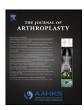
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Prospective Randomized Trial of the Efficacy of Continuous Passive Motion Post Total Knee Arthroplasty: Experience of the Hospital for Special Surgery



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ABSTRACT

Conflicting evidence has created substantial controversy regarding the use of continuous passive motion (CPM) in the in-patient setting post total knee arthroplasty (TKA). A total of 109 patients were randomly assigned to two groups, CPM or no CPM, applied after TKA. All patients received the same physical therapy protocol (3 sessions per day), with the only exception being the CPM. Both groups had a knee flexion of 115° at 6 weeks and 120° at 3 months, with no significant differences (P = 0.69 and P = 0.41, respectively). Length of stay was significantly less for the group who did not receive CPM. The use of CPM had no clinically relevant benefits with respect to AROM, clinical outcomes or discharge disposition and was associated with a cost of \$235.50 per TKA.

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Success of total knee arthroplasty (TKA) largely depends on reducing pain and improving the ability to perform daily activities. Restoring active range of motion (AROM) is crucial as most activities require a minimum of 90° of knee flexion [14]. In the 1970s, Salter et al. introduced continuous passive motion (CPM) after observing the adverse effects of joint immobilization [24–26]. He originally hypothesized that CPM after TKA would reduce postoperative pain, improve local circulation, reduce swelling, accelerate return of joint motion and reduce the incidence of adhesions [24]. While it has been well established that CPM has no long-term (6 months or more) benefits [2,5,10,15,16,18,21,22], it has been estimated that as of 2002, CPM devices were being used in over 17,000 hospitals, in 77 countries by 7 million patients [24].

In recent time controversy has grown over the use of CPM during the short acute in-patient phase of recovery. Some have reported benefits including faster recovery of flexion [12,19,20,28], improved flexion [12,13,16,27], lesser incidences of thrombophlebitis [28] and manipulations [27], reduced swelling [19,20], decreased analgesic use [3] and a shorter length of stay [4,12,13]. Others have found CPM to cause increased or more persistent swelling [18,21], extensor lags [22], increased analgesic use [21] and no improvement in early

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ambulation [8,18], patient reported outcomes [1,2,5,7,8,18], or ROM [1,2,5,6,8,9,15,18,22,28]. This debate was ended by a recent Cochrane Database analysis of 24 randomized clinical trials reported that CPM has no clinically important effects on knee active flexion, pain, function or quality of life [9]. While this has become common knowledge, the use of CPM remains the standard of care at many institutions, including Hospital for Special Surgery. In fact, a recent survey performed at our institution a priori, revealed that CPM continues to be routinely prescribed despite the evidence against the use of CPM (Appendix).

Therefore, in an effort to change the standard of care at our institution, we sought to determine the efficacy of CPM on (1) AROM, (2) complications and clinical outcomes, as well as (3) discharge disposition at six weeks and three months postoperatively. Additionally, we performed a cursory (4) cost analysis of CPM use at our institution per TKA.

Patients and Methods

Between December 2013 and May 2014, a prospective, randomized controlled clinical trial was performed to evaluate the efficacy of CPM applied during the acute in-patient phase after TKA. Following approval by our institution's ethics committee, patients over the age of 18 and scheduled to undergo primary unilateral TKA by one of the three senior authors (MMA, TPS, & ASR) were identified. One hundred and twenty patients were recruited for this study. Patients were excluded if they underwent surgery with a non-posterior-stabilized implant (n = 6), cancelled surgery (n = 3) or had any major intraoperative complications, such as patellar fracture (n = 2). One hundred and nine patients met our inclusion criteria (Fig. 1).

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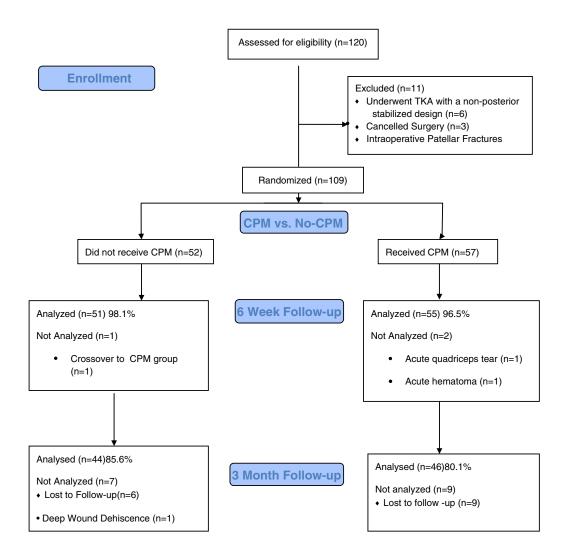


Fig. 1. Patient Flow Diagram.

Prior to TKA, an independent participant randomly assigned all one hundred and five patients into two groups: (1) [control group] patient to receive CPM (n = 55); or (2) [experimental group] patient not to receive CPM application (n = 50). Randomization was completed via a computer-based random number generator (1 or 2) prior to surgery. Study personnel, excluding the operative surgeon, were made aware of the assigned group and appropriate orders were placed. A coinvestigator daily confirmed that CPM was applied as per the clinical order set. The operating surgeon remained blinded to the assigned group until after the first application of the CPM device.

All operations were performed via the medial parapatellar approach via the standard of care of each respective surgeon. Anesthesia protocols were similar among both study groups. All patients received a combined spinal epidural (CSE) along with one of the following: patient controlled-analgesia (PCA), peri-articular injection (PAI), or a peripheral nerve block (sciatic, saphenous or femoral). Patients received one of four posterior-stabilized implants Sigma® Press-Fit Condylar (DePuy Orthopaedics, Warsaw, IN), Vanguard® (Biomet, Warsaw, IN), Optetrak Logic® (Exactech, Gainsville, FL), and Persona® (Zimmer, Warsaw, IN). The groups were similar with respect to implant distribution.

CPM and Physical Therapy Protocols

Patients assigned to the CPM group received three CPM sessions per day, each lasting two hours (total of six hours per day), with ROM increased as tolerated. This regimen began on postoperative day one and persisted until patient was discharged from the hospital. All patients in this study, regardless of their assigned group received a uniform physical therapy regimen. Starting either on day of surgery or postoperative day one, all patients received one-on-one physical therapy two times a day, and an additional ambulation session with a mobility technician.

Clinical Evaluations

All patients had clinical evaluations collected at three visits as per the current standard of care: preoperatively (baseline) and at six weeks and three months postoperatively. ROM was measured by the operating surgeon using a goniometer evaluating both extension and flexion values respectively. Full ROM was calculated as flexion minus extension. Indication for a manipulation under anesthesia was left to the discretion of the surgeon as per their standard of care (Typically

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