GMR
The Original

AN AUTOMATED MOTORIZED SPLINT DELIVERING PROGRAMMED PASSIVE DORSIFLEXION AS AN ADJUNCT TO CONVENTIONAL PHYSIOTHERAPY IN FOOT DROP: A PROSPECTIVE COMPARATIVE INTERVENTIONAL STUDY

Dr Ajay Ravi[1]*, Dr. Benjamin Vinodh. J[2], Dr.Vankamaddi Vishnuvardhan V.Sudarsan[3]

[1]Junior Resident, Department of Orthopaedics, Saveetha Medical College and Hospital, Saveetha Institute of Medical and Technical Sciences (SIMATS), Saveetha University, Thandalam, Chennai-602105
[2] Senior Resident, Department of Orthopaedics, Saveetha Medical College and Hospital, Saveetha Institute of Medical and Technical Sciences (SIMATS), Saveetha University, Thandalam, Chennai-602105
[3] Senior Resident, Department of Orthopaedics, Saveetha Medical College and Hospital, Saveetha Institute of Medical and Technical Sciences (SIMATS), Saveetha University, Thandalam, Chennai-602105
[1]ORCID ID: 0009-0007-9850-0079, [2]ORCID ID: 0009-0003-5261-2009, [3]ORCID ID: 0009-0007-3465-5434
*Corresponding Author: Dr Ajay Ravi

ABSTRACT

Background. Foot drop produces loss of swing-phase toe clearance, compensatory gait deviations and a raised risk of falling. Conventional physiotherapy and static ankle–foot orthoses stabilise limb position but deliver little repetitive joint excursion, and the therapeutic dose achieved between supervised sessions is small. A motorised splint capable of delivering programmed passive dorsiflexion could raise that dose without additional therapist time.

Objectives. To determine whether adding an in-house automated motorised dorsiflexion splint to conventional physiotherapy improves ankle dorsiflexion range of motion, plantarflexor tone and overground gait performance more than physiotherapy alone, and to assess device safety, comfort and usability.

Methods. Fifty adults with clinically confirmed unilateral foot drop of at least one month's duration were recruited from the orthopaedic and rehabilitation outpatient services of a tertiary teaching hospital and allocated by alternate sequential assignment to an intervention group (n = 25; motorised splint plus conventional physiotherapy) or a control group (n = 25; conventional physiotherapy alone). The splint delivered microcontroller-timed passive dorsiflexion cycles for 20–30 minutes daily, five days weekly, for 12 weeks. Primary outcomes were goniometric passive ankle dorsiflexion range of motion and the Modified Ashworth Scale; the secondary outcome was the 10-metre walk test. Comfort, satisfaction and adverse events were recorded.

Results. Groups were comparable at baseline. At 12 weeks the intervention group gained 10.36° (95% CI 8.98–11.74) of dorsiflexion versus 3.31° (2.22–4.41) in controls, a between-group difference of 7.05° (5.33–8.77; $p < 0.001$; Cohen d = 2.33). Modified Ashworth Scale scores fell by 0.86 versus 0.31 grades (difference −0.56, −0.74 to −0.38; $p < 0.001$) and 10-metre walk time by 5.61 s versus 2.22 s (difference −3.40 s, −4.53 to −2.26; $p < 0.001$). A dorsiflexion gain of 10° or more was reached by 16 of 25 intervention patients and none of the controls ($p < 0.001$). Mean comfort was 8.37/10; adverse events were minor and evenly distributed (12% versus 8%, p = 1.00), with no withdrawals.

Conclusion. Programmed passive dorsiflexion delivered by a low-cost motorised splint produced clinically and statistically superior gains in ankle mobility, tone and gait speed compared with physiotherapy alone over 12 weeks, with a favourable safety and tolerability profile. Confirmation in a randomised, assessor-blinded multicentre trial with instrumented gait analysis and longer follow-up is warranted.

KEYWORDS: foot drop; passive dorsiflexion; motorised splint; ankle–foot orthosis; rehabilitation robotics; spasticity; gait; range of motion

1. INTRODUCTION

Foot drop describes the inability to raise the forefoot against gravity because of weakness or paralysis of the ankle and toe dorsiflexors. It is a functional syndrome rather than a single diagnosis, and its unifying mechanical consequence is failure of swing-phase toe clearance. Patients compensate by exaggerating hip flexion, circumducting the limb or vaulting over the contralateral forefoot, and the resulting gait is slower, more variable and metabolically more expensive than normal walking [1]. Loss of controlled eccentric plantarflexion at initial contact also produces a characteristic foot slap that further destabilises early stance.

The aetiological spectrum is broad. Injury to the common peroneal nerve at the fibular neck, L4–L5 radiculopathy, upper motor neuron lesions from stroke or traumatic brain injury, spinal cord injury, inherited and acquired myopathies, and iatrogenic nerve injury during surgery about the knee and proximal leg all converge on the same clinical picture [1,2]. Among neurological causes, stroke predominates: a substantial minority of survivors retain dorsiflexor weakness sufficient to impair gait and increase fall risk, and peroneal neuropathy of traumatic, compressive or diabetic origin accounts for most of the remainder [2,3].

The consequences extend well beyond gait mechanics. Reduced walking speed and endurance restrict community ambulation, and the fall risk conferred by inadequate toe clearance carries its own morbidity, particularly in older patients [1,4]. Perhaps more importantly for the orthopaedic surgeon, the ankle held persistently in plantarflexion undergoes predictable soft-tissue adaptation. Sarcomere loss in the gastrocnemius–soleus complex, shortening of the Achilles tendon and capsular contracture progressively convert a dynamic neurological deficit into a fixed equinus deformity. Once established, that deformity limits what any neural recovery can deliver and may ultimately require surgical lengthening or tendon transfer.

Conservative management therefore has two distinct aims: to substitute for absent dorsiflexion during walking, and to preserve the passive excursion of the ankle so that recovery remains possible. Static and articulated ankle–foot orthoses address the first aim well, holding the foot in a neutral or slightly dorsiflexed position and demonstrably improving the stability of hemiparetic gait [5]. They do not, however, mobilise the joint; a rigid orthosis maintains position precisely by preventing excursion. Functional electrical stimulation and peroneal nerve stimulators actively generate dorsiflexion during swing and improve walking speed, but they require intact peripheral nerve and neuromuscular junction, are relatively costly, and their benefit over a well-fitted orthosis is modest in pooled analyses [2,3,7].

Supervised physiotherapy remains the foundation of care, combining passive stretching, dorsiflexor strengthening, balance work and gait re-education. Its principal weakness is one of dose. Manual passive stretching is variable in amplitude, hold time and frequency between therapists and between sessions, is limited by the fatigue of both patient and clinician, and in most Indian tertiary centres is available for only a few tens of minutes on a subset of days. Between visits the ankle is largely immobile, and stiffness accrues in precisely those intervals. Rehabilitation science increasingly recognises that repetition and cumulative dose, rather than the specific exercise chosen, drive both soft-tissue adaptation and neuroplastic change [24,25,29].

Powered ankle devices have emerged to close this gap. Pneumatic and shape-memory-alloy actuated orthoses assist dorsiflexion during swing and improve gait symmetry and foot clearance in real time [4,12]. Robot-assisted gait trainers with dorsiflexion assistance improve walking independence, motor recovery and confidence in weight bearing after stroke [8,11], and both the intensity and the frequency of robotic ankle training appear to modulate the magnitude of recovery achieved [10]. Continuous passive motion applied to the ankle reduces soleus hypertonia and increases passive dorsiflexion in spastic cerebral palsy [16], and home-delivered robotic ankle training achieves outcomes comparable with laboratory-based training [17]. Systematic reviews of wearable ankle robotics consistently report gains in peak swing-phase dorsiflexion, push-off propulsion and gait velocity, while noting that most published devices are research prototypes whose cost, mass and complexity place them beyond routine use in resource-constrained settings [11,20,23].

Two observations follow. First, the therapeutic mechanism most relevant to preventing contracture is not swing-phase assistance during walking but repeated, controlled passive excursion of the ankle through its available range, which can be delivered at rest and therefore does not depend on the patient being safe to ambulate. Second, a device intended for a public tertiary hospital in a middle-income setting must be simple, inexpensive, fabricable from locally available components and safe enough for use by ward staff and physiotherapists rather than engineers.

We therefore designed and fabricated an automated motorised foot-drop splint that mounts on a conventional rigid orthosis and delivers programmed passive dorsiflexion cycles under microcontroller control, with torque limitation, angle sensing and an emergency stop. The present study tested the hypothesis that adding this device to conventional physiotherapy would produce greater improvement in passive ankle dorsiflexion range of motion, plantarflexor tone and overground gait performance than conventional physiotherapy alone, and evaluated its safety, comfort and usability in routine clinical practice.

2. MATERIALS AND METHODS

2.1 Study design, setting and ethical approval

This was a prospective, two-arm, comparative interventional study conducted in the Department of Orthopaedics and the associated rehabilitation unit of Saveetha Medical College and Hospital, a tertiary teaching hospital in Thandalam, Chennai, India. Recruitment and follow-up spanned a 12-week intervention period for each participant. The protocol was reviewed and approved by the Saveetha Medical College and Hospital Institutional Ethics Committee (reference 008/09/2025/IEC/SMCH, 26 September 2025) and the study was registered prospectively with the Clinical Trials Registry – India (CTRI/2026/03/106824). All procedures conformed to the Declaration of Helsinki [39]. Written informed consent was obtained in English or Tamil, as preferred by the participant, using a bilingual consent document that described the device, the expected benefits, the anticipated adverse events and the unconditional right to withdraw. Reporting follows the CONSORT framework where applicable to a non-randomised parallel-group design [40].

2.2 Participants

Adults presenting with clinically confirmed foot drop were screened consecutively. Eligibility criteria were as follows.

Inclusion criteria

- Age between 18 and 70 years.
- Clinically confirmed unilateral foot drop with dorsiflexor power of Medical Research Council grade 3 or less.
- Symptom duration of at least one month, ensuring the deficit was established rather than transient.
- Passive ankle dorsiflexion achievable to at least the neutral position or a fixed equinus of no more than 10 degrees, so that a passive excursion arc existed for the device to work within.
- Ability to comprehend the protocol and provide informed consent.

Exclusion criteria

- Fixed bony ankle deformity or established rigid equinus beyond 10 degrees.
- Active infection, open wound, ulceration or fragile skin over the leg or foot.
- Fracture of the ankle, leg or foot within the preceding three months, unless cleared by the treating surgeon.
- Severe osteoporosis or other condition predisposing to fragility fracture.
- Known or suspected deep vein thrombosis, coagulopathy, or severe peripheral arterial disease of the affected limb.
- Modified Ashworth Scale grade 4 spasticity, or uncontrolled spasticity preventing safe passive mobilisation.
- Cognitive impairment precluding consent or cooperation, and pregnancy.

2.3 Group allocation

Eligible consenting participants were assigned to the intervention or control arm by alternate sequential allocation in order of enrolment. Concealment of allocation and blinding of participants were not feasible, since the device is visible and its use is self-evident to the patient. Outcome assessment was performed by the treating team and was not blinded; this limitation is addressed in Section 4.5.

2.4 Device design and fabrication

The splint was designed and fabricated in-house in the institutional device laboratory. A commercially available rigid posterior-shell ankle–foot orthosis served as the structural base, providing a validated interface with the leg and a footplate that distributes load across the plantar surface. Three adjustable hook-and-loop straps at the proximal calf, the ankle and the midfoot secured the limb and allowed fitting across a range of leg circumferences without custom moulding.

Motion was generated by a small brushed direct-current geared motor mounted laterally at the level of the ankle axis and coupled to the footplate through a cam-and-lever linkage, which converts continuous motor rotation into a reciprocating dorsiflexion–relaxation arc. A programmable microcontroller governed the cycle, permitting independent adjustment of the target dorsiflexion angle, the angular velocity, the dwell time at end range and the number of cycles per session. Power was supplied by a rechargeable lithium-ion pack carried on a proximal cuff, giving several sessions of use per charge and removing dependence on mains supply during therapy. The deliberate combination of a validated rigid base with locally sourced low-power electronics reflects the prevailing emphasis in wearable device engineering on minimal mass, modest power draw and simple robust sensing [30,31].

Three independent safety layers were incorporated, following established principles for the integration of general-purpose actuators into rehabilitation devices [28]. A mechanical torque limiter in the drive train slips before the applied moment can reach a level capable of straining the ankle ligaments. An angle sensor monitors joint excursion in real time and halts the motor if the programmed limit is exceeded or if resistance rises abruptly, as occurs during a spastic catch. A manually operated emergency stop within the patient's reach interrupts the motor circuit immediately. The functional architecture is summarised in Figure 1 and the fabricated device in clinical use is shown in Figure 2. Component specifications and operating parameters are listed in Table 1.

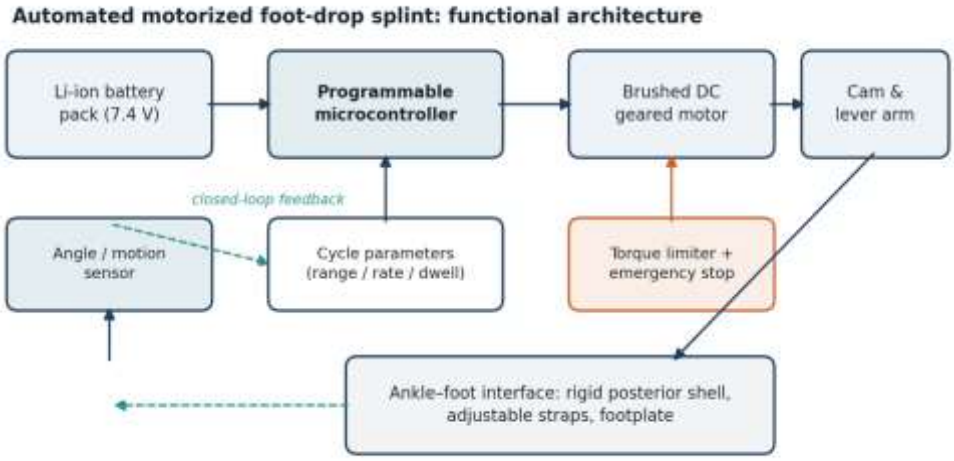

Figure 1. Functional architecture of the automated motorised foot-drop splint.

A microcontroller times the actuation cycle and receives continuous angular feedback from the ankle sensor (dashed path), while a mechanical torque limiter and patient-accessible emergency stop provide independent protection at the motor stage.

Table 1. Specifications and operating parameters of the automated motorised foot-drop splint

Parameter	Specification
Structural base	Commercial rigid posterior-shell ankle–foot orthosis with plantar footplate
Limb interface	Three adjustable hook-and-loop straps (proximal calf, ankle, midfoot); padded liner at bony prominences
Actuator	Brushed DC geared micromotor, laterally mounted at the ankle axis
Transmission	Cam-and-lever linkage converting motor rotation to reciprocating dorsiflexion arc
Control	Programmable microcontroller; adjustable target angle, angular velocity, end-range dwell and cycle count
Power supply	Rechargeable lithium-ion pack (nominal 7.4 V) on proximal cuff
Feedback	Ankle angle / motion sensor with real-time excursion monitoring
Safety systems	Mechanical torque limiter; sensor-triggered automatic cut-out on abnormal resistance; manual emergency stop
Session parameters used	20–30 min per session; target dorsiflexion arc titrated to individual pain-free passive range; 2–3 s end-range dwell
Treatment schedule	Once daily, five days per week, for 12 weeks, under supervision
Approximate material cost	Well below that of commercially available powered ankle orthoses; all components locally sourced

Note: DC, direct current. Cost is reported qualitatively because component prices varied over the fabrication period.

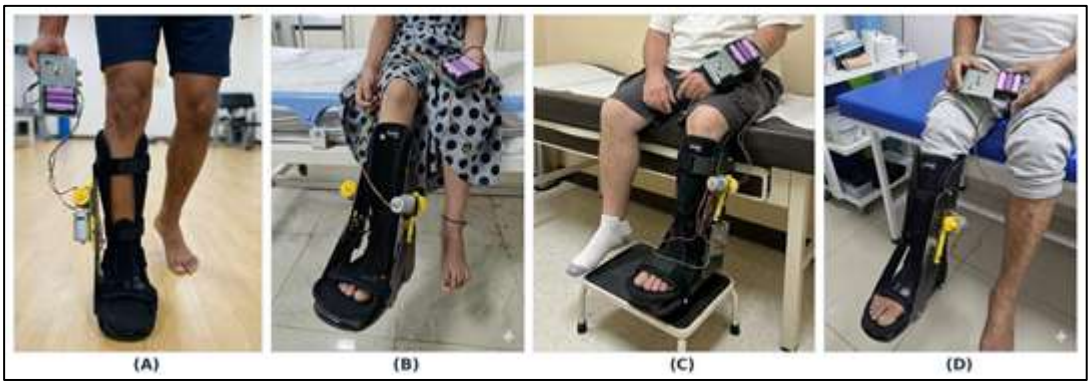

Figure 2. The fabricated device in clinical use.

(A) Anterolateral view showing the motor and cam-lever assembly mounted at the ankle axis of the rigid posterior-shell orthosis, with the battery pack on the proximal cuff. (B, C) Seated application during a supervised non-weight-bearing session. (D) Application with the limb supported on a footstool, the standard position used for treatment sessions in this study.

2.5 Intervention protocol

Participants in the intervention group received device therapy in addition to the standard physiotherapy programme. Each session was conducted in the rehabilitation unit under the supervision of a physiotherapist or trained ward staff member, with the limb supported and non-weight-bearing. The target dorsiflexion arc was titrated individually at the first session to the pain-free passive range determined by goniometry, and reviewed weekly; the device was never programmed to exceed the range achievable comfortably on manual examination. Each session lasted 20 to 30 minutes and was delivered once daily on five days per week for 12 weeks. Skin over the strap contact areas and bony prominences was inspected before and after every session. The device was applied only at rest; no ambulation, stair climbing or weight bearing was undertaken while it was mounted.

Both groups received the same conventional physiotherapy programme, comprising manual passive stretching of the gastrocnemius–soleus complex, progressive strengthening of the dorsiflexors and other lower-limb muscle groups, proprioceptive and balance training, and task-specific gait re-education. Control participants received this programme alone at the same frequency, so that the difference between arms was the addition of programmed

passive dorsiflexion rather than any difference in conventional therapy dose or in contact time with staff.

2.6 Outcome measures

Primary outcomes. Passive ankle dorsiflexion range of motion was measured with a standard universal goniometer with the knee extended and the subtalar joint held in neutral to prevent midfoot substitution, the axis aligned with the lateral malleolus, the stationary arm along the fibular shaft and the moving arm along the fifth metatarsal. Dorsiflexion beyond the neutral position was recorded as positive and residual equinus as negative. Goniometry remains the reference clinical method for joint excursion and is reliable when the technique is standardised and the same examiner repeats the measurement [32,33]. Plantarflexor tone was graded on the Modified Ashworth Scale from 0 to 4, assessed as resistance to brisk passive dorsiflexion with the knee extended; grade 1+ was recorded as 1.5 for analysis. The scale is the most widely used clinical instrument for spasticity and is sensitive to intervention-related change, although its ordinal structure and limited inter-rater agreement are recognised [34,35].

Secondary outcome. Overground gait performance was assessed with the 10-metre walk test, timed over a marked 10-metre level walkway with 2-metre acceleration and deceleration zones, at self-selected comfortable speed, using the patient's habitual walking aid and footwear but without the motorised device. The mean of two trials was recorded. Time in seconds was the primary expression of this outcome, with walking speed in metres per second derived for comparison with the literature. The test has excellent test–retest reliability in neurological populations and correlates closely with community ambulation [36,37].

Patient-reported and safety outcomes. At completion, intervention-group participants rated device comfort and usability on an 11-point numerical scale from 0 (intolerable) to 10 (entirely comfortable), and rated overall satisfaction on a four-level ordinal scale (excellent, good, fair, poor). Adverse events were solicited at every session and classified as skin irritation, pain or discomfort, muscle spasm, or other. An overall functional outcome was assigned at 12 weeks on a three-level ordinal scale by the treating team, integrating change in range of motion, tone and gait: significant improvement, moderate improvement, or minimal to no improvement.

All outcomes were recorded at baseline before the first treatment session and again at the end of the 12-week intervention period. No intermediate or post-intervention follow-up assessment was undertaken.

2.7 Sample size

The sample size was calculated for the primary outcome of ankle dorsiflexion range of motion. Assuming a between-group difference of 6 degrees, a common standard deviation of 5 degrees, 80% power and a two-sided alpha of 0.05, the two-sample comparison of means required 22 participants per arm. Allowing approximately 10% for attrition, 25 participants were recruited per arm, giving a total of 50. No dropouts occurred, and the achieved sample retained the planned power; the observed difference substantially exceeded the assumed effect.

2.8 Statistical analysis

Data were compiled in Microsoft Excel and analysed with IBM SPSS Statistics. Continuous variables are presented as mean ± standard deviation with 95% confidence intervals for mean change; categorical variables as frequency and percentage. Distributional assumptions were checked before parametric testing. Within-group change from baseline was tested with the paired t test, and ordinal Modified Ashworth Scale data were additionally examined with the Wilcoxon signed-rank test, which gave concordant results. Between-group comparisons of continuous variables used the independent-samples t test applied to change scores from baseline, which is the appropriate contrast for a parallel-group design and avoids the interpretive error of comparing a baseline value in one arm with a post-treatment value in the other. Post-treatment values are also reported for completeness. Categorical variables were compared with the Pearson chi-square test, or Fisher exact test where any expected cell count fell below five. The ordinal overall functional outcome was compared with the Mann–Whitney U test, which respects the ranking of categories and is more powerful than a chi-square test on the same data. Standardised effect sizes are reported as Cohen d. Responder analyses used prespecified clinically meaningful thresholds: a gain of 10 degrees or more in dorsiflexion, a reduction of at least one full Modified Ashworth grade, and an improvement of at least 10% in 10-metre walk time. Exploratory subgroup analyses by aetiology and correlations with baseline variables were performed with one-way analysis of variance and Pearson correlation respectively, and are interpreted as hypothesis-generating only. A two-sided p value below 0.05 was considered statistically significant. All 50 enrolled participants completed the protocol, so the analysed population is identical to the enrolled population and no imputation was required.

3. RESULTS

3.1 Participant flow and baseline characteristics

Sixty-one patients were screened, of whom 11 were excluded (seven did not meet eligibility criteria and four declined participation). Fifty were enrolled and allocated, 25 to each arm. All 50 completed the 12-week protocol and were analysed; there were no withdrawals, protocol violations or losses to follow-up. Participant flow is shown in Figure 3.

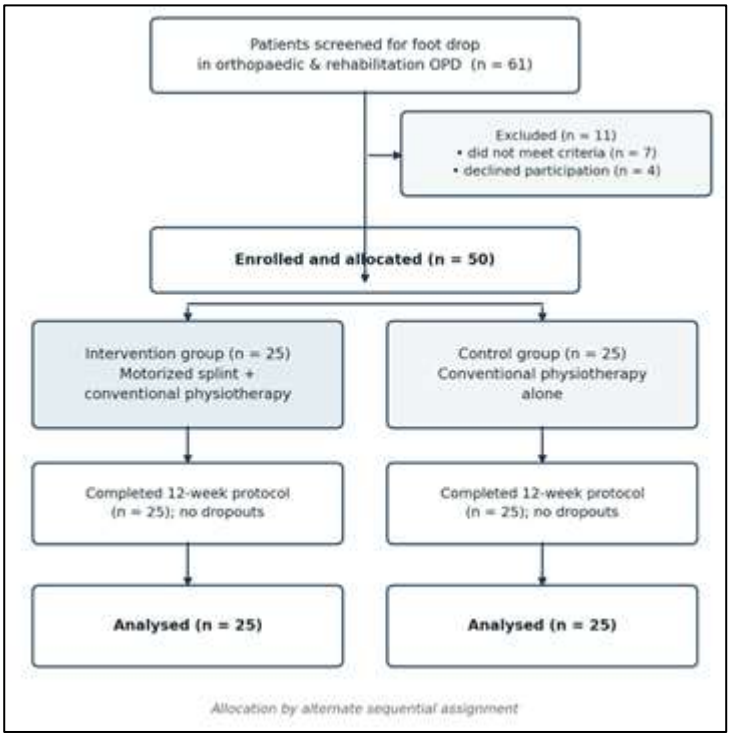

Figure 3. Flow of participants through the study. Allocation was by alternate sequential assignment; all enrolled participants completed the 12-week protocol and were included in the analysis.

Baseline demographic and clinical characteristics are presented in Table 2 and illustrated in Figure 4. The two arms were well matched. Mean age was 48.80 ± 8.07 years in the intervention group and 50.88 ± 7.58 years in controls (p = 0.352), with the majority of participants in both arms aged between 46 and 60 years. Men predominated in both arms (64% and 60% respectively; p = 1.000). The mean duration of foot drop was 5.40 ± 2.10 and 5.92 ± 1.89 months (p = 0.362), placing the cohort in the subacute to early chronic phase. Stroke was the commonest aetiology (56% and 52%), followed by peripheral nerve injury (28% and 32%) and other causes including radiculopathy and myopathy (16% in both arms; p = 0.949). Baseline dorsiflexion range of motion, Modified Ashworth Scale score and 10-metre walk time did not differ significantly between arms (p = 0.591, 0.627 and 0.213 respectively). Baseline range of motion was more variable in the control arm (standard deviation 3.96° versus 2.00°), reflecting two control participants who presented with a fixed equinus of −4° and −1.7° and one with an unusually preserved 14°.

Table 2. Baseline demographic and clinical characteristics of the two study groups

Characteristic	Intervention (n = 25)	Control (n = 25)	p value
Age, years (mean ± SD)	48.80 ± 8.07	50.88 ± 7.58	0.352
30–45 years, n (%)	6 (24)	4 (16)	0.730
46–60 years, n (%)	17 (68)	18 (72)	
>60 years, n (%)	2 (8)	3 (12)	
Male, n (%)	16 (64)	15 (60)	1.000
Female, n (%)	9 (36)	10 (40)	
Duration of foot drop, months	5.40 ± 2.10	5.92 ± 1.89	0.362
Aetiology: stroke, n (%)	14 (56)	13 (52)	0.949
Aetiology: peripheral nerve injury, n (%)	7 (28)	8 (32)	
Aetiology: other, n (%)	4 (16)	4 (16)	
Ankle dorsiflexion ROM, degrees	5.25 ± 2.00	4.77 ± 3.96	0.591
Modified Ashworth Scale score	2.10 ± 0.63	2.18 ± 0.45	0.627
10-metre walk test, seconds	18.03 ± 3.32	17.00 ± 2.33	0.213
Derived gait speed, m/s	0.58 ± 0.12	0.60 ± 0.08	0.459

Note: ROM, range of motion; SD, standard deviation. Continuous variables compared with the independent-samples t test; categorical variables with the chi-square test or Fisher exact test. Negative range-of-motion values denote residual fixed equinus.

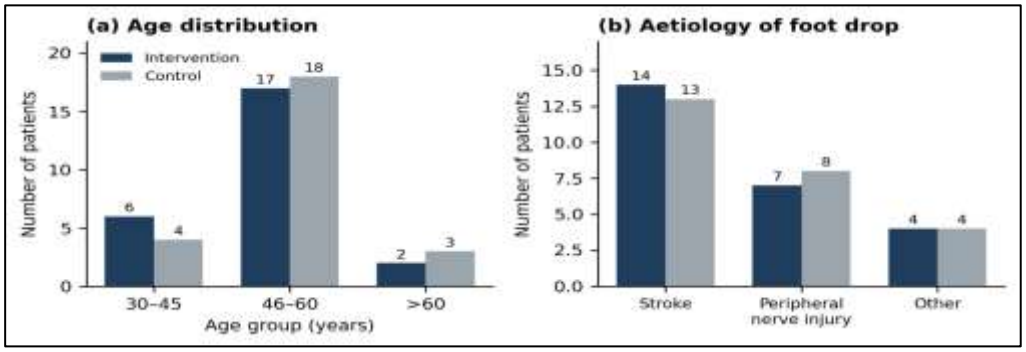

Figure 4. Baseline comparability of the two study arms. (a) Distribution by age category. (b) Distribution by aetiology of foot drop. Neither distribution differed significantly between groups (p = 0.730 and p = 0.949 respectively).

3.2 Within-group change over 12 weeks

Both arms improved significantly on all three outcomes, but the magnitude differed markedly (Table 3, Figure 5). In the intervention group, passive dorsiflexion range of motion increased from 5.25 ± 2.00° to 15.61 ± 3.88°, a mean gain of 10.36° (95% CI 8.98 to 11.74; t = 15.44, p < 0.001). Modified Ashworth Scale scores fell from 2.10 ± 0.63 to 1.24 ± 0.58, a mean reduction of 0.86 grades (95% CI 0.70 to 1.03; t = 10.80, p < 0.001; Wilcoxon p < 0.001). The 10-metre walk time shortened from 18.03 ± 3.32 s to 12.42 ± 4.39 s, a mean reduction of 5.61 s (95% CI 4.69 to 6.54; t = 12.50, p < 0.001), corresponding to an increase in mean walking speed from 0.58 to 0.94 m/s. The control group also improved on conventional physiotherapy alone. Range of motion rose from 4.77 ± 3.96° to 8.08 ± 4.40°, a gain of 3.31° (95% CI 2.22 to 4.41; p < 0.001); Modified Ashworth Scale scores fell by 0.31 grades (95% CI 0.23 to 0.39; p < 0.001); and 10-metre walk time shortened by 2.22 s (95% CI 1.51 to 2.92; p < 0.001), with mean speed rising from 0.60 to 0.70 m/s. The consistency of these within-group gains confirms that the conventional programme was itself effective and that the comparator was an active rather than a nominal one.

Table 3. Within-group change from baseline to 12 weeks in both study arms

Outcome	Baseline	12 weeks	Mean change	95% CI of change	p value
Intervention group (n = 25)					
Ankle dorsiflexion ROM, °	5.25 ± 2.00	15.61 ± 3.88	+10.36	8.98 to 11.74	<0.001
Modified Ashworth Scale	2.10 ± 0.63	1.24 ± 0.58	−0.86	−1.03 to −0.70	<0.001
10-metre walk test, s	18.03 ± 3.32	12.42 ± 4.39	−5.61	−6.54 to −4.69	<0.001
Gait speed, m/s	0.58 ± 0.12	0.94 ± 0.46	+0.37	0.22 to 0.51	<0.001
Control group (n = 25)					
Ankle dorsiflexion ROM, °	4.77 ± 3.96	8.08 ± 4.40	+3.31	2.22 to 4.41	<0.001
Modified Ashworth Scale	2.18 ± 0.45	1.87 ± 0.53	−0.31	−0.39 to −0.23	<0.001
10-metre walk test, s	17.00 ± 2.33	14.79 ± 2.93	−2.22	−2.92 to −1.51	<0.001
Gait speed, m/s	0.60 ± 0.08	0.70 ± 0.15	+0.11	0.06 to 0.15	<0.001

Note: Values are mean ± standard deviation unless stated. CI, confidence interval; ROM, range of motion. Paired t test; Modified Ashworth Scale results were confirmed by the Wilcoxon signed-rank test (p < 0.001 in both arms).

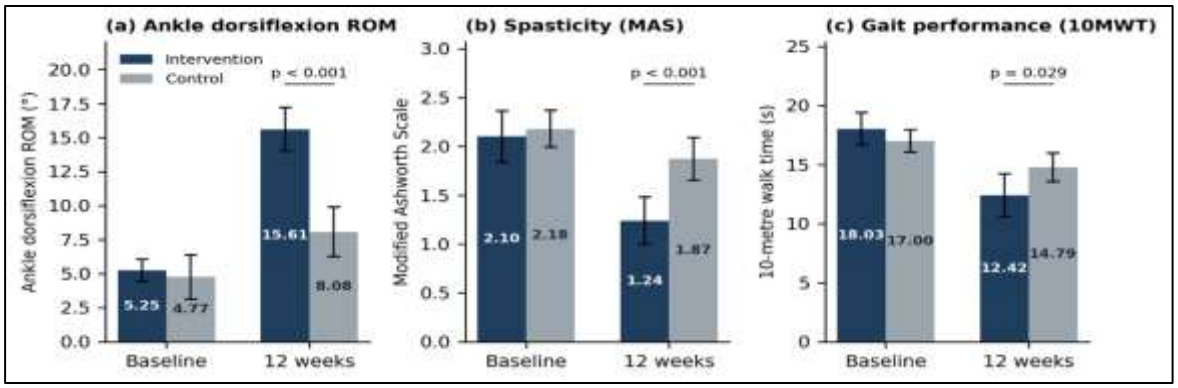

Figure 5. Outcomes at baseline and after 12 weeks in both arms.

(a) Passive ankle dorsiflexion range of motion. (b) Modified Ashworth Scale score for plantarflexor tone. (c) 10-metre walk time. Bars show group means with 95% confidence intervals; p values refer to the between-group

comparison of post-treatment values.

3.3 Between-group comparison

The between-group contrast, expressed as the difference in change from baseline, favoured the intervention on every outcome (Table 4, Figure 6). The additional dorsiflexion gain attributable to the motorised splint was 7.05° (95% CI 5.33 to 8.77; t = 8.24, p < 0.001), with a standardised effect size of 2.33, which is very large by conventional interpretation. The additional reduction in Modified Ashworth Scale score was 0.56 grades (95% CI 0.38 to 0.74; p < 0.001; d = 1.77) and the additional reduction in 10-metre walk time was 3.40 s (95% CI 2.26 to 4.53; p < 0.001; d = 1.70), equivalent to an additional gain of 0.26 m/s in walking speed (95% CI 0.11 to 0.41; p = 0.001).

Post-treatment values were correspondingly divergent: dorsiflexion 15.61 ± 3.88° versus 8.08 ± 4.40° (p < 0.001), Modified Ashworth Scale 1.24 ± 0.58 versus 1.87 ± 0.53 (p < 0.001) and 10-metre walk time 12.42 ± 4.39 s versus 14.79 ± 2.93 s (p = 0.029). The wider standard deviation of walk time in the intervention arm at 12 weeks reflects a subgroup of participants who improved dramatically alongside two who improved little, and is discussed below.

Table 4. Between-group comparison of post-treatment values and of change from baseline at 12 weeks

Outcome	Intervention (n = 25)	Control (n = 25)	Mean difference	95% CI	p value	d
Post-treatment values						
Dorsiflexion ROM, °	15.61 ± 3.88	8.08 ± 4.40	+7.53	5.17 to 9.89	<0.001	1.82
Modified Ashworth Scale	1.24 ± 0.58	1.87 ± 0.53	−0.63	−0.95 to −0.32	<0.001	1.14
10-metre walk test, s	12.42 ± 4.39	14.79 ± 2.93	−2.37	−4.49 to −0.25	0.029	0.64
Change from baseline						
Dorsiflexion ROM, °	+10.36 ± 3.35	+3.31 ± 2.65	+7.05	5.33 to 8.77	<0.001	2.33
Modified Ashworth Scale	−0.86 ± 0.40	−0.31 ± 0.20	−0.56	−0.74 to −0.38	<0.001	1.77
10-metre walk test, s	−5.61 ± 2.24	−2.22 ± 1.70	−3.40	−4.53 to −2.26	<0.001	1.70
Gait speed, m/s	+0.37 ± 0.35	+0.11 ± 0.10	+0.26	0.11 to 0.41	0.001	0.99

Note: Mean difference is intervention minus control; d is Cohen standardised effect size. Independent-samples t test. CI, confidence interval; ROM, range of motion. The change-from-baseline contrast is the primary between-group analysis.

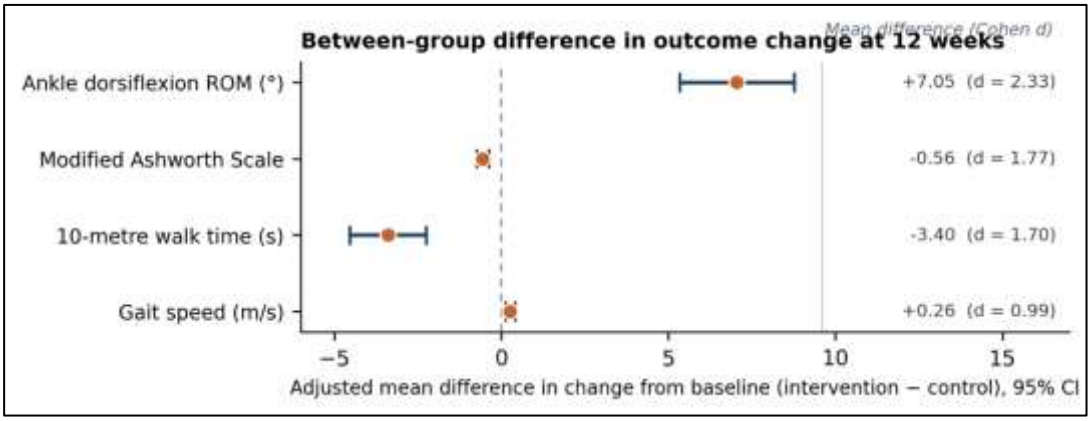

Figure 6. Between-group differences in change from baseline at 12 weeks, with 95% confidence intervals and standardised effect sizes.

Every interval excludes the null value. Because a favourable result is an increase for range of motion and gait speed but a decrease for Modified Ashworth Scale score and walk time, the sign of each estimate should be read against the outcome concerned.

3.4 Responder analysis

The threshold analyses show that the difference between arms was categorical rather than merely a shift in group means (Table 5, Figure 7a). A dorsiflexion gain of at least 10° was achieved by 16 of 25 intervention participants (64%) and by none of the 25 controls (p < 0.001). A reduction of at least one full Modified Ashworth grade occurred in 12 intervention participants (48%) and again in no control participant (p < 0.001). Improvement of at least 10% in 10-metre walk time was reached by 24 of 25 in the intervention arm (96%) versus 14 of 25 controls (56%; p = 0.002). Perhaps the most clinically meaningful figure is the proportion attaining at least 10° of passive dorsiflexion at 12 weeks, a range broadly sufficient for unimpeded swing-phase clearance: 22 of 25 (88%) in the intervention arm compared with 9 of 25 (36%) in controls (p < 0.001).

Table 5. Responder analysis using prespecified clinically meaningful thresholds

Threshold achieved at 12 weeks	Intervention n (%)	Control n (%)	p value
Gain in dorsiflexion ROM ≥ 10°	16 (64)	0 (0)	<0.001
Reduction in Modified Ashworth Scale ≥ 1 grade	12 (48)	0 (0)	<0.001
Improvement in 10-metre walk time ≥ 10%	24 (96)	14 (56)	0.002
Absolute dorsiflexion ROM ≥ 10° at 12 weeks	22 (88)	9 (36)	<0.001

Note: Fisher exact test throughout. ROM, range of motion.

3.5 Overall functional outcome

The ordinal overall functional grading assigned at 12 weeks favoured the intervention arm (Table 6, Figure 7b). Significant improvement was recorded in 16 intervention participants (64%) compared with 9 controls (36%); moderate improvement in 7 (28%) versus 10 (40%); and minimal or no improvement in 2 (8%) versus 6 (24%). The distributions differed significantly on the Mann–Whitney U test ($p = 0.037$), which is the appropriate test for an ordered categorical outcome. A three-by-three chi-square test on the same table did not reach significance ($\chi^2 = 4.49$, $p = 0.106$), as expected when the ranking of categories is discarded and expected cell counts are small; this discordance is reported transparently rather than selectively.

Table 6. Overall functional outcome at 12 weeks

Overall functional outcome	Intervention n (%)	Control n (%)	p value
Significant improvement	16 (64)	9 (36)	0.037
Moderate improvement	7 (28)	10 (40)	
Minimal or no improvement	2 (8)	6 (24)	

Note: Mann–Whitney U test on the ordered three-level outcome. A chi-square test on the same table gives $\chi^2 = 4.49$, $p = 0.106$.

3.6 Comfort, usability and satisfaction

Device tolerability was high (Table 7, Figure 7c). The mean comfort and usability score was 8.37 ± 1.26 out of 10, with individual scores ranging from 6.1 to 10.9 on the recording scale used. Overall satisfaction was rated excellent by 22 of 25 participants (88%) and fair by 3 (12%); no participant rated the experience poor. All three participants who gave a fair rating had experienced an adverse event, and two of those three were also the only participants classified as showing minimal improvement, suggesting that satisfaction tracked both tolerability and perceived benefit. Comfort score was not significantly correlated with the magnitude of dorsiflexion gain ($r = -0.34$, $p = 0.095$), indicating that participants did not simply rate the device highly because it worked well for them.

Table 7. Patient-reported comfort, usability and satisfaction in the intervention group (n = 25)

Patient-reported measure	Value	Range or n (%)
Comfort and usability score (0–10)	8.37 ± 1.26	6.1 to 10.9
Overall satisfaction: excellent	—	22 (88)
Overall satisfaction: good	—	0 (0)
Overall satisfaction: fair	—	3 (12)
Overall satisfaction: poor	—	0 (0)
Sessions completed as scheduled	100%	25 (100)
Participants requesting discontinuation	—	0 (0)

Note: Comfort score is mean ± standard deviation. Satisfaction was recorded on a four-level ordinal scale at the end of the intervention period.

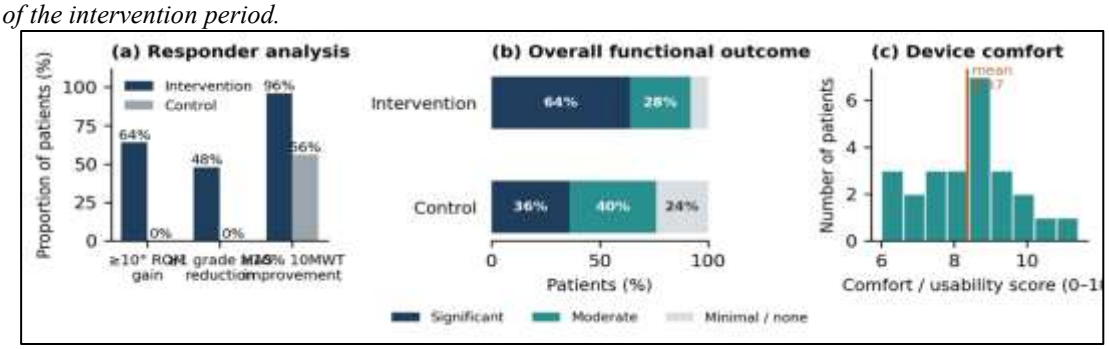

Figure 7. Clinical response, functional outcome and device tolerability.

(a) Proportion of patients reaching prespecified clinically meaningful thresholds in each arm. (b) Distribution of the ordinal overall functional outcome (Mann–Whitney U, p = 0.037). (c) Distribution of patient-rated comfort and usability scores in the intervention group, with the group mean indicated.

3.7 Safety and adverse events

Adverse events were infrequent, minor and self-limiting in both arms (Table 8). In the intervention group, mild skin irritation at a strap contact area occurred in 2 participants (8%), transient post-session pain or discomfort in 3 (12%) and a self-limiting muscle spasm in 1 (4%). Corresponding figures in the control group were 2 (8%), 2 (8%) and 2 (8%). Because events clustered within individuals, the number of participants experiencing any adverse event was 3 (12%) in the intervention arm and 2 (8%) in controls, a difference that was not statistically significant (p = 1.000). All events resolved with padding adjustment, temporary reduction of the programmed dorsiflexion arc or simple analgesia. No participant developed a pressure ulcer, ligament injury, thromboembolic event or nerve irritation; no device malfunction occurred; the torque limiter and emergency stop were never activated in an unplanned manner; and no participant withdrew for any reason.

Table 8. Adverse events over the 12-week intervention period

Adverse event	Intervention n (%)	Control n (%)	p value
Skin irritation at contact area	2 (8)	2 (8)	1.000
Transient pain or discomfort	3 (12)	2 (8)	1.000
Muscle spasm	1 (4)	2 (8)	1.000
Any adverse event (per participant)	3 (12)	2 (8)	1.000
No adverse event	22 (88)	23 (92)	1.000
Serious adverse event	0 (0)	0 (0)	—
Withdrawal due to adverse event	0 (0)	0 (0)	—

Note: Fisher exact test. Individual event categories are not mutually exclusive; three intervention participants and two control participants accounted for all recorded events.

3.8 Exploratory subgroup analysis

Dorsiflexion gain in the intervention arm was numerically greater in participants with peripheral nerve injury (12.43 ± 3.58°, n = 7) than in those with stroke (9.59 ± 3.29°, n = 14) or other aetiologies (9.45 ± 1.90°, n = 4), but the difference did not reach significance (one-way analysis of variance p = 0.158; stroke versus peripheral nerve injury p = 0.085). A similar pattern was seen in the control arm. Gain was not correlated with duration of foot drop (r = −0.12, p = 0.562), age (r = −0.25, p = 0.230) or baseline range of motion (r = −0.01, p = 0.947), suggesting that within the range studied the device performed comparably across the cohort. These analyses are underpowered and are presented only to inform the design of future trials.

4. DISCUSSION

4.1 Principal findings

Adding programmed passive dorsiflexion to conventional physiotherapy tripled the ankle mobility gained over 12 weeks, from 3.31° to 10.36°, and produced a between-group difference of 7.05° with a standardised effect size above two. Corresponding advantages were seen in plantarflexor tone and in overground gait speed. The responder analysis is arguably more informative than the mean differences: not one control participant achieved a 10° gain in dorsiflexion or a full-grade reduction in Modified Ashworth score, whereas 64% and 48% of intervention participants respectively did. The intervention therefore did not merely accelerate the same trajectory; it moved a substantial proportion of patients across thresholds that conventional therapy alone did not reach in any participant in this cohort.

The clinical significance of a 10° arc deserves emphasis. Normal walking requires roughly 10° of dorsiflexion in terminal stance and sufficient swing-phase dorsiflexion to clear the floor. At 12 weeks, 88% of intervention participants had reached at least 10° of passive dorsiflexion compared with 36% of controls. Whether or not active dorsiflexor power recovers, preserving that passive arc keeps the ankle out of fixed equinus, keeps orthotic fitting straightforward, and keeps tendon transfer or lengthening off the surgical agenda. For a device costing a fraction of a commercial powered orthosis, that is a substantial return.

4.2 Mechanistic interpretation

Three plausible mechanisms operate together. The first is mechanical. Repeated end-range excursion imposes cyclical tensile loading on the gastrocnemius–soleus complex and posterior capsule, and connective tissue responds to such loading with viscoelastic creep and, over weeks, with genuine remodelling of collagen alignment and sarcomere number. Manual stretching applies the same stimulus but cannot match a motorised device for repetition count or consistency of amplitude and hold. The second is neurophysiological. Slow, repeated passive

stretch attenuates the stretch-reflex response through presynaptic inhibition and reduced motoneuron excitability, an effect documented after continuous passive motion of the ankle in spastic cerebral palsy, where soleus hypertonia fell and passive dorsiflexion increased [16]. The parallel reduction in Modified Ashworth Scale score in our intervention arm is consistent with this. The third mechanism is permissive rather than direct: an ankle that moves more freely and resists less allows more productive gait re-education, so part of the observed gain in walking speed probably reflects better conventional therapy rather than the device acting on gait itself. This last point matters because our device was never worn during walking; the entire gait benefit must have been mediated through improved joint mechanics and tone.

The magnitude of the walking-speed change also invites caution. Mean speed in the intervention arm rose from 0.58 to 0.94 m/s, crossing the threshold conventionally associated with limited community ambulation, but the post-treatment standard deviation widened to 0.46 m/s. Inspection of individual data shows a genuinely bimodal response: most participants improved substantially while two improved marginally, and one recorded a slightly slower time at 12 weeks than at baseline. Group means alone would obscure this heterogeneity.

4.3 Comparison with existing literature

Our findings sit comfortably within the powered-ankle literature while occupying a distinct niche within it. Yoo and colleagues randomised stroke survivors to a motorised ankle stretching device or conventional care and reported superior gains in ankle range of motion, balance and gait that persisted at one month, with the control arm improving minimally [9]. The direction and pattern of our results replicate theirs, in a mixed-aetiology cohort and over a longer intervention period.

Yeung and colleagues delivered robot-assisted gait training with active dorsiflexion assistance to chronic stroke patients over approximately 20 sessions and found superior improvements in gait independence, walking speed, motor recovery and weight-bearing confidence compared with a sham condition, in which swing-phase dorsiflexion actually deteriorated [8]. Their intervention acted during gait; ours acted at rest. That both approaches improved walking speed suggests the two mechanisms are complementary rather than competing, and a device combining rest-phase mobilisation with swing-phase assistance is an obvious next step.

Shin and colleagues showed with a pneumatically powered orthosis that assisted dorsiflexion increases mean ankle angle across the gait cycle and reduces lower-limb asymmetry in hemiparetic foot drop, although hip kinematics changed little [4]. Lee and colleagues achieved forefoot dorsiflexion with a shape-memory-alloy actuator active for less than half the gait cycle, demonstrating that useful assistance need not be energetically expensive [12]. Adiputra and colleagues reported reliable foot clearance and positive patient feedback from a robotic orthosis individualised to patient preference, and recommended weight reduction and velocity control as development priorities [13]. Our device is mechanically simpler than all three and correspondingly cheaper, at the cost of providing no assistance during ambulation. Matsuda and colleagues restored trainable dorsiflexion in common peroneal nerve palsy using a hybrid assistive limb, illustrating that powered ankle training is applicable to lower motor neuron as well as upper motor neuron foot drop [6] — a point consistent with the numerically greater dorsiflexion gain we observed in our peripheral nerve injury subgroup. Asín and colleagues further showed that a motorised ankle–foot orthosis can serve simultaneously as an assessment and a treatment platform, with graded assistance producing dose-dependent increases in ankle excursion and angular velocity and measurable change in tibialis anterior and gastrocnemius activation [21].

The comparison with functional electrical stimulation is instructive. Kluding and colleagues randomised 197 chronic stroke patients to peroneal nerve stimulation or a conventional orthosis with dose-matched physiotherapy, and found comparable improvements in comfortable gait speed in both arms, with significantly greater user satisfaction in the stimulation group [3]. Two points follow. First, the within-group gait improvement we observed in our control arm is consistent with the effect of physiotherapy contact time itself, which their dose-matched design isolated. Second, neither arm of their trial addressed passive range of motion or tone, which were our primary outcomes; stimulation and static bracing substitute for lost dorsiflexion during walking, whereas passive mobilisation preserves the joint's capacity to be dorsiflexed at all. These are different therapeutic objectives, and a patient with subacute foot drop arguably needs both. A related observation comes from Lee and colleagues, who found that a flexible wire-based orthosis permitting a degree of dorsiflexion excursion improved static postural control significantly, whereas a rigid conventional orthosis conferred no advantage over barefoot standing [19]. Permitting and assisting motion, rather than merely preventing plantarflexion, appears to be what generates functional benefit.

Evidence from paediatric practice supports the durability of the mechanism we invoke. Chuang and colleagues reduced soleus hypertonia and increased passive dorsiflexion with four weeks of ankle continuous passive motion in cerebral palsy [16]; Lee and colleagues improved active dorsiflexion range and dorsiflexor strength with robotic ankle training [15]; and Chen and colleagues showed that home-delivered robotic ankle training matched laboratory-based delivery on clinical and biomechanical outcomes [17]. That last finding is directly relevant to the next stage of development of our device, since a supervised in-hospital protocol such as ours captures only a fraction of the achievable dose. The adult evidence points the same way: a proof-of-concept randomised trial of foot and ankle mobilisation combined with home stretching in diabetic peripheral neuropathy improved both ankle mobility and postural control measures [18]. Systematic reviews of wearable ankle robots and lower-limb exoskeletons reach the same overall conclusion of benefit while repeatedly noting small samples, heterogeneous

protocols and short follow-up [11,20,22,23] — limitations our study shares.

4.4 Clinical and health-system implications

Three features make this device relevant to Indian tertiary practice. It is built from locally available components on a commercial orthotic base, so unit cost is a small fraction of that of an imported powered orthosis. It requires no engineering expertise to apply, and in our study was operated by physiotherapists and trained ward staff after brief instruction. And because therapy is delivered at rest, it can be given to patients who cannot yet safely bear weight, including those in the early post-stroke or post-repair period when contracture risk is highest and conventional gait-based devices are unusable.

The device should be positioned as an adjunct, not a substitute. Every participant in both arms received the full conventional programme, and the control arm improved significantly on that programme alone. The appropriate clinical claim is that programmed passive dorsiflexion adds mobility and tone benefit to good physiotherapy, particularly where supervised therapist time is scarce and the alternative to the device is an ankle that does not move between visits.

4.5 Strengths and limitations

The strengths of this study are a prospectively registered protocol with ethics approval, complete follow-up of all 50 enrolled participants with no attrition, an actively treated comparator receiving matched conventional therapy and contact time, prespecified responder thresholds reported alongside mean differences, and transparent reporting of a discordance between two statistical tests of the same ordinal outcome.

The limitations are substantial and constrain the strength of inference. Allocation was by alternate sequential assignment rather than concealed randomisation, which is susceptible to selection bias, although the closely matched baseline profiles argue against material imbalance. Neither participants nor assessors were blinded; for goniometry and, more importantly, for the subjectively assigned ordinal functional outcome, this is a real risk of measurement bias in the direction of the hypothesis, and the borderline p value for that outcome should be read with this in mind. The Modified Ashworth Scale is ordinal with recognised inter-rater limitations, and treating it as continuous in a t test is a simplification, mitigated here by concordant non-parametric testing. The study was conducted in a single centre with 25 participants per arm, limiting generalisability and precluding reliable subgroup inference. Outcome assessment ended with the intervention, so we cannot say whether gains persist after device withdrawal — the question that matters most for a contracture-prevention rationale. We used clinical measures only, without three-dimensional gait analysis, electromyography, foot-clearance or symmetry measurement, or dorsiflexor strength dynamometry, so the mechanism of the walking-speed gain remains inferred rather than demonstrated. Finally, the device was applied only in supervised, non-weight-bearing sessions, so nothing in these data speaks to home use, unsupervised safety or performance during actual ambulation.

4.6 Directions for future work

The obvious next study is an assessor-blinded, concealed-randomised multicentre trial of at least 100 participants, with follow-up extended to 6 or 12 months after the intervention ends, to determine whether the acquired range of motion is retained and whether the incidence of fixed equinus and of subsequent tendon-lengthening surgery is reduced. Outcome measures should include instrumented gait analysis with foot-clearance and symmetry indices, surface electromyography of the tibialis anterior and triceps surae, dorsiflexor dynamometry, a validated balance measure and a quality-of-life instrument. In parallel, device development should pursue weight reduction and a lighter portable configuration suitable for validated home use with remote adherence monitoring, an ambulatory mode providing swing-phase assistance in addition to rest-phase mobilisation, adaptive control that modulates velocity and amplitude in response to measured resistance [14,27], integration with telerehabilitation platforms so that remote supervision and adherence monitoring become possible [26], eventual combination with emerging neuromodulatory approaches to gait recovery [38], and a formal cost-effectiveness analysis against static orthoses, functional electrical stimulation and commercial ankle robots.

5. CONCLUSION

In this prospective comparative study of 50 adults with subacute to early chronic foot drop, adding an in-house automated motorised splint delivering programmed passive dorsiflexion to conventional physiotherapy produced substantially greater improvement in passive ankle dorsiflexion range of motion, plantarflexor tone and overground walking speed than conventional physiotherapy alone over 12 weeks. Effect sizes were large, and clinically meaningful thresholds of improvement were reached by a majority of intervention participants and by no control participant. The device was well tolerated, generated only minor and self-limiting adverse events at a rate indistinguishable from the comparator arm, and was rated highly for comfort and usability. Given its low fabrication cost, mechanical simplicity and applicability to patients who cannot yet bear weight, programmed passive dorsiflexion merits evaluation as a routine adjunct in foot-drop rehabilitation. The present findings should be regarded as promising but preliminary; a randomised, assessor-blinded multicentre trial with instrumented gait analysis and post-intervention follow-up is required before the approach can be recommended for general adoption.

DECLARATIONS

Ethics approval and consent to participate. Approved by the Saveetha Medical College and Hospital Institutional Ethics Committee (008/09/2025/IEC/SMCH, 26 September 2025; registration ECR/724/Inst/TN/2015/RR-24). Written informed consent was obtained from every participant using a bilingual English and Tamil consent document.

Trial registration. Clinical Trials Registry – India, CTRI/2026/03/106824, registered prospectively on 24 March 2026.

Consent for publication. Participants photographed for Figure 2 gave written consent for the use of images in which they are not identifiable.

Availability of data. The anonymised participant-level dataset underlying all analyses is available from the corresponding author on reasonable request.

Funding. No external, institutional or commercial funding was received. The device was fabricated at the authors' own cost.

Competing interests. The authors declare no financial or non-financial competing interests. No patent covering the device had been granted at the time of submission.

Authors' contributions. AR conceived the study, designed and fabricated the device, recruited participants, collected and analysed the data and drafted the manuscript. BJV supervised the study, contributed to device design and revised the manuscript critically. VV assisted with clinical assessment and data collection. NKR provided departmental oversight and critical revision. All authors read and approved the final manuscript and accept accountability for its content.

Acknowledgements. The authors thank the physiotherapy and ward staff of the Department of Orthopaedics for their assistance with supervised sessions, the institutional device laboratory for support with fabrication, and above all the participants, without whose cooperation the study could not have been undertaken.

REFERENCES

1. Alnajjar F, Zaier R, Khalid S, Gochoo M. Trends and technologies in rehabilitation of foot drop: a systematic review. Expert Rev Med Devices. 2021;18(1):31–46.
2. Dunning K, O'Dell MW, Kluding P, McBride K. Peroneal stimulation for foot drop after stroke: a systematic review. Am J Phys Med Rehabil. 2015;94(8):649–64.
3. Kluding PM, Dunning K, O'Dell MW, Wu SS, Ginosian J, Feld J, et al. Foot drop stimulation versus ankle foot orthosis after stroke: 30-week outcomes. Stroke. 2013;44(6):1660–9.
4. Shin W, Nam D, Ahn B, Kim SJ, Lee DY, Kwon S, et al. Ankle dorsiflexion assistance of patients with foot drop using a powered ankle-foot orthosis to improve the gait asymmetry. J Neuroeng Rehabil. 2023;20(1):140.
5. Tsuchiyama K, Mukaino M, Ohtsuka K, Matsuda F, Tanikawa H, Yamada J, et al. Effects of ankle-foot orthoses on the stability of post-stroke hemiparetic gait. Eur J Phys Rehabil Med. 2022;58(3):352–60.
6. Matsuda D, Kubota S, Akinaga Y, Yasunaga Y, Sankai Y, Yamazaki M. Ankle dorsiflexion training with a newly developed Hybrid Assistive Limb for a patient with foot drop caused by common peroneal nerve palsy: a case report. J Phys Ther Sci. 2022;34(5):410–5.
7. He W, Yaning L, Shaohong Y. Effect of electrical stimulation in the treatment of patients with foot drop after stroke: a systematic review and network meta-analysis. J Stroke Cerebrovasc Dis. 2025;34(5):108279.
8. Yeung LF, Ockenfeld C, Pang MK, Wai HW, Soo OY, Li SW, et al. Randomized controlled trial of robot-assisted gait training with dorsiflexion assistance on chronic stroke patients wearing ankle-foot-orthosis. J Neuroeng Rehabil. 2018;15(1):51.
9. Yoo D, Son Y, Kim DH, Seo KH, Lee BC. Technology-assisted ankle rehabilitation improves balance and gait performance in stroke survivors: a randomized controlled study with 1-month follow-up. IEEE Trans Neural Syst Rehabil Eng. 2018;26(12):2315–23.
10. Zhang Q, Wang Y, Zhou M, Li D, Yan J, Liu Q, et al. Ankle rehabilitation robot training for stroke patients with foot drop: optimizing intensity and frequency. NeuroRehabilitation. 2023;53(4):567–76.
11. Shi B, Chen X, Yue Z, Yin S, Weng Q, Zhang X, et al. Wearable ankle robots in post-stroke rehabilitation of gait: a systematic review. Front Neurorobot. 2019;13:63.
12. Lee B, Park JS, Park S, Kim CH. Ankle foot orthosis for patients with drop foot using shape-memory-alloy actuators. Int J Precis Eng Manuf. 2023;24(11):2057–72.
13. Adiputra D, Asfari U, Abdul Rahman MA, Harun AM. Immediate effect evaluation of a robotic ankle–foot orthosis with customized algorithm for a foot drop patient: a quantitative and qualitative case report. Int J Environ Res Public Health. 2023;20(4):3745.
14. Arnez-Paniagua V, Rifai H, Mohammed S, Amirat Y. Adaptive control of an actuated ankle foot orthosis for

foot-drop correction. IFAC-PapersOnLine. 2017;50(1):1384–9.
15. Lee Y, Gaebler-Spira D, Zhang LQ. Robotic ankle training improves sensorimotor functions in children with cerebral palsy — a pilot study. J Clin Med. 2023;12(4):1475.
16. Chuang LL, Chuang YF, Ju YJ, Hsu AL, Chen CL, Wong AM, et al. Effects of ankle continuous passive motion on soleus hypertonia in individuals with cerebral palsy: a case series. Biomed J. 2022;45(4):708–16.
17. Chen K, Wu YN, Ren Y, Liu L, Gaebler-Spira D, Tankard K, et al. Home-based versus laboratory-based robotic ankle training for children with cerebral palsy: a pilot randomized comparative trial. Arch Phys Med Rehabil. 2016;97(8):1237–43.
18. Lepesis V, Paton J, Rickard A, Latour JM, Marsden J. Effects of foot and ankle mobilisations combined with home stretches in people with diabetic peripheral neuropathy: a proof-of-concept RCT. J Foot Ankle Res. 2023;16(1):88.
19. Lee JH, Choi IR, Choi HS. Immediate effects of ankle-foot orthosis using wire on static balance of patients with stroke with foot drop: a cross-over study. Healthcare (Basel). 2020;8(2):116.
20. Shah MN, Basah SN, Basaruddin KS, Takemura H, Yeap EJ, Lim CC. Ankle injury rehabilitation robot (AIRR): review of strengths and opportunities based on a SWOT analysis. Machines. 2022;10(11):1031.
21. Asín G, Barroso FA, Moreno JC, Pons JL. Assessment of the suitability of the motorized ankle-foot orthosis as a diagnostic and rehabilitation tool for gait. Proc Int Congr Neurotechnol Electron Inform. 2013:161–6.
22. Sarajchi M, Al-Hares MK, Sirlantzis K. Wearable lower-limb exoskeleton for children with cerebral palsy: a systematic review of mechanical design, actuation type, control strategy, and clinical evaluation. IEEE Trans Neural Syst Rehabil Eng. 2021;29:2695–720.
23. Liu Y, Lu W, Deng Y, Wang S, Hou Y, Zeng D. Configuration design of ankle rehabilitation robots: a systematic review and future prospects. J Neuroeng Rehabil. 2025;22(1):244.
24. Lingampally PK, Ramanathan KC, Shanmugam R, Cepova L, Salunkhe S. Wearable assistive rehabilitation robotic devices — a comprehensive review. Machines. 2024;12(6):415.
25. Morris L, Diteesawat RS, Rahman N, Turton A, Cramp M, Rossiter J. The state of the art of soft robotics to assist mobility: a review of physiotherapist and patient identified limitations of current lower-limb exoskeletons and the potential soft-robotic solutions. J Neuroeng Rehabil. 2023;20(1):18.