Official Title: To estimate the efficacy of BoNT A injection combining with exoskeleton Robotic assisted gait training in stroke patients with spastic stiff knee gait: Motor Function Performance and Neurophysiological evaluation

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Background:

Stiff-knee gait is a common abnormal gait pattern after stroke, characterized by limited knee flexion during the swing phase, which affects walking speed, gait symmetry, and participation in daily activities. botulinum toxin (BoNT) injection in the rectus femoris is considered a standard treatment; however, studies have shown its effects are limited, and it is recommended to combine BoNT injection with rehabilitation training. Robot-assisted gait training (RAGT) provides repetitive, task-oriented gait correction training, but its combined effect with botulinum toxin still requires further investigation.

Aim:

This study aims to investigate the effect of combining BoNT injection in the rectus femoris with exoskeleton robot training on stiff-knee gait in stroke patients.

Participants:

Inclusion criteria : We will recruit adult patients with ischemic or hemorrhagic stroke for more than 3 months, are able to walk independently with or without device on level ground (Functional Ambulation Category ≥4) (Holden et al., 1984) but have inadequate of knee flexion during the swing phase. Their affected RF has spasticity with the modified Ashworth scale between 1+ and **2**. (Rw & Smith, 1987). Patients are BoNT-A treatment-naive or treated with BoNT-A ≥4 months in the affected leg before recruitment. Patients receiving oral muscle relaxants or other medication for spasticity were on a stable dose for≥2 months before recruitment. They can obey simple order.

Exclusion criteria : participation in other trials; fixed contractures or bony deformities in the affected leg; previous treatment of the affected leg with neurolytic or surgical procedures(such as, phenol block, tendon lengthening of transfer, tenotomy, muscle release, arthrodesis); severe cardiovascular comorbidity (recent myocardial infarction, heart failure, uncontrolled hypertension, orthostatic hypotension), known sensitivity to BoNT-A, had an infection of the skin, soft tissue in the injection area; are pregnant.

Methods:

A crossover randomized controlled trial design was used. We recruited adult patients with ischemic or hemorrhagic stroke for more than 3 months, who were able to walk independently with or without device on level ground, but presented with spasticity of the knee extensor muscles. And randomly assigned to either an early injection group or a delayed injection group. Both groups received six weeks of exoskeleton robot-assisted gait training one week after injection (2–3 sessions per week, 40 minutes per session, for a total of 12 sessions) and were followed up at three months post-training. The injection site was then switched. The data were

combined according to whether the rectus femoris was injected: injection group (Group A) and non-injection group (Group B). The primary outcome was knee kinematics, including knee flexion angle and range of motion. Secondary outcomes included muscle strength, muscle tone, functional walking ability (6MWT, mEFA), balance (BBS), and self-efficacy (ABC, NEADL).

Analysis and Statistics:

All data were analyzed using IBM SPSS Statistics version 26.0 for Windows. Prior to selecting appropriate statistical tests for continuous variables, the Shapiro-Wilk test was conducted to assess the normality of data distribution. For variables exhibiting a normal distribution, independent samples t-tests or paired samples t-tests were applied. For non-normally distributed data, the Mann-Whitney U test or the Wilcoxon Signed Rank test was used instead. Treatment outcomes were assessed by comparing post-intervention time points with baseline measurements.