ABSTRACT

Background- Techniques that allow early muscle activation, such as closed kinetic chain (CKC) and open kinetic chain (OKC) exercises, may play a beneficial role in the early rehabilitation of the reconstructed knee. However, current rehabilitation regimens have not been shown to reverse post-operative quadriceps activation failure and weakness.

Objective- To investigate whether patients who use a continuous active motion (CAM) device that follows closed kinetic chain principles have better early post-operative functional improvements than patients who use a continuous passive motion (CPM) device that follows the principles of open kinetic chain principles.

Design- A prospective randomized controlled trial with non-blinded study staff.

Setting- A tertiary care clinic at a teaching hospital.

Participants- A total of 110 patients signed the consent form and 83 patients participated in the study.

Methods- Patients were randomly assigned to use either the CPM device for 4 hours daily for 3 weeks (control group), or a CAM device for 3 sessions of 20 minutes for 3 weeks (intervention group), starting 24 hours after knee replacement surgery

Main Outcome Measurements- The primary outcome measure was to identify the superiority, inferiority, or equivalence of one device at week 4 after knee arthroplasty using various functional outcome measures such as kinesthesia, quadriceps strength, coordination, general orthopaedic outcome measures and narcotic consumption.

Results- At 4 weeks, all outcome measurements were comparable between the two groups, with the exception of sit-to-stand test: in the treatment group the time was significantly shorter

compared to the control group ($p = 0.016$). Balance was significantly better in both control ($p = 0.001$) and treatment group ($p = 0.032$) compared to prior surgery.

Conclusions-Most clinical centers would like to expedite functional recovery of knee arthroplasty patients without increasing the risk of falls. We observed balance and kinesthesia improvements after surgery using either device which may be important to benefit fast recovery programs. Further research is warranted to see whether additional active closed kinetic chain exercised following knee replacement surgery could improve specific functional outcomes such the observed sit-to-stand test.

Key Words

Knee arthroplasty, proprioception, post-op, quadriceps strength

INTRODUCTION

In 2008, about 555,000 primary total knee replacements were performed, with annual growth rates between 5% and 6% (1). This rapid increase is primarily being driven by the growing elderly population worldwide, the obesity epidemic, and the large numbers of aging baby boomers who require joint replacements. Over the past decade, better surgical techniques and peri-operative pain management have improved recovery after knee arthroplasty. The most important element for rapid recovery is early functional rehabilitation with shorter length of stay (LOS), increase number of patients who can return home independently and to reduce overall costs by decreasing the number of patients being discharged to skilled nursing facilities. Achieving these goals require good pain control with improved multimodal pain management and femoral nerve blocks to reduce opioid usage and to reduce the side effects of narcotics used. Early independent mobilization with sufficient balance, enhanced coordination of daily tasks, good overall muscle strength without the risk of falls and readmissions are essential, especially in elderly patients (2) to successful fast recovery following knee replacement surgery.

Quadriceps strength can be decreased by as much as 60% (3) following total knee arthroplasty (TKA), and a 55% reduction has been observed at three weeks post-operatively (4). Although techniques that allow early muscle activation, such as closed kinetic chain (CKC) and open kinetic chain (OKC) exercises, may play a beneficial role in the early rehabilitation of the reconstructed knee (4-9), current rehabilitation regimens have not been shown to reverse post-operative quadriceps activation failure and weakness (2,5,6,10), which is the muscle group most affected due to the surgical approach of knee replacement. The use of continuous passive motion (CPM) devices following the principles of OKC have been used for rehabilitation of knee injuries, cartilage repair, and knee arthroplasty since being introduced by Salter 25 years ago

(4,11). CPM following knee arthroplasty was advocated not only for its proposed benefits of regaining better range of motion but also to reducing the need for mobilization under anesthesia. Over time the use of CPM became the standard of care following post-operative treatment of knee replacement surgeries. Yet the benefits of CPM following total knee replacement appear to be minimal (12), and its use may not be cost-effective. A meta-analysis of 20 randomized controlled trials (12-13) found that passive and active range of motion increased by only a few degrees, which did not justify using CPM following TKA. Due to lack of published evidence or benefits, including cost-related concerns, some centers have abandoned the routine use of CPM devices. Only two of the studies in the meta-analysis, however, reported on quadriceps strength (13-15), of which one showed a positive effect (16). None of the studies observed other more functional relevant outcome measures, such as the sit-to-stand test, kinesthesia, and proprioception. The goal of our study is to see whether these outcome measures could be improved with motion devices following knee replacement surgery and whether these devices could benefit early recovery following knee replacement surgery.

We wonder whether continuous active motion (CAM) devices, which are based on CKC exercises and allow variable active contractions of the quadriceps and hamstring muscles of the operated knee, could be more beneficial than CPM devices which are based on the principles of OKC exercises. CAM devices may reduce the anterior translation of the tibia relative to the femur, increase tibiofemoral forces and co-contraction of the hamstrings, and mimic functional activities. In one study (14), CAM device that follows the principle of CKC exercises was found to decrease the proprioceptive deficit that is commonly seen after ACL surgery (7,8,17,18). However, research has not been able to determine whether CKC is superior, equal, or inferior to OKC.

We conducted a randomized controlled trial to test the hypothesis that patients who used a continuous active motion (CAM) device that follows CKC principles have better early post-operative functional improvements compared to a continuous passive motion (CPM) device that follows the principles of OKC. Specifically, we wanted to see whether there are any differences in several functional outcome measures such as kinesthesia, quadriceps strength, coordination, but also general orthopaedic outcome measures and narcotic consumption with either device.

METHODS

In a parallel group design, we compared an active motion device (CAM) with a passive motion device (CPM) in patients following total knee replacement. The CPM group was the control group, and all data were collected at New England Baptist Hospital in Boston, MA. Following institutional IRB approval, individual patients were randomized to one of two parallel groups to identify the superiority, inferiority, or equivalence of one device to the other.

Between March 2007 and December 2010, we invited a consecutive series of 1153 patients with severe medial uni- or tri-compartimental unilateral knee osteoarthritis scheduled for medial UKA or TKR to participate in the study. Of those, 137 patients agreed to participate, 27 did not meet the inclusion criteria (Table 1), and a total of 110 patients signed the informed consent form (Figure 1).

Two surgeons (WF and RSD) performed a total of 110 knee arthroplasties. All patients underwent general anesthesia. All UKA received local infiltration analgesia and all TKA received a single shot femoral nerve block. All medial UKA (Oxford, Biomet, Warsaw, IN) were done through a short para-patellar approach without patella eversion and all TKA (Depuy PFC

Sigma CR, Warsaw, IN) were performed using a slightly more extended medial para-patellar approach going about 5 cm proximal to the patella.

Using a computer-generated randomization program, patients were assigned to use either the CPM device for 4 hours daily for 3 weeks (control group) or a CAM device for 3 sessions of 20 minutes for 3 weeks (intervention group), starting 24 hours after knee replacement surgery in addition to a standard rehab protocol. The CAM device is comparable to a bicycle but with a linear motion (Oped, Waltham, MA, USA) while the CPM device just extends and flexes the knee passively. Usage of either device and narcotic consumption was documented in diary. The patients were started on their devices in the hospital, and each had access to their assigned device whether they were discharged home or to a rehabilitation facility.

All patients were discharged home or to rehab on post-operative day 2 or 3 and given a diary to document the total time spent to use either device and the total daily narcotic consumption. All patients received a standardized physical therapy protocol but the difference was the assigned studied device only. All patients progressed to outpatient physical therapy between 2 and 3 weeks and were seen for testing 4 weeks after surgery.

All patients were evaluated and underwent measurement of our outcome measures during their pre-operative visit 1-2 weeks prior to their scheduled surgery and 4 weeks after surgery during their postoperative visit.

All testing were conducted by an independent but non-blinded research assistant. Since both devices look different and patients were much more intrigued to use the active device we could not blind study staff.

Each evaluation comprised the following outcome measures:

Kinesthesia, Quadriceps Strength, and Coordination

After one demonstration of the sit-to-stand test, standing up from a seated position without support, two tests were timed and the better value recorded. Knee-flexion was measured using an 8-inch goniometer. *Kinesthesia* was measured by recording the angle of the flexed knee and documenting how close the patient was able to reproduce the angle with closed eyes. The differences were recorded in degrees.

Quadriceps strength was measured using a hand-held dynamometer. The knee was positioned with 60 degrees of flexion, and the foot was unsupported to prevent use of plantar flexor muscles. The device was placed perpendicular to the tibia on the lower third of the tibia. After demonstration of the technique, two measurements were performed and the higher force measurement recorded in N.

Balance

Balancing was measured using a Biodex Balancer SD Stability System (Biodex, Shirley, New York), whose validity and reliability are well established (2,7,17-19). The system consists of a multiaxial standing platform with a maximum tilt of 20 degrees. All participants were tested on level 8, and a balance index was calculated using the time and deviation (in degrees) on the platform relative to a neutral position (16). Each participant was allowed three practice attempts, which were followed by one recorded test. We calculated the overall balance index (20). Lower values indicate better/greater stability.

General Orthopaedic Outcome Measures

We used three functional outcome questionnaires whose results were recorded at both time points: the SF 36, the Knee Society Score, and the Western Ontario and McMaster Universities Arthritis Index (WOMAC).

Other Outcome measures

Self-reported total pain medication consumption was recorded by patients and at the end of the four-week period converted into standard units for comparison. Also recorded were any adverse outcomes, including infection, erythema, drainage, and stiffness requiring manipulation under anesthesia.

No changes were made to outcomes after the trial began. Our target sample of 110 was 55 participants in each group. Inclusion criteria were patients scheduled for unilateral primary partial or total knee replacement, had no arthritis on the contralateral side, and agreed to participate in the follow-up visits and understood and signed the informed consent form. Exclusion criteria included bilateral knee replacement, any neurological or structural pathology to the contra-lateral side, patients who were on chronic narcotics or had chronic pain. Power and sample size calculations were based on a difference of 80% of the standard deviation of mean values to detect a probable significant difference between the two groups (effect size) and no interim analyses were performed**.** The computer-generated allocation list was generated by the principal investigator (WF) using www.randomization.org. This list was sealed in an envelope and given to the Research Assistant, who opened it after the patient's surgery and informed the patient of their assigned group.

General linear regression was used to compare the outcomes between CPM and CAM, and TKA and UKA, adjusting for pre-op measurements and surgeon effect. Wilcoxon test was performed to compare the pain medication consumption between the CAM and CPM groups. Statistical significance was considered at the level of $P \leq .05$. Statistical analyses were performed using SPSS software, version 17.0 (SPSS Inc., Chicago, Illinois).

RESULTS

The CAM group comprised 58 patients and the CPM group 52. All these patients were recruited between March 2007 and December 2010 and follow-up visits were scheduled between April 2007 and January 2011. All patients received the intended treatment, and completed the functional and outcome testing before and after surgery. Following allocation to their group, we excluded 27 patients (20 using CAM and 7 CPM) who did not finish the study due to non-compliance, leaving a total of 83 patients. All of these patients completed their post-operative testing 4 weeks after their operation. Of these, 38 patients (23 TKA, 15 UKA) used the CAM device and 45 patients used the CPM device (23 TKA and 22 UKA). Table 2 shows the baseline demographic and clinical characteristics for each group.

All tested parameters were comparable (Table 2). At 4 weeks all outcome measurements were comparable between the two groups with the exception of the sit-to-stand test: in the treatment group the time was significantly shorter compared to the control group. Strength in the CAM (12.08) and CPM (12.28) groups was similar. Balance was also similar 3.13 vs. 2.95 ($p = 0.51$). SF-36, KSS, and WOMAC scores were not statistically different (SF-36 55.19 vs. 51.96 ($p = 0.379$), KSS 67.8 and 71.03 ($p = 0.478$), WOMAC 45.33 vs. 46.93 ($p = 0.647$)) (Table 3).

Between both treatment groups at 4 weeks significant differences were: sit-to-stand test, knee flexion, strength and WOMAC score. Patients following UKA had better results (Table 4). Pain medication usage was not statistically significant between the two groups in either inpatient or outpatient settings (Table 4). No significant differences were found between the two surgeons in any of the measured outcomes. Comparing pre-operative with post-operative results, the sit-to-stand test was significantly better in the CAM group, and balance was significantly better in both groups (Table 5).

DISCUSSION

Both groups demonstrated improvement of kinesthesia four weeks after surgery, but the improvement was only significant in the control group. We also wondered whether the ability to balance would improve. Swanik et al. (21) were the first authors using the SD Balancer to study balancing following total knee replacement. They studied 20 patients undergoing cruciate retaining and cruciate substituting total knee and saw improvements in balance on a more difficult level (level 6) but not on a less difficult level (level 8) which is the level we used in all patients. We did observe a significant balance improvement in both groups. This is contrary to Swanik et al. (21) who was not able to demonstrate and improvement. However, back then, rehabilitation and length of stay was different and mobilization less aggressive which could explain the difference of his results compared to our results of this study.

Our intention was to study early post-operative functional improvements and we were able to show better standing balance 4 weeks after surgery in both groups. Gstottner et al. (22) studied a balancing focused rehab program over 6 weeks before surgery in patients undergoing total knee arthroplasty. They used the same device (SD Balancer) at the same level to measure standing balance. In their treatment group they found a significant improvement after their prehab program, but no difference comparing the standing balance immediate before surgery compared to 6 weeks post-op. This is different compared to our study where we showed an improvement of our pre-op measurements 1-2 weeks prior to surgery compared to 4 weeks post-op in both groups. We believe that less immobilization and more active activities may explain our different outcome. There could be an additional benefit of using either CPM or CAM after surgery. We believe this is the first study showing a significant improvement of standing balance

using either a CPM for 4 hours each day or a CAM for 1 hour a day after knee replacement surgery.

We were surprised to observe no loss in quadriceps strength following knee replacement surgery. Mizner et al. (5) found profound impairment of quadriceps muscle strength by 62% one month after knee replacement surgery, similar to Lenssen et al.'s findings (23). Their observations are different to our findings and may be related either to our devices or a more aggressive early mobilization. All our patients were compliant and used the CPM for four hours a day. Lenssen et al. (11) does not comment on the daily treatment time. By comparing a CAM device to the standard of care at the time of surgery using a CPM, we cannot comment what the effect on muscle strength would be if we didn't use a motion device at all. However, we showed that the use of either device resulted in no substantial quadriceps strength loss. Future research is necessary to test these devices against a control and relate quadriceps strength either to the devices or early mobilization.

We also used a less sophisticated HHD to measure quadriceps strength. Future research should address some of the concerns that were raised using a HHD in research studies, specifically measuring individual strength changes (24). Other studies support the use of a HHD in clinical studies. A systematic review comparing HHD to isokinetic devices concluded - considering their ease of use, portability, cost and compact size - that HHD is a reliable and valid instrument for muscle strength assessment in a clinical setting (25).

We ran into an unexpected problem in recruiting patients for this study. Many did not want to participate in this study, as they did not want to use the passive device and were not willing to use it 4 hours each day. This was also the reason why we could not blind the study staff. Most patients wanted to use the active CAM device, which intuitively made more sense to

them, and they liked having to use the device for only 20 minutes three times a day. We screened more than 1000 patients over almost three years to get sufficient numbers to agree to participate in this study. This clearly underlines the importance of patient compliance. Shorter treatment times and an active device like the CAM are attractive to patients and increase compliance.

The treatment group demonstrated a significant improvement for the sit-to-stand test, but not in the control group. This supports the hypothesis that early activation of the operated leg results in quicker functional rehabilitation. Kinesthesia (26) showed improvement in both groups, but was significant only in the control group. We cannot explain why our pre-operative measurements were worse in our control group (Table 2). Other comparisons with the literature are not possible, since all published studies were performed 7.6 or 18 months after TKR (21,27). We did not see any differences in our functional outcome questionnaires, SF 36, KSS and WOMAC, which are more general and less specific than our other measured functional outcome measures, such as balance and sit-to-stand test. Further studies need to focus on more specific functional testing for more detailed analysis.

CONCLUSION

Most clinical centers would like to expedite functional recovery of knee arthroplasty patients without increasing the risk of falls. Balance and kinesthesia improved with both devices and we did not see a reduction of quadriceps strength at four weeks after surgery. This could be very beneficial for fast recovery programs, and our observed improved balance may benefit our current goal to further decrease length of stay, and to increase the number of patients being discharged home earlier and safely with early independence of daily living activities. More sophisticated functional testing methods should be introduced to increase our knowledge

following routine knee arthroplasty patients, since the active motion device was superior compared to the traditional CPM device in regard to the functional sit-to-stand test. We support the use of motion devices after surgery to decrease quadriceps strength loss and improve proprioception. The daily use of three times of 20 minutes makes the active device more attractive to patients. Based on our observations, we wonder whether our current practice of not using any device after knee replacement surgery is justified.

PATIENT CONSENT

Signed informed consent was obtained from each study participant.

DISCLOSURE

To the best of our knowledge no major conflict of interest, financial or other, exists for any of the authors. The results of the study do not constitute endorsement by ACSM and the results of the study are presented clearly, honestly, and without fabrication, falsification, or inappropriate data manipulation.

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