Cover page for ClinicalTrials.gov

Name of the document:

Study protocol and Statistical Analysis Plan

Official Title of the Study:

A Pilot Study to Verify the Effectiveness and Safety of the Electrically Powered Orthopedic Exercise Device on Gait Ability in Patients Who Have Undergone Hip Surgery: Investigator-Initiated, Single-Center, Single-Group Clinical Trial

NCT number

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April 9, 2025

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Prospective Clinical Study Protocol

1. Study title, stage, protocol identification number, revision history, etc.

- Study title : A Pilot Study to Verify the Effectiveness and Safety of the Electrically Powered Orthopedic Exercise Device on Gait Ability in Patients Who Have Undergone Hip Surgery: Investigator-Initiated, Single-Center, Single-Group Clinical Trial
- Study phase : phase 4

2. Summary of study plan

Study objective	This study aims to evaluate the clinical feasibility of the Electrically Powered Orthopedic Exercise Device in patients who have undergone hip surgery by comparing gait function between non-wearing and wearing conditions. The study will assess the effectiveness of gait function improvement, device safety, and participant satisfaction.
Study design overview	Investigator-initiated exploratory clinical study Pilot study
Investigational Medical Device	Electrically Powered Orthopedic Exercise Device
Target Sample Size and Calculation Basis	Sample Size : 30 patients who have undergone hip surgery This study aims to compare and analyze changes in gait indicators between the non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device to verify its effectiveness and safety in improving gait function in patients who have undergone hip surgery. The target sample size has been determined considering clinical circumstances. Calculation Basis : The sample size was determined considering clinical circumstances with the goal of recruiting three participants per month.
Inclusion and exclusion criteria	1. Inclusion Criteria 1) Adults aged 19 or older 2) Individuals who have undergone hip surgery due to hip osteoarthritis, avascular necrosis of the femoral head, or hip fracture 3) Individuals who are at least two days post-hip surgery and are assessed to be medically stable

	4) Adequate cognitive ability (Korean Mini-Mental State Examination score ≥ 20) 5) Able to sit at the edge of a bed without assistance and stand for 10 seconds regardless of support 6) Functional Ambulatory Category (FAC) score of 1–3 7) Participants who visited Yongin Severance Hospital, understood the study, and signed informed consent 2. Exclusion Criteria 1) Individuals who, after undergoing hip surgery, present with exudate at the surgical site or report symptoms such as heat, redness, swelling, or severe pain at the affected area 2) Contraindications for lower limb weight-bearing such as severe joint contractures, osteoporosis, or untreated fractures 3) Progressive or unstable brain diseases or neurological paralysis from stroke 4) Active infections or open wounds hindering device use 5) Significant leg length discrepancies 6) Severe deformities or contractures in the lower extremities 7) History of poliomyelitis 8) Inability to maintain seated or standing positions independently 9) Severe spasticity (Modified Ashworth Scale grade ≥ 2) 10) Bone metastases from cancer 11) Severe internal diseases affecting device use (e.g., cardiovascular or respiratory diseases) 12) Cognitive impairments preventing cooperation with device use 13) Complaints of device-related side effects or potential rehabilitation discontinuation(e.g., severe obesity, skeletal deformity) 14) Patients who are determined to be pregnant or potentially pregnant based on the medical interview 15) Any other clinically significant findings deemed inappropriate by the investigator
Study Methods	After obtaining informed consent, clinical information is collected, and a screening test is conducted. The screening includes an interview regarding the participant's baseline symptoms and signs, as well as a physical activity questionnaire. Participants who pass the screening undergo an evaluation of gait

	function and balance ability without wearing the Electrically Powered Orthopedic Exercise Device. Afterward, the patient wears the electrically powered orthopedic exercise device for a total of four adaptation sessions. In each session, the patient performs short-distance walking within 10 meters while wearing the device to explore the appropriate assistive mode and level of support that match their physical condition. No evaluations are conducted while wearing the device during sessions 1, 2, and 3. After the 4th session, an evaluation identical to the one conducted without the device is performed while wearing it, and a satisfaction survey is conducted. Any device malfunctions are addressed and documented, and the type, severity, and frequency of side effects, such as pain associated with device use, are recorded. The evaluation results from the non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device, along with the satisfaction survey results, are compared.
Evaluation variable	1. Primary Evaluation Variable • 10-Meter Walk Test 2. Secondary Evaluation Variable • 6-Minute Walk Test • Timed Up and Go (TUG) Test • Berg Balance Scale (BBS) • Spatiotemporal Parameters of Gait • K-QUEST-based 10-question, 5-point scale satisfaction survey related to the use of Electrically Powered Orthopedic Exercise Device
Data analysis and statistical methods	1. Primary and Secondary Evaluation Variables: This pilot study explores the effectiveness and safety of the Electrically Powered Orthopedic Exercise Device by evaluating gait function and balance ability in both non-wearing and wearing conditions. The primary evaluation variable is the gait speed measured during the 10-Meter Walk Test. The measured results are compared and analyzed using a paired t-test, with a significance level set at $p < 0.05$, indicating a significant difference before and after wearing the device. The secondary evaluation variables include the 6-Minute Walk Test, spatiotemporal gait parameters, Timed Up and Go (TUG) Test, and Berg Balance Scale (BBS), which are also analyzed using paired t-

	tests with the significance level set at $p < 0.05$. In addition, a linear mixed model will be used to analyze the data, incorporating both the individual characteristics of participants due to repeated measures and fixed effects. 2. Satisfaction Evaluation: User satisfaction with the Electrically Powered Orthopedic Exercise Device is analyzed using descriptive statistics. The mean, standard deviation, minimum, and maximum values of each item are calculated. A mean score of 4 or higher is interpreted as positive satisfaction, while a score of 2 or lower is considered negative satisfaction.

3. Research background and theoretical basis

Gait is an essential daily activity performed through the complex coordination of the central and peripheral nervous systems and the musculoskeletal system.[1] Gait disorders can negatively affect quality of life, increase the risk of falls, decrease the ability to perform daily activities, and limit physical activity.[2] Gait disorders can result from various musculoskeletal conditions, with hip osteoarthritis, avascular necrosis of the femoral head, and hip fractures being the most representative causes.[3]

In the early stages of hip osteoarthritis, avascular necrosis of the femoral head, or non-severely displaced hip fractures, various intervention therapies, including rehabilitation exercise therapy and injection treatments, can be attempted.[4-8] However, these intervention therapies merely alleviate symptoms and cannot prevent disease progression. Consequently, most patients eventually experience thinning of the full-thickness hip cartilage, collapse of the femoral head, nonunion, or worsening displacement, which leads to restricted hip range of motion. As a result, lower limb muscle weakness and functional decline occur, ultimately requiring hip surgeries such as total hip arthroplasty or open reduction and internal fixation.[9] According to OECD statistics, more than one million total hip arthroplasty (THA) procedures are performed worldwide each year, with a particularly increasing trend in developed countries.[10] Although most patients experience a recovery in gait ability after hip surgery, some show a slower recovery rate or fail to achieve normal walking.[11] It has been reported that over 80% of function is recovered by three months after surgery; however, during this period, patients experience limitations in performing daily activities.[12] Additionally, reduced hip extension strength and range of motion in the operated hip can lead to asymmetrical lower limb coordination.[13-14] As a compensatory mechanism, excessive weight-bearing on the non-operated limb may occur, increasing the risk of overloading the non-operated hip.[15-17] This may lead to the development of osteoarthritis in the non-operated limb and has also been reported to increase the risk of falls.[18-20] Therefore, various methods are being studied to facilitate gait function recovery after hip surgery and promote an early return to daily activities.

With recent advancements in joint motion sensing and actuator efficiency, simpler and lighter wearable exercise assistive devices have been developed compared to traditional robots. Therefore, this study aims to explore the clinical feasibility of the Angel Suit H10 (Angelrobotics, Seoul, Korea) by assessing whether wearing the Electrically

Powered Orthopedic Exercise Device improves gait function in patients who have undergone hip surgery, along with evaluating user satisfaction and device safety.

4. Purpose of the study

This study aims to investigate the clinical feasibility of the Electrically Powered Orthopedic Exercise Device in patients who have undergone hip surgery by comparing gait function between non-wearing and wearing conditions. The evaluation focuses on the device's effectiveness in improving gait function, its safety, and participant satisfaction.

5. Risk/benefit analysis

The 10-Meter Walk Test is used in this study to evaluate gait function under both non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device. Other assessments of gait function and balance ability are also conducted, all of which are widely used in clinical settings and carry very low medical risk. To minimize the risk of falls during the tests, participants will undergo sufficient practice under the examiner's supervision before the evaluation and perform the tests in an environment equipped with safety bars. This device is designed to assist thigh muscle strength and is considered unlikely to cause imbalance or joint strain during walking. However, if the patient reports discomfort related to wearing the device, or if the principal investigator determines that its use may cause imbalance or joint strain during gait, the use of the device will be discontinued immediately.

Through participation in this study, subjects will receive information about their physical functions, including gait and balance abilities. The accumulated data during the study will be utilized to improve and enhance the rehabilitation device and to develop gait rehabilitation services. Additionally, the data may be used in research related to disease treatment and prognosis, contributing to advancements in medicine and improvements in the quality of clinical care. Therefore, the potential benefits of this study are expected to outweigh the possible risks.

6. Number of target audience and basis for calculation

This study will be conducted on all patients visiting Yongin Severance Hospital who consent to participate and meet the inclusion criteria. The target recruitment rate is three participants per month among the hospital's visitors. Considering the dropout rate and clinical circumstances, the target sample size has been set at 30 participants.

7. Subject selection/exclusion criteria

(1) Inclusion Criteria

1) Adults aged 19 or older
2) Individuals who have undergone hip surgery due to hip osteoarthritis, avascular necrosis of the femoral head, or hip fracture
3) Individuals who are at least two days post-hip surgery and are assessed to be medically stable
4) Adequate cognitive ability (Korean Mini-Mental State Examination score ≥ 20)
5) Able to sit at the edge of a bed without assistance and stand for 10 seconds regardless of support
6) Functional Ambulatory Category (FAC) score of 1–3
7) Participants who visited Yongin Severance Hospital, understood the study, and signed informed consent

(2) Exclusion Criteria

1) Individuals who, after undergoing hip surgery, present with exudate at the surgical site or report symptoms such as heat, redness, swelling, or severe pain at the affected area
2) Contraindications for lower limb weight-bearing such as severe joint contractures, osteoporosis, or untreated fractures
3) Progressive or unstable brain diseases or neurological paralysis from stroke
4) Active infections or open wounds hindering device use
5) Significant leg length discrepancies
6) Severe deformities or contractures in the lower extremities
7) History of poliomyelitis
8) Inability to maintain seated or standing positions independently
9) Severe spasticity (Modified Ashworth Scale grade ≥ 2)
10) Bone metastases from cancer
11) Severe internal diseases affecting device use (e.g., cardiovascular or respiratory diseases)
12) Cognitive impairments preventing cooperation with device use
13) Complaints of device-related side effects or potential rehabilitation discontinuation(e.g., severe obesity, skeletal deformity)
14) Patients who are determined to be pregnant or potentially pregnant based on the medical interview
15) Any other clinically significant findings deemed inappropriate by the investigator

8. Information and management of clinical investigational drugs/medical devices

Although this study does not conduct clinical trials, information and management methods for medical devices used in this study are as follows.

(1) Electrically Powered Orthopedic Exercise Device (Angel SUIT H10)

1) Item name: Electrically Powered Orthopedic Exercise Device

2) Classification number: A67020.02

3) Packaging unit: 1 set

4) Medical device grade: Grade 2

5) Model name: Angel SUIT H10

6) Manufacturer: Angel Robotics Co., Ltd.

7) Permit number: Manufacturing Approval Number. 25-4093

8) Appearance:

9) Principle of operation, How to use and precautions - refer to the attached document

(2) Device management

The Electrically Powered Orthopedic Exercise Device used in this study will be stored in the Rehabilitation Function Testing Room.

1) Security

The device, provided by Angel Robotics, will be stored according to the storage environment conditions specified in the instructions. It will be managed in a designated area equipped with a locking mechanism, located on the 2nd floor of the Rehabilitation Function Testing Room at Yongin Severance Hospital.

2) Infection Control

The device manager will perform thorough disinfection procedures before and after each use to minimize the risk of cross-infection between participants. Additionally, participants will be instructed to use hand sanitizer available in the testing area to ensure proper personal hygiene management before wearing the device.

3) Device Receipt and Inventory Management

Prior to the start of the study, the electrically powered orthopedic exercise device will be received through a handover process between the research team and Angel Robotics personnel. The medical device manager will manage the device's location and condition through inventory logs and conduct regular inventory checks.

4) Application Method and Duration per Participant

Each participant undergoes a total of four sessions using the electrically powered orthopedic exercise device

according to the manual, with each session lasting 20 minutes. After the final session, an evaluation is conducted while wearing the device, which takes approximately 60 minutes.

5) Return and Inventory Log

After use, the device will be returned to the Rehabilitation Function Testing Room. Upon return, its condition will be inspected, and the usage date and status will be recorded in the inventory log.

9. Study design (test group·control group, allocation, blinding and flow chart, etc.)

(1) Overview of study design

This investigator-initiated exploratory study is a pilot study designed to evaluate the effectiveness and safety of the Electrically Powered Orthopedic Exercise Device by measuring and analyzing gait function and balance ability in patients who have undergone hip surgery under both non-wearing and wearing conditions.

(2) Experimental Group and Evaluation Procedures

1) Participant Selection:

This study includes a single test group with a total of 30 participants. The selection of participants for the electrically powered orthopedic exercise device and the overall study process will be conducted under the prescription and guidance of a rehabilitation medicine specialist, and supervised by assistants (physicians and occupational therapists). The examiner will collect clinical information and conduct a screening assessment for each participant.

2) Evaluation Phase Without Device:

After the screening test, participants undergo assessments of walking ability and balance without wearing the electrically powered orthopedic exercise device. A 10-minute rest period is provided between each assessment. If the participant wishes, additional rest time is allowed and recorded in the case report form. The assessments include the 10-Meter Walk Test, the 6-Minute Walk Test, the Timed Up and Go Test, and the Berg Balance Scale. These evaluations are conducted in the rehabilitation function testing room on the second floor of the facility under the supervision of the research team (physician and either a physical or occupational therapist).

3) Pre-Adaptation Phase:

After the evaluations without the device, a total of four adaptation sessions are conducted, during which the participant wears the device and performs short-distance walking within 10 meters. These sessions are designed to help the participant become familiar with the operation and wearing method of the H10 device. Appropriate device settings are configured for each participant to minimize any potential inexperience or anxiety during use. Participants must complete all four adaptation sessions, and each session should be conducted within a two-week interval.

4) Evaluation Phase:

After completing all four adaptation sessions, participants undergo assessments of walking ability and balance while wearing the electrically powered orthopedic exercise device. A 10-minute rest period is provided between each assessment. If the participant wishes, additional rest time is allowed and recorded in the case report form. The assessments include the 10-Meter Walk Test, the 6-Minute Walk Test, the Timed Up and Go Test, and the Berg Balance Scale. These evaluations are conducted in the rehabilitation function testing room on the second floor of the facility under the supervision of the research team (physician and either a physical or occupational therapist). After the evaluations are completed, a usability and satisfaction survey regarding the electrically powered orthopedic exercise device is conducted.

(3) Random assignment & Control group

This pilot study is designed as a single-group study and does not include randomization or a control group.

10. Study Method

(1) Screening method

The examiner will interview the participant regarding baseline symptoms and signs, check vital signs to ensure the participant's medical stability, and then proceed with the following assessments.

1) Korea-Mini Mental State Examination

A test that assesses the degree of overall cognitive impairment, taking into account a person's level of education[21], and the test assesses time and place perception, attention and calculation, memory, language, and spatial and temporal organization. The examiner asks questions corresponding to the items on the test sheet below and record a score for the answers.

Patient's Name: _____ Date: _____

Instructions: Score one point for each correct response within each question or activity.

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day? Month?"
5		"Where are we now? State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then the instructor asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible.
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

2) Functional Ambulation Index Evaluation (Functional Ambulation Category)

Assessment of the subject's walking function.[22] The examiner observes the subject's gait and records a score based on the criteria in the assessment sheet below.

Stage	Desciption
0	Unable to walk or requires assistance from two or more people.
1	Requires continuous support from one person to maintain balance or shift body weight.
2	Requires intermittent assistance from one person to aid with balance or coordination.
3	Requires supervision or verbal cues without physical contact.
4	Able to walk independently on level surfaces but needs assistance on stairs, slopes, or uneven ground.
5	Able to walk independently.

3) Manual Muscle Test (Medical Research Council Scale) – Hip Joint, Knee Joint, Ankle Joint

The participant's muscle strength is assessed by group according to the criteria in the table below.[23] The participant's posture is positioned accordingly, and the evaluation scores are recorded.

Score	Description
0	No palpable or observable muscle contraction
1	Palpable or observable contraction, but no motion
1+	Moves limb without gravity loading less than one half available ROM[b]
2−	Moves without gravity loading more than one half ROM[b]
2	Moves without gravity loading over the full ROM[b]
2+	Moves against gravity less than one-half ROM[b]
3−	Moves against gravity greater than one-half ROM[b]
3	Moves against gravity less over the full ROM[b]
3+	Moves against gravity and moderate resistance less than one-half ROM[b]
4−	Moves against gravity and moderate resistance more than one-half ROM[b]
4	Moves against gravity and moderate resistance over the full ROM[b]
5	Moves against gravity and maximal resistance over the full ROM[b]

Joint	Muscle	Right	Left	Joint	Muscle	Right		Left
Hip	Flexors			Knee	Flexors			
	Extensors				Extensors			
	Abductors			Ankle	Dorsi-flexors			
	Adductors				Plantar-flexors			
	Int. rotators			Foot	Invertors			
	Ext. rotators				Evertors			

4) Range of Motion (ROM) Assessment – Lower Extremities

The participant's range of joint motion is assessed[24], with angles recorded according to the form below while the participant is in a supine position.

Lower Extremity										
Rt.						Lt.				
			125	flexion	Hip	flexion	125			
			10	extension		extension	10			
			45	abduction		abduction	45			
			10	adduction		adduction	10			
			45	E/R		E/R	45			
			45	I/R		I/R	45			
			140	flexion	Knee	flexion	140			
			0	extension		extension	0			
			20	D/F	Ankle	D/F	20			
			40	P/F		P/F	40			

5) Korean version of the International Physical Activity Questionnaire (K-IPAQ)

Tests that assess various aspects of an individual's daily physical activity[25], and it can provide information about activity level. The examiner questions the subject based on the questionnaire below, records related information, calculates the total activity time and intensity, and classifies it as 'low', 'medium', and 'high'.

1a. During the last 7 days, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling.?

Think about *only* those physical activities that you did for at least 10 minutes at a time.

_____ **days per week** ⇨ 1b. How much time in total did you usually spend on one of those days doing vigorous physical activities?

or _____ **hours** _____ **minutes**

☐ **none**

2a. Again, think *only* about those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week** ⇨ 2b. How much time in total did you usually spend on one of those days doing moderate physical activities?

or _____ **hours** _____ **minutes**

☐ **none**

3a. During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time? This includes walking at work and at home, walking to travel from place to place, and any other walking that you did sblely for recreation, sport, exercise or leisure.

_____ **days per week** ⇨ 3b. How much time in total did you usually spend walking on one of those days?

or _____ **hours** _____ **minutes**

☐ **none**

The last question is about the time you spent sitting on weekdays while at work, at home, while doing course work and during leisure time. This includes time spent sitting at a desk, visiting friends, reading traveling on a bus or sitting or lying down to watch television.

4. During the last 7 days, how much time in total did you usually spend *sitting* on a **week day?**

_____ **hours** _____ **minutes**

This is the end of questionnaire, thank you for participating.

6) Pregnancy Questionnaire

The examiner (a licensed physician) will conduct a pregnancy questionnaire to determine whether the participant is currently pregnant or has the potential to be pregnant. This assessment will include inquiries about the date of the

participant's last menstrual period and their average menstrual cycle.

(2) Evaluation of Gait Function and Balance Ability in Non-Wearing and Wearing Conditions of the Electrically Powered Orthopedic Exercise Device

Participants will perform each of the following assessments once under both conditions:

A. Non-Wearing Condition (Off Status)

B. Wearing Condition (On Status)

1) Primary Evaluation Indicator

① 10-Meter Walk Test

The 10-Meter Walk Test is used to assess gait speed in patients undergoing rehabilitation for neurological and musculoskeletal disorders.[26] Participants wear an insole-type gait analyzer and walk a 10-meter straight path at a consistent pace while the time taken is measured to evaluate gait ability.

a) A total straight path of 14 meters is prepared, with the first and last 2 meters serving as non-measurement zones.

b) Participants are informed that their walking speed will be measured over the 10-meter section and are instructed to walk at a comfortable pace.

2) Secondary Evaluation Indicator

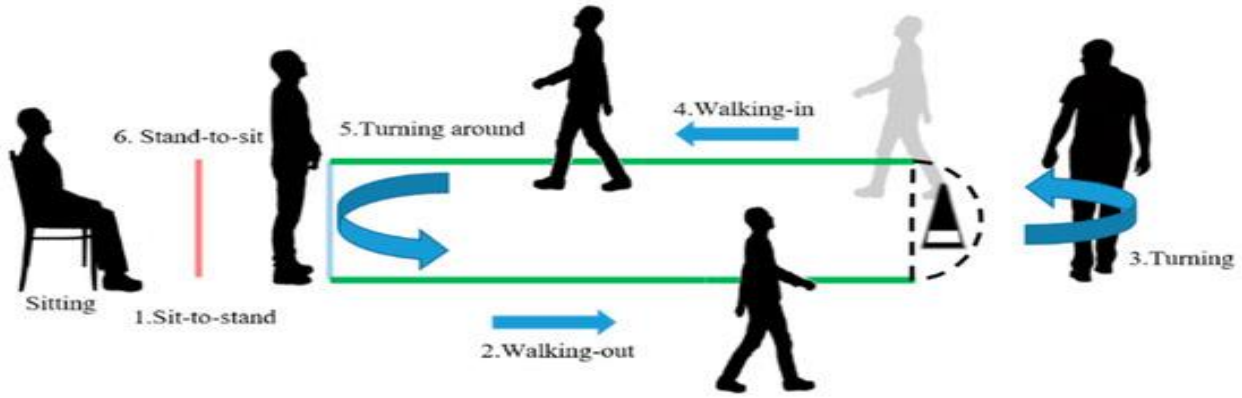
① Timed Up and Go (TUG) Test

This test evaluates both gait speed and balance ability during walking.[27] The assessment is conducted as follows:

a) Place a chair with armrests (46 cm in height) and position a cone 3 meters away from the chair. Instruct the

participant to sit in the chair.

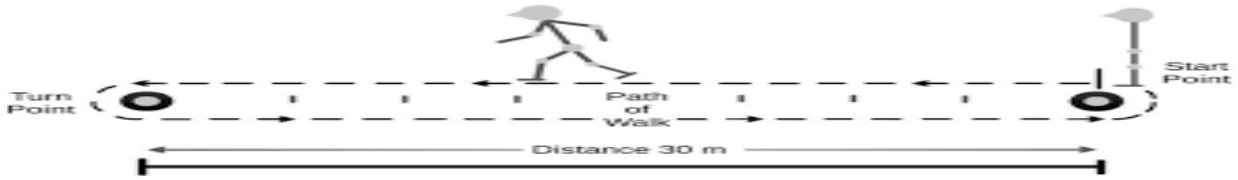
b) During the preparation phase, the participant should sit with their back against the chair and arms resting on the armrests. Upon the command "Start," the participant stands up, walks 3 meters, turns around the cone, walks back to the starting point, and sits down again.



② 6-Minute Walk Test

Participants perform the 6-Minute Walk Test, which closely simulates daily walking activities,[28] while wearing an insole-type gait analyzer. The examiner compares the average parameter data extracted from the analyzer with normal gait standards to provide feedback on the participant's walking. This test assesses gait endurance and is conducted as follows:

a) Set up colored cones marking a 30-meter straight path on the floor and prepare a stopwatch.
b) Instruct the participant to walk back and forth along the 30-meter path as many times as possible within 6 minutes.
c) Inform the participant that they may rest or stop during the test if needed. Only permitted phrases such as "You're doing well" or "Keep going" should be used for encouragement.
d) The examiner records the total distance covered, abnormal gait patterns, and the time of occurrence of any gait deviations.



③ Berg Balance Scale (BBS)

This test assesses both static and dynamic balance.[29] The examiner instructs the participant to perform the following 14 tasks and evaluates their performance based on the scoring criteria for each item.

Balance Section	Score
Sitting to standing	0 1 2 3 4
Standing unsupported	0 1 2 3 4
Sitting unsupported	0 1 2 3 4
Standing to sitting	0 1 2 3 4
Transfers	0 1 2 3 4
Standing with eyes closed	0 1 2 3 4
Standing with feet together	0 1 2 3 4
Reaching forward with outstretched arm	0 1 2 3 4
Retrieving object from floor	0 1 2 3 4
Turning to look behind	0 1 2 3 4
Turning 360 degrees	0 1 2 3 4
Placing alternate foot on stool	0 1 2 3 4
Standing with one foot in front	0 1 2 3 4
Standing on one foot	0 1 2 3 4
Total Score	_____ / 56

④ Spatiotemporal Parameters of Gait : While the participant performs the test wearing an insole-type gait analyzer, spatiotemporal gait parameters are collected and recorded. These parameters include total step count, cadence, walking speed, walking distance, and stride length.

a) Step Count: The total number of steps taken during walking.

b) Cadence: The number of steps taken per minute, measured in steps per minute (spm).

c) Self-Selected Walking Speed: The participant's walking speed when walking naturally at a comfortable pace.

d) Distance: The total distance covered during walking, measured in meters (m).

e) Stride Length: The distance between the heel of one foot to the heel of the same foot during consecutive steps. Measured in meters (m), stride length is adjusted for height to account for differences in body size.

(3) Recording of Adverse Events and Device Malfunctions

1) The examiner records the type and frequency of any safety incidents that occur while the participant is walking, as well as the reasons for any device malfunctions.

2) In cases where side effects, such as pain, occur, the following details are investigated and documented: Type of side effect, Severity, Frequency of occurrence, Name of adverse event, Onset and resolution dates, Nature of the side effect, Causal relationship with device use

(4) Satisfaction Evaluation

Participants will complete a satisfaction survey regarding the Electrically Powered Orthopedic Exercise Device, based on the Korean version of the Quebec User Evaluation of Satisfaction with Assistive Technology (K-QUEST 2.0).[30] The survey consists of 10 items, each rated on a 5-point scale to assess satisfaction with the assistive device and related services. Participants are instructed to provide reasons if they select any response other than "Very Satisfied."

1: Very unsatisfied. 2: Not satisfied 3: Average 4: Satisfied. 5: Very satisfied

	One	2	3	4	5
Are you satisfied with the specifications (size, height, length, width) of the smart insole? reason : _____					

How much does the smart insole weigh? reason : _____					
Is it convenient to adjust (fix and lock) the parts (accessories) of the smart insole? reason : _____					
Do you think smart insoles are safe and sturdy? reason : _____					
Are you satisfied with the durability (long-term usability) of the smart insole? reason : _____					
Was it convenient to use the smart insole? reason : _____					
Do you think smart insoles are comfortable to wear? reason : _____					
Are you satisfied with the effectiveness of the smart insole (effectiveness suited to the purpose of use)? reason : _____					
Are you satisfied with Smart Insole's service and delivery program (delivery process and time required)? reason : _____					
Are you satisfied with the professional service (information and precautions) you received while using the smart insole? reason : _____					

- Among the 12 items regarding satisfaction, please tick the 3 items you consider most important.

	O sign
1. Specifications	
2. Weight	
3. Convenience	
4. Safety	
5. Durability	
6. Usability	
7. Comfort	
8. Effect	
9. Service delivery	
10. Repair and maintenance services	
11. Professional services	
12. After-sales service	

(5) Definition of Analysis Population, and Management Plan for Missing and Outlier Data

1) Definition of Analysis Population

The analysis population includes all participants who have completed the evaluations of gait and balance abilities under both non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device. Data will be analyzed in conjunction with participants' age, diagnosis, physical function assessments, and other extracted information.

2) Management Plan for Missing and Outlier Data

If missing data occur due to participant withdrawal or dropout, a Complete Case Analysis will be used, analyzing only fully observed cases. Data from sessions with missing values will be excluded from the analysis. Outliers identified through boxplots and interquartile ranges will also be excluded to maintain data integrity and enhance the accuracy and reliability of the research. Information on participants excluded from the analysis will be documented.

(6) Pre- and Post-Condition Comparative Analysis

Upon completion of all evaluations under both non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device, the examiner will perform a comparative analysis of the collected participant data using a paired t-test. A significance level of $p < 0.05$ will be used as the criterion for statistical significance. In addition, a linear mixed model will be used to analyze the data, incorporating both fixed effects and individual variability of participants resulting from repeated measurements.

11. Study Procedure and Evaluation

Phase	Screening/Assessment/Adjustment	Adjustment	Adjustment	Adjustment/Assessment
Session	1	2	3	4
Written consent form	O			
Inclusion/Exclusion Criteria	O			
Clinical Information Collection and Screening Assessment	O			

Primary Outcome Measure Assessment	O			O
Secondary Outcome Measure Assessment	O			O
Wearing the electrically powered orthopedic exercise device	O	O	O	O
Satisfaction survey				O

*Each session should be conducted within a two-week interval.

12. Criteria for Study Termination and Early Withdrawal

(1) Termination and Early Discontinuation

1) If a participant withdraws consent before the study is completed

- In cases of consent withdrawal, only the data collected up to the point of withdrawal will be used for the study. These data will be stored for three years after the study concludes and then destroyed.

(2) Early Withdrawal : Participants will be withdrawn from the study under the following circumstances:

1) The participant or their legal representative requests to discontinue participation.
2) A serious adverse event occurs.
3) The medical team determines that continuing participation poses significant medical risks to the participant.
4) The participant undergoes surgery, takes medication, or uses other medical devices that could affect safety or efficacy evaluations.
5) The participant fails to follow the investigator's instructions or does not comply with the terms outlined in the consent form, potentially affecting the validity of the evaluation.
6) In cases where the participant is unable to continue the study after completing the pre-wearing gait evaluation and taking a 10-minute rest
7) Other situations deemed problematic for study continuation by the clinical trial investigator.
8) The participant develops a serious illness or experiences an accident during the study that could affect their functional abilities.

- In cases of early withdrawal, the participant’s voluntary intent will be reconfirmed to ensure the decision does not stem from unintended early termination. If the participant still consents to the use of their data, the information

collected up to the point of withdrawal will be anonymized and used in the study.

13. Safety Evaluation Criteria, Methods, and Reporting Procedures Including Adverse Events

(1) Safety Monitoring and Evaluation : To ensure participant safety, the principal investigator will act as the safety monitor and conduct ongoing safety evaluations

1) As this is a preliminary case study with minimal invasive procedures and low risk, monitoring will be conducted under the supervision of the principal investigator. Source documents, Case Report Forms (CRF), and the study protocol will be cross-checked to ensure data integrity and review participant safety data.

2) Participants have the right to withdraw from the study at any time if they experience discomfort. The principal investigator or study personnel will fully explain this right and obtain confirmation during the consent process.

(2) Violation and Deviation Reporting

In the event of study violations or deviations, the situation, corrective actions, and recurrence prevention measures will be promptly reported to the Institutional Review Board (IRB) in writing.

If a participant sustains an injury or if a new incident occurs during the evaluation, immediate treatment and monitoring will be provided, along with a thorough investigation into the cause. Treatment will follow the hospital's standard procedures. These incidents will be included in interim reports and documented in the study publication. Given the low likelihood of future adverse events, no additional research budget has been allocated for further treatment costs.

14. Data Analysis and Statistical Considerations

(1) Primary and Secondary Evaluation Variables : Differences in gait function and balance ability between the non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device will be analyzed using descriptive statistics. The analysis will present the mean, standard deviation, median, minimum, and maximum values. Changes in performance will be compared using a paired t-test. In addition, a linear mixed model will be used to analyze the data, incorporating both the individual characteristics of participants due to repeated measures and fixed effects.

(2) Satisfaction Evaluation : Satisfaction with the Electrically Powered Orthopedic Exercise Device will be analyzed using descriptive statistics to determine the mean, standard deviation, minimum, and maximum values for each item. (An average score of 4 or higher will be interpreted as positive satisfaction, an average score of 2 or lower will be interpreted as negative satisfaction)

15. Measures for Protecting Personal Information and Maintaining the Confidentiality of Research Data

(1) Protection of Participant Identity

When obtaining consent for the study, the researcher will explain the study to the participant and obtain consent in an independent consultation room within the outpatient rehabilitation department.

All information collected from this study will be kept confidential and will not be disclosed to anyone other than the research team involved in the study. It will be used solely for research purposes. Sensitive personal information that can identify individuals will not be shared with institutions outside the hospital and will undergo a de-identification process. De-identification will be conducted by assigning random numbers, ensuring that personal information is not exposed. Re-identification will only be allowed if necessary for the individual's treatment. Only the final analysis results will be disclosed to the medical device company, and data ownership will remain with the hospital.

(2) Confidentiality of Research Data

Paper documents will be securely stored in locked cabinets to prevent unauthorized access. Electronic data will be saved on access-restricted computers managed by the responsible researcher.

(3) Retention of Records

In accordance with the Enforcement Rules of the Bioethics and Safety Act, research-related materials involving human subjects must be retained for three years after the conclusion of the study. Documents containing personal information will be destroyed after the retention period following Article 16 of the Enforcement Decree of the Personal Information Protection Act. However, if further retention of the data is necessary for follow-up studies or record accumulation, an extension may be approved through review by the institutional committee.

16. Management, Storage, and Disposal Plan for Human-Derived Materials and Genetic Information

This study does not collect any human-derived materials or genetic information.

17. Participant Recruitment Methods and Consent Procedures

After obtaining approval from the Yongin Severance Hospital Institutional Review Board (IRB), participants will be recruited from patients visiting Yongin Severance Hospital who voluntarily decide to participate and provide consent. Interviews will be conducted in a private space to ensure confidentiality. Participants will be provided with an IRB-

approved information sheet explaining the study, after which informed consent will be obtained. A thorough explanation of clinical trial participation will be provided to ensure participants understand the study. Consent will be collected in a non-coercive environment, emphasizing that participants can withdraw consent at any time of their own volition. Participants' willingness to continue participation will be reconfirmed during study procedures, ensuring they are aware of their right to withdraw at any point.

18. Protection Measures for Recruitment of Vulnerable Participants

This study does not recruit vulnerable participants.

19. Information on the principal investigator and participating researchers, location of research conduct, and research period

(1) Research director

name	Affiliated organization	Major	spot	phone call
Nayoung Kim	Yonsei University medical school Yongin Severance Hospital	rehabilitation medicine	Clinical Assistant Professor	031-5189-8163 Kny8452 @yuhs.ac

(2) Test person in charge

The test manager checks whether the test subject meets the selection criteria at the testing institution and manages the overall process of the experiment.

name	Affiliated organization	Major	spot	phone call
Nayoung Kim	Yonsei University medical school Yongin Severance Hospital	Rehabilitation medicine	Clinical Assistant Professor	031-5189-8163 Kny8452 @yuhs.ac
Junyoung	Yonsei University	Orthopedic	Clinical	031-5189-8451

Park	medical school Yongin Severance Hospital	Surgery	Assistant Professor	JJUNYON@yuhs.ac
Hwi-woo Yang	Yonsei University Industry-Academic Cooperation Foundation	Occupational Therapy	Researcher	010-7360-4439 Rehab5@yuhs.ac

(3) Medical device manager

name	Affiliated organization	spot	phone call
Hwi-woo Yang	Yonsei University Industry-Academic Cooperation Foundation	Researcher	010-7360-4439 Rehab5@yuhs.ac

20. Location and duration of research

(1) Location of research

Organization name	location	phone call
Yonsei University College of Medicine Yongin Severance Hospital	363 Dongbaekjukjeon-daero, Giheung-gu, Yongin-si, Gyeonggi-do (Middle East)	031-5189-8891

(2) Period

12 months after IRB approval (e.g. March 2025 – February 2026)

21. Data safety monitoring plan

The safety inspector (principal researcher) monitors the overall research progress at monthly intervals, including the status of the research, whether the registration subjects are suitable for the selection criteria, the appropriateness

of the consent acquisition procedure, whether violations/deviations from the research plan have occurred, and whether the subjects have had adverse reactions. We aim to ensure the integrity of the data.

22. Research execution plan (schedule)

Detailed development details	Detailed promotion schedule (months)											
	1	2	3	4	5	6	7	8	9	10	1 1	1 2
Research plan and IRB approval	■											
Recruitment of subjects	■	■	■	■	■	■	■	■	■	■	■	
Conduct of research procedures and follow-up period	■	■	■	■	■	■	■	■	■	■	■	■

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