Clinical Guidelines for CPM following Rotator Cuff Repair: Synchronized or Isolated Protocol

The primary goal of post-surgical rehabilitation following rotator cuff repair is to control pain, protect repaired tissue during the healing process, restore function, improve range-of-motion, restore strength and prevent a recurrence of symptoms.³⁰ During the initial healing phase following surgery, six weeks of passive range of motion is performed to protect the surgical site.^{16,17,18,23,25,26,28} Active and active-assisted exercise that result in a muscle contraction are not performed during the initial healing stage in order to protect the integrity of the repair. The amount of protection that is needed for healing is determined by the size or quality of the tear and the type of procedure used for the repair. Protecting tissue does not mean avoiding motion. Passive range of motion is utilized to prevent adhesions, prevent the detrimental effects of immobilization, reduce pain, reduce edema, reduce inflammation and stimulate soft tissue healing.^{1,3,5,9,12,15,16,18,19,25,26} For a growing number of surgeons continuous passive motion (CPM) has become the Gold Standard for passive motion therapy during this six week period.^{6,9,12,15,16,28} CPM has demonstrated enhanced tendon healing that is statistically superior to intermittent motion and counters the harmful effects of immobilization.^{4,7,13,29}

Passive Motion Analysis via EMG Studies

CPM is a true passive motion modality with muscle activity consistently below 5%⁸. Over-head pulley exercise, bar raise exercise, and physical therapist assisted exercise can have muscle contractions over 25% secondary to postoperative pain and apprehension.^{8,21} In contrast to these other exercises, CPM significantly (p=0.046) reduces postoperative pain.¹⁹ Pulley exercises and bar raises are active-assistive exercise and more appropriate for phase two of the rehabilitation program.

Rotator Cuff Strain Analysis During Scapular Elevation and Rotation

Arm position during passive exercise can also apply tension that is significant enough to result in a failure of the repair.^{14,31} A "Tension Free Zone" has been determined for passive range of motion exercises following rotator cuff repair.^{14,31} This zone consists of scapular elevation/abduction performed above 30° and external rotation up to 60° in a scapular plane.^{14,30} The Kinex Rotator Cuff CPM performs passive motion precisely in this plane. Over-head pulley exercise, bar raise exercise and pendulum exercise are routinely performed outside of this "Tension Free Zone" increasing the chances of a poor result or failure.

Home Exercise Compliance Analysis

Patient directed exercises (over-head-pulley, bar raise, pendulum) have been prescribed as an alternative for passive exercise performed at home. However, follow through of these exercises have been sporadic at best with reports of 30-60% of non-compliance.²² Several authors have reported that patient directed exercises are difficult to perform and are painful, which may in part explain the poor compliance associated with these exercises.^{2,8} Typically, the number of physical therapy clinic visits will increase to compensate for poor follow through of home exercise programs. In contrast, CPM compliance is reported at 90%-122%.^{19,27,28} The high compliance reported for home CPM may be due to the pain reducing properties associated with CPM.

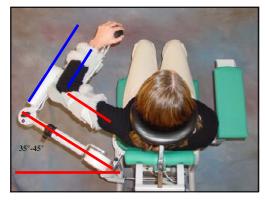
CPM Outcome Studies

Passive motion by a CPM device has been compared to passive motion by a physical therapist, passive motion by a trained third party, passive motion by patient self-directed home exercise and immobilization. CPM functional results are statistically equivalent or superior to physical therapy, manual passive motion by a third party, patient self-directed exercise or immobilization.^{5,9,12,1525,28} CPM is statistically superior in range-of-motion and pain outcome measures.^{19,25} Finally, CPM is more cost effective (saving 37% or \$990 per patient) than passive motion provided by a physical therapist.²⁸

Rotator Cuff Repair with and without Subacromial Decompression ± Distal Clavicle Excision

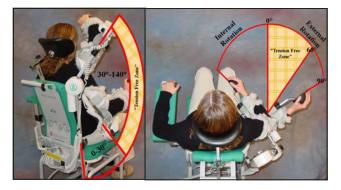
1. Set-up Guidelines

- The patient is fitted and instructed on use of the Kinex Shoulder CPM Device preoperatively if possible to improve compliance.
 - ⇒ Repeatable Anatomical Position: Kinex Head Positioner is aligned to the patient to ensure correct positioning each time the Kinex CPM device is used. Helps avoid repair stress.



- ⇒ Anatomical Shoulder Alignment: Kinex Multiplane Adjustable Arm helps ensure the CPM device is aligned with the shoulder throughout the arc-of-motion. Helps avoid stress on the repair.
- ⇒ Postsurgical Grade Computer Sensor: Kinex extra-sensitive sensor will reverse direction of movement if too much strain is detected; set between levels 15 (light) & 25 (heavy) depending on extremity size. Helps avoid stress on the repair.
- CPM use is initiated 24-48 hours postoperatively.^{9,18,19,24,25}
- Provide patient instruction and demonstration in the use of the device. Supervise patient understanding on use for ROM adjustments and machine on/off function.

 The Kinex Shoulder CPM Device is positioned in the "Tension Free Zone".
Passive glenohumeral joint motion in a nonimpingement and protective range.^{14,31}



- \Rightarrow Shoulder elevation is performed in the scapular plane.^{14,18,31}
- ⇒ Scapular elevation is 30° or above (Kinex device will not go below 30)°.^{14,18,31}
- \Rightarrow External rotation is 0°-60°.^{14,.31}
- CPM Device is <u>only</u> used in a pain free arc of motion to protect the repair.¹⁸
- Initial Range of Motion
 - \Rightarrow Scapular Elevation 30°-50° arc
 - \Rightarrow External Rotation 0°-10° arc

Note: Initial arc of motion will vary from patient to patient depending on the size of the tear and type of repair.

Protocol Option:

A. Synchronized CPM:

Scapular elevation is synchronized with external rotation (Kinex Shoulder CPM Synchronized Mode performs elevation and external rotation simultaneously in a safe arc).

Synchronized CPM Set-Up

(Synchronized Scapular Elevation & External Rotation)





0-2 Weeks 30-90° SE 0-20° ER

30-120° SE 0-40° ER

30-140° SE 0-60° ER

5-6 Weeks

SE= Scapular Elevation ER= External Rotation

3-4 Weeks

OR

B. Isolated CPM:

Scapular elevation is not synchronized with external rotation (Kinex Shoulder CPM ISO Mode performs elevation separately from external rotation [10:10 ratio]; elevation is performed with external rotation at 20°-30° and external rotation is performed with elevation at 30°). Scapular elevation/abduction is set at 0% and external rotation is set at 75% or 100%.

Isolated CPM Set-Up

(Separate External Rotation & Scapular Elevation)

0-2 Weeks 30-90° SE 0-20° ER

3-4 Weeks 30-120° SE 0-40° ER

5-6 Weeks 30-140° SE 0-60° ER



SE = Scapular Elevation ER = External Rotation

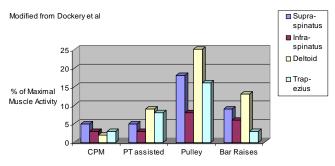
2. Wearing Schedule

- The CPM device is used for 6 weeks.^{16,25,28}
- The CPM device is used 3-6 hours a day.¹⁸
 - \Rightarrow Daily use guideline is 3-4 times a day for 1 or more hour intervals.
- Increasing Range of Motion Arc
 - \Rightarrow Scapular elevation is increased in a 2:1 ratio over external rotation.
 - \Rightarrow Scapular elevation is increased 2°-10° a day as tolerated in a pain free arc.
 - \Rightarrow External rotation is increased 1°-5° a day as tolerated in a pain free arc.

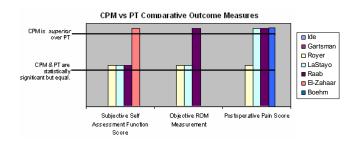
Examples:						
SE:	_ <u>2°</u>	_5°	10°			
ER:	1°	2°	5°			

3. End-Range Goals

- Scapular elevation end range goal is 140°-160°.
- External rotation end range goal is 40°-60°.
- Synchronized CPM: Scapular elevation is synchronized with external rotation (Kinex Shoulder CPM Synchronized Mode performs scapular elevation and external rotation simultaneously in a safe arc).



Muscle contraction in healthy shoulders by exercise type. Postoperative shoulders typically have higher contractions than depicted in the graph secondary to post-operative pain and apprehension with the exception of CPM because pain is diminished.



Peer-Reviewed Studies Evaluating Outcome Measures for the Efficacy of CPM Following Rotator Cuff Repair

Clinical Study	Self-Assessment Score	Range-of-Motion	Pain	Primary Finding
Evaluation and Cost Analysis in Use of Continuous Passive Motion After Rotator Cuff Tears, A Prospective, Randomized, Comparative Study; Royer et al (2000, Institutional Review Board at Henry Ford Hospital) Continuous Passive Motion after Repair of the Rotator Cuff,	Both the CPM and PT only group showed improvements in their scores at 6 weeks and 12 weeks: CPM (23.5 (pre-op), 43.6 (6 weeks), 66.9 (12 weeks); PT only 20.6 (pre- op), 38.7 (6 weeks) 61.7 (12 weeks). Statistical improvement for both groups with no statistical difference (p=.89). Both the CPM and manual PROM exercises by a 3rd party were	At one week flexion, abduction & internal rotation were all statistically higher in the CPM group. At the 6 and 12 week intervals both groups were statistically similar in their improvements (p=.05). Utilized Index of Shoulder and Elbow Surgeons. Both options revealed statistically significant improvements in	Pain was not measured during the first several weeks to evaluate differences in discomfort during the time of maximal pain. Both groups demonstrated significant reductions in pain at 6 and 12 weeks. The CPM group had a statistically significant	This postoperative protocol using CPM instead of PT provides a statistically equivalent result to those protocols that utilize PT. Given this result the case of CPM option is the more cost effective option. Both clinically effective protocols were compared. CPM cost significantly less then PT cost over the 6 week PROM only period. Savings of \$990 per case was realized. CPM was statistically equal to manual passive range of motion in all outcome
A Prospective Outcome Study; Lastayo et al (1998, Journal of Bone and Joint Surgery)	significantly successful pos-top rotator cuff repair (p>.05). Scores measured via the Shoulder Pain and Disability Index.	motion (p=.853).	reduction in pain compared to the non-CPM group (p=.046).	measures with the exception of pain reduction. CPM was statistically superior for reduction in pain compared to the manual group.
Early Results of Continuous Passive Motion After Cuff Repair, A Prospective, Randomized, Blinded, Controlled Study; Raab et al (1996, American Journal of Orthopedics)	Both the CPM group and PT group demonstrated statistically significant overall shoulder score improvements at 12 weeks. Shoulder score used in this study was developed by the author.		was seen in the CPM group for women p=0.0185 and	The primary result of this study indicates that both the CPM group and PT group improved over the 3-month period after the rotator cuff repair. The CPM group had statistically superior improvements in subjective pain scores and objective ROM scores.
The Value of the Continuous Passive Motion after Repair of the Rotator Cuff Tear in Athletes, An Arthroscopic Comparative Study; El-Zahaar et al (1996, Journal of Neurological and Orthopedic Medicine and Surgery)	Author reported superior results over a similar series by Tiborne et al (1986) in athletes by utilizing CPM post repair. The CPM group had 70.4% vs. 56% (good), 29.6 vs. 31% (fair) and 0% vs. 13% (poor) results. Good and fair results are considered satisfactory.		Reported a significant reduction in pain in this series. Pre-op 100% reported pain while post-op 78% reported no pain following the use of CPM. Pain reduction was not compared to Tiborne et al.	The primary result of this study indicated that the series with CPM resulted in superior outcomes compared to a similar series without CPM. This study was restricted to athletes (16-33 years of age).
Continuous Passive Motion in the Rehabilitation of the Surgically Reconstructed Shoulder, A Preliminary Report,; Craig (1986, Orthop Trans)	Pain was the only self reported measure.	ROM was reported in the time it took a patient to reach 130° of passive elevation and 35° of passive external rotation in which time they were released from the hospital. The CPM group achieved acceptable ROM by day 6 compared to the average 12 days for the non-CPM group.	The CPM group reported less pain compared to the non- CPM group.	This was an initial study on CPM use following repair of the rotator cuff. This study demonstrated that early passive motion with CPM is safe, reduces pain, and speeds recovery.

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