A randomized, double-blind, control trial study to compare clinical outcomes of users and nonusers of a walking support machine after total knee replacement surgery

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Research Article

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Abstract

Background

Rehabilitation is one of the keys to success following total knee replacement (TKR). Many methods can be used to reduce knee forces during weight-bearing exercises.

Objectives

The purpose of this study is to assess the effectiveness of a walking support machine (Co-walk) in improving clinical outcomes in TKR patients.

Methods

62 TKR patients were equally and randomly divided into two groups: the control group (Non Co-walk) and the experimental group (Co-walk). Both groups followed a standard 45-minute rehabilitation program. The Co-walk received an additional 15-minute Co-walk session once a week for 6 weeks. Outcomes were measured at admission and at 2 weeks, 6 weeks, 3 months, and 6 months in TKR patients.

Results

Participants in the Co-walk group demonstrated significantly different scores on the TUG test (18.10 ± 6.45) and the WOMAC pain scale (13.29 ± 5.49) at 2 weeks, 6 weeks, and 3 months (p < 0.001). WOMAC and ROM were statistically significant in the Co-walk group (36.10 ± 13.78) at 2 weeks, 6 weeks, 3 months, and 6 months (p < 0.001). WOMAC stiffness scores were statistically significant in the Co-walk group (6.03 ± 3.62) at 2 weeks (p < 0.001). Postural control for patients in the Co-walk group showed significant improvement in position (Left 16[8.5(6.5–14.0)]and Right 11[10.0(3.0–24.0)]) at 2 weeks, 6 weeks, 3 months, and 6 months. The experimental group and control group showed no significant difference in LOS (p = 0.379).

Conclusion

Co-walk effectively improves outcomes during the early rehabilitation period. It may be better than physical therapy rehabilitation programs alone.

Introduction

Rehabilitation remains crucial for achieving good clinical outcomes, such as short-term function, range of motion, patient quality of life, and prevention of postoperative complications, in total knee replacement
(TKR) [1, 2]. Decreased pain with greater range of motion and independence are important goals for physiotherapy [3, 4], while early rehabilitation is considered important for increasing range of motion and muscle strength [5, 6]. The trend toward early hospital discharge to reduce the length of stay has gained popularity in the last decade [7–10]. Postoperative knee range of motion (ROM) is one of the most crucial factors influencing patient satisfaction after TKR [11]. The mean 1-year Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score is lowest in the first three months [12]. It is important to avoid bad experiences during the early postoperative period including pain, knee stiffness, and hospital readmission due to complications such as falling. Weight-bearing activities such as walking are often considered highly effective in rehabilitation and promoting return to function. High knee forces (3 times body weight), non-weight-bearing, or partial weight-bearing are often recommended. Full weight-bearing may delay a return to full function. Many methods can be used to reduce the forces on the knee during weight-bearing exercises, such as hydrotherapy (walking in water) [13], the use of harness systems [14] that physically lift the patient, the use of lower body positive pressure (LBPP) chambers [15], and LBPP treadmills [16]. These methods produce a significant reduction in the weight the patient bears with minimal alteration to gait kinematics.

An increase in knee forces may affect postoperative rehabilitation, for example, through pain, which can lead to the restriction of motion and increased joint stiffness. The degeneration of immobilized muscle groups and early joint stiffness remain essential factors influencing whether there is a prolonged course of healing [17–20]. A study demonstrated improvements in pain intensity, gait velocity, cadence, and stride length as the result of a six-week gait physical therapy program after TKA [21]. The aim of our study was to improve clinical outcomes for patients following TKR by using a walking support machine (Co-walk) and compare the results over a 6-month period to those obtained with a standard rehabilitation protocol. There is some research that accelerated rehabilitation using machines can improve recovery outcomes after patient injuries. However, no research has investigated clinical outcomes in patients who underwent TKR. The aim of our study was to improve clinical outcomes of TKR patients by using a walking support machine (Co-walk) in addition to standard rehabilitation compared to a standard rehabilitation protocol alone. We assessed the results over a 6-month period and focused on improving ROM, timed up-and-go test (TUG) scores, Western Ontario and McMaster University (WOMAC) scores, weight-bearing balance, postural control, and Length of stay (LOS).

**Materials And Methods**

We performed an experimental clinical trial. The study was registered with the Thai Clinical Trials Registry (No. TCTR20210123002) (www.clinicaltrials.in.th) which legally conducts trials in Thailand under the Medical Research Foundation of Thailand (MRF), and we received ethical approval from the university’s ethics committee (EC 63–74). We enrolled patients and randomized them to the experimental group and control group as shown in the flow diagram in Fig. 1.

We randomly divided the patients into two groups using the block method. The samples in both groups included knee osteoarthritis patients who underwent TKR and were referred to physiotherapy for TKR
rehabilitation. The sample size was calculated by using data from a previous study by Mutsuzaki H et al. [11] mean ROM change from preoperative before surgery to 6 months after TKA. By using an unpaired t-test with a 2-sided significance level of 0.05, the study would have 90% power to detect a difference of 3.0 between Co-walk and Non Co-walk groups. The percentage of missing data was set at 7%. The number of participants needed was therefore 31 in each group, thus the minimum number of subjects to be recruited was 62 for study. The control group (31 subjects) (Non-Co-walk) who received the standard protocol for rehabilitation. The experimental group (31 subjects) (Co-walk) used the walking support machine (Co-walk) in addition to undergoing the standard protocol for rehabilitation. The inclusion criteria were patients who were willing to enroll in the program, were above 50 years old, had osteoarthritis of the knee, and had a severe stage of osteoarthritis that required TKR. The exclusion criteria were patients who had a history of cerebrovascular events such as ischemic stroke, hemorrhagic stroke, undetermined stroke, transient ischemic attack, and patients who were lost to follow-up. The withdrawal or termination criteria were as follows: greater pain intensity than before enrollment and discomfort with continuing the program. Both groups received the same postoperative pain control and rehabilitation protocol as shown in Table 1.

To reduce confounding factors, such as surgical techniques, the surgical skills of the surgeon, and the type of implants, all operations were performed by one experienced surgeon who used the same process, same implant type and same surgery method.

Data collection

The data were collected from 19 January 2021 until 30 July 2021 at Suranaree University Hospital. The evaluator and the physical therapist were different people. Patients were assessed for general demographics such as sex, age, and body mass index (BMI). We evaluated the primary outcome using the WOMAC, which consists of two domains— pain, stiffness, and function. Range of motion (ROM) was assessed by using a goniometer. The secondary outcomes were LOS, time up and go (TUG) score, weight-bearing balance, and postural control, as assessed by EP40 System Biometrics Ltd. We reevaluated both groups by using the same parameters before and after the operation. For the Co-walk group, we used Co-walk once a week for 6 weeks based on the Insall Scott Kelly® Institute for Orthopaedics and Sports Medicine protocol. The walking duration was 15 minutes. For the Non-Co-walk group, we used a 45-min rehabilitation program once a week for 6 weeks. Outcomes were measured on admission and at the 2nd, 6th, 12th, and 24th weeks.

Intervention

The innovative walking support machine (Co-walk) was invented by our staff and is shown in Fig. 2.

Co-walk helps reduce pressure by reducing the weight acting on the lower part of the body (such as the knees and ankles). The mechanism of Co-walk is the air pump piston support system that includes 4 pillars that maintain a specific vertical direction so as to only move up or down. The pillars connect to the patients via special canvas pants. The canvas elevates the patient using compressed air (propulsion
mechanism) delivered from the pillars. When the air is compressed into the propulsion mechanism, a large amount of pressure produces the lifting force. The result is that the patient is placed in a virtually weightless state that reduces pressure and the risk of shocks to the lower limbs that occur during physiotherapy. The physiotherapist or the caregiver can enter the desired elevation percentage on the panel to enable the device to send suitable air pressure. Instructing the device to start working causes the motor to rotate and the compressed air pump to drive when the air delivered to the driving mechanism meets the specified limits. After that, the patient can begin physical therapy by walking or running on a medical treadmill. In case of an accident or emergency, there is a circuit breaker that stops the electrical circuit causing the motor and compressed air pump to stop. Before exercise, each patient enters the machine, and the canvas connected with the waist seal is secured to isolate the pelvis and lower extremities in the machine. With the patient standing on a standard spring scale (placed on the treadmill), the pressure is increased by an air pump to determine the height needed to achieve 20% of baseline body weight. Next, the scale is removed. In random order, each patient walked for the first minute to 15 minutes at a comfortable walking speed of 0.67 m/second (1.5 mph). The Co-walk group participants performed gait training using the Co-walk, in addition to the total 45-min rehabilitation program. The walking duration was 15 minutes which took place once a week for 6 weeks. The control group participants performed the usual 45-min rehabilitation program once a week for 6 weeks, as shown in Table 1. Outcomes were measured on admission and at the 2nd, 6th, 12th, and 24th weeks.

**Statistical analysis**

Data are described using the mean (± standard deviation) or median (percentile 25-percentile 75) for continuous data and frequency (percentage) for categorical data. Student's t-test and the Mann Whitney test were used to compare continuous variables between the Co-walk and Non-Co-walk groups, whereas chi-square tests were performed for categorical variables. Repeated-measures ANOVA or Friedman's test was used to analyze changes in mean or median scores over 4 or more time points within the Co-walk and Non-Co-walk group. For all tests performed, a two-tailed p-value < 0.05 was considered to be statistically significant. PASW Statistic (SPSS) 18.0 (SPSS, Inc., Chicago, IL, USA) was used to perform all statistical analyses.

**Results**

Sixty-two patients with severe OA underwent TKR surgery in this clinical trial. This study randomized patients into two groups: the control group, which used the standard TKR rehabilitation protocol, as shown in Table 1, and the experimental group, which used gait training with the Co-walk in addition to 15 minutes of the usual 45-minute rehabilitation protocol. The cohort included 11 males (17.74%) and 51 females (82.26%). The participants' average age was 67.77 years old, the average height was 154.61 cm, and the average BMI was 26.44 kg/m2. The analysis of demographic characteristics revealed no significant difference between the two groups of patients, as shown in Table 2.
The results of the clinical trial established a normal distribution of the balance score data in both groups. No patients in either group experienced an injury during the rehabilitation process, and no surgery failed in either group, as shown in Table 3.
Table 3
ROM, Weight left or right between Co-Walk and Non Co-walk.

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<tr>
<th></th>
<th>(n = 62)</th>
<th>(n = 31)</th>
<th>(n = 31)</th>
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<tr>
<td></td>
<td>total</td>
<td>Co-walk</td>
<td>P*</td>
<td>Non Co-walk</td>
<td>P*</td>
<td>P**</td>
</tr>
<tr>
<td>Before surgery</td>
<td>89.68 ± 17.06</td>
<td>89.68 ± 12.45</td>
<td>&lt; 0.001</td>
<td>89.68 ± 20.89</td>
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<td>1–2 day after surgery</td>
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<td>87.10 ± 12.70</td>
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<tr>
<td>2wk after surgery</td>
<td>100.48 ± 15.25</td>
<td>103.39 ± 12.61</td>
<td>97.58 ± 17.22</td>
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<tr>
<td>6wk after surgery</td>
<td>111.26 ± 13.86</td>
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<td>109.52 ± 15.83</td>
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<tr>
<td>3mo after surgery</td>
<td>116.13 ± 13.01</td>
<td>119.84 ± 8.99</td>
<td>112.42 ± 15.32</td>
<td>0.024</td>
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<tr>
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<td>122.79 ± 10.09</td>
<td>124.29 ± 8.10</td>
<td>121.29 ± 11.69</td>
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<td>Average day 1- 6mo</td>
<td>104.87 ± 10.98</td>
<td>106.81 ± 8.98</td>
<td>102.93 ± 12.51</td>
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<td>71.82 ± 16.65</td>
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<td>2wk after surgery</td>
<td>30.01 ± 16.87</td>
<td>18.10 ± 6.45</td>
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<td>6wk after surgery</td>
<td>18.09 ± 10.41</td>
<td>13.23 ± 3.32</td>
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<td>3mo after surgery</td>
<td>14.08 ± 7.05</td>
<td>11.69 ± 2.52</td>
<td>16.47 ± 9.10</td>
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<td>6mo after surgery</td>
<td>11.90 ± 4.69</td>
<td>11.04 ± 1.87</td>
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<td>Average day 1- 6mo</td>
<td>28.80 ± 8.33</td>
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<td>49.44 ± 9.55</td>
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<td>50.03 ± 4.90</td>
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<td></td>
<td>3mo after surgery</td>
<td>6mo after surgery</td>
<td>Average day 1- 6mo</td>
</tr>
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<td>------------------</td>
<td>------------------</td>
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<tr>
<td>ROM</td>
<td>49.95 ± 4.25</td>
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<td>Weight Right</td>
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<td>2wk after surgery</td>
<td>50.10 ± 5.72</td>
<td>49.94 ± 4.91</td>
<td>50.26 ± 6.51</td>
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<tr>
<td>6wk after surgery</td>
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<td>50.13 ± 3.14</td>
<td>50.03 ± 5.21</td>
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<tr>
<td>3mo after surgery</td>
<td>50.15 ± 2.64</td>
<td>50.23 ± 2.14</td>
<td>50.06 ± 3.10</td>
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<td>6mo after surgery</td>
<td>50.15 ± 6.40</td>
<td>49.92 ± 4.58</td>
<td>50.38 ± 7.88</td>
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<tr>
<td>Average day 1- 6mo</td>
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<tr>
<td>Diff Weight Left to Right</td>
<td>-0.39 ± 26.71</td>
<td>-2.52 ± 20.45</td>
<td>1.74 ± 31.98</td>
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<tr>
<td>1–2 day after surgery</td>
<td>1.18 ± 19.12</td>
<td>1.00 ± 17.26</td>
<td>1.35 ± 21.11</td>
</tr>
<tr>
<td>2wk after surgery</td>
<td>0.21 ± 11.44</td>
<td>-0.10 ± 9.81</td>
<td>0.52 ± 13.02</td>
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<tr>
<td>6wk after surgery</td>
<td>0.13 ± 8.52</td>
<td>0.19 ± 6.23</td>
<td>0.06 ± 10.42</td>
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<tr>
<td>3mo after surgery</td>
<td>0.31 ± 5.29</td>
<td>0.48 ± 4.30</td>
<td>0.13 ± 6.20</td>
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<tr>
<td>6mo after surgery</td>
<td>0.29 ± 12.79</td>
<td>-0.19 ± 9.15</td>
<td>0.76 ± 15.76</td>
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</table>

* p-value within group related mean before surgery to 6 months after surgery by repeated measure ANOVA.

** p-value for comparison of mean between group by Independent t test.

The control group (Non-Co-Walk) and the experimental group (Co-Walk) of TKR patients were compared in terms of preoperative and postoperative ROM. The ROM of the experimental group (119.84 ± 8.99) was significantly different from that of the control group (112.42 ± 15.32) (p = 0.024) at 6 weeks, as shown in Fig. 3.

The TUG scores of the experimental group (18.10 ± 6.45) and those of the control group (41.92 ± 15.62) were significantly different (p < 0.001) at 2 weeks, 6 weeks, and 3 months, as shown in Fig. 4.
The WOMAC scores for pain of the experimental group (13.29 ± 5.49) and control group (22.52 ± 5.47) were significantly different (p < 0.005) at 2 weeks, 6 weeks, and 3 months. The WOMAC movement scores of the experimental group (36.10 ± 13.78) and control group (63.52 ± 12.71) were significantly different (p < 0.001) at 2 weeks, 6 weeks, 3 months, and 6 months. The WOMAC scores for stiffness of the experimental group (6.03 ± 3.62) and control group (10.16 ± 3.42) were significantly different (p < 0.001) at 2 weeks. (Figs. 5).

Weight-Bearing on the left and right was not significantly different in the experimental group. The experimental group showed significant improvement in postural control in position (Left 16[8.5(6.5–14.0)] and Right 11[10.0(3.0–24.0)]) when compared with that of the control group (Left 6[14.0(14.0–17.0)] and Right 22[24.0(13.0–30.0)]) (p = 0.024), (p = 0.019)) at 2 weeks, 6 weeks, 3 months and 6 months. However, the anterior and posterior positions were not significantly different, as shown in Fig. 8.

**Discussion**

In this study, we investigated the postoperative clinical outcomes of TKR patients using Co-walk. Variables measured during the study included ROM, the TUG, the WOMAC, weight-bearing balance, postural control, and LOS. We found no significant differences on postoperative day 1 or postoperative day 2; but, 2 weeks after surgery, we found that the experimental group demonstrated significantly decreased time on the TUG test. At 2 weeks after the operation, we compared preoperative and postoperative WOMAC scores. Scores decreased in all 3 domains (pain, movement, and stiffness) and were significantly different at 2 weeks, 6 weeks, and 12 weeks. Moreover, subjects who used Co-walk after surgery showed improved knee function and improved walking performance at admission and at 2 weeks compared with those who used the standard rehabilitation protocol. In addition, no adverse events occurred during the research. The results of this study were consistent with Wiliam D. et al. [21], who used the AlterG Anti-Gravity Treadmill in male and female subjects with mean ages of 66.5 years and 66.9 years, respectively, after posttraumatic, postmenopausal total knee arthroplasty (TKA). The results of the study found that pain was reduced and knee function improved after surgery. Ahmed AR et al. [22] studied a 6-week postoperative exercise program for patients following TKA; however, the time period of the study was not long enough to restore walking abilities to their pre-surgery values. A longer period of rehabilitation is needed to improve the quality of patient gait. Heike A. Bischoff and colleagues [23] studied the cut-off time of the TUG test in community dwelling and elderly women and found that community dwelling elderly women between 65 and 85 years of age should be able to perform the timed up and go test in 12 seconds or less. We found that using Co-Walk after surgery can improve gait ability. Patients who used Co-Walk were able to walk faster, as measured by the TUG test (11.69 seconds) than patients who underwent normal rehabilitation after 6 weeks. Further study over a long-term period should be conducted.

**Conclusion**
The findings in this study indicate that routine rehabilitation programs are important in improving gait capability. Co-Walk may be useful in improving gait ability and reducing pain after surgery. Rehabilitation that includes Co-Walk in the rehabilitation protocol for 6 weeks after TKR surgery positively enhances knee joint function and decreases pain after surgery.

Abbreviations

Total Knee Replacement: TKR, Walking support machine: Co-walk, Range of motion: ROM, Timed up and go test: TUG, Western Ontario and McMaster Universities Osteoarthritis Index: WOMAC, Length of stay: LOS.

Declarations

Acknowledgments

The researchers gratefully thank the Suranaree University of Technology Hospital and Center of Excellence in Biomechanics Medicine for supporting this project. The research could not have been done without the cooperation of the working team consisting of physicians, nurses, physical therapists, and engineers. They really cared about this project.

Ethical Approval

This study was approved by the university ethics committee (EC 59-13) The study was registered with the Thai Clinical Trials Registry (No. TCTR20210123002) (www.clinicaltrials.in.th).

Competing interests

All authors and corresponding author have no conflict of interest.

Authors’ contributions

B.S. designed the study and performed the experiments; S.W. and S.R. performed the experiments, analyzed the data. B.S. wrote the manuscript

Funding

no

Availability of data and materials

https://docs.google.com/spreadsheets/d/1sG2ms3FmoQjYM62UuodD9NTIAHM3qCmw/edit?usp=sharing&ouid=117861616414486288630&rtpof=true&sd=true
References


Table 1

Table 1 is available in Supplementary Files section.

Figures
Figure 1

CONSORT 2010 Flow Diagram
Figure 2

showed Co-walk with the treadmill
Figure 3

Range of Motion (ROM) between Control group (Non-Co-Walk) and Experimental group (Co-Walk).
Figure 4
Timed Up and Go test (TUG) between Control group (Non-Co-Walk) and Experimental group (Co-Walk).

Figure 5
Western Ontario and McMaster University index (WOMAC) movement, stiffness, and pain between Control group (Non-Co-Walk) and Experimental group (Co-Walk).
Figure 6

Weight-Bearing Left (A) and Right (B) between Control group (Non-Co-Walk) and Experimental group (Co-Walk).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table1.docx
- Table4TUGWOMAC.docx