Exoglide Clinical Trial Protocol for Patients with gait abnormalities status post stroke

Study Purpose

This study investigates whether the Exoglide orthosis can improve gait symmetry, dorsiflexion mechanics, balance, and functional mobility in individuals recovering from stroke. Post-stroke gait is often characterized by asymmetry, reduced dorsiflexion, compensatory movement patterns, and increased fall risk. Exoglide is designed to support talocrural joint mechanics and enhance proprioceptive input during gait, potentially improving stability and reducing compensatory strategies.

Rationale

Stroke rehabilitation focuses on restoring gait symmetry, improving ankle mobility, strengthening, and retraining motor control. However, persistent deficits in talocrural joint arthrokinematics and proprioception often limit recovery. Exoglide applies sustained posterior glide forces to the talus and anterior glide forces to the distal tibia and fibula, supporting dorsiflexion mechanics and improving joint alignment during movement. This may enhance gait smoothness, reduce variability, and improve confidence.

Study Overview

- **Design:** Randomized controlled trial
- **Participants:** Adults post-stroke (≥1 month), ambulatory with or without assistive device
- **Intervention:** Standard gait rehabilitation vs. standard rehabilitation plus Exoglide
- **Duration:** 8-week intervention with 12-week follow-up
- **Primary Outcome:** Gait symmetry (step length and stance time ratios)
- **Secondary Outcomes:** Balance, mobility, dorsiflexion ROM, gait speed, endurance, proprioception, fall frequency, patient-reported confidence
- **Video Assessments:** Baseline, immediate post-fit, weeks 2, 4, 6, and 12

Expected Impact

This study will provide the first controlled evidence on Exoglide's potential to improve gait symmetry and functional mobility in individuals post-stroke. Findings may inform clinical practice, guide rehabilitation strategies, and support future device development.

Full Protocol

1. Study Title

A Randomized Controlled Trial Evaluating the Effectiveness of the Exoglide Orthosis for Improving Gait Mechanics, Balance, and Functional Mobility in Individuals Post-Stroke

2. Background and Rationale

Stroke frequently results in hemiparesis, impaired motor control, abnormal gait patterns, reduced dorsiflexion, decreased proprioception, and increased fall risk. Common gait deviations include reduced stance time on the affected limb, foot drop, knee hyperextension, circumduction, and asymmetric step length.

Exoglide is a wearable orthosis designed to support talocrural joint arthrokinematics by applying directional glide forces that facilitate dorsiflexion mechanics. This may enhance proprioception, improve gait symmetry, and reduce compensatory gait patterns.

3. Study Objectives

Primary Objective

Evaluate whether Exoglide improves gait symmetry compared with standard gait rehabilitation alone.

Secondary Objectives

- Improve dorsiflexion range of motion

- Improve balance and postural control
- Increase gait speed and endurance
- Reduce fall risk
- Improve patient-reported confidence in walking
- Assess safety and tolerability

4. Study Design

- Prospective, parallel-group, randomized controlled trial
- Control group: Standard post-stroke gait rehabilitation
- Intervention group: Standard rehabilitation plus Exoglide
- Concealed allocation; stratified by stroke chronicity (subacute vs. chronic)
- Blinded outcome assessors
- 8-week intervention; 12-week follow-up

5. Participants

Inclusion Criteria

- Age 18–85
- Diagnosis of ischemic or hemorrhagic stroke
- Time since stroke ≥1 month
- Able to ambulate at least 10 meters
- Ankle mobility deficits or gait deviations consistent with TCJ dysfunction
- Medically stable

Exclusion Criteria

- Severe cognitive impairment
- Peripheral vascular disease or decreased sensation in lower extremities
- Severe spasticity (Modified Ashworth Scale ≥3 at ankle)
- Orthopedic conditions limiting gait
- Skin conditions preventing device use

6. Recruitment and Screening

Participants will be recruited from neurorehabilitation clinics, stroke support groups, neurology practices, and community rehabilitation centers. Screening includes neurological examination, gait assessment, ankle mobility testing, and safety evaluation. Written informed consent will be obtained.

7. Interventions

Standard Post-Stroke Gait Rehabilitation (Both Groups)

- Gait training
- Strengthening (hip, knee, ankle)
- Balance training
- Functional mobility training
- Task-specific walking practice
- Dorsiflexion facilitation techniques
- Fall-prevention education

Exoglide Intervention (Intervention Group Only)

- Worn over athletic footwear
- Used during all gait training sessions
- Recommended for daily walking during waking hours
- Duration: 8 weeks
- Standardized fitting and education
- Optional weaning after week 8

8. Outcome Measures

Primary Outcome

- Gait symmetry (step length symmetry ratio, stance time symmetry ratio)

Secondary Outcomes

- Dorsiflexion ROM (goniometry)
- Balance (Berg Balance Scale)
- Functional mobility (Timed Up and Go)
- Gait speed (10-Meter Walk Test)
- Endurance (6-Minute Walk Test)
- Proprioception (joint position sense)
- Fall frequency (weekly logs)
- Patient-reported outcomes (ABC Scale, Stroke Impact Scale – mobility domain)

9. Video-Based Gait Assessment Protocol

Assessment Time Points

- Baseline (before Exoglide application)
- Immediately after first Exoglide fitting
- Week 2
- Week 4
- Week 6
- Week 12 (follow-up)

Recording Procedure

- Fixed tripod at hip height
- Frontal and sagittal views
- Consistent lighting and background
- 10-meter walkway
- Tasks: comfortable-speed walking, fast-speed walking, optional dual-task walking
- Two passes per condition

Video Outcome Measures

Qualitative

- Foot clearance
- Step consistency

- Trunk sway
- Compensatory strategies (circumduction, hip hiking)

Quantitative

- Step length variability
- Step time variability
- Stance/swing ratio
- Stride-to-stride deviation

Blinding and Storage

- Videos coded and de-identified
- Independent raters blinded to group assignment
- Secure, encrypted storage

10. Sample Size and Statistical Analysis

- Powered to detect clinically meaningful improvement in gait symmetry
- Intention-to-treat analysis
- Mixed-model repeated measures
- Sensitivity analyses for missing data
- Subgroup analysis by stroke chronicity

11. Risks and Benefits

Risks

- Skin irritation
- Fatigue
- Temporary unsteadiness during adaptation

Benefits

- Potential improvement in gait symmetry
- Increased dorsiflexion
- Reduced compensatory gait patterns

- Improved confidence and mobility

12. Safety Monitoring

- Adverse events recorded at each visit
- Serious adverse events reported per institutional policy
- Weekly device tolerance checks

13. Confidentiality

All data coded and stored securely. Identifiable information stored separately.

14. Dissemination

Results will be shared through peer-reviewed journals, conferences, and stroke rehabilitation networks.

15. Appendices

- Informed consent form (to be developed)
- Recruitment materials
- Standard rehabilitation protocol
- Exoglide fitting and usage guide