

# Use of an Anti-Gravity Treadmill for Early Postoperative Rehabilitation After Total Knee Replacement: A Pilot Study to Determine Safety and Feasibility

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## Abstract

The objective was to determine the safety, feasibility, and effects of anti-gravity gait training on functional outcomes (Knee Injury and Osteoarthritis Outcome Score [KOOS], the Timed Up and Go test [TUG], Numerical Rating Scale [NRS] for pain) with the AlterG® Anti-Gravity Treadmill® device for total knee arthroplasty (TKA) rehabilitation. Subjects (N = 30) were randomized to land-based vs anti-gravity gait training over 4 weeks of physical therapy after TKA. Adverse events, complications, and therapist satisfaction were recorded. All patients completed rehabilitation protocols without adverse events. KOOS, TUG, and NRS scores improved in both groups with no significant

differences between groups. For the AlterG group, Sports/Recreation and Quality of Life subscales of the KOOS had the most improvement. At the end of physical therapy, TUG and NRS pain scores improved from 14 seconds to 8 seconds and from 2.8 to 1.1, respectively. Subjectively, therapists reported 100% satisfaction with the AlterG. This initial pilot study demonstrated that the AlterG Anti-Gravity Treadmill device was safe and feasible. While functional outcomes improved over time with use of the anti-gravity gait training, further studies are needed to define the role of this device as an alternative or adjunct to established rehabilitation protocols.

Patients undergoing total knee arthroplasty (TKA) may benefit from focused postoperative rehabilitation. Although there is limited research comparing different rehabilitation protocols after TKA,<sup>1</sup> any type of rehabilitation often helps to optimize range of motion (ROM), strength, balance, and ambulation.<sup>2</sup> Early mobilization and rehabilitation after TKA reduces pain, fear, anxiety, and risk of postoperative venous thromboembolic disease.<sup>3</sup> Earlier discharge to home or community settings decreases time for inpatient rehabilitation, patient and family education, and gait training, which places a greater emphasis on outpatient rehabilitation.<sup>4</sup>

Although rapid rehabilitation protocols have gained wide acceptance, concern remains that a higher intensity intervention initiated immediately

after hospital discharge could lead to an increased incidence of pain and swelling, and to poorer ROM and functional outcomes.<sup>5</sup> Progressive weight-bearing activities, such as walking, are routinely recommended during rehabilitation to facilitate return to normal function. Not all patients are capable of full weight-bearing activity in the early postoperative period and assistive devices (ADs), such as walkers, crutches, and canes, are routinely employed. An opportunity to enhance early TKA rehabilitation exists with devices that allow functional gait training while modifying weight-bearing forces across the joint. Assistive devices, hydrotherapy (walking in water),<sup>6,7</sup> and lower body positive-pressure chambers<sup>8</sup> can reduce the forces at the knee during weight-bearing exercise.

Lower body positive-pressure devices have

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been extensively studied in physiological response of healthy humans;<sup>9-12</sup> in disease states such as cerebral palsy<sup>13</sup> and obesity;<sup>14</sup> and in other postoperative orthopedic conditions, such as anterior cruciate ligament reconstruction, meniscectomy,<sup>8</sup> microfracture,<sup>15</sup> TKA,<sup>16</sup> and Achilles tendon repair.<sup>17</sup> These studies demonstrate that a lower body positive-pressure treadmill is associated with minimal cardiovascular effect while producing a significant decrease in ground reaction forces without altering gait kinematics.

We postulated that an anti-gravity treadmill may be safe and effective for gait training during rehabilitation following TKA. The primary objective was to determine the safety and feasibility of using the AlterG® Anti-Gravity Treadmill® device for postoperative gait training during rehabilitation following TKA. The secondary objective was to determine the effects of gait training (land-based vs anti-gravity) during postoperative rehabilitation on subjective patient outcomes assessed by Knee Injury and Osteoarthritis Outcome Score (KOOS), mobility assessed by the Timed Up and Go test (TUG), and pain assessed by a Numerical Rating Scale (NRS) to conduct a power analysis to determine sample sizes for efficacy studies based on these preliminary findings.

## Methods

### Participants/Patient Enrollment and Study Overview

After signing an Institutional Review Board-approved consent, 30 patients were enrolled, and TKA surgeries were performed by 1 of 5 surgeons at 1 hospital. To be enrolled in the study, subjects must have (1) had a unilateral primary TKA, (2) been discharged from the hospital to home (not to a skilled nursing facility), (3) had only 3 to 4 home physical therapy (PT) sessions, (4) agreed to further outpatient PT at a single site, and (5) agreed to complete patient questionnaires. Exclusion criteria included (1) inability to meet inclusion criteria, (2) gross musculoskeletal deformity, (3) uncontrolled chronic or systemic disease, and (4) inability to follow instructions because of mental impairment, substance abuse, or addiction. Home PT was conducted for 3 to 4 sessions after surgery, and outpatient PT was continued at the study site per protocol for 4 weeks; subjects were asked to return for follow-up 3 months postoperatively. Patients were randomized on the first day of their outpatient PT to either a land-based (control) or an anti-gravity-based group using the AlterG Anti-Gravity Treadmill (AlterG group) gait training

during outpatient PT sessions. Patients attended outpatient PT 2 days per week for 4 weeks for a total of 8 sessions. Therapy sessions lasted 45 to 60 minutes and included manual therapy, gait training, and therapeutic exercises/activities. The KOOS<sup>18,19</sup> and TUG<sup>20</sup> scores were evaluated at baseline (ie, first therapy session), end of physical therapy (EOPT) (ie, at final therapy session), and end of study (EOS) (ie, 3 months postoperatively). The NRS for pain was evaluated at baseline and at EOPT. Physical therapists were questioned for satisfaction with the anti-gravity rehabilitation protocol at EOPT.

### Physical Therapy Protocols

All patients were treated consistently by 1 of 5 physical therapists at 1 outpatient setting; physical therapists averaged 11 years of experience in treating orthopedic conditions. Care was delivered in accordance with professional standards and the therapist's assessment of medical necessity. Considerations included, but were not limited to, overall general health, any medical comorbidity, support system, and an ongoing assessment of ROM, strength, pain, and functional status. Each PT session started with a 5- to 10-minute warm-up on a standard cycle ergometer and was followed by manual therapy, gait training (land-based vs anti-gravity), therapeutic exercises/activities, and treatment modalities.

The time spent, activities selected, and modalities or physical agents chosen during the PT session were based on the patient's needs and progress toward his/her functional goals. Manual therapy techniques consisted of soft-tissue mobilization, passive ROM, joint mobilization, passive stretching, scar mobilization, manual resistive exercises, and proprioceptive neuromuscular facilitation techniques. Therapeutic exercises/activities consisted of lower extremity resistance exercises (weight bearing and non-weight bearing), ROM exercises, stretching, balance, stair training, agility, activities of daily life (ADL) training, and a comprehensive home exercise program. Modalities or physical agents used during this study included moist hot packs, cold packs, ultrasound, electrical stimulation, and Kinesio Tape. Physical agents were incorporated into the individual's plan of care based on medical necessity when deemed appropriate by the treating therapist. The exercise prescription was based on an individual's status and tolerance and the number of sets and repetitions were based on fatigue.

### Gait Training

The patients were randomized (1:1) to either land-based or anti-gravity gait training. For the control group, land-based gait training was performed with or without an appropriate AD and appropriate assistance, tactile cueing, and verbal cueing from a physical therapist. Duration (minutes) and gait-training progression were dependent on the participant's functional goals, pain level (assessed throughout treatment), and level of fatigue. For the AlterG group, gait training was performed in the AlterG Anti-Gravity Treadmill, M320 (Alter-G;

**Figure 1**). On day 1, the AlterG pressure chamber was set to allow only 50% of the patient's body weight to be transmitted to the treadmill floor, and speed was controlled by the patient according to his/her comfort level. The percentage of body weight was adjusted to allow for a safe and normalized gait pattern with a pain level no greater than 5 (0 to 10 scale) throughout the PT session. A report card was recorded at each PT session, including body-weight setting (%), speed (miles per hour), incline (%), and duration (minutes) (**Figure 2**). For subsequent visits, the body-weight setting was started from the end point of the previous session.

### Data Collection and Analysis

SPSS version 12.0 (SPSS Inc.) was used for all analyses, and an alpha level of .05 determined

statistical significance when comparing group differences. The safety and feasibility of the anti-gravity (AlterG) vs land-based (control) gait training was assessed by the presence (or absence) of adverse events (AEs) and complications, and the date the patient discontinued use of his/her AD. A chi-square test was used to assess differences between control and AlterG groups regarding patient discontinuance of an AD. Additionally, for patients randomized to AlterG, a report card summarized means and frequencies for body weight, speed, incline, and duration. At EOPT, the frequency of therapists who were satisfied with the AlterG Anti-Gravity Treadmill as part of the rehabilitation protocol was reported. The preliminary effects of gait training (land-based vs anti-gravity) during post-operative rehabilitation on functional outcomes (subjective patient outcomes assessed by KOOS, mobility assessed by the TUG test, and pain assessed by a NRS) were evaluated by independent sample *t* tests. Paired sample *t* tests were used to compare each of the functional outcomes at EOPT or EOS to the baseline value.

### Results

Of the 30 patients enrolled, 29 (96.7%; 29/30) patients completed the study; 1 patient, who could not complete all PT sessions because of medical and transportation issues, was excluded. The remaining 29 patients comprised the study population (control = 15; AlterG = 14). All patients were compliant with PT protocols.

Patient demographics were similar between the control and AlterG groups (**Table 1**). The control group comprised 9 women (60%; 9/15) and 6 men (40%; 6/15), age  $69.9 \pm 7.8$  years and a body mass index of  $28.8 \pm 4.2$ . Similarly, the AlterG group



**Figure 1.** The AlterG® Anti-Gravity Treadmill®.



**Figure 2.** The AlterG® Anti-Gravity Treadmill® control panel.

comprised 7 women (50%; 7/14) and 7 men (50%; 7/14), age  $66.5 \pm 7.8$  years and a body mass index of  $28.4 \pm 5.2$ .

At the baseline PT visit, patients in the control and AlterG groups had similar KOOS, TUG, and NRS scores. At baseline, mean KOOS for symptoms, pain, sports/recreation, ADL, and quality of life were 52.7, 52.9, 22.7, 64, and 31.8, respectively, although 50% of patients did not complete the sports/recreation subset of the KOOS. In addition, the mean time to complete the TUG test was 14.5 seconds, which was within the normal limits for disabled patients. This was slightly longer than normal mobility (TUG <10 seconds),<sup>20</sup> but patients

had relatively low levels of pain (mean NRS = 2.5, on a scale of 0-11).

All patients completed the PT protocols without indication of injury or AEs related to their operative knee. Three patients (10.3%; 3/29) experienced a deep venous thromboembolism (DVT), 2 in the control group (13.3%; 2/15), and 1 in the AlterG group (7.1%; 1/14). Venous thromboembolism protocol of enoxaparin 30 mg twice daily while in the hospital and enoxaparin 40 mg once daily for 10 days after discharge was followed for all patients.

Overall, more than half of patients (55.2%; 16/29) discontinued their AD during the 4-week PT period, with the remaining discontinuing prior to EOPT (24.1%; 7/29) or after EOPT (20.7%; 6/29). No statistically significant differences were found between the control and AlterG groups regarding discontinuance of AD.

Among those randomized to the AlterG group, all patients performed within the protocol established for the device for body-weight setting, treadmill speed, and duration of walking. The average body-weight treadmill setting increased by ~30% over the treatment period, from 55% at baseline to 84% at EOPT. The average speed increased by ~70%, from 1.6 mph at baseline to 2.7 mph at EOPT. The mean

duration of AlterG use increased by ~75%, from 7.2 minutes at baseline to 12.7 minutes at EOPT. All physical therapists (100%) reported satisfaction with the AlterG for use in early postoperative rehabilitation and reported that patients' treatment progressed positively.

While functional outcomes (KOOS, TUG, or NRS) did not vary with the type of gait training ( $P > .2$  for land-based vs anti-gravity), functional outcomes improved over time (all  $P < .01$  from baseline to EOPT and all  $P < .01$  from baseline to EOS).

The KOOS scores improved from baseline to EOPT and from baseline to EOS (ie, 3-month follow-up visit) for both treatment groups (Figure 3). More patients completed the sports/recreation portion of the KOOS scores at EOPT and EOS compared to baseline. Forty-three percent and 25% of patients did not complete KOOS sports/recreation questions at EOPT and EOS, respectively, compared to 50% at baseline. This suggests

Table 1. Patient Demographics

Variable	Control Group N = 15	AlterG Group N = 14
	Mean $\pm$ SD or %	Mean $\pm$ SD or %
Gender		
Female	60%	50%
Male	40%	50%
Age (y)	69.9 $\pm$ 7.8	66.5 $\pm$ 7.8
Height (in)	67.1 $\pm$ 4.8	69.2 $\pm$ 3.8
Weight (lb)	184.6 $\pm$ 32.0	193.2 $\pm$ 38.2
BMI	28.8 $\pm$ 4.2	28.4 $\pm$ 5.2

Abbreviations: BMI, body mass index; in, inches; lb, pounds; y, years.

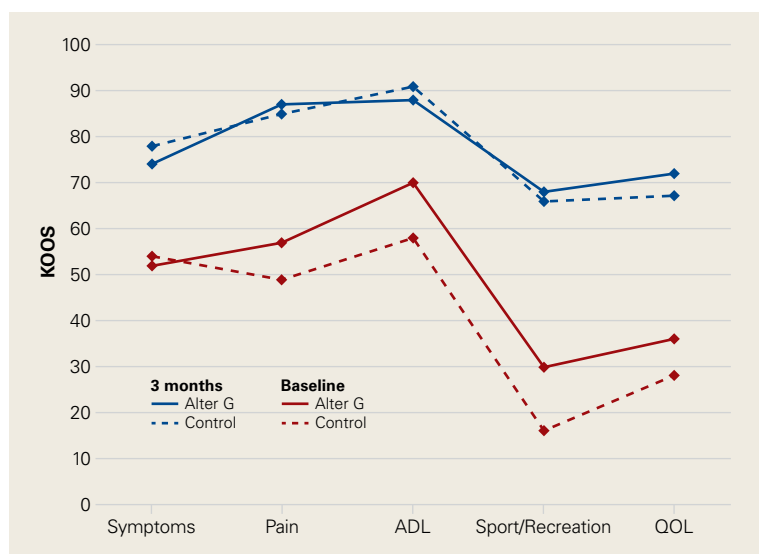


Figure 3. Line graph comparing Knee Injury and Osteoarthritis Outcome Score (KOOS) of Alter-G and control groups at baseline and 3 months.

Abbreviations: ADL, activities of daily life; QOL, quality of life.

that patients were improving to a level where sports/recreation scores were more applicable than directly after TKA surgery. The TUG scores had the greatest improvement from baseline to EOPT, with a decrease in time of 5 seconds and 7 seconds for the control and AlterG groups, respectively, and slight improvement from EOPT to EOS, with a decrease in time of 1 second and 2 seconds for the control and AlterG groups, respectively (Table 2). By the EOS, the values for the TUG tests for both treatment groups were within normal (<10 seconds) range.<sup>20</sup> The NRS scores improved from baseline to EOPT with a score of 1 ± 1 in both control and AlterG groups.

Using these preliminary efficacy results, a post-hoc power analysis ( $\alpha = .05$  and  $1\beta = 80\%$ ) was performed with the ADL domain of KOOS as the primary endpoint. Based on a standard deviation of 20 points and an effect size of 5 points, the sample size was estimated to be N = 250 per treatment group.

### Discussion

We conducted a pilot study to assess, primarily, the feasibility and safety, and, secondarily, the efficacy, of a lower body positive-pressure treadmill for rehabilitation of patients after TKA. This small study showed that use of the AlterG Anti-Gravity Treadmill was not only safe and feasible during postoperative TKA rehabilitation, but also was well tolerated by patients and was rated highly satisfactory by physical therapists. Patients who used AlterG during gait training improved functionally (in terms of KOOS, TUG, and NRS) after 8 treatment sessions compared to baseline. However, there were no statistical differences between groups (control vs AlterG). Thus, these results suggest that an anti-gravity device for gait training may be a useful adjunct for postoperative TKA rehabilitation, but further studies are needed to determine the efficacy of anti-gravity compared to traditional land-based gait training.

The study of rehabilitation protocols during postoperative PT involved consideration of a number of issues. First, differences in functional outcomes compared to traditional rehabilitation could not be detected in this study because of the small number of patients, but the patients treated with anti-gravity gait training showed improvement in

functional outcomes over time and did not report any added complications. Given that the primary outcome of this study was safety and feasibility, these added efficacy results are supplemental and useful in helping to plan studies. Second, the functional outcomes used to measure the efficacy of the anti-gravity treadmill may not be sensitive enough to detect differences between rehabilitation protocols. Use of a treadmill to measure speed improvement, endurance, and tolerance in both groups could be valuable in future studies. More studies may need to refine characteristics that are important to postoperative rehabilitation success, and quantitative and subjective measures that must be defined.

The results reported here using an anti-gravity treadmill for postoperative TKA rehabilitation support the safety and feasibility that has been reported in other orthopedic rehabilitation settings. Anti-gravity treadmills, which have been used to study patients after meniscectomy or anterior cruciate ligament reconstruction<sup>8</sup> and Achilles repair,<sup>17</sup> have demonstrated predictable decreases in ground reaction forces with increasing positive-pressure unweighting, reductions in pain with ambulation, and allowance of earlier institution of walking and jogging during rehabilitation.<sup>17</sup>

Patient safety is an important attribute for any postoperative rehabilitation protocol, especially in an elderly population undergoing major surgery. One of our important goals was to assess the safety of AlterG. We noted no AEs attributable to the device, which was supported by work indicating no adverse impact on systemic cardiovascular parameters in a similar lower body positive-pressure environment.<sup>9</sup> Although 3 patients (10%) developed symptomatic DVT, there were no differences between the groups in the incidence of DVT. Use

Table 2. TUG and NRS Scores for Control and AlterG Groups Over Time

Measurement	Control Group		AlterG Group		P value
	N	Mean ± SD	N	Mean ±SD	
<b>TUG (sec)</b>					
Baseline	15	13 ± 5	14	16 ± 9	.229
End of PT	15	8 ± 1	14	9 ± 3	.448
EOS (3 months postoperative)	15	7 ± 1	11	7 ± 1	.724
<b>NRS</b>					
Baseline	15	3 ± 2	14	2 ± 2	.173
End of PT	15	1 ± 1	14	1 ± 1	.591

Abbreviations: EOS, end of study; NRS, Numeric Rating Scale; PT, physical therapy; sec, seconds; TUG, Timed Up and Go.

of an anti-gravity treadmill has also been examined for cardiovascular responses in TKA patients. In a study of 24 adults with TKA, researchers found that anti-gravity support allowed TKA patients to walk at faster speeds and tolerate greater inclines with lower heart rate, blood pressure, and oxygen consumption.<sup>21</sup>

With respect to efficacy of the rehabilitation intervention, we demonstrated significant improvements in all functional outcomes in both groups but no differences between the study groups. We concluded that AlterG was at least as effective as standard therapy in this small cohort. TKA is a very successful procedure, and the improvement in pain and function after surgery is fairly dramatic in most patients, regardless of specific rehabilitation protocols.

Therefore, the substantial improvement in clinical outcomes may overshadow any enhanced benefits of the anti-gravity treadmill. Further investigations into the efficacy of AlterG are needed in a larger cohort to determine if this type of treatment is more beneficial than traditional land-based gait training.

Standard scoring systems such as KOOS, TUG, and NRS may not be sensitive enough to detect differences between treatment groups with small sample sizes. Given the results of the post hoc power analysis, a large number of patients (N = 250/group) would be necessary to detect any potential difference in clinical outcomes between the 2 groups. Larger studies are required to answer relevant questions, and additional outcome measures may be needed to detect differences between treatment groups. Relevant questions include whether earlier institution of the anti-gravity device during the immediate TKA postoperative period would be beneficial compared to standard postoperative PT, and whether PT enhanced with the anti-gravity device has incremental benefit in functional outcomes and in time to reach those goals. Finally, given the present attention to health-care expenses, a cost-benefit analysis of anti-gravity device treatment vs traditional PT would be useful. Once the patient has become familiar with the function of an anti-gravity treadmill, gait therapy could proceed without the direct intervention of the therapist, potentially improving efficient delivery of rehabilitation services.

Studying the effect of different postoperative rehabilitation protocols after orthopedic surgeries can be challenging. In a large (N > 350) randomized controlled trial to study the effect of ergometer cycling after hip and knee replacement, patients who used the cycle ergometer had a higher Western

Ontario and McMaster Universities Arthritis Index and greater satisfaction than those who did not after hip arthroplasty, but not after TKA.<sup>22</sup> Improvements in muscular coordination and proprioception with the cycle ergometer may have been offset by increases in edema, joint effusion, and pain from the loading of the joint and the relatively fast rate of cycling compared to passive motion or ambulation. While many therapists and surgeons advocate cycling for rehabilitation after knee surgery, the need remains for a better definition of an optimal TKA rehabilitation program. A study of 82 patients comparing early progressive strength training to no early strength training showed no difference in the 6-minute walk test at 8 weeks.<sup>23</sup> A systematic review of progressive resistance training (PRT) found that although postoperative PRT is safe and feasible, the methodological quality of existing studies is too low to allow conclusions regarding its efficacy.<sup>24</sup> Gait training in an environment where weight-bearing loads can be closely controlled, monitored, and individualized may be an ideal methodology to enhance rehabilitation and return to function for knee replacement surgery.

This current study showed that the use of AlterG as an adjunct for postoperative rehabilitation is safe, accepted by patients and therapists, and leads to clinical functional outcomes that are at least as good as traditional postoperative TKA rehabilitation. We conclude that AlterG demonstrates utility and a potential for innovation in TKA rehabilitation.

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