Original Article

A Pilot Study of End-effector Robotic Gait Training for Improving Gait and Balance Abilities in the Older Patients after Hip Fracture Surgery

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ABSTRACT

Objectives: To assess the effect of 'SensibleSTEP' end-effector type robotic gait training on gait and balance abilities in the older patients after hip fracture surgery

Study design: A quasi-experimental pilot study

Setting: The Department of Rehabilitation Medicine, Lerdsin Hospital, Bangkok, Thailand

Subjects: Older patients (aged ≥ 60) who underwent hip fracture surgery between March - September 2023.

Methods: Ten older subjects who had undergone hip fracture surgery were recruited for a robotic gait training program. The program consisted of 30-minute training sessions conducted twice weekly for four consecutive weeks, a total of eight sessions. The investigator evaluated the Functional Ambulation Category (FAC), Timed Up and Go (TUG), Single Leg Stance (SLS), Four Step Square (FSS), gait speed, stride length, cadence, visual analogue scale (VAS), gait aid use, and level of assistance both before and after the training program.

Results: Robotic gait training with SensibleSTEP showed statistically significant improvements in FAC, TUG, FSS, gait speed, and stride length. Trends of improvement were observed in SLS, cadence, VAS, gait aid use, and level of assistance.

Conclusions: End-effector robotic gait training for eight sessions can improve gait and balance abilities in the older patients who had undergone hip fracture surgery

Keywords: Robotic Gait Training, end effector type, older patient, hip fracture, gait, balance

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Introduction

Thailand has become an "aging society," as 17.1% of the current population is aged over 60 years. A significant demographic shift will occur within the next two decades when more than two-thirds of the population will be older than 60. Such an aging demographic presents unique challenges, particularly in the context of health and societal economics.[1]

Falls are recognized as a prevalent issue among older adults, with far-reaching negative impacts on individuals' health and quality of life as well as the economic stability of families and society. It is estimated that up to 10% of older individuals who experience a fall suffer severe injuries, including hip fractures and traumatic brain injuries which can lead to permanent disabilities, escalating the burden of care and support required.[2]

Hip fracture, defined as a proximal femur fracture,[3] can be divided into intracapsular fractures, e.g., femoral neck fractures, and extracapsular fractures, e.g., intertrochanteric and subtrochanteric fractures.[4] Hip fracture mainly occurs in older people[3] and is a leading cause of mortality in that age group.[5] Additionally, 50% of older adults are found to be dependent others for at least one activity of daily living after experiencing a hip fracture,[6] which causes a significant deterioration in their quality of life. This dependency underscores the need for effective preventive strategies and rehabilitation programs to mitigate the impact of such injuries in an aging society.[7]

Previous studies have reported that 41% to 64% of individuals experience at least one fall within a year after hip surgery.[8,9] Eleven percent of these falls occurred during their hospital stay.[8] Increased outdoor activity has also been associated with a higher risk of falling.[10,11] The incidence of falls was even more stark for individuals who transitioned to nursing homes after a hip fracture, with 40% passing away within two years.[12] Furthermore, 19% of older patients who suffered a hip fracture go on to experience a subsequent fracture.[13] Many factors are associated with this risk, including advanced age, poor general health, female gender, and environmental conditions. Among these factors, gait and balance abilities have been identified as predictors of recurrent injury, both of which are modifiable through targeted post-surgery rehabilitation. These associations highlight the importance of such interventions in improving patient outcomes.[9,14]

A variety of methods for rehabilitation in post-hip fracture surgery patients are available. The current conventional program includes range of motion, strengthening exercises, gait, balance, and activities of daily living (ADL) training.[15] Some programs also feature treadmill training either with or without partial body weight support.[16] Among these, it is evident that programs that specifically emphasize ambulatory skills and

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balance, such as those that include tandem walking or task-oriented training while changing position,[17] are more beneficial than conventional training in improving ADL, muscle strength, walking capabilities, and overall quality of life.[3,18,19]

Robotics-based rehabilitation has been mentioned as being superior to conventional therapy because it is able to deliver consistent training as prescribed and provide appropriate forces and movements according to the user's ability.[20] Robotic gait training was first used in rehabilitation in 1994 with a patient who had multiple fractures, delivering a safe and successful outcome.[21] Although studies focusing on robotic gait training for post-hip fracture surgery patients have been limited, a systematic review reported that the outcomes have been promising.[22] Most of the studies included in the review were preliminary, involving small sample sizes[23-25] or single-case reports.[26] Nevertheless, the findings across these studies have been consistently positive, suggesting that robotic assistance may offer superior recovery of gait and balance abilities compared to conventional training methods.[27,28]

"SensibleSTEP" is an end-effector-type robotic gait training device which has been approved by the Thai FDA. It is designed to provide safe and interruption-free body weight-supported gait and balance training with adjustable gait speed, step length as well as adjustable extent of vertical and horizontal weight support to suit the user's needs. Moreover, it gives continuous visual and kinesthetic feedback of the correctness of the magnitude and timing of body weight while shifting up on the moving two-foot plates. Although 'end-effector type' robotic gait training has been successfully deployed in the rehabilitation of subacute, severe, non-ambulatory stroke patients,[29] its efficacy in gait rehabilitation for older adults recovering from hip fracture surgery has not yet been documented. This absence of prior reports suggests a novel opportunity to explore and expand the device's rehabilitative applications.

This pilot study aimed to investigate the efficacy of 'end-effector type' robotic gait training for older patients who had undergone hip fracture surgery, focusing on the potential for improvements in gait and balance abilities.

Methods

Study design

This quasi-experimental pilot study was conducted at the Department of Rehabilitation Medicine, Lerdsin Hospital, Bangkok, Thailand, between March and September 2023. The study protocol was approved by the Lerdsin Hospital Ethics Committee (approval number LH661009).

Participants

Ten patients who had undergone hip fracture surgery, specifically hemiarthroplasty, open reduction and internal fixation (ORIF), or total hip replacement (THR), were recruited. The inclusion criteria were (1) age over 60 years, (2) allowed to engage in and capable of weight-bearing at least as tolerated, (3) sufficient cognitive capacity to understand and comply with the training sessions, and (4) able to adhere to a training schedule.

The exclusion criteria were (1) unstable medical conditions, (2) inadequate cardiovascular fitness to sustain light exercise for a minimum of 15 minutes, (3) painful musculoskeletal conditions or deformities that could potentially interfere with walking training, (4) skin breakdown which limits using a body weight support harness, and (5) individuals with pre-existing walking disabilities before their hip fracture. Patients meeting any of the criteria were excluded to allow accurate assessment of the impact of the postsurgical rehabilitation.

Intervention

Before the commencement of robotic gait training, the investigator evaluated the walking and balancing abilities of the participants. The training protocol involved 30-minute sessions twice weekly for four consecutive weeks, a total of eight sessions. Each session consisted of 20 minutes of practice with the robotic gait training device 'SensibleSTEP' (Figure 1) and 10 minutes allocated for preparation and rest. Vital signs were monitored and any abnormal symptoms were noted before and after each session, with precautions taken to avoid excessive flexion (over 90 degrees), adduction, or internal rotation of the hip joint to prevent adverse effects. All participants had previously participated in conventional physical therapy programs for post-hip fracture rehabilitation

Figure 1. 'SensibleSTEP' Robotic gait training device

from the postoperative period until discharged from the hospital, including muscle strengthening exercises, joint range of motion exercises, balance training, gait training, and proper hip joint positioning.

Outcome measurements

History-taking interviews and physical examinations, including baseline data on gender, age, weight and height as well as data on pre-existing conditions, location of the hip fracture, and pain levels were collected. In addition, participants were assessed for movement function, walking ability, and balance using the Functional Ambulation Category (FAC), Timed up and go (TUG), Single leg stance (SLS), and Four Step Square (FSS).

- FAC was used to assess functional dependency for ambulation, with or without a walking device, with the following scoring system: score '0' indicated unable to walk or in need of assistance from more than two persons, score '1' indicated requirement for firm continuous support from one person who helps with carrying weight and with balance, score '2' indicted requirement for continuous or intermittent support of one person to help with balance or coordination, score '3' indicted requirement for verbal supervision or stand-with help from one person without physical contact, score '4' indicated ability to walk independently on level ground, but requires help on stairs, slopes, or uneven surfaces and score '5' indicated ability to ambulate independently on nonlevel and level surfaces, stairs, and inclines.[30]
- TUG was used to assess functional mobility and balance. Patients were encouraged to walk at their preferred pace using their usual walking aids. The investigator recorded the time taken to rise from a chair with armrests, walk 3 meters, cross a line on the floor, turn around, walk back, and sit down again.[31]
- SLS was use static balance. The time spent standing on a single leg with eyes open was measured.[32]
- FSS was used to assess dynamic standing balance. The FSS is classified on an ordinal scale as follows: score '0' indicated the patient's inability to complete the test, score '1' indicated the patient's ability to complete the test but taking longer than 15 seconds, and score '2' indicated the ability to complete the test within 15 seconds.[33]
- Another essential variable was gait parameters, including average gait speed, cadence, and stride length. Parameters were assessed during a 10-meter walking test at a comfortable speed. Pain level, use of gait aids, and level of assistance required were also assessed during testing.[31] Pain levels were measured using a VAS, which consists of a 10 cm line with two endpoints denoted as 0 ('no pain') and 10 ('as much pain as possible'). Patients were asked to rate their current level of pain by marking it on the line.[34]

These assessments were conducted before the training (pre-training) and at the end of the 8th session (post-training). The collected data were subjected to statistical analysis and summarized to determine the study's outcomes.

Statistical analysis

The data were analyzed using IBM SPSS Statistics 29.0 software. The statistical significance level was set at a *p*-value less than 0.05, and the power of the test was 80%. The demographic data, including gender, age, weight, height, pre-existing conditions, location of the hip fracture, and pain levels, are reported as mean with standard deviation for continuous variable data, median with minimum and maximum values for ordinal variable data, and patient counts for categorical variable data. The following tests, including the FAC, TUG, SLS, FSS, Gait Parameters, VAS, gait aid use and level of assistance required were compared between pre-training and post-training using the Wilcoxon signed rank test and the generalized McNemar chi-square test.

Results

The characteristics of all participants are shown in Table 1. The participants had a mean (SD) age of 75.6 (6.2) years, weight of 51.2 (10.1) kg, height of 157.0 (4.1) cm, and body mass index of 20.7 (3.4) kg/m^2.

Regarding comorbidities, the subjects presented with the following conditions: diabetes (5 subjects), hypertension (7 subjects), dyslipidemia (5 subjects), history of cerebrovascular accident (1 subject), thyroid disorders (2 subjects), and atrial fibrillation (1 subject). All participants had been diagnosed with femoral neck fractures, five on the right side and five on the left side. Surgical interventions were predominantly hemiarthroplasty, performed on eight subjects. Of the remaining patients, one underwent open reduction internal fixation (ORIF) on the femoral neck system and one had a total hip replacement (THR). The median time from surgery to the start of training was 141 days, with an IQR of 17 to 518 days. All subjects were residing at home and were independent in basic activities of daily living (BADL). The number of falls before the study had a median of 0 with an IQR of 0 to 4.

Function and balance test

Patient FAC was categorized prior to training. Three participants were categorized as FAC3, 6 participants were FAC4, and 1 participant was FAC5. Post-training, none of the participants remained at FAC3; the number at FAC4 decreased to 3, and at FAC5 increased to 7. This change in FAC levels was statistically significant, with a *p*-value of 0.046.

The TUG test resulted in pre-training median scores of 31.35 seconds and post-training median scores of 19.65 seconds. The statistical significance of this improvement was a *p*-value of 0.005.

In the SLS test, median scores were 4.10 seconds and 7.54 seconds in pre-training and post-training, respectively, indicating a positive change although not statistically significant (*p*-value of 0.086).

Table 1. Demographics and clinical characteristics of participants

Characteristics	Participants (N = 10)
Age[1] (years)	75.6 (6.2)
Weight[1] (kg)	51.2 (10.1)
Height[1] (cm)	157.0 (4.1)
BMI[1] (kg/m^2)	20.7 (3.4)
Underlying disease[2]	
Diabetes	5 (50)
Hypertension	7 (70)
Dyslipidemia	5 (50)
Cerebrovascular accident	1 (10)
Thyroid disorder	2 (20)
Atrial fibrillation	1 (10)
Fracture[2]: right / left side	5 (50) / 5 (50)
Operation[2]	
Hemiarthroplasty	8 (80)
ORIF with femoral neck system	1 (10)
Total hip replacement	1 (10)
Time from surgery to the start of training (days)[3]	141 (17, 518)
Address[2]: home	10 (100)
BADL[2] (level): independent	10 (100)
Previous fall frequency[3] (times)	0 (0, 4)

[1]Mean (SD), [2]number (%), [3]median (min, max)
BMI, body mass index; ORIF, open reduction internal fixation; BADL, basic activities of daily living

In the FSS test, 6 of 10 participants initially scored '0' due to inability to complete the test during the pre-training evaluation. Whereas after the training, all participants could successfully complete the test with a score of '1' or '2' (Table 2). The statistical significance of this change was marked by a *p*-value of 0.046.

Gait parameters

Median gait speed was 0.30 in pre-training and increased to 0.57 in post-training. The median stride length also rose from 0.52 to 0.80. These improvements were statistically significant, with *p*-values of 0.008 and 0.005, respectively, while changes in cadence did not reach the level of statistical significance, with a *p*-value of 0.114.

The changes in VAS, gait aid use, and level of assistance required did not reach statistical significance, with *p*-values of 0.114, 0.059, 0.063, and 0.172, respectively. However, the trend in these parameters was positive compared to pre-training. The study results are displayed in Table 2.

Discussion

The study evaluated gait and balance abilities in older patients who had undergone hip fracture surgery followed by robotic gait training using the FAC,[35] TUG,[36] SLS,[37] FSS,[38] 10 Meter Walking Test[39], and VAS[40,] the validity and reliability all of which have been previously documented. Improvement in the FAC, TUG, FSS, gait speed, and stride length reached statistical significance. Much of our findings are consistent with previously published studies.

Regarding balance abilities, Yang et al.[22] demonstrated similarly significantly improved TUG, and Fujikawa et al.[23] also reported a positive TUG trend, supporting our findings.

Table 2. Comparison of gait and balance abilities before and after robotic gait training (N = 10)

Outcomes	Pre-training	Post-training	*p*-value
FAC[1] (score)			0.046
3	3 (30)	0 (0)	
4	6 (60)	3 (30)	
5	1 (10)	7 (70)	
Balance tests			
TUG[2] (seconds)	31.35 (24.41, 69.02)	19.65 (17.08, 28.09)	0.005
SLS[2] (seconds)	4.10 (0.98, 10.88)	7.54 (3.48, 16.21)	0.086
FSS[1] (level)			0.046
0	6 (60)	0 (0)	
1	3 (30)	7 (70)	
2	1 (10)	3 (30)	
Gait parameters			
Gait speed[2] (me-ters/second)	0.30 (0.18, 0.66)	0.57 (0.48, 0.70)	0.008
Cadence[2] (steps/minute)	79.57 (51.01, 109.47)	91.92 (77.50, 111.01)	0.114
Stride length[2] (meters)	0.52 (0.37, 0.80)	0.80 (0.69, 0.91)	0.005
VAS[2] (score)	0 (0, 1.3)	0 (0, 0)	0.059
Gait aid use[1]			0.063
- None	5 (50)	10 (100)	
- Walker	5 (50)	0 (0)	
Assistance required[1]			0.172
- None	5 (50)	10 (100)	
- Minimal	1 (10)	0 (0)	
- Contact	4 (40)	0 (0)	

[1]Number (%); [2]median (IQR); Wilcoxon signed rank test or the generalized McNemar chi-square test, statistically significant at $p < 0.05$
FAC, Functional Ambulation Category; TUG, Timed Up and Go; SLS, single leg stance; FSS, Four Step Square; VAS, visual analogue scale

The subjects of these two studies were similar to the present study, i.e., Asian older patients who had undergone surgery due to hip fracture and who trained with robotic assistive devices. Although those studies utilized different robot models (trunk control rehabilitation robot and hybrid assistive limb (HAL) lumbar type), they had common features with SensibleSTEP, e.g., all of them directly attached to the patient's lower limbs while training and were able to sense and adjust support according to the patient's movement. In addition, these two studies reported on two other significantly improved balance parameters: the Modified Functional Reach test (MFRT) and the Five Times Sit to Stand (FTSS) test together with references indicating their use in balance evaluation. The first was used to assess trunk balance in a sitting position,[41] and the latter could identify people with a balance disorder.[42]

Regarding gait speed, Röhner et al.[24] reported patients had significant improvement in gait speed after robotic training, which is consistent with our study. The robot in Röhner et al.'s study let the patients walk by themselves under analyzing and voice guidance, while ours worked on the very distal part of the kinetic chain. Both methods of training might be able to improve overall trunk and lower limb muscles. Setoguchi et al.[25] also showed some positive trends in gait speed after training, but the results were not statistically significantly different which the author hypothesized was owing to the limited sample size.

Stride length was significantly improved in our study, similar to Setoguchi et al.,[25] while Röhner et al.[24] did not report any improvement. The robotic device that Röhner et al. studied stands away from the patient, while the SensibleSTEP used in our study and HAL in the Setoguchi et al. study were directly attached and supported with step length adjusted for the patient during training, allowing uninterrupted practice resembling normal walking movement. Cadence, however, was improved in all studies, but this might need to be investigated further to determine its clinical and/or statistical significance.

Regarding improvements in VAS, Yang et al.[22] reported significant improvement in VAS after robotic gait training, in contrast to our study in which the pain level did not significantly change. This difference might be due to the low initial VAS and smaller sample size in the present study. All participants in this study received analgesic medication from orthopaedists, but no changes were made in medication during this study.

It must be noted that comparison between studies incorporating robotic training after hip fracture surgery was highly challenging due to the limited amount of available data, the different types of robots, and the different training protocols.

Another noteworthy result in our study is the improvement in ambulation status. Prior to the robotic training, half the participants (5 out of 10) relied on a walker for support, and the other half needed assistance for mobility. After the training program, none required gait aids or assistance from another individual. Although the change in ambulation status was not statistically significant, this does seem to be a noteworthy clinical improvement as the participants were more independently mobile. Walkers typically aid walking in people with impaired muscle power and balance,[43] so this improvement could be the result of better balance as mentioned above as well as increased muscle strength, especially the hip abductors, as weakness of those muscles is one of the common complications after hip surgery.[44,45]

The 'end-effector type' robot has succeeded in improving ambulation ability, activity of daily living, gait speed, step length, and endurance compared to conventional physical therapy in other situations such as severe non-ambulatory stroke patients.[29] Our study was the first to investigate the effect of 'end-effector type' robotic gait training in older patients after hip fracture surgery. The results showed benefits for this group of patients, suggesting the possibility of using this robotic model for training hip fracture surgery patients. It should be noted that this was a short-term intervention consisting of only eight therapy sessions. The performance of participants at the end of that short period speaks against the general common perception that an extended period might be necessary to achieve progression in geriatric rehabilitation.

The duration of post-surgery training by a robotic device in our study averaged at 4-5 months, ranging from 17 to 518 days. Even though this is quite a wide range, all participants showed improvement in balance and gait parameters, which suggests a possible benefit of training even in patients who have been operated on some time ago and who have already received conventional postoperative training.

There are some limitations in the present study. Being a pilot study, there was no blinding of the assessor and no control group for comparison. The preliminary findings, do, however, suggest the potential for a larger scale, randomized controlled trial to further investigate the efficacy of 'end-effector type' robotic gait training compared to conventional treatments. A longer follow-up period should also be included to determine the long-term effects. In addition, incorporating a health economic analysis into future research could provide valuable insights into the cost-benefit ratio of such interventions for older patients recovering from hip fractures.

Conclusions

End-effector robotic gait training can improve gait and balance abilities in older people following hip fracture surgery with eight training sessions.

Conflicts of interest

The author declares no relevant conflicts of interest in this study.

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