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Compensating the Symptomatic Increase in Plantarflexion Torque and Mechanical Work for Dorsiflexion in Patients with Spastic Paresis Using the "Hermes" Ankle–Foot Orthosis

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Abstract: Background/Objectives: "Hermes" is an ankle–foot orthosis (AFO) with negative stiffness designed to mechanically compensate the symptomatic increase in plantarflexion (PF) torque (i.e., ankle joint torque resistance to dorsiflexion, DF) in patients with spastic paresis. **Methods**: The effectiveness of "Hermes" was evaluated in twelve patients with chronic unilateral spastic paresis after stroke. Using a robotic ankle manipulator, stiffness at the ankle joint was assessed across three conditions: ankle without Hermes (A), ankle with Hermes applying no torque compensation ($A + H_{0\%}$), and ankle with Hermes tuned to compensate 100% of the patients' ankle joint stiffness ($A + H_{100\%}$). **Results**: A significant reduction in PF torque was found with Hermes applying compensation ($A + H_{100\%}$) compared to the conditions without Hermes (A) and with Hermes applying no compensation ($A + H_{0\%}$). Furthermore, a significant reduction in positive dorsiflexion work was found with Hermes applying compensation ($A + H_{100\%}$) compared to the condition with Hermes applying no compensation ($A + H_{0\%}$). Hermes did not significantly contribute to additional PF torque or positive work when applying no compensation ($A + H_{0\%}$). **Conclusions**: The reductions in PF torque achieved with Hermes are comparable to those seen with repeated ankle stretching programs and ankle robot training. Thus, Hermes is expected to assist voluntary dorsiflexion and improve walking in patients with spastic paresis.

Keywords: muscle spasticity; orthotic devices; stroke; equinus deformity; ankle work

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1. Introduction

The symptomatic increase in ankle stiffness or equinus foot is a prevalent clinical symptom in spastic paresis across a spectrum of neurological diseases, e.g., stroke, cerebral palsy, multiple sclerosis, and spinal cord lesions [1]. Increased ankle stiffness is characterized by increased internal plantarflexion (PF) torque, defined as the torque resistance to dorsiflexion (DF), and a limited range of motion (ROM) that originates from both neural (e.g., contracture and spasticity) and non-neural factors (e.g., muscle shortening), mainly affecting the plantar flexor or triceps surae (TS) muscles [2–4] (see Figure 1). Particularly, non-neural ankle stiffness originates from plantar flexor muscle tissues [5], here called passive ankle stiffness.

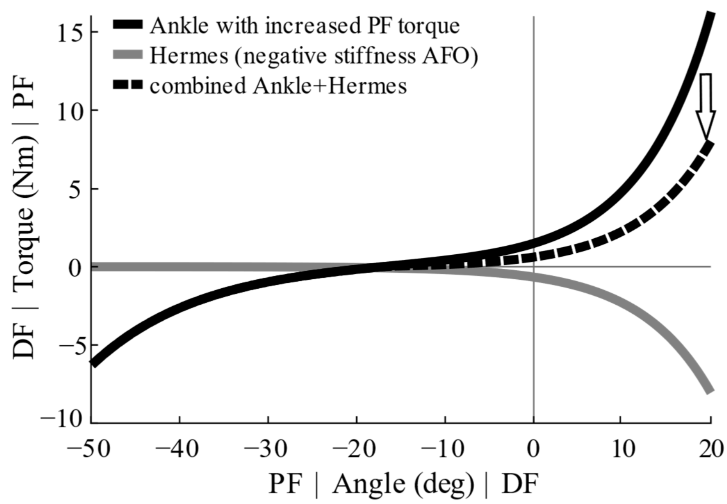

Figure 1. The passive torque-angle characteristic of the ankle is described by a positive (PF) exponential and a negative (DF) exponential (black solid line). The positive torques of the torque-angle characteristic correspond to the internal PF torque. Hermes compensates for the ankle stiffness with an external negative torque (gray line), resulting in a combined Ankle + Hermes torque-angle characteristic and stiffness (black dashed line). Relative to an ankle with increased passive stiffness, this combined Ankle + Hermes torque is aimed to be reduced towards a normal value and potentially allow for a larger ROM (arrow).

Increased ankle stiffness impairs individuals in various activities of daily living, including walking [2,6]. In clinical practice, the management of increased ankle stiffness typically starts with stretching exercises [2,7], which have been shown to decrease ankle stiffness and increase ROM [8,9]. However, the clinical effectiveness of stretching in inducing significant changes in joint mobility, pain, or spasticity in individuals with neurological disease is still a matter of debate [10]. As a result, there remains a challenge in the field of rehabilitation for patients with neurological diseases in reducing increased ankle stiffness to enhance ankle function during daily activities, e.g., gait [2,11].

In a previous study, we demonstrated the concept of mechanically compensating ankle stiffness with Hermes, an ankle–foot orthosis (AFO) that applies negative stiffness to the ankle joint, in patients with chronic stroke [12] (see Figure 1). The negative stiffness of Hermes was adjusted for each patient to compensate different percentages of their ankle stiffness, which was measured using a robotic manipulator. Specifically, Hermes' torque was adjusted based on the torque-angle characteristic of the measured PF torque defined by the ankle stiffness of each patient [12]. By wearing Hermes, the resulting total stiffness of the ankle joint was reduced without limiting the ROM as conventional AFOs tend to do [12]. Traditionally, the indication of AFOs is based on evaluations of the gait pattern in clinical settings [13]. We demonstrated that adding robotic measurements of ankle stiffness hold the potential to improve the customization of ankle–foot orthoses [12,14–17].

Building upon our initial findings [12], the goal of the present study is to validate the effectiveness of Hermes in compensating the ankle stiffness by extending the sample of stroke survivors in the chronic phase. Robotic measurements of the torque at the ankle were conducted. The effectiveness of Hermes in immediately compensating the ankle stiffness was assessed by comparing both the PF torques (i.e., the ankle torque resistance to DF) and positive work (i.e., the positive area under the torque-angle characteristic) with Hermes ($A + H$) and without Hermes (A). Positive work is an equivalent measure of the required mechanical energy to be exerted by the dorsiflexor muscle (e.g., tibialis anterior, TA) to bring the ankle to the maximum DF angle, for example, during walking. We hypothesized significant PF torque and work reductions in the condition with Hermes compared to that without.

2. Materials and Methods

2.1. Hermes AFO

Hermes is a one degree-of-freedom non-powered AFO that consists of orthotic foot and calf parts that are connected by a negative-stiffness mechanism designed by InteSpring BV (Rijswijk, the Netherlands). Negative stiffness arises because, unlike typical ankle–foot orthoses with positive stiffness, Hermes externally applies increasing dorsiflexion torque as the ankle moves towards dorsiflexion [12]. This counteracts the ankle's PF torque, mechanically compensating for the ankle's internal stiffness [12]. The experimental Hermes orthotic brace has a modular design of the foot and calf parts to fit the AFO to the lower legs of patients. The compensation delivered by the negative-stiffness mechanism of Hermes can be adjusted based on the patient-specific torque-angle characteristic of the internal PF torque.

2.2. Participants

Patients older than 18 years of age were recruited at the Department of Rehabilitation Medicine at the Leiden University Medical Centre. Inclusion criteria were a history of stroke (>6 months after), unilateral spastic paresis leading to equinus/equinovarus with limited ankle ROM, and an indication of a walking aid, e.g., orthopedic shoes or AFO. Patients were excluded if they were not able to understand the instructions, for example, due to aphasia or cognitive problems, or if they had ankle arthrodesis surgery or were not able to walk short distances (in home). The research protocol was approved by the Leiden-Den Haag-Delft Medical Ethical Committee, CCMO (Centrale Commissie Mensgebonden Onderzoek) trial registration number NL64640.058.19. All patients provided written informed consent prior to the experimental procedure.

2.3. Experimental Protocol

All measurements were conducted in a single session and at the same time of day for all patients. A physical medicine and rehabilitation physician assessed the ROM, severity of spasticity (MAS, Modified Ashworth Scale [18] or PRPM, Perceived Resistance to Passive Movement [19]), muscle strength (Medical Research Council [20]) at the ankle joint, and vibration sense at medial and lateral malleoli and at the first metatarsophalangeal (MTP-1) joint (3-point scale [21]). Subsequently, the Hermes orthotic brace was fitted to the patient's affected lower leg by selecting appropriate sizes for the foot and calf orthotic parts (see Figure 2).

Experimental set-up: Following the fitting, we used a robotic ankle manipulator ("Achilles," MOOG Inc., Nieuw Vennep, the Netherlands) to examine the patients' ankle stiffness without and with Hermes.

Patients were seated in front of the ankle manipulator on an adjustable chair with the hip and knee flexed approximately 70 deg and 45 deg, respectively. The patient's foot was attached to the rotational plate of the ankle manipulator using Velcro straps in the condition without Hermes or via the Hermes foot part in the condition with Hermes, as illustrated in Figure 3. 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. Before the measurements, the ankle manipulator was calibrated by positioning the patient's ankle at 25 degrees PF and then measuring the corresponding angle on the ankle manipulator. This calibration allowed for conversion between the manipulator's angle and the patient's ankle's angle.

Figure 2. A photo of a participant wearing Hermes on the left leg. Hermes is composed by calf and foot parts made of prepreg carbon fiber and fabricated by an experienced orthotist.

Figure 3. An example of how a patient was set up at the ankle manipulator for the measurement of the combined Ankle + Hermes PF torque. In this example, Hermes was used on the left leg.

In the Ankle only (A) condition, the ankle's passive ROM (pROM) and the torque over the pROM were measured without Hermes. The pROM, including maximum PF and DF angles, was recorded using the ankle manipulator in a standardized protocol by applying 15 Nm in DF and 7.5 Nm in PF onto the patient's ankle [5,15]. Subsequently, the ankle torque was measured across the pROM while the ankle manipulator applied DF and PF movements, respectively, spanning from the maximum PF angle to the maximum DF angle of the pROM and vice versa. The DF and PF movements followed a ramp-and-hold (RaH) shape with a ramp velocity of 5.0 deg$\cdot$s^{-1}, with randomly timed onset and hold periods of at least 10 s to prevent anticipation [22]. During all measurements, patients were instructed to avoid voluntarily activating any leg muscle or actively resisting the movements of the ankle manipulator. Therefore, the measured torques represent passive contributions.

Due to the viscoelastic properties of muscles, the torque-angle characteristic measured during DF and PF movements exhibits a hysteresis loop, with torque during the DF movement typically being higher than during the PF movement. For the first 5 patients, the patient-specific PF torque to be compensated by Hermes corresponded to the average torque-angle characteristic, obtained by averaging the torques across the DF and PF movements. To address the greater difficulty that patients with spastic paresis experience during DF movement and to potentially improve contrast in the experimental conditions, the patient-specific PF torque to be compensated by Hermes for the remaining 7 patients corresponded to the torque during the DF movement, here referred to as the DF torque-angle characteristic. The positive torque values of these characteristics were input into software developed by InteSpring B.V. to adjust the negative-stiffness mechanism of Hermes (v3.11). The DF stop of Hermes was set at the maximum DF angle of the pROM. This step ensures patient-specific calibration of Hermes as the DF stop dictates the angle at which Hermes delivers its maximum torque (see, for example, Hermes torque at 20 degrees DF in Figure 1).

After completing the Ankle (A) condition, patients proceeded to wear Hermes, which was adjusted to either apply no compensation ($A + H_{0\%}$ condition) or to compensate 100% of the patient-specific PF torque ($A + H_{100\%}$ condition). These Hermes compensation conditions were randomized. The combined Ankle + Hermes PF torques (i.e., in conditions $A + H_{0\%}$, $A + H_{100\%}$) were measured using the ankle manipulator, which applied DF and PF movements with a RaH shape at 5.0 deg.s^{-1} across the pROM measured in the Ankle (A) condition.

2.4. Outcome Measures

The effectiveness of Hermes in compensating the ankle stiffness was assessed by comparing the combined Ankle + Hermes PF torque and positive work across the three conditions, namely A, $A + H_{0\%}$ and $A + H_{100\%}$. For our analysis, we extracted PF torques from the DF torque-angle characteristic at 0 deg., 10 deg. DF, and at the maximum DF angle of each condition (see Figure 4). We selected 0 deg. and 10 deg. DF because these angles encompass the typical DF range during the swing phase of gait, where dorsiflexors generate torque and positive work for foot clearance and heel strike [23]. Additionally, assessing the maximum DF angle allowed us to evaluate the endpoint of the patients' ROM. In total, three torque values per condition were compared for each patient.

The positive work in each of the three experimental conditions was determined as the positive area under the DF torque-angle characteristics. The positive work in each condition was determined within the common ROM shared by the averaged torque-angle characteristics of the three conditions (see Figure 4). Thus, three work values per condition were compared for each patient. See Appendix A for further details on the calculation of positive work.

A repeated-measures one-way ANOVA was used to determine significant differences in positive work and in PF torque in each of the three ankle angles across the three conditions: A, $A + H_{0\%}$ and $A + H_{100\%}$. If the assumption of sphericity was violated, a Greenhouse–Geisser correction was applied. If significant main effects were found, a post hoc analysis was conducted involving multiple pairwise comparisons with Bonferroni correction ($\alpha = 0.05$) to find significant differences between conditions.

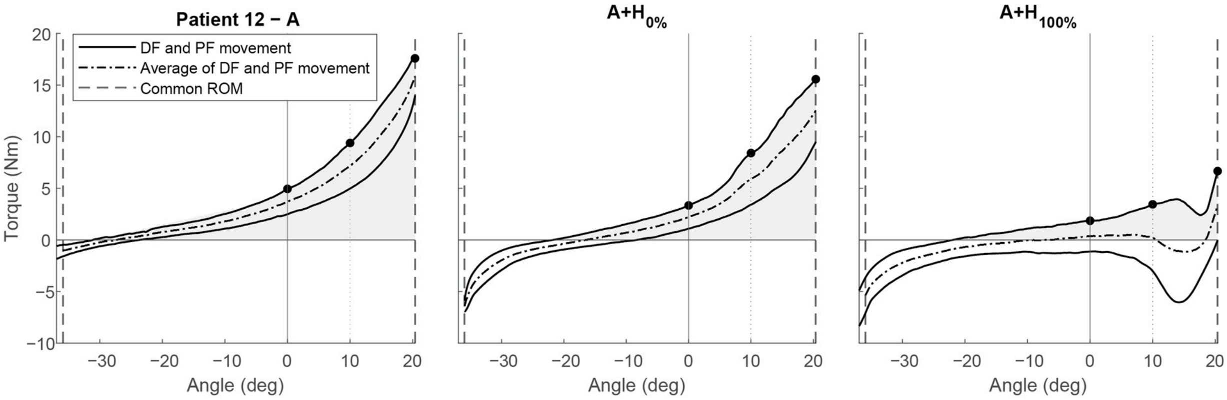

Figure 4. The torque-angle characteristics of Patient 12 measured without (A) and with Hermes ($A + H_{0\%}$ and $A + H_{100\%}$). In the Ankle (A) condition (left panel), the positive torques correspond to the patient-specific PF torque originated from the triceps surae and to be compensated by Hermes. The upper and lower solid lines in each panel denote the hysteresis loop comprising the DF (upper) and PF (lower) torque-angle characteristics. The dashed–dotted lines denote the average of the DF and PF torque-angle characteristic of each condition. The black-filled circles represent the PF torques of the DF torque-angle characteristic at 0 deg. (anatomical ankle angle), 10 deg, and at the max. DF angle used for comparison between patients. The dashed lines and shaded areas, respectively, denote the common ROM shared across conditions for this patient and the areas under the DF torque-angle characteristic (positive work).

3. Results

Twelve patients (eight males) were included in this study. The demographic characteristics and results of the physical evaluation are shown in Table 1. The raw data of four patients, numbered 2–5 in our previous study [12], were re-used for the current study. Note that while the raw data are the same, the outcome measures assessed in this study differ from those of the previous one [12]. All patients, except for Patient 2, underwent treatment with botulinum toxin medication in the calf muscles. Of the initial 12 patients, 10 were included in the group analysis; data from Patient 5 were omitted due to technical issues, and data from Patient 11 were excluded from analysis due to an absence of the limited pROM as measured with the ankle manipulator.

Table 1. Patient characteristics.

Patient Number		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Age (years)		68	51	58	38	65	44	74	58	63	65	42	69
Gender (F/M)		M	M	F	M	M	F	M	F	M	M	F	M
Height (cm)		190	180	178	174	180	176	172	168	197	182	168	179
Weight (Kg)		73	108	78	78	89	75	81	88	98	95	68	79
Affected side (R/L)		R	R	L	L	R	L	R	R	L	R	R	L
Stroke type (ischemic (I)/hemorrhagic (H)		I	I	I	H	I	I	H	H	H	I	H	I
Time since stroke (years)		5	5	8	5	12	16	11	1	2	9	2	7
Plantarflexor muscle spasticity [1] (PRPM, MAS for Patients 4 and 5)		0	1	4	0	3	2	3	3	3	3	1	3
Passive ROM [2] (deg.)	DF:	12	18	−2	13	−4	21	25	5	11	17	53	20
	PF:	42	27	37	32	38	49	39	54	47	45	56	48
Vibration sensibility [3]	A:	X	X	N	N	N	N	R	R	N	R	R	X
	F:	X	X	N	X	R	R	N	N	N	N	N	R
Botulinum toxin treatment (Y/N)		Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Walking aids [4]													

Table 1. *Cont.*

Patient Number	1	2	3	4	5	6	7	8	9	10	11	12
Orthopedic shoes:	+	+	+	+	-	-	+	+	-	+	+	-
AFO:	-	-	-	+	+	+	+	+	+	-	-	+
Cane:	+	-	+	+	+	-	-	-	+	+	-	+

[1] PRPM: Perceived Resistance to Passive Movement [24]. [2] The passive ROM measured with the ankle manipulator in the Ankle (A) condition. Negative values in DF indicate that the ankle did not reach 0 degrees (i.e., anatomical position) and the DF angle is in the PF range. [3] Vibratory sensibility was determined with a Rydel–Seiffer tuning fork placed on the first metatarsophalangeal joint of the foot (F) and the medial and lateral malleoli at the ankle (A) [21]. Sensibility at the ankle was considered to be reduced if the patient had no or reduced sensibility in any or both malleoli, and no sensibility was determined if the patient had no sensibility in both malleoli. [4] In addition to the listed walking aids, Patient 8 used a wheelchair for mobility. Abbreviations: DF: dorsiflexion, PF: plantar flexion; X: no sensibility, R: reduced sensibility, N: normal sensibility, AFO: ankle–foot orthosis.

Plantar Flexion Torque and Positive Work

Figure 4 shows an example of the recorded torque-angle characteristics and includes the PF torques and areas under the DF torque-angle characteristic per condition for comparison between patients. The torque-angle characteristics measured from all patients are shown in Appendix B. The maximum DF angle of Patient 8 was <10 deg., and the maximum DF angle of Patient 3 was <0 deg. in the ankle condition (A) (see Table 1). Consequently, the data of these patients were excluded from the statistical test at these angles.

The repeated-measures one-way ANOVAs revealed statistically significant differences at the group level in PF torque between conditions at 0 deg. ($F(2, 16) = 8.031$; $p = 0.005$), 10 deg. ($F(1.208, 8.458) = 10.308$; $p = 0.009$), and max DF ($F(2, 18) = 12.422$; $p < 0.001$). A post hoc analysis indicated that the PF torque with Hermes applying compensation ($A + H_{100\%}$) was significantly lower than both the PF torque with Hermes applying no compensation ($A + H_{0\%}$) and without Hermes (A) at the three assessed angles, i.e., 0 deg., 10 deg, and the max. DF angle (Figure 5). Additionally, no significant differences in PF torque were found between the condition with Hermes applying no compensation ($A + H_{0\%}$), and the condition without Hermes (A). Appendix C provides detailed results of the post hoc analysis.

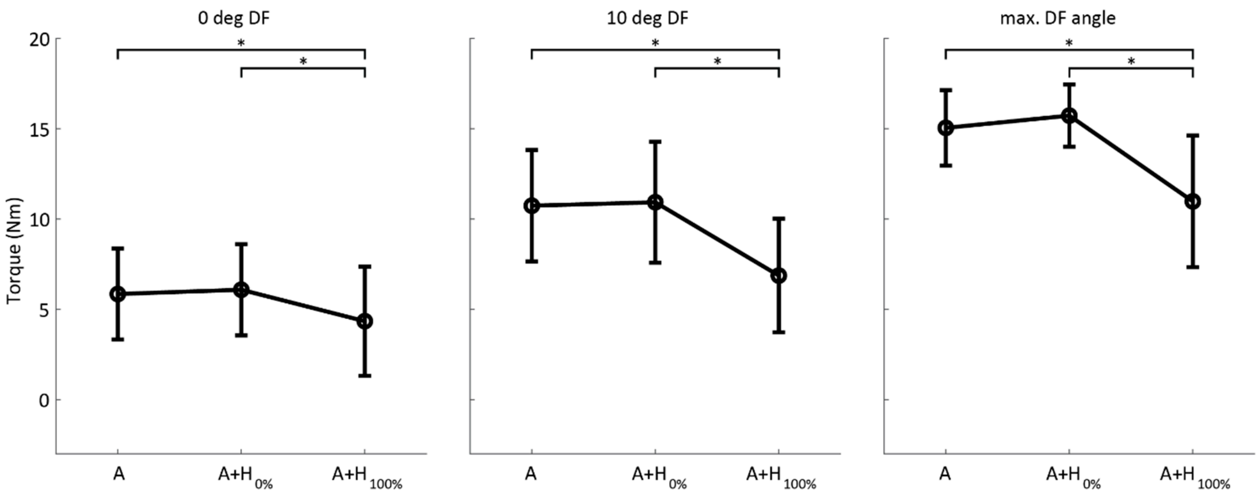

Figure 5. Mean torque values at 0 deg., 10 deg., and maximum DF angle between conditions across all subjects. Error bars represent standard deviations. Post hoc analysis after repeated-measures ANOVAs revealed that significant reductions in PF torque occurred at three assessed angles in the condition with Hermes applying compensation ($A + H_{100\%}$) compared to conditions without Hermes (A) and with Hermes applying no compensation ($A + H_0$). * indicates significant differences ($p \leq 0.05$).

Regarding positive work, the repeated-measures one-way ANOVA showed significant differences between conditions ($F(2, 18) = 5.878$; $p = 0.02$). The post hoc analysis revealed that positive work was significantly reduced when Hermes applied compensation ($A + H_{100\%}$) compared to the condition with Hermes applying no compensation ($A + H_0$) (69 (95% CI, 16 to 121) Nm·deg, $p < 0.05$), but not compared to the condition without Hermes (A) (31 (95% CI, 51 to 114) Nm·deg, $p > 0.05$), as illustrated in Figure 6. Furthermore, positive work in the condition with Hermes applying no compensation ($A + H_0$) was not significantly different from positive work without Hermes (A) ($p > 0.05$).

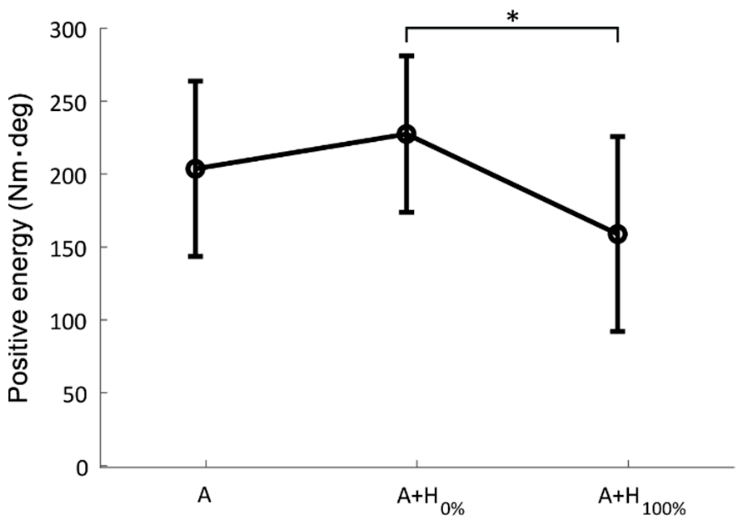

Figure 6. Comparison of mean positive work between conditions across all subjects. Error bars represent standard deviations. Multiple comparisons after repeated-measures ANOVA revealed significant reductions in positive work when Hermes applied compensation ($A + H_{100\%}$) compared to condition without compensation ($A + H_{0\%}$), but not compared to condition without Hermes (A). * indicates significant differences ($p \leq 0.05$).

4. Discussion

In this study, we found that Hermes did not contribute to additional stiffness at the ankle if torque compensation was off. When torque compensation was on, Hermes significantly reduced the PF torque at 0 degrees, 10 degrees, and maximum ankle dorsiflexion. These reductions in PF torque are comparable to the reductions reported after repeated ankle stretching programs [25] and training with an ankle robot in patients with chronic stroke [26]. Furthermore, for most patients in this study, the PF torques in the combined Ankle + Hermes torque-angle characteristic ($A + H_{100\%}$) are comparable to those reported in healthy controls [25], indicating that Hermes is capable of mechanically compensating the increased ankle stiffness in patients with spastic paresis, potentially achieving a clinical level of improvement.

We assume that the PF torque and positive work reductions observed in this study are able to assist voluntary dorsiflexion of the ankle joint, as demonstrated in our previous study [12], and to facilitate walking in patients with spastic paresis. Future research may evaluate the effects of Hermes' assistance during walking and explore the interaction between ankle stiffness compensation and the dynamics of the ankle joint during gait. We anticipate that Hermes may be integrated into clinical studies to manage symptomatic increases in PF torque due to spastic paresis. In the long term, this integration can not only improve ankle control and patient mobility but also potentially reduce costs associated with orthopedic shoes and neuromuscular blockade for addressing spastic paresis.

The significant reduction in positive work demonstrates that Hermes is able to accommodate the patient's passive ROM and reduce the positive work required from the dorsiflexor muscles to dorsiflex the ankle. However, positive work in the condition with Hermes applying compensation ($A + H_{100\%}$) was not significantly lower than positive work in the condition without Hermes (A) as opposed to the results in PF torque.

This lack of significant difference in positive work may be attributed to the inter-patient variability observed in the condition without Hermes, which may originate from differences in ankle stiffness and range of motion among patients. The larger variance in positive work compared to PF torque may also originate from the method of assessing the Hermes' effect. Positive work is determined by considering the entire torque-angle characteristic and provides an indication of the effect of Hermes across the whole range of motion. In contrast, assessing Hermes' effect by assessing the PF torque at specific angles offers insights into Hermes' compensation at precise points along the torque-angle characteristic.

Another limitation is the number of data samples in the group-level analysis. Insufficient data samples may have affected the statistical power to detect differences between conditions. For instance, data from Patients 3 and 8 were absent in some of the statistical tests because these patients were unable to attain 10 degrees DF in the ankle condition (Patient 3 could not reach 0 deg. DF) and therefore also in the Ankle + Hermes conditions. Furthermore, data from Patient 5 were omitted due to technical issues, and data from Patient 11 were excluded from analysis due to an absence of limited pROM as measured with the ankle manipulator. For future studies, a larger group of patients will be essential to validate the findings and generalize them to broader patient populations. Additionally, scaling and/or normalizing methods based on maximum DF torque or positive work could be implemented for more accurate and equitable comparisons across patients, accounting for individual variations in ankle stiffness and ROM.

In addition to slight differences in the results for PF torque and positive work, as explained above, we observed a large variation in the reductions in both PF torque and positive work among patients. This variation is partially because in Patients 6, 7, and 8, we did not observe reductions in PF torque and positive work when in the condition with Hermes applying compensation ($A + H_{100\%}$) compared to the condition without Hermes (A). Furthermore, in our previous study [12], we identified limiting factors contributing to the variability among patients, such as involuntary muscle activation and suboptimal orthotic fit of the modular Hermes orthotic brace. We believe that suboptimal orthotic fit was also a limiting factor in this study that could affect Hermes' ability to compensate ankle stiffness and change torque measurement across the ROM. Custom-made Hermes foot and calf parts, commonly used in clinical practice, are expected to offer a better orthotic fit, potentially reducing misalignment and compensation discrepancies. Another limiting factor in this study that may have led to insufficient torque provided by Hermes is that the setting of the negative stiffness mechanism was not always perfectly guaranteed due to assembly discrepancies. This was particularly observed in Patients 6–8. Future improvements in Hermes may involve the use of more durable mechanism components and a simpler adjustment process. A patient-specific cam and spring will simplify the construction of the negative stiffness mechanism and reduce errors of both assembly and adjustment.

In this study, the appropriate reference for the compensation of PF torque by Hermes was explored, corresponding to either the average torque-angle characteristic or the torque-angle characteristic during DF movement only. Compensating the torque-angle characteristic during DF movement would directly provide the necessary torque to ensure maximal dorsiflexion of the ankle. However, this approach would require the PF muscle to exert more PF work to plantarflex the foot. Conversely, compensating for the average torque-angle characteristic would ease voluntary PF movement but may be insufficient for achieving the DF angle required for certain activities, such as ascending stairs. We did not observe significant differences between using the two references. We analyzed factor compensation ($A + H_{100\%}$) versus no compensation (A, $A + H_{0\%}$), which justified pooling the results of all patients in the same analysis.

Most patients in this study were undergoing botulinum neurotoxin treatment. This and other treatments, such as stretching, may decrease ankle stiffness. Thus, the treatment may be a covariate that affects the PF torque and positive work outcomes. In this study, botulinum neurotoxin (BoNT) may have reduced the number of =patients who did not achieve 10 degrees and/or 0 degrees DF at baseline such that their outcomes were included in the "PF torque" analysis. Not controlling for individual ankle stiffness may be a limitation in the statistical analysis. However, the number of observations was too low to include additional covariates. In future studies, controlling for baseline ankle stiffness due to BoNT treatment and natural changes will be important.

The optimal Hermes' compensation for improving ankle function during walking and daily activities is subject to future studies. As Hermes use may also contribute to functional stretching, the initially required compensation may decrease as patients adapt to Hermes. Longitudinal studies are needed to reveal the long-term effects of compensation provided by Hermes.

5. Conclusions

Our results demonstrate that Hermes is able to effectively compensate ankle stiffness, leading to reductions in both the combined Ankle + Hermes PF torque and positive work compared to conditions without Hermes. We believe that the Hermes ankle–foot orthosis can provide a solution for reducing increased ankle stiffness, thereby enhancing ankle function during daily activities and improving walking ability for patients with spastic paresis. Additionally, our findings affirm that robotic measurements of ankle stiffness and combined Ankle + Hermes stiffness are valuable for the precise customization of torque provided by ankle–foot orthoses (precision orthotics). Based on our results, the next step in integrating Hermes into the management of spastic paresis is to evaluate its effects during walking.

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Institutional Review Board Statement: This research was conducted in accordance with the Declaration of Helsinki and was approved by the Leiden-Den Haag-Delft Medical Ethical Committee, CCMO (Centrale Commissie Mensgebonden Onderzoek) trial registration number NL64640.058.19. The research protocol was approved on 19 December 2019, and an update was then approved on 29 September 2022.

Informed Consent Statement: Informed consent was obtained from all subjects involved in this study. Written informed consent has been obtained from the patient(s) to publish this paper.

Data Availability Statement: The data presented in this study related to the plantarflexion torque and positive work are available in the 4TU. ResearchData repository (DOI: 10.4121/fab1a54d-3e68-4d6f-8d94-161c16539760). The participants data supporting this study is restricted to the research safety commission, a designated monitor from the Leiden University Medical Center (LUMC), and national and international supervisory authorities, such as the Dutch Healthcare and Youth Inspectorate (IGJ).

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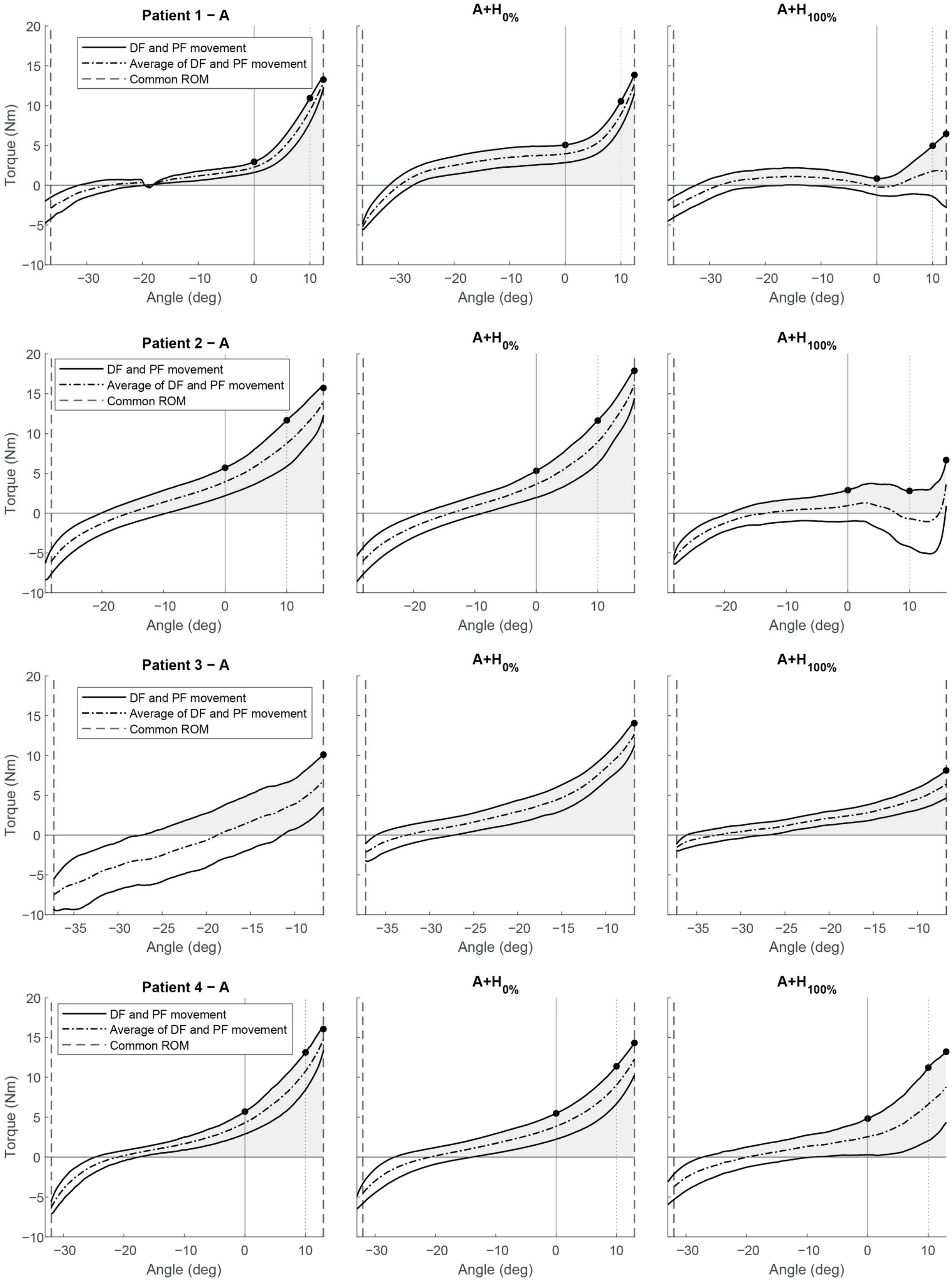
Conflicts of Interest: Frank Baas is affiliated with InteSpring that markets the mechanism utilized in the Hermes ankle-foot-orthosis. All the other authors declare no conflicts of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

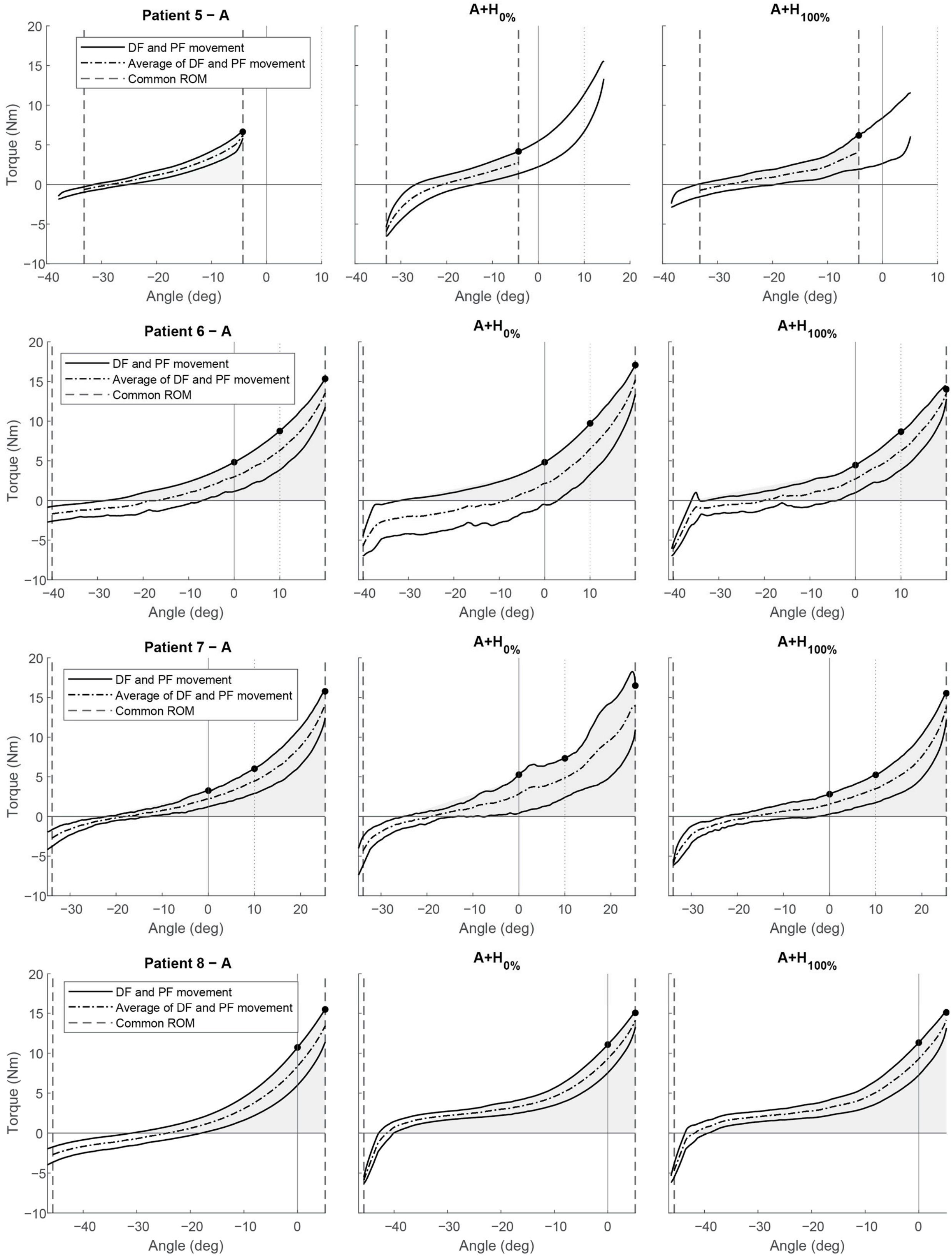
Appendix A. Calculation of Positive Work

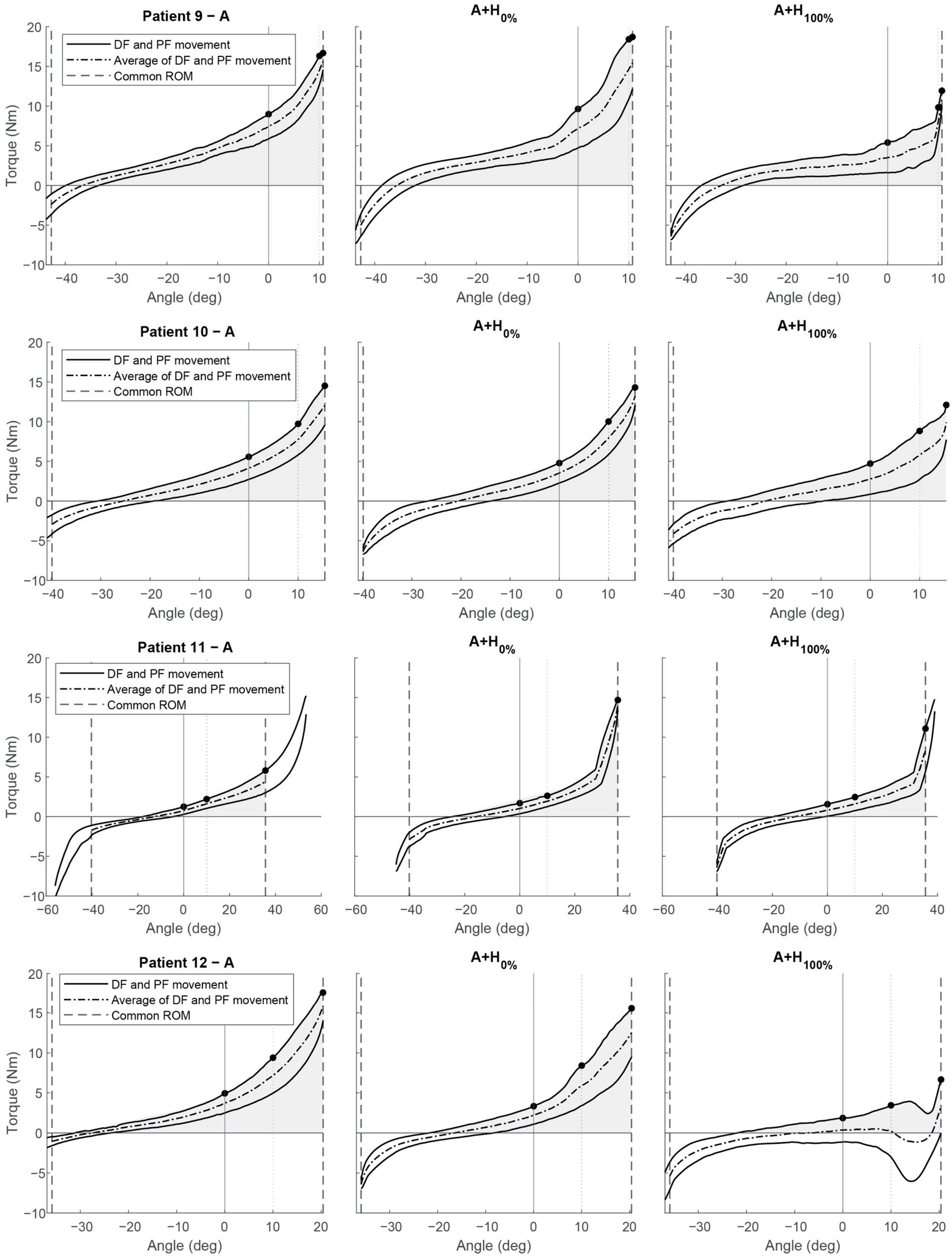
Since the patient's leg was removed from the ankle manipulator between conditions to put on or adjust Hermes, the calibration angle of the ankle manipulator could vary by several degrees between conditions. This variation was allowed to maintain consistent patient posture (i.e., similar hip, knee, and ankle angles before the start of each condition) but resulted in small differences in the passive ROM between conditions for some patients. To account for these small ROM differences and ensure a fair comparison of positive work, the common ROM shared by the averaged torque-angle characteristics across the three conditions was considered the passive ROM for determining the positive work. This common ROM refers to the angles where torque measurements were available for all three conditions.

Appendix B. Torque-Angle Characteristics Measured from All Analyzed Patients

The following figures show the torque-angle characteristics measured without (A) and with Hermes ($A + H_{0\%}$ and $A + H_{100\%}$) for all patients. Solid lines denote the hysteresis loop of the torque measured during the DF and PF movements applied by the ankle manipulator. The dashed–dotted lines denote the average torque of the measured DF and PF movements from the hysteresis loop. The black-filled circles represent the torque values at 0 deg., 10 deg., and max. DF angle for comparison between patients. The dashed lines denote the common ROM across conditions for each patient, while the shaded areas indicate the positive work, calculated as the areas under the torque-angle characteristic.


Patient 1 − A
A+H0%
A+H100%
Patient 2 − A
Patient 3 − A
Patient 4 − A
DF and PF movement
Average of DF and PF movement
Common ROM
Torque (Nm)
Angle (deg)


Patient 5 − A
A+H0%
A+H100%
Patient 6 − A
A+H0%
A+H100%
Patient 7 − A
A+H0%
A+H100%
Patient 8 − A
A+H0%
A+H100%
DF and PF movement
Average of DF and PF movement
Common ROM
Torque (Nm)
Angle (deg)



Appendix C. Post Hoc Analysis

After the repeated-measures ANOVAs, post hoc analyses were conducted to compare the PF torque between conditions (A, $A + H_{0\%}$, and $A + H_{100\%}$) at 0 deg and 10 deg, and at the max. DF angle. Table A1 shows the differences in PF torque (in Nm) along with the 95% confidence intervals for each comparison. Significant reductions in PF torque were observed in the condition with Hermes applying compensation ($A + H_{100\%}$) compared to both the baseline (A) and when Hermes applied no compensation ($A + H_{0\%}$) across all tested angles ($p < 0.05$).

Table A1. Post hoc analysis.

Angle	Comparison	Difference in Torque (Nm)	95% Confidence Interval	*p* Value
0°	$A + H_{100\%}$ vs. A	1.5	0.06 to 2.9	0.041
	$A + H_{100\%}$ vs. $A + H_{0\%}$	1.7	0.03 to 3.5	0.046
10° DF	$A + H_{100\%}$ vs. A	3.9	0.2 to 7.5	0.040
	$A + H_{100\%}$ vs. $A + H_{0\%}$	4.1	0.3 to 7.9	0.037
Max. DF Angle	$A + H_{100\%}$ vs. A	4.1	0.6 to 7.5	0.021
	$A + H_{100\%}$ vs. $A + H_{0\%}$	4.8	1.2 to 8.3	0.010

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