Clinical Study Protocol

Prediction of Patient-reported Outcome Measure and Performance-based Measure after Total Knee Arthroplasty Using Instrumented Insoles and Deep Neural Networks

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Clinical Study Protocol

1. Title and Study Phase

Prediction of Patient-reported Outcome Measure and Performance-based Measure after Total Knee Arthroplasty Using Instrumented Insoles and Deep Neural Networks

2. Principal Investigator, Co-Investigators, and Study Coordinator

Principal Investigator: Jehyeon Yoo

Study Coordinator: Yerim Do, Ph.D. Candidate, Gachon University

3. Medical Device Manager

Medical Device Manager: Jehyeon Yoo, Assistant Professor, Department of Rehabilitation Medicine, Gachon University Gil Hospital

4. Research Requester

N/A

5. Participating Institutions and Investigators

N/A

6. Study Setting and Expected Study Period

Study Site: Department of Rehabilitation Medicine, Gachon University Gil Hospital

Expected Study Period: From the date of IRB approval through December 31, 2026

7. Target Disease

Patients with knee osteoarthritis undergoing total knee arthroplasty (TKA)

8. Study Background

Gait abnormalities are common functional impairments in patients with knee osteoarthritis, and total knee arthroplasty (TKA) is widely performed to restore mobility and reduce symptoms [1]. In evaluating postoperative outcomes, it is essential to consider both subjective improvements in symptoms and objective recovery of physical function [2–4]. Objective functional recovery is typically assessed using performance-based measurements such as the 10-Meter Walk Test and the Timed Up and Go Test (TUGT) [5], whereas subjective symptoms are evaluated using patient-reported outcome measures (PROMs), including the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Knee Injury and Osteoarthritis Outcome Score (KOOS) [6].

However, discrepancies between subjective and objective outcomes have been frequently reported [7–9]. Improvements in PROMs may occur despite no measurable improvement in gait speed, and the opposite

pattern has also been observed [10,11]. The underlying reasons for these inconsistencies remain unclear, yet understanding and predicting this gap holds significant clinical importance. For orthopedic surgeons, preoperative indicators that predict postoperative outcomes may guide decision-making regarding optimal surgical timing and preoperative interventions. For physiatrists, early identification of domains likely to show insufficient recovery—such as mobility or pain—enables individualized rehabilitation planning. For patients, providing realistic expectations regarding symptom relief and functional recovery can enhance satisfaction and support engagement in postoperative rehabilitation.

A variety of clinical factors have been proposed as predictors of PROMs and performance-based outcomes after TKA [10,12]. Common predictors include age, body mass index (BMI), physical function, mental health, and pain levels [12,13]. However, the predictors associated with PROMs differ from those for performance-based outcomes, and their predictive strength varies widely across studies. For example, some studies have suggested that better preoperative physical function predicts more favorable postoperative outcomes [13], while others report that individuals with poorer baseline function experience greater postoperative improvement [14].

Efforts have also been made to predict surgical outcomes through gait analysis; however, conventional three-dimensional gait analysis systems and instrumented walkways require expensive equipment, extensive space, and specialized personnel, limiting their feasibility in routine clinical practice [15–17]. More recently, wearable devices incorporating accelerometers and pressure sensors have gained attention as tools for collecting gait and movement data in a more accessible manner [18,19]. For instance, pressure sensor analyses have been utilized to evaluate medication effects in patients with Parkinson's disease (ON/OFF states) [20], and accelerometer data have enabled quantification of three-dimensional movement characteristics such as mediolateral sway, propulsion, and braking forces [21]. Despite these advancements, studies using wearable sensors to assess and predict physical function in patients with knee osteoarthritis remain limited.

9. Objectives and Hypotheses

Numerous studies have attempted to predict postoperative patient-reported outcome measures (PROMs) or performance-based measures in individuals undergoing total knee arthroplasty (TKA) by using various preoperative predictive factors. However, investigations aiming to simultaneously predict both types of outcomes remain scarce. Furthermore, existing findings on the predictors associated with postoperative results have been inconsistent across studies.

This study aims to evaluate whether postoperative improvements in both PROMs and performance-based measures can be predicted using a deep neural network (DNN) model that incorporates diverse preoperative predictive factors, including movement data collected from wearable sensors. Specifically, the study seeks to assess the feasibility and validity of applying this model to a patient population treated at our institution.

10. Target Sample Size and Rationale

A total of 34 patients with knee osteoarthritis will be enrolled in this study.

The sample size was determined based on findings from a previous study that compared changes in performance-based measures after total knee arthroplasty according to preoperative gait characteristics. Using a large effect size (Cohen's d = 1.0), with a significance level of α = 0.05 and a statistical power of 0.80, the minimum required sample size was calculated to be 34 participants.

11. Eligibility Criteria

(1) Inclusion Criteria

- Participants will be eligible for enrollment if they meet all the following criteria:
- Adults aged 19 years or older
- Diagnosed with knee osteoarthritis (Kellgren–Lawrence Grade 1–4)
- Scheduled to undergo total knee arthroplasty (TKA) at Gachon University Gil Hospital
- Able to ambulate independently on level surfaces under supervision, with a Functional Ambulation Category (FAC) ≥ 3

(2) Exclusion Criteria

- Participants will be excluded if any of the following conditions are present:
- Individuals whose scheduled surgery is canceled and therefore do not undergo TKA
- History of a prior TKA procedure on the same knee
- Presence of neurological or musculoskeletal disorders that may affect gait
- Pregnant women or individuals with the possibility of pregnancy
- Any other clinically significant condition that, in the judgment of the principal investigator or study personnel, renders the participant unsuitable for the study

12. Recruitment Methods and Informed Consent Procedures

Participants will be recruited through a publicly posted study announcement at Gachon University Gil Medical Center. The principal investigator and the requesting institution will ensure that no eligible patient is unjustly excluded on the basis of race, socioeconomic status, or any other non-medical factor. All efforts will be made to facilitate the participation of individuals who meet the inclusion criteria, and patients will be informed of the study objectives so that the enrolled population adequately reflects the broader clinical population of patients receiving care for knee osteoarthritis at this institution.

The principal investigator will provide a thorough explanation of the study in a private and independent setting, ensuring that each potential participant fully understands the study procedures, potential risks, and expected benefits. Sufficient time will be given for questions and consideration, and the investigator will make every effort to support voluntary participation. Informed consent will be obtained only after confirming that the participant comprehends the study information and expresses willingness to participate without coercion.

13. Additional Protection for Vulnerable Populations

This study does not include any vulnerable populations.

14. Study Design and Methods

Study Design

(1) Overview of the Study Design

This study is a single-center, prospective observational study involving patients with knee osteoarthritis who are scheduled to undergo total knee arthroplasty (TKA) at Gachon University Gil Hospital. All participants will be assigned to a single study arm, and no control group will be included.

The primary aim of the study is to evaluate the feasibility and predictive performance of a previously developed artificial intelligence–based model—specifically, a deep neural network (DNN)—using preoperative clinical information and movement data collected from wearable sensors. The model will take various preoperative predictive factors as input and will predict postoperative outcomes at six weeks, including both patient-reported outcome measures (PROMs) and performance-based measures. The study will assess the validity and applicability of this model in the patient population at our institution.

(2) Study Arm and Assessment Procedures

At a single preoperative time point, the following predictive factors will be collected: demographic and clinical information, sarcopenia-related indices, comorbidity parameters, lower-limb muscle strength, radiologic findings, wearable sensor–based movement data, patient-reported outcome measures, and performance-based measurements.

At six weeks postoperatively, PROMs and performance-based measures will be reassessed. Using these data, the predeveloped DNN prediction model will be applied to classify postoperative outcomes into two categories—improved versus not improved—and the model's binary classification performance and feasibility will be evaluated.

(3) Randomization and Control Group

This preliminary study employs a single-group design; therefore, no randomization or control group is included.

Study Methods

(1) Screening Procedures

The examiner will review each participant's medical history, symptoms, and vital signs to confirm medical stability prior to conducting the following assessments.

1) Functional Ambulation Category (FAC)

Gait function will be assessed based on direct observation of the participant's walking ability, using the FAC scoring criteria outlined below:

Level	Description
0	Unable to walk or requires assistance from two or more people
1	Requires continuous support from one person for balance or weight shifting
2	Requires intermittent physical assistance from one person
3	Requires verbal supervision or standby observation without physical support

4	Independent on level surfaces but requires help on stairs, slopes, or uneven ground
5	Fully independent ambulation

2) Pregnancy Screening

A licensed physician will conduct a pregnancy screening interview to determine whether the participant is currently pregnant or may be pregnant. Information such as the date of the last menstrual period and the participant's menstrual cycle pattern will be recorded.

(2) Preoperative Predictive Factors

① Demographic and Basic Clinical Parameters

The following demographic and baseline clinical variables will be collected: age, sex, height, weight, and body mass index (BMI).

② Body Composition Analysis

Body composition will be assessed to quantify appendicular skeletal muscle mass. The procedures are as follows:

a) Bioelectrical impedance analysis (BIA) will be performed to measure body composition.

b) To ensure measurement accuracy, participants will be instructed to empty their bladder prior to testing and to refrain from consuming caffeinated beverages, food, or alcohol, as well as from engaging in vigorous physical activity for at least one hour before the assessment.

c) Appendicular skeletal mass will be normalized by height squared to account for height-related differences.

③ Grip Strength Test

Grip strength will be evaluated using the following standardized procedure:

a) Participants will be seated in an upright position with the elbow flexed to 90 degrees.

b) The dynamometer handle will be positioned between the first and second phalanges of the fingers, and participants will be instructed to grip maximally upon cue.

c) Measurements will be taken three times on each hand, and the highest value will be recorded.

④ Comorbidity Index

The Charlson Comorbidity Index (CCI) will be used to evaluate the severity of comorbid conditions. The CCI is a widely utilized clinical tool that quantifies baseline health status and comorbidity burden to estimate overall health risks and prognosis. It includes 17 disease categories spanning cardiovascular, endocrine, renal, hepatic, pulmonary, neurologic, and oncologic conditions. Each category is assigned a weighted score ranging from 1 to 6 depending on disease severity. The total CCI score is calculated by summing these weighted values, with higher scores indicating poorer overall health status and a greater likelihood of adverse clinical outcomes, including increased mortality risk.

Myocardial infarction	1
Congestive heart failure	1
Peripheral vascular disease	1
Cerebrovascular disease	1
Dementia	1
Chronic pulmonary disease	1
Connective tissue disease	1
Peptic ulcer disease	1
Mild liver disease	1
Diabetes without complications	1
Diabetes with complications	2
Hemiplegia or leukemia	2
Moderate or severe renal disease	2
Localized solid tumor	2
Moderate/severe liver disease	3
Metastatic solid tumor	6
AIDS	6

⑤ Kellgren–Lawrence Grade (K-L grade)

The Kellgren–Lawrence (K-L) grade is one of the most widely used international radiographic classification systems for assessing the severity of knee osteoarthritis. It categorizes structural joint changes into five grades (0–4) based on standard radiographic findings.

In this study, bilateral knee radiographs will be obtained preoperatively, and an experienced evaluator will determine the K-L grade according to established classification criteria.

The definitions of each K-L grade are as follows:

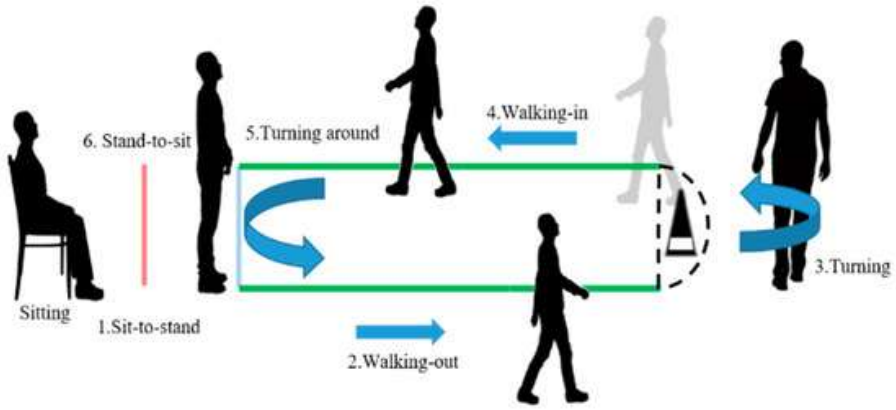
- Grade 0: Normal; no radiographic features of osteoarthritis
- Grade 1: Doubtful narrowing of joint space; possible early osteophyte formation
- Grade 2: Definite osteophytes; slight narrowing of joint space
- Grade 3: Moderate multiple osteophytes; definite joint-space narrowing; possible subchondral sclerosis
- Grade 4: Severe joint-space narrowing; large osteophytes; marked subchondral sclerosis and bony deformity

⑥ Timed up and go test

This test evaluates gait speed and dynamic balance during functional ambulation. The assessment is performed as follows:

a) A chair with armrests (seat height: 46 cm) is placed at a fixed distance of 3 meters from a cone. The participant is instructed to sit on the chair.

b) In the starting position, the participant sits with their back against the chair and their arms resting on the armrests. Upon the verbal cue "start," the participant stands up, walks 3 meters, turns around the cone, returns to the starting point, and sits back down on the chair.

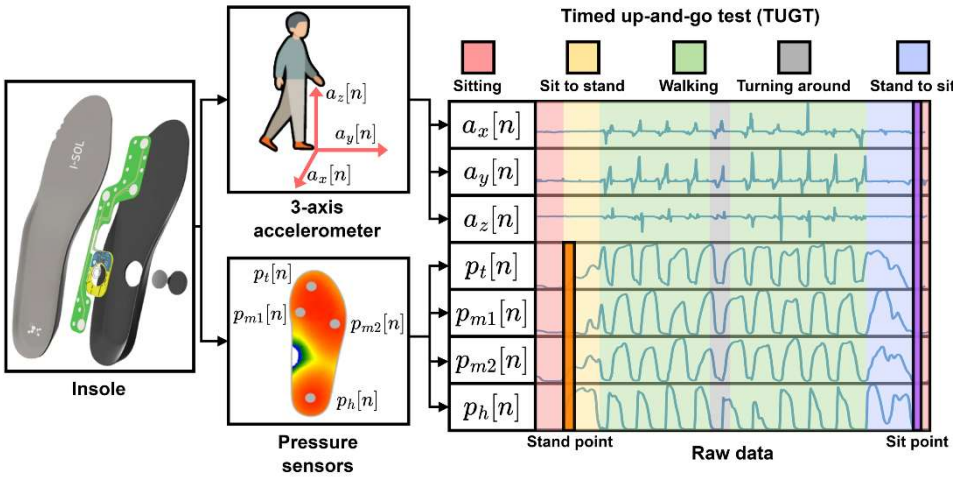


⑦ Gait Data Acquisition Using an Instrumented Insole System

Gait and movement characteristics during the Timed Up and Go Test (TUGT) will be quantitatively measured using an instrumented insole system. The device is equipped with a 3-axis accelerometer and four pressure sensors, allowing for the collection of seven data streams at a sampling rate of 40 Hz.

Participants will perform the TUGT according to standardized instructions while wearing the instrumented insoles inserted into both shoes. The acceleration and pressure signals obtained during the assessment will be segmented according to the functional subtasks of the TUGT (e.g., stand-to-walk transition, straight-line walking, turning). These segmented data will be used as input variables for the deep learning–based prediction model to determine postoperative outcomes.

The validity and reliability of this device have been demonstrated in prior studies, and it has been applied in clinical gait analysis and disease-classification models across various conditions, including osteoarthritis.



⑧ WOMAC(Western Ontario and McMaster Universities Osteoarthritis Index)

The WOMAC questionnaire will be used to assess subjective changes in pain, stiffness, and daily functional ability before and after surgery. WOMAC is a widely used patient-reported outcome measure (PROM) for individuals with osteoarthritis. It consists of 24 items, each rated on a 5-point Likert scale (0–4).

The subscale structure is as follows:

[Pain]

P1. Walking

P2. Stair climbing

P3. Nocturnal

P4. Rest

P5. Weightbearing

[Stiffness]

S1. Morning stiffness

S2. Stiffness occurring during the day

[Daily Function]

F1. Descending stairs

F2. Ascending stairs

F3. Rising from sitting

F4. Standing

F5. Bending to the floor

F6. Walking on flat surfaces

F7. Getting in/out of a car

F8. Going shopping

F9. Putting on socks

F10. Taking off socks

F11. Rising from bed

F12. Lying in bed

F13. Getting in/out of bath

F14. Sitting

F15. Getting on/off toilet

F16. Performing heavy domestic duties

F17. Performing light domestic duties

The total score ranges from 0 (best possible status) to 96 (worst possible status), with lower scores indicating less pain, reduced stiffness, and fewer functional limitations.

(3) Postoperative Outcome Measures

1) Primary Outcome Measure

- WOMAC(Western Ontario and McMaster Universities Osteoarthritis Index)

WOMAC will be administered both preoperatively and at six weeks postoperatively to evaluate changes in pain, stiffness, and functional ability. Improvement will be assessed based on the difference between pre- and postoperative scores. A minimal clinically important difference (MCID) will be defined as a reduction of 15 points or more. Participants will be categorized into "improved" and "not improved" groups according to this threshold, and this binary classification will serve as the target variable in the prediction model.

2) Secondary Outcome Measure

- Timed up and go test

TUGT will also be performed preoperatively and at six weeks postoperatively to assess changes in functional mobility. A postoperative reduction in TUGT completion time compared with the preoperative value will be interpreted as functional improvement. Participants whose time decreases after surgery will be classified as "improved," forming a binary outcome variable for the prediction model.

Phase	Screening/Pre-op assessment	Post-op Assessment
Session	1	1
Written Informed Consent	O	
Assessment of Inclusion and Exclusion Criteria	O	
Collection of Clinical Information and Screening Assessments	O	
Collection of Preoperative Predictive Factors	O	
Assessment of Primary Outcome Measure		O
Assessment of Secondary Outcome Measure		O

Detailed Development Plan	Detailed Timeline (Months)											
	1	2	3	4	5	6	7	8	9	10	11	12
Preparation of Study Protocol and IRB Approval	▮											
Participant Recruitment	▮	▮	▮	▮	▮	▮	▮	▮	▮	▮	▮	▮
Implementation of Study Procedures and Follow-up Assessments	▮	▮	▮	▮	▮	▮	▮	▮	▮	▮	▮	▮
Detailed Development Plan	**Detailed Timeline (Months)**											
	13	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**
Participant Recruitment	▮	▮	▮	▮	▮	▮	▮	▮	▮	▮		
Implementation of Study Procedures and Follow-up Assessments	▮	▮	▮	▮	▮	▮	▮	▮	▮	▮	▮	▮

15. Standard Treatment for the Target Disease

Following surgical treatment, postoperative prognosis is typically evaluated through routine clinical physical examinations.

16. Risks and Benefits to Participants

This study uses the Timed Up and Go Test (TUGT) to assess gait performance, including walking speed and balance. TUGT is widely utilized in clinical practice and is associated with very low medical risk. To minimize the possibility of falls during testing, participants will perform supervised practice trials beforehand, and all assessments will be conducted in an environment equipped with appropriate safety supports and under the direct supervision of trained personnel.

Participants may benefit from receiving quantitative feedback regarding their functional status, including walking speed, balance, and gait symmetry. This information may support a better understanding of individual recovery trajectories and can contribute to the development of personalized rehabilitation strategies. Additionally, the collected data may enhance the accuracy of predictive artificial intelligence models, support improvements in rehabilitation services, and contribute to the advancement and refinement of related medical devices.

Given the minimal risk associated with participation and the potential to contribute to clinical advancement and improved quality of care, the overall benefits of participation are considered to outweigh the associated risks.

17. Efficacy Endpoints and Assessment Methods

(1) Primary Endpoint

- WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index)

WOMAC will be administered preoperatively and again at six weeks postoperatively to evaluate changes in pain, stiffness, and functional limitations. Improvement will be assessed by calculating the difference between pre- and postoperative scores. A minimal clinically important difference (MCID) will be defined as a reduction of 15 points or greater. Based on this threshold, participants will be classified into "improved" or "not improved," and this binary outcome will serve as the dependent variable for the prediction model.

(2) Secondary Endpoint

- TUGT (Timed up and go test)

TUGT will be performed at baseline and at six weeks postoperatively to assess functional mobility and gait performance. A postoperative decrease in TUGT completion time compared to the preoperative value will be interpreted as functional improvement. Participants demonstrating reduced completion time will be categorized as "improved," and this binary classification will be used as an additional outcome variable in the predictive modeling.

18. Statistical Analysis

This study will evaluate the feasibility and predictive performance of an already developed prediction model by applying preoperative predictive factors to data collected from patients at our institution.

(1) Descriptive and Preliminary Analyses

Descriptive statistics, including mean, standard deviation, median, and range, will be calculated for all collected clinical and functional variables (e.g., age, sex, BMI, muscle strength, appendicular muscle mass, and K-L grade). Baseline characteristics of the study population will be summarized accordingly. Changes in WOMAC scores and TUGT times between the preoperative and six-week postoperative assessments will be analyzed using either a paired t-test or the Wilcoxon signed-rank test, depending on the normality of the data distribution.

(2) Application and Evaluation of Prediction Models

Preoperative predictive factors will be used as input variables to evaluate the performance of the following previously developed prediction models on the dataset collected at our institution:

- linear regression
- Random Forest
- Deep Neural Network (DNN)

All models will use the same set of input variables. Predictive performance will be assessed using metrics such as classification accuracy and area under the ROC curve (ROC-AUC). To validate model performance, the dataset will be divided into training, validation, and test sets. Feasibility and validity of applying the models to this institutional patient cohort will be evaluated comprehensively.

19. Criteria for Discontinuation or Withdrawal

If a participant's involvement in the study is discontinued, only the data collected up to the point of

discontinuation will be used for analysis. All collected data will be stored for five years after the end of the study and subsequently destroyed.

(1) Withdrawal Criteria

A participant will be withdrawn from the study under any of the following circumstances:

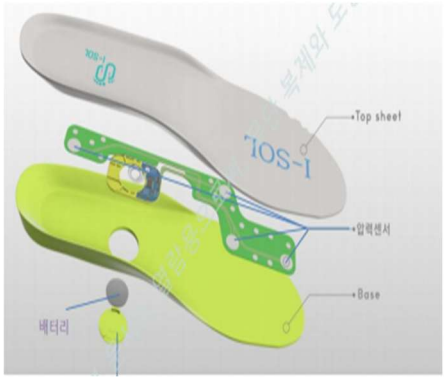
- The participant or his/her legally authorized representative requests discontinuation of study participation.
- A serious adverse event occurs.
- The investigator determines that continuation of study participation is not medically appropriate or may compromise the participant's safety.
- The participant undergoes concurrent surgery, receives medication, or uses other medical devices that may affect safety or interfere with the evaluation of efficacy.
- The participant fails to follow study instructions or does not comply with the requirements outlined in the informed consent, thereby affecting the validity of outcome assessments.
- The participant is unable to continue the study procedures after completing the gait assessment and a subsequent rest period of 10 minutes.
- The clinical investigator determines that continuation of the study is not feasible due to other issues arising during study participation.
- A significant medical condition or accident occurs during the study that may affect functional outcomes.

When withdrawal does not involve early termination of the entire study, the investigator will confirm the participant's voluntary intent regarding continued contribution of previously collected data. If the participant expresses willingness to allow use of existing data, information collected up to the withdrawal point may be retained and used in the study after being anonymized.

20. Medical Device Used in the Study

1) Device Classification: Grade I
2) Device Model Name: Instrumented Insole Gait Analysis System
3) Intended Use / Function:

Shape and Structure - Operating Principle



This product is a machine designed to understand the decline in walking ability and functional recovery following therapy. It consists of hardware and software (app). When a patient wears shoes equipped with the device and begins walking, pressure sensors and speed sensors installed in the device measure the pressure of the foot on the ground, the area of the foot that makes contact, walking speed, walking distance, and the number of steps to inform the patient of their walking pattern.

The sensors are comprised of pressure sensors and accelerometers. The accelerometer measures the acceleration acting on the sensor, and the pressure sensor operates on the principle that resistance changes when force is applied to the sensor, thereby measuring the corresponding voltage to determine pressure.

4) Handling and Storage Precautions: The device must be stored in a manner that prevents exposure to physical shock or impact.
5) Procedures for Receipt, Storage, Distribution, and Return: The device will be received, issued, and returned among study investigators within the Outpatient Clinic of the Department of Rehabilitation Medicine.

Following use, the device will be stored in the designated secure location.

6) Storage Location: Outpatient Clinic, Department of Rehabilitation Medicine

7) Supplier: Gilon Co., Ltd.

21. Potential Adverse Effects and Precautions for Use

Participants will perform gait assessments indoors while wearing the instrumented insole gait analysis system. Because there is a potential risk of falling during gait tasks, the investigator will provide continuous guidance and supervision throughout the entire procedure.

The device contains pressure sensors, a control and processing logic board, and an internal battery. Therefore, although unlikely, there is a potential risk of safety incidents such as electric shock or burns due to battery overheating or malfunction. To minimize such risks, the investigator will continuously monitor the device during testing, and if a participant reports discomfort or any abnormal sensation, the assessment will be stopped immediately and appropriate measures will be taken. Should any clinical care be required as a result of study participation, the associated medical costs will be covered by the research team; however, no additional compensation will be provided.

If technical issues arise—such as battery depletion, pairing errors, or device malfunction—the investigator will promptly take corrective actions, including battery replacement or device reset, to ensure that the assessment can proceed smoothly.

22. Safety Evaluation Criteria, Assessment Methods, and Reporting Procedures

(1) Safety Monitoring and Participant Protection

1) To ensure participant safety, the principal investigator will serve as the safety monitor and will conduct regular oversight of the study. As the study involves no invasive procedures and is considered low-risk, monitoring will be performed every 12 months under the supervision of the principal investigator. During monitoring, source documents, case report forms (CRFs), and the study protocol will be reviewed to ensure data integrity and to evaluate participant safety.

2) Participants may discontinue study participation at any time if they experience discomfort or wish to withdraw for any reason. The principal investigator or study staff will provide a full explanation of this right during the informed consent process and will confirm the participant's understanding before enrollment.

(2) Reporting of Protocol Violations, Safety Events, and Adverse Events

Any protocol deviation or participant withdrawal will be promptly documented, and a written report outlining the circumstances, corrective actions, and preventive measures will be submitted to the IRB without delay.

If a participant experiences an injury or any unexpected event during study procedures, immediate medical evaluation and treatment will be provided in accordance with the hospital's standard clinical procedures. A thorough assessment will be conducted to determine the cause of the event. Such events will be included in interim reports and documented in any resulting publications.

Given the minimal-risk nature of this study and the low likelihood of adverse events, no additional study funds have been allocated for treatment of potential complications.

23. Compensation for Research Participants

If a participant sustains an injury or experiences an unexpected event during study procedures, immediate medical evaluation and appropriate treatment will be provided in accordance with the hospital's standard

clinical care protocols. A thorough assessment will be conducted to determine the cause of the event. Such occurrences will be documented in interim reports and included in the final research publication.

Given that this study is considered minimal risk and the likelihood of adverse effects is low, no additional study funds have been allocated for compensatory payment beyond the standard medical care provided.

24. Protection of Personal Information and Confidentiality of Research Data

For the conduct of this study, personal information (e.g., name, medical record number) and sensitive information (e.g., medical history, health conditions, genetic information) will be collected. All identifiers will be replaced with a unique study code to ensure anonymization, and the linkage key will be stored separately. Research data will be kept in password-protected electronic files and securely stored in a locked research facility accessible only to authorized personnel. Strict confidentiality will be maintained throughout the study.

All study-related records will be documented in the hospital's secure electronic system and may be reviewed by the sponsor or relevant authorities for evaluation of treatment status or study validity. Monitoring personnel, auditors, the ethics committee, and regulatory authorities may access the participant's medical records within the scope permitted by applicable regulations for the purpose of verifying study procedures and data reliability. Such access will not compromise the confidentiality of the participant's personal information.

Any information that could identify a participant will be kept strictly confidential. Research findings will be published or presented only in anonymized form, ensuring that individual participants cannot be identified. Participants retain the right to refuse consent for the collection or use of personal information; however, refusal to provide such consent will preclude participation in the study.

All personal information and research-related documents collected for this study will be retained for three years after study completion, in accordance with institutional policy, and will be destroyed after the retention period has elapsed.

※ *Personal Information: Data that can identify an individual, such as name, address, or telephone number, or data that may become identifiable when combined with other information.*

※ *Sensitive Information: Personal information involving beliefs, union membership, political views, sexual life, or other privacy-invasive details, as well as genetic information obtained through genetic testing.*

25. Description of the statistical analysis plan, including the approach for any midpoint review and the criteria for early termination of the study if necessary.

N/A

26. Data and Safety Monitoring Plan (DSMP)

The principal investigator will monitor all safety information, including adverse events (AEs) and serious adverse events (SAEs). Case report forms will be reviewed periodically during the study, and any adverse events will be reported to the IRB in accordance with institutional requirements. The principal investigator will determine whether the study should continue or be discontinued based on the procedures and criteria outlined in the study protocol.

27. Reference

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