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Ankle-Foot-Orthosis "Hermes" Compensates Pathological Ankle Stiffness of Chronic Stroke—A Proof of Concept

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***Abstract*— Individuals with an upper motor neuron syndrome, e.g., stroke survivors, may have a pathological increase of passive ankle stiffness due to spasticity, that impairs ankle function and activities such as walking. To improve mobility, walking aids such as ankle-foot orthoses and orthopaedic shoes are prescribed. However, these walking aids generally limit the range of motion (ROM) of the foot and may therewith negatively influence activities that require a larger ROM. Here we present a new ankle-foot orthosis "Hermes", and its first experimental results from four hemiparetic chronic stroke patients. Hermes was designed to facilitate active ankle dorsiflexion by mechanically compensating the passive ankle stiffness using a negative-stiffness mechanism. Four levels of the Hermes' stiffness compensation (0%, 35%, 70% and 100%) were applied to evaluate active ROM in a robotic ankle manipulator and to test walking feasibility on an instrumented treadmill, in a single session. The robotic tests showed that Hermes successfully compensated the ankle joint stiffness in all four patients and improved the active dorsiflexion ROM in three patients. Three patients were able to walk with Hermes at one or more Hermes' stiffness compensation levels and without reducing their preferred walking speeds compared to those with their own walking aids. Despite a small sample size, the results show that Hermes holds great promise to support voluntary ankle function and to benefit walking and daily activities.**

***Index Terms*— Equinus deformity, joint range of motion, muscle spasticity, orthotic devices, stroke. *Clinical and Translational Impact Statement*—In this early clinical research study, the Hermes ankle-foot orthosis increased the voluntary ankle dorsiflexion by compensating ankle stiffness of chronic ambulant stroke patients with spastic hemiparesis and equinus foot.**

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This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the Leiden-Den Haag-Delft Medical Ethical Committee (METC-LDD) under Approval No. 186 NL64640.058.19.

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I. Introduction

INDIVIDUALS with an upper motor-neuron syndrome (UMNS), e.g., stroke survivors, patients with a cerebral palsy (CP), multiple sclerosis or spinal cord lesion may suffer from spastic paresis and a pes equinus or equinovarus [1]. This is an abnormal plantarflexed foot position characterized by increased internal plantarflexion (PF) torque and increased stiffness due to hypertonia (neural) and structural changes (non-neural) of the ankle joint muscles [2], [3], [4]. Increased stiffness of the plantarflexor muscles reduces active dorsiflexion (DF) and ankle range of motion (ROM), impairing the ankle function and affecting individuals with UMNS at activity level, e.g., during walking and other activities of daily living [1], [5]. Ankle-foot-orthoses (AFOs) and orthopaedic shoes are clinically prescribed walking aids that improve walking and reduce energy cost by stabilizing the base of support during stance and ensuring foot clearance during swing [2], [6]. AFOs and orthopaedic shoes are typically

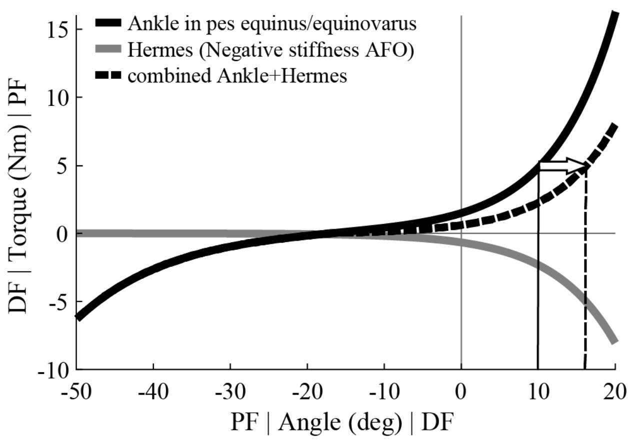

Fig. 1. The passive torque-angle characteristic of the ankle in pes equinus and equinovarus is described as the resultant of a positive and negative exponential (black, solid). The positive torque is the (internal) passive PF torque corresponding to the PF muscles' resistance to dorsiflexion, here called passive ankle stiffness. The Hermes compensates for the ankle stiffness with an external negative torque (grey) according to (1), resulting in a combined Ankle+Hermes torque-angle characteristic and stiffness (black, dashed). Relative to the pes equinus and equinovarus ankle stiffness, this combined Ankle+Hermes torque is reduced towards normal and allows a larger ROM (arrow).

passive devices that apply external DF torque within the PF range to regain a neutral ankle joint position, but unfortunately at the cost of restricting the ankle ROM [7], [8], [9], [10]. Mildly impaired children with CP benefited from AFOs with a larger ROM than typical high-stiffness AFOs during activities such as climbing stairs, moving from sitting to standing, or controlling perturbed balance [11], [12]. Hence, a current challenge in gait rehabilitation of patients with UMNS is to improve the ankle ROM, decrease ankle joint stiffness, and support ankle function [2], [13].

We have developed a hinged AFO called "Hermes" which has the purpose of increasing the ankle ROM in patients with UMNS by mechanically compensating for the increased non-neural ankle stiffness originating from the plantarflexor muscle tissues [14], here called passive ankle stiffness. Hermes mechanical compensation aims to counteract the internal plantar flexion torque to support voluntary dorsiflexion of the ankle joint, thus improving walking and activities negatively affected by ankle restriction in current AFOs and orthopaedic shoes ROM. Hermes is a one degree-of-freedom non-powered AFO, compliant for dorsiflexion-plantarflexion, and stiff for inversion-eversion and medio-lateral rotation.

The "Hermes" consists of an orthotic foot-part and calf-part integrated with a negative-stiffness mechanism designed by InteSpring BV. This mechanism comprises a spring-loaded cam-follower that applies an exponential external dorsiflexion torque opposing the pathologically increased internal plantarflexion torque (Fig. 1). Our previous design Rodriguez et al. [14] left points for improvement on maximum torque, hysteresis, and weight.

In this study, we first evaluated the required improvements of the Hermes with respect to the previous design [14], (Section A). Second, we used a robotic ankle manipulator to assess the improvement in voluntary ankle function due to compensation applied by Hermes in five ambulatory hemiparetic chronic stroke patients (Section B.1). Third, we tested the ability of these patients to walk for short distances safely on an instrumented treadmill wearing the Hermes on the most affected side (Section B.2). We hypothesized that the Hermes compensates the ankle stiffness, so that the combined 'Ankle+Hermes' stiffness improves the ankle's active range of motion and maximum active dorsiflexion angle.

II. Methods

A. Hermes Design

1) Hermes Functional Requirements: In line with our previous design [14], the Hermes was required to apply a dorsiflexion torque, T_H (Nm) following a natural exponential function of the Hermes angle, θ_H (deg) according to (1).

$$T_H = -c e^{K_H(\theta_H - \theta_{H_0})} \tag{1}$$

where K_H (-) is the Hermes stiffness coefficient, θ_{H_0} (deg) is the Hermes offset angle of the exponential curve relative to the Hermes angle, and c (-) the desired compensation as a fraction of the patient's passive ankle stiffness.

The Hermes was required to enable a physiological ROM of 70 deg ranging from 50 deg plantar flexion to 20 deg dorsiflexion relative to the anatomical position [15]. Like our previous design, the Hermes torque was required to compensate the internal plantarflexion torque of several patients with varying degrees of spastic paresis with a maximum torque of 16 Nm, based on a previous study [16].

The Hermes torque-angle characteristic, as defined in (1) is tuned by 3 settings: 1) the DF stop sets the maximum DF angle of Hermes and defines the angle at which the Hermes achieves its maximum torque (20 deg in Fig, 1); 2) the cam pre-rotation, together with 3) the spring pre-compression adjust the exponential shape of the Hermes torque-angle characteristic. An illustration of the required adjustability of the Hermes torque-angle characteristic is shown in Supplementary materials A (Fig. 6).

In a healthy subject, the weight (1.4 kg) and hysteresis (up to 40%) of the previous design seemed to mask the effects of stiffness compensation in a healthy subject [14]. Therefore, Hermes in combination with the users' shoe, was aimed to weigh 1.0 kg or less, which corresponds to the weight of robust shoes [17]. Hysteresis of the Hermes was not to exceed 25% when applying torques higher than 0.5 Nm. At torques lower than 0.5 Nm, the difference in torque between dorsiflexion and plantarflexion was not to exceed 1.0 Nm. Finally, the Hermes orthotic brace was required with a modular design to anatomically fit the lower leg of several patients.

2) Hermes Functional Evaluation: The Hermes torque and ROM was measured with a robotic single-axis ankle manipulator that measured and applied ankle torques and rotations ("Achilles", MOOG inc., Nieuw Vennep, The Netherlands). We evaluated Hermes in isolation, first tuned to its maximal capacity (i.e., maximum torque and ROM); and then tuned to compensate the patient-specific torque-angle characteristics at four compensation levels (as described in section B.1). The

Hermes foot-part was attached to a rotational plate of the manipulator and the calf-part was immobilized. 3D-printed plastic fillings accommodated the carbon foot-parts to align the axes of rotation of Hermes and the ankle manipulator. The manipulator applied slow ramp-and-hold (RaH) rotations to the Hermes footplate throughout the maximal Hermes ROM, while the reaction torque was being measured. The footplate angle and torque signals were sampled at 2048 Hz and post-processed with a low-pass filter (4^{th}-order Bessel filter at 20 Hz) applied in forward and reverse directions to attain zero-phase delay.

3) Hermes Torque Accuracy and Hysteresis: Due to hysteresis, the measured torque-angle characteristic describes a work-loop. Hysteresis was defined as 1) the percentage of the energy (integral of the torque over the angle) lost between dorsiflexion and plantarflexion movements,relative to the maximum stored energy, where Hermes applied $\geq$0.5 Nm; and defined as 2) the maximum absolute torque difference between the dorsiflexion and the plantarflexion movements, where Hermes applied <0.5 Nm. We calculated the averaged measured torque-angle characteristic by averaging the Hermes torques measured during the dorsiflexion and plantarflexion movements, across the ROM. Torque accuracy of the Hermes was assessed by the maximum torque error between the theoretical, as defined in (1), and the averaged measured torque-angle characteristic. The results for the accuracy and hysteresis at each torque level ($H_{L0...3}$) were subsequently averaged over patients.

B. Preliminary Clinical Evaluation

1) Patients: Patients were preselected from electronic files at the Rehabilitation department of the Leiden University Medical Centre, and subsequently invited to a first appointment to participate in this study. Inclusion criteria for preselection were stroke (cerebrovascular accident) in chronic phase (>6 months after), hemiparesis, and indication with a walking aid, e.g., orthopaedic shoes or AFO. During the first appointment, the remaining inclusion criteria were assessed, including ability to understand instructions and any degree of pes equinus or equinovarus at the most affected side, i.e., an increased passive ankle stiffness with limited active ROM in comparison to the less affected side (based on passive range of motion (ROM) during sitting and active ROM during walking through gait observation). Patients were recruited from the rehabilitation department of the Leiden University Medical Centre. The research protocol was approved by the Leiden-Den Haag-Delft Medical Ethical Committee (METC-LDD, approval number NL64640.058.19). All patients provided written informed consent prior to the experimental procedure.

2) Procedure: Patients were invited to a second appointment for the experimental session. First, a medical specialist performed a physical evaluation on the most affected side, which included an assessment of spasticity, vibration sensitivity and muscle strength of the lower leg. Then, the Hermes orthotic brace was fitted to the patient's leg by choosing suitable sizes for the foot and calf orthotic parts: the Hermes foot-part was chosen according to the patient's regular shoe size, while the Hermes calf-part was chosen according to the patient's calf circumference. Following the fitting, we employed the ankle manipulator to examine the ankle joint (B.1 Ankle function measurements) and tested the ability of patients to walk with the Hermes (B.2 Walking feasibility).

3) Experimental Conditions: For the Ankle function measurements, we measured the total internal ankle torque, and the ankle active and passive ROM in five conditions: without Hermes (*Ankle* condition: A), and with Hermes adjusted to compensate the passive ankle stiffness at four levels (*Ankle+Hermes* conditions: $A+H_{L0...3}$), in which $H_{L0}=0\%$ (with the Hermes not applying any PF/DF torque), $H_{L1}=35\%$, $H_{L2}=70\%$ and $H_{L3}=100\%$ of the internal passive PF torque. After a break of 10-20 minutes, we tested the walking feasibility at preferred walking speeds in 6 conditions: with their own walking aid (*Own aid* condition, i.e., with orthopaedic shoes or AFO), with flat shoes provided during the experiment (S*hoes only* condition), as well as with flat shoes and the Hermes at each of the four $H_{L0...3}$ levels ($A+H_{L0...3}$ conditions).

4) Ankle Function Measurements: Patients were seated in front of the ankle manipulator on an adjustable chair with the hip and knee angles flexed approximately 70 deg and 45 deg, respectively. The patient's foot was fixed to the rotational plate of the ankle manipulator via Velcro straps in the *Ankle* condition (A) or via the Hermes foot-part in the *Ankle+Hermes* conditions ($A+H_{L0...3}$), see Supplementary material F. Electromyography (EMG) electrodes (Ø 15 mm, approximately 24 mm inter-electrode distance) were placed on the tibialis anterior (TA) and triceps surae (TS): soleus (SO), gastrocnemius medialis and lateralis (together GA) muscles, according to SENIAM guidelines [18]. The rotations of the ankle manipulator were delimited by the ROM-tolerance of the patients as communicated to the experimenter when manually rotating the foot to dorsiflexion and plantarflexion.

a) Data collection: The ankle passive ROM (pROM) was determined by the ankle manipulator applying 15 Nm in DF and 7.5 Nm in PF onto the patient's ankle. The total internal ankle torque (T_A) across the ankle angles (θ_A) delimited by the pROM was measured while the ankle manipulator imposed 5.0 deg/s RaH rotations with randomly timed onsets and a hold period of at least 10 s to prevent anticipation [16]. During abovementioned passive measurements, patients were instructed to remain relaxed, i.e., 'do not resist motion'. Consecutively, ankle active ROM (aROM) was measured twice. Patients were instructed to dorsiflex and plantarflex the ankle as far as possible without resistance from the manipulator. Patients rested at least 30 s between subsequent measurements. The torque-angle characteristics of the Hermes applied to each patient at the $H_{L0...3}$ levels were measured after the patient measurements (see Hermes functional evaluation *A.2*).

b) Signal recording and (post)processing: Angle and torque signals were sampled at 2048 Hz and post-processed with a low-pass filter (4^{th}-order Bessel filter at 20 Hz). EMG was sampled at 2048 Hz (Porti7, TMSi B.V., The Netherlands). During post-processing, a 50 Hz notch filter was used to reject line power noise from the raw EMG signals. Consecutively, EMG signals were high-pass filtered (4^{th}-order recursive Butterworth at 25 Hz), rectified and low-pass filtered (4^{th}-order recursive Bessel filter at 10 Hz) to obtain the envelope. Digital filters were applied in forward and reverse directions to attain zero-phase delay.

c) Estimation of ankle torque components: The measurements during RaH rotations in the *Ankle* condition (A) were used to estimate the passive torque from the total internal ankle torque. For Patients 2-5, the passive torques were estimated using a nonlinear EMG-driven neuromuscular model [19]. The model distinguishes active, passive (T_{Ap}) and gravitational torques (T_{Ag}) from the total internal ankle torque (T_A), muscle activation (EMG) and ankle angle (θ_A); and comprises Hill-type muscle models of the SO, GA, and TA to account for the effect of muscle length and lengthening velocity on passive and active muscle force. For Patient 1, a slightly different method was followed in which did not distinguish the active and passive ankle torque components. For this reason, Patient 1 was not included in the group analyses. The methodology and results of Patient 1 are described in Supplementary materials A.

d) Definition of patient-specific hermes settings: The passive torque-angle characteristic to be compensated by Hermes, for each patient, was determined from the passive torque (T_{Ap}) and the ankle angles (θ_A), averaged across the dorsiflexion and plantarflexion movements. The passive torque-angle characteristic was then fitted to (1), which defined the maximum Hermes torque for each patient. Subsequently, the Hermes DF stop was set about 5 degrees beyond the maximum passive DF angle to enable an increase in the ROM. After that, software developed by InteSpring (InteSpring BV, Rijswijk, The Netherlands) was used to optimize the cam pre-rotation and spring pre-compression settings to tune Hermes to the $H_{L0...3}$ levels.

e) Stiffness parameterization: The total ankle stiffness coefficient (K_A) was estimated from the torque-angle characteristic formed by the ankle angle (θ_A) and the total internal ankle torque (T_A) averaged across the dorsiflexion and plantarflexion movements and subsequently fitted to a positive natural exponential function as defined in (2).

$$\hat{T}_A = e^{K_A(\theta_A - \theta_{A_0})} \tag{2}$$

where $\hat{T}_A$ is the fitted total torque, K_A the total ankle stiffness coefficient, θ_A is the ankle angle in the *Ankle* condition, and θ_{A_0} is an estimated angle offset (constant within patients across all conditions).

The passive ankle stiffness coefficient (K_P) was estimated from the torque-angle characteristic formed by the ankle angle (θ_A) and the estimated passive torque (T_P) averaged across the dorsiflexion and plantarflexion movements and subsequently fitted to a positive natural exponential function as defined in (3).

$$\hat{T}_{Ap} = e^{K_{Ap}(\theta_A - \theta_{A_0})} \tag{3}$$

where $\hat{T}_{Ap}$ is the fitted passive torque, K_{Ap} the passive ankle stiffness coefficient, θ_A is the ankle angle in the *Ankle* condition, and θ_{A_0} is the estimated angle offset (constant within patients across all conditions).

Similar to the *Ankle* condition, the combined Ankle+Hermes stiffness coefficients ($K_{A+H_{L0...3}}$) for the *Ankle+Hermes* conditions ($K_{A+H_{L0...3}}$), were estimated from the torque-angle characteristics formed by the Ankle+Hermes angles ($\theta_{A+H_{L0...3}}$) and the torques ($T_{A+H_{L0...3}}$) averaged across the dorsiflexion and plantarflexion movements and subsequently fitted with a positive natural exponential function as defined in (4).

$$\hat{T}_{A+H_{L0...3}} = e^{K_{A+H_{L0...3}}(\theta_{A+H_{L0...3}} - \theta_{A_0})} \tag{4}$$

where $\hat{T}_{A+H_{L0...3}}$ are the fitted torques, $K_{A+H_{L0...3}}$ are the stiffness coefficients, $\theta_{A+H_{L0...3}}$ are the ankle angles with Hermes, and θ_{A_0} the estimated ankle offset angles (constant within patients across all conditions).

As we aimed effects of compensation on the plantarflexion torque, we fitted in (2)-(4) the positive torque of the torque-angle characteristics. The fitting error was defined as the root mean squared error (RMSE) between the measured (T) and fitted ($\hat{T}$) torque-angle characteristics for each condition.

f) Outcome measures: The achieved compensation (AC) by Hermes in every *Ankle+Hermes* condition was calculated as a percentage of the passive ankle stiffness coefficient (K_{Ap}), determined in the *Ankle* condition, according to (5). The process from measurements to the calculation of the AC is illustrated in Fig. 8 of Supplementary materials C.

$$AC = \frac{K_A - K_{A+H_{L0...3}}}{K_{Ap}} \times 100\% \tag{5}$$

The maximum active ROM in every condition was calculated as the total excursion of the ankle between the maximum DF and PF angles and averaged over repetitions.

g) Assumptions: For the ankle function measurements with Hermes, we tested three underlying assumptions: (1) The Hermes and ankle axes of rotation are aligned such that the Hermes and ankle rotations are equal ($\theta_H = \theta_A$); (2) During passive measurements, the ankle muscles remained in a constant relaxed state (i.e., no phasic activation); (3) During active ROM measurements, the observed improvement on maximum active DF angle across conditions only depended on the level of compensation, and was not associated to an increase of TA activation.

We tested assumption 1 by quantifying any translations due to misalignment using a motion capture system with Patients 3 and 5 (details on the misalignment test in Supplementary materials F). Assumption 2 was tested by EMG. Muscles were considered to be relaxed when the EMG signals did not surpass the mean plus 2 times standard deviation of background activation EMG throughout a measurement trial. Background activation EMG was defined as the mean EMG signal between 200 ms to 20 ms prior to each ramp-and-hold rotation [20].

Assumption 3 was tested by evaluating the TA EMG during the measurements of Ankle+Hermes active ROM. TA activation was calculated as the area under the EMG signal within a window from 180 ms before movement onset to 180 ms before movement offset [21], [22]. The movement onset was identified as the time instant in which the ankle angular velocity towards DF surpassed 3 deg/s, likewise, the movement offset was identified as the ankle slowed down to less than 3 deg/s nearby the maximum active DF angle.

5) Walking Feasibility: Feasibility of walking was tested by asking patients to walk during one minute at their preferred speed on an instrumented treadmill (M-Gait, Motek ForceLink, The Netherlands). Patients were wearing a safety harness that did not provide body-weight support. Before recordings commenced, the belt speed was adjusted to the patients' preferable walking speed by manually increasing the belt speed if patients approached the front and decreasing when they approached the back of the belt. This was done for each of the 6 conditions (*Own Aid*, *Shoes only*, and *Ankle+Hermes* $L_{0\ldots3}$), the preferred walking speed was measured. Before recording, the belt speed was adapted to the preferred walking speed of the patient. Patients sat down to rest a few minutes between conditions and were given a few minutes to habituate to the treadmill and Hermes.

Statistical Analysis: The achieved compensation (AC in %), stiffness coefficients (K), fitting errors (RMSE in Nm), active ROM (deg) and maximum active DF angle (deg) were tested within patients over the *Ankle* and *Ankle+Hermes* conditions by a repeated-measures non-parametric Friedman test [23]. When the repeated-measures test showed significant main effects, we tested between conditions using multiple paired comparisons with Bonferroni correction of the alpha level ($\alpha = 0.05$). The TA activation and maximum active DF angle were averaged over repetitions within patients, consecutively, we evaluated association between them by calculating the Pearson's linear correlation coefficient (ρ). $\rho \geq 0.7$ was considered strong correlation, $0.7 > \rho \geq 0.4$ moderate correlation, and $\rho < 0.4$ weak correlation [24]. All statistical analyses were carried out in SPSS (IBM Statistics 26).

III. Results

A. Hermes Mechanical Design

Hermes was required to improve in maximum torque, hysteresis, and weight relative to our previous design [14]; and to fit the torque-angle characteristics of stroke patients measured in a previous study [16]. To decrease hysteresis and weight of the mechanism, the gas-spring of previous design was substituted by a small and light-weight coil spring with low energy loss. Consequently, the size and weight of the casing were also reduced. The cam shape required an adaptation in combination with the new coil spring stiffness to obtain the required torque-angle characteristics. To fit the Hermes to the subjects, a modular set of calf and foot orthotic parts for both left and right legs were used, matching small shoe size (37-39 EU), medium (40-42 EU), and large (43-45 EU). Fig. 2 shows a photo of Hermes and an exploded view of the optimized mechanism.

B. Experimental Results

Hermes Functional Evaluation and Patient-Specific Hermes Characteristics: Hermes achieved the targets on range of motion, maximum torque, weight, and hysteresis. Table I shows a summary of the targeted and achieved functional requirements versus those of the previous design [14]. Due to hysteresis, the maximum torque error, was larger than

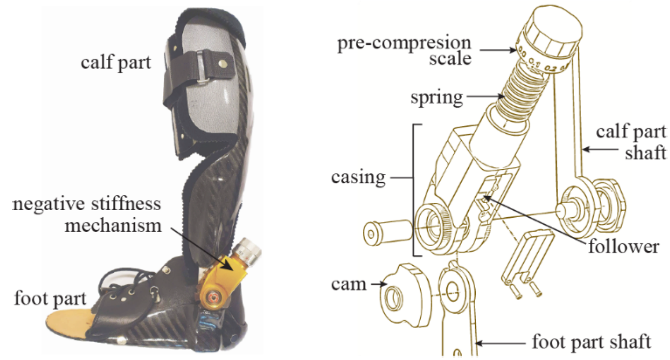

Fig. 2. Left: Photo of Hermes for the left leg, composed by a calf and a foot-part made of prepreg carbon fibre and fabricated by an experienced orthotist. The foot-part fits inside standard flat shoes. Right: Exploded view of the negative-stiffness mechanism. The casing contains a coil spring that rotates the cam via the follower. The cam centre aligns with the ankle axis of rotation; thus, the cam torque corresponds to the torque applied to the ankle.

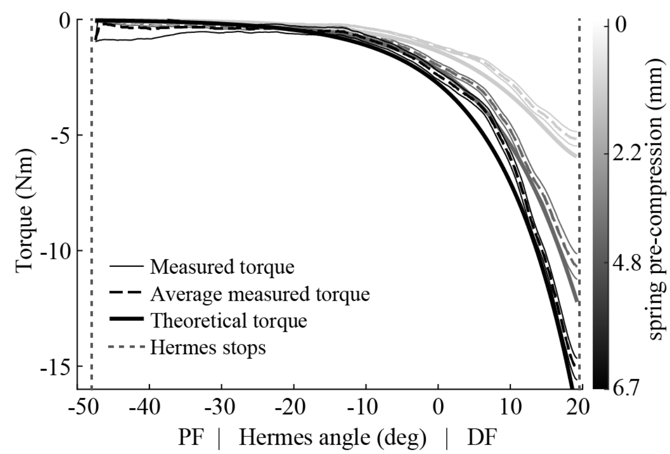

Fig. 3. Hermes torque-angle characteristics used to compensate for the ankle stiffness of Patient 3. For this patient, the DF stop was set to 20 deg. The torque levels ($H_{L1\ldots3}$) were set with 0 deg of cam pre-rotation and 2.3, 4.8 and 6.7 mm of spring pre-compression (see grey scale). Thick solid lines denote the theoretical Hermes torque as predicted by InteSpring software; thin solid lines denote the hysteresis loop of the Hermes torque measured in isolation, dashed lines denote the average measured torque from the dorsiflexion and plantarflexion movements of the hysteresis loop.

expected on the higher torque levels ($H_{L2,3}$). Fig. 3 shows an example of the Hermes torque-angle characteristics as adjusted to compensate for the passive ankle torque of Patient 3.

1) Preliminary Clinical Evaluation:

a) Patients: Five patients (3 male) participated in this study. Although Hermes settings in Patient 1 were based on total ankle stiffness in contrast to only passive ankle stiffness, the data are sound and included in Supplementary materials B. For Patients 2-5, demographic characteristics and results of the physical evaluation are shown in Table II. Patients 2, 4 and 5 were under treatment and received Botulinum toxin medication in the calf muscles 8 days, 3 months, and 2 months before the measurements, respectively.

b) Achieved compensation by Hermes and active rom: Hermes successfully reduced the combined Ankle+Hermes torque relative to the internal PF torque and despite GA and SO phasic

TABLE I
HERMES FUNCTIONAL REQUIREMENTS

Requirement	Previous design [17]	Targeted	Achieved
Range of motion (deg)	45	70	70
Maximum torque (Nm)	10	16	16
Mechanism weight (kg)	1.2	<0.8	0.2
Hermes weight[1] (kg)	1.4	<1.0	
Small size			0.73
Medium size			0.75
Large size			0.88
Hysteresis[2]:			Median (Range)
If Hermes torque ≥0.5Nm Hysteresis (%)	<48	<25	L_1: 9.0 (2.0-12.1) L_2: 11.6 (4.6-14.7) L_3: 11.6 (7.2-18.2)
If Hermes torque <0.5Nm Difference between DF and PF torque (Nm)		<1.0	L_1: 0.1 (0.1-0.9) L_2: 0.3 (0.1-0.6) L_3: 0.6 (0.4-1.2)
Hermes torque accuracy[3] Maximum error (Nm)	Mean (SD[4]) 2.71 (0.7)	<1.0	L_1: 0.5 (0.4-0.7) L_2: 1.0 (0.5-1.2) L_3: 1.2 (0.8-1.2)

[1]The weight of the shoe used with Hermes was 0.3-0.4 kg depending on the size. [2]Hysteresis was calculated for each compensation level ($A + H_{L1...3}$) and defined as the percentage of energy lost between the dorsiflexion and plantarflexion movements in case the Hermes torque was higher than 0.5 Nm. Hysteresis is described as the torque difference between the dorsiflexion and plantarflexion movements in case the Hermes torque was lower than 0.5 Nm. [3]The Hermes torque accuracy is described by the maximum torque difference between the theoretical torque and the average measured torque from the dorsiflexion and plantarflexion movement, at each compensation level. [4]SD: standard deviation.

TABLE II
PATIENT CHARACTERISTICS

	Patient 2	Patient 3	Patient 4	Patient 5
Age (years)	68	51	58	38
Weight (kg)	73	108	78	78
Height (m)	1.90	1.80	1.78	1.74
Gender (F/M)	M	M	F	M
Type of stroke	ischemic	ischemic	Ischemic	haemorrhagic
Most affected side	Right	right	Left	left
Time since stroke (years)	5	5	14	5
Plantarflexor muscles spasticity[1] (PRPM)	0	1	4	0
Plantarflexion strength[2] (MRC scale)	0	0	5	4
Dorsiflexion strength[3] (MRC scale)	0	0	5	TA=0, EDL=1, EHL=1
Vibration sensitivity[4] (0-8 scale)	F: 0 A: 0	F: 0 A: 0	F: 8 A: 6	F: 0 A: 8
Prescribed walking aid	High-top orthopaedic shoes	Low-top orthopaedic shoes	High-top orthopaedic shoes	solid AFO and shoe with heel rise
Additional aids[5]	cane	none	cane	cane
Use of walking aid	Every day, indoors and outdoors for 3 years.	Not used in daily life	~1 hour/ day, only outdoors, for 4 years	Every day, indoors and outdoors for 5 years.
Weight walking aid (kg)	1.00	Not used	Unknown	0.32
Passive ROM[6] (PF/DF deg)	-42.5/12.4	-27.1/18.0	-37.2/1.9	-32.0/13.0

[1]PRPM (Perceived Resistance to Passive Movement, from 0 to 4) [25]. [2]MRC scale (Medical Research Council, from 1 to 5) assessed with knee extended. [3]MRC scale of dorsiflexor muscles as a group unless the physician noticed differences between the muscles, i.e., tibialis anterior (TA), extensor digitorum longus (EDL) and extensor hallucis longus (EHL). [4]Vibratory thresholds were determined with a Rydel-Seiffer tuning fork placed on the interphalangeal joint of the hallux at the foot (F) and the lateral malleolus at the ankle (A) [26]. [5]Patient 5 used a cane in the *Own aid* condition during walking measurements. [6]Passive ROM measured with ankle manipulator in the *Ankle* condition.

activation (violating assumption 2) observed in Patients 2, 4 and 5 when the Ankle+Hermes were positioned in the dorsiflexion range. As an example, Fig. 4 shows torque-angle characteristics as measured from Patient 3. A reduced plantarflexion torque and stiffness (slope) is observed in the *Ankle+Hermes* L_2condition relative to *Ankle* condition. The patient-specific Hermes settings used during the experiments are given in Supplementary materials D; and the torque-angle characteristics measured from all five patients are shown in Supplementary materials E.

Results of the ankle function measurements of Patients 2-5 are shown in Fig. 5. There was a statistically significant difference in the stiffness coefficients $\chi^2(4) = 10.60$, p=.03) and the achieved compensation ($\chi^2(3) = 9.3$, p=.03) over the conditions. Pairwise multiple comparisons revealed significant reduction of Ankle+Hermes stiffness coefficient and significant increase of achieved compensation between *Ankle+Hermes* L_0 relative to *Ankle+Hermes* L_3 condition (p<.05). Moreover, wearing the Hermes with zero torque (*Ankle+Hermes* L_0 condition), did not significantly change the stiffness coefficient relative to the stiffness in the *Ankle* condition (p=.82). The fitting errors (RMSE) between the measured and the fitted torque-angle characteristics corresponded to a median (IQR) of 6.9 (2.2) % of the maximum measured torques and were found not to be different between conditions ($\chi^2(4) = 4.4$, p=.36), indicating a consistent low fitting error among patients and conditions. In two patients (3 and 5) we used a motion capture system to test the assumption that Hermes and ankle angles were equal. We observed a mismatch between the ankle and Hermes angles as well as a translation of the tibia cluster relative to the Hermes calf-part cluster. Supplementary Materials F provides further information of the misalignment test.

c) Active ROM: In Patients 2, 3 and 4, the active ROM and maximum active DF angle increased in at least one condition with the Hermes in comparison to *Ankle* condition, as shown

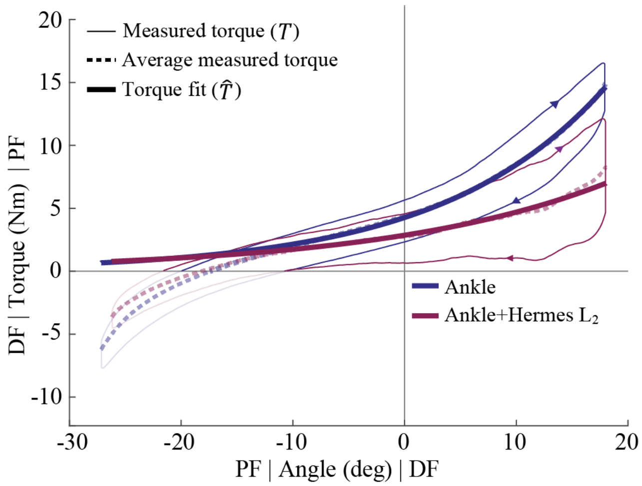

Fig. 4. Torque-angle characteristics of Patient 3 measured without the Hermes (Ankle condition) and when wearing the Hermes (Ankle+Hermes L_2 condition). Thin solid lines denote the hysteresis loop of the torque measured during the ramp-and-hold rotations. Thick dotted lines denote the average measured torque from the dorsiflexion and plantarflexion movements of the hysteresis loop. Thick solid lines represent the fitted torque according to (2) and (4). There is a larger hysteresis in the combined (Ankle+Hermes L_2) torque in comparison to the Ankle torque, as ankle and Hermes hysteresis add together.

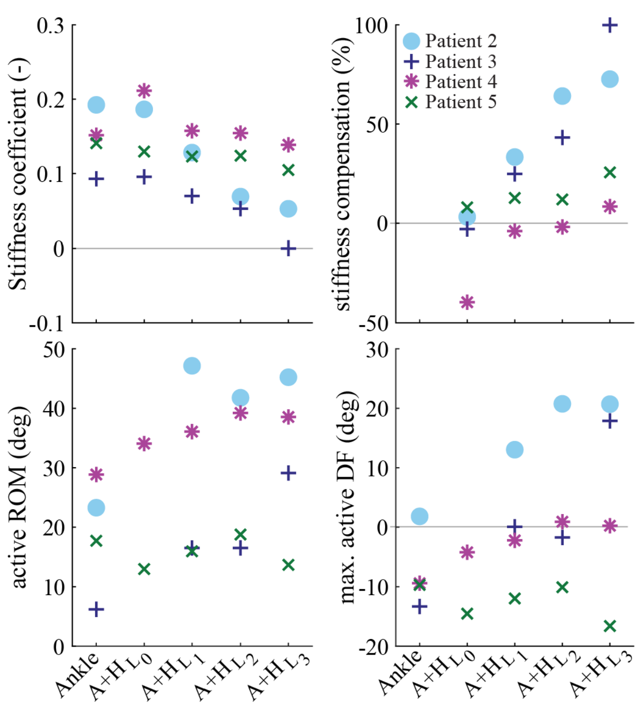

Fig. 5. Results of ankle function measurements at group level (Ankle+Hermes is abbreviated as A+H). The stiffness coefficients and achieved compensation were significantly different between conditions, in which stiffness coefficients decreased and achieved compensation increased with compensation level. In Patient 4, the use of the Hermes in $A+H_{L0}$ condition seemed to increase the stiffness coefficient, consequently resulting in a negative stiffness compensation. Active ROM and max. active DF angle show an increasing trend with compensation level in all four patients.

in Fig. 5. From Patients 2, 4, and 5, in which EMG data were recorded, we found no significant association between the maximum active DF angle and TA activation (assumption 3).

TABLE III
PREFERRED WALKING SPEED (M/S)

Condition	Patient 2	Patient 3	Patient 4	Patient 5
Own aid	0.71	0.57	0.19	0.29
Shoes only	0.56	0.40	0.19	
Ankle+Hermes L_0	0.56	0.59	0.17	
Ankle+Hermes L_1	0.65		0.18	
Ankle+Hermes L_2	0.82		0.18	0.30
Ankle+Hermes L_3	0.75		0.18	0.30

The reported preferred walking speed corresponded to a period of 30s, starting 15s after gait initiation.

Hermes allowed patients to plantarflex the ankle. In Patient 2, during the *Ankle+Hermes* $L_{2,3}$ conditions, the dorsiflexion movement reached the Hermes DF stop, surpassing the maximum passive DF angle measured in the *Ankle* condition (Table I). This indicates that Hermes compensation increased both the maximum passive and active DF angles. In Patient 3, the dorsiflexion movement reached the Hermes DF stop in the *Ankle+Hermes* L_3 condition,, but did not exceed the maximum passive DF angle measured in the *Ankle* condition. This is because the passive DF angle was already near the maximum DF angle of the ankle manipulator. Supplementary materials G provides a detailed description of the active ROM results.

2) Walking Feasibility: Patients 2, 4, and 5 felt confident enough to walk with the Hermes on the treadmill without falling. Patients 2 and 4 completed all walking conditions. Patient 3 withdrew from the walking measurements after the *Ankle+Hermes* L_0 condition due to discomfort in the lower leg. Table III shows the preferred walking speeds for the available conditions. Hermes did not have a negative impact on the patients' preferred walking speed compared to walking with their own aid. Notably, Patients 2 even showed a slight increase in preferred walking speed in two of the compensation conditions ($A + H_{L2,3}$) compared to walking with his own aid.

IV. DISCUSSION

In this study, we presented the functional evaluation and preliminary clinical effects of an ankle-foot orthosis with negative stiffness, called Hermes. We observed that (1) the Hermes mechanism, lighter and more efficient than our previous design [14], successfully compensated the patients' ankle stiffness; (2) 3 out of 4 patients benefited from this compensation, leading to increased active dorsiflexion angles and total ROM and (3) 3 out of 4 patients felt able to walk with the Hermes during the study session, despite the absence of training. We consider that, with a few improvements in the protocol and set-up, it will be possible to measure the compensated ankle stiffness more accurately and observe relevant benefits of the Hermes on the ankle joint function in a larger population of patients.

Hermes Design and Functional Evaluation: Our new design met the torque (16 Nm) and ROM (70 deg) requirements, enabling compensation of passive ankle stiffness in a wide range of UMNS patients (examples in literature: [27], [28], [29], [30]). Compared to clinically prescribed articulated AFOs with hinges and springs, the Hermes offers larger ROM, similar or higher maximum dorsiflexion torque and less hysteresis [31], [32], [33]. Although hysteresis slightly exceeded the maximum error requirement (<1.0 Nm) at the high torque levels ($H_{L2,3}$), it did not impede the Hermes from effectively compensating the ankle stiffness. As none of the patients of the study wore the large calf-part, the Hermes fulfilled the weight requirement of <1.0 kg. Future improvements, including a custom-made orthotic brace, cam, and spring are expected to further decrease Hermes' weight.

Achieved Compensation by Hermes: Significant reductions of the combined Ankle+Hermes stiffness with compensation level were found. However, the achieved compensation did not align with the expected compensation (35%, 70% and 100%). We suggest that other factors such as suboptimal orthotic fit or torque-angle characteristic fits influenced the reported results on the combined Ankle+Hermes stiffness. In the foreseen application, a custom-made Hermes, as provided in clinical practice, will approach optimal orthotic fit, substantially reducing the misalignment and likely solving the compensation discrepancies to a large extent.

A. Orthotic Fitting

In two patients we conducted kinematics analysis of the Hermes parts (calf and foot-part) and the lower leg (foot and tibia) during the ankle function measurements. We observed mismatches in the recorded rotations of the ankle and Hermes, which originated from misalignment between the ankle axis and the Hermes axis. During walking, misalignment may result in distal travel of the orthosis calf-part parallel to the lower leg, causing friction, pressure and discomfort [34] as well as inappropriate assistance from the Hermes. Additionally, suboptimal orthotic fit may increase the play between the Hermes calf-part and the lower leg, which may affect the Hermes torque transmission as soft calf tissues act as stiffness at the leg-AFO interface [35].

B. Torque-Angle Characteristic Fitting

The fitting error between the measured and fitted torques indicated that the shape of the measured Ankle+Hermes torque-angle characteristics slightly differed from the exponential function (4). Although the mean fitting errors were small relative to the maximum measured Hermes torque, it is likely that the torque fits estimated an average achieved compensation that was already biased by abovementioned effects of suboptimal orthotic fitting. Optimizing orthotic fitting will directly improve the torque-angle characteristic fitting. However, it is likely that small misalignments and interface stiffness will still affect the torque measurements by the ankle manipulator. Modelling the motion of the orthotic parts and lower limb would allow to discern between torques from misalignment, from interface stiffness and from Hermes, improving the precision of ankle stiffness compensation measurements.

1) Active ROM:

Voluntary ankle joint function was assessed using the ankle manipulator. Due to their treatment for spasticity, Patients 2 and 5 showed a more normal passive ROM (Table II). Yet, Patient 2 still benefited from Hermes stiffness compensation to improve the active ROM. Patients 2-4 showed an increased active DF angle with Hermes, despite Patients 2 and 3 reporting an MRC of 0 in DF muscles. We attribute the MRC of 0 to the patients' treatment with botulinum toxin for issues like toe extension (hitchhiker's toe) and equinovarus foot, in combination with the time between patient selection and actual inclusion. Additionally, the ankle manipulator fully constrains the movement to one axis (dorsiflexion/plantarflexion) which could encourage patients to activate all muscles that contribute to DF simultaneously, including those not assessed by MRC, such as the m. peroneus tertius. This could allow patients to present dorsiflexion capability during the test with the ankle manipulator. Furthermore, EMG measurements confirmed no association between maximum active DF angle and TA activation, indicating improved active ROM due to Hermes.

Differences in improvement of maximum active DF angle between patients may be attributed to residual strength and muscle selectivity: Patients with more severe impairment may need more ankle stiffness compensation to improve the active ROM. Patients 4 and 5 showed a similar maximum active DF angle at baseline (i.e., *Ankle* condition). Patient 4 showed a low achieved compensation relative to the other patients, yet the maximum active DF angle steadily increased with stiffness compensation up to 12 deg. In contrast, Patient 5 showed higher achieved stiffness compensation, but no substantial improvement on maximum active DF angle.

Impaired selectivity and involuntary muscle activation of the plantarflexor muscles [36] may have prevented Patient 5 from utilizing the compensated ankle stiffness to improve dorsiflexion. These results suggest that Patient 4 benefited more from Hermes assistance than Patient 5, who may require additional neural-related treatment and/or higher levels of compensation ($>60\%$) to improve ankle joint function. In patients with more severe impairments, compensation of both passive and involuntary active contributors of ankle stiffness may be necessary to achieve a more effective Hermes assistance to the ankle joint function.

Patients with milder impairments may improve active ROM with low levels of ankle stiffness compensation. For example, Patient 2 achieved the largest maximum active DF angle of the group in the *Ankle* condition and reached the maximum passive DF angle with approximately 35% compensation (*Ankle+Hermes* L_2). In contrast, Patient 3 required 75% stiffness compensation (*Ankle+Hermes* L_3) to reach maximum passive DF angle. These results suggest that, at the time of the measurements, Patient 3 had a more severe dorsiflexion weakness than Patient 2, thus needing more compensation for improved ankle dorsiflexion. Furthermore, patients 2 and 3 reached the Hermes DF stop in conditions with compensation (*Ankle+Hermes* $L_{2,3}$) despite setting the DF stop slightly higher than the maximum passive DF angle. Increasing the DF torque of the manipulator up to the patient's personal tolerance level instead of the 15 Nm as applied in this study, may maximize the potential improvement of active ROM.

2) Walking Feasibility: Three out of four patients felt confident enough to walk on a treadmill with the Hermes, indicative of the experienced walking feasibility and of the absence of negative effects on walking ability with Hermes. Among patients, Patient 2 attained the highest maximum active DF angles with Hermes during the ankle function measurements, and showed an indication of a higher walking speed ($\geq$0.1 m/s) similar to the improvement with typical AFOs in clinical practice [37]. A limitation of the current study is the short adaptation time with Hermes. We expect that gait training with Hermes will provide habituation and confidence in the assistance of the Hermes and improve ankle joint function during walking.

a) Study design limitations: The small number of patients in this proof-of-concept study limited the statistical power and analysis of above-mentioned factors. Additional limitations include the non-randomized order of conditions and potential effects of adaptation to the ankle manipulator or treadmill. However, as this is the first study applying ankle joint stiffness compensation, we could not predict the patients' tolerance to the Hermes. Thus, for safety reasons a predefined order of conditions with increasing levels of compensation was applied. For subsequent patient measurements randomization is advised to reduce adaptation effects.

V. Conclusion

The results of the current study indicate that Hermes, opposite to typical walking aids, assisted active dorsiflexion of chronic stroke patients with pes equinus or equinovarus and spastic paresis, without restricting plantarflexion. Patients were able to walk with the Hermes together with flat shoes. Ankle joint function may further improve with custom-made orthotic brace and shoes. Further research is needed to clinically validate these findings and evaluate the assistance during walking. We consider passive ankle stiffness compensation a promising new alternative to restore ankle function, with the potential to be incorporated into current treatment protocols [2] and further improve the mobility and independence of patients with UMNS.

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