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

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Abstract: As costs continue to increase in healthcare treatment, options, new and old, are being scrutinized not only for their efficacy but also for cost-effectiveness. Use of a continuous passive motion device after rotator cuff repair instead of physical therapy for the first six weeks is one option for decreasing the total cost of rotator cuff repair. However its effectiveness is still unclear with regard to rotator cuff repair. The purpose of this prospective randomized outcome study was to compare the results of continuous passive motion and physical therapy in the early post-operative period.

Thirty-four patients (thirty-four shoulders) were assigned randomly to one of two groups for post-operative management: continuous passive motion (seventeen patients) or physical therapy (seventeen patients) for their passive range of motion during the first six weeks. There were 25 women and 9 men. The average age was 55 years old (range thirty-seven to seventy-six). The patient's results were recorded for the first three months after repair.

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 = 23.47, 43.59, 66.88 PT= 20.62, 38.68, 61.68) These results were not statistically different.

Range of Motion testing also revealed similar results for CPM and PT at the six week (passive) and 3 months (passive and active) post-operative 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 6 week and 3 month measurements. Strength data revealed results showing no statistical difference in strength of the two groups in flexion (CPM=3.84, PT=4.01), abduction (CPM=4.01, PT=4.15) and external rotation (CPM=3.78, 4.09) at the three month measurement.

The use of the continuous passive motion device for the first six weeks is less expensive than physical therapy. The total saving for this period is $990.00 per patient using the continuous passive motion device. Postoperative therapy with the continuous passive motion device yielded similar results when compared to physical therapy. Thus, the continuous passive motion was a more cost-effective treatment than the physical therapy within this protocol.

In 1970 after significant observation and research Salter elaborated on the concept of continuous passive motion (CPM) to accelerate the healing of articular tissues. (Salter, 1989) Animal studies have confirmed a beneficial affect of continuous passive motion on the healing of articular cartilage, tendon, and ligaments as well as a faster re-absorption of hemarthrosis. (Drez\Delee, 1994) Claimed clinical benefits include good compliance, decrease in postoperative pain, maintenance of achieved range of motion and decreased incidence of complications (Coutts, 1988).

The concept of CPM has been applied in postoperative rehabilitation of multiple procedures especially of the knee and shoulder. Its most common use is postoperatively after total knee arthroplasty, first started in 1980. (Ververeli, 1995) The results have been mixed with many contradictory observations. (Ververli, 1995) 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. (Pope, 1997) Another study found that full range of motion was achieved earlier with reduced hospital stays and decreased use of analgesics (Coutts, 1988).

More recently the use of CPM devices has been applied in rotator cuff repair rehabilitative protocols. (Lastayo, 1998) Passive range of motion exercises in the early postoperative period help to protect the repair and prevent adhesions. (Cofield, 1997)

The healing of the rotator cuff (supraspinatus tendon) occurs in three phases; the inflammatory, collagen production phase, and remodeling. By 14 weeks collagen synthesis and maturation of cells cause a healed defect. (Gelberman, 1988)

Currently passive range of motion is accomplished with physical therapy. (Post, 1990) Two recent studies have evaluated the functional outcome with use of CPM after rotator cuff repair. Raab et. al. (Raab, 1996) compared two groups (26 patients), the first treated with physical therapy and the second treated with both physical therapy and the CPM device started in the recovery room and continuing for 3 weeks. The study concluded that CPM had no overall effect on shoulder function at 3 months when combined with physical therapy. However they did find a beneficial effect of continuous passive motion on the patients' shoulder range of motion.(Raab, 1996) Lastayo et. al. (Lastayo, 1998) compared two groups. The control group had their passive range of motion exercises manually by trained relatives or home nurses. The study group used the continuous passive range of motion device everyday for four weeks. This study found no statistical differences between the groups with respect to pain, range of motion or isometric strength.(Lastayo, 1998) Neither study examined the results of CPM compared to a group receiving only physical therapy nor for longer than four weeks. Experience following tendon repair surgery suggests adhesions form maximally at 10 days.(Gelberman, 1986)

The current environment of health care necessitates not only that treatment be clinically effective but that new treatments must also be cost effective. Ginzberg in 1989 noted that a major contributor to rising health care costs is unnecessary "high tech medicine" and that physicians in ambulatory settings rely too heavily on high-tech

therapies. (Ginzberg, 1990) The highest cost of rehabilitation after rotator cuff repair occurs in the first several months when the patient must obtain physical therapy for the passive range of motion. At our institution this involves two visits every week for six weeks, at an average cost of $240 per visit for a total of $2,880. Saving visits to physical therapy with a CPM device has its own costs including patient education, 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. (Ververeli, 1995) 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 flexion in the non-CPM group. Five manipulations under anesthesia were needed at a cost of $937/patient without CPM vs. $720/patient for the CPM group. Thus the CPM was cost effective in this study. A different study by Lastayo theorizes that the cost of CPM is higher because of a failure to achieve an improved functional outcome with continuous passive motion compared to the passive motion provided by the patient's family.(Lastayo, 1998) However the study does not support its conclusions with comparative results of physical therapy nor provide real dollar figures in its conclusions.

The purpose of this prospective, randomized study was to compare the functional outcome and cost of the first six week of rehabilitation with the use of a continuous passive motion machine to provide passive motion versus that provided by a physical therapist after rotator cuff repair surgery.

Experimental Design

The purpose of this prospective, randomized, and comparative study was to determine the effect of continuous passive motion on the functional outcome and cost of rehabilitation after rotator cuff repair. The Institutional Review Board at Henry Ford Hospital approved this study.

Patient Demographics

		CPM (n=17)	Physical Therapy (n=17)
Age			
	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

Patients

This study included thirty-four patients (34 shoulders) who were to undergo rotator cuff repair between August of 1999 and November of 2000. Nineteen were on the dominant arm and fifteen were on the non-dominant arm. Five of the tears were large (above 3 centimeters), 17 were of medium size (between 2 and 3 cms.) and 12 were small (below 2 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 IRB consent form. Two patients were dropped form the study, both were from the continuous passive motion

group. One was dropped due to postoperative myocardial infarction and the second wished to receive her physical therapy at an outside site. 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.

Preoperative evaluation

Each patient was preoperatively evaluated in two ways. The first is through the Shoulder Index of the American Shoulder and Elbow Surgeons.(Richards, 1994) This score assesses both pain and the self-reported ability of the patients to complete several activities of daily living. A visual analog scale from one to ten is used to evaluate the pain. It is scored 0 (no pain) to 10 (unbearable pain). This number is then subtracted from 10 and the resulting number is multiplied by five. There is a maximum possible of 50 points. Ten activities of daily living get a score from zero to three. Zero points indicate an inability to complete the activity and three indicates normal ability. The ten scores are combined and that number is multiplied by 5/3 for a total of zero to fifty points on this section. The two totals are then combined for a possible maximum shoulder score of 100.

The second preoperative evaluation was completed by a physical therapist at the Henry Ford Center of Athletic Medicine. The therapist measured active range of motion and strength. Range of motion of active flexion, active external rotation with the arm at zero, active abduction, and internal rotation with the arm at 90 degrees, was measured using a goniometer. The strength of active flexion, abduction, and external rotation were also recorded using the conventional strength scale (one to five).

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.(Pollock, 1997) 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 1 proline will be passed through the free end of the rotator cuff with an intraarticular suture punch and brought out through the lateral portal. The portal is then enlarged to a lateral mini-arthrotomy approach approximately three centimeters in length providing access to the greater tuberosity. The greater tuberosity is decorticated with the ronguer and a burr is 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 are 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 are tied attaching the rotator cuff to the greater tuberosity. The repair is evaluated by moving the shoulder. The deltoid is then repaired and skin portals sutured. Dressing is applied. The arm is then 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 is applied over the dressing.

Postoperative Management

Currently used postoperative management was standardized for the patients in the study. The patients all stayed in the 23 hour inpatient unit in their slings with the Polar Pak in place. Pain control was through the use of parenteral narcotics while inpatients and 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 continuous passive motion group and their families were instructed on the use of the continuous passive motion device, the OrthoRehab Inc. Danniflex 600, prior to the surgery. They were instructed to begin using the CPM device for passive abduction, internal and external rotation of the shoulder on postoperative day number two. Each session using the device was to last for two hours and occurring three times per day, two hours in the morning, afternoon, and night. 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 continuous passive motion 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 both their pain and functional ability by filling out the Shoulder Index of Shoulder and Elbow Surgeons preoperatively, six weeks and 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 90 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 Analysis

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 continuous passive motion device versus physical therapy in the context of those results was completed.

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 OrthoRehab Inc. The cost of using the 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 PT 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 different treatment plans is $990.00.

Patients were randomized into one of two groups: 1) physical therapy and 2) continuous passive motion. The subjects were evaluated for range of motion before surgery, at 1 week, 6 weeks, 3 months. They were also evaluated for strength before surgery and at 3 months. Also, the Shoulder Index score were calculated for each subject before surgery, 6 weeks, 3 months. Each of these measures is taken on a continuous scale.

Statistical Methods

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 and alpha level of 0.05. Student's t-tests for continuous variables was 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 were used to assess the differences across time for each outcome, SAS, passive motion, active motion, 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. 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 group also showed improvement from a mean of 20.6 at preop to 38.7 at six weeks to 61.7 at three months. Though the numbers are not as high for the physical therapy groups neither the t-test for each measurement nor the ANOVA(interaction p=0.89) detected a statistical difference.

Passive Range of Motion

Each group improved as expected with regards to motion. Flexion in both groups improved from week one (CPM = 98.53 degrees, PT= 60.76) to week six (CPM = 124.53, PT=130.12) and three month (CPM = 144.29, PT = 154.53). Statistically, these groups changed differently over time with a higher gain for the PT group from week one to week six (p=0.001). Similarly this difference was noted for internal rotation and abduction between week 1 and week 6 measurements. Passive abduction increased in each group (CPM = 79.24, 109.18, 130.41. PT = 61.71, 118.29, 144.82). Both CPM and PT patients improved in passive external and internal rotation as well. However, each group improved at a statistically similar rate.

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 PT group (alpha = 0.05). This was not true for external rotation.

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 for each group at the three-month measurement was increased. There were no statistical differences noted between the CPM and PT 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 and the ANOVA showed no statistically significant difference in the change over time for any of the strength measures. (Flexion, interaction p=0.84, abduction p=0.41, external rotation p=0.68)

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. 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 57 degrees at the one-week mark versus 36.3 for the PT group. At six weeks the difference was 70.9 degrees to 50.1. This difference decreased to 61.2 for the CPM group and 56.4 in the PT group at three months, which was not statistically different.

Mean (s.d.)	CPM group N=17	PT group N=17	p-value
SAS PRE-OP	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
RANGE OF MOTION MEASURES			
Pre Flex	109.1 (39.8)	119.4 (43.4)	0.48
Pre Abd	103.7 (44.2)	111.8 (45.8)	0.60
Pre ER	45.7 (23.9)	39.8 (21.1)	0.45
Pre IR	51.6 (24.3)	54.1 (24.4)	0.76
Week 1 Flex	98.5 (28.5)	60.8 (24.8)	<0.001
Week 1 Abd	79.2 (25.7)	61.7 (20.8)	0.036
Week 1 ER	22.6 (22.2)	20.8 (26.2)	0.82
Week 1 IR	47.2 (22.2)	28.5 (22.3)	0.020
Week 6 Flex	124.5 (24.1)	130.1 (28.7)	0.54
Week 6 Abd	109.2 (25.4)	118.3 (34.4)	0.39
Week 6 ER	38.9 (18.9)	46.1 (22.4)	0.32
Week 6 IR	61.1 (20.8)	48.4 (23.6)	0.11
Mo. 3 Flex Passive	144.3 (22.0)	154.5 (20.4)	0.17
Mo. 3 Flex Active	131.8 (31.1)	133.1 (37.0)	0.92
Mo. 3 Abd Passive	130.4 (29.6)	144.8 (27.4)	0.15

Mean (s.d.)	CPM group N=17	PT group N=17	p-value
RANGE OF MOTION MEASURES (continued)			
Mo. 3 Abd Active	**117.4 (32.4)**	**121.5 (40.3)**	**0.74**
Mo. 3 ER Passive	**54.1 (21.5)**	**63.8 (18.6)**	**0.17**
Mo. 3 ER Active	**43.1 (19.8)**	**47.3 (22.2)**	**0.56**
Mo. 3 IR Passive	**58.9 (19.5)**	**66.5 (19.6)**	**0.27**
Mo. 3 IR Active	**53.4 (19.1)**	**53.8 (25.8)**	**0.96**
STRENGTH MEASURES			
Pre Op Flex	**3.6 (0.6)**	**3.8 (0.6)**	**0.31**
Pre Op Abd	**4.0 (0.7)**	**3.9 (0.5)**	**0.72**
Pre op ER	**3.5 (1.0)**	**4.0 (0.8)**	**0.18**
Mo. 3 Flex	**3.8 (0.5)**	**4.0 (0.5)**	**0.34**
Mo. 3 Abd	**4.0 (0.4)**	**4.1 (0.5)**	**0.41**
Mo. 3 ER	**3.8 (0.6)**	**4.1 (0.5)**	**0.12**

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 continuous passive motion device or physical therapy for the first six weeks after surgery. A breakdown of subgroups revealed similar findings.

It does not appear that using continuous passive motion machine 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 continuous passive motion 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 continuous passive motion 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 continuous passive motion 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 mentioned in the paper 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 machine rental. The physical therapy is $990.00 more expensive per patient. This figure also does not take

into account the time spent getting to and from the physical therapist and 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 continuous passive motion protocol is less expensive, consequently it is the more "cost effective" of the two. Though this number is less than one thousand dollars per patient, if we multiply that by the number per year in the U.S. the cost savings would be significant. The primary surgeon in this study averages close to 100 rotator cuff repairs per year leading to a savings of $99,000.00 per year.

Raab et. al. in 1996 found that using a CPM device for 3 weeks after rotator cuff repair showed advantages in motion at three months but no overall effect on function.(Raab, 1996) We found that function was not significantly improved over physical therapy as well but we did not find a similar increase in range of motion. Lastayo et. al. in 1998 found that it was using a CPM was less cost-effective than manual therapy, that provided by a family member.(Lastayo, 1998) This study found that clinically the CPM was no different than manual therapy. They gave no specific numbers with regard to cost. They did not compare their results to those of patients receiving formal physical therapy.

There are several areas within the study 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. We however 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 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.

Overall we feel the current study has shown that as this postoperative protocol using CPM provides statistically equivalent results to those of physical therapy within the confines of this study. Given that is the case it is the more "cost-effective" option.