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Manipulation under anaesthesia for frozen shoulders: outdated technique or well-established quick fix?

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- Manipulation under anaesthesia (MUA) for frozen shoulder (FS) leads to a considerable increase in range of motion and Oxford shoulder score, a significant reduction in pain and around 85% satisfaction.
- A clearly defined indication for MUA in FS patients cannot be extracted from this review or the available literature. The associating criteria before proceeding to MUA vary widely.
- All but one study in this review lacked a control group without intervention. Therefore, firm conclusions about the role of MUA in the treatment of FS cannot be drawn from the current literature.
- An overall complication rate of 0.4% was found and a re-intervention rate of 14%, although most of the included papers were not designed to monitor complications.
- The following criteria before proceeding to MUA are proposed: a patient unable to cope with a stiff and painful shoulder; clinical signs of a stage 2 idiopathic FS; lessening pain in relation to stage 1; external rotation < 50% compared to contralateral shoulder joint; a minimal duration of symptoms of three months; and failure to respond to an intra-articular corticosteroid infiltration.

Keywords: frozen shoulder; adhesive capsulitis; manipulation

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Introduction

Frozen shoulder (FS), also known as adhesive capsulitis, is a common cause of a painful shoulder with restricted motion. It affects approximately 2% to 4% of the general population, mainly middle-aged persons, and occurs more frequently in women than men.[1,2] Loss of passive external rotation is the most characteristic finding at physical examination. The French physician S. Duplay first described the condition as 'peri-arthritis scapulo-humerale' in 1872.[3] Some 50 years later, Codman was the first to coin the term 'frozen shoulder' and formulated the Codman criteria for the diagnosis of FS (Table 1).[4] Codman already described FS as 'difficult to define, difficult to treat and difficult to explain'.[5] Nowadays, FS still is a condition with uncertainties about the aetiology, controversies about the optimal treatment strategy and the timing of intervention.

In 1945, Neviaser suggested the term adhesive capsulitis, because of his observation that the axillary fold became adherent to the humeral head. However, the existence of a true adhesion could not be confirmed in other studies.[6] Zuckerman et al formulated a descriptive consensus definition for FS: 'a condition characterized by functional restriction of both active and passive shoulder motion for which radiographs of the glenohumeral joint are essentially unremarkable'.[7] Based on the aetiology, FS can be classified into primary and secondary FS. In primary, or idiopathic, FS an underlying cause cannot be identified. In secondary FS, intrinsic or extrinsic factors can be related to the aetiology of FS. A list of possible related conditions of secondary FS is shown in Table 2.

The natural history of FS can be generally divided in three stages, as originally described by Reeves.[8] Stage 1 is called the freezing stage, with severe pain with every motion and increasing stiffness. At stage 2, or the frozen stage, there is established stiffness but with reduced pain levels, but specific pain at the end range of motion (ROM). In the third and final stage, the thawing stage, there is gradual recovery of shoulder joint motion with low levels

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Table 1. Codman's criteria for frozen shoulder

Symptoms	Condition comes on slowly
	Pain is felt near the insertion of deltoid
	Inability to sleep on the affected side
	Able to continue daily habits and routines
Signs	Painful, restricted elevation
	Painful restricted external rotation
	Restriction of both the active and passive type
	Atrophy of the spinate
	Little local tenderness
Investigations	Normal results on radiography

Table 2. Related conditions associated with secondary frozen shoulder

Condition	Example
Systemic conditions	Diabetes mellitus, thyroid disorders, hypo-adrenalism
Trauma	Proximal humeral fracture, clavicle fracture
Post-operative	Immobilization of the upper limb
Breast cancer treatment	Surgery or radiation therapy on the chest wall and axilla
Neurological conditions	Cervical radiculopathy, stroke

of pain or no pain. The duration of different stages can vary and clear cut-off values for each stage have not been defined.

Although the underlying pathophysiology of a FS is not entirely understood, studies suggest a chronic inflammatory cascade leading preliminary to a contracture of the joint capsule. Similar to Dupuytren's disease, the cells that are mainly involved are fibroblasts and myofibroblasts. They produce densely packed collagen type III in the extracellular matrix of the articular capsule.[9] This leads to a decreased intra-articular volume, often < 5 mL instead of around 20 mL, and a reduced capsular compliance.[10,11] The identified affected anatomic structures in FS are the rotator interval, the superior and inferior glenohumeral ligaments, and also the coracohumeral ligament.[12,13] Apparently, reversibility of these pathological changes is likely, as natural history studies show that the majority of patients have a functional recovery within one to three years.[14,15] However, residual symptoms and restriction of shoulder joint motion in the long term are not uncommon.[16,17] Hand et al reported mild residual symptoms, measured as a reduced Oxford Shoulder Score (OSS), in 35% of patients after four years in a natural history study.[18] In addition, Griggs showed that ROM does not fully return to normal after conservative treatment, with ROM generally 10% to 15% less than the contralateral shoulder.[19]

Although FS is considered to be a mild and self-limiting condition, patients experience pain and disabilities in daily activities, with a limited capacity to function at work for an extensive period of time. The self-reported working ability of patients with a FS was 5 out of 10 in the study by Kivimäki.[20] Therefore, treatment of FS should be focused on limiting symptoms and shortening the duration of disabilities. A wide range of treatment modalities have been described, such as supervised neglect,[21] physiotherapy,[22] intra-articular corticosteroid injections,[23] capsular distension injections,[24] manipulation under anaesthesia (MUA)[25] and arthroscopic capsular release (ACR).[26] Systematic reviews on treatment strategies for FS point to a lack of evidence; there is currently no consensus about the optimal treatment strategy.[27-29] Conservative treatment with (intra-articular) corticosteroid infiltrations with or without physiotherapy is sufficient to relieve symptoms for the majority of patients. However, conservative treatment can fail in several cases with prolonged symptoms. MUA is believed to be the most widely used non-conservative treatment option for these refractory cases. With MUA, the tight shoulder joint capsule is stretched and torn with manipulation. It is a time-efficient procedure and relatively easy to perform, resulting in rapid restoration of the ROM of the shoulder joint and reduces the symptoms of FS.[30] Opponents argue that it cannot be seen or felt what other structures than the joint capsule are damaged during manipulation. In addition, serious complications of MUA have been reported, such as a humeral shaft fracture, glenoid rim fracture, shoulder dislocation, brachial plexus traction injury or intra-articular damage to the cartilage or rotator cuff.[31-34] As a result, MUA can be considered a controversial procedure for FS, and orthopaedic surgeons have a different threshold for MUA.[35] Moreover, the optimal indication for MUA and the right timing of MUA are unclear. To gain better insight in the role of MUA in the treatment of FS, this systematic review was undertaken. The results of MUA on pain levels and the ROM in patients with FS are pooled and summarized. Patient demographics, indications, technical varieties in the MUA procedure itself, the post-operative rehabilitation protocol and the complications of MUA are addressed in this review. Furthermore, the purpose of this systematic review was to evaluate whether MUA is an effective and safe treatment option.

Materials and methods

Literature search

A literature search, assisted by a librarian, was conducted in EMBASE, MEDLINE and The Cochrane Library databases in June 2016. After removing duplicates, two reviewers (SP and TK) blindly screened the available titles and abstracts that were potentially relevant and these were retrieved as full-text documents for further analysis. Any disagreements about selection of certain titles were resolved through consultation with two senior authors (BT and LB). References from the selected full-text articles were also checked to retrieve additional relevant articles that were missed in the first phase of the original search

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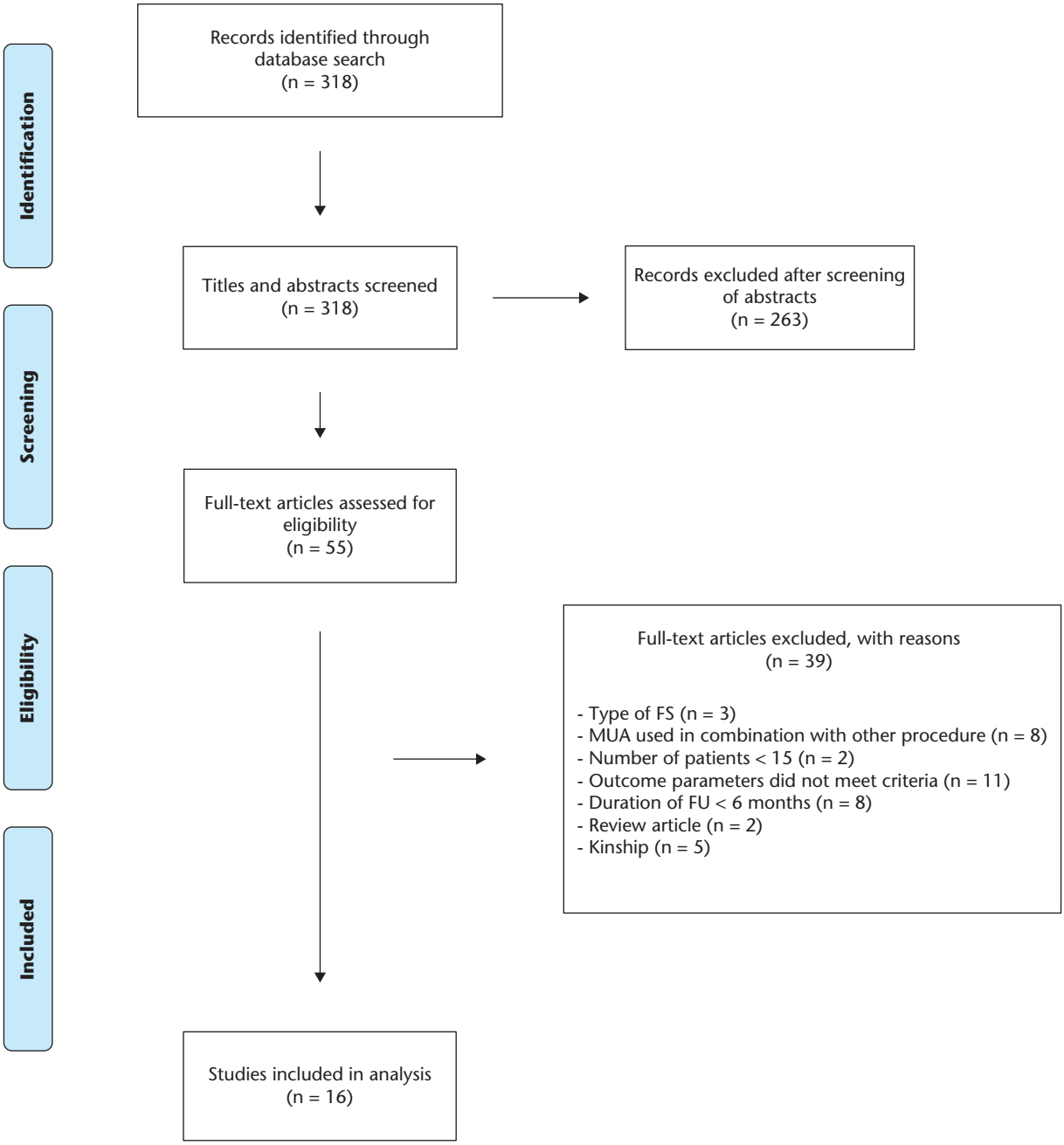

Figure 1. Flow diagram showing the result and evaluation process of our search, according to the PRISMA algorithm.

strategy. The flow diagram in Figure 1 shows the processing of the search results.

Study selection

The main intention was to find all published articles describing the clinical results of MUA in patients with a primary, idiopathic FS. Articles that reported on the results of MUA in patients with diabetes mellitus were allowed for inclusion because this is a substantial and important subgroup of patients with a FS. Articles with > 25% post-traumatic or post-surgical FS were not included. Types of articles that were eligible for inclusion were: retrospective case series; cohort studies; or randomized controlled trials (RCT). Outcome parameters should at least include a pain score and ROM of the shoulder joint or a functional outcome score including pain and ROM. Articles should report a minimum follow-up of six months and the publication date not before the year 1985. MUA in combination

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with an injection of corticosteroids in the shoulder region was allowed for inclusion.

Articles were excluded if MUA was combined with another treatment procedure such as an ACR or distension injections. Furthermore, articles were excluded if the number of treated patients was < 15, if no full text was available and if the language was other than English, Dutch or German. When more specific information than published was requested, the authors of the retrieved articles were contacted by email for any additional information. The retrieved studies were assessed again by three independent authors (SP, TK and BK) to ensure that they fulfilled the inclusion criteria.

Methodological quality assessment

For assessment of the methodological quality of the selected studies, the MINORS (Methodological Index for Non-Randomized Studies) criteria were used.[36] MINORS is a validated instrument for either comparative and/or non-comparative studies. For non-randomized studies, it consists of eight methodological items comprising three answer options: 'not reported' (0 points); 'reported but inadequate' (1 point); and 'reported and adequate' (2 points). Four additional items are scored for comparative studies. The best score for methodological quality for non-randomized studies is 16 points and 24 points for comparative studies. All included studies were independently assessed by two reviewers (SP and TK). A third senior reviewer (IS) was consulted for a final assessment if needed.

Statistical analysis

Weighted mean differences (WMD) with 95% confidence intervals (CIs) of pre- and post-operative outcome measures (ROM, CMS and VAS) were calculated at three time intervals after MUA: short term (< six weeks); mid-term (seven weeks to six months); and long term (> 12 months). Calculation of the WMD was based on means, standard deviations (SD) and number of patients of each cohort. Study results were pooled by use of the random effects model. In cases when only ranges were reported, SDs were calculated using the method by Walter and Yao.[37] For studies reporting the 95% CIs, the SD was estimated according to Higgins et al.[38] Heterogeneity between the studies was assessed by use of both χ^2 and the I^2 statistics. An I^2 value > 50% was considered substantial. Review Manager (Version 5.3, Cochrane Reviews, London, UK) was used to perform the meta-analysis.

Results

The search strategy resulted in 318 records eligible for inclusion. Of those, 263 studies were excluded after reviewing of the titles and abstract. Final full-text assessment of the 55 potentially relevant articles resulted in 16 eligible studies for this review. These consisted of three prospective randomized trials,[20,39,40] four comparative non-randomized trials[41-44] and nine non-comparative cohort studies.[25,30,45-51]. The mean MINORS was 10.6 (7 to 13) for comparative studies and 8.3 (7 to 9) for non-comparative studies.

Some authors have published multiple studies concerning MUA. They were contacted by email to verify if different study populations were used in the studies. We included three studies by Vastamäki et al, after the first author ensured us that the findings of different study populations were reported. Othman et al published two articles[46,52] from the same cohort of patients. We therefore chose to include only his first publication.[46] We found two reports by Wang et al[44,53] with an overlapping study population. We chose to include only the most relevant article, with the results of MUA concerning patients with or without diabetes.[44] The articles by Jenkins (2012)[41] and Leonidou (2014)[54] report the results of the same cohort of patients. The article by Jenkins focused on the subgroup of diabetic patients with a FS and the article by Leonidou on patients with a secondary FS after breast cancer. The control group in both studies is of interest to us but is overlapping. There was no response to our enquiries and only the most relevant article by Jenkins was included.[41] The characteristics of the included studies are shown in Table 3.

Demographics

The final selection of included studies comprised a total of 858 FS patients that were treated with MUA. The mean age of the patients was 52 years. The mean time from onset of symptoms to the intervention was seven months, with a wide range from one month[46] to three years.[25]

The diagnosis of FS was made by different criteria in the included articles. Most authors described a loss in both active and passive ROM for which no other cause could be identified. Pain at the end ROM was noted as a requisite by some authors.[43,48] Various diagnostic criteria and cut-off values that were used are shown in Table 4.

Conventional radiographs were used to rule out other diagnoses including osteoarthritis by most authors.[25,30,39,40,46] Additional imaging with ultrasound or MRI was sparsely reported.[44,47,55]

The indication for MUA

The indication for MUA varied between the different articles. Failure of conservative treatment was often not clearly defined. A minimal duration of symptoms was required by most authors. However, this varied highly, from one month,[46] two to four months,[44,45,47,48] until a minimum duration of six months.[43,55] Physiotherapy, analgesics and corticosteroid infiltrations (both subacromial

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Table 3. Characteristics of studies included in this review

Study design	Type of PS (as stated by authors)	Patients (n)	Age (mean, years)	Time onset to MUA (months)	Diabetes	Corticosteroids	Mean follow-up (months)	MINOR score
Prospective cohort	Primary, 'frozen'	39	53	8 (3-15)	Excluded	Yes	11 (6-18)	8
Retrospective cohort	Idiopathic	19	50	11 (2-36)	n = 8 (results not separately reported)	No	180 (97-247.2)	9
Retrospective cohort	Idiopathic	145	60	6.5	Excluded	Yes	62 (12-125)	9
Prospective randomized trial	Primary, 'freezing'	25	57	4.2	Excluded	No	Mean not reported, goal 24	13
Retrospective case control	Primary and secondary	214	51	6	n = 39	Yes	43 (8-127)	10
Prospective randomized trial	Not clearly stated	65	53	7.4 (3-22)	n = 9 (results not separately reported)	No	Mean not reported, goal 12	13
Prospective (non-randomized) comparative	Idiopathic, 'frozen'	30	52	9.9	Excluded	Yes, subacromial in 50%	Mean not reported, goal 12	12
Retrospective cohort	Not clearly stated, post-traumatic excluded	74	53	7.2 (1-20)	n = 5 (results not separately reported)	Yes	33	7
Prospective cohort	Idiopathic	39	50	7.3 (4-12)	Excluded	No	40.8 (26.4-51.6)	9
Prospective cohort	Not clearly stated	32	49	7.3	n = 4 (results not separately reported)	Yes, orally	14.4	8
Prospective randomized trial	Primary, stage II	16	55	8.8 (4-23)	n = 3 (re-intervention)	Yes	2.6	11
Prospective cohort	Idiopathic	15	54	8.6 (3-12)	Not reported	Yes	Mean not reported, goal 6	9
Retrospective cohort	Idiopathic 'spontaneous'	22	53	Not reported	n = 5	No	168 (24-288)	8
Retrospective cohort	Idiopathic 'spontaneous'	16	49	7.6 (4-12)	n = 4	No	276 (228-360)	7
Retrospective cohort	Idiopathic 'spontaneous'	65	54	Not reported	n = 10 (results not separately reported)	No	72	9
Retrospective, non-randomized, comparative	Idiopathic	42	56	7.4 (3-18)	n = 21	Yes	95 (18-189)	7

and intra-articular) were the mainstay of the conservative treatment modalities before MUA.[40,44-46,49]

The intervention manipulation under anaesthesia

MUA was performed under short general anaesthesia,[45] alone or with an additional brachial plexus block.[30,48] The sole use of regional brachial plexus anaesthesia for MUA was not reported in the included studies, although this is also a possibility according to other authors.[56] The patient was positioned supine in most papers. The use of the lateral decubitus position was reported by Jacobs.[39] The pre-manipulation ROM of the shoulder joint can be measured at this stage. The scapula was stabilized by the supine position, by gripping the top of the shoulder,[41] with the help of an assistant[49] or by supporting the scapula against the thoracic cage manually.[20] The use of a short lever arm was indicated by most authors to prevent fractures. The described sequence of manipulation is varying, as well as the additional methods to reduce the risk of complications (Table 4). The sequence of manipulation can be repeated until the maximal ROM of the shoulder joint was obtained. A typical cracking sound, a definitive snap or characteristic feeling of tissue breakdown in the shoulder was frequently reported.[20,44,46]

MUA was combined with an intra-articular corticosteroid injection in around half of the included studies.[30,40,41,44-46,49]

Physiotherapy after manipulation under anaesthesia

The purpose of physiotherapy after MUA is to maintain the shoulder joint ROM that is achieved during the manipulation. Overall, physiotherapy was frequently commenced immediately after MUA and continued on a daily basis for a short period of around one week.[30,47-49] After the initial phase, the frequency and duration of physiotherapy sessions varied among the included studies or was left up to the individual therapist and patient.[44] Pool exercises, or one to three hydrotherapy sessions succeeded by 'land-based' physiotherapy, was reported in two articles.[41,50] Home exercise programs are reported often, but only in a minority of studies without supervised physiotherapy sessions. Quraishi used a self-exercise program consisting of pendular exercises and wall climbing movements without further physiotherapy.[40] In the trial by Kivimaki et al, FS patients were instructed in two physiotherapy sessions and received written information for a home exercise program after MUA.[20]

Range of motion

All authors report a significant increase in shoulder joint ROM after MUA in the short term and a retained effect in the long term was persistently present. Passive ROM was measured, except for the articles by Meyer and Sokk, wherein the active ROM was reported.[49,55]

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Table 4. Various diagnostic criteria, cut-off values and imaging used in the diagnosis of frozen shoulder. The sequence of manipulation and the preventative measures as described in the included studies

Investigator	Year	Diagnostic criteria	Minimal duration of symptoms	Imaging	Sequence of manipulation	Additional preventative measures
Dodenhoff et al	2000	Lessening pain compared to stage I	n.a.	CR	ABD, EXT in ABD, EXT at side, ADD, INT	Scapular stabilization, short lever arm
Farrel et al	2005	Pain and limited active and passive ROM	n.a.	CR + MRI or arthrography	FLEX, EXT in ABD, ABD, INT, ADD	Gentle pressure on distal humerus
Flannery et al	2007	Codman's criteria	3 months	n.a.	FLEX, EXT, ADD, INT	Scapular stabilization, grip on inner aspect proximal humerus
Jacobs et al	2009	n.a.	n.a.	CR	ADD, FLEX, EXT, INT, ABD	Scapular stabilization, short lever arm
Jenkins et al	2012	n.a.	n.a.	n.a.	ABD, FLEX, EXT, ADD, INT	n.a.
Kivimäki et al	2007	Gradually increasing pain and stiffness, FLEX < 140, EXT < 30	n.a.	n.a.	FLEX, ABD, INT in 90, EXT in 90	Scapular stabilization
Meyer et al	2015	Codman's criteria, ABD < 90	6 months	CR + MRI	ABD, EXT in ABD, EXT in ADD, INT	Scapular stabilization
Othman et al	2002	FLEX < 100, EXT < 50% compared to contralateral side	1 month	CR	Alternate FLEX, ABD, EXT	Scapular stabilization, grip high on the proximal humerus
Pap et al	1998	Lessening pain	4 months	CR + ultrasound	ABD, ADD, FLEX, EXT, INT	n.a.
Placzek et al	1998	Pain at end ROM, total ROM loss > 40%	2 months	n.a.	ABD and FLEX, INT and EXT	Translational gliding technique, scapular stabilization
Quraishi et al	2007	Global loss of active and passive ROM, EXT < 50%	n.a.	CR	n.a.	Short lever arm
Sokk et al	2012	ROM < 50% compared to contralateral side in 1 of 3 directions, inability to sleep on affected side	n.a.	CR	FLEX, EXT at side, EXT in 90, INT, ADD	Scapular stabilization, using thumb and opposing 2 fingers
Vastamaki et al	2012	FLEX < 135, ABD < 125, 'severe' restriction in EXT, pain at end ROM	5 to 6 months	CR	n.a.	n.a.
Vastamaki et al	2013	FLEX + ABD < 120, EXT + INT 'almost absent'	6 months	CR	Gradual alternate ABD, FLEX, EXT, INT	'Care not to fracture the humerus'
Vastamaki et al	2015	FLEX < 120, ABD < 110, 'severe' restriction in EXT	n.a.	CR	Gradual alternate ABD, FLEX, EXT, INT	'Care not to fracture the humerus'
Wang et al	2010	FLEX < 100, EXT < 50% compared to contralateral side	1 month	CR + ultrasound	FLEX, EXT at side, EXT in 90, INT, ADD	Scapular stabilization, forced carefully applied with two thumbs

n.a., not available; CR, conventional radiography; ABD, abduction; EXT, external rotation; ADD, adduction; INT, internal rotation

Mean pre-operative range of motion was 80 (SD 29) degrees of flexion, 66 (SD 25) degrees of abduction and 22 (SD 14) degrees of external rotation. The weighted mean increase in degrees of shoulder joint motion from baseline for flexion, abduction and external rotation after MUA is shown in Table 5.

How shoulder joint ROM measurements were done was frequently not specified. For example, abduction measurements can be done in the true frontal (coronal) plane or in the scapular plane. Internal rotation measurement methods vary widely. A pooled analysis for internal rotation measurement values was not possible because of the heterogeneity of the data.

Vastamäki was the only author with higher abduction than flexion values of the shoulder joint after MUA in his group of patients. Since this is inconsistent with all other reports, this publication was left out of the analysis for ROM. Pap reported markedly lower values for abduction after MUA compared to the other articles.[47] It is unsure whether this difference can be clarified by an alternative measurement technique.

Pain and functional outcome scores

Improvement in pain can be measured with several methods. The visual analogue scale (VAS) from zero (no pain) to ten (maximum pain) was used most frequently in the included articles. Alternatively, pain levels were measured as part of a functional outcome score. The mean VAS pre-manipulation was 6.9 (SD 1.4). A significant reduction in weighted mean pain scores after MUA was found in the short, middle and long term. The mean reduction in VAS for pain after MUA in FS patients was 3.5 points (SD 3.4) within six weeks, 4 points (SD 1.5) within six months and 5.1 points (SD 1.8) after > 12 months (Table 6).

A variety of functional outcome scores were used: Constant score; OSS; Simple Shoulder Test; American Shoulder and Elbow Surgeons Score (ASES); and Shoulder disability questionnaire. The Constant score was by far the most common reported score. A pooled analysis was only possible for this score. The Constant score was developed in 1986 by Constant and Murley to asses pain, shoulder motion, strength and function.[57] Thirty-five points are reserved for patient-reported subjective assessment, 40

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Table 5. Results of the pooled analysis in shoulder joint range of motion (ROM), per follow-up period after manipulation. Results are shown as weighted mean differences (WMD) from baseline with 95% confidence intervals (CI) for flexion, abduction and external rotation. Study heterogeneity is shown as I^2

		Weighted mean difference from baseline (WMD)	95% CI	p-value	f value %
Flexion					
Baseline mean ROM in degrees (SD)	80.4 (29.4)				
1-6 weeks		55.2	32.7- to 78.0	< 0.0001	98
6-12 weeks		45.0	34.3 to 55.7	< 0.0001	53
3-6 months		66.4	45.3 to 87.6	< 0.0001	92
6-12 months		69.4	37.8 to 101.1	< 0.0001	96
> 12 months		67.3	54.6 to 80.1	< 0.0001	89
Abduction					
Baseline mean ROM in degrees (SD)	65.8 (24.7)				
1-6 weeks		72.5	48.5 to 96.4	< 0.0001	97
6-12 weeks		70.5	62.6 to 78.4	< 0.0001	0
3-6 months		86.6	29.2 to 116.1	< 0.0001	95
6-12 months		95.4	71.9 to 118.9	< 0.0001	94
> 12 months		91.8	84.3 to 99.3	0.03	62
External rotation					
Baseline mean ROM in degrees (SD)	22.2 (14.2)				
1-6 weeks		30.5	17.4 to 43.6	< 0.0001	96
6-12 weeks		21.2	9.2 to 33.2	0.008	79
3-6 months		29.4	12.0 to 46.7	< 0.0001	93
6-12 months		44.8	38.9 to 50.6	0.23	32
> 12 months		42.0	32.8 to 51.3	< 0.0001	83

points for ROM measurement and 25 points for strength of the shoulder. The maximum Constant score is 100, with 75 for the adjusted constant score without strength measurement. The Constant scores must be compared with normative constant scores based on age and gender. In the age category of 50 to 59 years, the normative Constant score is 94 for men and 84 for women.[58] The pre-manipulation mean Constant score was 32.9 (SD 8.8). The weighted mean increase in Constant score and adjusted Constant score is shown in Table 6.

Satisfaction

Six articles report relevant information about patient satisfaction scores after MUA.[25,30,40,43,45,51] Short-term satisfaction is given solely by Dodenhoff et al, who report 41% of FS patients with a satisfactory result after six weeks and 87% after three months.[30] At six months, 81% of the patients are satisfied or very satisfied in the study of Quraishi.[40] In the long term (> 6 months), 94% of patients are satisfied with the result of MUA in the study of Dodenhoff.[30] Farrel et al described a mean 8/10 satisfaction level after an average of 15 years.[25] In the article by Flannery, 90% of patients were satisfied after a mean follow-up of 62 months.[45] Similar to these results, Vastamäki et al report 55% of patients as very satisfied and 30% as satisfied after an average follow-up of nine years.[43] Overall, a minority of approximately 10% to 15% of patients are dissatisfied with the result of MUA.

Diabetes mellitus

A total of 108 patients with diabetes are present in nine out of the 16 included articles in this review. Diabetic patients were excluded in the remainder of the articles.[30,39,45,47,55] Vastamäki et al report the same results after MUA in the long term in a small subgroup of patients with diabetes compared to non-diabetic patients.[43] Jenkins compared the results of MUA in a diabetic group to a non-diabetic group and found a similar improvement in ROM and OSS, but an increased need for a repeated MUA procedure in diabetics (IDDM 39%, NIDDM 31%) compared to 15% in non-diabetic controls.[41] Wang et al report the results of MUA in 21 diabetic shoulders compared to 42 non-diabetics.[44] They found no significant differences with regard to shoulder pain, ROM and adjusted Constant score. However, only Asian people with non-insulin dependent diabetics were included. Quraishi report on a failed MUA followed by a successful hydrodilation procedure in one out of the three included patients with diabetes.[40] Furthermore, in the remaining articles, small subgroups of patients with diabetes were included, but the authors did not report their results separately from the non-diabetic patients.[20,25,46,48] As few results were separately reported for diabetics, a pooled analysis of the results of MUA in diabetic patients compared to non-diabetics was not possible.

Complications and re-interventions

A total of three known complications out of 696 patients were described in 11 studies reporting complications. This is an overall complication rate of MUA in FS patients of 0.4%. Six articles did not mention complications at all. The three reported complications were two inferior glenoid rim fractures and one anterior subluxation. In all cases, the authors stated that the clinical outcome was not

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Table 6. Results of the pooled analysis of pain (visual analogue scale (VAS)), Constant score (CMS) and adjusted Constant score, per follow-up period after manipulation. Reduction in pain and improvement in Constant score are shown as weighted mean difference (WMD) from baseline with 95% confidence intervals (CI). Study heterogeneity is shown as I^2

		Weighted mean difference from baseline (WMD)	95% CI	p-value	f value %
VAS					
Baseline mean VAS (SD)	6.9 (1.4)				
1-6 weeks		-3.5	-7.0 to -0.1	< 0.0001	99
6-12 weeks		-2.0	-3.6 to -0.4	0.02	82
3-6 months		-4.0	-5.5 to -2.4	0.03	78
6-12 months		-5.1	-5.2 to -5.0	< 0.0001	n.a.
> 12 months		-5.1	-6.9 to -3.3	0.002	93
CMS					
Baseline mean CMS (SD)	32.9 (8.8)				
1-6 weeks		43.5	31.8 to 55.2	0.001	90
6 weeks to 6 months		41.8	22.6 to 61.1	< 0.0001	96
6-12 months		52.1	33.0 to 71.3	< 0.0001	97
> 12 months		41.6	38.0 to 45.3	n.a.	n.a.
Adjusted CMS					
Baseline mean Adjusted CMS (SD)	24.8 (5.7)				
1-6 weeks		30.2	27.5 to 32.9	< 0.0001	n.a.
> 12 months		48.6	46.8 to 50.3	0.19	43

affected.[46,50] In our opinion, this might be an underestimation of the actual complication rate; for example, if the study design was not intended for the registration of complications, such as retrospective case series.

Six of the included studies report on re-interventions. A total re-intervention rate of 14% (56 out of 389 patients) after MUA was calculated. Dodenhoff reported one patient who needed an arthroscopic decompression, due to impingement with the increased ROM after MUA.[30] Jenkins report a second MUA procedure rate of 15%, in 42 out of 274 patients.[41] However, 214 out of these 274 patients were primary FS and there are no specific data which patients underwent the second MUA. Because of this relative high percentage of non-idiopathic FS, this is potentially biasing the re-intervention rate of truly idiopathic FS.

One repeated MUA procedure was reported by Othman. This patient had an optimal Constant score two weeks after manipulation, but symptoms recurred wherefore repeated MUA was done after one year.[46] In the article by Pap et al, 4/39 patients (10%) underwent ACR after MUA had failed.(47) Quraishi report on one diabetic patient who had an unsatisfactory result after MUA, but did well after a hydrodilatation procedure.[40] Farrel reports on one patient with an excellent initial result of MUA, but needed surgery for a symptomatic rotator cuff tear three years later.[25]

Discussion

This review summarizes the results of MUA in the treatment of idiopathic and diabetes-related FS. A significant increase in shoulder joint ROM and improved Constant scores along with a significant reduction in VAS levels for pain was found after MUA in the short term (< six weeks). In the long term (> 12 months), even better shoulder joint ROM, Constant scores and lower VAS scores were reported after MUA in FS patients. Around 85% of patients were satisfied with the result of MUA. However, these result must be interpreted with caution, because only one out of the 16 studies in this review is a RCT with a control group without an intervention procedure.[20] With a favourable natural history in the long term in the majority of FS patients, a control group demonstrating the course of the natural history of FS is of utmost importance to recognize the true effect of the manipulation.

A FS can certainly lead to disability and absence from work for a prolonged period. It appears justifiable to investigate if MUA shortens the duration of symptoms and does influence the ability to return to work. This subject seems underexposed in the articles in this review, since only two articles provide information about working ability with contrasting findings. Kivimaki et al were unable to find a positive effect of MUA compared to home exercises on working ability.[20] Meyer et al report that 90% of their patients with an idiopathic FS were unable to work, but that 80% were able to return to work six months after MUA.[55] In 1988, Hill et al stated in a small retrospective study that 70% of FS patients were able to return to work after an average of 2.6 months after manipulation.[59]

What is the right indication for MUA?

A clearly defined indication for MUA in FS patients cannot be extracted from this review or the available literature. In addition, there is no consensus on the criteria of failure of conservative treatment, as is demonstrated by the included literature. Orthopaedic surgeons with a low threshold for manipulation of FS may risk over-treatment. On the other hand, a wait and see policy in these patients can presumably lead to an unnecessary prolonged duration of symptoms. Differences are shown in the minimal duration of symptoms before MUA is

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indicated, whether corticosteroid injections are used and regarding physiotherapy treatment before proceeding to MUA. The use of corticosteroid injections in the conservative treatment of FS is generally accepted in the painful inflammatory first stage of the FS condition. However, De Carli et al showed in a prospective RCT that the results of an intra-articular corticosteroid injection were similar to MUA in stage 2 FS.[60] Taking this into account, and after a thorough review of the literature, we suggest the following criteria in FS patients before proceeding to MUA: a patient unable to cope with a stiff and painful shoulder; clinical signs of a stage 2 idiopathic FS; lessening pain in relation to stage 1; external rotation < 50% compared to contralateral shoulder joint; a minimal duration of symptoms of three months; and failure to respond to an intra-articular corticosteroid infiltration.

The importance of physiotherapy after MUA?

We found a large variety in physiotherapy protocols in FS. Intensive physiotherapy, commenced immediately after MUA and continued on a daily basis for a short period, was reported frequently.[30,47-49] On the other hand, non-supervised home exercise programs are also used.[20,40] It would be interesting to know whether the intensity of physiotherapy after MUA influences the results. However, a well-defined dichotomous distribution of studies with intensive physiotherapy *versus* a less demanding physiotherapy program or home exercises could not be made. In the study by Kivimaki et al, MUA followed by a home exercise program was not beneficial to a home exercise program alone. Intensive supervised physiotherapy was absent in this trial. The authors report initially successful manipulation, but with limited effect at longer follow-up, and recurrence of adhesions is hypothesized by the authors.[20] Although the data of this review are insufficient for a clear conclusion, immediate physiotherapy after MUA seems to be a generally accepted important factor for the result of MUA.

Complications and re-interventions

An overall complication rate of 0.4% after MUA in FS patients was found. This is in accordance with the estimated complication rate of 0.5% reported by Grant et al.[61] However, this must be interpreted with caution because the majority of articles were not specifically designed to register complications. There are concerns for iatrogenic damage to the cartilage, labrum and rotator cuff during manipulation, which are shown by Loew et al with arthroscopy after manipulation.[31] Inferior clinical results because of such lesions were not reported in the included articles; however, this can also be due to the fact that these lesions were not identified and could have gone unnoticed. Serious complications, such as humeral shaft fracture[34] or brachial plexus traction injuries,[32] were not reported in the included papers. Concerns about the rotator cuff integrity after MUA are contradicted by Atoun et al.[62] In their study, the rotator cuff was evaluated with ultrasound before and after manipulation; all rotator cuffs remained undamaged after MUA. Similar to this, Sasanuma et al found no rotator cuff tears on MRI scans after manipulation.[63]

Re-intervention procedures were mainly repeated MUA, ACR or hydrodilatation. An overall re-intervention rate of 14% after MUA in FS patients was calculated. Similarly, 10% to 15% of patients were dissatisfied with the result of MUA. It cannot be made clear out of this review which patients are at risk for failure of MUA, but an increased risk of failure to respond to MUA in diabetic patients is supported by the article by Jenkins.[41] These results are in accordance with the recently published findings of Woods et al, who report a repeated MUA procedure in 17.8% of a large consecutive series of patients. Even more, in patients with type 1 diabetes, an increased risk of 38% of requiring a second MUA procedure was found. Still, they found a good outcome and a low complication rate (0.2%) in this single surgeon consecutive series in patients treated with FS treated with MUA.[64]

The prevalence of FS in diabetic patients is as high as 10% to 20% and it is generally approved that the course of the disease can be prolonged and has a more refractory nature of the FS.[15,19,65] There are inconsistencies in the literature about the classification of FS in patients with diabetes mellitus. According to the definition of Zuckerman, diabetes mellitus is an underlying systemic condition and should be referred to as a secondary FS.[7] Other authors refer to diabetes mellitus as an associated condition in FS, but not causative related, and name it an idiopathic (spontaneous) FS in diabetics.[50]

Alternative interventions for MUA

One might consider whether MUA is the right procedure when conservative treatment of a FS fails. Other possible interventions are ACR and hydrodilatation, the latter also known as capsular distension injections. Systematic reviews were not able to demonstrate superiority of one of these treatment modalities.[27-29] Grant et al compared MUA with ACR and concluded no clear difference in ROM or patient-reported outcomes.[61] The available evidence was mainly level 4. MUA is relatively easy to perform and time efficient. ACR is visually controlled, but technically more demanding, less time-efficient and has its own specific risks (for example, chondrolysis due to thermal heat with coagulation, axillary nerve damage).[66] Furthermore, a combination of partial ACR followed by gentle manipulation of the shoulder joint seems to be a safe alternative. This potentially reduces the risks of MUA alone, because less force is needed for the manipulation. A clear indication for such a combined procedure is not evident, but is suggested for patients with diabetes.[65] Currently, a large

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RCT comparing conservative treatment, MUA and MUA combined with ACR is being undertaken in the UK (UK-FROST).[67]

Hydrodilatation is an alternative procedure for FS patients, which can be performed as an outpatient treatment. Quraishi compared hydrodilatation with MUA and found superior VAS, Constant scores and satisfaction in the hydrodilatation group. ROM was equal in both groups.[40] A Cochrane review on hydrodilatation in FS patients concluded that it provides short-term benefits in pain, ROM and function, but that it is uncertain whether hydrodilation is better than alternative interventions.[24]

Limitations

The quality of a systematic review is determined by the level of evidence and methodological quality of the available articles. Only three prospective RCTs could be included in this review and the majority of articles were non-comparative studies. The mean MINORS score is 10.6 for the comparative studies and 8.3 for the non-comparative studies, which indicates relatively low methodological quality. Another important limitation is that not solely idiopathic FS were included. Also, the type of the FS and the corresponding stage was frequently not clearly described. It remains difficult to extract if all included patients truly had a FS and no other shoulder morbidity. A pre-operative golden standard diagnostic test is not available. More certainty about the correct diagnosis can be obtained with examination under anaesthesia, the typical snapping or tearing sound during manipulation, or with evident synovitis in the rotator interval during arthroscopy. However, the rate in which the diagnosis was verified by these means is rarely reported. For example, Dodenhoff described that in only 27 of 39 shoulders was this typical tearing sound present during manipulation.[30]

Conclusion

This review shows that considerable increase in ROM and Constant score, reduction in pain and around 85% of satisfaction are possible with manipulation under anaesthesia for FS patients. A low overall complication rate of 0.4% was found and a re-intervention rate of 14%. However, all but one study lacked a control group without intervention. Based on this review, there is hardly any evidence in favour of or against MUA. We recommend being careful when considering MUA in FS because the relative mild natural course of the disease and potential serious complications. If considered appropriate, we suggest the following criteria before proceeding to MUA: a patient unable to cope with a stiff and painful shoulder; clinical signs of a stage 2 idiopathic FS; lessening pain in relation to stage 1; external rotation < 50% compared to contralateral shoulder joint; a minimal duration of symptoms of three months; and failure to respond to an intra-articular corticosteroid infiltration. Immediate physiotherapy after MUA is generally recommended to avoid a loss of ROM in the first weeks after MUA. However, to recognize the true effect of MUA on symptoms, RCTs with a control group should be undertaken on shoulder joint ROM and the ability to return to work.

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