Early Mobilization Following Arthroscopic Rotator Cuff Repair: A Randomized Clinical Trial

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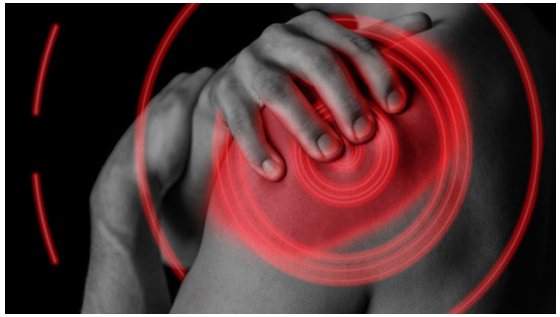
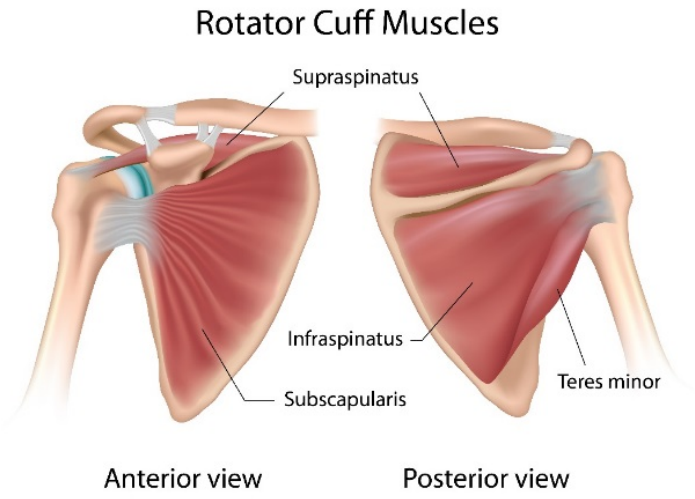


Rotator Cuff Disease



- Shoulder pain is common, ranging from **70-260/1000 persons in the general population**[1,2, 3,4]
- RC pathology the most common source of **shoulder pain and functional limitations**[5,6].
- Injuries can be insidious or traumatic
- **Symptoms**: Pain, Weakness and Limited Mobility
- **Treatment**: Non-op (PT, cortisone Injection) and Surgery if needed

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Rotator Cuff Repair Rehabilitation

Three Phases

- **Phase 1 – Protective** – Allows for rotator cuff healing (6 weeks)
- **Phase 2 – Recovery** – Reestablishes range of motion (6-12 weeks)
- **Phase 3 – Functional** – Progression to strengthening (12-24 weeks)

RETURN TO WORK AND MANUAL LABOUR AT 6 MONTHS

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Phase I - Unknown

- Is it better to move or immobilize?
- How much motion is too much?
- Is active motion safe?

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■ SHOULDER AND ELBOW

Early mobilisation following mini-open rotator cuff repair

A RANDOMISED CONTROL TRIAL

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This study compared the clinical outcomes following mini-open rotator cuff repair (MORCR) between early mobilisation and usual care, involving initial immobilisation. In total, 189 patients with radiologically-confirmed full-thickness rotator cuff tears underwent MORCR and were randomised to either early mobilisation (n = 97) or standard rehabilitation (n = 92) groups. Patients were assessed at six weeks and three, six, 12 and 24 months post-operatively. Six-week range of movement comparisons demonstrated significantly increased abduction (p = 0.002) and scapular plane elevation (p = 0.006) in the early mobilisation group, an effect which was not detectable at three months (p > 0.51) or afterwards. At 24 months post-operatively, patients who performed pain-free, early active mobilisation for activities of daily living showed no difference in clinical outcomes from patients immobilised for six weeks following MORCR. We suggest that the choice of rehabilitation regime following MORCR may be left to the discretion of the patient and the treating surgeon.

2015 RCT 189 pts – early active motion after mini-open rotator cuff repair

- earlier restoration of ROM at 3 months post operatively
- no increase in adverse events including asymptomatic re-tears

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Clinical Question

Is it safe to allow **EARLY ACTIVE ROM** during **Phase I** following ***arthroscopic*** rotator cuff repair?

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Study Design:

- **Randomized, controlled, single-blind, superiority trial**
- 7 fellowship trained shoulder surgeons from 2 sites, Edmonton, AB

Subjects:

Inclusion:

- 18 years and older
- **Failed 3 months of non-operative management**
- **Confirmed full thickness tear on MR or US**

Exclusion:

- Full thickness subscapularis or teres minor tear
- Bankart lesion requiring repair
- Excessive repair tension requiring abduction pillow
- Previous surgery
- Advanced glenohumeral arthritis

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Methods: Intervention (0 - 6 weeks)
Post-op Randomization into 2 Groups

Early Active ROM (EM)	Standard Immobilization (SR)
▶ Wear shoulder immobilizer ***as needed***	▶ Shoulder immobilizer for ***6 weeks***
▶ Pain-free ***active*** ROM allowed for ADLs	▶ ***No active shoulder motion***

Same rehab protocol for both groups

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Outcome Measurements

Baseline	• ROM, Pain (VAS),Strength, WORC, SF-36
6, 12 Weeks	• ROM, Pain (VAS), WORC, SF-36
6, 12, 24 Months	• ROM, Pain (VAS), **Strength**, WORC, SF-36
12 Months	• US Evaluation of Rotator Cuff Integrity

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Sample Size

Study Power

- Powered (σ=25°; α=0.05; β=0.2) to detect a 10º change in ROM between groups

Number needed to detect clinically significant difference

81 SUBJECTS PER GROUP

- 20% subject attrition

Number needed to detect clinically significant difference

100 SUBJECTS PER GROUP

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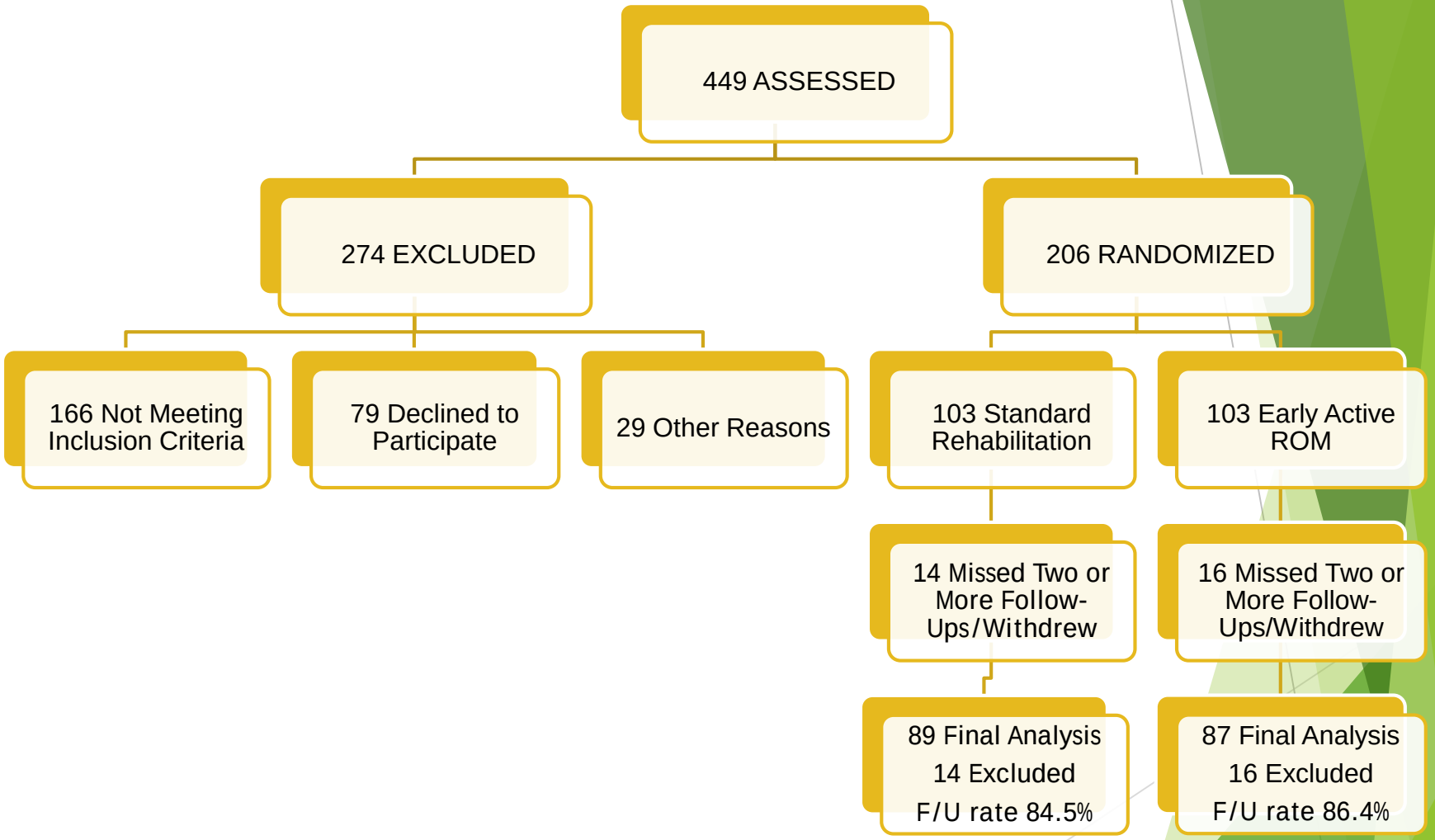
RESULTS



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Baseline (n=206)

	EM (n=103) (%)	SR (n=103) (%)	p - value
Mean Age (SD)	55.5 (8.3)	56.2 (10.1)	0.60
Males (%)	65 (63.1)	66 (64.1)	0.89
Working Fulltime (%)	68 (66.0)	61 (59.2)	0.65
Manual Laborers (%)	23 (22.3)	25 (22.3)	0.56
Right Side Dominant (%)	95 (92.2)	90 (87.4)	0.25
Dominant Side (%)	70 (68)	50 (53)	0.09

Groups demonstrated *no difference* in Baseline Characteristics

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Baseline Characteristics (n=206)

	EM (n=103)	SR (n=103)	p - value
Range of Motion (FF)	132	127	0.59
Strength (scaption)	14.2	13.9	0.55
Pain (Rest)	3.1	2.9	0.55
WORC	38.9	40.6	0.50
SF-36	72.1	71.7	0.84

Groups demonstrated *no difference* in Baseline ROM, Strength, Pain, or HRQL

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Tear Characteristics (n=206)

	EM (n=103) (%)	SR (n=103) (%)	
Small (<1.0 cm)	9 (8.7)	12 (11.7)	p = 0.473
Medium (1.1-2.9 cm)	62 (60.2)	61 (59.2)	
Large (3.0-4.9 cm)	26 (25.2)	28 (27.2)	
Massive (>5.0 cm)	6 (5.8)	2 (1.9)	

Groups demonstrated *no difference* in tear size

NOTE: >30% of patients had tears >3.0cm

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Results

- **Both Groups** demonstrated significant improvement in ***all outcomes measures*** at 24 months post operatively:

  - Range of Motion
  - Strength
  - Pain
  - WORC
  - SF-36

  } P <0.001

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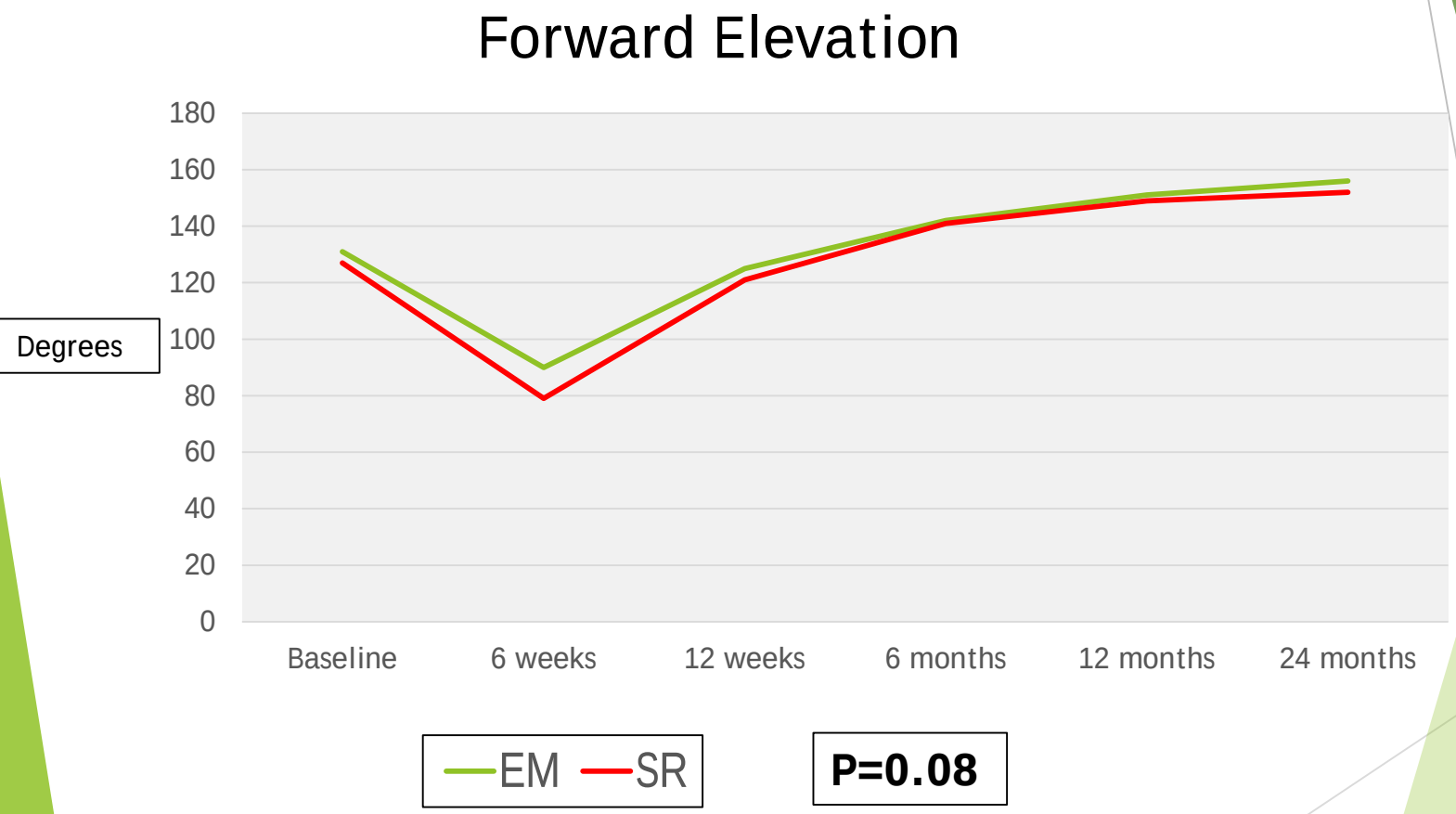
RESULTS: ROM (EM v. SR)



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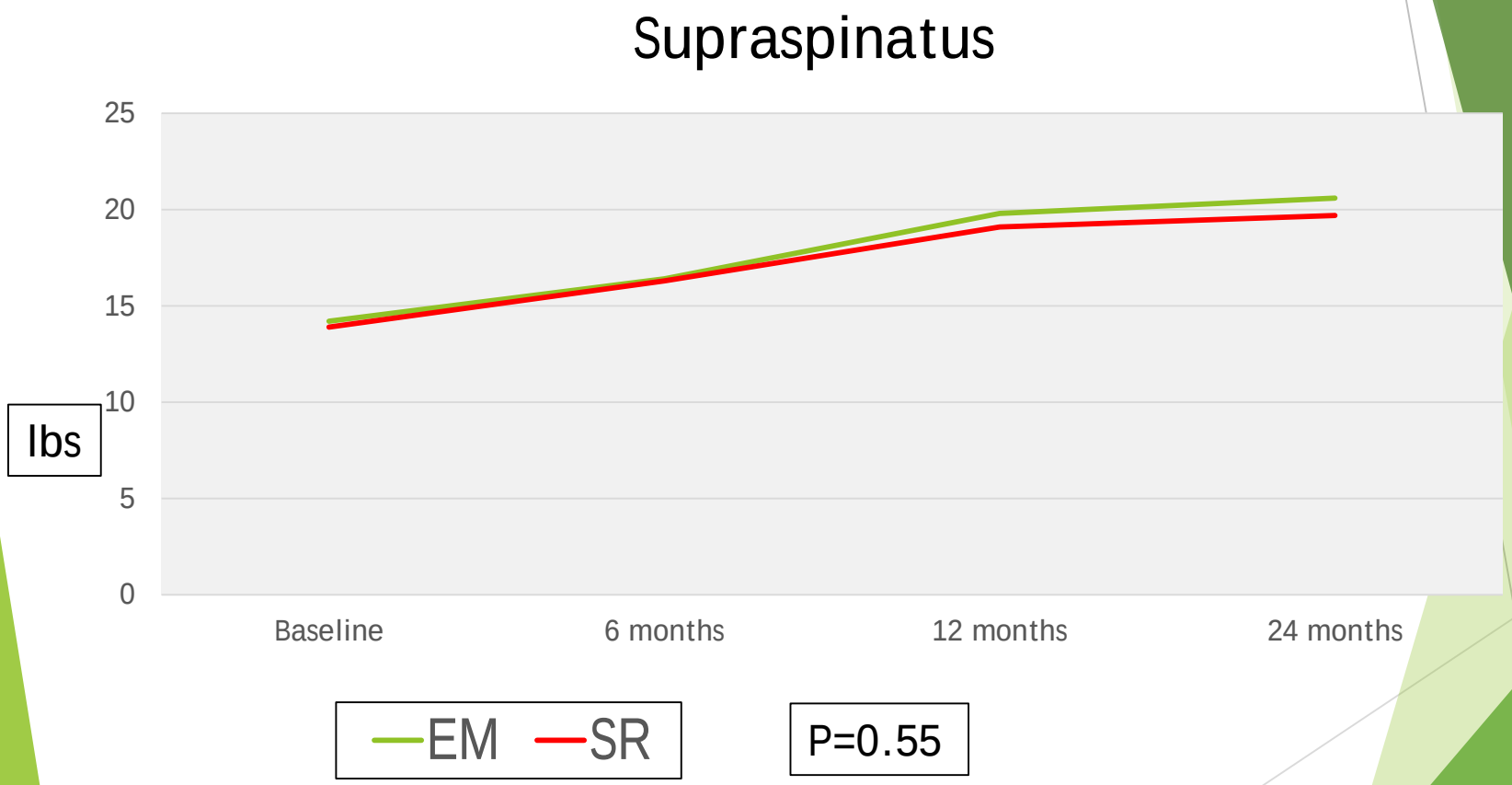
Results: **Strength (EM v. SR)**



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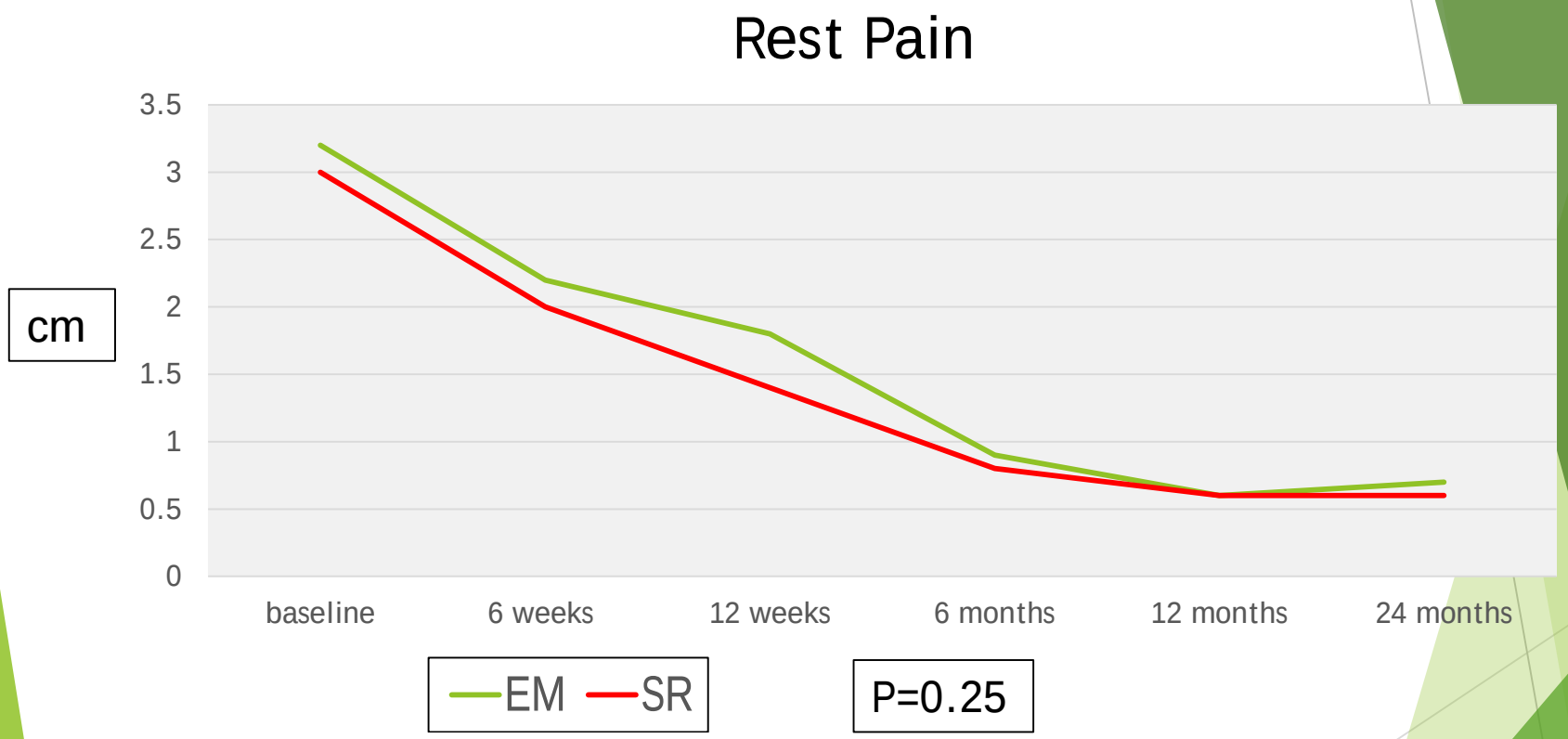
Results: PAIN (EM v. SR)



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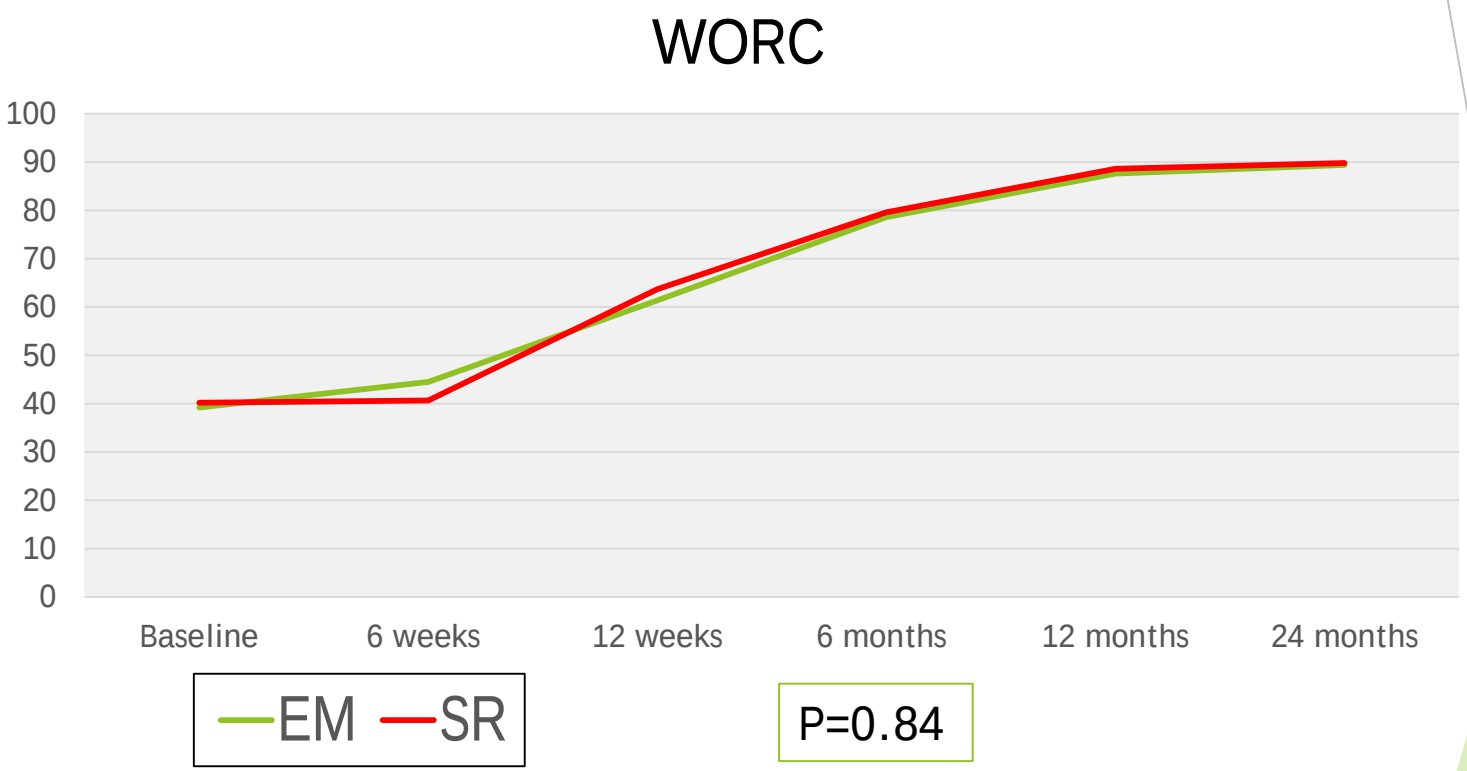
Results: HRQL (EM v. SR)



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Re-tears – **12 month US**

Ultrasounds in 165 (80%) participants: 79 EM *v.* 86 SR (p = 0.85)

Tendons	EM (n=79)	SR (n=86)	
Supraspinatus	19	21	p=0.987
Infraspinatus	1	1	
Supraspinatus and Infraspinatus	2	3	
Total	22	25	

The was *no difference* in re-tear rates between the 2 groups

Note: overall re-tear rate was 28.5%

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Non-compliance

Defined as:

- **SR group *not wearing* their sling** and ***performing active ROM***
- **EM group *wearing* their sling**

Standard Rehabilitation (SR) – 85%

Early Active ROM (EM) – 94%

p = 0.03

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Conclusions

Early active ROM following **arthroscopic rotator cuff repair**:

- Resulted in a ***similar*** restoration of **ROM** and a similar improvement in **PAIN**, **STRENGTH**, and **WORC**
- ***Did not*** have an impact on **ROTATOR CUFF RE-TEAR RATE**

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Conclusions

While early active motion following ARCR seems to be safe, it does not appear to offer any significant advantage to our standard rehabilitation protocol.

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Rotator Cuff Strength

STRENGTH	Time (months)	EM	SR	p - value
Infraspinatus	6	18	19	0.81
	24	25	25	
Subscapularis	6	27	27	0.67
	24	30	31	
Supraspinatus	6	16	16	0.55
	24	21	20	

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PAIN @ 24 months

PAIN	EM	SR	p - value
Rest	0.7	0.6	0.25
Activity	1.2	1.0	0.06
Night	0.9	0.7	0.34

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ROM	Time	EM	SR	p - value
Forward Flexion	6 weeks	90	79	0.08
	24 months	156	152	
Abduction	6 weeks	75	67	0.33
	24 months	153	152	
External rotation	6 weeks	22	20	0.09
	24 months	76	72	
Internal Rotation	6 weeks	14	12	0.50
	24 months	41	39	
Adduction	6 weeks	8	6	0.48
	24 months	20	20	
Scaption	6 weeks	80	76	0.44
	24 months	152	150	