Early Active Motion Versus Sling Immobilization After Arthroscopic Rotator Cuff Repair: A Randomized Controlled Trial

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Purpose: To compare the effect of early mobilization (EM) with standard rehabilitation (SR) over the initial 24 months following arthroscopic rotator cuff (RC) repair. **Methods:** A total of 206 patients with full-thickness RC tears undergoing arthroscopic repair were randomized following preoperative assessment of shoulder range of motion (ROM), pain, strength, and health-related quality of life (HRQOL) to either EM (n = 103; self-weaned from sling and performed pain-free active ROM during the first 6 weeks) or SR (n = 103; wore a sling for 6 weeks with no active ROM). Shoulder ROM, pain, and HRQOL were reassessed at 6 weeks and 3, 6, 12, and 24 months postoperatively by a blinded assessor. At 6, 12, and 24 months, strength was reassessed. At 12 months, ultrasound verified RC integrity. Independent t tests assessed 6-week group differences and 2-way repeated measures analysis of variance assessed changes over time between groups. **Results:** The groups were similar preoperatively ($P > .12$). The mean age of participants was 55.9 (minimum, 26; maximum, 79) years, and 131 (64%) were men. A total of 171 (83%) patients were followed to 24 months. At 6 weeks postoperatively, EM participants had significantly better forward flexion and abduction ($P < .03$) than the SR participants; no other group differences were noted. Over 24 months, there were no group differences in ROM after 6 weeks ($P > .08$), and pain ($P > .06$), strength ($P = .35$), or HRQOL ($P > .20$) at any time. Fifty-two (25%) subjects (30% EM; 33% SR) had a full-thickness tear present at 12-month postoperative ultrasound testing ($P > .8$). **Conclusions:** EM did not show significant clinical benefits, but there was no compromise of postoperative ROM, pain, strength, or HRQOL. Repair integrity was similar at 12 months postoperatively between groups. Consideration should be given to allow pain-free active ROM within the first 6 weeks following arthroscopic RC repair. **Level of Evidence:** Level I, high-quality randomized controlled trial.

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Shoulder pain is common, ranging from 70 to 260/1,000 persons in the general population,[1-4] with rotator cuff (RC) tears the most common source of shoulder pain and disability.[5,6] When patients do not respond to nonoperative treatment (e.g., physical therapy, cortisone injection), surgical RC repair is recommended.

Surgical repair is effective for full-thickness RC tears, with arthroscopic approaches most commonly used.[7]

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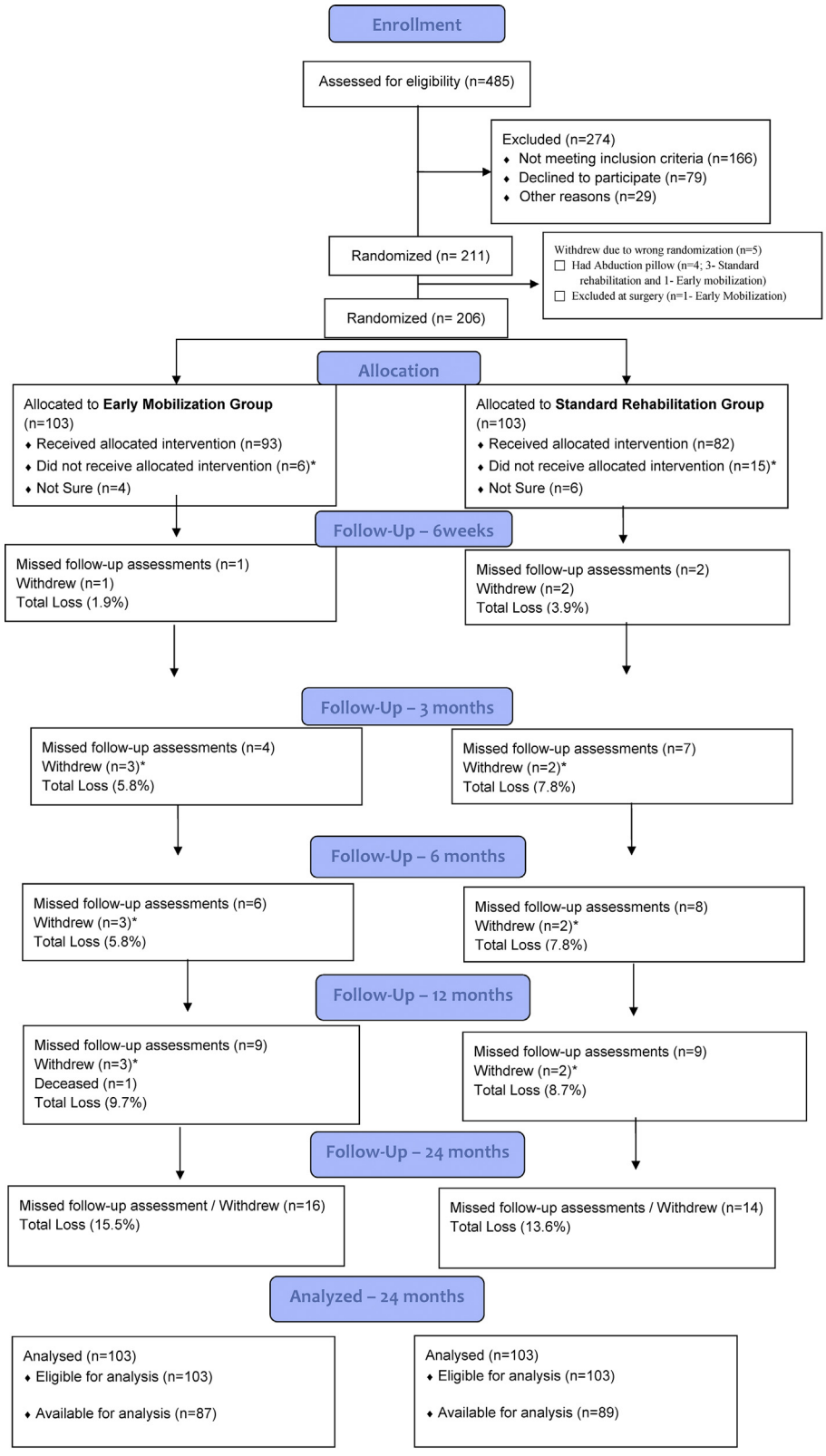

* Non-allocation is due to patient self-reported non-compliance. However, all patients were analyzed in the groups they were originally randomized to.

Fig 1. Flow diagram of 24 months' analysis.

Table 1. Baseline Characteristics of 206 Subjects Undergoing AARCR

	EM (n = 103)	SR (n = 103)	*P*
Subject characteristics			
Mean age (SD, range)	55.5 (8.3, 31-73)	56.2 (10.1, 26-79)	.60*
Males (%)	65 (63.1)	66 (64.1)	.89†
Working full time (%)	68 (66.0)	61 (59.2)	.65†
Manual laborers (%)	23 (22.3)	25 (22.3)	.56†
Shoulder characteristics			
Dominant side injury (%)	70 (68)	55 (53)	.09†
Mean duration of symptoms, yr (SD, range)	2.6 (1.8, 1-5)	7.8 (12.3, 0-22)	.54*
ROM			
Mean forward flexion (SD, range)	132.1 (30.7, 57-180)	127.7 (35.6, 20-180)	.35*
Mean abduction, (SD, range)	122.0 (36.6, 54-180)	118.9 (39.8, 22-180)	.57*
Mean external rotation in 90° abduction (SD, range)	61.0 (34.8, 0-112)	61.6 (31.8, 0-108)	.90*
Mean internal rotation in 90° abduction (SD, range)	30.8 (19.1, 0-88)	33.3 (17.8, 0-77)	.34*
Mean horizontal adduction (SD, range)	13.7 (9.8, 0-48)	14.8 (10.5,0-45)	.46*
Mean scaption (SD, range)	124.7 (31.8, 50-172)	123.4 (34.9, 25-177)	.77*
Pain			
Mean pain at rest score measured, cm, (SD, range)	3.1 (2.3, 0-9)	2.9 (2.4, 0-10)	.51*
Mean pain with activity measured, cm (SD, range)	6.1 (2.4, 0-10)	5.7 (2.4, 0-10)	.33*
Mean pain at night, cm (SD, range)	4.8 (2.6, 0-9)	4.3 (2.7, 0-10)	.19*
Strength			
Mean forward flexion (SD, range)	19.2 (10.9, 0-69)	20.1 (12.3, 0-81)	.89*
Mean abduction (SD, range)	18.0 (9.8, 0-48)	18.0 (9.8, 3-43)	.95*
Mean external rotation in 90° abduction (SD, range)	11.2 (8.3, 0-38)	11.9 (9.3, 0-47)	.59*
Mean internal rotation in 90° abduction (SD, range)	17.6 (12.3, 0-54)	19.4 (14.0, 0-66)	.32*
Mean horizontal adduction (SD, range)	17.4 (11.8, 0-53)	20.2 (13.3, 0-48)	.12*
Mean scaption (SD, range)	124.7 (31.8, 0-34)	123.4 (34.9, 0-39)	.77*
Mean WORC score (SD, range)	38.9 (18.5, 6.5-89.8)	40.6 (17.2, 8.6-87.5)	.50*
Mean SF-36 score (SD, range)			
Physical Functioning	72.1 (15.8, 25-100)	71.7 (16.3, 5-100)	.84*
Role Physical	33.5 (39.2, 0-100)	35.7 (36.8, 0-100)	.68*
Bodily Pain	44.7 (17.2, 12-100)	46.7 (18.9, 0-100)	.42*
General Health	78.8 (15.8, 27-100)	76.0 (17.6, 20-100)	.24*
Vitality	61.0 (20.7, 0-100)	62.2 (18.1, 15-100)	.66*
Social Function	79.6 (21.9, 12.5-100)	76.1 (22.1, 25-100)	.25*
Role Emotional	78.6 (37.3, 0-100)	80.3 (33.8, 0-100)	.75*
Mental Health	78.4 (15.1, 28-100)	77.7 (13.7, 40-100)	.71*
Surgical characteristics			
Mean length of tear AP, cm (SD, range)	2.1 (1.1, 0.1-5)	2.1 (1.0, 0.1-5)	.92*
Mean length of tear ML, cm (SD, range)	1.9 (1.1, 0-6)	1.9 (1.1, 0.1-5)	.90*
No biceps pathology (%)	36 (36.0)	36 (35.3)	.77†
No labral pathology (%)	69 (67.0)	66 (64.1)	.36†

AARCR, all-arthroscopic rotator cuff repair; AP, anteroposterior; EM, early mobilization; ML, mediolateral; ROM, range of motion; SD, standard deviation; SR, standard rehabilitation; WCB, Worker's Compensation Board; WORC, Western Ontario Rotator Cuff.

*Analyzed with a 2-tailed independent t-test.

†Analyzed with a χ-square test; $P < .05$.

Postsurgical rehabilitation takes between 4 and 12 months, with patients typically immobilized in a sling for 4 to 6 weeks postoperatively. Current evidence regarding the optimal period of postoperative immobilization is controversial.[7-9] Early mobilization may decrease patient burden, incidence of postoperative shoulder stiffness, and muscle atrophy, but may potentially increase the risk of retears.[7,10-12]

Most animal research on the RC suggests that early range of motion (ROM) may increase the risk of retears compared with delayed mobilization.[13-15] Conversely, a recent randomized controlled trial (RCT) showed that early active ROM did not affect clinical outcomes compared with 6 weeks of immobilization following miniopen RC repair.[16] Furthermore, a recent meta-analysis[8] also did not identify significant differences in clinical outcomes or retears between early and delayed ROM in patients undergoing arthroscopic RC repairs. This RCT compared the effect of early mobilization (EM) to standard rehabilitation (SR) over the initial 24 months following arthroscopic RC repair. We hypothesized that patients allowed early movement would have better ROM at 6 weeks postoperatively compared with patients using sling immobilization, but that both groups would achieve similar outcomes within 24 months of surgery, including RC integrity.

Table 2. Surgical Characteristics of 206 Subjects Undergoing AARCR

	EM (n = 103)	SR (n = 103)	*P*
Repair type			
Single row (%)	11 (10.7)	11 (10.7)	1.0*
Double row/transosseous	92 (89.3)	92 (89.3)	1.0*
Biceps tendon			
Debrided (%)	6 (6)	2 (2.9)	.77*
Released (%)	7 (7)	10 (9.8)	.77*
Tenodesed (%)	45 (45)	45 (44.1)	.77*
Acromioclavicular joint			
Acromioplasty performed (%)	78 (75.7)	79 (77.5)	.77*
Removed osteophytes (%)	11 (10.7)	13 (12.6)	.44*
Excised distal clavicle (%)	16 (15.5)	10 (9.7)	.44*

AARCR, all-arthroscopic rotator cuff repair; EM, early mobilization; SD, standard deviation; SR, standard rehabilitation.
*Analyzed with a chi-square test; $P < .05$.

Materials and Methods

Design

This prospective, randomized, parallel-arm, double-blind (clinical assessor and radiologist) multicenter superiority trial enrolled 211 participants who underwent arthroscopic RC repair performed by fellowship-trained shoulder surgeons (n = 5).

Inclusion and Exclusion Criteria

Participants were ≥18 years of age, failed nonoperative management (i.e., persistent pain and/or disability following 3 months of conservative treatment including analgesic/anti-inflammatory medications, intra-articular corticosteroids, activity modification, and physical therapy), and had a confirmed full-thickness RC tear by either ultrasound or magnetic resonance imaging. All tear sizes were included, provided the repair could be completed arthroscopically. Exclusion criteria were partial-thickness tear, full-thickness subscapularis tear, irreparable tear, anteroinferior labral (Bankart) lesion, previous surgery on the affected shoulder, severe glenohumeral osteoarthritis, inability to understand/read English, or unwillingness/inability to complete study follow-up.

Operative Procedure

Under general anesthesia, diagnostic arthroscopy confirmed a full-thickness RC tear including size, tendon retraction, and tissue quality. Participants with >50% tearing or degenerative changes in the biceps tendon underwent tenodesis or tenotomy. Subacromial bursectomy and acromioplasty were performed as indicated. Arthroscopic RC repair was performed according to tear morphology and surgeon preference and included single-row, double-row, transosseous-equivalent (suture bridge), or transosseous (Arthro-Tunneler) approaches. Marginal convergence was performed if indicated. Surgical details were recorded using a standardized form. Surgeons confirmed eligibility, but were not involved in randomization.

Randomization

The randomization sequence was computer-generated in blocks of 10, with a 1:1 allocation stratified by surgeon and tear size (<3 cm or ≥3 cm). We stratified surgeon and tear size to ensure that surgeons contributed similar numbers of participants to each group and that there were similar tear sizes in each group. Randomization codes were stored in opaque sequentially numbered envelopes and were opened post-operatively following eligibility criteria confirmation. Prior to discharge, randomization envelopes containing group allocation were opened by operating room staff and participants were given additional written instructions based on group allocation (Appendix Fig 1, available at www.arthroscopyjournal.org).

Procedures

Between 2011 and 2015, we screened 485 participants and enrolled 211 (Fig 1), who were randomized to SR (sling for 6 weeks; no active shoulder ROM) or EM (sling as needed; pain-free active shoulder ROM for activities of daily living). Participants were evaluated preoperatively (shoulder ROM, pain, strength, health-related quality of life [HRQOL]) by 1 of 2 research registered physical therapists (PTs) blinded to group allocation; these PTs did not treat any participants. Demographics (age and sex), patient-specific factors (working status, workers' compensation status, dominant hand, recreational activities, comorbidities), and duration of shoulder symptoms were also collected preoperatively.

Postoperatively, ROM, pain, and HRQOL were reassessed at 6-weeks and 3-months and ROM, pain, strength, and HRQOL were reassessed at 6, 12, and 24 months by the same PTs. Complications were documented intraoperatively and at each assessment. RC integrity was assessed at 12 months via ultrasound.

Active ROM at 6 weeks was the primary outcome. It was measured using a universal goniometer with standardized patient positioning, including active flexion, scaption, and abduction in standing, and active flexion, abduction, horizontal adduction, and external and internal rotation in 90° of abduction in supine. Reliability of shoulder ROM assessment was ensured by training of both assessors until consistent measurements were achieved; furthermore, each assessor was responsible for his or her own patients.

Shoulder pain was assessed using visual analog scales in which 0 equaled no pain and 10 the worst possible pain. Subjects rated pain at rest, with activity, and at night.[17,18]

Table 3. Shoulder ROM, Strength, and Pain Over Time

	EM	SR		
ROM (°)	Mean (SD)	Mean (SD)	*P*	
Forward flexion				
Baseline	131.5 (30.0)	127.4 (34.9)	Group effect	.08*
6 weeks	90.0 (33.4)	78.9 (34.5)	Time effect	<.001
3 months	125.5 (28.5)	121.0 (30.1)	Interaction	.274
6 months	142.3 (22.6)	141.3 (22.6)		
12 months	150.9 (12.6)	149.0 (19.9)		
24 months	155.5 (12.7)	152.2 (18.5)		
Abduction				
Baseline	121.1 (36.0)	118.6 (39.4)	Group effect	.33*
6 weeks	75.4 (36.8)	67.1 (32.9)	Time effect	<.001
3 months	119.1 (31.3)	116.0 (37.6)	Interaction	.586
6 months	139.4 (23.5)	139.5 (27.6)		
12 months	150.0 (15.3)	148.4 (22.4)		
24 months	153.5 (14.6)	152.2 (21.9)		
External rotation in abduction				
Baseline	62.2 (34.1)	61.6 (31.6)	Group effect	.09*
6 weeks	22.0 (29.2)	19.5 (28.8)	Time effect	<.001
3 months	53.0 (27.6)	44.2 (28.8)	Interaction	.432
6 months	67.6 (21.0)	62.9 (21.6)		
12 months	75.3 (16.2)	70.6 (18.8)		
24 months	76.0 (14.8)	71.5 (17.8)		
Internal rotation in abduction				
Baseline	30.6 (18.6)	33.2 (17.6)	Group effect	.495*
6 weeks	14.1 (18.6)	11.8 (16.6)	Time effect	<.001
3 months	30.2 (15.2)	25.9 (16.3)	Interaction	.136
6 months	35.9 (12.1)	35.5 (12.2)		
12 months	39.0 (12.4)	40.1 (14.4)		
24 months	40.9 (12.0)	38.7 (12.4)		
Mean horizontal adduction				
Baseline	13.2 (9.2)	14.4 (10.3)	Group effect	.48*
6 weeks	8.2 (10.0)	6.4 (9.3)	Time effect	<.001
3 months	14.9 (9.7)	13.0 (9.7)	Interaction	.285
6 months	19.4 (13.5)	18.1 (9.9)		
12 months	19.1 (10.4)	18.9 (10.4)		
24 months	20.4 (10.5)	19.5 (11.5)		
Scaption				
Baseline	124.6 (31.3)	123.6 (34.8)	Group effect	.44*
6 weeks	80.4 (33.1)	75.8 (36.3)	Time effect	<.001
3 months	120.7 (28.0)	118.5 (31.0)	Interaction	.888
6 months	138.0 (21.4)	137.9 (23.6)		
12 months	148.7 (11.7)	146.7 (20.2)		
24 months	151.7 (12.8)	149.7 (18.8)		
ROM_TOT				
Baseline	483.1 (134.3)	478.7 (137.9)	Group effect	.157*
6 weeks	290.1 (134.0)	259.4 (141.1)	Time effect	<.001
3 months	463.4 (117.1)	438.7 (134.4)	Interaction	.575
6 months	542.6 (77.6)	535.2 (97.1)		
12 months	583.0 (51.1)	573.6 (83.4)		
		Strength (Measured in lb)		
Forward flexion				
Baseline	19.6 (10.9)	19.8 (12.3)	Group effect	.59*
6 months	26.3 (12.6)	27.1 (10.8)	Time effect	<.001
12 months	29.7 (13.7)	31.0 (12.7)	Interaction	.916
24 months	28.3 (11.5)	29.1 (11.7)		
Abduction				
Baseline	18.6 (10.0)	17.8 (10.1)	Group effect	.89*
6 months	23.2 (10.1)	23.2 (9.3)	Time effect	<.001
12 months	26.8 (10.7)	26.9 (10.5)	Interaction	.451
24 months	26.9 (9.6)	28.2 (10.6)		

(continued)

Table 3. Continued

ROM (°)	EM Mean (SD)	SR Mean (SD)	P	
External rotation in abduction				
Baseline	11.5 (8.4)	11.9 (9.6)	Group effect	.81*
6 months	18.2 (9.4)	18.7 (10.1)	Time effect	<.001
12 months	23.3 (12.5)	24.0 (12.3)	Interaction	.001
24 months	25.1 (12.5)	24.8 (11.8)		
Internal rotation in abduction				
Baseline	18.1 (12.7)	19.5 (14.1)	Group effect	.67*
6 months	27.1 (14.5)	26.7 (12.5)	Time effect	<.001
12 months	30.9 (15.2)	32.3 (14.4)	Interaction	.600
24 months	30.6 (13.1)	31.3 (13.4)		
Mean horizontal adduction				
Baseline	17.7 (12.2)	20.0 (13.4)	Group effect	.66*
6 months	25.7 (12.1)	25.4 (10.7)	Time effect	<.001
12 months	28.1 (11.3)	28.4 (11.6)	Interaction	.285
24 months	27.9 (9.8)	28.2 (11.1)		
Scaption				
Baseline	14.2 (7.1)	13.9 (7.2)	Group effect	.55*
6 months	16.4 (6.9)	16.3 (6.5)	Time effect	<.001
12 months	19.8 (7.3)	19.1 (7.0)	Interaction	.784
24 months	20.6 (7.0)	19.7 (7.2)		
		Pain		
Pain at rest, cm				
Baseline	3.2 (2.3)	3.0 (2.4)	Group effect	.25*
6 weeks	2.2 (2.0)	2.0 (1.9)	Time effect	<.001
3 months	1.8 (2.1)	1.4 (1.6)	Interaction	.857
6 months	0.9 (1.3)	0.8 (1.0)		
12 months	0.6 (1.0)	0.6 (1.0)		
24 months	0.7 (1.3)	0.6 (1.3)		
Pain with activity, cm				
Baseline	6.1 (2.4)	5.8 (2.3)	Group effect	.06*
6 weeks	4.4 (2.5)	3.9 (2.1)	Time effect	<.001
3 months	3.4 (2.4)	2.8 (1.9)	Interaction	.598
6 months	2.2 (1.9)	1.8 (1.5)		
12 months	1.2 (1.4)	1.2 (1.4)		
24 months	1.2 (1.6)	1.0 (1.6)		
Pain at night, cm				
Baseline	4.8 (2.6)	4.4 (2.7)	Group effect	.34*
6 weeks	3.3 (2.5)	2.8 (2.1)	Time effect	<.001
3 months	2.3 (2.4)	2.1 (2.0)	Interaction	.498
6 months	1.1 (1.6)	1.0 (1.2)		
12 months	0.6 (0.8)	0.8 (1.4)		
24 months	0.9 (1.6)	0.7 (1.4)		

EM, early mobilization; ROM, range of motion; SD, standard deviation; SR, standard rehabilitation.
*Analysis adjusted for nonsphericity using Greenhouse-Geisser correction.

Strength was measured using a dynamometer (micro-FET3, Hoggan Health Industries, West Jordan, UT). Isometric shoulder flexion, abduction, external rotation, and internal rotation were measured with the arm in neutral (neutral abduction, 90° elbow flexion). Peak values were recorded during each contraction, which was held for 3 seconds. Strength values were expressed as raw values as well as proportional to the unaffected shoulder.[19,20]

HRQOL was measured using the Western Ontario Rotator Cuff (WORC) Index and Short-Form 36-Item Health Survey (SF-36). The WORC is a 5-part (physical symptoms, sports/recreation, work, lifestyle, emotions), 21-item, disease-specific questionnaire that assesses HRQOL in patients with RC pathology.[21] The SF-36 is a general health status questionnaire that incorporates multiple health domains (physical functioning, role physical, bodily pain, general health, vitality, social function, role emotional, and mental health).[22]

Complications, both medical (urinary, gastrointestinal, cardiac, pulmonary, metabolic) and surgical (nerve

Table 4. WORC and SF-36 Scores Over Time

	Early Mobilization	Standard Rehabilitation		
	Mean (SD)	Mean (SD)	*P*	
WORC, %				
Baseline	39.2 (18.4)	40.2 (17.3)	Group effect	.84*
6 weeks	44.5 (16.6)	40.7 (14.0)	Time effect	<.001
3 months	61.4 (19.0)	63.7 (17.6)	Interaction	.283
6 months	78.6 (16.8)	79.6 (15.2)		
12 months	87.6 (14.1)	88.6 (13.1)		
24 months	89.4 (13.4)	89.8 (13.4)		
		SF-36		
Physical functioning				
Baseline	72.8 (15.2)	71.3 (16.7)	Group effect	.25*
6 weeks	68.2 (14.2)	64.7 (15.2)	Time effect	<.001
3 months	75.0 (15.9)	73.7 (16.3)	Interaction	.852
6 months	84.4 (14.1)	82.7 (18.1)		
12 months	89.3 (13.2)	86.3 (18.2)		
24 months	86.8 (15.4)	85.7 (16.9)		
Role physical				
Baseline	33.2 (39.1)	36.6 (37.7)	Group effect	.23*
6 weeks	14.7 (28.8)	10.6 (25.4)	Time effect	<.001
3 months	40.9 (42.7)	37.5 (41.2)	Interaction	.628
6 months	71.1 (37.6)	65.6 (40.2)		
12 months	86.1 (29.6)	79.8 (35.8)		
24 months	81.8 (33.6)	74.4 (38.8)		
Bodily pain				
Baseline	43.5 (16.4)	46.3 (18.6)	Group effect	.47*
6 weeks	50.2 (22.8)	45.5 (24.0)	Time effect	<.001
3 months	62.5 (22.5)	66.5 (20.5)	Interaction	.177
6 months	69.5 (17.8)	71.7 (19.2)		
12 months	74.6 (20.0)	75.5 (20.8)		
24 months	73.2 (22.2)	76.7 (22.7)		
General health				
Baseline	79.0 (15.4)	76.0 (17.9)	Group effect	.68*
6 weeks	78.0 (17.1)	77.7 (17.0)	Time effect	<.001
3 months	77.6 (14.7)	79.3 (17.0)	Interaction	.310
6 months	81.1 (13.5)	79.7 (15.4)		
12 months	80.3 (14.6)	80.1 (15.7)		
24 months	78.8 (17.3)	77.2 (20.0)		
Vitality				
Baseline	61.0 (20.3)	63.2 (18.2)	Group effect	.42*
6 weeks	58.9 (18.8)	57.3 (19.2)	Time effect	<.001
3 months	65.9 (18.1)	68.0 (16.7)	Interaction	.520
6 months	70.4 (15.4)	72.9 (14.0)		
12 months	73.2 (15.4)	73.9 (14.0)		
24 months	70.7 (19.9)	73.9 (16.3)		
Social function				
Baseline	79.0 (22.2)	76.5 (22.1)	Group effect	.46*
6 weeks	70.0 (26.3)	61.7 (26.1)	Time effect	<.001
3 months	82.4 (20.0)	81.1 (20.6)	Interaction	.05
6 months	90.5 (16.5)	90.4 (15.4)		
12 months	90.4 (17.1)	91.1 (17.2)		
24 months	86.4 (21.3)	88.7 (18.8)		
Role emotional				
Baseline	80.2 (36.2)	81.4 (33.9)	Group effect	.37*
6 weeks	65.9 (42.7)	64.2 (43.0)	Time effect	<.001
3 months	78.0 (37.6)	74.5 (38.4)	Interaction	.825
6 months	89.4 (26.7)	82.8 (34.5)		
12 months	90.7 (25.8)	89.3 (25.3)		
24 months	92.2 (20.9)	88.2 (27.5)		
Mental health				
Baseline	79.0 (13.9)	78.5 (13.4)	Group effect	.68*
6 weeks	79.5 (15.6)	76.3 (15.4)	Time effect	<.001

(continued)

Table 4. Continued

	Early Mobilization	Standard Rehabilitation		
	Mean (SD)	Mean (SD)	*P*	
3 months	79.8 (15.8)	82.4 (12.8)	Interaction	.03
6 months	81.9 (13.8)	83.9 (12.4)		
12 months	82.8 (15.0)	83.1 (12.2)		
24 months	81.4 (14.8)	84.1 (12.0)		

ROM_TOT, total range of motion; SD, standard deviation; SF-36, 36-Item Short Form; WORC, Western Ontario Rotator Cuff.
*Analysis adjusted for nonsphericity using Greenhouse-Geisser correction.

injury, superficial or deep infection, dislocation, frozen shoulder, fracture, hematoma, biceps rupture, failure of tendon healing, dermatitis, RSD, persist pain, re-injury), were monitored throughout the study. Postoperative RC integrity was evaluated by ultrasound using a Logiq E9 Ultrasound system (General Electric Healthcare, Milwaukee, WI) with 15-MHz linear transducer probes. All scans were performed "hands on" by 1 of 2 fellowship-trained musculoskeletal radiologists. Before the study, the radiologists performed consensus scanning to establish interpretation thresholds. Supraspinatus and infraspinatus tendons ultrasounds were performed based on European Society of Skeletal Radiology examination protocols.[23] The tendons were interrogated in long and short axis with acquisition of static images and cine sequences. Dynamic maneuvers to optimize visualization and aid assessment of integrity were also performed. Tear size, if present, was documented at time of scanning. Technically difficult scans were reviewed by the second radiologist and a consensus evaluation documented.

Intervention

All participants were placed in a sling, and postoperative self-assisted ROM exercises were demonstrated by a hospital PT in the recovery room regardless of group allocation. SR participants were told to wear the sling at all times except when performing the passive and self-assisted activities. EM participants performed the same passive and self-assisted activities, but were also told that the sling was only needed for comfort and could be taken off and discharged at the patient's discretion. EM participants were advised to perform pain-free activities only, with the exception of resisted activities (i.e., lifting objects weighing more than 1-2 lb), which were contraindicated. After 6 weeks, all participants followed the same rehabilitation protocol.

At 6 weeks, all participants completed a compliance questionnaire regarding daily activities and sling use (e.g., duration of sling use, daily sling use, arm movement, night-time sling use). Noncompliance occurred if SR participants performed active ROM and did not wear their sling or EM participants used the sling and did not perform active ROM. Compliance data were entered independently to maintain blinding of clinical assessors to group allocation.

Statistics

The study was powered ($\sigma = 25°$; $\alpha = 0.05$; $\beta = 0.2$) to detect a 10° group difference in ROM at 6 weeks, which was determined to be a clinically important difference.[24] With 81 participants required per group and additional participants enrolled to account for up to 20% attrition, a total of 200 participants (100/group) was required. This sample size also met power requirements for pain, strength, and HRQOL evaluations.

Statistical analysis was performed using intention-to-treat with all outcomes attributed to the assigned group. Descriptive statistics were used for group comparisons with independent t-tests for continuous and χ-square tests for categorical variables at baseline and 6 weeks postoperatively. Two-way repeated-measures analysis of variance compared ROM, pain, strength, and HRQOL between groups over the 24-month evaluation period. Mauchly's test of sphericity assessed sphericity on the repeated-measures analysis of variance; if sphericity was not met, Greenhouse-Geisser adjusted values were reported.

Table 5. Logistic Regression Examining Retears Between Groups When Stratifying by Preoperative Tear Size (<3 cm and ≥ 3 cm) and Repair Method

	β	SE	Wald	DF	Sig.
Group assignment	−0.038	0.36	0.011	1	0.92
Tear size (<3 cm and ≥3 cm)	0.861	0.37	5.4	1	0.02
Repair type	−0.45	0.51	0.78	1	0.38
Constant	−0.88	0.55	2.5	1	0.42
Model summary					0.06

DF, degrees of freedom; SE, standard error; Sig., significance.

For participants who missed only 1 postoperative visit (excluding the 24-month assessment), the group's mean score was imputed to maximize use of available data.[25] A subanalysis using logistic regression examined retears between groups when stratifying by preoperative tear size (<3 cm and ≥3 cm) and repair method. The level of significance was set at $\alpha = 0.05$. Statistical analysis was performed with SPSS (Predictive Analytics SoftWare, version 21.0; SPSS, Chicago, IlL).

Ethics

The regional Health Ethics Research Board approved this study in 2010 (Pro00014046). All subjects volunteered to be part of this study. After oral and written information about the study, subjects were required to sign an informed consent form. This trial is registered at ClinicalTrials.gov (NCT01333527).

Results

Participants

Between 2011 and 2015, 211 participants with full-thickness RC tear booked for arthroscopic repair were enrolled and randomized. Five participants were excluded after randomization because they did not meet eligibility criteria (4 used an abduction sling; 1 was erroneously randomized); thus, 206 participants were randomized and retained for follow-up, with 103 allocated to EM and 103 to SR. A total of 176 (85%) participants completed the 24-month assessment (Fig 1). Scores were imputed for 31/1030 (3%) participant visits (SR, 22/515; 4%; EM, 9/515; 2%) to maximize use of available data.

The groups were similar in baseline (Table 1) and surgical characteristics; >90% of repairs were double row or transosseous equivalent (Table 2). The mean age of participants was 56 (minimum 26, maximum 79) years and 131 (64%) were men. A total of 129 (63%) participants worked full-time. Based on reported compliance, 94% of EM participants used their sling only for comfort and started restricted active ROM as tolerated, whereas 85% of SR participants used their slings as ordered for the first 6 weeks postoperatively ($P = .03$).

ROM

At 6 weeks, EM participants had significantly better forward flexion and abduction than SR participants ($P < .03$). Over 24 months, groups had similar ROM ($P > .08$) and showed improvement over time ($P < .001$) postoperatively (Table 3).

Pain

Shoulder pain at rest, with activity, and at night were not significantly different at any postoperative evaluation. Both groups improved over time ($P < .001$) (Table 3).

Strength

Preoperatively, both groups had substantial strength limitations (Table 3). Postoperatively, strength significantly improved ($P < .001$), with no group differences ($P > .35$).

HRQOL

HRQOL also improved substantially over time ($P < .001$), with no differences between groups over time. The mean 24-month WORC score was 89.4 ± 13.4 for EM and 89.8 ± 13.4 for SR participants ($P = .84$) (Table 4). Scores for SF-36 were similar over time for both groups ($P > .14$) (Table 4).

Rotator Cuff Integrity

Ultrasound testing was completed in 165 (80%) participants (79 EM; 86 SR; $P = .85$). Full-thickness tears were identified in 45 (27%) supraspinatus (26.6% EM; 27.9% SR) and 7 (4%) infraspinatus (3.8% EM; 4.7% SR), tendons with no group differences ($P > .79$). Atrophy was documented in 33 supraspinatus (13 EM; 20 SR; $P = .28$) and 30 infraspinatus (12 EM; 18 SR; $P = .34$). Further, most participants lacking RC integrity were asymptomatic, with mean 24-month WORC scores of 86.1 ± 15.9. Stratifying patients by tear size (<3 cm and ≥3 cm) and repair type also showed no significant group differences ($P = .07$) (Table 5).

Adverse Events

Complications were reported by 31 (15%) participants (17 EM, 14 SR; $P > .3$) over 24 months. These included superficial infection (1, 0.5% [0 EM, 1 SR]; $P = .32$), frozen shoulder (3, 1.5% [1 EM, 2 SR]; $P = .56$), biceps rupture (2, 1% [1 EM, 1 SR]; $P = 1.0$), persistent pain (16, 7.8%) [10 EM, 6 SR]; $P = .3$) and reinjury not requiring reoperation (9, 4.4% [5 EM, 4 SR]; $P = .73$). Five (2.5%) patients (1 EM; 4 SR; $P = .17$) had reoperations because of traumatic reinjury (2), persistent pain (2), and failure tendon (1).

Discussion

Early active shoulder ROM did not affect patient outcomes (ROM, pain, strength, HRQOL) or repair integrity compared with standard postoperative sling immobilization following arthroscopic RC repair. Although EM participants had significantly greater forward flexion and abduction at 6 weeks postoperatively, both groups improved significantly and similarly over 24 months postoperatively in all outcomes, similar to a previous RCT[16] that assessed the effect of early active mobilization on recovery following miniopen RC repair. These results supported

the initial hypothesis that patients allowed early movement would have better ROM at 6 weeks postoperatively compared with patients using sling immobilization and that both groups would achieve similar outcomes within 24 months of surgery, including RC integrity.

Current evidence of early ROM effect on the tendon healing after arthroscopic RC repair is controversial. Recent studies comparing early passive ROM during the initial 6 weeks to strict immobilization and/or limited passive ROM reported that both groups improved over time, independent of the immobilization period, similar to our findings comparing active ROM versus immobilization).[26-29] Animal models evaluating anterior cruciate ligament grafts and flexor tendon repairs reported that early postoperative ROM improved healing.[30,31] Conversely, animal models on RC healing demonstrated immobilized shoulders had superior mechanical properties compared with shoulders that actively exercised early.[13,15,32]

One systematic review[33] comparing early versus delayed active ROM after RC repair in humans reported that the risk of retear increased in the early ROM group dependent upon type and size of repair. For tears <3 cm, retear risk increased for single-row repairs; for tears ≥3 cm, retear risk increased even for double-row suture bridge repairs. They concluded that early active ROM was associated with increased risk for retears and would not be advised. Our pre-specified sub-analyses did not support these findings as we detected no group differences in repair integrity either by tear size or repair type when assessed by ultrasound at 12 months postoperatively. Retear rates were higher among patients with large tears (≥3 cm), but was not affected by the postoperative mobilization protocol. Moreover, we found no group differences in shoulder strength, which aligns with current literature stating that a significant number of recurrent retears are still associated with improved pain and strength.[34,35] Our findings likely differ from the systematic review because most included studies were nonrandomized and had small sample sizes.

Our findings are supported by a recent pilot RCT of 30 patients assigned to either primary passive ROM or early isometric loading of the RC muscles after arthroscopic RC repair.[36] The early activated group had better Constant Murley scores, particularly at 12 weeks postoperatively. They also found decreased pain at 6 and 24 weeks in the early active compared with the passive ROM group and no group differences in ROM, strength, or HRQOL.

Strengths of our RCT include study design, adequate power to detect clinically important differences in shoulder ROM, strength, power, pain (at rest, at night, and with activities), and disease-specific HRQOL and participant retention (83% completed the 24-month evaluation). We also assessed RC integrity in 80% of participants at 12 months. The randomization process stratified patients by tear size and by surgeon and tears ranged from small to large (<3 cm [70%] and ≥3 cm [30%]) and were similarly distributed between groups; thus, our results are likely applicable to most RC tears, regardless of size, if reparable arthroscopically. The results should also generalize to an adult population undergoing arthroscopic repair for full-thickness RC tear because our participants were drawn from a large urban area with multiple fellowship-trained shoulder surgeons delivering surgical care.

Limitations

Study limitations include the omission of a measure to evaluate participants' perception of the impact of sling use in the first 6 postoperative weeks; future work should include measurement of subjects' preference and satisfaction in the initial 6 postoperative weeks. Further, the trial was also limited by measurement of compliance through a questionnaire, variable repair types, and potential ultrasonographer variability in assessing RC integrity; however, we would expect that these limitations applied to both groups and should not have resulted in any systematic measurement error. Finally, the study was not powered for comparing repair integrity, but reported group differences suggest that retears were similar between groups.

Conclusion

EM did not show significant clinical benefits, but there was no compromise of postoperative ROM, pain, strength, or HRQOL. Repair integrity was similar at 12 months postoperatively between groups. Consideration should be given to allow pain-free active ROM within the first 6 weeks following arthroscopic RC repair.

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All Arthroscopic Rotator Cuff Repair Rehabilitation Protocol (GROUP A: Immobilization x 6 weeks)

Phase 1 Immobilization (0-6 weeks)

- *Remain in shoulder immobilizer for 6 weeks*
- *May remove sling for physio, bathing and in controlled settings*
- *Codman's pendular exercises*
- *Self-assisted range of motion (SAROM) in all planes of motion without limits, as pain allows*
- **No active motion of the shoulder**
- *Initiate scapular stabilization exercises (upper/*lower trapezius, serratus anterior)*
- *Encourage active ROM of hand & elbow*
- *To begin general conditioning program of choice*

Phase 2 Initial mobilization (6-10 weeks)

- *Shoulder immobilizer completely off by 6 weeks*
- *Active ROM as pain allows – all planes*
- *Gentle stretching into terminal ROM by patient only*
- *Progress scapular stabilization*
    - *AROM on a stable scapular base*
    - *Correct scapulohumeral rhythm with active elevation*
    - *Initiate closed chain exercises (prone on elbows; 4 point kneel; standing, using wall, as anti-gravity strength allows)*

Phase 3 Strengthening (10-26 weeks)

- *Begin progressive strength program*
    - *Isometric strengthening*
    - *Progress to isotonic strengthening within pain-free ROM*
    - *Closed chain strengthening e.g. wall push-ups*
    - *Overhead strengthening once full ROM achieved & pain well controlled*
    - *Should not lift >15 lb. unless specified by physician*
- *Continue with stretching (therapist may now assist)*
- *Joint mobilization permitted*

All Arthroscopic Rotator Cuff Repair Rehabilitation Protocol (GROUP B: Early Mobilization)

Phase 1 Immobilization as needed (0-6 weeks)

- *Wear shoulder immobilizer for comfort and support as needed*
- *Wean from shoulder immobilizer as soon as pain/comfort allows*
- *Codman's pendular exercises*
- *Self-assisted range of motion (SAROM) in all planes of motion, without limits, as pain allows*
- ***Pain-free active range of motion permitted for ADLs***
- *Initiate scapular stabilization exercises (upper/*lower trapezius, serratus anterior)*
- *Encourage active ROM of hand & elbow*
- *To begin general conditioning program of choice*

Phase 2 Initial mobilization (6-10 weeks)

- *Shoulder immobilizer completely off by 6 weeks*
- *Active ROM as pain allows – all planes*
- *Gentle stretching into terminal ROM by patient only*
- *Progress scapular stabilization*
  - *AROM on a stable scapular base*
  - *Correct scapulohumeral rhythm with active elevation*
  - *Initiate closed chain exercises (prone on elbows; 4 point kneel; standing, using wall, as anti-gravity strength allows)*

Phase 3 Strengthening (10-26 weeks)

- *Begin progressive strength program*
  - *Isometric strengthening*
  - *Progress to isotonic strengthening within pain-free ROM*
  - *Closed chain strengthening e.g. Wall push-ups*
  - *Overhead strengthening once full ROM achieved & pain well controlled*
  - *Should not lift >15 lb. unless specified by physician*
- *Continue with stretching (therapist may now assist)*
- *Joint mobilization permitted*

Compliance Questionnaire

Date on which you last wore your sling: _____ / _____ / _____
dd mmm yyyy

At what times did you wear your sling? *(Please check all that apply)*

- ☐ I wore my sling at all times except for when I showered/bathed and did my exercises.
- ☐ I would remove my sling often throughout the day as long as my shoulder was pain-free. This included when I was up and about in addition to when I was resting.
- ☐ I would move my operated shoulder to help dress or wash myself.
- ☐ I would move my operated shoulder without assistance to do activities of daily living as long as it did not hurt.
- ☐ I would use my operated arm to do pretty much anything as long as it did not hurt.
- ☐ I slept with my sling on every night for the past six weeks.
- ☐ I would sleep with my sling on only if my shoulder hurt.

Please check off which group you were randomized to: *(Check one)*

- ☐ Sling for 6 weeks. No active shoulder movement allowed.
- ☐ Sling as needed. Shoulder movement allowed for activities of daily living.

Appendix Fig 1. (continued).