AN ORIGINAL STUDY

Early Results of Continuous Passive Motion After Rotator Cuff Repair

A Prospective, Randomized, Blinded, Controlled Study

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ABSTRACT

Purpose: To determine the effect of continuous passive motion (CPM) on rotator cuff repair (RCR).

Methods: A prospective, randomized, blinded, controlled study was performed on all patients undergoing primary RCR between December 1992 and January 1994. A preoperative "shoulder score" was calculated for each patient based on four scales: function (50%), pain (20%), muscle strength (15%), and range-of-motion (ROM) (15%). A standard questionnaire and single blinded physical therapist were employed. At the time of operation, patients were randomized into the control group (postoperative physical therapy [PT]) or the study group (PT plus CPM). Postoperative shoulder scores were then calculated by repeat questionnaires and physical examinations at 3-month follow-up.

Results: Twenty-six patients (12 control, 14 study; 24/26 tears were full thickness) underwent RCR and completed 3-month follow-up. Both groups had similar age and sex distributions; the study group had larger tears than the control group. All patients underwent RCR and subacromial decompression. No statistically significant difference in shoulder score increases was seen between the two groups at follow-up. A statistically significant ($P = 0.0138$) increase in ROM subscore was seen in the study group. Other subscores showing improvement with CPM included pain relief in female patients ($P = 0.0185$), and pain relief in patients ≥60 years of age ($P = 0.0364$).

Conclusions: CPM has no effect on overall shoulder score at 3-month follow-up. CPM has a beneficial effect on ROM for all patients, as well as on pain relief in female patients and patients ≥60 years of age.

Repair of a torn rotator cuff is performed to decrease pain, increase function, and improve range of motion.[1] Residual postoperative pain and stiffness can remain a problem despite adequate repair.[2] Continuous passive motion (CPM) has been used in the postoperative period after surgical procedures involving the knee. In 1960, Nickel, as cited by Maloney et al,[3] employed skeletal fixation pins in the distal femur and proximal tibia in a patient after synovectomy of the knee. A machine then moved the knee very slowly; this procedure was not published. In the 1970s and 1980s, Salter and colleagues[4,5] demonstrated the beneficial effects of CPM on joint function. Coutts et al[6] reported on early CPM machine design and results for the knee. Maloney et al,[3] in a prospective study in 1989, showed no statistically significant differences in late range-of-motion (ROM) between 146 knees treated with or without CPM after total knee arthroplasty (TKA); however, ROM was achieved earlier with CPM. Colwell and Morris,[7] in a 1992 prospective randomized study involving 22 TKA patients, showed decreased use of narcotic analgesics and decreased length of hospital stay with the use of CPM. Theoretically, CPM could improve the results of rotator cuff repair. To our knowledge, no prospective, randomized, blinded, controlled studies have been conducted to determine if CPM is effective in improvement of shoulder function after rotator cuff repair.

The purpose of this investigation was to determine the effect of CPM on functional outcome after rotator cuff repair. Ernest Codman,[8] in his text *The Shoulder*, described rupture of the supraspinatus tendon for the first time in the American literature. He also described his "end-

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result idea," which, in his own words, was "merely the common sense notion that every hospital should follow every patient treated long enough to determine whether or not the treatment has been successful, and then to inquire, 'if not, why not?' with a view to preventing similar failure in the future." This investigation addresses the early (3-month) postoperative effects of CPM on functional outcome after rotator cuff repair. This outcomes research is based on Codman's end-result idea.[9]

PATIENTS AND METHODS

A prospective, randomized, blinded, and controlled study was designed to determine the effect of CPM on functional outcome after rotator cuff repair (Figure 1). All patients undergoing rotator cuff repair between December 1992 and January 1994, regardless of surgical method or cuff tear size, were eligible to be enrolled in this study. All rotator cuff repairs were performed at two community hospitals affiliated with an orthopedic residency program. Approval was obtained from the appropriate committee for research involving human subjects.

Prior to rotator cuff repair, demographic information from each patient was collected by a questionnaire form and filed in a database managed by the research coordinator. Each patient was given a copy of the study protocol and was requested to sign an informed consent for participation in the study. Patients retained the option to drop out of the study at any time.

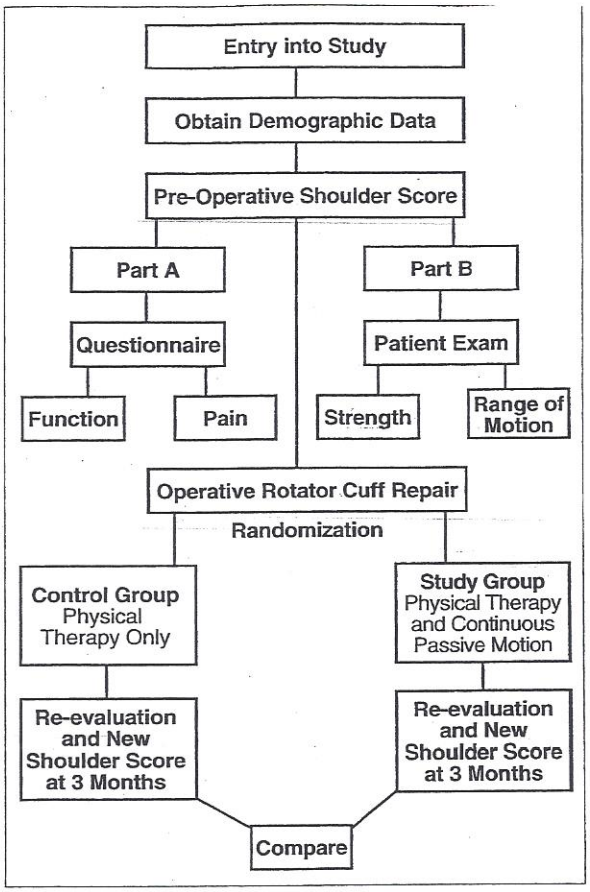

Figure 1. Flowchart of study.

Table I. Shoulder Score Form for Patients With Rotator Cuff Injury: Patient Questionnaire

Function (50 points)

Activity	Normal	Slightly Difficult	Moderately Difficult	Very Difficult	Need Help	Can't Do
Combing hair	5	4	3	2	1	0
Reaching back pocket	5	4	3	2	1	0
Washing opposite armpit	5	4	3	2	1	0
Using fork/knife/spoon	5	4	3	2	1	0
Wiping after toilet	5	4	3	2	1	0
Dressing	5	4	3	2	1	0
Sleeping on shoulder	5	4	3	2	1	0
Working around house	5	4	3	2	1	0
Shaking hands	5	4	3	2	1	0
Brushing teeth	5	4	3	2	1	0

Pain (20 points)

	When Using Arm	When Arm at Rest
None: No pain	10	10
Mild: Occasional pain; no medication or ice	8	8
Moderate: Tolerable pain; use heat/ice after use	5	5
Bad: Pain requiring nonnarcotic medication	3	3
Severe: Pain requiring narcotic medication	1	1

Table II. Shoulder Score Form for Patients With Rotator Cuff Injury: Physical Examination

Motion	Normal	Good	Fair	Poor*	Trace	None
		Muscle Strength (15 points)				
Forward flexion	5	4	3	2	1	0
Abduction	5	4	3	2	1	0
External rotation	5	4	3	2	1	0

Range of Motion (15 points)†	Maximum
Forward flexion	4
Abduction	4
External rotation	3
Internal rotation	3
Horizontal shoulder adduction	1

*Moves with gravity eliminated.
†1 point per 30° motion.

Preoperative evaluation included determination of a shoulder score with a maximum of 100 points. Subscores included function (50 points), pain (20 points), muscle strength (15 points), and ROM (15 points). Numerical scores only were used; no attempt was made to define categories (excellent, good, etc). The shoulder score was based in part on portions of the Hospital for Special Surgery System for Assessing Shoulder Function[10] and the Mayo Clinic Pre and Post Operative Analysis of the Shoulder (Unpublished Data, 1992). The subjective portion of the shoulder score was calculated from a questionnaire filled out by the patient preoperatively (Table I). The objective portion of the shoulder score was calculated based on a physical examination performed by a single physical therapist (Table II). This shoulder score emphasizes functional results and pain relief while still including ROM and strength. All patients received preoperative roentgenograms. Computed tomography, arthrograms, and MRI examinations varied by attending physician.

Envelopes, which contained a slip of paper with either "CONTROL" or "STUDY" written on it, were sealed prior to the beginning of the study in a 50-50 proportion. An envelope was randomly selected and given to the operating room circulating nurse at the end of each operation. Randomization was carried out by opening the sealed envelope at the conclusion of the operation. In this manner, the operating surgeon was blinded to the patient's postoperative group assignment while performing the rotator cuff repair. If, for any reason, the surgeon elected not to enroll the patient in the study, based on intraoperative findings or results, this decision was made BEFORE the envelope was opened at the conclusion of the case. The patient's group assignment, control or study, was filed in the database. In addition, a surgical data form was completed detailing cuff tear size, repair method, cause of injury, and preoperative studies.

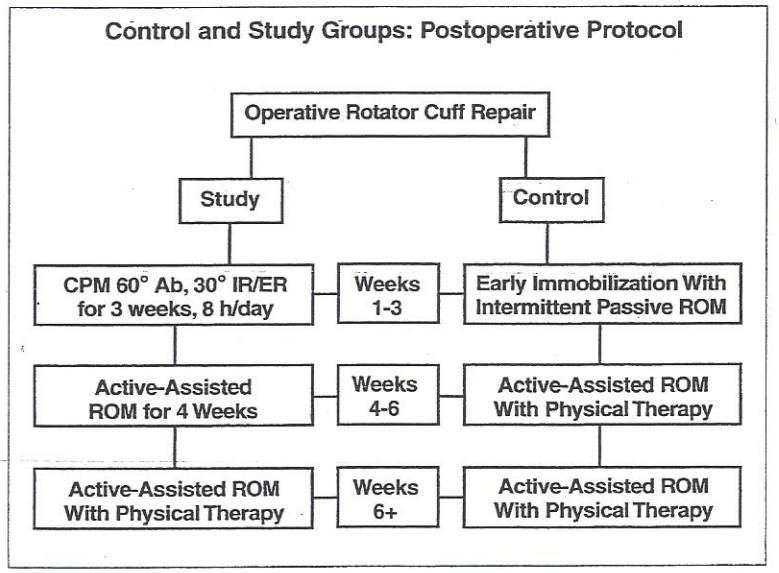

Figure 2. Postoperative protocol. ROM = range of motion; CPM = continuous passive motion; Ab = abduction; IR/ER = internal rotation/external rotation.

Control Group

Patients in the control group underwent a standard postoperative physical therapy protocol (Figure 2). They were then reevaluated, and a new shoulder score was calculated at 3-month follow-up. This required a repeat questionnaire and physical examination. Shoulder score data at 3-month follow-up was then filed in the database.

Study Group

Patients in the study group underwent a similar postoperative physical therapy program, but with the addition of shoulder CPM, commencing in the recovery room and continuing for 3 weeks (Figure 2). CPM units (Therakinetics, Mount Laurel, New Jersey) were supplied at no cost to the patient or to the hospital, and were set up in the recovery room. A standard postoperative CPM order was used for all patients, as follows: "Position shoulder in 30° horizontal adduction. Begin with arm abducted 60° in neutral rotation. Progress as tolerated within pain-free limits to maximum abduction of 120°, maximum internal rotation of 15°, and maximum external rotation of 30°. All movements are to be within pain-free limits. If any pain occurs, decrease ROM to pain-free interval. Begin in recovery room; continue 8 hours per day for first 3 weeks post-op." While the patients were in the hospital, CPM units were managed by the hospital orthopedic technicians. Home CPM units were managed by the vendor representative.

Patients in the study group were reevaluated, and a new shoulder score was calculated at the 3-month follow-up. This required a repeat questionnaire and physical examination. Shoulder score data at follow-up were then filed in the databank. During follow-up evaluation, the physical therapist performing the evaluation was blinded to whether the patient was in the study or in the control group. Comparison of the study and control groups at 3 months postoperatively determined the effect of CPM in the rehabilitation of rotator cuff repairs.

Study Population

Between December 1992 and August 1993, 65 primary rotator cuff repairs were performed at the two hospitals included in this study; 41 patients were enrolled in the study and gave preoperative consent. Of the 24 patients who underwent rotator cuff repair but did not enter the study, 22 patients refused to enter the study; 2 patients' physicians felt that their pain threshold was too low to participate. Of the 41 patients enrolled in the study who underwent rotator cuff repair, 32 were randomized into one of the two groups—control or study. Nine patients were withheld from the study based on intraoperative findings or per the attending physician's desire (ie, the repair was "too tight" [n = 7] or no tear found [n = 2]). Of the 32 patients remaining in the study at this point, 26 completed the CPM or control protocol to the 3-month follow-up visit. Of the 6 patients who did not, 1 patient was taken out of CPM on postoperative day [illegible] work at 6 weeks after surgery and sustained a repeat tear; 3 patients never returned for follow-up; and the preoperative evaluation forms on 1 patient were lost.

The final cohort of patients followed up for 3 months totaled 26 patients. After randomization, 12 patients were placed in the control group (conventional rehabilitation) and 14 were placed in the study group (conventional rehabilitation plus CPM).

Statistical Analysis

Preliminary data analysis consisted of the calculation of descriptive measures, such as means and standard deviations, as well as correlations between age and outcome measures. The second stage of data analysis consisted of applying *t* tests and chi-square tests to evaluate the influence of potential confounding variables. The final stage of analysis contained several analysis-of-variance models designed to evaluate specific research questions. For example, to examine the primary research question of whether or not CPM treatment was different from no CPM, a two-factor, split-plot analysis of variance was employed. The between-subjects factor was group, consisting of CPM and no CPM; and the within-subjects factor was time (before and after treatment). Additional split-plot designs were used to examine specific research questions regarding the effects of age, size of tear, and sex. All outcome measures were converted to a percentage score to help adjust for missing data before analysis. Statistical significance was set at the 5% level.

RESULTS

Patient Characteristics

Both groups had similar age and sex distributions (Table III). There were two previous musculoskeletal injuries involving the affected upper extremity in the control group: cervical discectomy and glenohumeral dislocation. In the study group, one patient had suffered a childhood wrist fracture involving the affected extremity, and one patient had a previous "hand fracture." No affected shoulder in either group, control or study, had undergone any type of previous operation. Hobbies and work types were similar for the two groups.

Clinical Descriptions

Operative findings (Table III) revealed that the study group had patients with larger tears than the control group. Tears were graded according to the classification system of Hawkins[11]: (small tear—

Table III. Characteristics of Patients With Rotator Cuff Repair		
Variable	Control	Study
No. of patients	12	14
Age (y)	58	54
Sex (% M/F)	75/25	64/36
Small or medium tear (%)	9 (75)	6 (43)
Large or massive tear (%)	3 (25)	8 (57)
Repair with bony trough (%)	10 (83)	12 (86)
Suture anchor device (%)	3 (25)	1 (7)
Subacromial decompression (%)	12 (100)	14 (100)

diameter <1 cm; medium, 1 to 3 cm; large, 3 to 5 cm; and massive, >5 cm). All tears were full thickness except for one partial, medium-sized tear in the study group and one transverse, partial-thickness tear in the control group. All patients underwent subacromial decompression as part of the procedure. All tears were chronic tears. Repair was carried out either by direct suture repair or by repair using a bony trough and tunnels. Suture anchor devices were employed as well.

Research Findings

Preoperative and 3-month follow-up shoulder scores for the two groups—control and study—as well as the subscores for function, pain, strength, and ROM, are displayed in Table IV. The primary results of this study indicate that the overall shoulder score for both the control and the study groups improved over the 3-month period after rotator cuff repair. The difference in gain for the two groups, however, was not statistically significant. The control group began and ended with a lower overall shoulder score than the study group. Gains among subscores—with no statistically significant difference in gains—were seen for the subscores of function, pain, and strength. However, a statistically significant ($P = 0.0138$) improvement was seen in the ROM subscore of the study group compared with that of the control group. Specifically, the control group ROM subscore, which started higher, decreased over 3 months, and ended lower than that of the study group, which improved over time.

Further statistical evaluation was carried out to determine if sex, tear size, and age subgroups were affected by CPM (Table IV). The results of analysis by sex showed no statistically significant increases

Table IV. Effect of Continuous Passive Motion on Rotator Cuff Repair										
	Shoulder Score		Function		Pain		Strength		ROM	
Group	Preop	3 Month	Preop	3 Month	Preop	3 Month	Preop	3 Month	Preop	3 Month
All										
Control (n=12)	63	73	68	81	46	68	72	73	60	50
Study (n=14)	68	83	75	88	52	88	75	78	56	66*
Male										
Control (n=9)	64	75	69	82	42	72	77	77	64	55
Study (n=9)	71	86	78	91	60	90	78	81	57	70*
Female										
Control (n=3)	59	65	63	79	58	57	56	60	49	36
Study (n=5)	62	78	71	83	38	85*	69	73	55	57
Small/medium tears										
Control (n=9)	64	71	69	79	48	67	72	73	59	51
Study (n=6)	73	85	81	89	53	90	80	79	68	74
Large tears										
Control (n=3)	60	76	63	88	40	73	71	71	62	47
Study (n=8)	64	82	71	87	52	87	71	77	48	59
Age <60 years										
Control (n=7)	63	78	68	85	38	76	76	78	66	58
Study (n=9)	72	85	80	87	52	89	79	84	63	70
Age ≥60years										
Control (n=5)	63	65	67	76	57	58	65	65	52	39
Study (n=5)	60	79	67	86	52	87	67	67	44	57

ROM = range of motion; Preop = preoperative.

in overall shoulder scores or subscores, for the study group compared with the control group. However, a statistically significant ($P = 0.0185$) improvement in pain subscore for women was seen with the use of CPM; as well as in the ROM subscore for men with CPM ($P = 0.0128$). The results of analysis by tear size showed no statistically significant increases in overall shoulder scores or subscores for the study group compared to the control group. Striking improvements were seen, however, in ROM subscores for small/medium and large/massive tears treated with CPM, as opposed to the control group, whose scores actually decreased. These improvements were not statistically significant due to small sample size.

Finally, the patient cohort was divided using a cutoff age of <60 and ≥60 years. Again, no statistically significant increase in overall shoulder score was seen for the study group compared with the control group. A statistically significant ($P = 0.0364$) improvement in pain relief was seen in the subgroup of patients ≥60 years of age who received CPM.

DISCUSSION

ROM does seem to be improved by the use of CPM in the postoperative period. A statistically significant improvement in ROM was seen with CPM in the entire patient cohort (n = 26) and in the subgroup of male patients (n = 18). Other subgroups showed improvement as well, but these differences were not statistically significant. Lack of statistical significance in these subgroups (female sex, tear size, and age) was most likely due to small sample size. The most likely explanation for this beneficial effect is the prevention of intra-articular and musculotendinous adhesions in the early postoperative period with the use of CPM.

Pain relief was improved in two specific subgroups: women (n = 8) and patients ≥60 years of age (n = 10), and this was to a striking degree. Several patients reported using the CPM to obtain pain relief outside their assigned times. The cause of this beneficial effect is unknown.

Despite beneficial effects on ROM and pain relief, the overall shoulder score did not improve in a statistically significant manner for either the entire group or any of the subgroups. This must be kept in mind, and perhaps CPM should be reserved at this time for female patients, or patients ≥60 years of age; as well as patients in whom maximum ROM return is highly desirable.

Whether or not the previously mentioned improvements seen in the study group persist remains to be seen at 2-year follow-up, currently in progress. There are certain aspects of the study design that [illegible] size was only 26 patients, winnowed from an operative group of 65 patients. Twenty-two patients refused to enter the study for various reasons, including refusal to make an extra visit to the therapist for preoperative evaluation, difficulty understanding the study, fright, and plain lack of interest. As the point of entry into the study was usually the attending physician's office, and in particular, the office nurse, these efforts partly determined the success or failure of entering the patient into the study. Seven patients were withheld from the study because the surgeon felt the repair was too tight, however, abduction of 60° in the CPM machine should actually reduce tension on the repaired rotator cuff. Caution is required, however, when moving in and out of the CPM machine. With a longer study period, and a greater sample size, the quality of the study would be improved.

Second, the rehabilitation protocols as detailed in Figure 2 were merely guides suggested to the various surgeons in the study. The study directors had no control over the actual rehabilitation provided to the patient; only the use or absence of CPM. These protocols were devised as an acceptable guide for all surgeons participating in the study. Surgeons wishing a long period (up to 4 weeks) of postoperative immobilization did not participate in the study. It would be desirable to have the study repeated by one surgeon with a high volume of rotator cuff repairs with absolute reproducible control of the rehabilitation program so that rehabilitation is not a variable.

Third, a 3-month follow-up period gives no information on the long-term effect of CPM after rotator cuff repair. However, at 3 months after surgery, patients may be approaching return to work, and the early results could be important in this regard. Furthermore, early pain relief and quicker improvement in ROM could be quite important to the individual patient. Two-year follow-up studies are in progress.

One patient did experience quite a bit of pain up to postoperative day 6 while using CPM and was therefore removed from the machine and dropped from the study. Another patient was returned to work at 6 weeks by the rehabilitation representative, inducing a repeat tear.

CONCLUSION

Continuous passive motion had no effect on overall shoulder score at 3-month follow-up. CPM had a beneficial effect on ROM for all patients, as well as for pain relief in female patients and patients ≥60 years of age.

In summary, this study would be improved if performed by a single surgeon, with standard rehabilitation protocols, in large numbers, with long follow-up, and no loss of patients in the follow-up period. To the extent that these variables could be controlled, they were.

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Evaluation and Cost Analysis in Use of Continuous Passive Motion after Repair of Rotator Cuff Tears

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This study was approved by the Institutional Review Board at Henry Ford Hospital in Detroit, Michigan

ABSTRACT: **Continuous passive motion (CPM) devices used as rehabilitation tools following joint surgery has been debated in various studies, examining both its effectiveness to rehabilitate the joint, and its ability to contain costs. The purpose of this prospective, randomized study was to compare the functional outcome and cost of the first six weeks of rehabilitation with the use of a shoulder CPM device to provide passive motion versus that provided by a physical therapist after rotator cuff repair surgery. Postoperative therapy with the CPM device yielded similar results when compared to physical therapy in this study. The use of the CPM device for the first six weeks is less expensive than physical therapy; the total saving for this period is $990 per patient. Thus, the CPM device was a more cost-effective treatment than physical therapy within this protocol.**

As costs continue to increase in healthcare treatment, both new and old options are being scrutinized, not only for their efficacy, but for cost-effectiveness. One option for decreasing the total cost of rotator cuff repair is use of a continuous passive motion (CPM) device after rotator cuff repair instead of physical therapy for the first six weeks. However, its effectiveness is still unclear with regard to rotator cuff repair. The purpose of this prospective, randomized study was to examine the method of passive motion delivery during the first six weeks of rehabilitation following rotator cuff repair surgery. The use of a CPM device versus that provided by a physical therapist was compared, focusing on functional outcome and cost.

In 1970 after significant observation and research, Salter elaborated on the concept of CPM to accelerate the healing of articular tissues[11]. Animal studies have confirmed a beneficial effect of CPM on the healing of articular cartilage, tendon, and ligaments as well as a faster re-absorption of hemarthrosis[5]. Claimed clinical benefits include good compliance, decrease in postoperative pain, maintenance of achieved range of motion, and decreased incidence of complications[3].

Conceptually, CPM has been applied in postoperative rehabilitation of multiple procedures especially of the knee and shoulder. Its most common postoperative use is after total knee arthroplasty, first started in 1980[11]. The results have been mixed with many contradictory observations. Pope in 1997 found that the use of CPM after total knee arthroplasty offered no improvement in function or range of motion, use of analgesics, or blood loss[9]. In contrast, a metaanalysis study found significant improvements in active knee flexion, reduced hospital stays and decreased use of analgesics[1].

More recently, the use of CPM devices has been applied in rotator cuff repair rehabilitative protocols[6,8]. Passive range-of-motion exercises in the early postoperative period help to protect the repair and prevent adhesions[2]. An electromyography study of shoulder passive motion modes found that physical therapist-assisted exercise and a CPM device were more passive compared to self-assisted pulley and bar raise exercises[4].

Two recent studies have evaluated the functional outcome with use of CPM after rotator cuff repair. Raab et. al.[10] compared two groups comprised of twenty-six patients. The first group was treated with physical therapy, and the second group was treated with a combination of physical therapy and CPM device, which was started in the recovery room, and continued for three weeks. The study concluded that CPM had no overall effect on shoulder function at three months when combined with physical therapy. However, they did find a beneficial effect of CPM on the patients' shoulder range of motion and reduced pain in sub-groups[10]. Lastayo et. al.[7] also conducted a comparison study. The control group had their passive range of motion exercises performed manually by trained relatives or home nurses. The study group used the CPM device everyday for four weeks. This study found no statistical differences between the groups with respect to range of motion or isometric strength. However, they did find a statistically significant reduction in postoperative pain in the CPM group[7]. Neither study examined the results of CPM compared to a group receiving only physical therapy, or for longer than four weeks.

The current environment of health care necessitates not only that treatment be clinically effective, but that new treatments must also be cost effective. The highest cost of rehabilitation after rotator cuff repair occurs in the first several months when the patient must obtain physical therapy for passive range of motion. A CPM device has its own costs including patient educa-

tion, setup, and rental. These costs must be considered and compared to that of physical therapy visits.

A comparative cost analysis has been done for CPM use after total knee arthroplasty (TKA). Ververeli et. al.[12] found that using the CPM device after TKA resulted in a significant increase in active flexion while decreasing the necessity of manipulation for lack of motion in the non-CPM group[12]. Five manipulations under anesthesia were needed at a cost of $937 per patient without CPM. Thus, the CPM device was cost effective in this study. A different study by Lastayo et al.[7] theorizes that the cost of CPM is higher because of a failure to achieve an improved functional outcome with CPM compared to the passive motion provided by home-care nurses or trained family members. However, the study does not support its conclusions with comparative results of physical therapy nor provide real dollar figures. The purpose of this prospective, randomized, comparative study was to determine the effect of CPM on the functional outcome and cost of rehabilitation after rotator cuff repair.

TABLE I
PATIENT DEMOGRAPHICS

Variable	Continuous Passive Motion (N=17)	Physical Therapy (N=17)
Age *(yrs.)*		
Average	60	55
Range	37-76	37-73
Gender†		
Male	4	5
Female	13	12
Side of operation†		
Dominant	10	9
Non-Dominant	7	8
Size of tear†		
Small	6	6
Medium	8	9
Large	3	2

† The values are given as the number of patients

Materials and Methods

Patients

This study included thirty-four patients (thirty-four shoulders) who underwent rotator cuff repair between August of 1999 and November of 2000 (Table I). Nineteen were on the dominant arm and fifteen were on the non-dominant arm. Five of the tears were large (above three centimeters), seventeen were of medium size (between two and three centimeters) and twelve were small (below two centimeters). These were measured visually by the surgeon at the time of surgery. Those who had a previous rotator cuff repair on the affected side were excluded. All patients signed the informed consent for surgery and the Institutional Review Board (IRB) consent form.

The patients were assigned randomly to one of two groups for post-operative management: CPM (seventeen patients) or physical therapy (seventeen patients) for their passive range of motion during the first six weeks. There were twenty-five women and nine men. The average age was fifty-five years old (range, thirty-seven to seventy-six). The patients' results were recorded for the first three months after repair. The patients were randomly assigned to either the CPM group or the physical therapy group by a list generated through numbers drawn from an envelope. Two patients were dropped from the study; both were from the CPM group. One was dropped due to postoperative myocardial infarction, and the second wished to receive her physical therapy at an outside site.

Operative Technique

All of the rotator cuff repairs were completed by the same surgeon (P. K.) in an arthroscopically assisted mini-open fashion under general anesthesia. This procedure to date has yielded good results. The arthroscope was first placed into the glenohumeral joint. This allowed for inspection of intraarticular pathology, including evaluation of the articular side of the rotator cuff. Debridement of the subacromial space is then completed with a thermal ablator, or shaver blade, and acromioplasty accomplished with the high speed burr. Examination of the bursal surface of the rotator cuff was done to confirm the tear.

Once a tear was confirmed, a number one proline was passed through the free end of the rotator cuff with an intraarticular suture punch, and brought out through the lateral portal. The portal was then enlarged to approximately three centimeters in length through the lateral mini-arthrotomy approach, providing access to the greater tuberosity. The greater tuberosity was decorticated with the ronguer. A burr was used to create a trough for placement of three tunnels into the bone using a curved sharp awl and hooked crochet to pass three number one unbraided non-absorbable sutures. The sutures were passed through the free end of the rotator cuff tendon using a Mason-Allen stitch. Suture anchors were used as an alternative to the trough as deemed necessary. The sutures were tied, attaching the rotator cuff to the greater tuberosity. The repair was evaluated by moving the shoulder. The deltoid was then repaired, and skin portals sutured. Dressing was applied. The arm was placed into either a regular or abduction sling. This was determined by the staff surgeon at the time of the repair based on the tension of the repair. Cold therapy was applied over the dressing.

Postoperative Management

Currently used postoperative management was standardized for the patients in the study. The patients

all stayed in the twenty-three hour inpatient unit in their slings with the cold pack in place. Pain control was through the use of parenteral narcotics while inpatients, and was switched to oral medication upon discharge the next day. Toradol 10mg orally for four days was prescribed for all patients unless contraindicated by existing medical conditions. The oral narcotic regimen varied by the needs of the patient. On postoperative day number one, the patient had the dressing changed by the physician and was discharged home.

The patients assigned to the CPM group and their families were instructed on the use of the CPM device, Orthologic Corporation, prior to the surgery. They were instructed to begin using the CPM device for passive abduction, and external rotation of the shoulder on postoperative day number two. Each session using the device was to last for two hours, occurring in the morning, afternoon, and evening. The patients used the device for six weeks postoperatively. Compliance with the use of the CPM device was verified by a visit to the patients' home once per week to read the monitor on the machine. At this time patient and family questions about the device were answered. The CPM device was supplied to the patient at no cost. It was discontinued after the sixth week.

Patients assigned to attend physical therapy did so for the passive range of motion two times per week for an average of one hour per visit for the first six weeks postoperatively. They each followed a standardized physical therapy protocol. This included modalities as well as instruction on home exercises.

After the first six weeks both groups were placed into physical therapy and began active range of motion, active assisted, and passive range of motion exercises as well as strengthening per protocol.

Outcome Measures

Both groups were asked to assess their pain and functional ability by filling out the Shoulder Index of Shoulder and Elbow Surgeons preoperatively, at six weeks, and at three months postoperatively. Each participant had their active range of motion measured in flexion, abduction, external rotation with the arm at zero degrees, and internal rotation with the arm at ninety degrees at the preoperative visit and at three months. Their passive range of motion was similarly measured at one week, six weeks, and three months. Their strength in active flexion, abduction, and external rotation was measured at the preoperative visit and three months.

Statistical Methods

Using the data gathered through the Shoulder Index, range of motion, and strength measurements, a statistical analysis was done to evaluate and compare the functional results of the control and study groups. Based on those results, a comparative cost analysis of using the CPM device versus physical therapy in the context of those results was completed.

Patients were randomized into one of two groups: physical therapy and CPM. The subjects were evaluated for range of motion before surgery, at one week, six weeks, and three months. They were also evaluated for strength before surgery and at three months. Finally, the Shoulder Index Score was calculated for each subject before surgery, six weeks, and three months. Each of these measures was taken on a continuous scale.

Chi-squared tests were used to evaluate each group for statistical difference in the categorical variables of age, gender, hand dominance, and tear size. There were no statistical differences noted with an alpha level of 0.05. Student's t-tests for continuous variables were then used to compare each result between the groups. Again an alpha level of 0.05 was applied.

Lastly, an analysis of variance (ANOVA) for repeated measures was used to assess the differences across time for each outcome, shoulder assessment score (SAS), passive motion, active motion, and strength. This design has a single between factor: group, and a single repeated factor: time. Main and two-way interaction between group and time were tested. The interaction term was significant at an alpha level of 0.05.

Results

Shoulder Assessment Score

Both groups showed improvement in their self-assessed scores (Table II) Shoulder Assessment Score (SAS) Measures. The CPM group had improvement from a mean score of 23.5 at the preoperative evaluation to 43.6 at the six week mark and 66.9 at the three month score. The physical therapy (PT) group also showed improvement from a mean of 20.6 preoperatively, to 38.7 at six weeks, to 61.7 at three months. Though the numbers were not as high for the physical therapy group, neither the t-test for each measurement nor the ANOVA (interaction p=0.89) detected a statistical difference.

TABLE II
SHOULDER ASSESSMENT SCORE (SAS) MEASURES

Mean (s.d.)	CPM Group (N=17)	PT Group (N=17)	P-value
SAS Preoperative	23.5 (14.7)	20.6 (14.2)	0.57
SAS 6 week	43.6 (17.9)	38.7 (15.4)	0.40
SAS 3 month	66.9 (12.7)	61.7 (22.3)	0.41

Passive Range of Motion

Each group improved as expected with regards to range of motion (Table III). Flexion was measured in both groups at week one, week six and three months. Both groups improved in week one: CPM = 98.5°, PT= 60.8°, as well as week six: CPM = 124.5° PT=130.1°. The final flexion at three months was CPM = 144.3°, physical therapy = 154.5°.

TABLE III
RANGE OF MOTION MEASURES

Mean (s.d.)	CPM Group (N=17)	PT Group (N=17)	P-value
Preoperative			
Flexion	109.1 (39.8)	119.4 (43.4)	0.48
Abduction	103.7 (44.2)	111.8 (45.8)	0.60
External Rotation	45.7 (23.9)	39.8 (21.1)	0.45
Internal Rotation	51.6 (24.3)	54.1 (24.4)	0.76
Week 1			
Flexion	98.5 (28.5)	60.8 (24.8)	<0.001
Abduction	79.2 (25.7)	61.7 (20.8)	0.036
External Rotation	22.6 (22.2)	20.8 (26.2)	0.82
Internal Rotation	47.2 (22.2)	28.5 (22.3)	0.020
Week 6			
Flexion	124.5 (24.1)	130.1 (28.7)	0.54
Abduction	109.2 (25.4)	118.3 (34.4)	0.39
External Rotation	38.9 (18.9)	46.1 (22.4)	0.32
Internal Rotation	61.1 (20.8)	48.4 (23.6)	0.11
Month 3			
Flexion Passive	144.3 (22.0)	154.5 (20.4)	0.17
Flexion Active	131.8 (31.1)	133.1 (37.0)	0.92
Abduction Passive	130.4 (29.6)	144.8 (27.4)	0.15
Abduction Active	117.4 (32.4)	121.5 (40.3)	0.74
External Rotation Passive	54.1 (21.5)	63.8 (18.6)	0.17
External Rotation Active	43.1 (19.8)	47.3 (22.2)	0.56
Internal Rotation Passive	58.9 (19.5)	66.5 (19.6)	0.27
Internal Rotation Active	53.4 (19.1)	53.8 (25.8)	0.96

Statistically, these groups changed differently over time with a higher gain for the physical therapy group from week one to week six (p=0.001). Similarly this difference was noted for internal rotation and abduction between week one and week six measurements. Passive abduction increased in each group: CPM = 79.2°, 109.2°, 130.4°; physical therapy = 61.7°, 118.3°, 144.8°. Both CPM and physical therapy patients improved in passive external and internal rotation as well. However, each group improved at a statistically similar rate.

There were no statistical differences noted at the three month mark. The only difference detected was at the one week and six week internal rotation measurements. The CPM group measured 47.2° at the one week mark versus 28.5° for the physical therapy group. At six weeks the difference was 61.1° to 48.4°. This difference decreased to 58.9° for the CPM group and 66.5° in the physical therapy group at three months, which was not statistically different.

Statistical differences were noted here in several measurements. Student's t-tests were carried out for all of the measurements. At the one week mark, the passive flexion, abduction, and internal rotation were all statistically higher in the CPM group than in the physical therapy group (alpha = 0.05).

This statistical difference was not found at the six week and three month measurements. By the six week exam, the flexion, abduction, external rotation, and internal rotation were all statistically similar at a 0.05 level. This was also true at three month level.

Active Range of Motion

Active motion had increased for each group at the three month measurement. There were no statistical differences noted between the CPM and physical therapy patients in either the preoperative or three month measurements for flexion, abduction, internal rotation, and external rotation.

Strength

There were no statistical differences in strength between the two groups at the preoperative or 3 month time period in flexion, abduction, or external rotation (Table IV). The ANOVA showed no statistically significant difference in the change over time for any of the strength measures (flexion p=0.84, abduction p=0.41, external rotation p=0.68).

TABLE IV
STRENGTH MEASURES

Mean (s.d.)	CPM Group (N=17)	PT Group (N=17)	P-value
Preoperative			
Flexion	3.6 (0.6)	3.8 (0.6)	0.31
Abduction	4.0 (0.7)	3.9 (0.5)	0.72
External Rotation	3.5 (1.0)	4.0 (0.8)	0.18
Month 3			
Flexion	3.8 (0.5)	4.0 (0.5)	0.34
Abduction	4.0 (0.4)	4.1 (0.5)	0.41
External Rotation	3.8 (0.6)	4.1 (0.5)	0.12

Subgroups

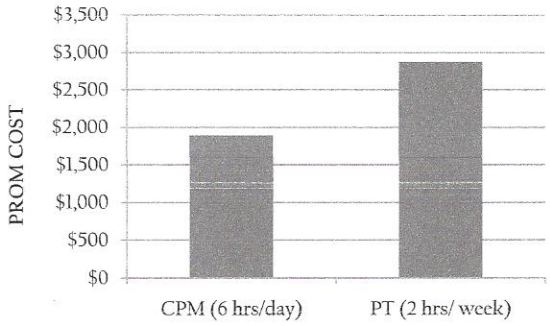
All data was analyzed in subgroups with respect to sex and size of tear, small, medium, and large. At the three month mark there were no statistically significant differences noted between the physical therapy and CPM groups in either the male or female subgroups. This was also true with regards to the size of the tear. Statistically all tear sizes did equally well within their subgroups, small, medium and large.

Compliance

Compliance with use of the CPM device was recorded by the machine. Recommended use was 6 hours per day. In our group the average use was 5.06 hours per day. The range was from 3.59 hours to 6.83 hours per day. Analysis was completed for subgroups of patients who used the CPM over 5 hours per day, total 210 hours, and those under 5 hours per day.

Cost

The cost of each method of passive range of motion has been determined with information provided by the physical therapy department at Henry Ford Center for Athletic Medicine and by Orthologic Corporation. The cost of using physical therapy can be estimated by the amount which is billed by the physical therapists, but does not include time to drive to the appointments, gasoline, and mileage. Currently billing for physical therapy is done by units at $60 a unit. One unit equals fifteen minutes. Each patient went to physical therapy for approximately two hours per week or eight units. This comes to a total of $2,880. (60 x 4 x 2 x 6). The cost of renting the machine per day is $45/day for six weeks. The total is $1,890 for the six weeks. The difference in cost of the two treatment plans is $990.



PASSIVE MOTION THERAPY – 6 WEEKS
FIG. I

Graph showing the cost of passive motion therapy during the first six weeks postoperatively, as indicated by patients managed with continuous passive motion (CPM) and those managed with physical therapy (PT). The group that was managed with continuous passive motion had statistically equal outcomes than the group that was managed with physical therapy but at a lower cost.

Discussion

The findings of this prospective randomized study are several. The first is that at three months postoperatively, both groups of patients were doing similarly well with regards to their functional and pain status as measured by the patients with the self-assessment score. The second is that the motion and strength measurements of both groups improved as expected using either the CPM device or physical therapy for the first six weeks after surgery. A breakdown of subgroups revealed similar findings.

It does not appear that using a CPM device provided a better outcome within this time frame, but we did note the statistically significant differences in passive range of motion at the one week mark in flexion, abduction, and internal rotation. This led to differences for the way the groups changed over time as detected by our ANOVA analysis for these categories. We hypothesize that this difference was due to the CPM group starting their motion on day two postoperatively. The physical therapy group generally did not have their first visit with the therapist until the fifth postoperative day. This "jump start" on early motion did not appear, in this study, to convey an advantage in terms of increased motion or strength at three months over the physical therapy group.

The Index of Shoulder and Elbow Surgeons patient self-assessment reflects the patients' status on both pain and function of the shoulder with one-half of the number reflecting pain. The CPM patients did not appear to be in any increased pain at the six week mark or three month mark as compared to the physical therapy group based on the self-assessment scores. A weakness of the study was in not measuring the pain separately during the first several weeks to evaluate differences in discomfort during the typical time of maximal pain.

A major concern with the CPM device is that of compliance. However, we found in our study that the average was 5.06 hours of use per day. Though this is one hour shy of the recommended use, the motion and function data reveal equivalent results with physical therapy at this level of use. Within group analysis did not reveal any statistical difference with respect to use over 5 hours per day. We were encouraged by the amount of compliance and feel it is a reflection of the patients comfort level with use of the device. Future studies or larger groups may show a higher degree of variability in CPM use and a "minimum level of use" may be determined in order to achieve the desired results.

The cost-effectiveness of each protocol was also a consideration. As previously noted for our institution, the six weeks of physical therapy costs $2,880. This compares to a total cost of $1,890 for the six weeks of the CPM device rental. The physical therapy is $990 more expensive per patient. This figure also does not take into account the time spent getting to and from the physical therapy clinic nor cost of transportation.

Given the results of the motion, strength, and self-assessment data it appears the two protocols are clinically equivalent within the confines of this study and institution. The CPM protocol is less expensive consequently it is the more "cost effective" of the two. Though this number is less than $1000 dollars per patient, if we multiply that by the number of rotator cuff repairs performed in the U.S., the cost savings would be significant. The primary surgeon in this study averages close to one hundred per year leading to an annual savings of $99,000.

Raab et. al.[10] found that using a CPM device for three weeks after rotator cuff repair showed advantages

in motion at three months and a significant reduction in post operative pain among subgroups but no overall effect on function. Though we found that function was not significantly improved over physical therapy as well, we did not find a similar increase in range of motion. Lastayo et. al.[7] found that the CPM device group demonstrated a significant reduction in postoperative pain. We did not evaluate postoperative pain. In addition, the authors stated that using a CPM device was less cost-effective than manual therapy provided by a family member or health care worker. However, they gave no specific numbers with regard to cost nor did they compare their results to those of patients receiving formal physical therapy.

Limitations of the study

There are several areas to be considered in future studies. The first is the ability to detect when the difference in motion seen in the CPM group versus the physical therapy group at the first week is eliminated. This could be determined with more frequent measurements at weekly intervals during the first six weeks. However, we believed it would be a significant burden on the patients to be seen weekly for measurements.

Secondly, early assessment of post-operative pain for each protocol group should be better measured. The greatest amount of pain should be immediately postop and any differences between the groups at that time would be interesting data.

Thirdly, future assessment of these patients would give further insight into the longer term effects of these protocols. We believe, however, that any significant differences would be expected to be seen at our studied time when the CPM and physical therapy protocols differ. Given that our data at three months show no significant differences after each group has had physical therapy in the second six weeks, we would not expect a significant divergence in future measurements.

Summary

The results of the subjective data collected using the American Shoulder and Elbow Surgeons patient self-evaluation form showed similar results for both groups of patients. Both groups had similar improvement in their scores from the preoperative to six week and three month scores (CPM = 23.5, 43.6, 66.9; PT= 20.6, 38.7, 61.7). These results were not statistically different.

Range-of-motion testing also revealed similar results for CPM therapy and physical therapy at the six week (passive) and three month (passive and active) postoperative measurements. Statistical difference was noted at the one week measurement with increased passive motion in the CPM group in flexion, abduction, and internal rotation. This difference was not seen in the six week and three month measurements. Strength data revealed results showing no statistical difference in strength of the two groups in flexion (CPM=3.8, PT=4.0), abduction (CPM=4.0, PT=4.1), and external rotation (CPM=3.8, PT=4.1) at the three month measurement.

At our institution, physical therapy involves two visits every week for six weeks, at an average cost of $240 per visit for a total cost of $2,880. The use of the CPM device for the first six weeks is less expensive than physical therapy, at $1,890. The total saving for this period is $990 per patient using the CPM device. Postoperative therapy with the CPM device yielded similar results when compared to physical therapy. Thus, the CPM device was a more cost-effective treatment than the physical therapy within this protocol.

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