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The MyFlex-ζ Foot: a Variable Stiffness ESR Ankle-Foot Prosthesis

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***Abstract*— Most commercially available foot prostheses are passive ESR feet, which store and release energy to reduce metabolic costs and improve comfort but cannot adjust to varying walking conditions. In contrast, bionic feet adapt to different tasks but are hindered by high weight, power consumption, and cost. This paper presents MyFlex-ζ, an ESR foot with a variable stiffness system, as a compromise between these two categories. MyFlex-ζ adjusts stiffness by varying the sagittal-plane distance between two key points, altering force interactions within the prosthesis and affecting overall stiffness. Clinical tests with three transfemoral amputees evaluated stiffness variation across two sessions: the first subjective, where participants assessed stiffness settings during different tasks, and the second biomechanical, measuring performance parameters. Two participants selected different stiffness settings for various tasks, while the third, with limited perception of stiffness changes, showed less distinction in outcomes. Greater sagittal-plane rotation and higher energy absorption were observed in most tasks with more compliant settings, although one participant's results were limited due to selecting close stiffness settings. Overall, these findings suggest MyFlex-ζ offers adaptability and performance improvements over traditional ESR feet. With further actuation and control system development, MyFlex-ζ could mark significant progress in prosthesis technology.**

***Index Terms*— Amputation, biomechanical tests, prosthesis design, prosthetic feet, variable stiffness.**

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I. Introduction

LOWER limb amputation has a profound psychological impact on individuals, as documented in various studies [1]–[5]. The resulting loss of mobility further amplifies these effects, although prosthetic limbs can help partially restore function. Prosthetic feet, commonly classified as passive, semi-active, or active (bionic) [6]–[8], are essential for mobility. Passive Energy-Storing-and-Releasing (ESR) feet, the most widely prescribed, are valued for their simplicity and their ability to store and release energy during walking, which reduces metabolic costs and improves comfort [9]–[11].

Typically, Certified Prosthetist Orthotists (CPO) and physiotherapists select prosthetic type and stiffness based on factors like body weight and activity level. However, the fixed stiffness of ESR feet limits their adaptability to changing conditions. Research suggests that stiffer feet are beneficial for standing and fast walking [12]–[14], while lower stiffness helps with activities like load carrying, stair climbing, and ramp walking [15]–[17]. Nevertheless, recent studies show that patient preferences for stiffness can vary [18].

Recent advances in bionic feet have aimed to enhance performance in activities beyond normal ground walking by incorporating actuators and optimized control systems. Fully or partially actuated prosthetic feet can supply mechanical power to improve gait during walking [19]–[23], adjust stride cadence [24], enable ramp, stair walking [25], [26], running [30], movement on uneven terrain [31], and support specialized activities like climbing [32] or dancing [33]. Despite these advantages over ESR feet, bionic feet face challenges such as complexity, increased height, weight, power consumption, and cost, limiting widespread adoption. Currently, the Empower foot (Otto Bock, Duderstadt, Germany) remains the only commercially available bionic foot.

Semi-active prosthetic feet have emerged as a solution to address both ESR and bionic feet limitations, offering greater adaptability than ESR feet while being lighter, less complex, and more affordable than bionic feet. They can adjust mechanical properties using more compact actuators. Commercial examples include the Elan Foot (Endolite), OdysseyK2 and K3 (College Park), Meridium and Smart Ankle (Ottobock), and Kinnex (Freedom Innovations), which use hydraulic units to regulate damping and adapt to various terrains like uneven ground and ramps. However, hydraulic resistance dissipates energy that could otherwise assist in completing the gait cycle [34], [35]. The Proprio Foot (Össur) takes a different

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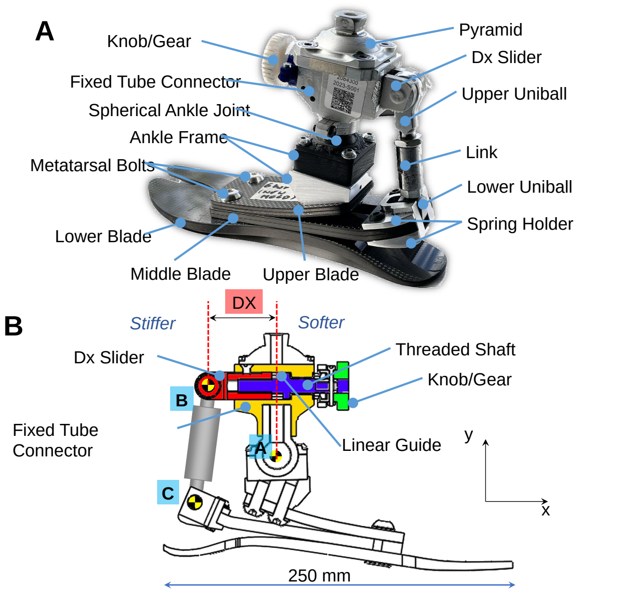

Fig. 1. MyFlex-ζ's (A) picture and schematic of (B) Dx Slider Mechanism.

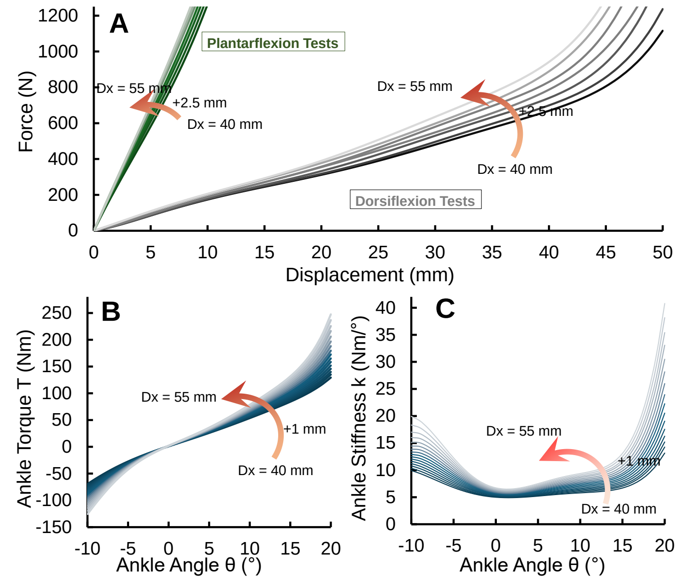

Fig. 2. MyFlex-ζ's sagittal plane characteristics. (A) Displacement - force curves have been obtained from static tests, while (B) ankle angle - ankle torque and C) ankle angle - ankle stiffness curves have been obtained from FEAs.

approach, using a compact actuator and control system to adjust the ankle angle, improving toe clearance on slopes and stairs, while also storing energy during walking [36], [37]. Semi-active prosthetic feet category includes also the variable stiffness foot prostheses as sub-category. The stiffness in the Variable Stiffness Prosthetic Ankle-Foot (VSPA Foot) [38] by Shepherd and Rouse is adjusted by changing the free length of a fixed elastic element with a movable support. Similar working principle is found in the Variable Stiffness Foot (VSF) by Glanzer and Adamczyk [39]. Variable Stiffness Ankle (VSA)'s stiffness is modified by altering the force application distance on a cantilever beam elastic element [40]. A pneumatic system is used to adjust the overall stiffness of Mrazasko et al's prosthesis [41]. Tryggvason et al. [42], [43] implemented a damping system in series and parallel with elastic elements, allowing damping properties to influence the prosthesis's stiffness. Additionally, Rodgers-Bradley et al. [44] developed a system enabling the selection of the number of elastic elements engaged during walking.

In this paper, MyFlex-ζ is introduced as a promising alternative to existing variable stiffness prosthetic feet. It is an ESR foot prosthesis with several distinct advantages. The first is its spherical ankle joint, built with carbon fiber composite, which allows for better absorption of terrain irregularities, enhancing user sensations while keeping the device lightweight. The second advantage is a system that continuously adjusts torsional stiffness in the sagittal plane, designed for both manual user operation and motorized control via an electric motor. While this motor adds weight, it increases automation; users unconcerned about weight can choose automatic actuation, while those preferring manual adjustment can forgo the motor. MyFlex-ζ evolves from MyFlex-ϵ, which is based on MyFlex-δ. The latter has already shown improvements in users' perceptions when walking on uneven surfaces, for its spherical ankle joint [46]. Compared to previous works found in literature concerning variable stiffness foot prosthese, no actuation system was used during clinical tests, since the focus was on understanding how stiffness variations affect the sagittal plane kinematics of users. Future work may incorporate an actuation system once MyFlex-ζ's variable stiffness system is validate clinically. While it is not claimed that MyFlex-ζ is a definitive improvement over past designs, it is positioned as a viable alternative.

To describe thoroughly the features and potential advantages of MyFlex-ζ, the remainder of the paper is structured as follows. In Sec. II, the foot prosthesis is described (Sec. II-A), details about the clinical tests participants are given (Sec. II-B) and the properties of the instrumented treadmill are provided (Sec. II-C). In Sec. III, how the initial stiffness setting is selected is described (III-A), as well as how the alignment is carried out (III-B). Moreover, the procedure followed to let the participants familiarize with MyFlex-ζ and select their preferred stiffness for different activities is described in Sec. III-C. The descriptions of the procedure followed for the measured tasks and how specific biomechanical parameters are calculated are given in Sec. III-D. Finally, results are given in Sec. IV and discussed in Sec. V.

II. Materials

A. The Foot Prosthesis

MyFlex-ζ (Fig. 1A) is an ESR foot prosthesis that inherits its general configuration from MyFlex-γ, MyFlex-δ, and MyFlex-ϵ [45]–[47]. Specifically, it adopts the configuration of MyFlex-ϵ, with a redesigned variable stiffness system (the Dx Slider system), ankle frame, and middle blade. The Dx slider moves forward or backward by rotating the knob-threaded shaft system (Fig. 1B), adjusting the Dx parameter between 40 mm and 55 mm. Although modifications were made to address the limitations of MyFlex-ϵ, MyFlex-ζ retains the

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TABLE I
MYFLEX-ζ'S STIFFNESS CHARACTERISTICS: SAGITTAL PLANE TORSIONAL STIFFNESS kT AT SPECIFIC ANGLES AND SPECIFIC DX VALUES, AND VARIATION FROM THE MOST COMPLIANT CONFIGURATION (DX = 40 MM).

	θ (°)	Dx = 40 (Nm/°)	Dx = 44 (Nm/°)	Dx = 45 (Nm/°)	Dx = 47 (Nm/°)	Dx = 50 (Nm/°)	Dx = 55 (Nm/°)
Absolute	-10	9.93	11.65	12.06	12.91	14.46	19.93
	-5	6.79	8.00	8.32	9.01	10.14	12.26
	0	4.99	5.38	5.48	5.69	6.04	6.74
	5	5.20	5.70	5.85	6.13	6.61	7.51
	10	5.80	6.66	6.89	7.37	8.11	9.38
	15	6.70	7.95	8.31	9.05	10.31	13.11
	20	13.14	16.27	19.04	22.27	28.17	40.78
Relative	-10	-	17 %	21 %	30 %	46 %	101 %
	-5	-	18 %	23 %	33 %	49 %	81 %
	0	-	8 %	10 %	14 %	21 %	35 %
	5	-	10 %	12 %	18 %	27 %	44 %
	10	-	15 %	19 %	27 %	40 %	62 %
	15	-	19 %	24 %	35 %	54 %	96 %
	20	-	24 %	45 %	69 %	114 %	210 %

TABLE II
PARTICIPANTS' CHARACTERISTICS AND WALKING SPEEDS.

		Participant 1	*Participant 2*	*Participant 3*
Characteristics	Age (years)	63	48	47
	Gender	M	M	M
	Years of amputation	5	4	5
	Height (m)	1.83	1.88	1.91
	Weight (kg)	72.9	81.8	89.5
	Pros. weight (kg)	3.8	4	3.3
	Leg length (cm)	86	90	92.5
	Res. length (cm)	10.5	20	7
	Pros. knee	Symbionic Leg 3	C-Leg 4	C-Leg 4
	Pros. foot	Symbionic Leg 3	Trias	Velocity
Speeds	Slow (km/h)	2.8	2.1	3.3
	Level (km/h)	4.0	3.0	4.7
	Fast (km/h)	5.2	3.9	6.1
	Up-Hill (km/h)	2.0	2.5	3.0
	Down-Hill (km/h)	1.4	0.8	3.0

same working principle as its predecessor, detailed in [47] and [48]. The prototype developed for this study features a size of 27 (foot shell length of 270 mm, corresponding to shoe size 42), a build height of 153 mm, and a weight of 1.0 kg without the foot shell. The stiffness characteristics and variations of MyFlex-ζ, determined using the procedure outlined in [47], are presented in Fig. 2 as *displacement-force* (Fig. 2A, determined experimentally), *angle-torque*, and *angle-stiffness* (Fig. 2B and Fig. 2C, determined numerically) curves. Additionally, the stiffness in the sagittal plane at specific angles is detailed in Table I, showing that increasing the Dx parameter increases stiffness in both plantarflexion and dorsiflexion. Each curve in Fig. 2B has an increasing trend in torque with the increase in rotation in MyFlex-ζ, and this results in a concave shape for the curves; according to several studies, this shape reduces the pressure exerted by the prosthesis on the residual limb of the amputee [49]–[53].

B. Participants

Three male left-side transfemoral amputees with osseointegration have been recruited to test MyFlex-ζ. They all underwent amputation due to trauma, exhibited a high level of daily activity (medicare functional classification level: K3 and K4), and reported no issues with their own prosthesis, including alignment considerations. To ensure compatibility with the MyFlex-ζ prototype, participants have been selected with 42 as shoe size. In Table II, participants' details are reported. Participant 1 had a Symbionic leg (Össur) as a daily prosthesis, with the knee prosthesis (Rheo Knee, Össur) and foot prosthesis (Proprio Foot, Össur) electronically and mechanically combined. Therefore, during the present investigation, he had to use a distinct Rheo Knee to allow MyFlex-ζ attachment. The CPO set the control system of the new Rheo Knee adapting it to Participant 1's Rheo Knee. Participants 2 and 3 used their own knee prostheses.

Clinical tests performed for the present study aimed to investigate the variable stiffness prosthesis' effects on users and assess them, both subjectively, through users' feedback,

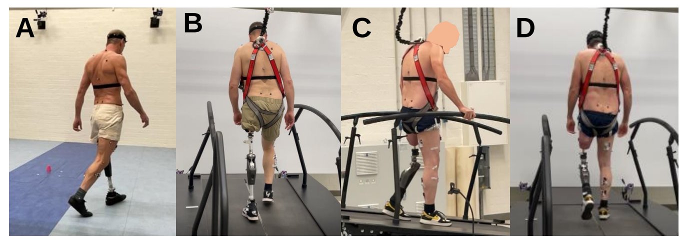

Fig. 3. First and second sessions tasks. (A) overground walking and turning step during first session, (B) uphill, (C) downhill walking and (D) level walking at three different walking speeds on treadmill during first and second sessions. Participants' characteristics and walking speeds during measured tasks are reported in Table II.

and kinematically, through measurements of specific biomechanical parameters. Clinical tests have been assessed by the Ethical Committee CMO Arnhem-Nijmegen (ethical register number 2022-13595) and complied with the guidelines defined in the Declaration of Helsinki. The participants involved gave their written consent to carry out the activities required for this study.

C. Instrumented Treadmill and Kinematics Measurement

In most of the tasks during the clinical tests, participants walked on an instrumented treadmill (M-Gait, Motekforce Link, Netherlands): it includes two embedded force plates to independently measure the ground reaction forces for each foot at a sampling rate of 2000 Hz. Participants' kinematics were captured during second session using a 3D movement analysis system (Vicon Motion Systems, Inc., Lake Forest, CA, USA) and reflective markers placed on their skin. The resulting marker position data were sampled at a rate of 100 Hz. Walking speeds are reported in Table II.

III. METHOD

A. Initial Stiffness Setting Selection

The initial stiffness setting selection was made by the experimenters (CPO, the physiotherapist, and the MyFlex-ζ designers), based on the participants' and their prosthetic feet's characteristics, as well as their experience with the MyFlex foot family. Participant's characteristics refer to their ambulation level and body weight, while prosthetic characteristics refer to the type of prosthetic feet they use in their daily life. Experience with the MyFlex family of feet refers to both the knowledge of MyFlex-ζ's stiffness characteristics and its predecessors', as well as the clinical tests conducted on MyFlex-δ [46]. Based on these factors, the initial value of the Dx parameter was set at 44 mm for Participant 1 and Participant 2, while for Participant 3, a Dx value of 46 mm was chosen.

B. Alignment

The CPO replaced the foot prosthesis of each participant and fitted MyFlex-ζ, attaching it to the knee prosthesis. MyFlex-ζ was set at the initial Dx setting. Afterwards, the alignment was carried out using the 3D L.A.S.A.R. Posture (Ottobock). The CPO and the physiotherapist placed the alignment reference line at a distance of 30 mm posterior to the midpoint of the foot (a practice commonly recommended for commercially available feet). Two sessions in the same day were carried out for each participant. Details are described in the following sections.

C. First Session: Familiarization and Participants' Preferences Selections

After the CPO replaced the participants' prostheses with MyFlex-ζ, set the initial Dx value, and adjusted the alignment, the participants engaged in various tasks to familiarize with the new device and identify their stiffness preferences. Initially, participants performed sit-to-stand and stand-to-sit tasks to verify the stability of MyFlex-ζ during these basic movements. Subsequently, they performed overground walking with support while using MyFlex-ζ at the initial Dx value to acclimate to the prosthetic device during locomotion. Following these tasks, participants walked on overground (Fig. 3A) as well as on inclined (Fig. 3B) and declined (Fig. 3C) treadmills, without recording any biomechanical parameters. Participants repeated each task for up to five trials with corresponding stiffness settings. Each trial lasted one minute, and participants were given the opportunity to rest sufficiently between consecutive trials. The experimenters asked participants to describe their perceptions in real-time and after each trial. With each change in stiffness setting, they were also requested to indicating whether they preferred the current stiffness over their previously stated preferred setting. At the end of each task, each participant provided an overall assessment of the settings they had tried in order to determine which one they considered the best.

D. Second Session: Measured Tasks with Two Stiffness Settings

To objectively assess the impact of stiffness variation on walking, several biomechanical parameters were measured during treadmill tasks. Participants tested different stiffness settings across multiple activities to determine their effects. To mitigate fatigue-related bias, each participant was instructed to select only two Dx stiffness values to be used across the following tasks: normal walking (at a self-selected comfortable speed) for one minute, slow walking (30% slower than normal) for one minute, fast walking (30% faster than normal) for one minute, uphill walking (at a comfortable speed with a 10° incline) for two minutes, and downhill walking (at a comfortable speed with a 10° decline) for two minutes.

Participants were free to choose the settings to use in the second session, but they were encouraged to select values that would serve as a compromise between those best suited for each of the various activities to be performed in the subsequent session. For each activity, participants began without knowing which of the two selected settings had been applied as first stiffness. From this second session, variables such as *gait–sagittal plane ankle angle* (calculated for all tasks), *gait–sagittal plane ankle torque*, *sagittal plane ankle angle–ankle torque* curves, stored energies, plantarflexion and dorsiflexion peaks were computed, as well as the durations of stance subphases (only for slow walking, level walking, and fast walking). The *gait–sagittal plane ankle angle* curves were derived by averaging 30 consecutive steps, and the same procedure was applied to obtain the *gait–sagittal plane ankle torque* curves. The ankle *angle–ankle torque* curves in the sagittal plane were built from the first two curves. Plantarflexion and dorsiflexion peaks were calculated by first determining each peak across the 30 steps, resulting in 30 plantarflexion peaks and 30 dorsiflexion peaks. The mean and standard deviation were then calculated for both rotations.

For each step, the stored energies during level treadmill walking were calculated by determining the area under the *sagittal plane angle-torque* curves, using the trapezoidal rule for numerical integration. More specifically, the plantarflexion energy was calculated from 0° to maximum plantarflexion (from heel strike to toe strike), while the dorsiflexion energy was calculated from 0° (equilibrium position during mid stance) to maximum dorsiflexion (heel off). A total of 30 stored energies during plantarflexion and 30 stored energies during dorsiflexion were obtained. Subsequently, the means and standard deviations were calculated for each participant and each task.

Finally, from the second session, contact time and stride time were also recorded. Stance phase duration was determined for each of the 30 consecutive strides as the ratio between contact time and stride time. The stance phase subphases are: early stance, mid stance and late stance. Early stance phase is defined as the interval from heel strike to toe strike (when maximum plantarflexion is reached), mid stance phase is calculated as the period from toe strike to heel off (when maximum dorsiflexion is reached), and late stance phase is the period from heel off to toe off (when the foot leaves the ground). Their durations were calculated as follows: firstly, these durations were calculated in seconds, considering when maximum plantarflexion and maximum dorsiflexion are reached to determined early stance and mid stance phases. Late stance phase is calculated as the difference between the total stance phase duration and the first two sub-phases durations. Subsequently, their durations in percentage were calculated with respect to the stride duration. Finally, mean

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values and standard deviations of this durations in percentage were calculated.

IV. Results

A. First Session Results: Perceptions and Preferred Stiffness

1) Participant 1: began the overground walking task with a Dx 44, noticing knee flexion during early stance—a typical movement for a healthy leg but unusual for his prosthetic knee. Initially insecure about the flexion, he gradually felt more comfortable. After one minute of walking, he noted that the stiffness felt insufficient but not overly compliant. Without informing him, the experimenters adjusted the Dx to 45 and then to 46. He ultimately found Dx 45 to be the best for level walking. For the uphill task, he started with Dx 45, which the CPO increased to 46 and then 47 based on observations. He rated Dx 46 as optimal for uphill walking, noting improved stance stability. During the downhill task, he returned to Dx 45 but requested more stiffness, leading to adjustments. He eventually rated Dx 47 as ideal, citing better stability and rollover, with increased toe stiffness helping him maintain an upright position.

2) Participant 2: also began with Dx 44, initially noting a firm heel strike and smooth rollover. Although the Dx was increased, the adjustments remained close to the original, resulting in minimal perceived differences. As a result, the experimenters set the Dx to 55. With this setting, Participant 2 experienced a more pronounced heel strike and better rollover compared to lower stiffness levels. Noticing limited differences between intermediate Dx settings, he chose to test also Dx 40. This setting made downhill walking more challenging compared to his own prosthesis. Despite these extremes, he still perceived limited differences. After discussions with the experimenters, it was hypothesized that the minimum stiffness setting of MyFlex-ζ might have been higher than what he was accustomed to, potentially limiting his ability to discern differences at higher settings.

3) Participant 3: began level walking with a Dx setting of 46 mm, immediately noticing that the MyFlex-ζ, weighing 1.0 kg without the foot shell, felt heavier than his own prosthesis (College Park Velocity: 0.631 kg with the shell). Although the MyFlex-ζ provided favorable rollover and energy return at toe-off, he experienced a discomforting ”knock” when the foot returned to neutral after detaching from the ground. This sensation may arise from the interaction between the MyFlex-ζ's elastic elements and its ankle joint, which differs from his usual prosthesis that lacks an ankle joint. During level walking, Participant 3 tried both lower and higher stiffness settings but ultimately rated the initial setting as the most suitable, noting that the heel strike was adequately attenuated while the toe had enough stiffness for effective propulsion. He then walked uphill on the treadmill, starting again with Dx 46. Noticing minimal changes with close stiffness settings, he tested Dx 40 and Dx 55, rating Dx 55 as providing better stability and enhanced energy return during push-off. For downhill walking, he used Dx 46, Dx 40, and Dx 55 without knowledge of the stiffness settings. Initially, he preferred Dx 40 for its smooth rollover and quick transition to foot flat, which he felt increased stability between early stance and beginning of mid stance. However, he later concluded that Dx 55 was superior, offering greater stability during stance despite a slower transition to foot flat, resulting in a safer overall stance phase and improved energy return.

B. Stiffness Settings Used in the Second Session

Based on their perceptions from the first session, in accordance with the experimenters, Participant 1 chose Dx 45 as the compliant setting and Dx 47 as the stiff setting; Participant 2, who experienced limited perceptual variations, opted for Dx 40 and Dx 55; lastly, Participant 3 selected Dx 44 and Dx 55. In the previous session, he favoured Dx 55 for both uphill and downhill walking due to its stability, although he acknowledged some positive aspects of Dx 40 despite its lower stability. He chose Dx 44 as compliant setting, which is a compromise between the advantages of Dx 40 and his preferred setting of Dx 46 for normal ground walking.

C. Sagittal Plane Ankle Angle and Torque

The sagittal plane *gait-ankle angle* curves across the five tasks are shown from Fig. 4A to Fig. 4F, while the sagittal plane *gait-ankle torque* curves are shown from Fig. 4G to Fig. 4L, and the sagittal plane *ankle angle-ankle torque* curves are shown from Fig. 4M to Fig. 4R. Finally, plantarflexion and dorsiflexion peaks are displayed from Fig. 5A to Fig. 5C. The plantarflexion and dorsiflexion peaks for Participant 1 did not show significant differences between the two stiffness settings across all the tasks, neither a consistent variation (Fig. 4A, Fig. 4D, Fig. 5A). This has been expected due to the closeness of the two settings chosen by Participant 1 for the second session. Consistent variations, however, were observed for both Participant 2 (Fig. 4B, Fig. 4E, Fig. 5B) and Participant 3 (Fig. 4C, Fig. 4F, Fig. 5C), with only one exception: reduction in both plantarflexion and dorsiflexion peaks when using the stiffer setting was observed in dorsiflexion across all activities, while the same consistency was seen also for plantarflexion with the exception of the for Participant 2 during slow walking. An important aspect to highlight is the significantly reduced range of motion in plantarflexion during uphill activities, particularly for Participant 1 (Fig. 5A) and Participant 2 (Fig. 5B).

Concerning the ankle torque, all participants showed lower ankle torque in plantarflexion and dorsiflexion with more compliant settings, even if the difference is minimal for Participant 1 (Fig. 4G, Fig. 4J), again for the reason mentioned earlier. Significant variations can be observed for Participant 2 across all activities (Fig. 4H, Fig. 4K), and the same for Participant 3, except for the minimal variations obtained in conditions of slow walking (Fig. 4I) and downhill walking (Fig. 4L).

D. Stored Energies

The stored energies calculated from *ankle angle-ankle torque* curves (Fig. 4M-Fig. 4R) are shown in Fig. 6. As the energies stored during plantarflexion are roughly ten times

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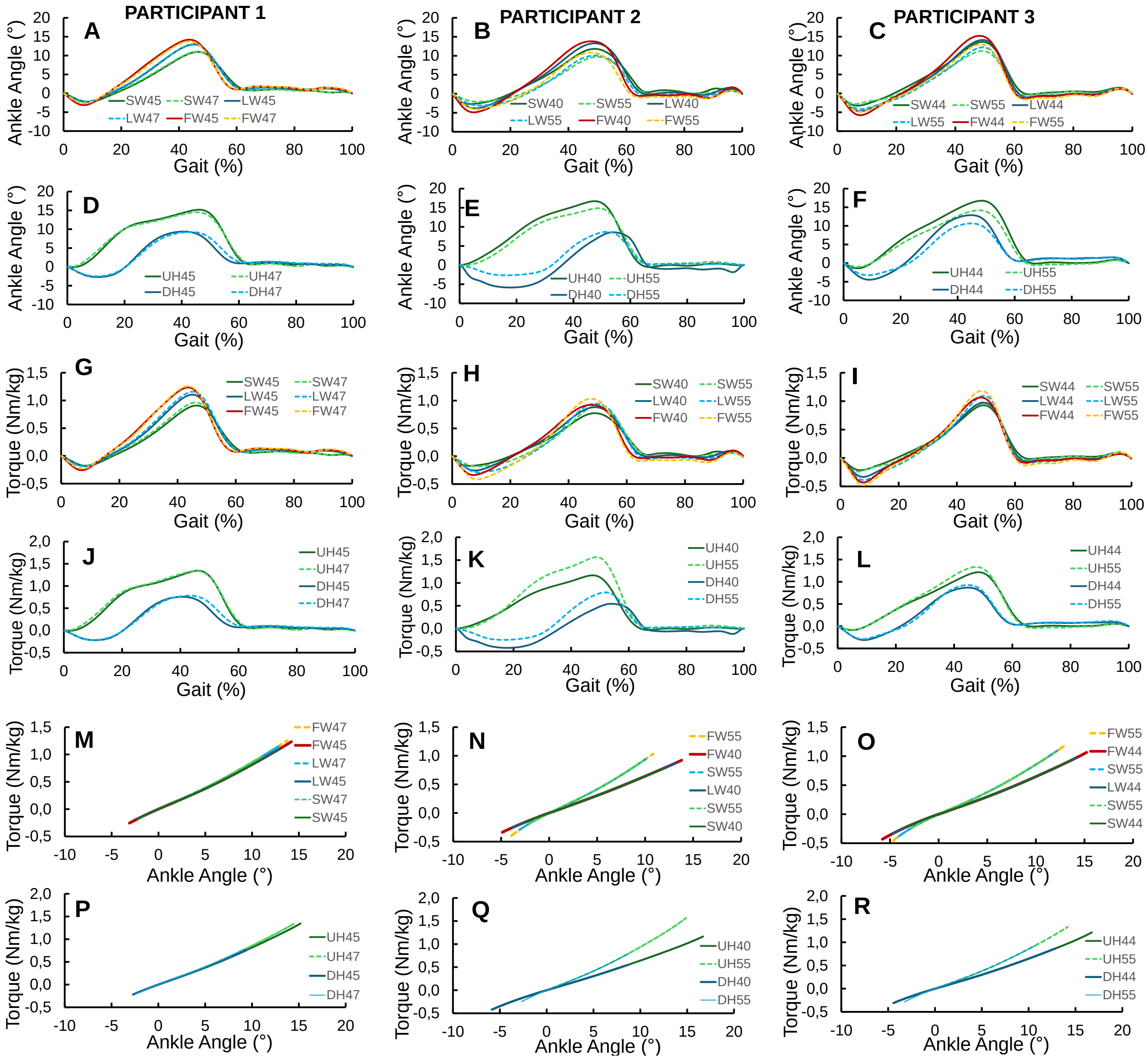

Fig. 4. Sagittal plane kinematic results: (A-C) slow, level, and fast walking *gait-ankle angle* curves; (D-F) uphill and downhill walking *gait-ankle angle* curves. Sagittal plane ankle torque results: (G-I) slow, level, and fast walking *gait-ankle torque* curves; (J-L) uphill and downhill walking *gait-ankle torque* curves; (M-O) slow, level, and fast walking *ankle angle-ankle torque* curves; and uphill and downhill walking *ankle angle-ankle torque* curves. SW = slow walking, LW = level walking, FW = fast walking, UH = uphill walking, and DH = downhill walking. Participant 1 performed second session with Dx 45 and Dx 47, Participant 2 used Dx 40 and Dx 55, and finally, Participant 3 tested Dx 44 and Dx 55.

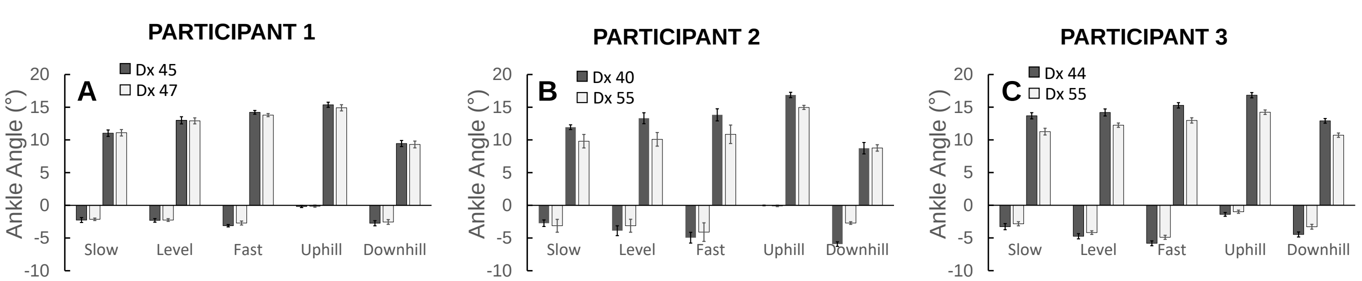

Fig. 5. Sagittal plane peaks for all tasks. For each task, the first two bars correspond to the plantarflexion peaks (negative angles), while the last two bars correspond to the dorsiflexion ones (positive angles).

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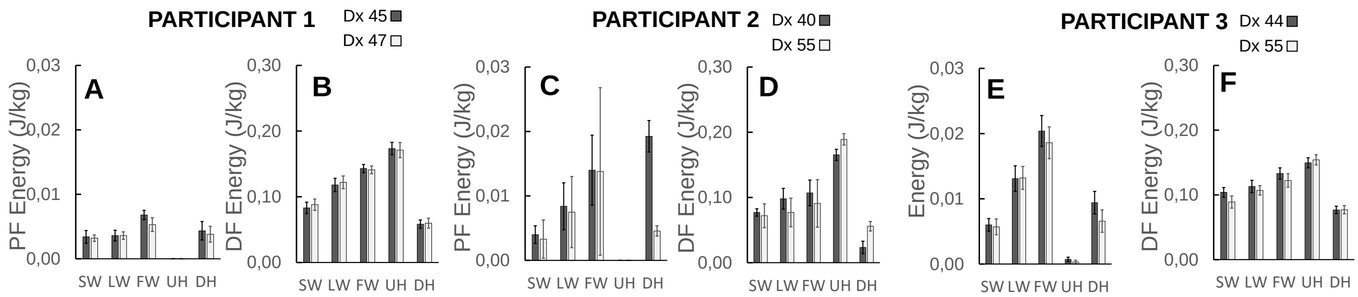

Fig. 6. Sagittal plane stored energies across all activities.

lower than those stored during dorsiflexion, two separate graphs with different scales are provided for each participant.

Since the stored energy is calculated based on the ankle angle and torque, and given that ankle torque reflects the prosthesis's behavior relative to the same ankle angle, similar stored energy values in both plantarflexion and dorsiflexion for Participant 1 were expected. For the other two participants, a more consistent and coherent variation was observed between the two stiffness settings, at least for level treadmill walking (slow walking, level walking, and fast walking), with greater energy stored when the prosthesis is set at lower stiffness. In contrast, inconsistent results were also observed for Participant 2 and Participant 3 regarding uphill and downhill. In the case of uphill, the energy stored in dorsiflexion by Participant 2 and Participant 3 is greater with the stiffer prosthesis. However, in the case of downhill, both stored more energy with the less rigid setting in plantarflexion. For Participant 2, the energy stored in dorsiflexion is greater with the hard setting, while for Participant 3, the results are quite similar.

Regarding the standard deviations observed for Participant 2 (Fig. 6C and Fig. 6D), they were already larger compared to the other two participants, even in the case of the bar graphs in Fig. 5B. These standard deviations are even more pronounced in the case of the stored energy, particularly during fast walking. These results could somehow confirm Participant 2's limited perception of the variation in stiffness expressed during the first session.

E. Gait Phases and Subphases Durations

An analysis was conducted to investigate the effect of varying stiffness settings of the prosthetic foot on the main stanche sub-phases' durations. Specifically, the mean values and standard deviations were calculated for the early stance, mid stance, and late stance (or push-off). As shown in Fig. 7, only Participant 2 demonstrated consistent results across all walking speeds and in all three sub-phases of the stance phase when transitioning from the lower to the higher stiffness setting: shorter early stance with the compliant setting, and shorter mid stance and late stance with the stiff setting. For Participant 1, the lack of consistency was again expected due to the proximity of the two stiffness, while for Participant 3 showed consistency only in the late stance duration, i.e., it was shorter with the stiffer setting.

V. Discussion

This paper presents the MyFlex-ζ, a variable-stiffness prosthesis, and the two-session clinical tests conducted with three male transfemoral amputees. In the initial session, participants walked on both level ground and a treadmill, evaluating various stiffness settings. These evaluations enabled them to determine their preferred stiffness settings for different activities. Based on these preferences, the participants identified a pair of stiffness settings to use in the second session, which focused on biomechanical measurements. During the second session, all activities were performed on a treadmill, starting with a horizontal treadmill at three different speeds for each participant: slow, level (comfortable), and fast speeds. This was followed by inclined treadmill tests simulating uphill and downhill walking. The types of tasks performed during the second session were aligned with what has been performed in works found in literature [54].

Each task and each participant had to start with an initial stiffness setting. For the present work, the initial stiffness setting was not standardized across all patients (i.e., participants did not start from the same setting), as, instead, done in works where stiffness effect on prosthetic behaviour was studied, e.g., Armannsdottir et al. [18], Halsne et al. [55], Caputo et al. [56], nor was it assigned randomly, as done by Shepherd and Rouse in Ref [57]. For the present study, the initial stiffness selection was carefully based on the information the experimenters had regarding the participants' prostheses, MyFlex-ζ and the characteristics of the three participants themselves. The choice for the present work was driven by the need to avoid extending the testing duration, which could have led to participants fatigue, potentially altering their gait and, therefore, the results.

In previous works, different methods to perform tests in order to identify the preference concerning the prosthetic foot or exoskeleton settings and different method to identify these preferences have been used [54]–[59], [61]. In the present work, the participants were asked to rate the different stiffness settings of MyFlex-ζ they tested during the first session using forced-choice. This method is subjective, since it is purely based on the users' perceptions, and it is very similar to the method used by Shepherd et al [57], and Tucker et al [58]. In addition, participants were asked to clarify their choice.

The method followed allowed to determine the specific preferences of two participants for each task. Specifically, they preferred stiffer settings for uphill walking compared to overground walking at comfortable speed, and even stiffer

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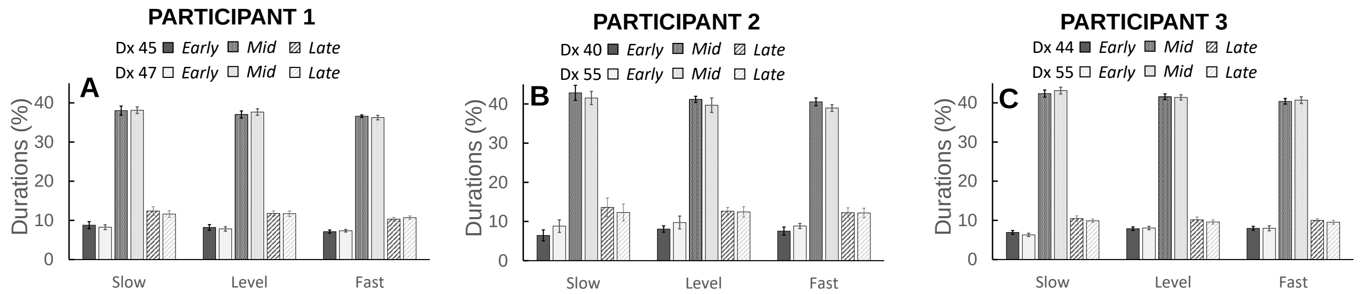

Fig. 7. Stance sub-phases durations. For each task, first two bars correspond to the early stance durations, third and fourth bars correspond to the mid stance durations, and finally, last two bars correspond to the late stance durations.

setting or the same setting for downhill walking compared to uphill walking. These results somewhat contradict previous findings in the literature: in fact, some studies concluded that lower stiffness levels provided better perception for users [16], [17]. The other participant did not find any variations in perceptions and in situ, experimenter hypothesized that the most compliant setting of MyFlex-ζ was already too stiff for the participant who did not perceive any variations. However, it was seen later in the kinematic data measured during the second session, that MyFlex-ζ gave even higher range of motion compared to his fixed stiffness daily prosthesis. Later in this section, further discussions concerning this aspect are made. However, considering that two of three participants exhibited varying preferences and adaptations to the MyFlex-ζ foot prosthesis across the different tasks in the first session, it highlights the importance of a foot prosthesis that allows to customize the stiffness settings. Generally, the selections of the participants' preferred stiffness were motivated by smoother rollover and safer in terms of stability, especially for ramp walking.

Concerning body weight and preferred stiffness relationship, Clites et al.'s that no linear relationship was found between amputees' body weight and preferred stiffness [61]. For the present work, it is challenging to draw a conclusion for the participant that did not express specific preferences for the different activities. However, for the other two, it was observed that the heavier one selected three stiffer settings for overground walking at comfortable speed, uphill walking and downhill walking compared to the lighter one. The difference between the stiffness settings chosen for overground walking was minimal (Dx 45 for the lighter participant, Dx 46 for the heavier one), while it is more consistent both in uphill (Dx 46 for the ligher participant and Dx 55 for the heavier one) and down hill (Dx 47 vs Dx 55). For the two participants that felt differences among the stiffness settings, it can be drawn that there is a relation ship between preferred stiffness and body weight, however, it can not be considered a general conclusion at it is based only on two individuals. Therefore, a larger participant pool would likely have provided greater insight into the possible correlation between body weight and preferred stiffness with MyFlex-ζ.

Concerning the results from the second session, the study's findings highlight the significant influence of stiffness settings on the range of motion of plantarflexion and dorsiflexion of prosthetic limb during various activities and walking speeds. Overall, it was observed that lower stiffness settings brought a greater prosthetic range of motion in the sagittal plane, aligning with expectations and what has been found by others in previous works [18], [38], [40], [59]–[61]. One of the participants stood out as an exception, showing minimal differences in range of motion between stiffness settings. This was attributed to his selection of stiffness settings that were very similar to each other, suggesting that small variations in stiffness may not significantly alter the gait outcomes. This case exemplifies how, with closely matched stiffness settings, compensatory mechanisms can possibly occur and influence foot prosthesis kinematics and provide inconsistent variations. For example, compensations can be made at knee level, especially by high-level ambulators [57]. When stiffness settings differed considerably, lower stiffness consistently allowed for greater rotations, regardless the walking speed or terrain slope (whether uphill or downhill).

The second session was limited by the fact that no correlation study was conducted between the biomechanical results (the focus of the second session) and the preferences/feedback of the three participants, making it impossible to understand the relationship between speed and preferred stiffness. Clites et al. [61] conducted an investigation concerning the correlation between speed and preferred stiffness: it showed that there is no linearity between speed and preferred stiffness. This does not indicate that stiffness does not affect the biomechanical parameters. Indeed, the results in the present work indicated that as speed increases, the range of motion in the sagittal plane increases (comparing the kinematics obtained from the same stiffness setting). Regardless, it can be said that if an amputee wants to have the same range of motion while varying speed, they can choose to adjust the stiffness of their prosthesis. If an amputee wants to maintain the same rotation they have during comfortable walking even when walking fast, they can choose to increase the stiffness of their prosthesis. The same reasoning applies when walking at a speed lower than their comfortable speed; they can decide to reduce the stiffness.

Torque patterns did not show clear relationship with stiffness across all participants in the first part of the stance phase, i.e., early stance, while it showed a clearer relationship with stiffness settings across all participants from toe strike to heel off. In this second part of the stance phase, higher stiffness consistently yielded higher recorded torque, independently from the walking speed, and it is aligned with Shepherd and

Rouse's findings in [38].

As described earlier, the energy stored in the elastic elements depends on the profiles of the ankle angle and ankle torque curves. The ankle torque curve itself is non-linearly dependent on the ankle angle, as highlighted in previous sections and in [47], where torque increases with the angle (in absolute terms). Consequently, the energy, computed as outlined in the Methodology section, exhibits an even steeper exponential dependency on the ankle angle. Kinematic results revealed greater rotation with the less stiff setting. Accordingly, in most cases, the final results showed higher energy storage with the more compliant configuration. Conversely, if a generic user were to compensate at the hip or knee joint to maintain the same ankle range of motion across two stiffness settings, and if they desired greater energy storage, they might prefer a stiffer setting. This finding further underscores the critical importance of adjustable stiffness in a prosthetic foot.

Concerning stance sub-phases durations, the limited consistency observed in the variation of phases durations in relation to stiffness may be attributed to the fact that walking speeds are controlled by the treadmill, rather than being self-imposed by the participants. This mechanism of imposed speed can significantly influence motor behavior and biomechanical response, limiting the subjects' ability to express their natural walking style. Therefore, there is a need to conduct future clinical studies letting users walk overground instead of only on the treadmill. This approach would allow for the observation of how stiffness and other biomechanical factors influence walking in more realistic conditions, enabling participants to freely modulate their speed and motor behavior. Moreover, a larger sample of participants would provide obtain more generalizable results. In conclusion, an experimental design that includes both testing modalities (treadmill and overground) could provide a more comprehensive understanding of the dynamics of walking and their relationship with stiffness, leading to more significant and clinically applicable results.

Despite limitations, MyFlex-ζ can still be placed alongside other variable stiffness prostheses [38]–[43] as an alternative to allow adaptation to various walking conditions. Together with the aforementioned variable stiffness prostheses, MyFlex-ζ can also help determine the preference of amputees, both transtibial and transfemoral, as well as unilateral and bilateral, during the initial assessment to understand which prosthesis to prescribe, despite it is limited compared to the emulator by Caputo et al. [62], [63], since MyFlex-ζ has already predefined stiffness curves and it can only adjust to them, while with the emulators, multiple parameters can be tuned.

Concerning the variable stiffness foot prostheses state of the art, according to the authors' current knowledge, all variable stiffness prostheses [38]–[43], including MyFlex-ζ, share a limitation: the fact that the adjustment of stiffness in plantarflexion is not independent of the adjustment of stiffness in dorsiflexion. This means that users must always find a compromise for the stiffness setting because, with current technologies, when one wants to increase the stiffness of the prosthesis in dorsiflexion, it also happens in plantarflexion. This could be a limitation, for example, in cases where a user wants to have a much more compliant prosthesis in plantarflexion during a descent to reach flat foot conditions more quickly while simultaneously wanting greater stability with a stiffer prosthesis once flat foot is achieved. This example occurred with one of the participants: indeed, he was initially prompted to the most compliant setting during downhill walking since he perceived that reaching flat foot earlier could provide more stability. However, once flat foot condition is reached, the stability is felt higher with stiffer setting, which means the dorsiflexion stiffness setting must be higher. Current variable stiffness prostheses [38]–[43] allow for stiffness variation when they are unloaded, either when in swing phase with an actuation system or when they are not in use at all, with adjustments made manually, as is the case with MyFlex-ϵ and MyFlex-ζ. So far, no variable stiffness foot prosthesis is able to adjust during stance phase, since it would require high power actuation system which is able to inject power in fractions of a second to allow the adjustment. The future direction for prostheses could be to have two distinct stiffness variations for dorsiflexion and plantarflexion. .

VI. Conclusion

In this paper, the characteristics of a variable stiffness ESR foot prosthesis, MyFlex-ζ, were illustrated. MyFlex-ζ is capable of varying its stiffness until 101% for 10 degrees plantarflexion and 96% at 15 degrees dorsiflexion. These variations were possible thanks to the system that varies the relative inclinations among rigid and elastic parts of kinematic chain configuration of MyFlex-ζ. Moreover, the clinical tests performed with three transfemoral amputees wearing MyFlex-ζ were described. The three participants expressed various preferences regarding stiffness across different activities, i.e., slow walking, level walking, fast walking on level ground, uphill walking and downhill walking. This indicates the importance of having a variable stiffness prosthesis to conduct various types of activities without necessarily having to compensate for or accept the fixed stiffness of an ESR prosthesis. In the clinical tests presented, the prosthesis stiffness was manually adjusted, as the main objective was to investigate the influence of stiffness on users' perceptions and their kinematics. Having confirmed that there is a benefit of a variable stiffness prosthesis both in perception and kinematics, future works will also include integrating an actuation system and optimising a control system capable of adjusting stiffness when necessary. The current mechanical configuration is set up to couple an actuator to the Dx Slider System: in fact, the mechanical element used to manually adjust the Dx can also be used as a gear to connect the system to an electric motor.

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