

Appendix 6.6 Distension

Study	Inclusion/exclusion criteria and diagnosis of FS				Participant characteristics (age, sex, diabetes)	Condition-related characteristics (duration and stage of FS, previous treatments, secondary FS)
<p>Buchbinder 2004⁴³</p> <p>RCT</p> <p><i>Country, setting and treatment provider:</i> Australia; single radiologist; community-based rheumatology practice</p>	<p><i>Inclusion criteria:</i> Aged > 18 years, pain and stiffness in predominantly one shoulder for ≥ 3 months, restriction of passive range of movement of > 30° in two or more planes of movement, measured to onset of pain</p> <p><i>Exclusion criteria:</i> Severe pain at rest (> 7 out of 10 on VAS), previous arthrographic distension, systemic inflammatory joint disease (including rheumatoid arthritis, polymyalgia rheumatica); radiological evidence of osteoarthritis of the shoulder or fracture, calcification about the shoulder joint, reason to suspect a complete rotator cuff tear</p> <p><i>Method of diagnosis:</i> Passive range of movement was measured to onset of pain using a gravity inclinometer; radiography</p> <p><i>Terminology used:</i> Painful stiff shoulder</p>				<p><i>Age (years), mean (SD):</i> Arthrographic distension: 57.2 (8.6); sham distension: 57.5 (8.1)</p> <p><i>Female:</i> 80%</p> <p><i>Any participants with diabetes? Yes.</i> Arthrographic distension: <i>n</i> = 8 (32%); sham distension: <i>n</i> = 5 (24%)</p>	<p><i>Duration of FS at baseline (days), median (range):</i> Arthrographic distension: 118 (102 to 194); sham distension: 114 (96 to 402)</p> <p><i>Stage of FS at baseline:</i> Not reported</p> <p><i>Previous treatments for FS:</i> Previous corticosteroid injection: arthrographic distension: <i>n</i> = 7 (28%); sham distension: <i>n</i> = 6 (28.6%)</p> <p><i>Participants with secondary FS:</i> Yes. Total: <i>n</i> = 1 (2.2%); arthrographic distension: <i>n</i> = 0; sham distension: <i>n</i> = 1 (postoperative capsulitis)</p>
Intervention 1	Intervention 2	Intervention 3	Control		Concomitant treatment and details of home exercise	
<p><i>Arthrographic distension + steroid:</i> Participants were in a supine position with the affected arm externally rotated and a sandbag on the hand. The image intensifier was centred on the glenohumeral joint, cone open to include scapula and upper third of the humerus, and the image intensifier to table top distance set at 50 cm. The skin was marked for arthrogram needle site and infiltrated with local anaesthetic. The arthrogram needle was positioned, connected to the connector tap and tube and 0.5–1 ml of contrast injected and a radiographic image taken; 40 mg of methylprednisolone acetate (Depo-Medrol®, 1 ml) and up to 82 ml of normal saline was then injected (total volume 30–90 ml). The end point of the procedure was filling of the subscapular bursa, capsular rupture, injection of the total volume of liquid or the participant requesting termination of the procedure</p>				<p><i>Placebo:</i> Arthrogram only. Same as for intervention except that there was no injection of steroid and saline</p> <p><i>Home exercise</i></p>		<p>Paracetamol; codeine preparations allowed. Participants were asked to stop taking any NSAIDs</p> <p>No manual treatment (e.g. physiotherapy, massage, chiropractic) or other medical interventions (e.g. intra-articular steroid injection) were allowed</p> <p><i>Home exercise:</i> Participants received a simple exercise programme comprising pendular exercises and scapular setting (isometric scapular retraction)</p>
<i>Home exercise</i>						

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<p>Gam 1998⁹⁶ RCT <i>Country, setting and treatment provider:</i> Denmark; hospital</p>	<p><i>Inclusion criteria:</i> FS of >6 weeks' duration; aged between 18 and 70 years; nocturnal accentuation of pain; passive range of shoulder external rotation <50% of opposite shoulder; no effusion in glenohumeral joint; normal radiography of affected shoulder; normal erythrocyte sedimentation rate, haemoglobin, leucocytes and alkaline phosphatase and negative immunoglobulin M rheumatoid factor</p> <p><i>Exclusion criteria:</i> Trauma to shoulder in previous 6 months that caused pain or restricted movement of shoulder within 1 week (trivial minor injuries accepted); diabetes; treatment for FS (except analgesics) during study period</p> <p><i>Method of diagnosis:</i> Diagnosis by authors. Diagnosis was defined after clinical examination, blood samples and radiography or diagnostic ultrasound</p> <p><i>Terminology used:</i> FS; adhesive capsulitis; scapulohumeral periarthritis</p>				<p><i>Age (years), median (25–75 percentiles):</i> Steroid injection: 47 (43–54); steroid injection + distension: 53.5 (50–63) <i>Female:</i> 59% <i>Any participants with diabetes?</i> No</p>	<p><i>Duration of FS at baseline (months), median (25–75 percentiles):</i> Steroid injection: 4.5 (3.3–5.8); steroid injection + distension: 5 (4.3 –6.0) <i>Stage of FS at baseline:</i> NR <i>Previous treatments for FS:</i> NR <i>Participants with secondary FS:</i> None reported</p>
Intervention 1	Intervention 2	Intervention 3	Control		Concomitant treatment and details of home exercise	
<p><i>Distension + steroid:</i> Intra-articular injection, confirmed by ultrasound, of 20 mg of triamcinolone hexacetonide into the affected glenohumeral joint using the posterior approach with a 1.5-inch needle perpendicular to the scapular spine. Once per week for a maximum of 6 weeks or until no symptoms. An additional 19 ml of lidocaine 0.5% was injected for distension</p>	<p><i>Steroid injection:</i> As for combined intervention except no injection of lidocaine for distension</p>				<p>Analgesic use (details not specified)</p>	

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<p>Tveita 2008³⁶</p> <p>RCT</p> <p>Country, setting and treatment provider: Norway; hospital</p>	<p><i>Inclusion criteria:</i> Limitation of passive movement in the glenohumeral joint compared with the unaffected side, > 30° for at least two of forward flexion, abduction or external rotation; patients with previous FS in opposite shoulder accepted even if difference between sides was < 30°; pain in predominantly one shoulder lasting > 3 months and < 2 years; age > 18 years or > 70 years</p> <p><i>Exclusion criteria:</i> Patients who could not comply with range of movement measurement procedures; diabetes mellitus; trauma to shoulder in the previous 6 months that required hospital care; serious mental illness; various contraindications to injections; patients currently taking corticosteroid tablets; reduction of glenohumeral range for reasons other than 'classic' adhesive capsulitis</p> <p><i>Method of diagnosis:</i> Clinical history and radiography</p> <p><i>Terminology used:</i> Adhesive capsulitis</p>				<p>Age (years), mean (SD): Steroid injection: 52 (7); hydrodilataion: 51 (6)</p> <p>Female: 59%</p> <p>Any participants with diabetes? No</p>	<p>Duration of FS at baseline (months), mean (SD): Steroid injection: 7 (4); hydrodilataion: 7 (4)</p> <p>Stage of FS at baseline: NR</p> <p>Previous treatments for FS: At baseline: patients undergoing physiotherapy n= 13 (8 in steroid injection group, 5 in hydrodilataion group); patients taking analgesics daily n= 20 (9 in steroid injection group, 11 in hydrodilataion group)</p> <p>Participants with secondary FS: None reported</p>
Intervention 1	Intervention 2	Intervention 3	Control	Concomitant treatment and details of home exercise		
<p><i>Arthrographic distension + steroid:</i> Dilatation with a corticosteroid, a contrast agent, local anaesthetic and saline necessary for dilatation and rupturing of the joint capsule. Injections were performed as for the corticosteroid group, except that the 4 ml of contrast medium, 2 ml of triamcinolone acetonide, 4 ml of local anaesthetic and 10 ml of saline were injected slowly into the joint. When resistance was met the injection was halted for a while and then continued. The capsule would usually rupture in the wall of the subscapular recess or sometimes in the wall of the bicipital or axillary recess, which was recorded as a loss of resistance, and contrast leakage was identified by fluoroscopy. If rupture had not occurred, more Ultravist/Marcain was injected until rupture. Three injections with 2-week intervals were given. The steps of the dilatation procedure were documented with repeat radiography examinations</p>	<p><i>Steroid injection:</i> The Kaye–Schneider technique was used to perform arthrograms. Patients were supine and a mark was made with a pen on the glenohumeral joint space at about the junction of its middle and lower third using image-intensified fluoroscopy. The joint was punctured by a needle (22-gauge intramuscular needle); 3–4 ml of contrast medium (iopromide, Ultravist 300, Schering AG), 2 ml of triamcinolone acetonide (Kenacort, 10 mg/ml) and 3–4 ml of bupivacaine hydrochloride (Marcain, 5 mg/ml) were injected slowly. The position of the needle was checked frequently using fluoroscopy. Three injections with 2-week intervals were given. The steps of the injection were documented with repeat radiography examinations</p>			<p>Pain medication organised by the patients' primary care physicians</p> <p>Patients were allowed to proceed with their current physiotherapy programme; no patients were prescribed new physiotherapy programmes during the study</p>		

FS, frozen shoulder; NR, not reported; PT, physiotherapy.