Online-only material

Trial protocol

The trial protocol has been published at ClinicalTrials.gov (accession numbers NCT00695981 and NCT00637013)

Protocol for active rehabilitation after recruitment before randomization

Patients applied a cold pack for 10 to 15 min before exercise, when necessary for pain relief. The exercise program was designed according to best practices at that time[1 2].

Physiotherapists demonstrated and guided the exercises. The load for the first three visits was assessed individually, and each exercise was performed with 20 repetitions maximum (RM), for three sets. After one month, the load was increased, and the number of repetitions was reduced to 15 RM. After two months, the load was increased, and the number of repetitions was reduced to 10 RM. All exercises were to be performed three times per week, and the load was increased by 1 kg, when possible, to achieve the goal RM.

The glenohumeral joint was stretched passively. Hanging exercises were recommended to improve mobility. All patients, except those with hypermobility, hung for 30 s three times per

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day. When the shoulder range of motion (ROM) was limited, the physiotherapist mobilized the glenohumeral joint with a muscle energy technique, applied in the direction of restricted movement. This treatment included isometric contraction for 5 s and static stretching for 5-10 s, and the sequence was repeated 8 times. In addition, the scapulothoracic joint was mobilized, when the ROM was restricted.

All physiotherapists performed manual therapy according to instructions. After 5 min of cold pack treatment, the supraspinatus was cross-friction massaged (20x3x30 s at 30 s intervals). The same procedure was repeated on the infraspinatus, subscapularis, teres minor, and teres major muscles. Manual treatments were applied to the trapezius, deltoid, long head of the triceps, and the biceps sulcus areas.

Shoulder rehabilitation exercises included: Bent-over row on with dumbbells, biceps curl with dumbbells, dumbbell bench press, cable adduction, internal rotation with dumbbells, lying on the side or standing, with an elastic resistance band, external rotation with dumbbells, lying on the side or standing, with an elastic resistance band and arm flexion with dumbbells.

1. Kibler WB, McMullen J and Uhl T. Shoulder rehabilitation strategies, guidelines, and practice. Orthop Clin North Am 2001; 32: 527–38.
2. Wilk KE, Meister K and Andrews JR. Current concepts in the rehabilitation of the overhead throwing athlete. Am J Sports Med 2002; 30: 136–51.

Protocol for surgical treatment

All operations were performed by orthopaedic surgeons that regularly practiced arthroscopic shoulder surgery (TF, KS, KP, TR). Patients were placed in a beach-chair position and received

general and/or interscalene anaesthesia. Cefuroxime (1.5 g) was administered intravenously, before the operation. Initially, the glenohumeral joint and subacromial space were evaluated arthroscopically. Then, patients without a full-thickness tendon lesion underwent arthroscopic subacromial decompression (subacromial bursectomy and resection of the anterior-inferior surface of the acromion). In patients with full-thickness tears, the tendon(s) was re-attached to the head of humerus, in a single-row fashion. Surgeons used one or more bone anchors and implemented either an arthroscopic or a mini-open approach.

Post-operative rehabilitation treatment protocol

All patients underwent the same early post-surgery rehabilitation protocol and used a sling for three weeks. A physiotherapist demonstrated and guided the patient on how to perform the exercises, starting the first postoperative day. Patients were advised to perform 10 repetitions of each home exercise, three times daily, according to instructions. The exercises included active elbow and finger flexion and extension, shoulder and scapula retraction, pendulum exercises, and passive internal rotation.

Three weeks after surgery, patients visited a physiotherapist at the study hospital outpatient clinic, and the training instructions were repeated. The patients started passive exercises three times per day, including: 10 repetitions of shoulder flexion up to 90°, external rotation up to 20-30°, and internal rotation exercises (lifting the dorsum of the hand behind the lower back). Strength training was commenced with 10 repetitions of light, isometric, 5-s contractions of the shoulder muscles, performed when the shoulder was extended, internally rotated, and externally rotated.

At six weeks, patients visited a physiotherapist at the local primary health care centre or an occupational health clinic. Patients were instructed to start dynamic range of motion

exercises daily; these exercises included ten repetitions in flexion, and five repetitions each in external and internal rotations. These exercises were started with yellow resistance bands (Thera-Band®, The Hygenic Corporation Akron, Ohio, USA) and/or light dumbbells. Each exercise was repeated ten times in three sets, three times per week, for at least 24 weeks. The operating surgeon examined patients after three months of rehabilitation.

Supplementary Tables

Table S1. Frequency of missing data at baseline, 3, 6, 12 and 24 months.

	Non-surgery group (N=95) N (%)	Surgery group (N=95) N (%)
Constant score		
Baseline	3 (3)	2 (2)
3 months	25 (26)	34 (36)
6 months	22 (23)	20 (21)
12 months	18 (19)	18 (19)
24 months	14 (15)	15 (16)
Pain VAS		
Baseline	0	0
3 months	25 (26)	34 (36)
6 months	22 (23)	20 (21)
12 months	19 (20)	18 (19)
24 months	15 (16)	15 (16)

Table S2. Pain measured by visual analogue scale and Constant score at baseline and the change at the 2-year follow-up.

	Baseline		Change from baseline to months 24		P values between groups	
	Non-surgical Mean (SD)	Surgical Mean (SD)	Non-surgical Mean (95% CI)	Surgical Mean (95% CI)	Crude	Adjusted[a]
Rotator cuff disease (All) n=190						
Mean Pain	49.1 (23.3)	47.0 (22.4)	-30.5 (-35.2 to -25.8)	-34.4 (-39.0 to -29.7)	0.25	0.23
Pain at rest	37.0 (26.4)	36.2 (24.8)	-23.7 (-28.5 to -19.0)	-27.8 (-32.5 to -23.0)	0.24	0.21
Pain in arm activity	59.6 (22.7)	55.1 (26.2)	-34.4 (-40.0 to -28.7)	-36.5 (-42.2 to -30.8)	0.60	0.57
Pain at night	50.6 (29.0)	49.6 (28.5)	-33.4 (-38.9 to -27.8)	-38.9 (-44.5 to -33.4)	0.16	0.15
Constant score	59.1 (14.9)	60.7 (14.7)	17.0 (14.4 to 19.7)	20.4 (17.8 to 23.1)	0.077	0.074
Non-full-thickness rupture n=92						
Mean Pain	54.2 (24.9)	46.5 (22.5)	-37.9 (-45.0 to -30.8)	-31.1 (-38.3 to -23.9)	0.19	0.17
Pain at rest	41.0 (28.4)	34.0 (24.7)	-29.3 (-36.7 to -21.9)	-23.2 (-30.7 to -15.7)	0.25	0.27
Pain in arm activity	64.4 (23.7)	57.8 (25.8)	-41.9 (-50.5 to -33.4)	-36.6 (-45.2 to -28.0)	0.39	0.36
Pain at night	57.4 (29.7)	47.8 (30.1)	-42.4 (-50.3 to -34.4)	-33.5 (-41.5 to -25.5)	0.12	0.098
Constant score	57.0 (15.2)	59.3 (14.2)	21.6	20.9	0.79	0.75

			(17.8 to 25.3)	(17.1 to 24.7)		
Full-thickness rupture n=98						
Mean Pain	44.0 (20.8)	47.4 (22.5)	-23.8 (-29.8 to -17.7)	-37.1 (-43.1 to -31.0)	0.002	0.001
Pain at rest	33.1 (24.0)	38.2 (25.0)	-18.8 (-24.8 to -12.7)	-31.7 (-37.7 to -25.7)	0.003	0.002
Pain in arm activity	54.9 (20.8)	52.8 (26.6)	-27.6 (-35.1 to -20.1)	-36.3 (-43.7 to -28.8)	0.061	0.091
Pain at night	44.0 (26.9)	51.2 (27.2)	-25.3 (-32.9 to -17.7)	-43.3 (-50.9 to -35.8)	<0.001	<0.001
Constant score	61.0 (14.6)	61.9 (15.2)	13.0 (9.4 to 16.7)	20.0 (16.4 to 23.7)	0.008	0.008

[a]Adjusted for baseline values

Table S3. Implementation of non-surgical treatment modalities during 2-year follow-up.

	Non-surgical treatment, n (%)	Surgery, n (%)	p values between groups
Physiotherapist visits	24 (25)	48 (50)	<0.001
Home-based exercises	39 (41)	49 (52)	0.15
Corticosteroid injections	12 (13)	3 (3)	0.015

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