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ORIGINAL ARTICLE

Randomized Controlled Trial of the Effectiveness of Continuous Passive Motion After Total Knee Replacement

Janet A. Herbold, PT, MPH,[a,b] Kristen Bonistall, MS, MSW,[a] Marielle Blackburn, PT, DPT, OCS,[a] Jonila Agolli, PT, DPT,[c] Shawn Gaston, PT, DPT,[c] Chana Gross, PT, DPT,[c] Aleksandra Kuta, PT, DPT,[c] Suzanne Babyar, PT, PhD[c]

From the [a]Department of Outcomes and Clinical Research, Burke Rehabilitation Hospital, White Plains, NY; [b]Department of Physical Therapy, Nova Southeastern University, Fort Lauderdale, FL; and [c]Department of Physical Therapy, Hunter College/Graduate Center of City, University of New York, New York, NY.

Abstract

Objective: To determine the effects of using a continuous passive motion (CPM) device for individuals with poor range of motion (ROM) after a total knee replacement (TKR) admitted for postacute rehabilitation.

Design: Randomized controlled trial.

Setting: Inpatient rehabilitation facility (IRF).

Participants: Adults (N=141) after TKR with initial active knee flexion <75° on admission to the IRF.

Intervention: Two randomized groups: group 1 (n=71) received the conventional 3 hours of therapy per day, and group 2 (n=70) received the addition of daily CPM use for 2 hours throughout their length of stay.

Main Outcome Measures: The primary outcome measure was active knee flexion ROM. Secondary outcome measures included active knee extension ROM length of stay, estimate of function using the FIM and Timed Up and Go test, girth measurement, and self-reported Western Ontario and McMaster Universities Osteoarthritis Index scores.

Results: All subjects significantly improved from admission to discharge in all outcome measures. However, there were no statistically significant differences in any of the discharge outcome measures of the CPM group compared with the non-CPM group.

Conclusions: CPM does not provide an additional benefit over the conventional interventions used in an IRF for patient after TKR, specifically in patients with poor initial knee flexion ROM after surgery.

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Total knee replacement (TKR) surgery is a common surgical procedure used to reduce pain and improve function for individuals suffering from knee impairment associated with end-stage osteoarthritis. The number of TKR surgeries will rise to 3.5 million in the United States by the year 2030,[1] which will create considerable demand for rehabilitation services. Continuous passive motion (CPM) is a typical intervention added to the physical therapy (PT) services in acute care hospitals to encourage early knee motion; however, within postacute rehabilitation, its use is controversial.

The goal of rehabilitation after TKR is to facilitate the patient's return to an active lifestyle. Adequate range of motion (ROM) after surgery is linked to the performance of functional activities. CPM treatment has been used since the early 1980s to promote early mobilization and improve knee flexion ROM. From a theoretical perspective, the passive exercise provided by the CPM helps maintain ROM and reduces edema. Increased ROM enables active exercise and greater strengthening.[2] Adequate ROM to perform many activities of daily living (ADL) has been identified[3]: 90° to descend stairs, 105° to rise from a toilet or low chair,[4] and 106° to tie shoes.[5] The incidence of postoperative stiffness appears to be 8% to 12%; that of complete fibrous ankylosis after

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TKR is <1%.[6,7] Although many factors affect ROM after surgery, Bong,[8] Ritter,[9] and colleagues identified preoperative risk factors, such as limited ROM, underlying osteoarthritis, prior knee surgery, and knee deformity (varus, valgus, flexion contractures).

Studies have reported conflicting results regarding the effectiveness of CPM. Early work comparing CPM application after TKR with an immobilized knee postoperatively demonstrated improvement in knee ROM[10] and wound healing with CPM.[11] Other studies supported its use when applied immediately after surgery.[12-16] The positive results of immediate CPM application were for the short term. An equal number of studies refuted these findings and found CPM to be of little value in rehabilitation after TKR surgery.[17-25] These earlier works demonstrating improvements in ROM and reduction in length of stay (LOS) frequently compared the outcomes of patients using CPM with those with immobilized knees; however, immobilization is not contemporary practice. When additional outcomes, such as calf swelling, wound healing, and functional tests (eg, Timed Up and Go [TUG]), and subjective measures (eg, Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC] and Knee Society Score[26]) were analyzed, researchers similarly concluded that CPM offers no additional benefit.[27] All initial studies were done in the acute care hospital but were conducted using a variety of ROM settings, treatment times, and days of use.

To summarize the evidence, 3 systematic reviews were conducted. Two reviews favored the use of CPM in the initial postoperative phase after TKR[2,28]; a later Cochrane review did not.[29] The Brosseau et al[2] review suggested that CPM combined with PT intervention increased active knee flexion by 4° at 2 weeks post-knee replacement relative to PT alone. The meta-analysis reviewed 20 randomized controlled trials of 1335 patients and reported similar findings. CPM use in acute care hospitals may offer a small short-term, but not long-term,[30] benefit. Its use needs to be carefully weighed against the inconvenience and expense. However, these reviews were conducted in acute care settings or in the home, and none involved patients receiving rehabilitation at an inpatient rehabilitation facility (IRF).

One prospective study compared patients randomly assigned to either a CPM group or a non-CPM group and found no differences between groups.[31] A second IRF-based study compared a control group receiving PT alone with 2 experimental groups (one received 35min of CPM, the other received 2h as an adjunct to PT treatment). The results did not support the addition of CPM in the rehabilitation setting.[17] In our prior work,[32] using a matched cohort design, we reported no differences in ROM gain, FIM, ambulation device use, or the need for homecare after discharge in 126 matched patients in an IRF setting.

Although the preponderance of evidence does not support the benefit of CPM, no prior CPM study, to our knowledge, conducted in an IRF selected patients most at risk for poor knee ROM after a TKR. The purpose of this study was to determine the effects of using a CPM device for individuals with poor ROM after a TKR who were admitted for postacute rehabilitation.

List of abbreviations:

ADL	**activities of daily living**
ANCOVA	**analysis of covariance**
AROM	**active range of motion**
CPM	**continuous passive motion**
ICC	**intraclass correlation coefficient**
IRF	**inpatient rehabilitation facility**
LOS	**length of stay**
PT	**physical therapy**
ROM	**range of motion**
TKR	**total knee replacement**
TUG	**Timed Up and Go**
WOMAC	**Western Ontario and McMaster Universities Osteoarthritis Index**

Methods

Participants

All patients transferred directly to the IRF within 5 days after their surgery between November 2011 and November 2012 were assigned a primary therapist who assessed the patient's active knee flexion and extension ROM on the day of admission. Patients were enrolled consecutively according to the following inclusion criteria: (1) transferred to an IRF after a single knee replacement; (2) etiology of osteoarthritis; (3) aged 40 to 80 years; (4) initial maximal knee flexion ROM between 45° and 75° of flexion; and (5) body mass index <40. Exclusion criteria were as follows: (1) revision to a previous TKR; (2) bilateral TKR; and (3) comorbid medical conditions that could interfere or complicate recovery (eg, stroke, Parkinson's disease, significant cognitive impairment). The institutional review board approved the study, and written informed consent was obtained for each participant. Consented subjects were randomly assigned to either the control or experimental group based on their unique, episode-specific account number. The control group received conventional PT. The experimental group received conventional PT and daily CPM application for 2 hours. With a medium effect size of .50 and a desired power of .80, the minimum acceptable sample size was 65 persons per group for a total of 130 subjects. The patients and therapists were not blinded to the study group.

We defined conventional therapy as 3 hours per day of PT and occupational therapy as part of the interdisciplinary plan of care. The experimental group received an additional 2 hours per day of CPM. On the day of admission, the CPM machine was set based on the maximum flexion tolerated, and the extension was set at 0°. The patients were instructed about how to stop the machine if they experienced more than minimal discomfort.

During the initial PT evaluation, the patients were assessed on each of the study variables. The discharge date and discharge destination were determined by the physician-led interdisciplinary team, who were blinded to the group assignment. On the day prior to discharge, the outcome variables were reassessed. LOS was calculated by subtracting the discharge date from the admission date to the IRF. One week after discharge, the WOMAC survey was mailed to the patient's home. Follow-up phone calls were made to facilitate survey return.

Measures

The outcome measures studied were active range of motion (AROM), TUG score, knee girth, total FIM scores, ambulation device at discharge, LOS, and self-reported WOMAC score.

AROM measurement was taken with a universal goniometer. Its axis was placed in line with the center of the knee, the fixed arm aligned with the greater trochanter, and the mobile arm aligned with the lateral malleolus. Both flexion and extension ROMs were measured in the supine position. Intertester reliability

for knee ROM was previously reported as high for flexion (intraclass correlation coefficient [ICC], .89−.98) and fair to good for extension (ICC, .64−.92).[33,34]

The TUG test is a functional test where the patient rises from an armed chair, walks for 3m, turns, and walks back to resume a seated position. A standard set of instructions to the patient were provided, and the use of an ambulation device was permitted.[35]

Knee circumference was measured at the joint line and recorded in centimeters using a standard tape measure. This measurement was used to determine girth as an indicator of swelling. The interrater reliability (ICC) ranged from .98 to .99 when both experienced and less experienced therapists for girth measures a prior study.[36]

The FIM instrument is a well-standardized measure used to estimate the burden of care associated with 18 functional and cognitive items.[37-39]

The ambulation device was recorded as a nominal category and included no device, single cane, bilateral cane, crutches, or walker.

LOS was calculated by subtracting the discharge date from the IRF admission date.

The WOMAC is a self-report measure assessing the patient's perception of their pain, stiffness, and ability to perform ADL.[40]

The primary outcome of interest was maximum discharge knee flexion ROM. Secondary outcomes included the discharge ambulation device, active knee extension, total FIM score, TUG test, girth, LOS, and WOMAC scores. Additional patient characteristics, such as age, sex, race, and date of onset (surgery), were obtained.

Statistical analysis

For this randomized controlled trial, data were analyzed with the SPSS IBM version 21 for Windows.[a] Descriptive statistics were performed for all variables measured. To confirm group similarity, nominal data were analyzed with a Fisher exact test, and continuous data were analyzed with independent *t* tests. Preliminary analyses evaluating the homogeneity of slope assumption indicated no significant relation between the covariates and dependent variable. Therefore, we used analyses of covariance (ANCOVAs) of discharge knee flexion and extension AROM, discharge total FIM scores, discharge girth, and discharge TUG scores with the initial value of respective variables as the covariates. The overall significance level was set at $P<.05$, but the Bonferroni correction for the 6 variables of interest yielded $P<.008$.

Results

During a 12-month study period, 145 patients consented and enrolled in the study. Of these, 4 were unable to complete the study. CPM was unavailable for use on 2 patients: one experienced skin irritation from the pads, and another disliked the CPM. Therefore, outcome data were available for 141 patients (99 women, 42 men): 70 in the CPM group, and 71 in the control group. Average age was 72±7 years. Most were white (88%), with 7% black, 4% Hispanic/Latino, and <1% Asian. Prior to admission, 72% did not use an ambulation device, whereas 23% used a cane, and 5% used either a walker or crutches. During the acute care hospital stay (average, 3.8±1.1d), 91% used a CPM immediately after surgery. Demographic characteristics, prior CPM use, ambulation device use, and days in the acute care hospital did not differ between treatment groups. Baseline clinical measurements (table 1) were similar between groups. For patients in the CPM group, on average, the machine was used for a total of 12.5±9.6 hours and 626.7±376.6 cycles during their rehabilitation stay. A cycle is defined as movement beginning in extension through the available flexion and return to full extension.

Table 1 Baseline clinical characteristics of all subjects (n=141) by study condition

Variables	CPM Group (n=70)	Control Group (n=71)	*P*
Initial range of motion (deg)			
Active knee flexion	61.3±7.8	63.6±7.4	.076*
Active knee extension	−4.7±3.4	−4.6±3.3	.861*
Initial FIM			
Motor score	43.2±4.7	42.7±4.1	.494*
Cognitive score	28.0±1.6	28.1±1.6	.794*
Total FIM score	71.3±5.5	70.8±4.7	.609*
Initial knee girth (cm)	47.0±5.9	46.5±5.4	.576*
Initial WOMAC			
Pain subscale	10.2±3.6	10.6±3.5	.578*
Stiffness subscale	4.6±1.4	4.7±1.5	.713*
Difficulty with ADL	35.3±11.8	34.4±12.0	.765*
Total score	50.2±15.7	50.3±15.0	.973*
Initial TUG (s)	39.3±15.6	40.9±18.2	.614*
Presurgical ambulation device			
Device (walker or cane)	17 (24)	22 (31)	.452†
No device	53 (76)	49 (69)	

NOTE. Values are mean ± SD, n (%), or as otherwise indicated.
* *P* value from paired *t* test (2 tailed).
† *P* value from Fisher exact test (2 tailed).

All patients demonstrated significant improvements in the clinical outcome measures from admission to discharge, which included the following: knee flexion ($t_{140}=-23.3$, $P<.001$); knee extension ($t_{139}=-5.5$, $P<.001$); TUG score ($t_{104}=14.1$, $P<.001$); FIM score ($t_{140}=-81.1$, $P<.001$); and girth ($t_{133}=2.4$, $P<.019$). Improvement in the patient's perceptions of pain, stiffness, and ADL function as measured by the WOMAC were also significant when comparing admission scores with the 7-day follow-up survey ($t_{59}=7.8$, $P<.001$).

Primary outcome

For the primary outcome variable, discharge knee flexion AROM, a 1-way ANCOVA was conducted. CPM use (independent variable) was compared with discharge knee flexion ROM (dependent variable) after treatment, with initial active knee flexion ROM as the covariate.

The mean flexion AROM in the CPM group was 83°±10°, and the control group not using the CPM was 86°±7.9° at discharge, revealing no significant difference ($F_{1,138}=3.1$, mean square error=81.38, $P<.08$). In addition, there was no relation between the use of the CPM and discharge knee flexion ROM as assessed by a partial eta squared, with the CPM factor accounting for 2% of the variance of the dependent variable, holding constant the initial maximum knee flexion AROM.

Secondary outcomes

Secondary outcomes of interest were also examined at discharge using ANCOVAs, including maximum active knee extension ROM, total FIM score, TUG score, girth, and WOMAC score. ANCOVA results indicated no significant effect in discharge knee

Table 2 Results of ANCOVA on outcome variables for the CPM and control groups at discharge

Outcome Variables	CPM Group (n=70)	Control Group (n=71)	df	F	P
Active knee flexion	83.5±10.0	86.4±7.9	1,138	3.100	.080
Active knee extension	−2.7±2.8	−3.3±3.3	1,137	1.580	.211
Total FIM score	107.0±4.1	107.8±3.2	1,138	2.140	.146
TUG score	19.9±7.5	19.8±6.1	1,102	0.394	.532
Knee girth measurement	46.1±5.3	46.2±5.0	1,131	1.860	.175
WOMAC score	30.2±14.6	33.3±14.4	1,57	1.120	.294

NOTE. Values are mean ± SD or as otherwise indicated.

extension ROM, total FIM, TUG, girth, and follow-up WOMAC (table 2), indicating no impact of CPM use when controlling for initial values of each of the variables of interest.

In terms of LOS, an independent *t* test revealed that both groups stayed an average of 8 days in the IRF (CPM mean, 8.3±1.7 compared with no CPM mean, 8.7±2.7, $t_{139}=1.01$, $P<.311$). The combined LOS beginning with the acute care hospital stay through the postacute hospitalization also demonstrated no significant difference between groups (CPM mean, 12.1±2.3d compared with the control group mean, 12.6±3, $t_{139}=1.03$, $P<.306$). In addition, 98% of the patients in both conditions were discharged home, revealing no group difference. With regard to an ambulation device, most patients were discharged using a single point cane for walking (87% of the control group, 90% of the CPM participants). A Fisher exact test showed no statistically significant group difference ($P<.792$).

For the follow-up portion of the study, we had a 55% return rate of the WOMAC survey. Although responses from 7 surveys indicated worse results than at the time of admission, the average improvement from admission to discharge was 17±17.3 points. This difference exceeds that determined to represent a minimal clinically important difference by Escobar et al[41] in patients after TKA at 6 months. The minimal clinically important difference for TKR is around 15. CPM did not improve WOMAC scores. The mean difference between the control group and CPM group was −2.3±15 points, which was not statistically or clinically significant ($P<.47$).

Discussion

CPM use in postacute rehabilitation (eg, within homecare services or in an IRF setting) does not appear to offer long-term benefits after unilateral TKR, regardless of initial ROM.[17,22,31,32,42] Our study further explored its use by applying it only to patients with active maximum knee flexion ROM between 45° and 75°, which identified patients most at risk for stiffness. The findings confirm that in patients with poor initial ROM, CPM use offers no added benefit to discharge ROM values when compared with conventional PT alone. Moreover, CPM application did not have any additional effect on the secondary outcomes measurements of the TUG test, FIM, WOMAC questionnaire, girth reduction, and LOS. The CPM intervention in this study may have been applied beyond the time period where passive knee ROM to reduce stiffness will yield benefit.[43] Another explanation may lie in the nature of postacute rehabilitation where active participation in therapy is the hallmark of its services. In acute care hospitals, PT is less aggressive compared with IRF settings, which provides 3 hours of therapy daily, promoting movement and functional recovery. Simple functional activities (eg, rising from a low chair) may introduce a greater degree of knee flexion than the CPM facilitating a greater degree of functional independence during the postacute rehabilitation phase.

Because preoperative factors play a major part in determining postoperative ROM, identifying these factors would enable specific and focused use of PT resources. A study following >500 patients with TKR identified the most important factors impacting postoperative knee ROM.[44] The diagnosis of osteoarthritis and preoperative knee flexion <75° were the best predictors of postoperative ROM, whereas total knee prosthesis, sex, age, and diagnosis of rheumatoid arthritis were not.[9] Knowledge of a patient's preoperative clinical findings may help identify those patients most at risk for stiffness; therefore, effective early interventions can be promoted.

CPM as a component of the PT program in acute care hospitals is quite common. Our findings demonstrate that >90% of patients enrolled in our study used a CPM in the acute hospital. Its continued use in the acute care hospital immediately after surgery is likely based on the short-term benefit it offers, especially when used with the early flexion parameters described by Jordon and others.[10,16,45]

Study limitations

The first limitation relates to the lack of preoperative knee alignment and preoperative ROM information. When patients are transferred from an acute care hospital to freestanding rehabilitation facilities, the IRF staff do not have access to presurgical ROM; although, knowledge of this may ultimately explain results or provide a means of early identification of patients at risk for stiffness.[8] Because frontal plane deformities can impact ROM, knowledge of this information would have been useful but was unavailable to the postacute facility.[7]

In addition, we did not evaluate the intertester reliability of ROM of our staff, though the unit was staffed by a consistent group of 4 or 5 physical therapists who were trained in a standard measurement protocol. Additionally, despite encouraging CPM use in the evening, patients had the ability to terminate the treatment prior to the prescribed 2 hours per day. Preselection of patients with ROM <75° at the start of the study and the error associated with goniometric measurement may have resulted in a regression of the mean for flexion at discharge. Finally, of the 52 control subjects who completed the WOMAC on admission, only 34 returned it; and of the 57 CPM subjects, only 40 returned it. Although the return rate is not unusual, it reduces potentially useful information on subject's ability to function at home.

Conclusions

This study provided a strong sample size using patients with initially poor knee flexion ROM to study the impact of CPM in an inpatient rehabilitation setting. Our pragmatic approach to studying this intervention, analyzing both ROM values and functional outcomes, found no significant benefit of CPM use during the postacute rehabilitation phase compared with conventional care. Because CPM did not contribute to the improvements in either primary or secondary outcomes for patients after TKR surgery, its routine use at our facility was terminated.

Supplier

a. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

Keywords

Knee replacement arthroplasty; Rehabilitation

Corresponding author

Janet A. Herbold, PT, MPH, Burke Rehabilitation Hospital, 785 Mamaroneck Ave, White Plains, NY 10605. *E-mail address:* jherbold@burke.org.

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