pain. However, at this point, it still is often challenging to make the diagnosis, especially if a minor trauma has also been involved. The diagnosis can be confirmed when restriction in the passive ROM occurs.

2.7. DIFFERENTIAL DIAGNOSTICS

The two most important differential diagnostics are osteoarthrosis and chronic dislocation. These together with frozen shoulder cause marked restriction in passive ROM. Hsu pointed out that although many conditions of the shoulder cause pain and seemingly reduce the ROM, no true capsular contracture and restriction of the passive ROM occur. These conditions are for instance calcific tendonitis, bicipital tenosynovitis, glenohumeral and acromioclavicular arthritis, and tears of the rotator cuff. Thus, these cases should not be labeled adhesive capsulitis (75). Reasons for shoulder stiffness can also be fusion of the joint, and tightness of the soft tissues after an operation. Among throwing athletes, posterior capsular tightness may occur in pitchers, likely an adaptive
change from the powerful forces created in repetitive pitching. One reason for selective stiffness in limited external rotation may be that patients have undergone an anterior stabilization operation. In these cases, the reason for stiffness may be over-tightening (87).

In the very beginning of frozen shoulder, during the first stage, it is often difficult to differentiate it from other painful conditions such as impingement, because there is as yet no restriction in passive range of motion. A stiff shoulder may often simulate supraspinatus-tendinitis/rotator cuff tendinitis (110). Diagnosis is clinical examination with a careful medical history. The key feature in diagnosis is the restriction of shoulder movement in all directions both actively and passively (125). Sometimes associated with stiffening of the shoulder, especially after a minor trauma, a partial rotator cuff tear may be detected in imaging studies. Physicians should be aware not to treat an insignificant tear surgically when the true cause of the pain is frozen shoulder.

2.8. SCORING AND EVALUATION OF SHOULDER PAIN AND FUNCTION

Several scoring systems exist to evaluate shoulder function. In Europe, a widely used scoring system has been the Constant-Murley Score (CS) (35). It includes both subjective patient-reported and an observer-reported evaluation of the shoulder. The CS is a 100-points scale with four subscales: pain (15 points), activities of daily living (20 points), strength (25 points) and range of motion: flexion, abduction, external and internal rotation (40 points). The higher the score is, the higher the quality of the function is. In frozen shoulder, specifically ROM and activities of daily living are affected along with the pain.

The Simple Shoulder Test (SST) is a purely patient-reported evaluation of the shoulder. It is a questionnaire with 12 questions with yes or no responses and was devised to assess improvement in shoulder function after treatment interventions for all shoulder conditions. The minimal clinically important difference in SST has reported to be 2 points (172). Visual Analogue Scale (VAS) is a questionnaire and purely subjective patient-reported scale. It is continuous and measures pain on a scale from 0 (no pain) to 10 (maximal imaginable pain).

Other scales in evaluating shoulder ROM, function or pain would be for instance The Shoulder Pain and Disability Index (SPADI), Oxford Shoulder Score (OSS), the American Shoulder and Elbow Surgeons (ASES) score (95), The University of California at Los Angeles Shoulder Rating scale
(UCLA), the Disabilities of the Arm, Shoulder and Hand (DASH) score, and the Shoulder Disability Questionnaire (SDQ) (95, 138, 210).

2.9. STAGES OF FROZEN SHOULDER

The course of frozen shoulder has typically been divided into three stages. More recent classification separates stage 1 into two phases, thus giving four overlapping stages of frozen shoulder (163).

STAGE 1. The first stage of frozen shoulder is characterized by increasing pain on movement. The pain is described as achy at rest and sharp with end range of motion. The night pain usually makes sleeping and lying on the affected side difficult or impossible. There is as yet no restriction of passive motion under anesthesia (months 0-2), making it challenging to differentiate for instance from supraspinatus tendonitis. The first stage might also be called the pre-adhesive stage.

STAGE 2. The second stage resembles stage 1 but with progressive stiffening and loss of motion in the shoulder, often with severe pain. Passive restriction of glenohumeral joint becomes clear. Stages 1 and 2 together are usually referred to as the painful phase (months 1-6). Significant sleep disturbance may exist. According to Nagy, stage 2 lasts for 3 months (117). In Reeves’ prospective study of natural history, the painful phase lasted for 2.5-9 months (148).

STAGE 3. During the third stage, pain gradually decreases, but stiffness remains. Considerable restriction occurs in range of movement (months 4–15). In Reeves’ prospective study on natural history, the period of stiffness lasted for 4 to 12 months (148).

STAGE 4. During the last stage, range of motion improves. At this point, patients usually report minimal pain. There is capsular remodeling (months 9-24) (109,163).

We may simplify the course of frozen shoulder as follows:

- Stage 1 = PAIN.
- Stage 2 = PAIN + FREEZING.
- Stage 3 = FROZEN/STIFF.
- Stage 4 = RESOLUTION/THAWING.
2.10. NATURAL COURSE

The natural course of idiopathic frozen shoulder is usually self-limiting, but may be prolonged. The reported average duration is from 1 to 2.5 years, but in a proportion of individuals, symptoms may also persist indefinitely (44,148,159). Frozen shoulder can be highly painful and debilitating, affecting daily and social activities and the ability to work. According to Maund (109), “there is variation across case series in the proportion of patients who do not regain full shoulder motion, possibly a reflection of variation in how outcome was assessed”.

The largest series including 223 frozen-shoulder patients followed up for 3 years via questionnaire, showed 59% with normal or near-normal shoulders, 35% with mild to moderate symptoms with pain being the most common complaint, and 6% with severe symptoms (69). In another series, after 3 years, 43% continued to suffer pain and stiffness (165). At 7 years, 50% had mild pain, stiffness or both; a high 60% had measurable restriction of passive mobility, and 11% reported mild functional limitation (159). Even among the satisfied patients, a substantial number are not pain-free (62). Recurrence is extremely unusual.

2.11. TREATMENT MODALITIES

For frozen shoulder, numerous treatment methods exist, both operative and conservative. These include 1) supervised neglect or so-called watchful waiting, meaning, the natural course, 2) oral medications, such as non-steroidal anti-inflammatory drugs (NSAID) and oral steroids, 3) gentle exercise supervised by a physiotherapist or as part of a home-exercise program and different kinds of physical therapies, 4) intra-articular corticosteroid injections, 5) arthrographic distension or hydrodilatation 6) manipulation under anesthesia (MUA), and 7) arthroscopic capsular and open surgical release. Acupuncture, sodium hyaluronate, stellate ganglion block and low-power laser treatment are other techniques mentioned (109,169,207). “Advocates of each approach have published supporting results in the general population” (63,80,116,151). In the past ten years, some 19 RCT:s have appeared in the literature (TABLE 1).
TABLE 1. Randomized controlled trials concerning treatment of frozen shoulder published during the last 10 years.

<table>
<thead>
<tr>
<th>Author (ref.nro)</th>
<th>Year</th>
<th>Study type and Level of evidence</th>
<th>Intervention (number of patients)</th>
<th>Comparison (number of patients)</th>
<th>Follow-up time (months)</th>
<th>Primary outcome score</th>
<th>Result (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paul et al. (138)</td>
<td>2014</td>
<td>RCT, Level II</td>
<td>Countertraction + physiotherapy (n=50)</td>
<td>Physiotherapy (n=50)</td>
<td>0.5</td>
<td>Oxford Shoulder Score, ROM, VAS-pain</td>
<td>In counteraction group 60% reached a satisfactory shoulder function vs. 18% of physiotherapy group p&lt;0.001</td>
</tr>
<tr>
<td>Russell et al. (156)</td>
<td>2014</td>
<td>RCT, Level I</td>
<td>Group exercise class</td>
<td>1) individual physiotherapy 2) home exercises alone</td>
<td>12</td>
<td>Constant Score</td>
<td>In group exercise class better Constant Score improvement p&lt;0.001</td>
</tr>
<tr>
<td>Ohta et al. (129)</td>
<td>2014</td>
<td>RCT, Level II</td>
<td>Celecoxib 100 mg x2 (n=37)</td>
<td>Loxoprofen 60 mg x3 (n=33)</td>
<td>0.5</td>
<td>Pain on VAS*</td>
<td>Celecoxib better for nocturnal pain (VAS p= 0.028), otherwise comparable.</td>
</tr>
<tr>
<td>Lim et al. (95)</td>
<td>2014</td>
<td>RCT, Level II</td>
<td>Intra-articular injection of hyaluronate 20 mg (n=29)</td>
<td>Intra-articular injection of methylprednisolone 40 mg (n=34)</td>
<td>3</td>
<td>VAS, ASES, CS</td>
<td>External rotation better in corticosteroid group (p=0.015). Otherwise both effective with no difference between groups.</td>
</tr>
<tr>
<td>Yoon et al. (210)</td>
<td>2013</td>
<td>RCT, Level II</td>
<td>Ultrasound-guided intra-articular injection with 40 mg triamcinolone acetonide (n=20)</td>
<td>1) 20 mg of triamcinolone acetonide (n=20) 2) Placebo (n=13)</td>
<td>3</td>
<td>SPADI**, VAS, passive ROM</td>
<td>Corticosteroid better than placebo (VAS 2.4 vs 4.6, p= 0.004, SPADI 14.1 vs 18.3 vs 37.1, p= 0.007, abduction 140 vs 128 vs 96, p&lt;0.001) with no difference between doses.</td>
</tr>
<tr>
<td>Dehghan et al. (39)</td>
<td>2013</td>
<td>RCT, Level II</td>
<td>NSAID (naproxen) (n=28)</td>
<td>Intra-articular corticosteroid injection (triamcinolone) (n=29)</td>
<td>6</td>
<td>ROM*** and pain</td>
<td>Both effective, no difference in diabetic patients all p&gt;0.12.</td>
</tr>
<tr>
<td>Park et al. (135)</td>
<td>2013</td>
<td>RCT, Level II</td>
<td>Hyaluronic acid 20 mg + capsular distension (n=45)</td>
<td>Steroid injection alone (triamcinolone 40 mg) (n=45)</td>
<td>1.5</td>
<td>SPADI, VNS, passive ROM</td>
<td>Both effective, with hyaluronic + distension better external rotation (p&lt;0.5)</td>
</tr>
</tbody>
</table>
TABLE 1. (continues)

<table>
<thead>
<tr>
<th>Author (ref.nro)</th>
<th>Shin et al. (164)</th>
<th>Ma et al. (103)</th>
<th>Hsieh et al. (74)</th>
<th>Roh er al. (153)</th>
<th>Yang et al. (209)</th>
<th>Oh et al. (128)</th>
<th>De Carli et al. (37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study type and Level of evidence</td>
<td>RCT, Level II</td>
<td>RCT, Level II</td>
<td>RCT, Level II</td>
<td>RCT, Level II</td>
<td>RCT, Level II</td>
<td>RCT, Level I</td>
<td>RCT, Level II</td>
</tr>
<tr>
<td>Intervention (number of patients)</td>
<td>Intra-articular corticosteroid injection</td>
<td>Whole-body cryotherapy (WBC) + physical therapy + joint mobilization (n=15)</td>
<td>Physiotherapy + i-a hyluronate 20 mg injection (n=32)</td>
<td>Home stretching exercise + intra-articular corticosteroid injection (40 mg triamcinolone)</td>
<td>End-range mobilization / scapular mobilization treatment approach (EMSMTA) (n=10)</td>
<td>Glenohumeral steroid injection (n=37)</td>
<td>Manipulation + arthroscopic arthrolysis (n=23)</td>
</tr>
<tr>
<td>Comparison (number of patients)</td>
<td>1) Subacromial 2) subacromial + intra-articular 3) Medication</td>
<td>Physical therapy + joint mobilization (n=15)</td>
<td>Physiotherapy (n=31)</td>
<td>Home stretching exercise</td>
<td>Physiotherapy (n=10)</td>
<td>Subacromial steroid injection (n=34)</td>
<td>Intra-articular steroid injection (n=21)</td>
</tr>
<tr>
<td>Follow-up time in months</td>
<td>6</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Primary outcome score</td>
<td>ASES# and VAS</td>
<td>VAS, active ROM, ASES</td>
<td>SPADI, ROM, SDQ##, SF-36</td>
<td>Vas pain, ASES score and ROM</td>
<td>ROM, disability score &amp; shoulder complex kinematics</td>
<td>VAS, CS, ROM</td>
<td>CS###, ASES, UCLA, SST</td>
</tr>
<tr>
<td>Result (p-value)</td>
<td>Corticosteroid injection better at 4 months than medication, no difference in location. At 6 months no diff between the 4 groups (p= .117).</td>
<td>WBC yielded better VAS, ROM and ASES (p&lt;.01).</td>
<td>No added benefit from the hyaluronate (all p&gt;0.15)</td>
<td>Intra-articular corticosteroid injection yielded to better results in diabetic patients at 3 months (p=0.02), no diff. at 6 months.</td>
<td>EMSMTA more effective,</td>
<td>GH steroid led to better pain relief at 3 weeks (p=0.023), otherwise similar effect.</td>
<td>Both effective, but significant improvement occurred earlier (1.5 vs. 3 months) in MUA+arthrolysis-group (p&lt;0.03).</td>
</tr>
<tr>
<td>Author (ref.nro)</td>
<td>Lorbach et al. (100)</td>
<td>Lee et al. (93)</td>
<td>Jacobs et al. (78)</td>
<td>Quraishi et al. (145)</td>
<td>Kivimäki et al. (86)</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td>2010</td>
<td>2009</td>
<td>2009</td>
<td>2007</td>
<td>2007</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study type and Level of evidence</strong></td>
<td>RCT, Level I</td>
<td>RCT, Level II</td>
<td>RCT, Level I</td>
<td>RCT, Level II</td>
<td>RCT, Level II</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intervention (number of patients)</strong></td>
<td>Intra-articular cortisone x3</td>
<td>Ultrasound-guided intra-articular injection of triamcinolone 20 mg (n=20)</td>
<td>Intra-articular steroids + distension (n=24)</td>
<td>MUA (n=15)</td>
<td>MUA + home exercise (n=37)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Comparison (number of patients)</strong></td>
<td>Oral cortisone</td>
<td>Blind (unguided) technique (n=20)</td>
<td>MUA (n=19)</td>
<td>Hydrodilatation (n=18)</td>
<td>Home exercise alone (n=42)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Follow-up time in months</strong></td>
<td>12</td>
<td>1.5</td>
<td>24</td>
<td>6</td>
<td>12</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Primary outcome score</strong></td>
<td>CS, SST, VAS, function, satisfaction</td>
<td>VAS, ROM, shoulder function</td>
<td>CS, VAS, SF36</td>
<td>CS, VAS, ROM</td>
<td>ROM, SDQ, pain, working ability.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Result (p-value)</strong></td>
<td>Superior ROM, CS, SST and patient satisfaction in the intra-articular steroid group (p&lt;0.05).</td>
<td>Ultrasound-guidance recommended, better early results (p&lt;0.5)</td>
<td>No difference, steroid injection + distension recommended.</td>
<td>Hydrodilatation yielded better CS (p=0.02) and VAS (P&lt;0.0001). Similar ROM.</td>
<td>At 3 months flexion sign better in MUA group, no other sign differences between the groups.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* VAS = Visual analogue scale  
**SPADI = Shoulder Pain and Disability Index  
***ROM = Range of motion  
#ASES = American Shoulder and Elbow Surgeons score.  
##SDQ = Shoulder Disability Questionnaire  
###CS = Constant-Murley Score  
nSST = Simple Shoulder Test
2.11.1. CONSERVATIVE TREATMENT

1) Watchful waiting or supervised neglect means letting the condition run its natural course. It involves explaining the condition to the patient, and providing education and advice about mobilization within pain limits, plus use of pain relief (44).

2) Oral medications including non-steroidal anti-inflammatory drugs (NSAIDs) and oral steroids. Oral steroids such as prednisolone or cortisone (144) are one treatment for frozen shoulder. The Buchbinder group’s review on oral steroids for adhesive capsulitis (18) included five trials: two trials with oral steroids and placebo, one with oral steroid and no treatment, one with oral and intra-articular steroid, and one with MUA + intra-articular steroid combined with or without oral steroids. They concluded that there was no certain long-term benefit, but in the short-term, oral steroids may be beneficial in reducing pain and disability and increasing motion (18). They also concluded that use of oral steroids for a short time does not lead to serious side effects. Oral steroids were mostly given for 3 to 4 weeks and sometimes, if stiffness and pain persisted, for another 3 to 4 weeks. The equivalent amount of prednisolone ranged from 8 to 30 mg daily, often in gradually decreasing doses. In a randomized control trial, a 3-week course of prednisolone daily had a significant short-term benefit not maintained beyond 6 weeks (17). Oral steroids are no longer a commonly used intervention for frozen shoulder in Finland. Concerning other pain relief, non-steroidal anti-inflammatory drugs can be effective, but no randomized controlled trial documents their efficacy compared to that of placebo (201). NSAIDs have been effective in comparison to intra-articular corticosteroid injections in diabetes patients (39). The selective cyclo-oxygenase-2 inhibitor celecoxib (100 mg x2) for 1 to 2 weeks was comparable to loxoprofen (60 mg x3) in terms of analgesic efficacy (129).

3) Physiotherapy. Various kinds of physiotherapies and techniques have been introduced, including supervised exercise, mobilization, acupuncture, osteopathic and chiropractic techniques (95,126), and electrotherapeutic interventions such as laser therapy and ultrasound (46). It is believed that, intensive physiotherapy in the early stages of the disease, inflammation, proliferation, and perhaps even the early phase of the fibrotic stage would only activate the inflammatory process and result in inferior outcome compared to that with the natural course of frozen shoulder (44).
According to one recent review, based on the qualities of studies concerning physiotherapies or other therapeutic techniques, the following conclusions could be reached: short-wave diathermy (SWD) (190) with stretching may be more effective than home exercise; a high-grade mobilization technique (HGMT) may be more effective than a low-grade mobilization technique (LGMT); it may be beneficial to add physiotherapy to steroid injection; and steroids and physiotherapy are better than placebo (109).

4) Intra-articular corticosteroid injections have reduced inflammation and provided pain relief, and a range of doses and of number of injections introduced (15,39,40,100,128,143,205). This intervention is usually delivered early in the disease, in the synovitis phase, stage 1. According to the Clinical Practice Guidelines, there is strong evidence that “intra-articular corticosteroid injections combined with shoulder mobility and stretching exercises are more effective in providing short-term (4-6 weeks) pain relief and improved function than is shoulder mobility and stretching exercise alone (84). On the other hand, Arslan found no short-term difference between intra-articular corticosteroid and physiotherapy in their 20 patients (6). In one meta-analysis, higher doses of corticosteroids provided greater improvement of shoulder pain (5).

5) Arthrographic distension, hydrolitilation.
In dilatation treatment, the joint capsule is dilated with sterile saline or other solution such as a local anesthetic or steroid, guided by radiological imaging (ultrasound or arthrography) (16,162). The injection is continued with high enough pressure until the contracted capsule expands and ruptures; this usually requires 30 to 40 ml. The rupture usually occurs through the subscapular bursae, but occasionally down the biceps sheath (145). By the hydrolitilation method, fluid is injected into the glenohumeral joint.

2.11.2. OPERATIVE TREATMENT

6) Manipulation under anesthesia (MUA) forces the adhesive and contracted capsule of the glenohumeral joint to break free under brief general anesthesia. (71,77,161,189,201,203). This can be undertaken as a one-day procedure, but it is important to secure adequate postoperative physiotherapy. In retrospective series, after MUA, 75% have had satisfactory results and 8% had recurrences (3), diabetes did not lead to deterioration in results. However, RCT studies have shown no long-term benefit from MUA. For instance, MUA added no more benefit to home exercise (86),
the MUA result did not exceed the results of hydrodilatation (145), and no difference emerged between MUA and intra-articular steroid injection + distension (78). However, one RCT has shown some short-term benefit from MUA, for instance MUA + arthrolysis showed earlier significant improvement than did steroid injection (37). Complications related to MUA are unusual, but they do exist (121,131): ones like articular lesions (99) or glenoid fracture (105).

7) Arthroscopic capsular release is a surgical procedure conducted under general or regional anesthesia, during which the contracted capsule is released under visual control (167,197,198). Open capsular release is another surgical option, usually recommended in those resistant to arthroscopic intervention (130). Each can be undertaken as a one-day procedure. The key step in arthroscopic capsular release is to release the rotator interval region from the biceps to the upper level of the subscapularis. In open surgical release, excision of the coracohumeral ligament is said to produce immediate release (130). In pan-capsular arthroscopic release, all the following steps may be done: dissection of the rotator interval, resection of the coracoacromial and part of the coracohumeral ligaments from the coracoid process, and dissection of the superior, middle, and inferior glenohumeral ligaments, as well as of the posterior capsule (127).

Walther et al found no significant differences in outcome ROM between the three surgical procedures for persistent frozen shoulder: Arthroscopic capsular release + subacromial decompression, subacromial decompression with MUA, or arthroscopic capsular release (193).

No general agreement exists on which treatment is the best. Often, several treatment methods are combined. Criticism has arisen towards any interventional approach for frozen shoulder due to the absence of true evidence as to whether the interventions actually change the outcome from the natural course (81). Many specialist do, however, agree that treatments chosen should depend on the stage of frozen shoulder and that conservative treatments should be chosen before surgical ones (36,43,107). Aggressive mobilization should be avoided in the early stages with its intense pain. Surgery is nowadays usually adopted only in rare, resistant cases (107). No consensus exists on when exactly a surgical intervention would be indicated.
2.12. COST EFFECTIVENESS

Studies that include or present any cost-effectiveness data, or precise economic data for frozen shoulder barely exist (109). Concerning physiotherapy, one suggestion is that a low-grade mobilization technique (LGMT in the pain-free zone) may be more cost-effective than high-grade mobilization (HGMT with intensive end-range motion) (181). However, from the clinical point of view, HGMT has been reported to be statistically more effective for the patients (190). Another study of patients with unilateral shoulder pain suggests that steroids alone may be more cost-effective than steroids plus physiotherapy or physiotherapy alone (79). With current evidence it is impossible to develop a full economic model of frozen shoulder.

2.13. POSTOPERATIVE FROZEN SHOULDER

Postoperative stiff shoulder after RCR is a common complication (54,55,72). It has also been called “postoperative frozen shoulder” by some experienced shoulder surgeons (72). It has been postulated that a larger amount of tissue in RCT meaning a smaller tear may be associated with postoperative stiffness (106).
3. AIMS OF THE PRESENT STUDY

The purpose of this academic dissertation was to investigate the long-term outcome of frozen shoulder. The specific aims of the study were to discover:

I. The long-term outcome of the natural course of idiopathic frozen shoulder.

II. The very long-term outcome after manipulation under anesthesia (MUA) for idiopathic frozen shoulder.

III. The incidence and long-term outcome of postoperative frozen shoulder after an open rotator cuff repair including factors predicting postoperative stiffness.

IV. Whether timing of MUA has any association on the outcome of MUA.

V. The long-term outcome of diabetic frozen shoulder, comparing it with the outcome of frozen-shoulder patients without diabetes.
4. PATIENTS AND METHODS

Over 15,000 patient records were manually evaluated to identify 234 patients with frozen shoulder. Of these patients, 177 were seen and diagnosed at ORTON Orthopaedic Hospital by a shoulder surgeon and at his private-practice office. In addition, 57 frozen-shoulder patients with manipulation under anesthesia were traced from Rauma Hospital, Rauma Finland, and also diagnosed and treated by a shoulder surgeon. The total number of shoulders and patients included in this project is 198 shoulders (178 patients) with idiopathic frozen shoulder, 56 patients (59 shoulders) with postoperative frozen shoulder, and 61 control patients with 69 shoulders with no stiffness after surgery. Altogether, 234 patients (257 shoulders) were clinically followed up and evaluated for their long-term outcome. The mean follow-up time for idiopathic frozen-shoulder patients was 9.7 years and, for postoperative frozen-shoulder patients, 8.7 years. All the initial diagnoses of frozen shoulder were made by a specialized shoulder surgeon. The final follow-up examinations, interview and clinical examinations, ROM and Constant-Murley Scores, were made by an independent physician specializing in surgery. All surgeries (open rotator cuff repairs) were performed in a similar fashion under general anesthesia at the ORTON Orthopaedic Hospital, Helsinki (Study III). All planned manipulations under anesthesia were performed either at the ORTON Orthopaedic Hospital, Helsinki (Study II and V) or Rauma Hospital, Rauma (Study IV).

TABLE 2 Summary of number of patients and shoulders and follow-up times in Studies I-V.

<table>
<thead>
<tr>
<th>STUDY</th>
<th>PATIENTS (SHOULDERS)</th>
<th>CONTROL PATIENTS (SHOULDERS)</th>
<th>FOLLOWUP TIME years, mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>51 (52)</td>
<td>52 (54)</td>
<td>9 (2-27)</td>
</tr>
<tr>
<td>II</td>
<td>15 (16)</td>
<td>-</td>
<td>23 (19-30)</td>
</tr>
<tr>
<td>III</td>
<td>56 (59)</td>
<td>61 (68)</td>
<td>9 (3-20)</td>
</tr>
<tr>
<td>IV</td>
<td>57 (65)</td>
<td>-</td>
<td>6 (2-12)</td>
</tr>
<tr>
<td>V*</td>
<td>27 (29)</td>
<td>151 (169)</td>
<td>10 (2-30)</td>
</tr>
</tbody>
</table>

*Patients from Studies I, II, and IV with 3 patients added.
This thesis evaluates function both subjectively and objectively by use of the Simple Shoulder Test (166) and the Constant-Murley Score (35). The range of motion has been evaluated as flexion, abduction, and external and internal rotation. Some suggest that more clinically suitable ways to examine the motion of the shoulder include “hand behind the neck,” “hand behind the back,” and “hand to the opposite shoulder” and by movements of activities of daily living (110). These we have used in the Constant-Murley Score and in the Simple Shoulder Test. Flexion, abduction, and external rotation have been measured with a goniometer to an accuracy of 5 degree.

4.1. The natural course of frozen shoulder

Between 1975 and 2006, a mean 9 years before the final follow-up, 103 patients were diagnosed with idiopathic frozen shoulder. At that time, all these patients were thought to need no other treatment except for supervised neglect. The mean age at symptom onset was 53. Only 51 of these patients (52 shoulders) were treated, however, solely with supervised neglect (the untreated, natural-course group), 32 had received some kind of non-operative treatment (the non-operative group with conservative treatment). After the initial consultation, 20 patients (22 shoulders; 13 women) had undergone manipulation under anesthesia (MUA) elsewhere. Patients who had undergone MUA or any conservative treatment served as controls for the natural-course group. The mean age of these patients was 49, with a minimum follow-up of 2 years (mean, 14 years; range, 2–24 years). Duration of the disease, pain levels, ROM, Simple Shoulder Test, and Constant-Murley scores were factors determined.

4.2. Very long-term outcome after manipulation under anesthesia for idiopathic frozen shoulder

Between 1977 and 1989 26 patients with idiopathic FS had their shoulders manipulated under anesthesia by the senior author of Study II. These patients were first long-term evaluated in 1992 with a mean follow-up of 7 years (range, 3-14 years) (185). Back in 1992, mean flexion had been $155^\circ$, abduction $175^\circ$, and external rotation $51^\circ$, along with satisfactory pain relief. We wanted to evaluate whether these findings after manipulation would persist over time.

Four patients had died. Of the remaining 22, 15 (16 shoulders) participated in the final, very long-term follow-up evaluation a mean 23.1 years (range, 19-30 years) after MUA. Of 15, 12 were
women (80%). The mean age of these patients was 48.5 at MUA and 72 at final follow-up. Four patients had diabetes. Between their onset of symptoms and the manipulation, the time averaged 7.6 months. Inclusion criteria were: 1) No, or only minor shoulder trauma, 2) Marked loss of active and passive shoulder motion (forward flexion $<120^\circ$ and/or abduction $<120^\circ$, external and internal rotation almost absent, 3) Normal findings on a true AP radiograph of the glenohumeral joint, 4) Diagnosis of FS by an experienced orthopedic surgeon, 5) Manipulation under anesthesia done. Exclusion criteria were: 1) An intrinsic glenohumeral disorder such as arthritis or rotator-cuff tear, 2) Any history of substantial shoulder trauma, 3) Previous or subsequent shoulder surgery. Pain levels, ROM, the Simple Shoulder Test, and Constant-Murley Scores were determined.

4.3. The outcome of postoperative frozen shoulder after open rotator cuff repair

Between 1988 and 2004, 416 consecutive open rotator-cuff repairs (RCR) were performed at ORTON Orthopaedic Hospital, Helsinki, Finland. Among them we identified a total of 103 patients with severe painful postoperative restriction of ROM. Of these, 15 were excluded for various reasons: preoperative posttraumatic stiff shoulders manipulated before surgery, posttraumatic adhesive capsulitis diagnosed and manipulated at surgery, shoulders treated only for partial repair (poor tendon quality, severe retraction), and manipulation done 2 months after surgery. Of the 88 patients remaining, one had an evident re-tear with poor shoulder strength, and in four instances, clinical follow-up data were insufficient, leaving 83. Of these, four had died. Of the 56 patients (71%, 59 shoulders) who volunteered to participate, 39 were men (70%) and 17 women. Forty-five (76%) tears were traumatic. Mean age during surgery was 56 (range, 40-83 years). Time from beginning of symptoms to surgery averaged 8.4 months (range, 2 weeks to 84 months, median, 4.0 months). Operative delay was $<6$ months in 38 cases and less than one year in 78%. All operations were performed in a similar manner. The mean size of the tear was 3x4 cm (12.6 cm$^2$). The supraspinatus tendon was involved in all cases, the subscapular in seven (12%). Mean follow-up time was 8.7 years (3–20 years). In many studies, preoperative stiff patients have also been included. We wanted to study purely postoperative stiffness and therefore carefully excluded all those patients who already had preoperative or perioperative passive shoulder stiffness. We included only patients who had free passive range of motion pre- and peri-operatively. We believe this provides better information on pure postoperative stiffness. The incidence is greater, if one
includes preoperative stiff shoulders too. We determined range of motion, pain, shoulder strength, Constant-Murley Score and Simple Shoulder Test.

4.4. Does timing of MUA for frozen shoulder associate with results?

Study IV is a retrospective evaluation of single-surgeon, single institution consecutive series of frozen shoulder patients that were manipulated under anesthesia from April 1997 to October 2002 in Hospital of Rauma. Two independent investigators evaluated the long-term results. 57 (65 shoulders) participated in the study (71%). Mean follow-up time was 6 years (range, 2-12), and of the participants, 30 were women (53%). Mean age at MUA was 54.0 (range, 37-59). Delay from the beginning of symptoms to MUA averaged 8.8 months (range, 3-36 months). Ten patients (18%) were diabetic. The right shoulder was involved in 30 (46%), and 16 patients (28%) had a history of minor trauma prior their symptoms. Inclusion criteria for Study IV were 1) No, or only minor shoulder trauma, 2) Marked loss of active and passive shoulder motion (forward flexion <120, abduction <110, severe restriction in external rotation, 3) Normal findings on a true antero-posterior radiograph of the glenohumeral joint, 4) Diagnosis of frozen shoulder made by an experienced orthopedic surgeon and, 5) MUA performed. We excluded patients who had any intrinsic glenohumeral disorder such as rotator cuff tear or glenohumeral arthritis, any history of substantial shoulder trauma, such as traffic accidents, fracture of the ipsilateral extremity or insufficient patient status recordings (no mention of preoperative ROM in degrees).

The pre-operative flexion averaged 95° (10°-130°) and abduction 80° (10°-120°). Seven frozen shoulders were bilateral and one simultaneous bilateral. Non-operative treatment prior to the MUA included physiotherapy in 3 patients and subacromial corticoid injection (mean 1.9 injections per shoulder) in 26. Only 8 (14%) smoked, and 35 (61%) drank some alcohol weekly.

Referring to the earlier literature concerning timing of manipulation of FS, two groups were formed; Those mobilized between 6 and 9 months (Group A, 25 shoulders, MUA done at ≥6 - <9 months after symptom onset), and the others (Group B, 40 shoulders, MUA at <6 or ≥9 months after symptom onset). The two groups did not differ when it came to patient age, gender, affected-shoulder side, range of motion in flexion or abduction prior to MUA, smoking, or alcohol consumption. We determined pain by a patient-generated VAS and recorded ROM, SST, and CS at follow-up.
4.5. **The outcome of diabetic frozen shoulder**

Study V included 29 diabetic frozen shoulders of 27 diabetic patients compared to 151 non-diabetic patients (169 non-diabetic shoulders) with frozen shoulder. These patients comprised all the primary FS patients in this project, meaning patients from Studies I, II, and IV with three patients added. In total, Study V involved 198 idiopathic frozen shoulders (178 patients). Mean follow-up time was 9.7 years (range, 2-30 years, median, 7 years). We had 15 patients with insulin-dependent diabetes mellitus (17 shoulders) and one with non-insulin treatment. One diabetic patient had only dietary treatment. Of all the 198 frozen shoulders, 110 were manipulated under anesthesia (56%), including 20 diabetic shoulders (69%) and 90 non-diabetic shoulders (53%). The other 88 shoulders, including 9 diabetic shoulders, received conservative treatment or just thoughtful observation. We used the Constant Score, a validated measure of shoulder disability incorporating 40% of subjective and 60% of objective results including pain, range of motion and functional status.
5. RESULTS

Range of motion after idiopathic frozen shoulder reached the level of the contralateral, unaffected shoulder. Pain was minimal at follow-up, a mean 10 years after symptom onset. Function was at the normal level.

**TABLE 3. Outcome in range of motion (ROM) in 178 patients with 198 shoulders, a mean 10 years after idiopathic frozen shoulder.**

<table>
<thead>
<tr>
<th>ROM</th>
<th>Once frozen shoulder mean ° (range)</th>
<th>Contralateral shoulder mean ° (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLEXION</td>
<td>155 (95-190)</td>
<td>155 (60-185)</td>
</tr>
<tr>
<td>ABDUCTION</td>
<td>170 (60-195)</td>
<td>167 (30-190)</td>
</tr>
<tr>
<td>EXTERNAL ROTATION</td>
<td>51 (0-90)</td>
<td>51 (0-80)</td>
</tr>
<tr>
<td>INTERNAL ROTATION</td>
<td>LI (next to thigh-ThVII)</td>
<td>LI (next to thigh-ThVII)</td>
</tr>
</tbody>
</table>

**TABLE 4. Function, Constant Score and Simple Shoulder Test and pain on the Visual Analogue Scale in 178 patients with 198 once frozen shoulders mean 10 years after idiopathic frozen shoulder.**

<table>
<thead>
<tr>
<th>Function</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAIN AT REST</td>
<td>0.6/10 (0-7.0)</td>
</tr>
<tr>
<td>PAIN AT NIGHT</td>
<td>1.0/10 (0-8.2)</td>
</tr>
<tr>
<td>PAIN AT EXERTION</td>
<td>1.5/10 (0-9.6)</td>
</tr>
<tr>
<td>CONSTANT SCORE</td>
<td>82/100 (30-98)</td>
</tr>
<tr>
<td>SIMPLE SHOULDER TEST</td>
<td>10.5/12 (3-12)</td>
</tr>
</tbody>
</table>

Twenty (11%) verified bilateral frozen shoulders filled the criteria of bilateral frozen shoulder. Of these bilateral patients, four (2.3%) had simultaneous bilateral FS; none had either diabetes or thyroid dysfunction. At final follow-up, both their shoulders were quite painless; two of them had
all pain (rest, activity and night) rated as <1/10. One had rest and activity pain <1 but pain during the night at 2.3/10. One patient with simultaneous bilateral frozen shoulder had no pain at all in her shoulders.

The specific results of the study were:

5.1. Natural course of frozen shoulder

The duration of frozen shoulder averaged 15 months (range, 4–36 months) in the natural course group, and 20 months (range, 6–60 months) in the non-operative group with no statistically significant difference (p=0.080). At final follow-up, the range of motion had improved to the contralateral level in 94% of the natural-course group, in 91% in the non-operative group, and in 91% in the MUA group. The percentage of patients that were totally pain-free at rest, during the night, and with exertion was 51% with the natural-course patients, 44% in non-operative group, and 30% in the MUA group. Pain at rest was less than 3 on the Visual Analogue Scale in 94% of patients in the natural-course group, 91% in the non-operative group, and 90% in the manipulation group. The mean Constant-Murley score was 83 in the untreated group, 81 in the non-operative group, and 82 in the manipulation group.

Four patients had long-term follow-up with Constant Score <70/100; One 61-year old male farmer with Dupuytren’s disease who had 65 Constant Score points had a severe osteoarthrosis in his glenohumeral joint and a high level of pain. One 78-year-old male patient had a Constant Score of only 35 with no arthrosis, but with a high level of pain in his shoulder. He also had a high level of pain and swelling in both his wrists, and in addition his prosthetic knee had been operated on three times for pain. The recommendation was laboratory investigations for rheumatism. The passive range of motion in his glenohumeral joint was not restricted. One 59-year-old retired female patient had a Constant Score of 69 with no osteoarthrosis, a free passive ROM of her glenohumeral joint, and abduction power of 6.5 kg. However, her Simple Shoulder Test score was a full 12 points. She had diabetes and Maya Maya disease and a recent history of loss-of-consciousness attacks. The fourth natural-course patient with a poor follow-up Constant Score of 54 points was a 61-year-old female retired bank clerk with no osteoarthrosis and very little pain, but inferior active flexion of 135 and also passive flexion restricted to 145 degrees. Her abduction was 155, external rotation 45, and internal rotation LIII. These patients with a poor final Constant Score did not experience
specifically poor ROM during frozen shoulder. We could find no specific frozen-shoulder related conjunctive reason to explain their poor final Constant Score results.

5.2. Very long-term outcome after manipulation under anesthesia for idiopathic frozen shoulder

At 7 years, improvement had occurred in forward flexion to 155°, in abduction to 175°, in external rotation to 51°, and in internal rotation to the T7 level. During the next 16 years, ROM deteriorated by 8° to 23°, but still equaled the contralateral shoulder’s ROM. On a VAS (range, 0–10; 0 = none, 10 = maximal), pain averaged 0.3 at rest, 0.8 at night, and 1.5 with exertion. The mean Constant-Murley score was 70 (range, 34–88), with 12 patients reaching an age- and sex-adjusted normal Constant-Murley score. Two small fractures of the inferior glenoid rim were visible in the 1992 x-rays. They had no history of trauma, nor any arthrosis at final follow up.
TABLE 5. Short-, long-, and very long-term range of motion in patients who had undergone manipulation under anesthesia (MUA) for frozen shoulder. Mean values.

<table>
<thead>
<tr>
<th>Time period</th>
<th>FLEXION</th>
<th>ABDUCTION</th>
<th>EXTERNAL ROTATION</th>
<th>INTERNAL ROTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month before MUA</td>
<td>99</td>
<td>75</td>
<td>21</td>
<td>Buttock</td>
</tr>
<tr>
<td>Just before MUA</td>
<td>100</td>
<td>78</td>
<td>11</td>
<td>Buttock</td>
</tr>
<tr>
<td>6 days after MUA</td>
<td>145</td>
<td>132</td>
<td>33</td>
<td>LV</td>
</tr>
<tr>
<td>3 months after MUA</td>
<td>150</td>
<td>137</td>
<td>31</td>
<td>LV</td>
</tr>
<tr>
<td>7 years after MUA</td>
<td>155</td>
<td>175</td>
<td>51</td>
<td>ThXII</td>
</tr>
<tr>
<td>23 years after MUA</td>
<td>145</td>
<td>152</td>
<td>43</td>
<td>LI</td>
</tr>
<tr>
<td>Contralateral shoulder 23 years after MUA</td>
<td>147</td>
<td>152</td>
<td>47</td>
<td>LII</td>
</tr>
<tr>
<td></td>
<td>p=0.440</td>
<td>p=0.882</td>
<td>p=0.115</td>
<td>p=0.135</td>
</tr>
</tbody>
</table>

5.3. Outcome of postoperative frozen shoulder after open rotator cuff repair

Incidence of postoperative frozen shoulder was 20%. Healing after surgery was delayed by 3-6 months, but resolution occurred a mean 6.3 months postoperatively. External rotation resolved first, corresponding to that of the controls at 3 months. Flexion and abduction corresponded to that of the controls at 1 year after surgery. The mean summarized ROM (flexion + abduction + external rotation) reached 93% of the controls’ ROM by 6 months and 100% by one year. Range of motion improved to the contralateral level as did pain, strength, and function. Factors associated with postoperative frozen shoulder were higher age at surgery and good condition of the biceps tendon.
5.4. Does timing of MUA for frozen shoulder associate with results?

Timing of MUA was statistically associated with the long-term outcome of frozen shoulder. Preoperatively, no difference appeared between the groups in flexion or abduction. At follow-up, abduction ($177^\circ$ vs. $167^\circ$) and external rotation ($61^\circ$ vs. $51^\circ$) were statistically significantly better in Group A. Forward flexion was also better in Group A, but not significantly ($162^\circ$ vs. $156^\circ$). The final ROM of the once-frozen shoulder was similar to that of the contralateral, unaffected shoulder ($p=0.528-0.926$). Regarding function, Simple Shoulder Test scores were better in Group A (11.3 vs. 9.5), at statistical significance: $p=0.002$. Constant Score was also better, but not significantly (87 vs. 83).

Regarding pain, patients manipulated between 6 and 9 months from onset of symptoms reported significantly less pain at rest and night than did other patients. They had less pain also during exertion, but not significantly. Subjectively, patients in Group A were more satisfied with their results: 91% of Group A were satisfied or very satisfied, in Group B 72% ($p=0.076$). All the patients who were either dissatisfied or very dissatisfied were from Group B (their frozen shoulders had been manipulated at 3, 5, 12, and 19 months after the beginning of symptoms). Sick-leave after the manipulation was similar and averaged 1.3 months (range, 0-7 months). In Group A, 84% felt that their symptoms improved after manipulation, in Group B 75% ($p=0.084$). During the year before the follow-up, nine patients (16%) had suffered shoulder complaints in daily living activities, with a tendency toward a significant difference between groups (one patient, 4%, in Group A, and eight, 20%, in Group B ($p=0.068$). At follow-up, glenohumeral motion was somewhat restricted in nine patients and severely restricted in one patient from Group B. Group A had only one patient with a little restriction in the glenohumeral joint ($p=0.054$). Of the 57 patients, 26 continued to work, and 28 (49%) had retired, none due to any shoulder disorder. Under the same circumstances, 95% of the patients in Group A and 75% in Group B would have chosen the manipulation again. Five re-manipulations took place in each group with no evident significance, not even when calculated between patients manipulated before 6 months versus all the others ($p=0.259$). When evaluating a subgroup of patients manipulated later than 12 months after symptom onset, the results were more clearly inferior compared to results for those manipulated between 6 and 9 months.
5.5. The outcome of diabetic frozen shoulder

ROM of the non-diabetic shoulders improved to the contralateral level, but ROM of affected diabetic shoulders remained significantly inferior compared to ROM of affected shoulders among patients without diabetes. However, the final ROM of the diabetic shoulders did not differ from that of the diabetic contralateral, unaffected shoulders. The mean difference between a diabetic patient’s ROM and the ROM of his or her unaffected shoulder was in flexion 2°, abduction 0°, external rotation 4°, and in internal rotation none. When comparing these differences between one’s affected vs. unaffected shoulder between diabetics and non-diabetics, no difference emerged.

TABLE 6. Range of motion of affected (once frozen) and unaffected shoulders in diabetic and non-diabetic patients at final follow-up, a mean 10 years after frozen shoulder.

<table>
<thead>
<tr>
<th></th>
<th>DIABETIC patients' AFFECTED shoulder n = 29</th>
<th>NON-diabetic patients' AFFECTED shoulder n = 169</th>
<th>p-value between DIABETIC and NON-diabetic patients' AFFECTED shoulders</th>
<th>DIABETIC patients' UNAFFECTED shoulder n = 29</th>
<th>NON-diabetic patients' UNAFFECTED shoulder n = 169</th>
<th>p-value between DIABETIC and NON-diabetic patients' UNAFFECTED shoulders</th>
<th>p-value between DIABETIC patients' AFFECTED and UNAFFECTED shoulders</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLEXION</td>
<td>144</td>
<td>157</td>
<td>0.001</td>
<td>146</td>
<td>157</td>
<td>0.013</td>
<td>0.172</td>
</tr>
<tr>
<td>ABDUCTION</td>
<td>154</td>
<td>173</td>
<td>0.008</td>
<td>154</td>
<td>169</td>
<td>0.048</td>
<td>0.262</td>
</tr>
<tr>
<td>EXTERNAL ROTATION</td>
<td>41</td>
<td>53</td>
<td>0.002</td>
<td>45</td>
<td>52</td>
<td>0.049</td>
<td>0.744</td>
</tr>
<tr>
<td>INTERNAL ROTATION</td>
<td>LIII</td>
<td>ThXII</td>
<td>&lt;0.001</td>
<td>LIII</td>
<td>ThXII</td>
<td>0.001</td>
<td>0.970</td>
</tr>
</tbody>
</table>

Non-diabetic patients reported less pain during exertion on VAS (p = 0.034), but pain at night and during rest were similarly low. Of those without diabetes, 44%, and 28% of those with diabetes had totally painless shoulders. No difference appeared in pain level between insulin-dependent and non-insulin-dependent patients. Neither was there any significant difference in follow-up pain between diabetes patients treated conservatively or by MUA.
Constant-Murley Score and Simple Shoulder Test figures were better in non-diabetes patients than in diabetes patients, 82 vs. 76 (p=0.055), and 11 vs. 9, (p=0.005). There was no difference in functional scores between insulin-dependent and non-insulin-dependent patients.

Insulin-dependent diabetes patients had inferior internal rotation and a tendency towards inferior external rotation compared to non-insulin dependent diabetes patients during frozen shoulder but not statistically significantly. Those insulin-dependent patients had inferior external rotation to other diabetics also at follow-up (p=0.035). Otherwise, their outcome was similar with non-insulin dependent diabetics.
6. DISCUSSION

6.1. The duration of frozen shoulder in natural course

To our knowledge, only two published studies report on the long-term outcome of the natural course of frozen shoulder with no treatment (44, 148). The reported mean duration of the natural course from onset to recovery in these studies amounted 15 months (44) and 30.1 months (148). In our study, we also found the mean resolution time to be 15 months. Furthermore, the duration did not correlate with the disease severity when it comes to a specifically poor range of motion during frozen shoulder. Reeves found that a shorter period of the so-called painful stage was associated with a shorter recovery time (148). The shortest mean duration of recovery time after non-operative treatment was 12 months in a well-documented 7-year follow-up study (159), and the longest was 20 months, as with our patients (113).

TABLE 7. Literature on outcome of the natural course of frozen shoulder.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Follow-up in years</th>
<th>DURATION in months</th>
<th>MOTION</th>
<th>PAIN</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>REEVES et al</td>
<td>41</td>
<td>5-10</td>
<td>30</td>
<td>54% slight restriction</td>
<td>7% limited function</td>
<td></td>
</tr>
<tr>
<td>DIERCKS &amp; STEVENS</td>
<td>45</td>
<td>2</td>
<td>15</td>
<td>7% marked restriction</td>
<td>CS** 89/100. 89% CS&gt;80.</td>
<td></td>
</tr>
<tr>
<td>VASTAMÄKI et al</td>
<td>52</td>
<td>9</td>
<td>15</td>
<td>6% inferior to contralateral shoulder</td>
<td>94% VAS-pain at rest &lt;3/10</td>
<td>CS 83/100. STT* 11/12.</td>
</tr>
</tbody>
</table>

*STT = Simple Shoulder Test, **CS = Constant-Murley Score

We determined the natural history of our idiopathic frozen shoulder patients, the length of symptoms, recovery of ROM, pain relief, and function at a mean 9 years follow-up. The results
were similar to those reported by Diercks et al (44), but better than those reported by Reeves et al (148), their patients took twice as long to recover from their frozen shoulder. This difference was unexplainable. Diercks stated that supervised neglect for patients with FS yields better outcomes than does intensive physical therapy and passive stretching. Our study yielded similar outcome results: Patients in the present natural course, or untreated group had better pain relief, ROM, and function than did those with the present non-operative, meaning conservative treatment, such as physiotherapy group. The present study and the literature show most patients with idiopathic FS as experiencing resolution without any treatment. We believe it is important to be able to tell a patient with some confidence that an idiopathic frozen shoulder generally recovers well without any restriction of motion or pain.

6.2. Long-term range of motion and function after frozen shoulder

Of Reeves’ frozen shoulder patients, 39% had a full recovery in the natural course, and 54% had a clinically detectable limitation with no effect on their normal functional activities. This amounts to 93% with no effect on patients’ daily function. Of our 51 natural-course patients, a similar 94% eventually had ROM as good as on the contralateral side. Binder et al reported that 12% of patients after non-operative treatment had severe restriction, and 28% had mild restriction at 4 years (9). Shaffer et al reported that 30% had measurable restriction at 7 years (159). However, even better results after non-operative treatment have occurred (46). After non-operative treatment, 92% of the patients in the present study achieved ROM similar to that of the contralateral shoulder, suggesting that the recovery of ROM after non-operative treatment for an idiopathic frozen shoulder is better than reported earlier. The patients with a specifically poor range of motion during frozen shoulder had as good ROM in long-term follow-up as did others, except for the external rotation that was inferior in these patients (40.4° vs 52.7°). Also, our patients with a poorer final Constant Score did not have specifically poor ROM during frozen shoulder.

Numerous retrospective studies suggest that the duration of symptoms of idiopathic frozen shoulder may be reduced by manipulation under anesthesia (45,52,81,109,127,127,143,146, 174,175,190,195,196). However, the very long-term clinical outcome after MUA is unknown, with only one questionnaire survey available (49). In 1992, a substantial increase in ROM and appropriate pain relief were evident in 26 patients following a mean 7 years after MUA for spontaneous frozen shoulder (185,186). ROM also improved to normal in a retrospective study with
32 patients on average 13 weeks after MUA, and lasted for at least 5 years (143). Improvement in ROM lasted at least 3.5 years in one retrospective study of 246 patients (175) and 5 years in another study with 145 patients (52). For 18 patients, 15 years after MUA, forward flexion estimated by the patients reached 180° and external rotation reached 90° in almost all shoulders. This was, however, a questionnaire study (49). The patients were a mean 66 years old at the time of the survey. A healthy population very seldom attains such a perfect ROM at that age, and patients tend to overestimate ROM in questionnaires.

The results of Farrell (49) resemble those of our Study II. Here, ROM had recovered to normal at the 7-year evaluation but had deteriorated by 6% to 16% during the next 16 years, however, reaching the contralateral level. Such deterioration could be explained by the patients’ aging. Thomas et al (175) report that 3.5 years after MUA, the Oxford Shoulder Score (OSS) improved from a mean of 27 to 44. Flannery et al report that 5 years after MUA, the OSS improved from a median of 12 to 40 (52). In Farrell’s questionnaire survey with a follow-up time of 15 years, the SST averaged 9.5 of 12 and the American Shoulder and Elbow Surgeons score 80 of 100 (49). Our present Study II showed that, of 15 patients, 12 reached the age- and sex-adjusted normal Constant-Murley score, and the SST averaged 10 of 12. Diercks considered 80 points out of 100 to indicate a normally functioning shoulder (44).

The full range of motion of the shoulder joint does not remain the same throughout life, but deteriorates with age (7). In addition, “although shoulder abduction is reported to be 180 degrees, biomechanical studies show that it is rarely greater than 170 degrees” (110). In Study II, ROM also deteriorated between 7 and 23 years after manipulation. However, MUA leads to full improvement of ROM and leaves no pain in 90% of cases also in the long run. For patients with excessively severe pain and stiffness not responding to non-operative treatment in 6 months and being unable to work, MUA can be considered as one treatment option; however, with respect to the RCT studies, only in selective, rare cases.

Concerning the long-term ROM of diabetic frozen shoulder, the primary outcome of this study is that the ROM of diabetes patients’ once frozen shoulder does reach the same level as that of their unaffected contralateral shoulder. During frozen shoulder, diabetes patients’ ROM was similar to non-diabetes patients’ ROM. Nor did Cinar (30) find any significant differences in preoperative functional scores between diabetic and non-diabetic frozen shoulder patients. Follow-up ROM of diabetic patients was inferior to ROM of non-diabetic patients in all directions. Griggs (63) also
reported that diabetes in frozen shoulder patients is associated with worse outcome of ROM. The results of arthroscopic capsular release for frozen shoulder in diabetic patients are also less good concerning ROM (30). Diabetic patients had inferior results also after open surgical release (130). However, in Study V, at follow-up, the ROM of the diabetes patients’ once frozen shoulder did reach the same level as that of their non-affected shoulder. According to the present study, frozen shoulder does not make diabetes patients’ shoulder ROM inferior to their own other, non-affected shoulder. The other studies lack comparison of ROM to their own contralateral level.

Concerning function in patients with diabetes, Constant-Murley Score results were in accordance with our hypothesis. However, diabetes patients self-evaluated their function as inferior to that of non-diabetes patients in the Simple Shoulder Test. Cinar (30) reported the CM score in those with diabetes as 82 versus 94 in the others (p<0.05) Omari (130) an ASES (American Shoulder and Elbow Score) score 61 vs. 75, and Jenkins (81) an Oxford Shoulder Score 42 vs. 45 (p<0.001). Callinan et al. (27) found that diabetes patients’ gain in flexion 6 weeks after hydroplasty was 7.5 degrees inferior to that of those without diabetes. However, in their study, all without diabetes also received intra-articular corticosteroids, but some with diabetes and concerned about glucose control received no corticosteroid. It is thus difficult to compare results, considering the differing treatment protocols.

6.3. Pain after frozen shoulder

We found no published studies regarding pain in an untreated frozen shoulder. Diercks et al stated that 89% of their patients had normal or near-normal painless shoulder function, but they used only the Constant-Murley questionnaire and not a VAS (44). In the present study, 94% of the patients reported pain at rest as less than 3/10 on a VAS, showing good recovery. The threshold level of 3 on the Visual Analogue Scale was chosen because patients who report pain level ≤3/10 on VAS are interpreted to have minimal pain and low irritability of the shoulder (84). Concerning non-operative treatment, 43% of patients were reported to have persistent pain at 3 years (165), 35% mild pain at 7 years (159), and 27% mild or moderate pain at 1.8 years (63). With the non-operatively treated patients in the present study, pain at rest was less than 3/10 in 91%.

Bulgen followed patients for only 8 months. He found, in a prospective and randomized study (20), that the decrease in pain was at its greatest by the fourth week of treatment. After that time, pain
continued to slowly decrease. He suggested that local steroid injection should be the first treatment of choice, and that treatment should be given during the first month.

Concerning pain after MUA, “Pain diminished from a mean VAS score of 7.6 to 1.5 in 31 patients at 14 months’ follow-up after MUA (75) and from a median VAS score of 8 to 1 for 146 patients at a mean 5-year clinical follow-up (52). In a 15-year long-term questionnaire review of 18 patients, only two experienced transitional pain in the manipulated shoulder (49). In this Study II, pain also was minimal after 23 years, except for two arthritic shoulders.

Concerning pain after diabetic frozen shoulder, we found the outcome similar to that of non-diabetic individuals at rest and during the night, but worse during exertion. In the literature, pain occurred in 26% of those with diabetes, but in none of those without diabetes (30), and after open surgical release VAS pain averaged a respective 4.3 and 1.1 (130). Several researchers describe how frozen shoulder causes pain both at rest and during exertion, but especially during the night time (68,109,163). For this reason, we wanted to evaluate the pain on the VAS scale in three different ways: pain at rest, pain during exertion/activity, and pain during the night time.

We found two fractures of the glenoid rim (13%). This is a rather high complication rate. Complications related to MUA are unusual, but they do exist (121,131). Magnusson reported one glenoid fracture during manipulation under anesthesia for adhesive capsulitis (105). However, no difference was detected in our two patients’ final follow-up pain, ROM, or function, when compared to others. Nor did their range of motion differ at discharge, a few days after the manipulation.

6.4. Outcome of postoperative stiff shoulder after open rotator cuff repair

Rotator-cuff repair (RCR) is a common orthopedic procedure (1,11,12,57,58,89-91,160,183,184,200). Postoperative stiff shoulder after RCR is a common complication (54,55,72,173,188,191,199), resolving normally in 6 months. In 2004, Simon Bell from Australia stated that after open RCR incidence of postoperative stiffness was 25% (9th International Conference for Shoulder and Elbow Surgery, Washington, DC), but he never published his results. In other studies, incidence was 3% after open RCR (106), and 16% after open revision surgery (8). In our Study III, the incidence was 20%. The reason for differing incidences may be the fact that in
Study III, diagnosis of postoperative stiffness occurred at an earlier stage, just 6 weeks after surgery and after 2 to 5 days of physiotherapy. In a similar population of 209 patients after open RCR (177), when the inclusion criterion fell into the lower quartile of passive ROM, stiffness incidence at 6 weeks after surgery was 17%. Postoperative stiffness of the shoulder joint shoulder tends to recover within 6 months. When evaluating postoperative stiffness at 3 or 6 months after RCR, incidence should be even lower. In a review of 500 rotator cuff repairs, when evaluated at 9 months, 4% had significant arthrofibrosis after RCR (106) and 5% after arthroscopic RCR (76).

Duration of symptoms of postoperative stiff shoulder is not reported precisely. Brislin et al (14) did state that their patients’ postoperative stiffness after arthroscopic RCR resolved with almost no deficit of ROM at all (<10% passive loss in any plane) in a mean 5 months after the operation, in 14 of 23 patients. The other 39% still had significant lack of passive ROM at 5 months (14). In Study III, postoperative stiffness lasted approximately 6 months and had resolved before one year. Thus the length of the symptoms was shorter than for idiopathic frozen shoulder.

Motion usually improves steadily between 6 weeks and 76 weeks postoperatively, reaching nearly complete recovery (177). In Study III, ROM began to improve on average at 3 months and had improved to almost normal (93% of ROM in the control group) on average by 6 months without any treatment other than physiotherapy. External rotation resolved first, in 3 months, as occurred also in Cho’s study of 15 patients with arthroscopic RCR of preoperatively stiff shoulders (29).

Pain caused by postoperative stiffness after RCR has received any mention only rarely. Pain scores improved from 5.6 to 2.0 among patients with stiff shoulders (p = 0.590) and from 5.1 to 1.7 among ones free of stiffness (p = 0.820). With Trenerry’s patients, some of them already experiencing preoperative stiffness, pain subsided by 24 weeks (177). In Study III, pain resolved well.

Flatow (137) found no statistically significant difference between mean 1-year ASES scores among stiff-shoulder patients and ones without stiffness, as well as Constant-Murley scores of 77 and 74. For the present population, Constant-Murley scores for postoperative frozen shoulders for 56% averaged 78, being ≥ 80. Thus, postoperative stiff shoulder does not seem to affect shoulder function in the long term.

After rotator-cuff repair, postoperative stiff shoulder is an important complication that should receive more recognition. However, it resolves without any surgery within 6-12 months quite well. Its etiology still remains unknown. Warner & Holovacs, in their chapter on acquired shoulder stiffness, conclude that “It is not clear whether the cause of posttraumatic or postsurgical capsulitis
is different from that of idiopathic adhesive capsulitis or whether some patients simply develop adhesive capsulitis in the context of trauma or surgery” (201). Our study showed that postoperative frozen shoulder was associated with a sound biceps tendon. This strengthens Mansat et al.’s finding of the more tissue is present, the greater risk for postoperative frozen shoulder.

6.5. Does timing of MUA for frozen shoulder associate with outcome?

To our knowledge, only four published papers handle the effect of timing of manipulation under anesthesia (50,52,136,175). These four present very conflicting results on the effect of timing on the outcome. Flannery (52) examined 145 patients with a mean follow-up time of 5 years and found that MUA that was performed less than 9 months from the beginning of symptoms yielded better results (Oxford shoulder Scores) than did MUA after 9 months. Mobility and VAS pain were also better than among those manipulated after 9 months. Kelly (50) reported that the modified Neer questionnaire scores of patients manipulated during 6 months after onset of symptoms did not differ from scores of the others. Kelly stated that manipulation can thus be considered a viable treatment in the early stages of frozen shoulder. Pap (136) found that the patients manipulated at a mean 8.4 months from the beginning of symptoms had a better outcome than did those manipulated at a mean 5.7 months. He recommended manipulation at stage III, and at stage II only if the pain is already decreasing and limitation in ROM is the main symptom. Thomas (175), in his questionnaire survey, found no correlation between timing and the results.

We can add some weight to Flannery’s conclusion that MUA before 9 months results in a better outcome. However, clinical significance cannot be considered as remarkable as statistical significance.

Flannery (52) also reported that patients who were manipulated less than 9 months after symptom onset had better ROM in all directions, but only their gain in external rotation reached statistical significance, 77° vs. 72°, p=0.049. Based on the long clinical experience of those senior in our study group, we earlier believed that early manipulation, MUA performed before 6 months from onset of symptoms, may lead to a relapse. This was not shown in the Study IV. Nowadays, we prefer intra-articular corticosteroid injections at the earlier stages of the disease during the inflammation period.
Summarizing the results of Study IV and Colville’s (52) findings, we all found that MUA before 9 months yielded significantly better results than did treatments with MUA after 9 months. In addition, Study IV showed that MUA between 6 and 9 months yielded better ROM in abduction and external rotation. Clinically the difference was, 10° for both. On the other hand, Thomas’s survey found no differences concerning timing of MUA (175). One reason may be differing inclusion criteria. Thomas included patients with good preoperative flexion and abduction as great as 170° and external rotation up to 70°. We find it challenging to make a definite diagnosis of frozen shoulder along with such a good range of motion. Moreover, no questionnaire survey is as accurate as a clinical examination. Colville’s (52) study included no figures on results for patients manipulated between 6 and 9 months, which perhaps would have strengthened his findings. Today, we rarely manipulate, but if needed, preferably between 6 and 9 months after symptom onset.

Concerning pain, we found no articles showing influence of timing. Flannery (52) used VAS pain intensity score, but the results did not show any effect of timing. However, our results showed significant influence, VAS pain at rest was 0.2 vs. 1.2, p=0.039 and at night 0.6 vs. 2.0, p=0.049, but the difference in pain with exertion 0.7 vs. 2.5, p=0.114 was not significant. Minimal clinically important difference (MCID) in the visual analogue scale is 1.2 to 1.4 cm (56,171) and 3.0 cm after adequate pain control (92), meaning that our results may not be clinically very relevant. The minimum clinically significant difference in Visual Analogue Scale pain score does not differ with severity of pain (85).

When it comes to function, Flannery et al. (52) showed that MUA before 9 months yielded a significantly better Oxford Shoulder Score than did MUA after 9 months, 13 vs. 16, (p=0.0024). Study IV had similar results: patients manipulated between 6 and 9 months had a significantly better Simple Shoulder Test scores than did other patients (p=0.002). However, some feel that a two-point difference on the Simple Shoulder Test is clinically significant (172). In the present study, the difference was only 1.8 points, not 2.0 (9.5 vs 11.3). It is also difficult to compare earlier results, because treatment methods vary. In Flannery’s study (52), an intra-articular steroid injection was added to MUA; Study IV involved no intra-articular steroid injections.

In consideration of manipulation, a favorable option seems to be to avoid performing it too early or too late; if done late, more than 9 months after symptom onset, the results deteriorate. In randomized controlled trials, MUA has not been more favorable than other treatments (86,145). For instance, Quraishi et al. (145), in their RCT, found that hydrodilatation led to significantly better results than MUA at 6 months. VAS was 2.7 in that MUA group and 1.7 in the hydrodilatation
group, p<0.0001). CS was 59.5 for MUA and 65.9 for the hydrodilatation group, p=0.02. Adolfsson and his group stated that the minimal important change in Constant-Murley score is 17 for patients with subacromial pain (73). ROM was similar between the groups.

On the other hand, many researchers defend MUA as the treatment of choice. If supervised neglect or non-operative treatment has not helped sufficiently, and limitation of shoulder motion is too burdensome, manipulation can be considered in rare, selective cases, preferably after 6 months but before 9 months after symptom onset.

6.6. Limitations of the study

The current study has several limitations. First, we used the Constant-Murley Score (Studies I-V), popular in Europe for functional assessment of the shoulder. Today, the relevance of the Constant-Murley score is disputed, and for frozen shoulder it may not be the best choice, especially with muscle strength included (132). The strength of a normal shoulder often differs by gender and deteriorates with age (83). Thus, the Constant-Murley Score may also decrease in absolute value while still reflecting a normal score.

Second, due to the retrospective nature of this study, we did not obtain Constant-Murley Scores or Simple Shoulder Test scores at the time the patients were initially seen (Studies I-V). Although we place great value on longitudinal assessment of outcome measures, only ROM and strength measurements were available. We excluded patients whose medical records inadequately provided ROM, and included only those with appropriate records.

Third, it is difficult to estimate the influence of MUA (II, IV), because the natural course of frozen shoulder is mostly beneficial. Our indications for manipulation were therefore stringent. Fourth, the patient population for Study II was small. We could reach only 15 of the original patients, 4 were dead, and some others were too old to attend the last follow-up evaluation because of the very long-term follow-up time. Fifth, active internal rotation of the arm behind the back was assessed by the method we have used for decades, by determining the vertebral level reached by the dorsum of the hand. Recent authors (66) have questioned the accuracy of this method and suggest their measuring-tape method, the distance between the C7 spinous process and the point reached.
Sixth is a possible selection bias (I, II, III, V) because our hospital is a third-level referral hospital, meaning perhaps with more difficult cases, but we also have many private patients coming directly to our hospital. Seventh, the arm was immobilized in an abduction splint for a mean 5 weeks in most cases (Study III). Today, most shoulder surgeons do not use a splint, and even using a sling, they mobilize the arm early. We found, however, no correlation between incidence of postoperative stiff shoulder and use of the abduction splint. As a matter of fact, abduction splints were used more often and longer for our control patients (80% vs. 93%, mean 4 vs. 5 weeks).

Eighth, concerning preoperative ROM in Study IV, we obtained exact figures for flexion and abduction, but external and internal rotation was mostly listed only as “severely restricted.” We excluded patients whose ROM was inadequately documented in their medical records, and included only patients with appropriate records for flexion and abduction. Ninth, a possible selection bias may arise from the number of drop-outs. We were able to include in the study 234 patients. The participation rates were 67% (I), 58% (II), 67% (III), and 71% (IV). This may be considered acceptable with regards to the very long follow-up times and the fact that the patients live all over Finland. However, the purpose of this academic dissertation was to study the very long-term outcome of frozen shoulder, and this large retrospective material gave us the possibility.

6.7. Strengths of the study

First, all the patients are examined clinically. We believe that clinical examination is crucial when it comes to exploring such important factors involving the shoulder joint as movement and range of motion. As Hazleman (70) and also Bulgen (20) have previously found, patients often may claim that they have regained full movement, but when tested objectively, that has not been so. Thus, objective, clinical examination of the range of motion is very important.

Second, the follow-up time was long, several years (III, IV) or, even decades (I, II, V). One paper presents the longest clinically examined series on outcome of frozen shoulder after manipulation under anaesthesia (II).

Third, we have had strict inclusion criteria. All the patients were examined at first consultation by an orthopedic surgeon experienced in shoulder surgery. Thus, we believe that diagnosis has been appropriate from the beginning. Only patients with appropriate status recordings, measured degrees of flexion, abduction, and external rotation (I, II, III, V) or that of flexion and abduction with severely decreased rotations (IV) were included.
Fourth, some studies included in this thesis work are exceptional concerning the large population. One article presents, to our knowledge, the largest-ever clinically examined series published on the true natural course of frozen shoulder (I), another, the largest clinically examined series published on the outcome of postoperative stiff shoulder (III).

This study covers both idiopathic/primary and secondary frozen shoulder, whether secondary means post-surgical or systemic, such as those with diabetes.

6.8. Recommendations for future research

The fact that populations are aging, and the number of patients with diabetes is increasing in every country (Diabetes Atlas, IDF), also makes frozen shoulder an epidemiologically increasing condition. It causes intense pain, deteriorated function, and inability to work. In addition, its true etiology still remains somewhat of an enigma, making it an important focus for research. Further studies are vital, and we recommend prospective, randomized controlled trials in which different treatment methods are judged against the natural course of frozen shoulder, and both efficacy, effectiveness, and cost effectiveness are considered. Considering the intense pain that also may produce mental stress often with inability to work, one interesting possibility concerning physiotherapy might be some kind of group therapy with peer support.
7. MAIN FINDINGS

Idiopathic frozen shoulder generally recovered well throughout its natural course without pain or restriction of motion. The worst frozen shoulder cases with the poorest range of motion during the condition also recovered as well as the others except for external rotation. Diabetic frozen shoulder also recovered to the contralateral level concerning range of motion.

The outcome of MUA for frozen shoulder was generally good with long-term follow-up. Timing had some association with outcome of manipulation of the idiopathic frozen shoulder. Concerning postoperative stiff shoulder after open rotator cuff repair, this was a common finding with an incidence of 20%. It generally resolved in 6 months.

8. CONCLUSIONS

Codman originally described a self-limiting natural history of frozen shoulder that lasts less than 2 years. In this project, we were able to confirm Codman’s view (I). We recommend supervised neglect with, throughout, patient information and an explanation of the condition and what can be expected. Systematic status records should be kept, from which both the clinician and the patient can monitor recovery.

The natural course of frozen shoulder, though benign, often includes a long period of pain and deteriorated function and inability to work. These are the main reasons for interventions other than supervised neglect. At the beginning of the condition, during the inflammatory phase, an intra-articular corticosteroid injection can be considered. Concerning physical therapies, during the first stages, we recommend concentrating on reducing the pain, and only after that, regaining the ROM. Although retrospective series show good results of MUA, RCTs do state that MUA does not add benefit. If supervised neglect or conservative treatment is insufficient, manipulation under anesthesia should only be considered in rare, selective cases. In conclusion, the long-term outcome of frozen shoulder is good.
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In Kaarina, in April 2015,

Heidi Vastämäki
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