Continuous Passive Motion and Physical Therapy versus Physical Therapy Alone in Total Knee Arthroplasty

Neal A. Cashman
University of North Dakota

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CONTINUOUS PASSIVE MOTION AND PHYSICAL THERAPY
VERSUS PHYSICAL THERAPY ALONE
IN TOTAL KNEE ARTHROPLASTY

By

Neal Cashman
Bachelor of Science in Physical Therapy
University of North Dakota, 1999

An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine and Health Sciences
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Master of Physical Therapy

Grand Forks, North Dakota
May
2000
This Independent Study, submitted by Neal A. Cashman in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Michelle Labrecque  
(Faculty Preceptor)

(Graduate School Advisor)

(Chairperson, Physical Therapy)
PERMISSION

Title Continuous Passive Motion Versus Physical Therapy Versus Physical Therapy in Total Knee Arthroplasty

Department Physical Therapy

Degree Master of Physical Therapy

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Signature [Signature]

Date December 14, 1999
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ACKNOWLEDGEMENTS

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I thank my wife Stephanie for supporting, helping, and putting up with me over the years, especially the last three. I would also like to thank my parents Lloyd and Sharon for giving me the strength and willpower to accomplish anything to which I put my mind.
ABSTRACT

This study investigated the effect of continuous passive motion (CPM) on the rehabilitation of patients undergoing total knee arthroplasty (TKA). Over the years, CPM use in the treatment of TKA has been debated whether it is effective enough to justify the medical expense that accompanies it.

Sixteen subjects who underwent TKA surgery participated in the study. Twelve subjects were in the CPM group and four subjects were in the non-CPM group. Groups were determined by the surgeon's rehabilitation preference of using the CPM or not using the CPM.

Post surgical subjects were treated with the CPM and physical therapy or with physical therapy alone. Knee flexion and extension active range of motion, perceived pain, ambulation, and length of stay were measured and compared between groups with independent t-tests.

No significant difference was found between groups for knee flexion and extension active range of motion, perceived pain, ambulation distance, and length of hospital stay.

The findings suggest that there is no difference in outcomes when using a CPM machine during the rehabilitation process of total knee arthroplasty. Due to the small research population and several limitations to the study, these findings cannot be related to the general population. This study is a pilot study; further
research with better control of variables and a larger research population would allow for application to the general public. With advanced research, a more time and cost efficient program will be created for the acute rehabilitation for total knee arthroplasty.
CHAPTER I

INTRODUCTION

The Arthritis Society has estimated that 3.4% of the population of North America or 8.5 million people suffer from pain and limitation of motion of one or more joints due to some form of arthritis. According to Salter, the founder and primary researcher of continuous passive motion, "the development of total joint excision and prosthetic joint replacement for irreversibly destroyed arthritic joints in older persons has been without question the most important technological and biomechanical advance in orthopedic surgery of the present century."

Due to the high number of total knee arthroplasties being performed each year to alleviate pain and regain motion, rehabilitation of this procedure has become very important in the success of patients returning to their highest functioning level in the most efficient and cost effective manner. The primary objectives of rehabilitation for status post total knee arthroplasty (TKA) is to regain motion, mobility, stability, alleviate pain, and provide the beneficial aspects of motion on living tissue. These objectives have been met with a continuous passive motion (CPM) machine in the hospital setting. The CPM machine is a mechanical device that is preprogrammed to move a joint continually and passively through a controlled and tolerable range of motion (ROM). (See picture in Appendix A.) The rationale behind the CPM is to
1) stop the effects of prolonged immobilization of synovial joints which are persistent stiffness, pain, muscle atrophy, disuse osteoporosis, and late degenerative arthritis, 2) provide clinical observation of the beneficial local effects of early active motion versus immobilization, 3) prevent the harmful effects of immobilization as shown by research of rabbit knee joints under compression clamp or by immobilization of joints in a forced position, and 4) prevent the harmful effects of prolonged immobilization of a flexed knee joint without compression.¹

Health care is emphasizing cost containment while maintaining high levels of practice standards prompting more rehabilitation protocols to be formed to merit these criteria.⁴ The easiest way to determine the effectiveness of these protocols is through research of various treatments for each diagnosis. Investigations have examined the potential benefits of CPM, but the results are contradictory.⁴

Problem Statement

Research involving CPM in conjunction with physical therapy compared to physical therapy alone has presented mixed results. Due to these results, it is important to revisit this subject to see if there are clearer results at the present time.

Purpose of the Study

The purpose of this study is to examine knee active extension and flexion range of motion (AROM), involved knee circumference measurements, patients subjective pain rating, distance ambulated, and length of hospital stay between
patients receiving CPM and physical therapy versus physical therapy alone after TKA.

Significance of Study

This study will help determine the most effective treatment plan for patients with total knee arthroplasties. By determining the most effective treatment, the patient will achieve higher functional levels more quickly which will allow for an earlier discharge from the hospital thereby leading to decreased medical costs for the patient. With decreased medical costs, the insurance companies will have smaller medical reimbursements, which should be seen in a decrease in premiums or charges paid by the patients. An effective treatment plan will allow physical therapists to treat more patients in a timely manner leading to a more efficient and productive department.

Research Questions

Research Question #1: What is the effect of CPM on knee flexion and extension active range of motion?

- Research Question #2: What is the effect of CPM on knee circumference measurements?
- Research Question #3: What is the effect of CPM on ambulation distance?
- Research Question #4: What is the effect of CPM on patients’ perceived pain?
- Research Question #5: What is the effect of CPM on patients’ length of hospital stay after TKA?
Hypothesis

- Null Hypothesis #1: There is no significant effect on knee flexion and extension active range of motion with or without the use of CPM on the day of hospital discharge.
- Null Hypothesis #2: There is no significant effect of CPM on knee circumference measurements after TKA.
- Null Hypothesis #3: There is no significant effect of CPM on ambulation distance at the time of hospital discharge.
- Null Hypothesis #4: There is no significant effect of CPM on patients' perceived pain from post surgical day one before treatment began as compared to their perceived pain at the time of hospital discharge.
- Null Hypothesis #5: There is no significant effect of CPM on patients' length of hospital stay.
CHAPTER II
LITERATURE REVIEW

After looking at the history and uses of continuous passive motion, the debate of whether CPM is of benefit to patients undergoing total knee arthroplasty will be explained. Included is a brief anatomical review of the knee and patellofemoral joint, indications for total knee arthroplasty, the general surgical procedure for TKA, and the rehabilitation after surgery.

History of CPM

Salter\textsuperscript{1} began to investigate the effects of continuous passive motion on synovial joints in the early 1970s. He learned from cardiac, peripheral vascular, and thoracic surgery that injured tissues do not need to be put to rest in order to heal, rejecting past theories that rest and immobilization were the best way to heal injured tissue. An example of this idea was that costovertebral joints continuously move with every breath throughout ones life span yet rarely does degenerative arthritis appear. He also followed Wolff's law that states unless collagen fibrils are stressed, they are laid down in a random pattern, limiting flexibility. In 1970, Salter proposed continuous passive motion as a possible means of stimulating the healing and regeneration of articular cartilage, as well as other articular tissue, and of either preventing or overcoming joint stiffness.
Salter hypothesized that "CPM should have the following beneficial effects in synovial joints: 1. Enhanced nutrition and metabolic activity of articular cartilage; 2. Stimulation of pluripotential mesenchymal cells to differentiate into articular cartilage as opposed to fibrous tissue or bone thereby leading to regeneration of cartilage; 3. Acceleration of healing of both articular cartilage and periarticular tissues such as tendons and ligaments." Salter and his colleagues began testing the hypothesis of CPM on a wide variety of experimental models of disorders and injuries in adolescent and adult rabbits. Examples of some of their studies include the long and short term effects on full thickness defects in articular cartilage, partial thickness laceration of the patellar tendon, surgical wound healing, and clearance of a hemarthrosis. Each experiment had CPM initiated immediately after surgery and continued for various periods and frequencies of time. The partial thickness laceration of the patellar tendon experiment demonstrated that animals with CPM had significantly thicker callus formation and better alignment of tendon fibers than the animals without CPM. With surgical wound healing, the group using CPM demonstrated significantly stronger, stiffer, and tougher healed wounds with a superior histological structure of organized collagen fibers. The hemarthrosis experiment showed the rate of clearance was twice as fast with the CPM than with immobilization. CPM was shown to be significantly superior to immobilization or intermittent active motion in stimulating the healing and regeneration of articular tissues as well as preventing joint stiffness. Salter concluded over his years of CPM research that: "1. CPM is well tolerated by adolescent and adult rabbits
and seems to be relatively painless; 2. CPM has a significant stimulating effect on the healing of articular tissues including cartilage, ligaments, and tendons; 3. CPM prevents adhesions and joint stiffness; 4. CPM does not interfere with healing of incisions; 5. CPM rejects the principle that healing tissues must rest to heal.\(^n^1(p23)\)

In 1978, Salter\(^1\) moved from research on animals to clinical application. He found when using the CPM that patients had freedom from pain, which confirmed the observations from the rabbit research. Salter felt that the pain relief might be from the gate control theory of pain by Mezlack which was "inhibition of the central effects of nociceptors (afferent pain fibers) that is produced by low threshold afferents, the latter block the gate to transmission of impulses in the pain fibers."\(^5(p152)\) With CPM, it is possible that the continuous generation of proprioceptive impulses from the continuously moving joint and their transmission to the spinal cord or brain may block transmission of pain impulses to the brain.\(^1\)

In 1983, Coutts et al\(^6\) compared two groups of patients undergoing unilateral TKA; one group used the CPM and physical therapy, the other had physical therapy alone. The results showed CPM was beneficial because of reduced hospital stay, a faster return of ROM, less pain was reported, wounds healed better, and venous dynamics improved. A follow-up study showed an additional 22° of knee flexion at discharge, decreased length of stay by two days, improved wound healing, and a decreased incidence of deep vein thrombosis.\(^6,7\)
In a retrospective study by Romness and Rand, they looked at 94 knees with CPM therapy and compared them to 116 knees with no postoperative CPM following TKA. They felt the rationale for CPM was to improve motion, improve collagen orientation, decrease length of hospital stay, decrease swelling by acting as a venous pump, decrease thrombophlebitis, and a mechanism to decrease pain. They found a faster postoperative recovery of motion with more patients achieving 90° of flexion and a greater average knee flexion at hospital discharge. They found no significant difference in knee flexion at two to three months or at one year after the operation; no difference in length of hospital stay; and no significant difference with hemoglobin levels, operative blood loss, or transfusion requirements.

In a study by Ververeli et al, CPM combined with physical therapy was compared with physical therapy alone examining ROM, length of hospital stay, wound complications, postoperative pain, incidence of pulmonary embolism, manipulation, and cost. Their results showed that CPM was significantly effective in improving active knee flexion and increasing patients' mobility and activity in the immediate postoperative period. They found CPM had no significant effect regarding pain, wound healing, knee swelling, wound drainage, pulmonary embolism, and knee ROM two years later. This study cited several other studies that had proven CPM reduced the length of hospital stay. The study reported in 1995 the average length of stay was six days; however, due to current changes in health care, Ververeli et al were unable to prove that CPM could reduce that time.
9

Other Uses of the CPM

Besides being a useful tool for TKA rehabilitation, the CPM is used in other procedures for the foot, ankle, hip, finger, elbow, and shoulder. In hand therapy, the CPM is used for flexor and extensor tendon repairs, tenolysis, burns, joint reconstruction, crush injuries, and intraarticular injuries. In rehabilitation of the shoulder, the CPM plays an important role in shoulder reconstruction, hemiarthroplasty, and small tears in the rotator cuff. The CPM has also been used for ankle and foot arthroplasty, neuroma excision, bunionectomy, and tendon repairs. In pediatric orthopedics, the CPM is becoming very valuable in abnormal joint cartilage alignment, severe trauma, infections, synovitis, slipped capital femoral epiphysis, juvenile rheumatoid arthritis, septic arthritis, and tibial and femoral fractures.

Anatomy of the Knee

The knee consists of two joints: the patellofemoral and tibiofemoral joints. Bones involved in the two joints are the femur, tibia, and patella. The surfaces of the distal end of the femur and proximal end of the tibia are lined with articular cartilage to protect the bone during weight bearing and movement. The joint lining produces fluid that lubricates the joint and nourishes the avascular articular cartilage. The quadriceps muscles, patellar tendon, and anterior cruciate ligament stabilize the knee joint anteriorly. The popliteus and semimembranosus muscles and posterior cruciate ligament maintain posterior stabilization. The biceps femoris and tensor fascia lata muscles and lateral collateral ligament preserve lateral stabilization. The semitendinosus, sartorius, and gracilis
muscles and the medial collateral ligament sustain medial stabilization. The quadriceps femoris functions primarily to extend the knee and the hamstrings provide the majority of knee flexion.\textsuperscript{13} For total knee arthroplasty, the knee is divided into three compartments; the medial and lateral tibia femoral compartment and the patellofemoral compartment are all replaced in a tricompartmental TKA.

Indications for TKA

Potential TKA patients usually present to their doctor with significant pain, mechanical instability at the knee, and limited knee ROM. Most of these signs and symptoms come from several arthritic conditions. Osteoarthritis is the most common condition affecting between 16 to 40 million people. Inflammatory conditions including infection, metabolic conditions (pseudogout, gout, hemophilia), and autoimmune disorders (rheumatoid arthritis) may cause degenerative changes in the joint. X-rays are often taken to determine bone quality, varus/valgus alignment, joint space loss, appearance of osteophytes, and evidence of effusion. Factors for performing TKA are advancing age and corresponding decrease in life expectancy, patients with severely diminished ROM, especially in conjunction with significant flexion contracture, significant synovitis and/or sensitivity of the joint, and certain uncorrectable instability, especially rough, deformed, and depressed joint surfaces. Contraindications for TKA are active infection, morbid obesity, quadriceps paralysis, and/or inability to participate in postoperative rehabilitation.\textsuperscript{14-16}
Surgical Procedure

The surgical procedure for total knee arthroplasty is varied depending mainly on the amount of damage to the bone, the lower extremity alignment of the patient, the surgeon's preference, and other small factors too numerous to mention. The procedure consists of a surgical incision, retraction to expose the knee joint, bone remodeling, prosthetic fitting, and surgical closure of the knee.15

The main goal when opening the knee for total knee replacement is exposure of the femur and tibia to allow the surgeon to accurately cut and remodel these bones to ensure precise prosthetic fit and correct alignment of the knee joint. The surgical incision is routinely along the medial aspect of the patella and may be curved or straight. The patella is positioned out of the way by turning down the quadriceps muscle either proximally or distally by a tibial tubercle osteotomy. The fascia is cut deeper as the surgeon moves proximally. The capsule is then incised, exposing the proximal tibia with the knee in 20° to 40° of flexion. The anterior cruciate ligament is cut close to the femoral insertion. The tibial portion of this ligament is removed with the proximal tibial bone cut later in the surgical procedure. The posterior cruciate ligament is often left intact; if not, it is later reattached but is not a major rehabilitation concern later. The collateral ligaments are also left intact and are retracted for the bone to be cut. In the presence of a fixed varus or valgus deformity, a soft tissue release (one of the collateral ligaments is incised) will be performed to allow proper cutting depth.15
For proper prosthesis fit, the tibia, femur, and patella have to be cut and remodeled. Considerations for tibial resection are its depth, varus/valgus deformity, passive knee flexion/extension, and rotational orientation so the cut can be perpendicular to the long axis of the tibia. If there is an abnormal varus cut, it will cause increased prosthetic wear and anterior downhill sloping leading to component fixation failure within 12 months. Femoral resection is done by using a straight anterior posterior cut and angled superior to inferior at the anterior and posterior aspects of the femur. With patellar resection, the least amount of bone is removed which is difficult due to the hardness and abnormal wearing of the patella. The goal of bone resection is to provide a good bony interface, proper alignment, adequate bony support and to avoid excessive iatrogenic thickening of the patella.15

Most artificial knees consist of a multiradius, modular femoral component that recreates the anterior trochlear notch to allow for patellofemoral resurfacing. Tibial components consist of a metal, high backed, high density polyethylene lining that articulates with the femoral component.14 The patellar component is also manufactured from a high density polyethylene. A trial reduction is performed where several different components are tried for best fit with the least amount of drawbacks. Once the components are selected, the bone is cleaned and prepared for final component fitting. For the cement technique, two types of cement, regular viscosity or low viscosity, can be used. The cement is then applied and the components secured. For porous ingrowth arthroplasty, the
components are loose at the beginning but are eventually secured by the surrounding bone.\textsuperscript{15}

Once the components are secure, patellar stability and tracking are checked to prevent patellar subluxation. A soft tissue release may be performed to insure better patellar tracking. During the procedure, the tourniquet is released so the knee can be examined for bleeding points. Once the bleeding points are stopped, the tourniquet is re-inflated. Following one more inspection, the wound is closed. The capsule and tendinous layers are closed and a wound suction drainage tube is placed in the interarticular space. After placement of the drainage tube, the skin is sutured closed.\textsuperscript{4}

Rehabilitation

The general physical therapy protocol as per communication with the primary therapist at United Medical Center on June 1, 1999 for total knee arthroplasty consists of ambulation to patient tolerance several times per day. Exercises performed are quadriceps sets, hamstrings sets, ankle pumps, heel slides, and straight leg raises. Along with the exercises, the knee is stretched into flexion and extension and range of motion is performed passively, with assistance, and actively. Patient education regarding preventing complications, decreasing swelling and pain, returning to home activities, and home exercise program are included in the treatment.

Use of CPM following a total knee arthroplasty varies with the type of procedure performed and physician recommendation. For a cemented TKA, the CPM is started in the recovery room starting at 30° to 60° of knee flexion to full
knee extension. The CPM is usually increased 5° to 10° each day or is increased by patient tolerance. CPM use and duration varies significantly depending on surgeon's preference ranging from using it as much as possible to a few hours per day. For an uncemented TKA, the CPM is usually not used for 12 to 36 hours post surgery.\textsuperscript{15}

Considerations of acute rehabilitation for TKA include which modifications to the surgical technique were performed, whether the components are cemented or uncemented, bleeding and infection, and the patient's pain tolerance. Surgical procedures like tibial tubercle osteotomy and Coonse-Adams Quadriceps Turn Down leave the extensor mechanism much more vulnerable to injury and weakness. In general, uncemented arthroplasties require a slower weight bearing progression than cemented ones. The patient's pain threshold, if low, may slow progression of rehabilitation. If the patient does complain of moderate to significant pain, it may be due to relative confinement of bleeding in the essentially intact joint capsule region or the area may be infected. Significant warmth may continue for several months but does not imply an underlying problem or infection.\textsuperscript{16}

The goals for acute rehabilitation of TKA are geared toward regaining function of the knee joint and surrounding musculature. According to Kettelkamp et al\textsuperscript{17} and Laubenthal et al,\textsuperscript{18} they found that approximately 83° of knee flexion was needed to go up stairs, 84° to go down stairs, 90° to sit, and 70° for normal swing phase of gait using electrogoniometry. A functional straight leg raise (SLR) is important to demonstrate good quadriceps control which facilitates
transfers, gait training, and increased weight bearing. Knee range of motion needs to increase to minimize pain from flexor contracture and to prevent or minimize quadriceps antagonism or the guarding response. Patients' failure to achieve adequate ROM may be correlated to preoperative ROM or postoperative discomfort. At least unilateral support with an assistive device is recommended for the first six weeks to prevent knee buckling and trauma.15,19
CHAPTER III

METHODOLOGY

The study was approved by United Medical Center and University of North Dakota Institutional Review Boards (Appendix B) prior to initiating subject consent and data collection. Subjects for this study were patients of varying pathology who underwent a primary unilateral or bilateral total knee arthroplasty at United Medical Center in Cheyenne, Wyoming, from June 1999 through mid-September 1999. Patients excluded from the study included minors, individuals having a total knee revision, or having a secondary diagnosis (ex: Alzheimer's disease, reflex sympathetic dystrophy, cancer). A consent form (Appendix C), signed by all participating patients, informed them that their treatment would not be modified for this study and not altered if patients were excluded or dropped from the study.

A memo was sent to all orthopedic surgeons for their inspection and approval to participate (Appendix D). Seven orthopedic surgeons performed the surgeries using a variety of prosthetic designs and surgical procedures and then referred the patients to physical therapy. Five of the seven surgeons used the CPM in conjunction with rehabilitation.

Subjects were assigned to a CPM or non-CPM group according to the physicians' rehabilitation preference. The CPM group received the CPM
machine immediately after surgery with duration and range of motion variables determined by each physician's guidelines. The non-CPM group received no CPM machine throughout the rehabilitation process.

The mean age of the non-CPM group was 68.7 and 64.1 years old for the CPM group. There were three females and one male in the non-CPM group and eight females and four males in the CPM group. The surgery was performed three times on the left and once on the right in the non-CPM group. In the CPM group, TKA was completed three times on the left, eight times on the right, and once bilaterally. The bilateral TKA was accomplished concurrently and was recorded as two separate knees in this study.

The CPM device used in this study was a Dani Flex 460 unit (Daniger Medical Supply, Columbus, Ohio). Range of motion was measured with a standard universal goniometer. Girth measurements were taken using cloth tape measure.

The consent form was given to and explained to each subject by the treating physical therapist. Individual data collection sheets (see Appendix D) and consent forms were kept in the patient's chart to ensure confidentiality. A total of eight physical therapists (two primary therapists) on the acute care orthopedic rotation at United Medical Center participated in data collection for this study. The physical therapists background ranged from two to seven years of clinical experience. All physical therapists were oriented to the study by the researcher and used the same total knee arthroplasty protocol and needed measurements.
Patients were referred to physical therapy at the surgeon’s discretion. Data collection commenced with the initial physical therapy evaluation once MD referral was received. Thus, physical therapy was initiated on the first or second postoperative day as per physician request. Patients were seen two times per day every day, including weekends, until physical therapy was discontinued or hospital discharge occurred. The general physical therapy exercise protocol consisted of straight leg raise, quadriceps and hamstring sets, heel slides, knee ROM, and ankle pumps. At initial evaluation, demographic information was obtained and measurements including passive knee flexion and extension, pain rating, and knee girth were recorded. Passive range of motion and pain rating were measured once a day. At the time of discharge from physical therapy or the hospital, knee flexion and extension AROM, girth measurements, perceived pain, ambulation distance in feet, and total length of stay in days were recorded.

The CPM machine was set up by the physical therapist with the patient supine in the recovery room or in the patient’s room post surgery. The hip and knee axis of the CPM unit was aligned to the greater trochanter of the hip and the patient’s knee joint respectively by adjusting the thigh length of the machine. The mid thigh and mid calf straps were secured. The CPM duration and range of motion were then set according to each physician’s specific guidelines with adjustments being made by the therapist for increase in pain or ROM.

Patients were positioned for comfort in a supine position to measure passive knee flexion and extension range of motion. For all knee range of motion measurements, the fulcrum of the goniometer was centered over the
lateral epicondyle of the femur. The proximal arm was aligned with the lateral midline of the femur, using the greater trochanter for reference. The distal arm was aligned with the lateral midline of the fibula using the lateral malleolus and fibular head for reference.²⁰

At the beginning of one treatment session each day, the patient was asked by the treating therapist to rate his or her knee pain on a pain intensity number scale of 0 to 10, with 0 being no pain and 10 being the worst pain possible. At the end of the treatment session, the patient was again asked to rate his or her pain and this information was recorded on the data collection sheet.

Girth measurements were taken with the patient positioned for comfort in supine. The treating therapist palpated the patella through the bandages and measured girth at the midpatella, four inches above, and four inches below the midpatella.
CHAPTER IV

RESULTS

No significant difference was found between the group receiving continuous passive motion and the group receiving physical therapy without CPM. The variables of knee active flexion and extension range of motion, perceived pain, distance ambulated at the time of discharge, and length of hospital stay as shown in Table 1.

Table 1. Independent Measures t Test for Differences in Clinical Variables Between Groups

<table>
<thead>
<tr>
<th>CLINICAL MEASURE</th>
<th>GROUP</th>
<th>N</th>
<th>MEAN</th>
<th>S</th>
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<td>AROM Flexion (in degrees)</td>
<td>CPM</td>
<td>13</td>
<td>74.1</td>
<td>11.9</td>
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<td>Perceived Pain</td>
<td>CPM</td>
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<td>.05</td>
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<td>1.0</td>
<td>4.5</td>
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<td>Distance Ambulated (in feet)</td>
<td>CPM</td>
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<td>162.3</td>
<td>96.2</td>
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<td>24.0</td>
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<td>Length of Hospital Stay (in days)</td>
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<td>.05</td>
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CHAPTER V

DISCUSSION

The rationale for the use of continuous passive motion following total knee arthroplasty is to aid in healing of the incision, decrease length of hospital stay, reduce swelling, improve motion, and provide a mechanism to decrease pain. The results of this study demonstrate that there is no difference in knee flexion or extension active range of motion (AROM) in patients with or without the CPM at the time of hospital discharge. Patients in the non CPM group (n=4) had an average knee flexion AROM of 64.5° and extension AROM of -8.8° from neutral. The CPM group (n=12) had an average knee flexion AROM of 74.2° and extension AROM of -7.84° from neutral at the time of discharge. In electrogoniometric studies by Kettelkamp et al\textsuperscript{18} and Laubenthal et al,\textsuperscript{19} they found that approximately 70° of knee flexion and 0° of knee extension were required for the normal swing phase of gait. The CPM group, therefore, had enough knee flexion for normal swing phase according to the average. The non-CPM group had near normal values for knee flexion according to the average. In this non-CPM group, one patient attained 105° of functional knee flexion and the other three attained approximately 50° of knee flexion and were far below the functional average for gait. Both groups were lacking terminal extension for normal gait specifically during the terminal swing phase when full extension is
needed for initial contact of the heel with the ground. There were two patients in the CPM group who had functional ROM immediately after surgery and, therefore, no significant increases in knee ROM occurred during their hospital stay. These results match multiple studies\textsuperscript{3,7,22} including a study by Ritter, et al\textsuperscript{23} who demonstrated no significant difference in ROM in bilateral total knee arthroplasties in which one knee was treated with CPM and physical therapy while the other knee was treated with physical therapy alone.

There was no difference between groups in distance ambulated at the time of discharge. The patient with bilateral knee replacement was only able to ambulate 15 feet before being discharged from acute care; with or without this subject, there was still no significant difference between groups. According to the Functional Independence Measure, patients are considered a household ambulators if they can ambulate 150 feet with or without an assistive device. The patient with bilateral knee replacement and one patient in the CPM group did not meet the 150-foot criteria for household ambulation; however, all the other subjects were able to ambulate at least 150 feet. Ambulation distance was not a variable measured in any of the other studies found through the literature review. Although walking does not require full knee range of motion, it is an important functional aspect that should be analyzed for knee replacement outcomes and for discharge from the acute setting.

Pain was not affected by the use of CPM from pretreatment day one to the time of discharge using the perceived pain intensity number scale 0-10 with 0 being no pain and 10 being the worst pain possible as compared to the non-CPM
group. Three people from both groups rated their pain on the first day of physical therapy an eight or above, demonstrating severe pain. Remaining patients in both groups rated their pain initially a five or below. By the time of discharge, all the patients in both groups had a mean decrease in pain of 1.4 points from their first day of physical therapy on the pain intensity number scale. The pain did not seem to limit any of the patients in regaining motion or functional ability.

The length of hospital stay was also unaffected by either treatment. Overall, the length of stay was just under five days for both groups. The study did not track the patient after hospital discharge, so it is difficult to determine if the patient was able to go home, was transferred to an extended care facility, or went home with extra medical or family support. The length of hospital stay may be more of an indicator of managed care than the patient being functionally ready to leave the hospital.

Since there was no significant difference in the variables measured in this study, it is possible that there are other pre-surgical factors that play a larger role in regaining function and ROM after knee replacement surgery. According to Ritter, et al, motion might return with varying difficulty. Motion was often directly related to preoperative diagnosis, overall condition of the extremity, the patient's general physical status, and the patient's motivation.

**Limitations of Study**

The small sample size overall as well as for each group severely limits generalization of the results to other patients undergoing total knee replacement.
and their therapy afterwards. There was not enough data to make any definite conclusions on effectiveness of CPM use. A larger sample size for both groups would improve analysis and allow generalizations to be made to the general population. With these generalizations, policies or protocols could be formed for knee replacement rehabilitation, the cost for each treatment could be compared, and the most cost-effective treatment identified.

The procedure for measuring girth lacked standardization during measurement and produced such high variability that it was discarded for statistical calculations. The different bandaging and wrapping technique used by the different surgeons, difficulty in measuring girth due to different physical therapists and their inability to palpate the patella with any certainty caused the high variability.

No specific physical therapy protocol was established for this study, except for the general exercises. Without a definite protocol, there was possible variation between treatment techniques for each therapist for each group. Using one physical therapist for all the patients involved in the study could have reduced this variability, but due to the time constraints, this was not possible. With a varied staff rotation for acute care therapy on the weekend, several different therapists potentially could see the patient and further increase the amount of variability between individuals. Intra- and inter-rater reliability for each measurement procedure also led to high variability between therapists.

This study used seven orthopedic surgeons who performed knee replacement surgery. The study did not differentiate between surgeon, surgical
procedure, and prosthetic appliance type for knee replacement. This variability may also have an effect on the results of this study.

The variability between patient's age, gender, pain perception, degree of disability before surgery, and strength were also limitations. Age of the patients who participated in the study ranged from 42 to 79 years old. There were more females than males, which may have an underlying effect on perceived pain and lower extremity strength. Since there were no preoperative measurements, functional ability and disability may have varied greatly between patients.

**Ideas for Future Studies**

Further studies are recommended to examine the effects of CPM on total knee arthroplasty and rehabilitation. Determining whether there is a difference between patients using the CPM and patients receiving only physical therapy is still undetermined. By looking at more variables such as pre-surgical and post-surgical range of motion, range of motion at different periods in the rehabilitation process, the frequency of knee manipulations by M.D.s to increase range of motion and the cost associated with the procedure performed on each group would help determine functional outcomes and cost effectiveness of each treatment. Further studies could be performed looking at the effects of ROM and functional outcomes including altered application time of CPM, speed of CPM, or use of CPM while in the hospital versus outpatient use.
CHAPTER VI
CONCLUSION

The results of this study show that there is no significant difference in knee AROM flexion and extension, pain, length of stay, and ambulation distance between patients receiving continuous passive motion and physical therapy and patients receiving only physical therapy post total knee arthroplasty surgery. From the results of this study, the patient appears to gain comparable knee active range of motion with and without CPM assistance. The CPM did not enhance the ability to ambulate farther as compared to physical therapy alone. Neither group attained terminal knee extension range of motion to allow for normal swing gait mechanics. Despite the CPM's documented pain-relieving ability, there was no significant difference in subjective pain reports between groups. Since the length of hospital stay was relatively equal, the cost for renting the CPM was possibly an unnecessary expense for the patient at $90 per day or $450 for an average of five days. This study raises further questions regarding the efficiency of CPM as part of the total knee arthroplasty treatment program and the cost effectiveness of the treatment especially with managed care becoming more prevalent.
APPENDIX A
Continuous passive motion (CPM) is applied by a mechanical device that
is preprogrammed to move a joint continually and passively
through a controlled and tolerable range of motion (ROM). The use
of CPM in the rehabilitation of patients after total knee
arthroplasty (TKA) is a treatment method designed to increase
knee ROM and prevent joint stiffness. Studies have also shown
CPM use to decrease other symptoms such as patient's pain, deep-vein
thrombosis (DVT) occurrence, and swelling. There have been numerous
studies comparing CPM to conventional physical therapy with mixed
results. The purpose of this study is to determine if CPM has a significant
effect on patient's pain, knee ROM for flexion and extension, girth
measurements, final distance ambulated, and length of stay versus
conventional physical therapy.
PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. **PROTOCOL:** (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

The subject pool will come from patients undergoing a TKA operation performed at United Medical Center during the study's time parameter of May-September of 1999. The people who will be eligible for the study are all patients of any age except for those patients with surgical complications (infection and deep vein thrombosis), a secondary diagnosis (some examples being Alzheimer's disease or dementia, past hip fracture, reflex sympathetic dystrophy, neurological diseases, and some types of cancer), TKA revision, and minors. The pool will consist of about 30 subjects with an unknown number in each group. The subject groups will be determined by the surgeons' preference of using the CPM or not. Before physical therapy treatment is initiated the physical therapist will explain the study and have the consent form signed by the patient for eligibility into the study. The CPM equipment used will be United Medical Center's Dani Flex 400 from the Physical Rehabilitation Services department. After surgery each patient will participate in a standard physical rehabilitation protocol with one group using the CPM and the other not using the CPM. Each day the patient's perceived pain using a visual scale of 0-10 (0-being no pain and 10-worst possible pain) will be taken before and after treatment intervention. Knee active range of motion of flexion and extension using a goniometer in sitting will be measured after one treatment each day. Girth measurements at the middle of the patella, 4 inches superior and inferior to the patella will be measured at the initiation of physical therapy evaluation and treatment after the surgery has been performed and when the patient is discharged from the hospital or if/when physical therapy is discontinued prior to hospital stay. Length of stay will be recorded from the time after surgery to the time when the patient is discharged from the hospital or if/when physical therapy is discontinued prior to hospital stay in days. The distance ambulated by the time of discharge will also be recorded. All data will be recorded by the patient's primary physical therapist on the data collection form and kept in the patient's chart until time of discharge from the hospital or if/when physical therapy is discontinued prior to hospital stay (see attachment). The data sheets will be numbered to insure patient confidentiality. Data will be analyzed with independent measures statistical T tests for significance.
3. **BENEFITS:** (Describe the benefits to the individual or society.)

The benefits in conjunction with this study are to determine a more efficient way of providing rehabilitation to patients undergoing TKA, increases in rehabilitation productivity, and the patient's positive experience of being involved in a research study. By proving or disproving the effects of the CPM and physical therapy after TKA versus conventional physical therapy, it will benefit physical therapy practice by making it more efficient and cost effective when caring for these patients. This will benefit the patient by lower health care costs in the future.

4. **RISKS:** (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

The measurements used for this study are a standard protocol of the physical therapy practice for rehabilitation of TKA. There is no additional risks with this study to the patient. There is also no risk involved by having or withholding the CPM treatment. The physical therapy treatment with or without the CPM may cause possible muscle soreness, increased pain, and fatigue which may be experienced despite this study. Physical therapist are trained to minimize the risks to the patient during rehabilitation after TKA. If there is an adverse reaction to the therapy or measurements taken the patient's primary physical therapist will intervene at that time and properly document and refer if necessary. If there are additional costs for medical treatment, cost responsibility will be handled by the patient or their insurance.
5. CONSENT FORM: A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

Describe where signed consent forms will be kept and for what period of time.

Signed consent forms will be kept in a locked cabinet for 3 years following completion of the study by the supervising instructor/preceptor of this project. After 3 years all data will be destroyed.

6. For FULL IRB REVIEW forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development
University of North Dakota
Grand Forks, North Dakota 58202-7134

On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.

For EXEMPT or EXPEDITED REVIEW forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

SIGNATURES:

Principal Investigator ___________________________ Date __________

Project Director or Student Adviser ___________________________ Date __________

Training or Center Grant Director ___________________________ Date __________

(Revised 3/1996)
STUDENT RESEARCHERS: As of June 4, 1997 (based on the recommendation of UNO Legal Counsel) the University of North Dakota IRB is unable to approve your project unless the following "Student Consent to Release of Educational Record" is signed and included with your "Human Subjects Review Form."

STUDENT CONSENT TO RELEASE OF EDUCATIONAL RECORD

Pursuant to the Family Educational Rights and Privacy Act of 1974, I hereby consent to the Institutional Review Board’s access to those portions of my educational record which involve research that I wish to conduct under the Board’s auspices. I understand that the Board may need to review my study data based on a question from a participant or under a random audit. The study to which this release pertains is ________________________________

I understand that such information concerning my educational record will not be released except on the condition that the Institutional Review Board will not permit any other party to have access to such information without my written consent. I also understand that this policy will be explained to those persons requesting any educational information and that this release will be kept with the study documentation.

Date ___________________________ Signature of Student Researcher

1Consent required by 20 U.S.C. 1232g.
May 28, 1999

Mr. Neal Cashman
UMC Health & Fitness
1620 East Pershing Boulevard
Cheyenne, WY 82001

Dear Mr. Cashman:

I have reviewed the information you submitted on your study entitled Continuous Passive Motion Versus Physical Therapy in Total Knee Arthroplasty, and the Information and Consent Form.

As Chairman of the Institutional Review Board (IRB) of United Medical Center and under the expedited review provisions of 45 CFR 46.110 and 21 CFR 56.110, I hereby approve your study with you as principal investigator.

A report on the study will be presented to the IRB at its next regular meeting. The Board members would be interested in a summary from you at the conclusion of your study.

Sincerely,

STANLEY E. HARTMAN, M.D.
Chairman
Institutional Review Board

SEH:jf
APPENDIX C
INFORMATION AND CONSENT FORM

TITLE: Continuous Passive Motion Versus Physical Therapy in Total Knee Arthroplasty.

You are invited to participate in a study conducted by Neal Cashman, a physical therapy student at the University of North Dakota. The purpose of this study is to determine if using continuous passive motion after total knee arthroplasty (replacement) has a significant effect on any of these factors: patient pain, knee active range of motion, knee girth measurements, and length of stay at the time of discharge from the hospital compared to the physical therapy protocol for total knee arthroplasty without the use of continuous passive motion.

You have been selected for this study due to your recent knee replacement surgery. The study will continue for the duration of your hospital stay and will end at the time of discharge from physical therapy.

After total knee arthroplasty each patient follows a physical therapy protocol designated by their surgeon using continuous passive motion and physical therapy or conventional physical therapy. During one of the treatment sessions each day the measurements taken will be used for this study. The measurements are a subjective pain scale (0-10) 0- being no pain to 10- being excruciating or unbearable pain, knee active range of motion which is measurement of how much you knee bends and extends, knee circumference measurements to measure the amount of swelling in your knee, and the length of stay you are in the hospital.

This study is to determine if physical therapy can be more cost effective and still provide the best care possible to the consumer. These benefits will hopefully be in reduced costs to the consumer in the future.

With this study there are no other foreseeable risks associated with your physical therapy treatment. If an injury occurs report it to your attending physical therapist who will take the necessary measures to care for the injury. If there are additional costs for emergency medical treatment, cost responsibility will be assumed by the patient or their medical insurance.

Your name will not be used in any reports or in the results of this study. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. The data collected will be kept by a University of North Dakota faculty member for the next three years. The data will be identified by number and known only by the investigator. The investigator or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to his/her health from the measurements taken. Your decision whether or not to participate will not prejudice your future relationship with your physician, the physical therapy
department, United Medical Hospital, or the University of North Dakota. If you decide to participate, you are free to discontinue participation at any time without prejudice.

The investigator involved is available to answer any questions you have concerning this study. In addition you are encouraged to ask any questions concerning this study that you may have in the future. Questions may be asked by calling Neal Cashman at (307) 634-6667, Whitney Meier at (307) 778-5506, or Michelle LaBreque at (701) 777-2831. A copy of this consent form is available to all participants in the study.

ALL OF MY QUESTIONS HAVE BEEN ANSWERED AND I AM ENCOURAGED TO ASK ANY QUESTIONS THAT I MAY HAVE CONCERNING THIS STUDY IN THE FUTURE. MY SIGNATURE INDICATES THAT, HAVING READ THE ABOVE INFORMATION, I HAVE DECIDED TO PARTICIPATE IN THE RESEARCH PROJECT.

I have read all of the above and willingly agree to participate in this study explained to me by _____________________.

______________________________
Participant's Signature       Date

______________________________
Witness (not the scientist)   Date
Memo

To: 

From: Neal Cashman  

CC: 

Date: 

Re: Master Thesis on Post-op TKA  

I am a student from the University of North Dakota proposing a study on Post-op Total knee surgeries to be conducted at United Medical Center. This study is a requirement for my Masters Degree in Physical Therapy.

A brief outline of the study is as follows:

Measure and compare the following variables 1-day to five days post-op TKA

1. Knee active ROM both extension and flexion.

2. Pain scale.


4. Distance ambulated at the time of discharge

Two groups

1. Those that use CPM.

2. Control group patients that do not use a CPM.

All participating physicians will receive results of this study.

I have approval from the Institutional Review Board from United Medical Center and need your signature of approval to complete the process for the University of North Dakota’s Institutional Review Board. I will contact each office to set up a time to collect the signatures this week. At that time I will answer any questions or concerns that you have regarding the study. Thank you Neal Cashman

I approve and am willing to participate in the study ________________________.
DATA COLLECTION SHEET

#________
DEMOGRAPHIC DATA
*AGE ___
*SEX ___
*DX __________
*GROUP ________
(1-CPM 2-no CPM)

MEASUREMENTS

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<tr>
<td>4 inches below</td>
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Final distance ambulated ______

Total Length of Stay (in days) ______
REFERENCES


