Research Report

Effectiveness of Continuous Passive Motion and Conventional Physical Therapy After Total Knee Arthroplasty: A Randomized Clinical Trial

Background and Purpose. This randomized clinical trial was conducted to compare the effectiveness of 3 in-hospital rehabilitation programs with and without continuous passive motion (CPM) for range of motion (ROM) in knee flexion and knee extension, functional ability, and length of stay after primary total knee arthroplasty (TKA). **Subjects.** Eighty-one subjects who underwent TKA for a diagnosis of osteoarthritis were recruited. **Methods.** All subjects were randomly assigned to 1 of 3 groups immediately after TKA: a control group, which received conventional physical therapy intervention only; experimental group 1, which received conventional physical therapy and 35 minutes of CPM applications daily; and experimental group 2, which received conventional physical therapy and 2 hours of CPM applications daily. All subjects were evaluated once before TKA and at discharge. The primary outcome measure was active ROM in knee flexion at discharge. Active ROM in knee extension, Timed "Up & Go" Test results, Western Ontario and McMaster Universities Osteoarthritis Index questionnaire scores, and length of stay were the secondary outcome measures. **Results.** The characteristics of and outcome measurements for the subjects in the 3 groups were similar at baseline. No significant difference among the 3 groups was demonstrated in primary or secondary outcomes at discharge. **Discussion and Conclusion.** The results of this study do not support the addition of CPM applications to conventional physical therapy in rehabilitation programs after primary TKA, as applied in this clinical trial, because they did not further reduce knee impairments or disability or reduce the length of the hospital stay. [Denis M, Moffet H, Caron F, et al. Effectiveness of continuous passive motion and conventional physical therapy after total knee arthroplasty: a randomized clinical trial. *Phys Ther.* 2006;86: 174–185.]

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The biological concept of continuous passive motion (CPM) was introduced by RB Salter in the late 1970s. He demonstrated that CPM for rabbit knees after cartilage injury enhanced cartilage healing and regeneration compared with prolonged articular rest.[1,2] Later, his research focused on the effects of CPM on a variety of injuries in rabbits and in clinical applications for human subjects.[3] Coutts et al[4] first initiated CPM use immediately after total knee arthroplasty (TKA). Their reasoning was based on Salter's research and the postulate that CPM enhanced collagen tissue healing with better fiber orientation, avoiding cross-linking and thus generating better movement restoration.[4,5]

The effectiveness of postoperative CPM applications has been studied in a large variety of protocols after TKA. Knee flexion range of motion (ROM) was usually the primary outcome measure, evaluating either short-term effectiveness (measured at the end of the hospital stay) or long-term effectiveness (measured 2–12 months after TKA). Most authors[6–15] agree on the lack of efficacy of long-term CPM for knee flexion ROM; however, there is still controversy regarding its short-term effectiveness. Many researchers have reported significant knee flexion ROM gains of between 7 and 22 degrees (relative to results for control groups)[4,9,10,13–17] or faster knee flexion recovery during the hospital stay.[4,12,17–19] In these studies, duration of CPM applications could vary from 10 hours to 24 hours per day and were performed during 2 to 7 days after TKA.[4,9,10,12–17,19] In the majority of these studies, subjects' knees in the control group were immobilized for 2 to 7 days, whereas subjects in the experimental groups received early postoperative CPM applications.[4,9,13–17] These results cannot be applied to contemporary practice, because a long period of immobilization is no longer recommended after TKA, and early movement is always promoted in the TKA population. In addition, description and standardization of knee flexion measurements have been neglected in many experiments, and only a few studies have provided detailed methodology.[6,9,15,20,21] Other researchers[6,8,11,18–20,22–25] have concluded that CPM applications do not provide any additional gains in knee flexion at the end of the hospital stay. In a large proportion of these studies, knee flexion exercises in the control group began when CPM applications were initiated in the experimental groups.[6,11,20,22,24,25] However, either knee flexion ROM measurements were performed 11–22 days after TKA[18,19,22,23,25] or CPM application parameters were not applicable for actual practice.[8,11,24]

Besides knee flexion ROM, length of stay (LOS) and function also have been used to measure CPM efficacy after TKA. In some studies, LOS was reduced by 2 to 5 days in groups receiving CPM applications. However,

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The Centre Hospitalier Universitaire de Québec–Hôtel-Dieu de Québec ethics committee approved the study.

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discharge criteria other than knee flexion ROM were not always clear enough to make inferences about the influence of CPM on LOS.[4,15,17,18,22,26] In some studies,[8–10,14,20,23] function was measured with questionnaires at various times, between 6 weeks and 2 years, after surgery. Comparable results on these questionnaires were observed for groups receiving and groups not receiving CPM applications.

At Centre Hospitalier Universitaire de Québec–Hôtel-Dieu de Québec, the effectiveness of CPM applications was questioned when rehabilitation protocols after TKA were revised. The applications were performed for 35 minutes per day every day until discharge. The question was to decide whether or not to maintain these low-intensity CPM applications or whether to add applications of moderate intensity as part of the rehabilitation protocols after TKA. The purpose of this single-blind randomized clinical trial was to compare the effectiveness of 3 in-hospital rehabilitation programs with various intensities of CPM applications for knee flexion ROM, functional ability, and LOS after primary TKA. Our hypothesis was that when CPM applications were performed in conjunction with conventional physical therapy, there would be no additional benefit in terms of knee flexion ROM, functional ability, or LOS, compared with results obtained with conventional physical therapy alone.

Method

Subjects

This study was conducted between February 2001 and February 2003 at Centre Hospitalier Universitaire de Québec–Hôtel-Dieu de Québec, where over 100 TKAs are performed every year. Subjects were asked to participate if they had a diagnosis of knee osteoarthritis, were expecting primary TKA, were ambulatory, and were literate. Subjects with previous major lower-limb surgery, such as contralateral TKA or total hip arthroplasty, were included, as long as the previous surgery had occurred at least 12 months before the current TKA. Exclusion criteria were: (1) medical conditions or diseases that could interfere with test performance, (2) collaboration or comprehension problems, (3) neuromuscular or neurodegenerative disease, (4) concurrent intervention during surgery that could interfere with outcomes (eg, collateral ligament repair), (5) infection of the affected knee, and (6) any major health complication during the hospital stay (eg, pulmonary embolism, heart attack, problems with scar healing).

Recruitment

The eligibility of subjects was verified on the basis of their medical files obtained from the orthopedic surgeons' waiting list. Subjects were asked to participate when they attended their routine preoperative medical visit. All participants signed an informed consent form.

Study Design

All subjects were assessed twice by an experienced physical therapist: once at the preoperative visit, 2 to 4 weeks before TKA, for baseline measurements and again at discharge, 7 or 8 days after TKA.

Randomization

After surgery, all subjects were randomly assigned to one of the following 3 groups: (1) a control group (CTL), which received conventional physical therapy intervention only, without CPM applications; (2) experimental group 1 (EXP1), which received conventional physical therapy intervention and CPM applications for 35 minutes daily (low intensity); and (3) experimental group 2 (EXP2), which received conventional physical therapy intervention and CPM applications for 2 consecutive hours daily (moderate intensity). Two strata were created for an equivalent distribution of subjects with and subjects without previous major surgery of the lower limbs in the 3 groups. One set of prenumbered, sealed envelopes was prepared for each stratum, and subjects were assigned to the group specified in the envelope.

Measures

For each participant, anthropometric, personal, and clinical characteristics were reported, including sex, age, weight, height, social status, comorbid conditions, previous disease or surgeries, and time from the onset of symptoms. A questionnaire also was administered to measure the frequency and intensity of physical activity usually performed by the subjects.[27] The same measurements were taken at baseline and at discharge. The primary outcome was maximal active ROM in knee flexion in a seated position. The secondary outcomes were active ROM in knee extension, Timed "Up & Go" Test (TUG) results, and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire scores. Assessments were performed by 4 experienced physical therapists who were unaware of group assignment. The theoretical LOS and the real LOS also were reported. All assessments at discharge were performed at the same time of day, that is, in the morning before physical therapy interventions, if those were still needed.

Maximal active ROM in knee flexion. The ROM measurement was taken with a 1-degree-increment goniometer. Its center of rotation 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. The criterion validity and the intratester and intertester reliability of data obtained with the goniometer have been demonstrated to be high.[28–31] To

maximize reliability, the subject's position was standardized[30,32] as follows: the subject was seated on an adjustable table, the foot of the affected leg was placed on a cloth, and the contralateral foot was placed on an ~7.6- to 15.2-cm-high (3- to 6-in-high) bench. Subjects were asked to actively bend their knee by sliding their foot backward to the maximum ROM tolerated.

Maximal active ROM in knee extension. The same procedure was applied for the extension movement, except that subjects were lying supine on the adjustable table and had to actively slide their foot forward on a wooden board to the maximum ROM tolerated.

Two trials were performed for both ROM measurements. If the difference between those trials was more than 5 degrees, a third trial was performed and the mean of the 2 closest ROM measurements was registered. All evaluators were required to participate in a standardization session for the entire procedure of ROM measurements.

TUG. This functional test records the time required to get up from a chair with armrests, walk 3 m, turn around, walk back to the chair, and sit down. Our chair seat was 46 cm in height, and permanent painted lines on the floor delimited the 3-m walkway. The standardized procedure included a demonstration for the subject and 2 trials with walking aids if necessary. Good correlation with the Berg Balance Scale, walking speed, and the Barthel Index has established the validity of TUG scores.[33] Intratester and intertester reliability and responsiveness also have been shown to be high for this test.[33,34]

WOMAC. The WOMAC questionnaire is a self-administered, activity-based, and lower-limb–specific questionnaire that contains 24 items covering pain (n=5), stiffness (n=2), and functional difficulty (n=17). Excellent validity and reliability have been shown with many populations and specifically with TKA and total hip arthroplasty populations.[35–38] The visual analog scale and the French version were used. At discharge, several questions regarding functional difficulty were excluded from the original form—getting in and out of the car and the bath, shopping, and managing light or heavy household work—as subjects were unable to attempt these tasks at the early postoperative stage.

LOS. The real length of each subject's hospital stay was recorded. This measure was dependent on other factors: organic complications or disease, difficulties in the organization of support at home, or delayed transportation to home. Therefore, a theoretical LOS also was recorded. It was defined as the time needed to reach discharge criteria for the knee condition. Those criteria were obtaining independence and security in transferring, in walking with aids, and in managing stairs; furthermore, the subject had to demonstrate good progression in recovery of active ROM in knee flexion, which had to be approximately 75 degrees at discharge. Finally, the scar had to be healing appropriately.

Interventions

CPM. Subjects in both experimental groups received one daily CPM session, beginning on the second day after TKA until discharge or day 7 or 8. Nurses installed the CPM device, and the procedure was standardized. Teaching sessions were organized, and written and audio-video instructions were provided. Identical installations were performed for both groups: subjects lay supine in their bed, and the CPM device was placed under the affected leg with the knee extended. For stability, one strap surrounded the subject's thigh, another strap surrounded the subject's lower leg, and the apparatus was prevented from sliding down by the edge of the bed. In the first group (EXP1), CPM was used for 35 minutes continuously, including a 5-minute warm-up period. In the second group (EXP2), CPM was used for 2 consecutive hours, including a 5-minute warm-up period. This 2-hour application was performed in the evening in order to avoid interfering with all other daytime medical and rehabilitation activities.

On the second day after TKA, 35 to 45 degrees of flexion was reached with CPM for all subjects in both groups. From the third day after TKA to the end of the clinical trial, increments of ROM in flexion were determined by the physical therapist on the basis of the maximal ROM in knee flexion obtained during the conventional physical therapy intervention. All information regarding ROM and duration of CPM applications and the reasons for disparity between the prescribed and the actual applications were recorded every day.

Conventional physical therapy intervention. At Centre Hospitalier Universitaire de Québec–Hôtel-Dieu de Québec, a standardized clinical procedure is followed after TKA. All subjects in the 3 groups received the same daily (including weekends) conventional physical therapy intervention, which was supervised by a physical therapist. On the first day after surgery, respiratory and circulatory exercises were encouraged. Isometric knee extensor muscle exercises were performed, and extension knee alignment was maintained in a splint. On the second day, the splint was removed. Active and passive knee flexion, abduction and adduction of the hip in the horizontal plane, and knee extensor muscle exercises were performed. Next, teaching for transferring and walking with the appropriate device was begun. Func-

tional exercises with weight bearing were added on day 4. Management of stairs, if needed, was performed on day 6 or 7 before discharge. All subjects had to practice exercises and walk on their own in addition to the supervised sessions. The detailed content of each supervised session, such as the type and the number of exercises, was recorded by the physical therapist.

Co-interventions. The number and content of the occupational therapist's visits and information about daily medications were collected from each subject's medical chart. Details on the surgery protocol and the type of prosthesis were available for all subjects a few weeks after surgery. This information was used to verify the comparability of the groups regarding the type of surgery.

Adherence to intervention. In EXP1 and EXP2, the number of CPM applications planned, the number of CPM applications received, their duration, and the ROM progression were recorded. The number of conventional physical therapy sessions planned, the number of conventional physical therapy sessions received, and their content also were recorded in the 3 groups.

Sample Size

A consensus was reached between orthopedic surgeons and physical therapists with respect to the criterion for the maintenance of CPM applications as part of the recovery program after TKA: for active ROM in knee flexion, a minimum effect size of 10 degrees was established. This value corresponds to the mean difference between the control group (CTL) and either of the experimental groups (EXP1 or EXP2). On the basis of the relevant literature and subject files reviewed over 6 months, the estimated standard deviation of the primary outcome was 10 to 12 degrees. With a two-sided α (type I) error level of .05 and a statistical power of 80%, the sample size for each group was estimated to be 26 subjects.[39]

Data Analysis

A first analysis was based on the intention-to-treat principle. Demographic and clinical characteristics of the subjects and baseline measurements were compared between groups by use of analysis of variance (ANOVA) for continuous variables and chi-square tests for categorical data. The nonparametric Kruskal-Wallis test was used when data were not normally distributed. At discharge, the primary and secondary outcomes were compared between groups by use of ANOVA or the Kruskal-Wallis test when necessary. Pain, stiffness, functional difficulty, and total WOMAC questionnaire scores were transformed to a percentage of the total score available for questions answered in each category. The 95% confidence interval of the group differences was calculated for each variable. Adherence to interventions in each group was analyzed by comparing their content, their frequency, and their duration. Finally, a second analysis was carried out according to the per-protocol principle; subjects showing 75% participation in interventions were included. The SPSS version 10 statistical program* was used for all analyses.

Results

From February 2001 to February 2003, 98 subjects were evaluated at baseline (Fig. 1); 82 of them were randomly assigned to 1 of 3 groups: 27 were assigned to CTL, 26 were assigned to EXP1, and 28 were assigned to EXP2. One subject was excluded after being randomly assigned by mistake; his preoperative diagnosis was infection, not osteoarthritis, as specified in the inclusion criteria. For the main analysis (intention-to-treat principle), 81 subjects were considered. Personal characteristics, comorbid conditions, physical activity levels, and measurement outcomes at baseline were similar in the 3 groups (Tab. 1).

No significant difference was found among the 3 groups for surgery characteristics, such as patella resurfacing (CTL, 85%; EXP1, 69%; and EXP2, 64%; P=.19) or postero-cruciate-substituting prosthesis (CTL, 22%; EXP1, 27%; and EXP2, 7%; P=.15).

Primary Outcome

No significant difference was found among the 3 groups in active ROM in knee flexion (P=.33) (Tab. 2, Fig. 2).

Secondary Outcomes

No significant difference was found among the 3 groups in active ROM in knee extension in TUG duration, or in total and subscale WOMAC questionnaire scores. Both real LOS and theoretical LOS were similar among the 3 groups (Tab. 2). Similar results for primary and secondary outcomes were found with analysis by the per-protocol principle when only subjects showing 75% adherence to interventions were included.

Adherence to Interventions

Adherence to the CPM applications was very high; only one subject in the EXP1 group and 3 subjects in the EXP2 group did not receive 75% of the planned interventions (Fig. 1). The mean numbers of CPM applications were similar (P=.14) in both experimental groups: EXP1, 4.9 applications (SD=0.9), and EXP2, 4.5 applications (SD=1.4). The percentages of subjects who received CPM applications daily were comparable between the groups (Fig. 3). The mean durations of CPM applications were 35.7 minutes (SD=2.5) in EXP1 and 118.9 minutes (SD=7.6) in EXP2 (Fig. 3). Daily ROM progressions were similar in both groups. Adher-

* SPSS Inc, 233 S Wacker Dr, Chicago, IL 60606.

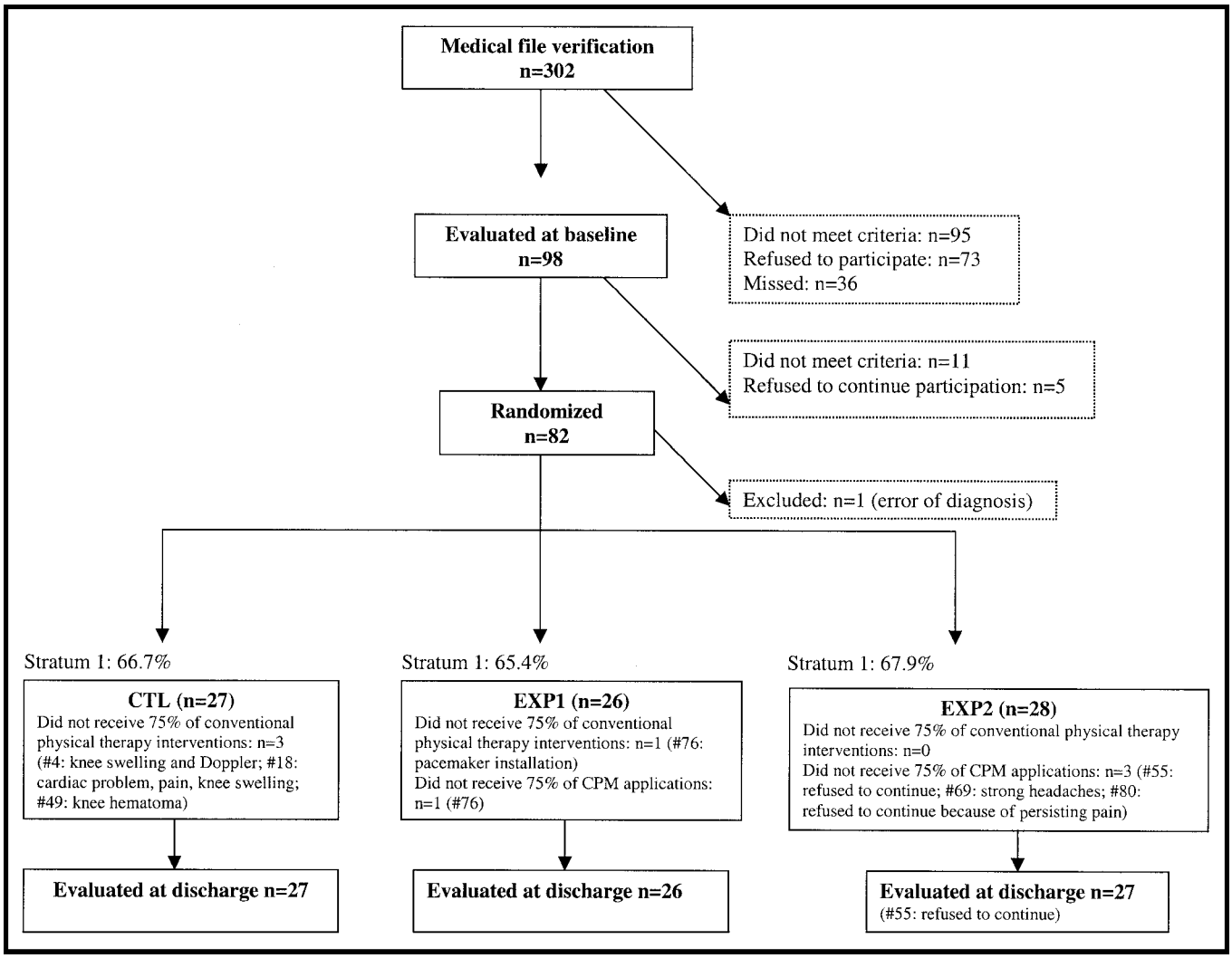

Figure 1.
Subject enrollment, distribution, and participation in interventions. CTL=control group, EXP1=experimental group 1, EXP2=experimental group 2, CPM=continuous passive motion, Doppler=deep vein thrombosis diagnosis test.

ence to conventional physical therapy interventions also was very high; 3 subjects in CTL and 1 subject in EXP1 did not receive 75% of the physical therapy interventions (Fig. 1). The mean numbers of physical therapy sessions were similar among the 3 groups (P=.24): CTL, 5.7 (SD=1.0); EXP1, 6.0 (SD=1.0); and EXP2, 6.0 (SD=0.7). Exercises performed and percentages of subjects performing specific exercises were comparable.

Co-interventions

In the first 36 hours after TKA, all subjects had an intravenous analgesic perfusion that they used as needed. Afterward, the analgesic medication was adjusted according to pain and discomfort requirements. Subjects in the 3 groups received similar numbers of visits from the occupational therapist (P=.87): CTL, 2.6 (SD=1.8); EXP1, 2.7 (SD=0.8); and EXP2, 2.8 (SD=1.4).

Complications

One subject in each group developed a knee hematoma; superficial vein thrombosis was present in one subject each in CTL and EXP1, and deep vein thrombosis (DVT) occurred in one subject in EXP2. Scar bleeding was seen in one subject in CTL, 2 subjects in EXP1, and no subjects in EXP2. Three subjects in CTL and 3 subjects in EXP1 had pulmonary or cardiac problems, and only 1 subject in EXP2 had these problems. No subject was required to undergo knee manipulation under anesthesia before discharge.

Discussion

Our results confirm that adding CPM applications of low or moderate intensity to conventional physical therapy interventions has no short-term effect on active ROM in knee flexion. Moreover, CPM applications did not have any additional effect on secondary outcome measure-

Table 1.
Subject Characteristics and Outcome Measurements at Baseline[a]

Characteristic	CTL (n=27)	EXP1 (n=26)	EXP2 (n=28)	*P*
Men, n (%)	13 (48.1)	10 (38.5)	15 (53.6)	.53
Age, y, $\bar{X}$ (SD)	67.1 (7.6)	69.6 (6.7)	68.4 (7.4)	.47
Weight, kg, $\bar{X}$ (SD)	85.8 (15.6)	79.3 (9.4)	80.7 (16.6)	.22
Height, m, $\bar{X}$ (SD)	1.7 (0.1)	1.6 (0.1)	1.6 (0.1)	.42
Live alone, n (%)	6 (22.2)	10 (38.5)	11 (39.3)	.32
Duration of symptoms, y, $\bar{X}$ (SD)	8.6 (7.9)	8 (6.2)	11 (8.2)	.30
Affected side, left, n (%)	15 (55.6)	19 (73.1)	12 (42.9)	.08
Physical activity, none, n (%)	12 (44.4)	11 (42.3)	14 (50.0)	.84
Comorbid conditions, n (%)				
Hypertension	17 (63.0)	13 (50.0)	18 (64.3)	.50
Cardiac problems	6 (22.2)	7 (26.9)	8 (28.6)	.86
Pulmonary problems	3 (11.1)	2 (7.7)	2 (7.1)	.85
Diabetes	5 (18.5)	5 (19.2)	5 (17.9)	.99
Cancer	1 (3.7)	4 (15.4)	5 (17.9)	.24
Outcomes, $\bar{X}$ (SD)				
Flexion, °	115.8 (11.5)	117.1 (7.9)	118.8 (9.7)	.53
Extension, °	−7.1 (5.6)	−8.8 (4.0)	−6.9 (3.8)	.25
TUG duration, s	16.4 (12.3)	17.2 (11.3)	16.9 (5.9)	.96
WOMAC score, %, $\bar{X}$ (SD)				
Pain	51.5 (20.7)	52.5 (17.0)	48.9 (17.9)	.77
Stiffness	61.1 (28.0)	66.5 (23.7)	62.4 (24.7)	.73
Incapacity	55.2 (21.8)	51.2 (18.4)	53.7 (20.6)	.77
Total	55.0 (20.7)	52.8 (16.5)	53.4 (18.9)	.91

[a] TUG=Timed "Up & Go" Test, WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index, CTL=control group, EXP1=experimental group 1, EXP2=experimental group 2.

Table 2.
Primary and Secondary Outcome Measurements at Discharge[a]

	Outcomes[b]			*P*	Intervention Effects[c]		
Parameter	CTL (n=27)	EXP1 (n=26)	EXP2 (n=28)	(Analysis of Variance)	CTL-EXP1	CTL-EXP2	EXP1-EXP2
Flexion, °	80.4 (11.8)	78.7 (10.6)	83.3 (11.9)	.33	1.7 (−5.8, 9.2)	−2.9 (−10.3, 4.5)	−4.6 (−12.1, 2.9)
Extension, °	−8.0 (3.5)	−7.0 (3.7)	−6.5 (3.7)	.30	−1 (−3.4, 1.4)	−1.5 (−3.9, 0.8)	−0.5 (−2.9, 1.9)
TUG duration, s	41.9 (21.4)	50.7 (22.6)	52.3 (34.9)	.33	−8.7 (−26.8, 9.2)	−10.4 (−28.0, 7.3)	−1.6 (−19.6, 16.4)
WOMAC score, %							
Pain	39.8 (24.8)	36.8 (15.6)	27.7 (17.1)	.07	3.0 (−9.9, 15.9)	12.1 (−0.6, 24.9)	9.1 (−3.8, 22)
Stiffness	53.8 (26.1)	59.3 (19.3)	50.1 (24.1)	.36	−5.4 (−20.8, 10.0)	3.8 (−11.5, 19.0)	9.2 (−6.2, 24.6)
Functional difficulty	33.0 (22.7)	40.0 (20.2)	31.0 (23.9)	.32	−7.0 (−21.7, 7.7)	1.9 (−12.6, 16.5)	8.9 (−5.7, 23.6)
Total	37.1 (22.6)	41.2 (17.6)	32.2 (20.6)	.28	−4.1 (−17.5, 9.3)	4.9 (−8.4, 18.1)	9.0 (−4.4, 22.4)
LOS, d							
Real	7.8 (2.0)	8.1 (2.0)	8.0 (2.1)	.83	−0.3 (−1.7, 1.0)	−0.2 (−1.5, 1.1)	0.2 (−1.2, 1.5)
Theoretical	7.5 (1.4)	7.9 (1.6)	7.6 (1.8)	.71	−0.4 (−1.4, 0.7)	−0.2 (−1.2, 0.9)	0.2 (−0.8, 1.3)

[a] TUG=Timed "Up & Go" Test, WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index, LOS=limits of agreement, CTL=control group, EXP1=experimental group 1, EXP2=experimental group 2.
[b] Reported as $\bar{X}$ (SD).
[c] Reported as mean differences between groups (95% confidence interval).

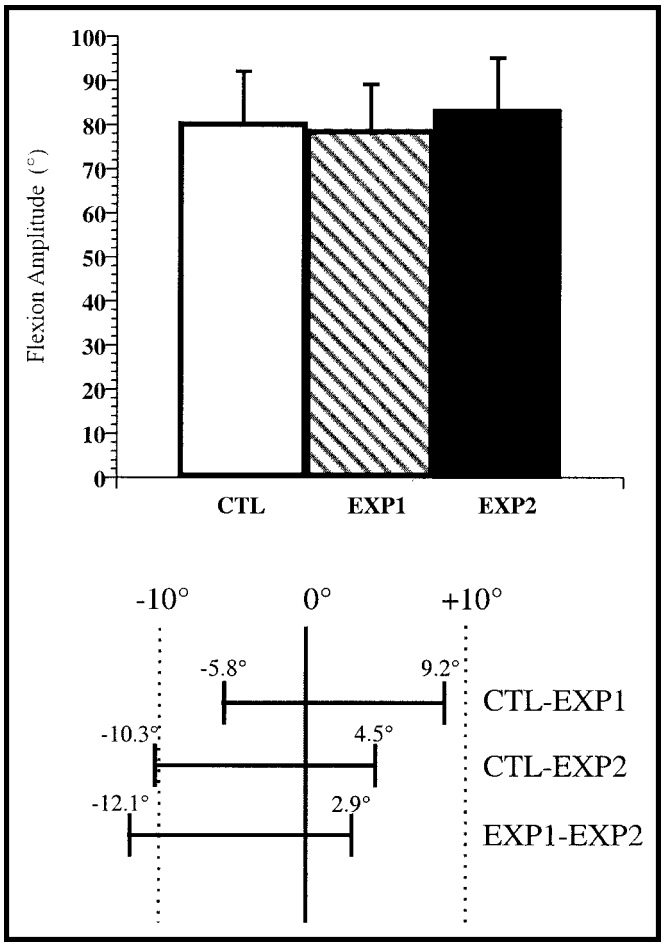

Figure 2.
(Top) Mean and standard deviation of active range of motion in knee flexion in each group (CTL=control group, EXP1=experimental group 1, EXP2=experimental group 2) at discharge. (Bottom) Ninety-five percent confidence interval for intergroup differences at discharge: 0° means no difference among groups; the dotted vertical lines illustrate the range of differences not considered clinically important.

ments, including active ROM in knee extension, TUG results, WOMAC questionnaire scores, and LOS.

Our results confirm those of other studies in which CPM applications did not have any additional effect on knee flexion ROM.[6,8,11,18–20,22–25] Agreement also was reached for the mean knee flexion ROM at discharge. In some studies,[11,20,24] this ROM varied from 62.7 to 76.5 degrees 7 to 10 days after TKA, all groups taken into account. In studies supporting the efficacy of CPM applications,[9,10,16,40,41] similar ranges of knee flexion (70°–82°) were observed 7 days after surgery. When the mean knee flexion ROM was found to be greater (86°–93°) at discharge, the LOS also was longer, reaching 15 to 20 days.[12,13,15,18,19] In our clinical trial, the mean knee flexion ROM at discharge for the entire population of subjects (N=81) was 80.8 degrees (SD=11.5) for a mean LOS of 8 days (SD=2).

One of the adverse effects that could occur with CPM applications is an increased lack of active or passive ROM in knee extension. However, only a few studies[10,11,14] demonstrated a significant decrease in knee extension ROM at discharge in the experimental groups using CPM applications. In all of these studies, the duration of applications was 20 hours per day. In our study, active knee extension was not found to be decreased in groups receiving CPM applications (CTL, −8°; EXP1, −7°; and EXP2, −6.5°). Nevertheless, in all 3 groups, there was a lack of knee extension of about 7.2 degrees (SD=0.7). Comparable ROMs (−4° to −10°) have been observed at discharge (5–14 days after TKA) in other studies, regardless of study duration or the protocol used.[6,9,17,20,25,40] Difficulties in performing knee extension may be explained by extensor muscle weakness, stiffness in flexor muscles, knee swelling, pain, or a combination of these impairments, given the acute-stage condition.

One could surmise that subjects who received additional CPM applications would have decreased functional abilities because they remained inactive during the duration of CPM interventions. To our knowledge, no study with CPM applications has measured functional abilities at discharge. All assessments of functional abilities were performed 6 weeks to 2 years after TKA. However, at these postoperative periods, no adverse effect of CPM applications on functional abilities was found.[8–10,14,20,23] In our study, functional abilities, as measured by the TUG and the WOMAC questionnaire, were comparable among the 3 groups at discharge. The mean TUG duration for all subjects in the 3 groups was 48.2 seconds (SD=27.2), 3 times longer than that at baseline (16.8 seconds, SD=9.8). Furthermore, 81.5% of our subjects (CTL, 85.2%; EXP1, 76%; and EXP2, 88.9%) were using a walker for ambulating; therefore, walking speed was decreased. In a previous study not involving CPM applications, Walsh et al[42] evaluated functional performance at 1 week after TKA, and their results showed that TUG duration was only twice that measured at baseline. However, the subjects in that study seemed to have greater preoperative functional abilities, as suggested by their superior performance on the TUG (12.9 seconds, SD=0.7). In addition, the majority of their subjects used a cane (78%) instead of a walker.[42] In our study, WOMAC questionnaire scores were comparable among the 3 groups. However, it is important to note that the results may have been influenced by the withdrawal of several nonrelevant items from the functional difficulty subscale, because the subjects were not exposed to these during the early postoperative stage. This methodological choice may have reduced the validity of the corresponding subscale and the total score on the WOMAC questionnaire. There is a need to develop and validate an appropriate functional outcome measure for the weeks immediately after TKA.

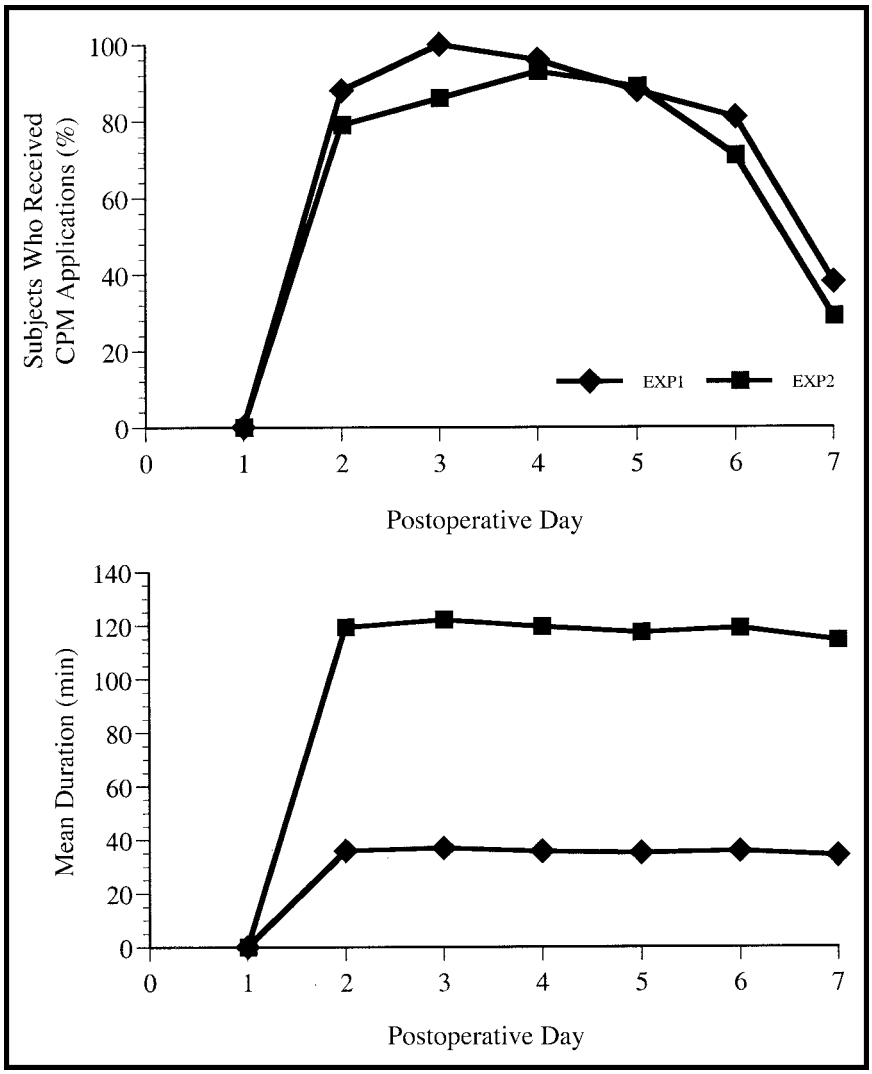

Figure 3.
Adherence to continuous passive motion (CPM) interventions. (Top) Percentages of subjects in experimental group 1 (EXP1) and experimental group 2 (EXP2) who received CPM applications for each day of the clinical trial. (Bottom) Mean duration (in minutes) of daily CPM applications for each experimental group.

Differences in WOMAC pain component scores were close to significance at discharge (P=.07). A secondary analysis of the 5 items of this pain component revealed a significant difference between CTL subjects and subjects who received moderate-intensity CPM applications for the fourth item, which evaluates the intensity of pain at rest (ANOVA, P=.003; Tukey honestly significant difference *post hoc* test, P=.002; 95% confidence interval for intergroup differences=7.4%–37.7%). For the other items, pain in managing stairs (item 1), in walking (item 2), at night (item 3), or in the sit-to-stand activity (item 5), no difference among groups was found, even for pain at night, when subjects were also in a resting position. One may question the validity of this finding. That is, is it the result of chance, or does it actually reflect the effect of intervention for subjects who received moderate-intensity CPM applications?

In the past 10 years, pre-established discharge criteria have evolved concurrently with decreasing LOS, which now varies between 5 and 10 days after TKA.[8,20,24,43–46] Therefore, the 90 degree knee flexion discharge criterion was modified to a smaller ROM, and functional ability was emphasized to accelerate discharge.[46,47] In some studies,[8,20,24] the mean knee flexion ROM at discharge varied from 63 degrees to 80 degrees for an LOS between 5 and 10 days after TKA. In our study, one of our discharge criteria in addition to independence in functional activities was active ROM in knee flexion, which had to be approximately 75±5 degrees. Eighty-three percent of our subjects reached more than 70 degrees of knee flexion at discharge (CTL, 81%; EXP1, 81%; and EXP2, 86%). Others were allowed to return home because they had reached the functional independence goal and because they continued to be partially supervised for their exercises. All subjects were discharged with home-supervised physical therapy interventions. In our clinical trial, when all groups were taken into account, real LOS and theoretical LOS were 8 days (SD=2) and 7.6 days (SD=1.6) after TKA, respectively. The slight difference between the 2 LOS measures was mostly attributable to delays in transportation for subjects living in outlying regions.

Deep vein thrombosis can develop in 40% to 80% of subjects after TKA. This proportion decreases with prophylactic anticoagulant therapy.[48–51] There is controversy concerning the effect of CPM on DVT. Many authors did not find any difference in DVT with CPM applications,[13,14,20,21,52] whereas others found less DVT in CPM application groups, although this finding may have been attributable to the fact that their control subjects were immobilized.[4,15,19,53] In our study, a majority of subjects received anticoagulant therapy, and the same very small proportions of side effects, including DVT, were observed in the 3 groups.

Our choice of CPM application duration could be criticized. Indeed, many protocols with various CPM

application durations have been studied, for instance, 1 hour 3 times per day,[22] 2 hours 3 times per day,[20] comparison of moderate and intensive durations of 5 and 20 hours per day,[21] mean applications between 4 and 8 hours,[6] and applications as long as 20 hours per day for 1 to 6 days after TKA.[8,11,23] None of these studies demonstrated any additional effect of CPM applications on knee flexion. Adherence to CPM interventions was reported in 2 studies and was less than the prescribed duration.[6,20] For example, Beaupré et al[20] reported an adherence of 1.7 hours 1.8 times per day, which was less than the prescribed application of 2 hours 3 times per day. In this case, 61% of subjects missed the morning session because of interference with other activities.[20] In our study, the 35-minute duration in EXP1 corresponded to the usual length of the CPM application in our rehabilitation practice after TKA. The 2-hour CPM application was added to the research protocol to explore the effect of a more intense, yet still feasible, CPM intervention. This second group (EXP2) received the CPM application in the evening to avoid interference with other postoperative activities routinely performed during the hospital stay. This 2-hour duration was chosen on the basis of a consensus among the health care professionals (orthopedic surgeons, physical therapists, and nurses) involved in rehabilitation after TKA. We determined that CPM applications could not be any longer than 2 hours in the acute-care context after TKA because subjects had daily conventional physical therapy interventions, occupational therapy visits, nursing care, and radiographic and medical assessments. Furthermore, subjects needed time to achieve all of their rehabilitation goals, in addition to knee flexion, such as independence and security in transferring and in walking with aids, before being discharged and sent home.

Our study has many factors that contribute to the validity of the results. First, our 3 groups were comparable at baseline in terms of personal and clinical characteristics and outcome measurements. Second, there was a high degree of adherence to interventions. Only 1 subject in EXP1 (4%) and 3 subjects in EXP2 (11%) did not receive 75% of the planned CPM applications. Three subjects in CTL (11%) and 1 subject in EXP1 (4%) did not receive 75% of the conventional physical therapy interventions. Third, all subjects in the 3 groups began CPM mobilization and knee flexion exercises at the same time after TKA to avoid a delayed exposure to knee movement in CTL. Furthermore, the levels of co-interventions were comparable among the groups. Finally, in this study, considering the variability observed and the pre-established parameters (α error=5% and effect size in active knee flexion of $\geq 10^\circ$ among groups), the calculated statistical power was high (86%).

This study has some limitations. First, we did not document the intertester reliability of our own evaluators, especially for knee flexion ROM measurements with a goniometer. However, the ROM measurement procedure was standardized and practiced by evaluators with volunteers before the beginning of the study. Second, the conclusions of this study are limited to populations and CPM application protocols similar to those described in our clinical trial. In specific situations, such as when important restrictions in knee flexion are present before TKA or after knee manipulation, CPM application efficacy still needs to be tested.

Conclusion

The results of this study suggest that adding CPM applications to conventional physical therapy interventions does not favor better knee flexion ROM. Furthermore, the results indicate that CPM applications do not have any additional effect on knee extension ROM, functional ability, or LOS. Therefore, we believe that CPM should not be routinely used during in-hospital rehabilitation programs after primary TKA for people with osteoarthritis.

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