The Utilization of the Knee Exerciser Pro® ROM Device to Enhance Post-Operative Outcomes Following TKA

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Introduction

Total Knee Arthroplasty (TKA) is the most frequently performed orthopedic surgical procedure in the U.S. annually, with an estimated 700,000 procedures completed in 2016 [1]. The annual volume of TKAs is expected to grow to nearly 3.48 million by 2030. The goal of this procedure is to relieve pain, improve quality of life (QOL), and restore active knee flexion and extension Range of Motion (ROM). However, one of the most significant issues facing patients in their return to normal function is regaining full ROM, which can affect pain levels and QOL. Two significant contributing factors preventing patients from regaining full ROM are

a) An inability to effectively tolerate current recommended protocols for post-operative rehabilitation, including the use of a Continuous Passive Motion (CPM) machine and

b) Performing flexion and extension exercises unassisted while not under the direct supervision of a physical therapist.

Most protocols followed by orthopedic surgeons and hospitals for post-operative rehabilitation includes the use of a CPM machine in the first ten (10) to fourteen (14) days post-operatively. However, a literature review has shown that the CPM does not have clinically important effects on knee flexion ROM, pain, function or quality of life to justify its routine use [2]. It may reduce the risk of manipulation under anesthesia and risk of developing adverse events, however the quality of evidence supporting these findings are very low and low, respectively [2].

Although the intent of using a CPM is good, often times results achieved while using a CPM as part of an in-home rehabilitation program are less than desirable due to patient non-compliance or improper use. In the case of improper use, there is an increased risk of doing additional harm, which can lead to unnecessary complications and affect long term QOL. Additionally, insurance companies continue to push back on reimbursing for the use of CPM machines, further complicating the ability for orthopedic surgeons to recommend the use of this device as part of a post-operative rehabilitation program.
part of a post-operative rehabilitation program (Figure 1A and 1B). The use of this device to drive passive ROM for knee flexion and extension is less likely to result in knee soreness post use. The device was specifically designed using a self-powered pulley system to multiply the amount of force created by a patient’s own strength (Figure 1C). This pulley system more safely and effectively delivers improved ROM in flexion and extension.

Methods

Fifteen (15) patients were recruited from a sample of convenience from Dr. William Tucker’s Orthopedic practice in Dallas, Texas. Participants with a planned TKA were provided with an informed consent prior to surgery. Once a patient provided consent, the patient underwent an elective TKA by Dr. Tucker. Following discharge from the hospital, the patient was seen in the home setting for a total of 9 physical therapy visits over a three (3) week timeframe. This protocol, developed by Dr. Tucker, is an accelerated home physical therapy protocol as compared to the most common protocol, which ranges from twelve to eighteen (12-18) visits over a four to six (4-6) week timeframe. The most common home physical therapy protocol also involved daily exercises the patient was advised to complete on their own to enhance ROM and strength in the affected extremity.

At the baseline evaluation, a home health physical therapist assessed knee flexion ROM, knee extension ROM, baseline pain scales using the Numeric Pain Rating Scale, and fall risk using the Timed Up and Go (TUG) method. Knee flexion and extension were measured by the physical therapist using a goniometer, a common ROM measurement tool used in everyday practice. The Numeric Pain Rating Scale is a 0-10-point scale asking a patient to rate their current level of pain on a continuum from zero (0) meaning “no pain” to ten (10), meaning “unimaginable/unspeakable”. The TUG is a fall risk assessment that has been recognized in the literature as a valid, portable assessment to discern a patient’s fall risk. The test involves standing from a seated position, walking 10 meters, and returning back to a seated position. A patient scoring more than 20 seconds represents a significant fall risk. The assessments were collected at baseline and again at discharge.

To provide a basis of comparison as a standard of care, a sample of ten (10) patients undergoing a TKA from Dr. William Tucker’s Orthopedic practice were provided a standard of care home therapy program, only the use of the Knee Exerciser Pro® device was not utilized in this sample. These patients only received a standard of care exercise program that consisted of range of motion and strengthening exercises for a total of nine (9) visits over three (3) weeks.

Results

This trial consisted of the use of the Knee Exerciser Pro® device in a sample of fifteen (15) patients following a TKA seen for physical therapy in the home setting. The Knee Exerciser Pro® was utilized as an adjunctive tool to the standard of care physical therapy program. The variables assessed in this trial were baseline and discharge pain, ROM for knee flexion and extension and, fall risk using the TUG method. Data was analyzed for differences between means using independent paired samples t-test using SPSS 24.0 Statistical Analysis software.

The results of the analysis revealed multiple statistically significant conclusions. From these results, it is apparent that the difference in the mean from baseline to discharge for the four variables are all statistically significant: pain (p < 0.0001), TUG (p < 0.001), knee flexion ROM (p < 0.0001), and knee extension ROM (p < 0.017). These results indicate a significant improvement in multiple patient reported outcome measures when patients utilized the Knee Exerciser Pro in conjunction with typical home physical therapy program following TKA. Table 1 illustrates the means and standard deviations with corresponding p-value from the t-test.

| Variable | Mean   | Std. Deviation | P-Value |
|----------|--------|----------------|---------|
| PainDC   | 1.7333 | 1.38701        | 0.0001  |
| TUGDC    | 17.0667| 16.57652       | 0.0001  |
| FLEXDC   | -34.2  | 15.34927       | 0.0001  |
| EXTDC    | -2.9333| 4.18273        | 0.017   |

As compared to the Knee Exerciser Pro® group, the control group also experienced changes from baseline as noted in other trials analyzing a standard of care exercise program following
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a TKA. From these results, it is apparent that the difference in the mean from baseline to discharge for the four variables are all statistically significant: pain (p< 0.004), TUG (p < 0.002), knee flexion ROM (p < 0.0001), and knee extension ROM (p< 0.001). These results indicate a significant improvement in multiple patient reported outcome measures when a traditional home physical therapy program is utilized following TKA. Table 2 illustrates the means and standard deviations with corresponding p-value from the t-test.

In order to evaluate the effectiveness of the Knee Exerciser Pro® with standard of care versus standard of care alone, one needs to examine the mean and standard deviations of each variable to fully comprehend the differences between variables. While there are similarities between both groups, comparing means illustrates a more significant reduction in pain in the Knee Exerciser Pro® group, which indicates a more rapid reduction in pain using the device over standard of care alone. There was also a greater overall accelerated improvement in level of range of motion of flexion and extension at the beginning of the trial, with both groups demonstrating improvement over the three weeks but the Knee Exerciser Pro® group demonstrating a slight improvement over standard of care group.

Limitations and Recommendations for Future Research

No study would be complete without recognition of the potential limitations of this study as well as recommendations for future research assessing the treatment efficacy of the Knee Exerciser Pro®. First, this study involved a sample of convenience from the orthopedic practice of a single physician. These results may not be generalizable to all patients of all Orthopedic Surgeons performing TKA all over the U.S. for a number of reasons, including differences in surgical technique and length of stay before discharge to home. Second, the sample size was small. In the treatment group 15 participants were enrolled, while in the control group we only included 10 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants. A power analysis of this study, with the power set at 0.8 and an effect size of 0.2, yielded a need to enroll a total of 40 participants.

There were no adverse events reported during this trial, with no increase in patient soreness attributed to the Knee Exerciser Pro®. This lack of soreness with device use was likely a result in a higher degree of patient compliance and engagement, which lead to the best possible outcomes with the least likely risk for adverse events. In addition, the fall risk for patients following TKA is of significant concern. Although the use of opioids for pain is decreasing due to concerns over addiction and anesthetic techniques are becoming more sophisticated, this patient population is still considered to have an increased fall risk, which can result in further injuries and complications. The substantial decrease in pain while using the Knee Exerciser Pro® will likely lead to a decrease in reliance on pain medications which, further decreases the risk for medication addiction.

The results of this trial suggest that the Knee Exerciser Pro®, when used as an accompaniment to a standardized in-home physical therapy protocol, improves knee flexion and extension ROM, decreases pain scores and improves TUG. The improvement in patient QOL, the potential cost savings realized for the episode of care due to fewer visits needed and the decrease in fall risk are additional direct benefits of utilizing Knee Exerciser Pro® as part of a post-operative rehabilitation program.
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