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Feasibility of Community-Based Gait-Synchronised Functional Electrical Stimulation in Individuals with Transtibial Amputation and Chronic Pain: A Randomised Crossover Study

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Abstract

Background: Chronic pain and altered gait commonly co-occur after transtibial amputation. Previous musculoskeletal modelling identified the residual knee extensors as a potential target for functional electrical stimulation (FES) to improve gait mechanics. Subsequent laboratory studies have demonstrated improved gait mechanics and suggested potential benefits for pain management. However, the feasibility and effects of prolonged FES use during daily life remain unclear.

Methods: Fourteen individuals with unilateral transtibial amputation and chronic pain completed a randomised crossover study comprising five weeks of daily quadriceps FES synchronised to the stance phase of gait and five weeks without FES, separated by a six-week washout. The primary outcome was feasibility, including retention, adherence, device use, safety, and participant feedback. Exploratory outcomes included knee kinematics assessed using wearable inertial measurement units and OpenSim-based inverse kinematics, and pain intensity and interference assessed using the Brief Pain Inventory (BPI-5 and BPI-9). FES was switched off during gait assessments to evaluate training rather than immediate orthotic effects. Scalar outcomes were analysed using baseline- and period-adjusted linear mixed-effects models.

Results: Retention was 100%, mean adherence was 94%, and no serious adverse events occurred. Device use averaged 3.52 ± 2.97 hours per active day. Mean frame-wise knee flexion symmetry index was significantly lower following FES than non-FES (adjusted difference −15.56 percentage points; $p = 0.029$), whereas other knee kinematic outcomes did not differ significantly between treatments. Pain intensity (BPI-5) was significantly lower following FES than non-FES (adjusted

difference −1.80 points; $p < 0.001$). Pain interference (BPI-9) did not differ significantly between treatments ($p = 0.144$), although an exploratory post-hoc subgroup analysis suggested reduced interference among participants with baseline BPI-9 ≥ 3 ($p = 0.013$). Phantom limb pain intensity decreased by 2.78 points following FES among participants reporting phantom limb pain at baseline ($n = 9$; $p < 0.001$).

Conclusions: Community-based quadriceps FES during gait was feasible and well tolerated, with high adherence. Exploratory findings suggested improvements in knee flexion symmetry and reduced pain intensity, although other kinematic measures and pain interference showed less conclusive effects. The observed reduction in phantom limb pain warrants prospective evaluation in adequately powered trials.

Trial registration: ISRCTN16755878 (retrospectively registered).

Keywords: Electric Stimulation Therapy; Amputees; Computer Simulation; Gait Analysis; Phantom Limb; Pain Measurement; Rehabilitation

1. Introduction

Lower limb amputation is a life-changing condition with a substantial and growing global burden [1], driven in part by the increasing prevalence of diabetes and vascular disease [2]. Among the most persistent and disabling complications following amputation is chronic pain, including phantom limb pain (PLP), residual limb pain, and secondary musculoskeletal pain such as low back pain [3–5]. Pain frequently persists long after rehabilitation and can substantially limit prosthetic use, physical activity, and community participation, contributing to long-term functional decline and reduced quality of life [4,6,7].

Pain and mobility impairment are closely interconnected. Our scoping review of 84 studies identified consistent associations between PLP, residual limb pain, and low back pain and poorer functional outcomes, including reduced walking capacity, altered gait, impaired balance, and restricted prosthetic use [4]. This relationship may also be bidirectional: pain can restrict mobility, while altered loading and compensatory movement may contribute to secondary musculoskeletal pain [8,9]. Yet pain and physical function have largely been investigated separately, limiting our understanding of the mechanisms linking the two [4]. This in turn constrains the development of rehabilitation strategies that address both.

The biomechanical consequences of transtibial amputation provide a plausible mechanistic pathway through which gait dysfunction and pain may be mutually reinforcing. Individuals with unilateral transtibial amputation typically exhibit reduced knee flexion moments during stance, a more extended knee posture on the amputated side, and compensatory loading of the intact

limb [10]. This asymmetry increases mechanical loading on the intact knee and may contribute to the elevated risk of secondary musculoskeletal complications such as osteoarthritis [11], while compensatory gait and altered trunk and pelvic mechanics may also contribute to low back pain [9]. At the same time, disuse and atrophy of the residual knee extensors may reduce the capacity of the amputated limb to generate force during walking [12,13]. The residual knee extensors therefore represent a potentially modifiable component of the biomechanical pathway linking impaired gait, asymmetric loading, and secondary pain.

Conventional rehabilitation following lower limb amputation primarily relies on prosthetic prescription and gait training [14]. Although advances in prosthetic technology have improved mobility [15,16], they do not directly target residual musculature or necessarily resolve asymmetries in neuromuscular function [17,18]. Substantial gait asymmetry, abnormal musculoskeletal loading, and chronic pain therefore remain common despite contemporary rehabilitation [4,19]. An intervention that directly engages the residual musculature during walking may provide a complementary strategy for addressing these persistent deficits.

Functional electrical stimulation (FES) is a neuroengineering intervention that may address these challenges. FES delivers controlled electrical pulses to peripheral nerves and muscles to facilitate muscle activation and enhance functional movement [20]. The technology is well established in neurological rehabilitation, including in individuals with stroke [21], spinal cord injury [22], and multiple sclerosis [23], with evidence from systematic reviews supporting orthotic and therapeutic benefits for walking, particularly walking speed and endurance [24]. Beyond its effects on movement, electrical stimulation may also influence pain through mechanisms

104 associated with muscle activation and afferent sensory input [25,26]. In the context of gait
105 rehabilitation, FES has the additional characteristic of delivering these motor and sensory signals
106 in temporal association with functional movement [27,28]. These combined effects make FES a
107 particularly relevant intervention candidate for individuals with lower limb amputation, in whom
108 gait dysfunction and chronic pain frequently coexist.
109 Recent advances in musculoskeletal modelling and simulation have provided a mechanistic
110 foundation for developing targeted rehabilitation strategies in this population. In our previous
111 work, we showed in simulation that altered muscle coordination could reduce knee joint loading
112 in the intact limb during walking and other functional activities [29]. Building on this, we
113 integrated muscle-driven musculoskeletal simulations with optimal control methods to design an
114 FES strategy [30], identifying increased activation of the vasti muscles of the residual limb as a
115 means of reducing excessive loading of the intact knee. These model predictions were
116 subsequently evaluated in a laboratory-based gait study, in which FES targeting the quadriceps
117 muscles of the residual limb during the stance phase of gait produced favourable immediate
118 alterations in musculoskeletal dynamics during stimulated walking [30]. Together, these
119 modelling and experimental studies established a mechanistic rationale and proof-of-concept for
120 targeting the quadriceps of the residual limb with FES to modify gait biomechanics. However, the
121 laboratory findings primarily demonstrated the immediate biomechanical effects of FES during
122 stimulation and did not establish whether the intervention could be feasibly adopted for
123 repeated use during everyday walking or whether multi-week use might be accompanied by
124 broader changes in gait and pain.

The next translational step was therefore to evaluate this model-derived intervention as a sustained community-based therapy. We conducted a randomised two-period crossover study in individuals with unilateral transtibial amputation, evaluating five weeks of community-based FES targeting the quadriceps muscles of the residual limb. The primary aim was to determine the feasibility, safety, adherence, and acceptability of repeated FES use during habitual walking. We additionally explored changes in knee kinematics during gait, pain intensity, and pain interference relative to a non-FES condition. We hypothesised that sustained community use would be feasible and well tolerated. Effects on gait symmetry and pain were examined as exploratory outcomes to inform the design of a definitive efficacy trial.

2. Methods

2.1 Participants

Potential participants were identified through the West Midlands Rehabilitation Centre, Birmingham Community Healthcare NHS Foundation Trust, between May and November 2025. Individuals who expressed an interest in the study self-referred to the research team, after which eligibility was assessed by a consultant specialising in amputee rehabilitation.

All participants provided written informed consent prior to participation. The study received a favourable ethical opinion from the West Midlands–Black Country Research Ethics Committee (REC reference: 25/WM/0061; IRAS project ID: 354627; protocol number: RG_25-009), together with the required Health Research Authority approval. All procedures were conducted in

accordance with the approved protocol and the Declaration of Helsinki. The study was retrospectively registered with the ISRCTN registry (ISRCTN16755878).

As this was a feasibility study, no formal power calculation was performed. Fourteen participants who met the eligibility criteria were included in the present analysis.

Participants were enrolled in rolling cohorts of up to three individuals because of the capacity requirements of the crossover protocol.

Inclusion criteria were: (1) a unilateral transtibial amputation more than one year previously; (2) regular use of a prosthesis for at least six months; (3) the ability to walk continuously for six minutes without a walking aid; and (4) current chronic pain, or chronic pain experienced within the previous six months, that affected mobility, walking, or prosthetic use as indicated by a "yes" response to Question 1 of the Brief Pain Inventory-Short Form (BPI-SF) at baseline. Exclusion criteria were: (1) contraindications to FES, including implanted electronic devices such as pacemakers; (2) neurological disorders affecting gait; (3) uncontrolled cardiovascular conditions; (4) open wounds, active skin breakdown, or other residual-limb conditions preventing safe FES application; and (5) a self-selected walking speed greater than 1.25 m/s. All participants used their habitual prostheses during study assessments.

2.2 Experimental Protocol

This study employed a randomised two-period crossover design to evaluate the feasibility of community-based, gait-synchronised FES targeting the vasti muscles of the amputated limb and to explore its effects on gait and pain in individuals with unilateral transtibial amputation.

Following baseline assessment, participants were randomly allocated to receive either five weeks of FES followed by five weeks without FES, or the same two conditions in the reverse order. The two intervention periods were separated by a six-week washout period to minimise potential carryover effects. The randomisation schedule was computer-generated, and treatment allocation was disclosed to the research team only after eligibility had been confirmed and the baseline assessment completed. Given the nature of the FES intervention, blinding of participants or treating clinicians to treatment allocation was not possible. A sham-FES condition was not used because gait-synchronised stimulation produces a clearly perceptible and visible muscle contraction, making a credible sham difficult to maintain.

During the FES intervention period, participants were instructed to use the FES device during walking activities for a cumulative minimum of 20 minutes per day as part of their habitual daily mobility. The minimum daily duration of 20 minutes was informed by previous electrical-stimulation and FES-assisted gait rehabilitation studies using approximately 15–20 minutes of stimulation or gait training per session [31,32]. During the non-FES period, participants continued their usual daily activities without FES assistance and were advised to walk for at least 20 minutes per day.

Assessments were conducted immediately before and at the end of each five-week intervention period. Following completion of Period 1, participants underwent a six-week washout period before commencing Period 2. Gait was assessed using wearable inertial measurement units, and participants completed the Brief Pain Inventory (BPI) at each assessment. All gait assessments

were completed while participants used their habitual prostheses without concurrent FES stimulation.

Weekly follow-up interviews using a structured questionnaire with predefined questions were conducted by clinicians throughout the study period to monitor adherence, systematically solicit and document adverse events, and document participants' experiences with FES, including perceived changes in walking and pain and any practical difficulties with device use. In addition, participants completed a final feedback interview at Week 19, following completion of the 16-week crossover period, to capture their overall experience of the intervention, including device usability and acceptability, perceived benefits, practical challenges, views on the intervention duration, persistence of perceived benefits, and potential future use of FES in rehabilitation. Participant feedback was recorded by clinicians as contemporaneous notes during the structured weekly follow-up interviews and the Week 19 feedback interview and was summarised descriptively; no formal qualitative analysis was undertaken.

2.3 FES Intervention

FES was delivered using the ODFS®Pace XL (Odstock Medical Limited, Salisbury, UK). The stimulation target and timing used in the present intervention were derived from our previous musculoskeletal modelling work, which identified activation of the vasti muscles of the amputated limb during stance as a strategy to increase the prosthetic-side knee flexion moment while reducing contralateral knee loading [30]. Accordingly, stimulation was applied unilaterally to the quadriceps of the amputated limb during the stance phase of gait (Figure 1).

A heel pad footswitch was used to trigger stimulation

from heel strike, with stimulation continuing while the footswitch remained loaded during stance and ceasing as weight was removed from the switch.

Two surface electrodes were positioned over the quadriceps muscles of the amputated limb by specialist physiotherapists experienced in FES prescription for gait rehabilitation, with the lateral electrode placed proximally over the vastus lateralis and the medial electrode distally over the vastus medialis. Electrode placement was individually optimised to elicit a comfortable and functionally visible quadriceps contraction and the placement could be reproduced across sessions for each participant.

Stimulation parameters were selected and individually adjusted during FES fitting by a specialist physiotherapist to achieve a comfortable and functionally visible muscle contraction during walking. Further adjustments were made as required following discussion during the weekly follow-up interviews. The stimulation frequency was set at 40 Hz, with rising and falling ramp times of 200 ms and 300 ms, respectively, and a timeout duration of 2500 ms; these parameters were standardised across participants. Pulse width (45–126 μs) and current amplitude (35–80 mA) were individually adjusted for each participant (Figure 1).

Participants completed an initial familiarisation session and received instruction on safe device use prior to commencing the intervention. They were also provided with photographs of their electrode placement to support consistent positioning during home use. They were subsequently instructed to use the FES device during habitual daily walking activities for a minimum of 20 minutes per day throughout the five-week intervention period.

2.4 Wearable IMU-based Gait Assessment

Wearable inertial measurement units (IMUs; Delsys Trigno IM, Delsys Inc., Natick, MA, USA) were used to assess lower-limb kinematics during walking with FES switched off, at a sampling frequency of 148.15 Hz. The IMU-based inverse-kinematics workflow used in this study has previously demonstrated accuracy and inter-operator reliability comparable with marker-based motion capture for most lower-limb kinematic measures during walking [33]. Sensors were positioned on the pelvis and bilaterally on the thighs, shanks, and feet according to a standardised placement protocol. After sensor placement on the intact limb, sensors on the amputated side were positioned to mirror the corresponding locations and orientations as closely as anatomically feasible, with the residual limb and prosthesis treated as the functional counterparts of the intact-limb segments. Before each walking assessment, participants completed a static standing calibration trial to establish the reference alignment between the IMUs and the corresponding body segments.

Participants performed repeated 10-m overground walking trials at a self-selected walking speed while wearing their habitual prostheses. Sufficient trials were collected at each assessment session to obtain 10–15 complete gait cycles per participant for subsequent kinematic analysis.

Raw accelerometer and gyroscope signals were processed at the native sampling frequency using a quaternion-based Mahony sensor-fusion filter to estimate the orientation of each IMU. Kinematic analysis was subsequently performed in OpenSim version 4.5 (OpenSim, Stanford University, Stanford, CA, USA) following the previously established IMU-based workflow [33]. The static standing trial and estimated IMU orientations were used to calibrate the model with the

OpenSim IMU Placer tool. The pelvis IMU was specified as the base sensor, with the z-axis used as the heading axis, and standard sensor-to-OpenSim coordinate-system rotations were applied. Lower-limb joint angles were then estimated using the OpenSim IMU Inverse Kinematics Tool, which minimises the orientation discrepancies between the measured IMUs and the corresponding virtual IMUs attached to the skeletal model.

Joint angle signals derived from the inverse kinematics analysis were smoothed using a third-order Savitzky–Golay filter with an approximately 0.4-s window before gait-cycle segmentation. Individual gait cycles were identified from the knee flexion angle waveform by detecting successive local minima following major flexion peaks of ≥25°. Specifically, the threshold was applied to candidate local maxima in the smoothed knee flexion waveform, with only peaks reaching at least 25° retained. The local minimum following each retained peak was then identified as a gait-cycle boundary, with successive boundaries defining individual gait cycles [34]. The 25° threshold was empirically determined through visual inspection of the knee flexion waveforms in the present dataset to distinguish major flexion peaks from smaller fluctuations and minimise spurious cycle detection. The detected gait cycles were visually inspected to confirm appropriate segmentation. The first second of each walking trial was excluded to minimise the influence of gait initiation. Up to five complete gait cycles were extracted from each walking trial, yielding 10–15 cycles per participant per assessment session. Each gait cycle was subsequently time-normalised to 101 data points, representing 0–100% of the gait cycle, using linear interpolation to facilitate comparisons across participants, conditions, and assessment sessions.

2.5 Outcome Measures

The primary outcomes related to study and intervention feasibility and acceptability. These included recruitment and retention, adherence to prescribed FES use, device-use duration, FES-assisted step count, adverse events, and participant-reported acceptability. Recruitment was characterised by the number of participants enrolled and the duration of the recruitment period. Retention of at least 80% of enrolled participants and adherence on at least 70% of prescribed intervention days were used as progression criteria [35]. An adherent day was defined as a day on which FES was used for at least 20 minutes.

FES use duration and days of use were self-reported during weekly clinician follow-up interviews, whereas FES-assisted step counts were obtained from the ODFS Pace device and recorded during these contacts. Adherence was calculated as the proportion of prescribed intervention days meeting the minimum 20-minute use criterion. Reasons for missed days, temporary discontinuation, adverse events, and practical difficulties with device use were also documented. Participant feedback collected during the weekly follow-ups and final interview was summarised descriptively to characterise device usability and intervention acceptability.

Exploratory clinical outcomes included knee kinematics during walking and participant-reported pain. Knee kinematics were assessed using prosthetic- and intact-limb knee flexion waveforms, with inter-limb coordination characterised using whole-cycle symmetry measures and discrete knee-flexion peak amplitude and timing. These outcomes were selected to examine potential changes in inter-limb knee kinematics associated with the model-informed quadriceps FES intervention. General pain was assessed at each assessment session using the Brief Pain

Inventory (BPI). Pain intensity (BPI-5) was rated from 0 (no pain) to 10 (pain as bad as you can imagine), while pain interference (BPI-9), reflecting pain-related interference with daily functioning, was calculated as the mean of seven items assessing the impact of pain on daily activities, also scored from 0 to 10, with higher scores indicating greater pain and interference. PLP intensity was additionally assessed using an 11-point Numeric Rating Scale (NRS), ranging from 0 (no pain) to 10 (worst imaginable pain). At each scheduled assessment visit, participants were directly asked to rate the intensity of their PLP over the preceding 24 hours, alongside the BPI and gait assessments. For the exploratory analysis, PLP scores obtained immediately before and after the five-week FES intervention were compared among participants reporting PLP at FES baseline.

2.6 Data Analysis and Statistics

Knee flexion kinematics were analysed using time-normalised gait cycles (0–100% gait cycle) for the prosthetic and contralateral intact limbs.

Waveform-level differences were first examined using one-dimensional statistical parametric mapping (SPM1D). For each participant and assessment, a signed inter-limb waveform was calculated as the prosthetic-limb knee angle minus the intact-limb knee angle across the normalised gait cycle. Within-period change waveforms were then calculated as post-intervention minus baseline. FES and non-FES change waveforms were compared using a paired two-tailed SPM{t} test among participants with complete waveform data under both treatment conditions. Statistical inference was performed at $\alpha = 0.05$.

Whole-cycle knee flexion symmetry was subsequently quantified frame-by-frame using the following symmetry index:

$$\text{Symmetry Index}_i = |\text{Prosthetic limb}_i - \text{Intact limb}_i| \,/\, [0.5 \times (|\text{Prosthetic limb}_i| + |\text{Intact limb}_i|)] \times 100$$

where *i* represents each normalised frame of the gait cycle. Lower symmetry index values indicate greater similarity between limbs. The mean frame-wise symmetry index across the complete gait cycle was calculated for each assessment. Because this formulation may be sensitive to small joint-angle values, two additional whole-cycle measures of inter-limb similarity were examined: the mean absolute error between prosthetic- and intact-limb knee angles across the gait cycle, and the Nigg symmetry index [36], a range-normalised measure of inter-limb symmetry. Discrete knee-flexion characteristics were examined at two a priori defined regions of the gait cycle: 10–30% (Peak 1) and 60–80% (Peak 2). Peak amplitude and its timing (% gait cycle) were identified independently for the prosthetic and intact limbs within each region. Inter-limb peak differences were quantified primarily as absolute differences, |prosthetic − intact|, with smaller values indicating closer inter-limb matching. Signed prosthetic-minus-intact differences were additionally examined to characterise the direction of asymmetry; negative amplitude differences indicated a lower peak amplitude in the prosthetic limb, while positive timing differences indicated a later peak in the prosthetic limb.

For scalar gait outcomes, treatment effects were estimated using linear mixed-effects models incorporating all available FES and non-FES intervention periods. Post-treatment values were modelled as the dependent variable, with the corresponding period-specific baseline value,

330 treatment condition, and treatment period included as fixed effects and participant included as
331 a random intercept. The treatment coefficient therefore represented the baseline- and period-
332 adjusted post-treatment difference between FES and non-FES conditions (FES minus non-FES).
333 Treatment sequence was additionally included as a sensitivity analysis. Pre-to-post change scores
334 were calculated for descriptive purposes but were not used as the dependent variable in the
335 principal treatment-effect models. This approach was applied to the whole-cycle symmetry
336 measures and discrete peak amplitude, timing, and inter-limb difference outcomes.
337 Pain outcomes were analysed separately. The principal analyses of BPI-5 and BPI-9 used linear
338 mixed-effects models comparing post-treatment scores between FES and non-FES conditions,
339 adjusted for the corresponding period-specific baseline value and treatment period, with
340 participant included as a random intercept. The treatment coefficient represented the adjusted
341 difference in post-treatment outcomes between FES and non-FES, calculated by subtracting the
342 non-FES estimate from the FES estimate. Treatment sequence was additionally included as a
343 sensitivity analysis. Additional analyses were performed to characterise the temporal pattern and
344 consistency of observed effects, including change-score analyses and within-condition
345 comparisons. These analyses were considered supportive and exploratory and were not used to
346 override inference from the principal mixed-effects model.
347 BPI-5 and BPI-9 were initially analysed without applying a baseline pain severity threshold.
348 Because low baseline scores could limit the potential for improvement, secondary post-hoc
349 analyses were conducted separately for BPI-5 and BPI-9 among participants with a study-entry

score ≥3 on the corresponding outcome. These analyses were undertaken to explore the potential influence of floor effects and were not pre-specified.

PLP was not a pre-specified outcome. PLP intensity was examined exploratorily among participants reporting PLP at the baseline of their FES intervention period (n = 9). Changes in PLP intensity from before to after FES were analysed using a paired *t*-test. Responder analyses determined the proportions of participants achieving reductions of at least 2 points and at least 30% from baseline, thresholds previously associated with clinically important improvement in pain intensity [37].

Continuous variables are presented as mean ± standard deviation (SD), unless otherwise stated. For the principal pain mixed-effects analyses, standardised treatment effect sizes were calculated as Cohen's *d* by dividing the adjusted FES versus non-FES treatment coefficient by the pooled standard deviation of the endpoint measurements under the two treatment conditions. Cohen's *dz* for the paired PLP comparison was calculated as the mean pre–post difference divided by the standard deviation of the paired differences.

Statistical significance was set at $p < 0.05$. As the efficacy analyses were exploratory, no adjustment for multiple comparisons was applied. Approximately 25 exploratory inferential tests were performed; findings should therefore be interpreted accordingly. Effect estimates, 95% confidence intervals, and exact *p*-values are reported to facilitate interpretation. All statistical analyses were performed using MATLAB (MathWorks, Natick, MA, USA).

3. Results

3.1 Participant Flow and Baseline Characteristics

A total of 14 individuals contacted the research team, all of whom met the eligibility criteria and were enrolled in the study. All 14 participants completed both intervention periods, with no withdrawals or losses to follow-up. Participant demographic and amputation-related characteristics are presented in Table 1. The cohort showed substantial heterogeneity in time since amputation (median 47 months, IQR 21–262; range 14–530), as well as variation in amputation aetiology and pain phenotype.

(insert Table 1 here)

3.2 Feasibility, Adherence, and Safety

(insert Table 2 here)

Fourteen participants were included in the present analysis, all of whom completed the study with no dropouts, resulting in a retention rate of 100% and

exceeding the pre-defined feasibility threshold of ≥80%.

All participants met the minimum daily duration criterion on every day of use; adherence was therefore determined primarily by the proportion of prescribed days on which the device was used. Mean self-reported adherence was 94% across the cohort (individual range: 74–100%), with all participants exceeding the pre-defined threshold of 70%. Reasons for non-use included planned travel, rest days, forgetting to use the device, and, in one case, mild electrode-related skin redness prompting temporary discontinuation.

Self-reported average FES usage was 3.52 ± 2.97 hours per active day, substantially exceeding the prescribed minimum duration. Several participants reported wearing the device for prolonged periods throughout the day and using it regularly during community walking and

longer-distance ambulation. No serious adverse events associated with FES use were reported during the study period. One non-serious adverse event was recorded: mild skin redness associated with electrode use, which prompted temporary discontinuation of FES and subsequently resolved. No other adverse events were reported. Feasibility outcomes are summarised against the pre-defined progression criteria in Table 2.

3.3 Gait Outcomes: Knee Kinematic Symmetry

Changes in the signed inter-limb knee-angle waveform (prosthetic minus intact) were assessed using SPM1D. No significant suprathreshold clusters were identified across the gait cycle (critical $|t| = 6.42$; $\alpha = 0.05$) (Figure 2E).

Mean frame-wise symmetry index decreased from 81.2 ± 28.8% to 71.7 ± 30.6% following FES, whereas it changed from 68.1 ± 22.6% to 70.5 ± 25.6% during the non-FES condition. In the baseline- and period-adjusted linear mixed-effects model, the between-treatment difference was statistically significant (adjusted difference −15.56 percentage points, 95% CI −29.35 to −1.77; $p = 0.029$). No significant between-treatment differences were observed for mean absolute inter-limb error (adjusted difference 0.60°, 95% CI −0.98 to 2.17; $p = 0.437$) or Nigg symmetry index (adjusted difference 0.01, 95% CI −0.03 to 0.04; $p = 0.665$) (Figure 3).

3.4 Gait Outcomes: Knee-flexion peak characteristics

Peak knee-flexion amplitude and timing were examined separately during early stance (Peak 1) and swing (Peak 2), with peaks identified independently for the prosthetic and intact limbs within the predefined gait-cycle windows (Figure 2A–D). No statistically significant between-treatment differences were observed in peak amplitude for either the prosthetic or intact limb at Peak 1 or

Peak 2 (all $p \geqslant 0.191$). Similarly, peak timing did not differ between treatments for either limb at either peak (all $p \geqslant 0.155$).

For inter-limb peak differences, there was no evidence of a significant between-treatment effect on absolute amplitude differences at Peak 1 (adjusted difference 2.69°, 95% CI −0.60 to 5.98; p = 0.103) or Peak 2 (3.40°, 95% CI −1.46 to 8.25; p = 0.159). Absolute timing differences also did not differ significantly between treatments at Peak 1 (−1.53% gait cycle, 95% CI −3.94 to 0.88; p = 0.199) or Peak 2 (0.38% gait cycle, 95% CI −0.69 to 1.44; p = 0.470) (Figure 4).

Signed prosthetic-minus-intact analyses similarly showed no significant between-treatment differences in peak amplitude at Peak 1 (−1.42°, 95% CI −4.88 to 2.05; p = 0.402) or Peak 2 (−2.93°, 95% CI −10.05 to 4.18; p = 0.398), or in peak timing at Peak 1 (1.13% gait cycle, 95% CI −1.77 to 4.04; p = 0.424) or Peak 2 (−0.75% gait cycle, 95% CI −1.91 to 0.41; p = 0.191).

3.5 Pain Outcomes

3.5.1 Pain Intensity (BPI-5)

BPI-5 pain intensity decreased with FES use, whereas it increased slightly during non-FES use (Figure 5). In the full dataset, mean BPI-5 scores changed from 4.60 ± 1.35 to 3.50 ± 1.72 during FES and from 3.91 ± 2.07 to 4.36 ± 2.50 during non-FES. Although baseline BPI-5 was 0.69 points higher before FES than non-FES, the mixed-effects model adjusted for the corresponding period-specific baseline value. In the primary mixed-effects model adjusting for period-specific baseline

and treatment period, post-treatment BPI-5 was 1.80 points lower following FES than non-FES (adjusted difference −1.80, 95% CI −2.28 to −1.31; $p < 0.001$; Cohen's d = 0.83).

The treatment effect was also evident in the post-hoc analysis restricted to participants with study-entry BPI-5 ≥3 (n = 10). Mean BPI-5 scores changed from 4.89 ± 1.05 to 3.89 ± 1.27 during FES and from 4.75 ± 1.75 to 5.50 ± 1.69 during non-FES. The adjusted between-treatment difference was −1.82 points (95% CI −2.34 to −1.30; $p < 0.001$; Cohen's d = 1.23). Treatment estimates were materially unchanged in sensitivity analyses additionally adjusting for treatment sequence.

3.5.2 Pain Interference (BPI-9)

BPI-9 pain interference decreased during both treatment conditions, with a larger descriptive reduction during FES (Figure 6). In the full dataset, mean BPI-9 scores changed from 3.79 ± 2.40 to 2.38 ± 1.86 during FES and from 3.62 ± 2.21 to 3.04 ± 2.29 during non-FES. In the primary mixed-effects model adjusting for period-specific baseline and treatment period, there was no evidence of a between-treatment difference in post-treatment BPI-9 (adjusted difference −0.77, 95% CI −1.82 to 0.29; $p = 0.144$; Cohen's d = 0.37).

In the secondary post-hoc analysis restricted to participants with study-entry BPI-9 ≥3 (n = 9), mean BPI-9 scores changed from 4.97 ± 1.26 to 3.00 ± 1.68 during FES and from 4.98 ± 1.40 to 4.37 ± 1.66 during non-FES. In this subgroup, the adjusted between-treatment difference was −1.43 points (95% CI −2.49 to −0.37; $p = 0.013$; Cohen's d = 0.85). Additional adjustment for treatment sequence did not materially alter the treatment-effect estimates or conclusions.

3.6 Exploratory Phantom Limb Pain (PLP) Outcomes

PLP was not a pre-specified outcome. However, nine participants reported PLP at the baseline of their FES intervention period, of whom seven were receiving pharmacological treatment for pain at enrolment and two were unable to tolerate medication because of contraindications. PLP intensity was therefore examined as an exploratory outcome using the Numeric Rating Scale (NRS).

Among participants reporting PLP at the baseline of their FES intervention period (n = 9), mean PLP intensity decreased from 4.00 ± 2.18 before FES to 1.22 ± 1.79 following the FES intervention, corresponding to a mean reduction of 2.78 points (Figure 7). The reduction was statistically significant on paired analysis ($t(8) = 6.40$, $p < 0.001$; Cohen's $dz = 2.13$). Responder analysis showed that eight of nine participants (89%) achieved a reduction of at least 2 points and all nine participants (100%) achieved a reduction of at least 30% from baseline.

As this was an exploratory pre-post analysis within the FES condition among participants reporting PLP at baseline of their FES intervention period, rather than a pre-specified comparison between FES and non-FES, these findings should be interpreted as hypothesis-generating.

3.7 Device Usage and Participant Feedback

Device usage was further characterised using weekly self-reported FES usage duration. Participants reported using the FES device for a mean of 23.48 ± 20.70 hours per week, with considerable inter-individual variability in usage. On days when FES was used, all participants met or exceeded the prescribed minimum duration of 20 minutes, although occasional non-use days resulted in variation in overall adherence. The ODFS Pace recorded a mean of 15,414 ± 7,507

steps per week during FES use, indicating substantial engagement with the device during habitual walking.

Participant feedback collected during weekly follow-up interviews and the Week 19 feedback interview indicated that the intervention was generally well accepted. All 14 participants described the device as usable and acceptable in daily life, and 13 reported perceived improvements in walking, including greater stability, increased walking endurance, improved knee movement, and greater walking confidence. Six participants reported perceived reductions in pain, including PLP, low back pain, and residual limb discomfort. One participant described being able to walk *"with a spring in your step, pain-free and enjoyable"* for the first time in years, while another described previously severe and uncontrollable PLP as becoming manageable during device use.

Five of 14 participants reported practical challenges, including difficulty donning the device, electrode placement, screen readability, and battery management, although most considered these issues minor relative to their perceived benefits. At the Week 19 feedback interview, 11 of 14 participants felt that the five-week intervention period was sufficient to adapt to the device and experience meaningful benefit, whereas three suggested that a longer intervention might allow greater functional improvement or better evaluation of sustained effects. Eleven of 14 participants reported perceived persistence of benefits after the FES intervention, including improvements in walking efficiency, activity levels, strength, or pain management. All 14 participants considered that FES might be valuable during the early stages of post-amputation

rehabilitation, particularly for gait retraining, strengthening, prevention of maladaptive gait patterns, and pain management.

4. Discussion

The findings indicate that daily community-based use of quadriceps-targeted FES timed to the stance phase of gait is feasible, safe and well tolerated, with high adherence and no serious adverse events. Exploratory analyses suggested improvements in mean frame-wise knee flexion symmetry and reductions in pain intensity, although no significant between-treatment differences were identified for other kinematic measures. Pain interference findings were less conclusive, with evidence of a treatment effect limited to a post-hoc subgroup with higher study-entry pain interference. Collectively, these findings support the feasibility of quadriceps-targeted FES during habitual daily walking and justify further evaluation of its effects on pain and gait biomechanics in adequately powered trials.

4.1 Feasibility and Acceptability

The study achieved 100% participant retention, with mean adherence of 94%, substantially exceeding the pre-defined threshold of 70%. Self-reported FES usage averaged 3.52 hours per active day, far exceeding the prescribed minimum, suggesting participants incorporated FES into extended periods of habitual mobility. This level of real-world exposure is relevant for future efficacy trials evaluating whether repeated FES use produces cumulative biomechanical or analgesic effects. No serious adverse events were recorded, further supporting the feasibility and tolerability of quadriceps-targeted surface FES for community use in this population.

Participant feedback further supported the acceptability of the intervention. All participants described the device as usable during daily activities, and thirteen of fourteen reported perceived improvements in walking, including greater stability, confidence, endurance, and knee control. Although these perceived improvements should be distinguished from the objectively measured gait outcomes, they provide important complementary information regarding participants' experiences of using FES during everyday mobility.

4.2 Gait Outcomes

Knee flexion symmetry was selected to capture inter-limb coordination during walking rather than walking performance alone. Previous research following lower limb amputation has predominantly assessed mobility using measures such as walking speed, walking distance, and timed mobility, with comparatively less attention to biomechanical characteristics of gait [4]. Altered knee kinematics and kinetics are characteristic features of unilateral transtibial gait, with clear differences reported between the prosthetic and intact limbs [10,38]. In the present intervention, FES was timed to activate the quadriceps muscles of the residual limb during stance, with the aim of increasing the contribution of the prosthetic-side knee during walking. Our previous model-driven work predicted that this stimulation strategy would increase the prosthetic-side knee flexion moment while reducing peak knee contact forces in the intact limb [30]. Knee flexion symmetry was therefore considered a relevant measure of whether repeated FES-assisted walking could influence coordination between the two limbs.

The present gait analyses, conducted with FES switched off, provided mixed findings regarding sustained changes in knee kinematics. Waveform-level analysis using SPM1D identified no

significant differences between FES and non-FES conditions in the change in inter-limb knee-angle patterns across the gait cycle. However, the baseline- and period-adjusted mixed-effects analysis demonstrated a significant between-treatment difference in mean frame-wise symmetry index, with lower values following FES. In contrast, neither mean absolute inter-limb error nor Nigg symmetry index differed significantly between treatments. These findings suggest a potential improvement in knee flexion symmetry following FES, although this effect was not consistently observed across the different symmetry measures.

Analysis of discrete knee-flexion characteristics provided further context for these findings. FES did not significantly alter the amplitude or timing of either the early-stance (Peak 1) or swing-phase (Peak 2) knee-flexion peaks in either limb. Moreover, absolute inter-limb differences in peak amplitude and timing, which were used to quantify the magnitude of peak-level asymmetry, did not differ between FES and non-FES conditions. Signed prosthetic-minus-intact differences also did not differ between treatments, providing no evidence that FES systematically shifted peak amplitude or timing of the prosthetic limb relative to the intact limb. Together, these findings suggest that the improvement detected in mean frame-wise symmetry index was not accompanied by significant changes in the overall inter-limb knee-angle waveform or discrete peak characteristics. This indicates that the observed kinematic response may depend on the specific symmetry measure used.

Several factors may explain why improvements were detected in mean frame-wise symmetry index but not consistently across other kinematic measures. Knee flexion symmetry varied considerably between participants, as reflected by the large variability in symmetry index at

baseline and follow-up. In addition, many participants had been living with their amputation and using a prosthesis for several years, and their gait patterns were therefore likely to reflect well-established adaptations to prosthetic walking. Five weeks of FES-assisted walking may have been insufficient to produce consistent changes across multiple aspects of these established movement patterns. Differences in the mathematical properties and sensitivity of the symmetry measures may also have contributed to the variation in findings. Previous studies nevertheless indicate that individuals with transtibial amputation retain the capacity to adapt inter-limb gait symmetry in response to repeated task-specific walking exposure [39]. Whether a longer intervention, earlier application during prosthetic rehabilitation, or a more intensive gait-training paradigm could produce more consistent kinematic adaptations therefore warrants investigation. These findings should also be considered alongside our previous laboratory evaluation of model-driven FES, which examined the immediate orthotic effects of stimulation during walking. Quadriceps stimulation increased knee extensor muscle forces in the amputated limb and reduced peak knee contact forces in the intact limb during walking [30], supporting the model-predicted effect of increasing the mechanical contribution of the prosthetic-side knee and redistributing loading between the two limbs. However, these mechanical changes were accompanied by limited changes in conventional spatiotemporal gait parameters [30]. In contrast, the present study assessed the training effect of repeated FES use, with gait evaluated while FES was switched off. The improvement in mean frame-wise symmetry index suggests a potential sustained kinematic adaptation, although the absence of consistent effects across other measures indicates that any such adaptation may be limited or difficult to detect using the

current assessment methods. Changes in muscle activation, joint moments, or internal joint loading may also occur without producing proportional changes in knee kinematics. Notably, participant feedback indicated perceived improvements in walking, including greater stability, endurance, confidence, and knee control, despite the limited evidence of consistent changes across objective knee-kinematic outcomes. Although these observations were subjective, they suggest that effects experienced during daily walking may not have been fully captured by the knee-kinematic measures examined in this study. As participants were not blinded, these perceived improvements may also have been influenced by expectations of benefit. The present findings therefore suggest that knee kinematics alone may be insufficient to characterise the biomechanical response to model-driven quadriceps FES. Future studies should complement knee kinematics with measures that more directly capture the proposed biomechanical mechanism, including knee moments, muscle-force estimates, and internal joint loading. Incorporating these biomechanical measures would help determine whether the mechanical changes observed during single-session FES-assisted walking [30] translate into sustained biomechanical adaptations during prolonged community use.

4.3 Pain Outcomes

Exploratory analyses provided preliminary evidence that FES may reduce pain, although the magnitude and consistency of the findings differed between pain intensity and pain interference. In the principal baseline- and period-adjusted mixed-effects analysis, post-treatment BPI-5 pain intensity was 1.80 points lower following FES than non-FES (95% CI −2.28 to −1.31; $p < 0.001$), corresponding to a standardised effect size of $d = 0.83$. A similar treatment effect was observed

596 in the post-hoc analysis restricted to participants with a study-entry BPI-5 score ≥3 (adjusted
597 difference −1.82 points, 95% CI −2.34 to −1.30; $p < 0.001$), with a larger standardised effect size
598 ($d = 1.23$).
599 For pain interference, there was no evidence of a between-treatment difference in the full
600 analysis. However, in the post-hoc analysis restricted to participants with a study-entry BPI-9
601 score ≥3, FES was associated with lower post-treatment pain interference. The larger
602 standardised effect sizes observed in analyses restricted to participants with study-entry scores
603 ≥3 for both pain intensity and pain interference may partly reflect greater scope for improvement
604 among participants with a higher initial pain burden or regression to the mean. However, these
605 subgroup analyses were post-hoc, and differential treatment response according to baseline pain
606 severity was not formally tested. They should therefore be interpreted as exploratory evidence
607 of a possible influence of baseline pain burden rather than evidence that treatment efficacy
608 differs according to baseline pain severity. Additional adjustment for treatment sequence did not
609 materially alter the treatment-effect estimates or conclusions.
610 An important consideration in interpreting these findings is that the BPI captures overall pain
611 burden without distinguishing between individual pain types. Pain following lower limb
612 amputation is heterogeneous, with PLP, residual limb pain, and secondary musculoskeletal pain
613 such as low back pain frequently coexisting within the same individual [3]. Our recent scoping
614 review also demonstrated considerable heterogeneity in the assessment and reporting of pain
615 following lower limb amputation, with different pain types frequently examined separately
616 across studies [4]. Consequently, although the present findings suggest reductions in overall pain

intensity and, among participants with higher study-entry pain interference, pain interference, it is not possible to determine which pain type contributed to these changes. The observed effects could reflect improvement in one particular pain type or smaller changes across several coexisting pain types.

This distinction is also important when considering potential mechanisms. FES may influence pain through several pathways, including repeated sensory input associated with electrical stimulation [40,41] and changes in muscle activation and mechanical loading during walking [30]. However, because the individual pain types contributing to the BPI scores were not assessed separately, the present study cannot determine whether the observed changes were related predominantly to sensory, mechanical, or other mechanisms. The BPI findings should therefore be interpreted as a preliminary signal of change in overall pain burden rather than evidence of an effect on a specific pain type or analgesic mechanism.

4.4 Exploratory Phantom Limb Pain

Against this background, an exploratory observation was the reduction in PLP intensity among participants who reported PLP at the baseline of their FES intervention period (n = 9). Mean PLP intensity decreased by 2.78 points, with 89% of participants achieving a reduction of at least 2 points and all participants achieving at least a 30% reduction. These changes exceeded the commonly used thresholds of a 2-point or 30% reduction, for clinically meaningful improvement in pain intensity [42]. However, PLP was not a pre-specified outcome, and the analysis was based on a small subgroup and a within-FES pre–post comparison rather than a randomised FES versus non-FES contrast. It is therefore not possible to distinguish an effect of FES from temporal

638 variation, regression to the mean, or other non-specific effects. These findings should
639 consequently be considered hypothesis-generating rather than evidence of efficacy.
640 The mechanism underlying the observed PLP reduction cannot be determined from the present
641 study. PLP is thought to arise from interacting peripheral and central mechanisms, including
642 altered afferent input and changes in sensorimotor processing following amputation [43].
643 Previous neuroprosthetic studies suggest that restoring sensory information related to the
644 missing limb may reduce PLP, including approaches in which sensory feedback is linked to
645 prosthetic loading or movement [44,45]. Complementary evidence from non-invasive spinal
646 neuromodulation suggests that modulation of spinal sensorimotor pathways may also influence
647 PLP [46]. Although the present intervention was not designed specifically to restore sensation
648 from the missing limb, FES may have provided afferent sensory input alongside muscle activation
649 during prosthetic walking. As stimulation was timed to stance, this sensorimotor input may have
650 occurred in temporal association with prosthetic limb loading and movement. These
651 characteristics provide a plausible sensorimotor basis for the observed PLP response, although
652 the underlying mechanisms were not directly assessed and require further investigation.
653 **4.5 Limitations**
654 Several limitations should be acknowledged. First, recruitment relied on self-referral following
655 local advertisement, and the number of potentially eligible individuals exposed to recruitment
656 materials was not available. Although the target sample was recruited within the planned
657 timeframe, recruitment efficiency and generalisability to broader clinical pathways therefore
658 remain uncertain. Generalisability is also limited by the characteristics of the study sample: 13 of
32

14 participants were male and 57% had traumatic amputation. In addition, participants were required to walk continuously without a walking aid and those with a self-selected walking speed greater than 1.25 m/s were excluded, limiting applicability to individuals at either end of the mobility spectrum.

Second, the study was designed primarily to evaluate feasibility and included a relatively small sample, limiting the precision of treatment-effect estimates for the exploratory gait and pain outcomes. This is particularly relevant to the post-hoc BPI subgroup and exploratory PLP analyses, which involved smaller samples. In addition, the BPI did not distinguish between different pain phenotypes, limiting subtype-specific interpretation of the pain findings.

Third, participants and clinicians could not be blinded to the intervention, and no sham-FES condition was used. Expectancy effects may therefore have influenced self-reported pain and participant feedback, while non-specific effects associated with wearing the device or changes in walking behaviour cannot be separated from the specific effects of electrical stimulation. Analgesic use was not controlled or systematically monitored across intervention periods, which may also have influenced the pain outcomes. Adherence and FES usage duration were based on participant self-report, although device-recorded step counts provided an objective measure of intervention exposure.

Fourth, although a six-week washout period was included, carryover effects cannot be fully excluded in a crossover design, particularly as some participants reported persistence of perceived benefits after FES use. Multiple exploratory analyses were also conducted without adjustment for multiple comparisons, which should be considered when interpreting the findings.

Finally, the IMU-based gait assessment characterised knee kinematics but did not directly assess joint moments, muscle forces, or internal joint loading. Consequently, biomechanical effects of FES may have occurred that were not captured by the kinematic outcomes examined here, and future studies incorporating more comprehensive biomechanical assessment may help clarify these effects.

4.6 Conclusions and Future Directions

This study indicates that a five-week programme of community-based quadriceps-targeted FES is feasible and well tolerated in individuals with unilateral transtibial amputation, with high retention, adherence, and participant-reported acceptability. Exploratory analyses suggested improvements in mean frame-wise knee flexion symmetry and reductions in pain intensity, although other knee kinematic measures did not show significant between-treatment differences. Pain interference did not differ significantly between treatments in the principal analysis, although a post-hoc analysis among participants with study-entry BPI-9 scores ≥3 showed lower pain interference following FES. These efficacy findings require prospective confirmation. Overall, the results support further evaluation of model-driven FES beyond controlled laboratory settings and demonstrate the practical implementation of this approach during habitual daily mobility.

Future studies should evaluate these preliminary efficacy findings in larger, adequately powered randomised trials, with pain intensity as a primary clinical outcome, a more rigorous control condition, and an intervention period of at least five weeks, alongside pre-specified assessment of specific post-amputation pain phenotypes and biomechanical outcomes more closely aligned with the proposed mechanisms of action. Combining laboratory-based assessment of joint

kinetics, muscle forces, and internal joint loading with wearable monitoring of habitual mobility may help distinguish the immediate orthotic effects of FES from sustained training effects following prolonged community-based use. The exploratory reduction in PLP observed following FES warrants prospective investigation with PLP included as a pre-specified outcome, alongside further investigation of the sensory and biomechanical mechanisms through which FES may influence post-amputation pain.

Declarations

Ethics approval and consent to participate

This study received a favourable ethical opinion from the West Midlands–Black Country Research Ethics Committee (REC reference: 25/WM/0061; IRAS project ID: 354627; protocol number: RG_25-009) and approval from the Health Research Authority. All participants provided written informed consent before participation. The study was conducted in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and analysed during the current study are available from the corresponding author upon reasonable request, subject to applicable ethical and data protection requirements.

Competing interests

Paul Taylor is seconded from Salisbury NHS Foundation Trust to Odstock Medical Limited (OML), where he serves as Clinical Director. The other authors declare that they have no competing interests.

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Authors' contributions

ZD and TN conceived and designed the study. JK coordinated the study, contributed to data collection, performed the data analysis, and drafted the manuscript. QB contributed to gait data processing and analysis. CS and PR contributed to participant recruitment, functional electrical stimulation (FES) fitting, and clinical assessments. PT provided clinical and technical expertise in FES implementation. LC and TN contributed to the interpretation of findings and critically revised the manuscript. ZD supervised the research, contributed to the interpretation of findings, and critically revised the manuscript. All authors reviewed and approved the final manuscript and agreed to be accountable for their contributions and the integrity of the work.

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Table 1. **Participant demographic, amputation-related and clinical characteristics at study entry (N = 14)**

Characteristic	Value
Age, years	54.2 ± 11.1
Sex, male/female, n	13/1
Body mass index, kg/m²	27.5 ± 5.3
Time since amputation, months	47 [21–262]; range 14–530
Amputation side, left/right, n	6/8
Cause of amputation, n (%)	Trauma: 8 (57); dysvascular: 5 (36); other: 1 (7)
Pain phenotype at enrolment, n (%)	PLP: 2 (14.3); RLP: 3 (21.4); LBP: 2 (14.3); multiple pain types: 7 (50)

Values are mean ± SD, median [Q1-Q3], or n (%), as appropriate. BPI, Brief Pain Inventory; LBP, low-back pain; PLP, phantom limb pain; RLP, residual limb pain. Multiple pain types were defined as the coexistence of two or more pain types, including PLP, RLP, and/or LBP.

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917 Table 2. **Feasibility outcomes and FES use metrics (N = 14)**

Feasibility domain	Pre-defined criterion	Observed outcome
Recruitment	Target sample of 14 participants recruited within the pre-specified timeframe	14 participants enrolled between May and November 2025; all 14 individuals who contacted the research team were eligible and enrolled
Retention	⩾80% of enrolled participants retained through study completion	100% (14/14); no withdrawals
Adherence	⩾70% of prescribed days with FES use ⩾ 20 min/day	Mean 93.8% of prescribed days (individual range: 74–100%); all participants exceeded the threshold
Total FES use days	Descriptive intervention-exposure measure	460 of 490 prescribed participant-days (93.9%)
Average daily FES usage duration	Descriptive intervention-exposure measure	3.52 ± 2.97 h/day
FES-assisted step count	Descriptive intervention-exposure measure	15,414 ± 7,507 steps/week
Safety and tolerability	No serious adverse events attributable to the intervention	0 serious adverse events; 1 non-serious adverse event (mild skin redness associated with electrode use, which resolved following temporary discontinuation)
Participant acceptability	Supporting feasibility indicator	14/14 participants (100%) described the device as usable and acceptable

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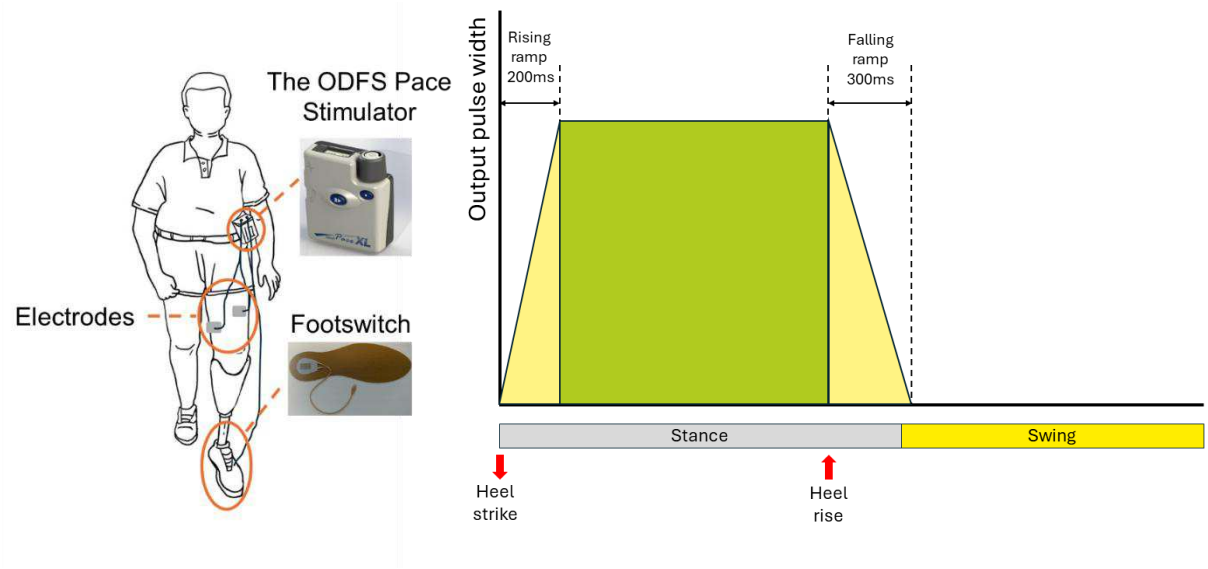
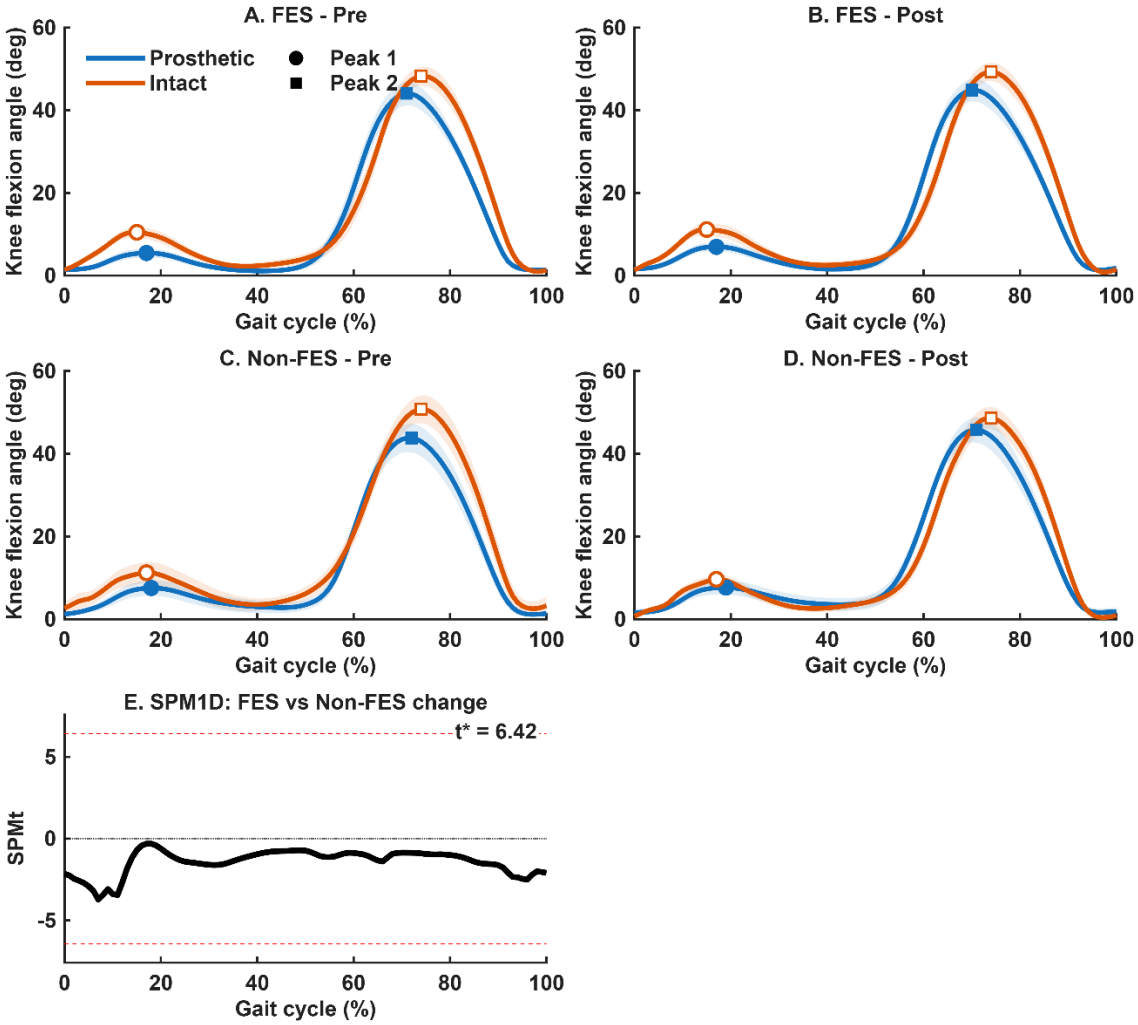


Figure 1. ***FES setup and stimulation timing during walking****. Left: ODFS® Pace XL stimulator, quadriceps electrode placement, and heel footswitch. Right: stimulation timing diagram showing FES delivery during the stance phase of gait, from heel strike until unloading of the footswitch.*



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935 *Figure 2.* ***Knee flexion kinematics, peak characteristics, and waveform-level treatment***

936 ***comparison.*** *(A–D) Mean knee flexion waveforms for the prosthetic (blue) and intact (orange)*

937 *limbs before (Pre) and after (Post) the FES (A, B) and non-FES (C, D) intervention periods, with*

938 *shaded regions representing the standard error of the mean (SEM). Peak 1 (10–30% gait cycle;*

939 *circles) and Peak 2 (60–80% gait cycle; squares) indicate peak flexion amplitude and timing,*

940 *identified independently for each limb. Filled blue and open orange symbols represent the*

941 *prosthetic and intact limbs, respectively. (E) One-dimensional statistical parametric mapping*

(SPM1D) comparison of within-period changes in the signed inter-limb knee-angle waveform (prosthetic minus intact) between FES and non-FES conditions. The solid black line represents the SPM{t} statistic, and the red dashed lines indicate the critical threshold ($|t| = 6.42$, $\alpha = 0.05$). No significant suprathreshold clusters were identified.

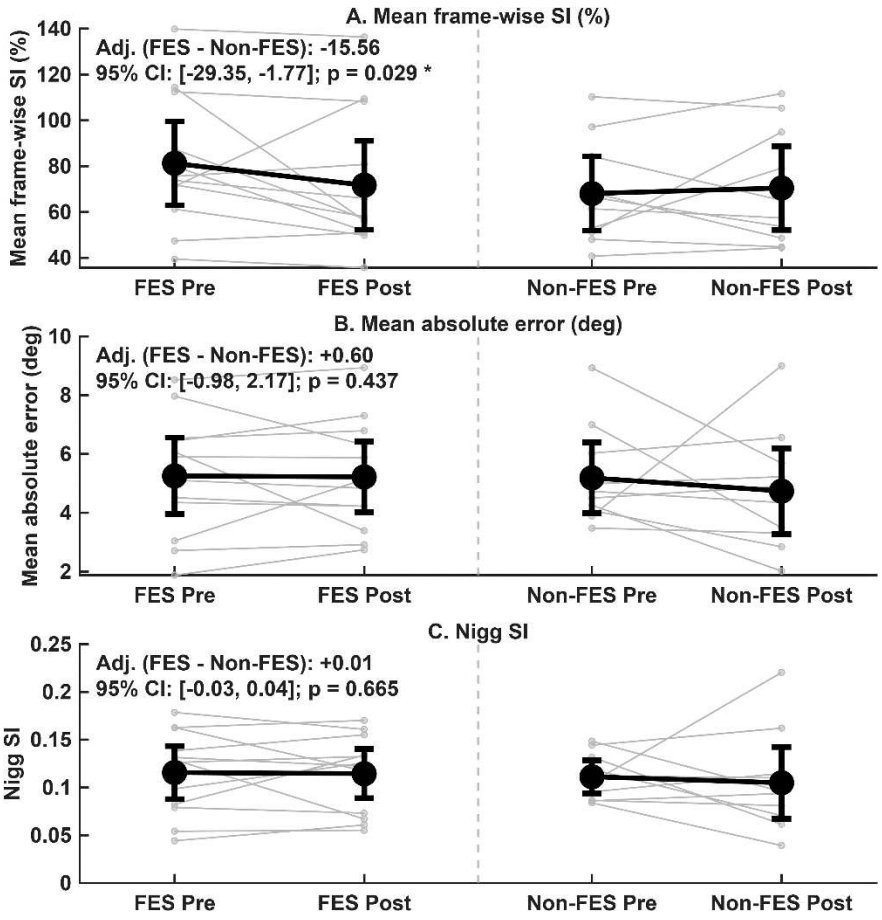


Figure 3. ***Whole-cycle knee flexion symmetry before and after FES and non-FES intervention periods.*** *Individual participant values are shown in grey and group means ± SD in black. Inter-limb similarity was quantified using (A) mean frame-wise symmetry index (SI), (B) mean absolute inter-limb error, and (C) Nigg symmetry index (Nigg SI), with lower values indicating greater similarity. Values within each panel show baseline- and period-adjusted FES versus non-FES treatment effects with 95% confidence intervals and p-values.*

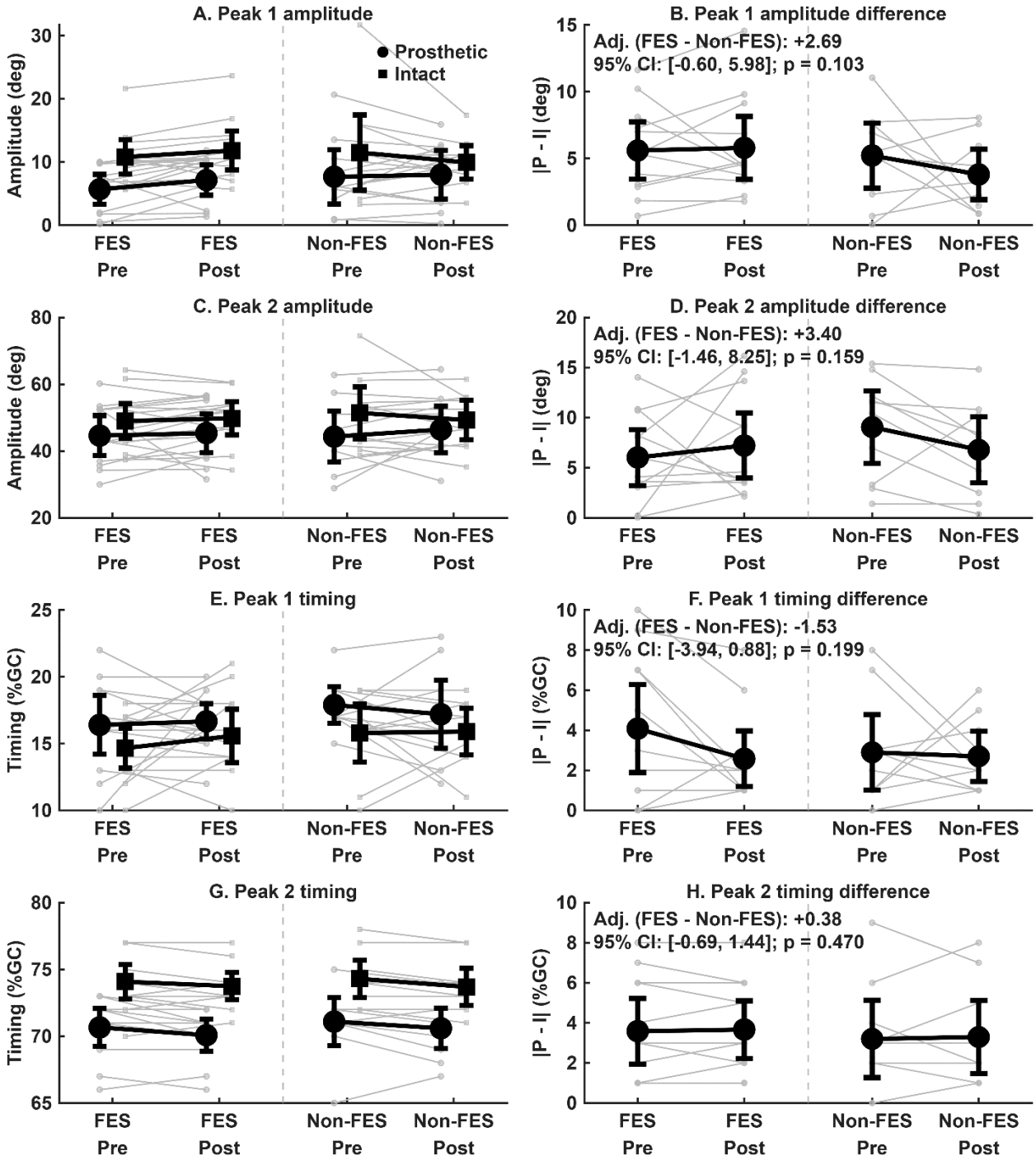
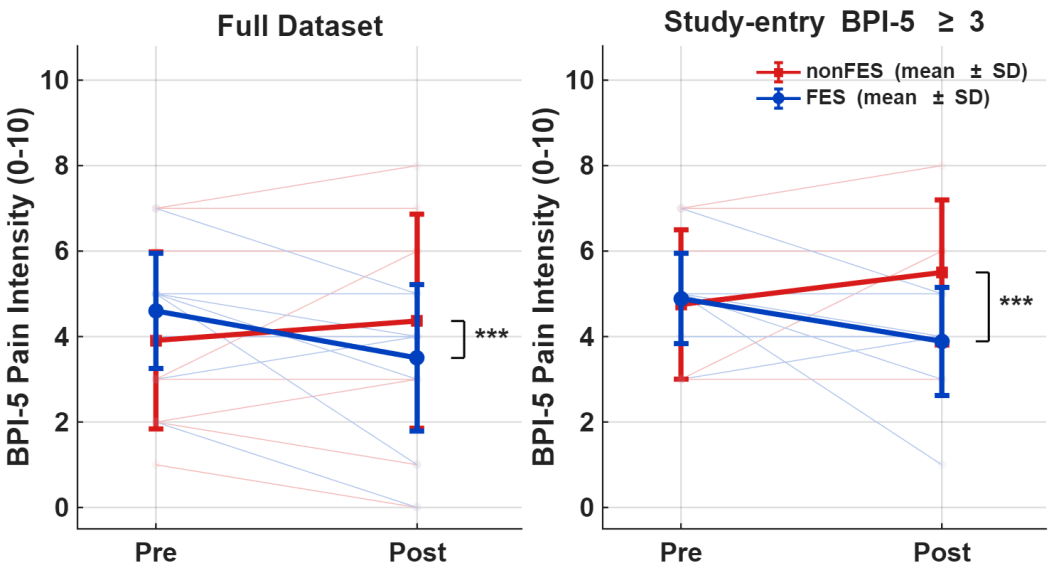


Figure 4. ***Knee-flexion peak characteristics and absolute inter-limb differences before and after FES and non-FES intervention periods.*** *Peak amplitude (A, C) and timing (E, G) are shown for the*

prosthetic and intact limbs at Peak 1 (10–30% gait cycle) and Peak 2 (60–80% gait cycle). Absolute inter-limb differences in peak amplitude (B, D) and timing (F, H) are also shown, with lower values indicating closer inter-limb matching. Grey lines represent individual participants and black symbols with error bars represent mean ± SD. Values in panels B, D, F, and H show baseline- and period-adjusted FES versus non-FES treatment effects with 95% confidence intervals and p-values.



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974 *Figure 5.* ***BPI-5 pain intensity before and after FES and non-FES intervention periods.*** *Individual*

975 *pre-to-post trajectories are shown by thin lines, with group means ± standard deviations shown*

976 *by thicker lines and symbols. The left panel shows the full analysis dataset, and the right panel*

977 *shows the post-hoc analysis restricted to participants with a study-entry BPI-5 score ≥3 (n = 10).*

978 *Black brackets and asterisks indicate significant adjusted between-treatment effects from the*

979 *baseline- and period-adjusted linear mixed-effects models (***p < 0.001).*

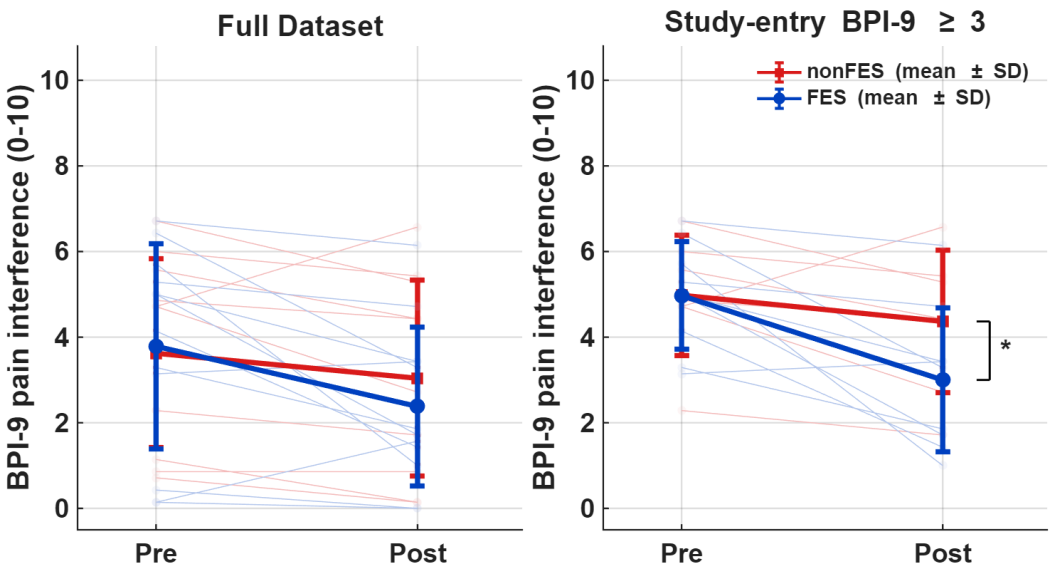

Figure 6. ***BPI-9 pain interference before and after FES and non-FES intervention periods****. Individual pre-to-post trajectories are shown by thin lines, with group means ± standard deviations shown by thicker lines and symbols. The left panel shows the full analysis dataset, and the right panel shows the post-hoc analysis restricted to participants with a study-entry BPI-9 score ≥3 (n = 9). The black bracket and asterisk indicate a significant adjusted between-treatment effect from the baseline- and period-adjusted linear mixed-effects model (*p < 0.05).*

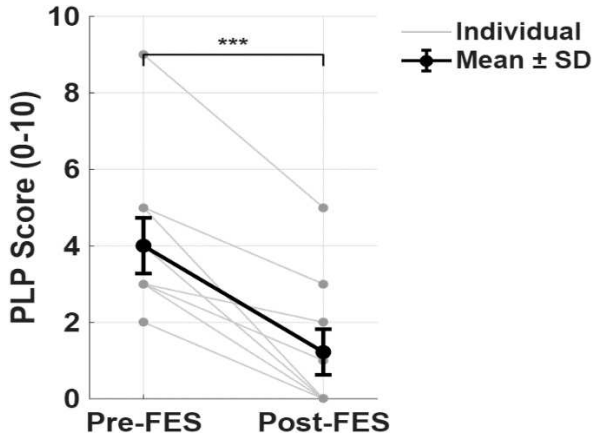

Figure 7. ***Change in phantom limb pain intensity following FES intervention****. Individual participant trajectories are shown as grey lines, with the group mean ± standard deviation (SD) shown in black. PLP intensity was assessed using the Numeric Rating Scale (0–10) before and after the FES intervention among participants reporting PLP at the baseline of their FES intervention period (n = 9). *** indicates a significant pre–post reduction based on the paired t-test (p < 0.001).*