



Improved range of motion after manipulation under anesthesia versus physiotherapy for stage two frozen shoulder: a randomized controlled trial

Tim Kraal, MD, PhD^a, Yordi de Wit, MD^{b,c,*}, Bertram The, MD, PhD^{b,c}, Leonieke van Boekel, PhD^{b,c}, Iris Koenraadt-van Oost, MSc^{b,c}, Ronald Boer, MD^b, Maaïke vd Borne, MD^b, Pjotr Goossens, MSc^b, Koen Koenraadt, PhD^c, Denise Eygendaal, MD, PhD^d

^aDepartment of Orthopedic Surgery, Flevo Hospital, Almere, the Netherlands

^bDepartment of Orthopedic Surgery, Amphia Hospital, Breda, the Netherlands

^cFoundation for Orthopedic Research, Care & Education, Amphia Hospital, Breda, the Netherlands

^dDepartment of Orthopedic Surgery, Erasmus MC, Rotterdam, the Netherlands

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Background: Frozen shoulder (FS) is a common cause of shoulder pain and stiffness. Conservative treatment is sufficient for the majority of patients with long-term recovery of shoulder function. Manipulation under anesthesia (MUA) is known as a well-established treatment option if conservative treatment fails. It is unknown whether MUA does indeed shorten the duration of symptoms or leads to a superior outcome compared to conservative treatment. The objective of the current trial is to evaluate the effectiveness of MUA followed by a physiotherapy (PT) program compared to a PT program alone in patients with stage 2 FS.

Methods: A prospective, single-center randomized controlled trial was performed. Patients between 18 and 70 years old with stage 2 FS were deemed eligible if an initial course of conservative treatment consisting of PT and intra-articular corticosteroid infiltration was considered unsatisfactory. Patients were randomized, and data was collected with an online data management platform (CASTOR). MUA was performed by a single surgeon under interscalene block, and intensive PT treatment protocol was started within 4 hours after MUA. In the PT group, patients were referred to instructed physiotherapist, and treatment was guided by tissue irritability. The primary outcome was the Shoulder Pain and Disability Index (SPADI) score. Secondary outcomes were pain, range of motion (ROM), Oxford Shoulder Score, quality of life, and ability to work.

Results: In total, 82 patients were included, 42 in the PT group and 40 in the MUA group. There was a significant improvement in SPADI, Oxford Shoulder Score, pain, ROM, and quality of life in both groups at 1-year follow-up. SPADI scores at three months were significantly improved in favor of MUA. MUA showed a significantly bigger increase in anteflexion and abduction compared to PT at all points of follow-up. No significant differences between both groups were found for all other parameters. No fractures, dislocations, or brachial plexus injuries occurred in this trial.

Conclusion: MUA in stage 2 FS can be considered safe and results in a faster recovery of ROM and improved functional outcome, measured with SPADI scores, compared to PT alone in the short term. After 1 year, except for slightly better ROM scores for MUA, the result of MUA is equal to PT.

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The CCMO (National Central Committee of Human Bound Research) approved this study, number NL56143.101.16, and Dutch Trial Register number NTR6182.

*Corresponding author: Yordi de Wit, MD, Department of Orthopedic Surgery, Amphia Hospital, Molengracht 21, 4818 CK Breda, Netherlands.

E-mail address: yordidewit@gmail.com (Y. de Wit).

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Frozen shoulder (FS) or adhesive capsulitis is a common cause of shoulder problems. It affects 2%–4% of the general population³⁵ and is most frequently seen in women around the age of 50 years. Diabetes mellitus and thyroid disease are the most common associated conditions.^{13,34} The impact of this condition on a patient's life is substantial since symptoms of pain and limited range of motion (ROM) can last up to one to three years.^{10,18,28,30} It has great impact

on a patients work and recreational life, which can result in absenteeism at work, sleep disturbance and lacking the ability of physical strain.^{8,13,15,31} The natural course of FS is divided in three stages.²⁵ Stage one is the ‘freezing phase’ and is characterized by active capsulitis, insidious pain and the onset of stiffness. Stage 2 is the ‘frozen phase’ where pain does still persist, mainly at the end ROM, but is diminished compared to stage one and the ROM is severely limited. In stage three, the ‘thawing phase’, the ROM recovers gradually. FS is often considered to be self-limiting.¹³ However, this can be questioned since ROM does not always return to normal, and mild to moderate residual symptoms are reported in up to 35% of patients.^{10,12,28}

Conservative treatment of a FS consists of intra-articular corticosteroid injections in combination with physiotherapy (PT). Therefore, the treatment stated as above is one of the inclusion criteria to become eligible for the current study. At long term, conservative treatment is sufficient for the majority of patients. However, in patients where conservative treatment is not sufficient, there are several invasive interventions in order to try to shorten the duration of symptoms and to improve outcome. Examples are hydrodilatation or arthrographic joint distension,⁵ arthroscopic capsular release³ and manipulation under anesthesia (MUA).^{8,22,32}

Nevertheless, based on systematic reviews on treatment strategies for FS, there is currently no consensus on the optimal treatment strategy.

MUA is traditionally known as a well-established treatment option for FS when conservative treatment is insufficient. It is less time consuming and more cost effective compared to arthroscopic capsular release.²⁴ Although MUA can lead to potential serious complications in rare cases such as a humeral shaft fracture, osteochondral lesions, and brachial plexus injury,^{2,4,20,21} a systematic review showed only an overall complication rate of only 0.5%.⁹

It is unknown whether MUA does indeed shorten the duration of symptoms or leads to a superior outcome compared to conservative treatment. The objective of the current trial is to evaluate the effectiveness of MUA followed by a PT program compared to a PT program alone in the treatment of patients with stage 2 FS. We hypothesize that the course of the disease can be shortened with MUA, resulting in a quicker functional recovery and gain in ROM compared to PT treatment alone.

Materials and methods

Study design

A prospective, single-center randomized controlled trial was performed at the Amphia hospital in Breda, the Netherlands. The study was registered by the CCMO (National Central Committee of Human Bound Research) under the number NL56143.101.16 and registered in the Dutch Trial Register under the number NTR6182. The study protocol has been approved by the medical ethical committee TWOR (toetsingscommissie wetenschappelijk onderzoek rotterdam e.o.) of Maasstad Hospital Rotterdam and local feasibility was tested by the AMOA (adviescommissie mensgebonden onderzoek amphia) ethical committee of the Amphia Hospital Breda. The detailed study protocol for this trial has been published elsewhere.¹⁷

Participants

Patients between 18 and 70 years old with stage 2 FS were screened for eligibility to participate in this trial. Stage 2 was defined as:

- Symptoms of pain and stiffness for longer than 3 months.
- Restriction of $\geq 30^\circ$ in passive external rotation plus a second plane, compared to the contralateral side.

- The pain was most severe at the end of the ROM and diminished compared to the maximum amount of pain in stage one.

Patients were only deemed eligible after a course of conservative treatment consisting of PT treatment for six weeks and an intra-articular corticosteroid infiltration within the previous three months. Unsatisfactory result of this treatment was needed for inclusion. Conventional X-rays were taken to rule out osteoarthritis. Inclusion and exclusion criteria are shown in Table 1. Diabetes mellitus was not an exclusion criterion.

Randomization

Patients were randomized through a secure web-based randomization program named CASTOR EDC. Only the research coordinator had access to the randomization schedule and allocated patients to the treatment groups (MUA and PT) with an allocation ratio of 1. Blinding participants and healthcare professionals to treatment allocation was not possible. Crossing over (from PT to MUA) was potentially possible because patients were allowed to quit participation in the trial as a personal choice. However, the results will be analyzed based on the initial treatment allocation using the intention to treat analysis.

Intervention

One orthopedic surgeon performed all the MUA procedures. MUA of the glenohumeral joint was then performed in the supine position, moving the joint through anteflexion, followed by abduction, external rotation in 90 degrees of abduction, internal rotation in 90 degrees of abduction, horizontal adduction with dorsal compression, and finally through external rotation in neutral position. A recognizable tearing sound was typically present when dealing with a FS. This sequence could be repeated until full ROM was acquired. PT was started within 4 hours after the intervention and was continued on a daily basis for the first week. All contributing physiotherapists were experienced shoulder therapists within our regional shoulder network and were closely instructed to use the study protocol.¹⁷ Passive mobilizations and active ROM exercises were used together with a home exercise program.

Patients in the PT group were referred to the same group of experienced shoulder therapists. Advice and education about the natural course of the disease were given. The PT program was based on the guidelines for the treatment FS of the Dutch Physiotherapy

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
Age between 18 and 70 years old
Frozen shoulder stage 2 (see manuscript for a detailed description)
Intra-articular injection with corticosteroids
Physiotherapy for at least 6 consecutive weeks within the last 3 months
Conventional X-rays without signs of osteoarthritis.
Exclusion criteria
Numeric Pain Rating Scale at rest ≥ 7
Previous surgery to the shoulder
Systemic inflammatory joint disease
Evidence of complete rotator cuff tear of physical examination or imaging
Disorders of the upper limb
Therapeutic anticoagulation, which cannot be interrupted without bridging therapy
Other known shoulder pathology such as infection or tumor
Contra-indication to corticosteroid injection, allergy to contrast, or local anesthetic
The inability to give informed consent and fill out questionnaires

Shoulder Network.³³ Treatment intensity was guided by tissue reactivity with parameters of pain and ROM. Passive stretching, mobilization techniques, active scapulothoracic exercises, and cuff exercises were used. A repeated corticosteroid injection was given only on an individual basis if pain did not diminish sufficiently. The duration of PT treatment in both groups was left to the therapists and the individual patients.

Measurements

Participants filled out questionnaires preoperatively and at 1 month, 3 months, and 12 months of follow-up. The primary outcome was the Shoulder Pain and Disability Index (SPADI)²⁶ at 1 month compared to baseline.

Secondary outcome measures consist of the

- Oxford Shoulder Score (OSS)⁶
- Shoulder pain at rest and during activity was determined through the Numeric Pain Rating Scale (NPRS)¹⁴
- Quality of life measured with EQ-5D⁷
- Passive ROM
- The Single Item Workability²⁹
- The Work-related questionnaire for upper extremity disorders (WORQ-UP) questionnaire¹
- Duration of symptoms
- Usage of analgesics
- Number of repeated corticosteroid infiltrations
- Number of complications

Statistical analysis

Descriptive analyses were used to describe patient's demographic and clinical characteristics at baseline. To check whether intervention groups were comparable at baseline in terms of age, distribution of sex, duration of complaints, and functional limitations (primary outcome measure SPADI score), baseline scores between the two intervention groups were compared using an independent t-test or chi-square test in case of categorical variables.

For ROM, the degrees of movements were reported. For the other variables, delta scores were calculated (SPADI, OSS, NPRS, and EQ-5D) to see progress between the different follow-up moments. In addition, paired-sampled t-test was used to check whether scores between the follow-up moments were significantly different. The assumption of normally distributed data was violated for SPADI scores, ROM, EQ5D, and NPRS since Shapiro-Wilk tests were significant and also visual check of histograms and plots showed skewed distributions. Therefore, SPADI scores, ROM, EQ5D, and NPRS scores were compared between the MUA and PT groups using nonparametric Mann-Whitney U tests. Visual interpretation

of the distribution of scores on OSS and WORQ-UP implies a rather normal distribution. However, Shapiro-Wilk tests were significant for OSS at 3 and 12 months (respectively $W(50) = 0.945$ and 0.864 ; $P = .021$ and $.000$) and WORQ-UP scores at 3 and 12 months (respectively $W(50) = 0.912$ and 0.946 ; $P = .001$ and $.023$). We compared scores between the MUA and PT groups on OSS and WORQ-UP using an independent t-test since the assumption of normal distribution was not violated at baseline and 1 month follow-up. We compare these results with Mann-Whitney U test to check whether the results are comparable.

Finally, complications were counted by type of complication and by intervention group, and adverse events were summarized. All estimated treatment effects were accompanied by 95% confidence intervals and P values. Analysis was performed using the SPSS statistical package (SPSS version 25.0; IBM Corp., Armonk, NY, USA).

Results

A total of 82 patients were included, of which 42 were allocated to the PT group and 40 to the MUA group. Patients' demographic characteristics, ROM at baseline, SPADI score at baseline, and duration of symptoms were comparable between both treatment groups at baseline (Table II).

Loss of follow-up

In the MUA group, ROM was measured in 100%, 90%, 90%, and 70% of the patients at baseline, 1, 3, and 12 months of follow-up, respectively. Questionnaires were completed by 95%, 90%, 83%, and 75% of the patients, respectively.

In the PT group, ROM was measured in 100%, 83%, 95%, and 79% of the patients at baseline, 1, 3, and 12 months, respectively. Questionnaires were completed by 88%, 81%, 81%, and 79% of the patients, respectively. There was one cross-over from PT to MUA.

Primary outcome measure

The primary outcome measure, the SPADI score at 1 month of follow-up showed a median of 44.62 (interquartile range = 44.04) in the PT group, compared to 32.69 (interquartile range = 31.54) in the MUA group. This difference was not significant ($U = 558.000$; $P = .526$).

Secondary outcome measures

SPADI at all times of follow-up

The median delta scores from baseline and 1 month follow-up for the PT group are -13.46 and -19.23 for the MUA group ($W = 502.000$; $P = .466$). At 3 months of follow-up, the total SPADI score decreased in both groups with a significantly higher delta

Table II
Patient demographics and baseline characteristics.

	MUA + PT	PT alone	T (df)/chi-square	P value
Age in y	51.68 (7.93)	53.60 (7.69)	1.113 (80)	.269
Sex			1.172	.279
Men	18	14		
Women	22	28		
Presence of diabetes	2	6	-	-
History of smoking	5/37	9/37		
Usage of analgesics	14/37	16/37		
SPADI	58.70 (14.89)	58.25 (19.78)	-0.112 (73)	.911
Symptoms (duration in weeks)	35.46 (14.32)	31.14 (14.16)	-1.306 (72)	.196

SPADI, Shoulder Pain and Disability Index; PT, physiotherapy; MUA, manipulation under anesthesia.

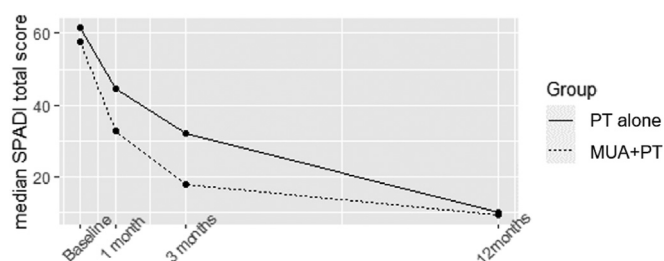


Figure 1 The mean SPADI total score for both groups. SPADI, Shoulder Pain and Disability Index; MUA, manipulation under anesthesia; PT, physiotherapy.

score in the MUA group (median PT = -23.08, median MUA = -40.77, $W = 369,500$; $P = .025$). The median delta SPADI scores 12 months postoperatively were not significantly different between the PT and MUA groups. An overview of the can be seen in Figure 1. The delta score on the SPADI-subscale restrictions was significantly different between the MUA and PT groups at 3 months (median MUA = -38.78, median PT = -27.50, $W = 366.00$, $P = .022$), implicating less restrictions among the MUA group at 3 months compared to the PT group. The delta scores on the SPADI-pain subscale were not significantly different between the MUA and PT groups.

Range of motion

At baseline, both groups had comparable scores on ROM. Both groups showed significant increase in anteflexion, external rotation, and abduction at all points of follow-up compared to baseline. MUA showed a significantly bigger increase in anteflexion compared to PT at all points of follow-up. The gain in abduction was also significantly greater in the MUA group at all follow-up moments compared to the PT group. For external rotation, no significant difference was found between the two groups at any point of follow-up. See Figures 2–4 for details about differences in ROM between the groups.

Functional outcome as measured through the OSS showed improvement over time for both groups at all points of follow-up. No significant differences between the MUA and PT groups were found. No significant differences in pain at rest and during activity between the MUA and PT groups were found. The EQ-5D showed a significant improvement at all points of follow-up for both groups. No difference between the 2 groups was observed. For both groups, an improvement in WORQ-UP score was shown at all points of follow-up. No difference between the 2 groups was observed. In the MUA group, additional injections were given to six patients. Of these 6 patients, 2 received an injection around the long head of the biceps tendon, 2 in the subacromial bursa, and 2 intra-articular. For the PT group, this was the case in 8 patients.

Complications

In the MUA group, one case of avascular osteonecrosis of the humeral head was reported. This was diagnosed through magnetic resonance imaging. There were no signs of involvement of the articular surface. The patient was scheduled for follow-up but never returned to the outpatient clinic. One patient in the MUA group reported pain around the biceps tendon. Imaging did not show any signs of pathology, and over time, the complaints dissolved. One patient in the MUA group reported symptoms of paresthesia (pins and needles) in her fingers 3 months after the intervention. After subacromial infiltration with corticosteroids, these symptoms diminished. One patient reported recurrent episodes of lateral elbow pain, which was considered unrelated to

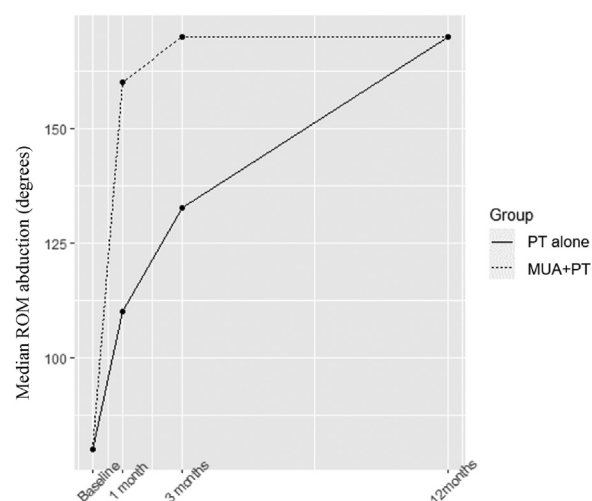


Figure 2 The median ROM for abduction in degrees for both groups. ROM, range of motion; MUA, manipulation under anesthesia; PT, physiotherapy.

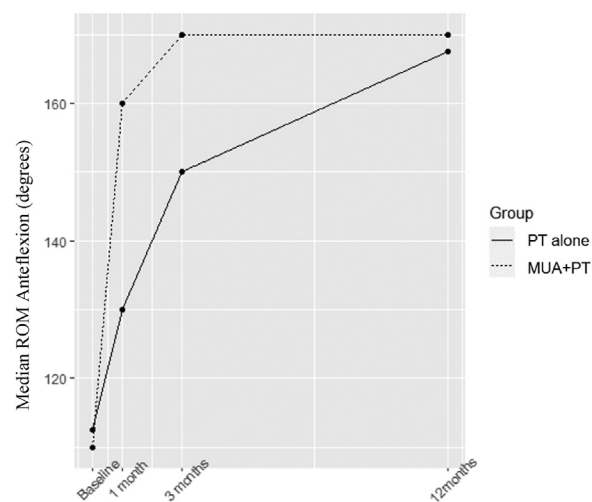


Figure 3 The median ROM for anteflexion in degrees for both groups. ROM, range of motion; MUA, manipulation under anesthesia; PT, physiotherapy.

MUA. In the PT group, there was one patient who developed cervical hernia nuclei pulposi (unrelated), one patient had complaints of muscle aches around the shoulder and neck area (unrelated), and one patient developed subacromial pain of the contralateral shoulder (unrelated).

Discussion

The aim of this randomized trial was to evaluate the effectiveness of MUA followed by a PT program compared to PT alone in the treatment of patients with stage 2 FS. The results showed that ROM and function (measured with SPADI) were significantly better in the MUA group compared to PT at three months. However, at 12 months of follow-up, no differences were found between the groups for all outcome measures. The results implied a faster recovery of shoulder function with MUA followed by PT compared to PT alone. In addition, considering the absence of major complications, MUA seems like a safe treatment option.

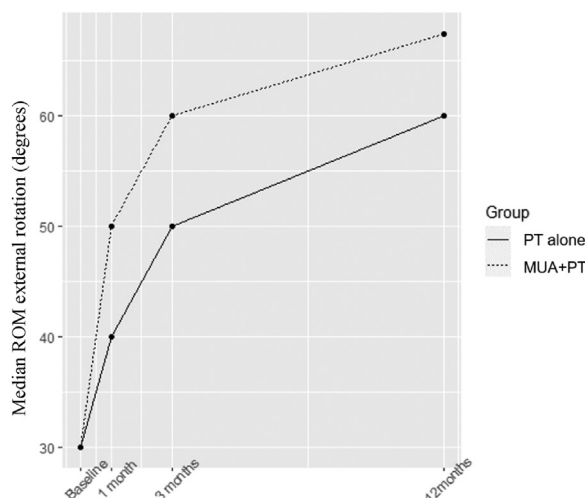


Figure 4 The median ROM for external rotation in degrees for both groups. ROM, range of motion; MUA, manipulation under anesthesia; PT, physiotherapy.

The difference in the SPADI scores at 3 months follow-up between both groups does seem to be clinically relevant, since it exceeds the minimal clinically important difference of 8.²³ Nevertheless, no differences between the treatment groups were found on the measure of function (Oxford Shoulder Score); pain scores and work ability were similar in both groups. At 12 months, no significant differences between both groups were found for all outcome measures.

It is unclear why SPADI showed significant improvement in the short term and OSS did not. Since ROM was significantly better after MUA and pain scores were not, it is possible that ROM accounts stronger in the SPADI questionnaire than in the OSS. It also implies that the magnitude of clinically relevant improvement of MUA over PT in the short term is small and must not be overestimated. Although the results for both groups were similar after one year, the difference in SPADI and ROM at short-term follow-up can still be of clinical importance.

The UK FROST study is a recently published large multicenter randomized trial comparing conservative treatment to MUA and arthroscopic capsular release.²⁴ In a health-economic comparison, they found MUA to be the most cost-effective intervention. For the OSS at 12 months of follow-up, the MUA group had a higher mean OSS than the PT group. However, this difference was not significant and did not exceed the minimal clinically important effect size, and therefore, the clinical relevance is questionable. This is in line with the current study.

An important difference between the current study and the UK-FROST study is that all patients in the current study had already received an intra-articular corticosteroid injection prior to become eligible for inclusion. In the UK-FROST study, an intra-articular corticosteroid injection was given at the start of the early structured PT program in the conservative treatment group. This could perhaps explain why patients in the UK-FROST did not have a short-term benefit from MUA.

A slightly improved ROM of the shoulder was found at three months for the MUA group compared to PT. This was not found by Kivimäki et al, who concluded that the results of MUA were similar to those of a home exercise program.¹⁵ These differences can possibly be attributed to the different postprocedural PT protocols. Patients in the study of Kivimäki et al received PT advice in two sessions and written instructions for a home exercise program. In our study, the PT program had a more aggressive approach, with mobilizations started directly (<4 hours) after MUA by a

physiotherapist, which were continued on a daily basis for the first week in order to try to prevent recurrent stiffness. The study of Kivimäki et al, unfortunately, experienced a high number of patients lost to follow-up (34%) after 6 months, and only 3 patients were available at 12 months of follow-up, attributing to a cautious interpretation of the given results.

One of the possible reasons why orthopedic surgeons tend to be cautious towards MUA is because of the risk of serious complications. Humeral shaft fractures, osteochondral lesions, and brachial plexus injuries are reported in rare cases.^{2,4,20,21} None of these serious complications were encountered during our study or in the UK-FROST trial. They reported two patients with severe complications in a total of 201 cases (1%). Based on the findings of these studies, it can be stated that MUA is a safe intervention for stage 2 FS. This is in line with the systematic review of Kraal et al.¹⁶

Strengths and limitations

The randomized and prospective design, with an adequate sample size and a great diversity of measurements and follow-up moments, strengthens the findings of the current study.

This study had several limitations. First of all, our study lacked a control group without any treatment. Without a “wait and see” or “supervised neglect” group, the intervention couldn’t be compared to the true natural course of FS. However, this was chosen intentionally due to foreseeable lower inclusion numbers if a third option, ‘supervised neglect’ was available. Second, the study duration took longer than anticipated due to the fact that patients were only eligible for inclusion if conservative therapy including a corticosteroid injection was insufficient. A substantial number of patients had enough relief of symptoms after a corticosteroid injection that further intervention (and thus inclusion) was unnecessary. Additionally, some patients were deterred by the written patient information letter, which included potential serious complication of MUA. Third, external validity of the study findings is limited since all manipulations (in order to avoid complications) were performed by one orthopedic surgeon with experience performing MUA. It is unsure whether this was an unnecessary precaution.

Future research

It remains unknown whether MUA remains a safe treatment when performed infrequently and by rather inexperienced orthopedic surgeons. To further investigate whether or not our precaution to perform the procedure by one experienced orthopedic surgeon was unnecessary, it is of importance that in future research MUA is performed by orthopedic surgeons of different levels of experience. In addition, a comparison of the intervention with the natural course of FS is lacking, and this is needed to determine the added value of the intervention. Furthermore, a cost-effectiveness study comparing MUA with PT, PT alone, and ‘supervised neglect’ is of importance to determine whether or not MUA results in an earlier return to work or improved quality of life. To determine the role of the design of the intensive PT program, a comparison between different PT protocols in combination with MUA and MUA stand-alone should be further researched.

Future research should also emphasize more on prognostic factors and the pathophysiology of FS. With more understanding of the pathophysiology, it should ideally be possible to predict the natural course of FS in an individual patient and thus find out which patients will have a prolonged course of the disease. Advanced targeted medical therapy might then become available in order to interrupt the cascade of inflammation and fibrosis early on in the disease. Transforming growth factor β has a major regulatory role in the process of inflammation.^{11,19} Local injections with transforming

growth factor β inhibitors could potentially be of therapeutic value, as they have shown promising results in rats.³⁶ Calcitonin has been shown to be effective in a clinical trial but needs confirmation with more robust data.^{27,37} Profiling patients based on markers of inflammation and also taking into account the ability of patients to cope with pain might help to categorize patients based on whether they will benefit from orthopedic intervention for their FS or not.

Conclusions

The results of this single-center randomized controlled trial show that MUA in stage 2 FS is safe and results in a faster recovery of ROM and improved functional outcome measured with SPADI scores compared to PT alone in the short term. The end result at one year after treatment is equal for MUA and conservative treatment.

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