Development of an Ankle-Foot Orthosis That Provides Support for Flaccid Paretic Plantarflexor and Dorsiflexor Muscles

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***Abstract*— ADJUST, a novel ankle-foot orthosis (AFO) that we have developed, allows the ankle a normal range of motion (ROM) while providing support for flaccid ankle-muscle paresis. It consists of two leaf-spring hinges that independently control plantarflexion and dorsiflexion stiffness. To evaluate whether ADJUST meets the minimum mechanical requirements, we quantified its ankle ROM and stiffness. To evaluate whether it meets the minimum ankle kinematic and kinetic goals for normal gait, a patient with both plantarflexor and dorsiflexor paralysis used it, and his own AFO, to walk. When fitted with stiff springs, ADJUST met all requirements and goals. During the stance and the swing phases, ankle ROM was within the normal range when ADJUST was fitted with stiff springs. Ankle ROM during stance was outside the normal range both with the patient's own AFO and with ADJUST when it was fitted with flexible springs. Power at the ankle met the minimum goal but was lower with ADJUST than with the patient's own AFO. The optimal stiffness configuration that would result in a higher power at the ankle with a normal ankle ROM was not reached for this patient. Walking with ADJUST seems feasible and could be profitable in patients with flaccid ankle muscle paresis.**

***Index Terms*— Ankle foot orthosis, ankle range of motion, ankle muscle paresis, patient-centered.**

I. Introduction

An ankle-foot orthosis (AFO) can improve, but also hamper, the performance of activities of daily living (ADL) in people with flaccid ankle muscle paresis [1]. Most solid AFOs in use have a single stiffness, while the optimum varies with body weight, gait phase, gait speed, and depends on the severity of the paresis [1]–[3]. These AFOs also limit the range of motion (ROM) of the ankle [1], and that hampers the performance of ADL that require a high ankle ROM such as walking on slopes [4] and stairs [5], or walking on a level surface [6].

Focusing on normal gait as a main activity [7], we see that the stance phase can be divided into three phases relevant to the functioning of the ankle muscles [8] (Fig. 1). These phases are different from the oft-used rocker phases, which are not directly relevant to the functioning of the ankle muscles [6]. The phases during stance are controlled plantarflexion (CPF: initial contact till maximum plantarflexion), controlled dorsiflexion (CDF: maximum plantarflexion till maximum dorsiflexion), and powered plantarflexion (PPF: maximum dorsiflexion till toe off) [8]. During CPF, plantarflexion ROM is needed to regain stability [6]. Most AFOs limit plantarflexion ROM and thereby decrease stability [1], [6]. During CDF, dorsiflexion ROM is needed so that the tibia inclines in a manner that is controlled by the plantarflexors while the ground reaction force (GRF) progresses [6]. AFOs that limit plantarflexion ROM during CPF can also increase the inclination of the tibia at the beginning of CDF [6]. Increased inclination of the tibia often coincides with greater demands on the knee extensors, and these in turn raise the metabolic cost [6]. In AFOs that limit dorsiflexion ROM [1], more time is needed to bring the body forward, and as a result, gait speed decreases [6]. During PPF, power is generated at the ankle to propel the body forward through an active and timed [9] plantarflexion ROM and moment [6]. In AFOs that limit plantarflexion ROM [1], plantarflexion power can be decreased, and this in turn can increase the metabolic cost of maintaining a certain gait speed [10].

Three non-motorized AFOs are known that partly overcome these problems. Two of these, which are currently being used in a clinical setting, make use of adjustable dorsiflexion and plantarflexion springs (Neuro Swing, Fior & Gentz [11], and ankle hinge 17B66, Ottobock [12]). However, like solid AFOs, these AFOs can store energy only when the ankle dorsiflexes beyond their neutral alignment (that is, the angle between shank/calf cover and footplate when no external moment is applied [3]). This characteristic may be another reason why, despite the use of an AFO that should compensate for

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plantarflexor paresis, plantarflexion power with AFOs is still lower than in a healthy population [1], [3]. Another AFO whose neutral alignment can change to allow a more efficient way of harvesting energy is the "unpowered exoskeleton" [13], which does not, however, assist during CPF and the swing phase, has not been tested on patients with flaccid ankle muscle paresis, and is currently in the development stage [13]. Several motorized AFOs (lightweight AAFO [14], powered AFO [15], variable-impedance AFO [16]) and prosthetic feet (AMP-Foot 3.0, and BiOM Ankle) are designed to mimic an active normal gait pattern. A disadvantage of these systems is their weight (even the "lightweight" AAFO weighs 1.7kg [14]), which can explain why they are not used by patients. Patients ranked lightness among the most important characteristics of an AFO [17]. An ideal AFO should be light, should not hamper normal ankle ROM, and should provide adequate dorsiflexor and plantarflexor moments to compensate for the ankle muscle paresis [1], [3]. This AFO should function primarily during normal gait, but also during other ADL [18].

In this study, the development and proof of concept of a novel non-motorized AFO are described, following the "methodical design process of biomedical products" [19]. This process consists of several phases: problem definition, the formulation of goals, the listing of requirements, and several design phases. It ends with a newly designed product [19]. This process includes a patient centered approach [20]. One can identify different problems when comparing dorsiflexor to plantarflexor paresis [6]. In the case of dorsiflexor paresis, the AFO should enable initial *heel* contact [6]. During CPF, the AFO should allow plantarflexion ROM without resulting in foot slap, so that stability can be maintained [6]. During the swing phase, the foot should be lifted to prevent foot drag and tripping [6]. In the case of plantarflexor paresis, the AFO should control dorsiflexion ROM during CDF [6]. When dorsiflexion is controlled, the forward progression of the GRF is also controlled, and there are no excessive demands on the knee extensors [6]. During PPF, ankle power should be generated [6] to maintain gait speed without increasing metabolic demands [10]. The goals that are needed for each paresis type and gait phase are schematically presented in Fig. 1. They are:

1) During CPF
   a) allow 4-12°* plantarflexion ROM (our normal data)
2) During CDF
   a) allow 18-28°* dorsiflexion ROM (our normal data)
3) During PPF
   a) provide ≥28°* plantarflexion ROM (our normal data)
   b) provide ≥0.6Nm/kg* maximum plantarflexion moment (existing AFOs [1])
   c) provide ≥0.5W/kg* maximum plantarflexion power (existing AFOs [1])
4) During the swing phase
   a) provide dorsiflexion motion to enable initial heel contact

* = 95% confidence interval

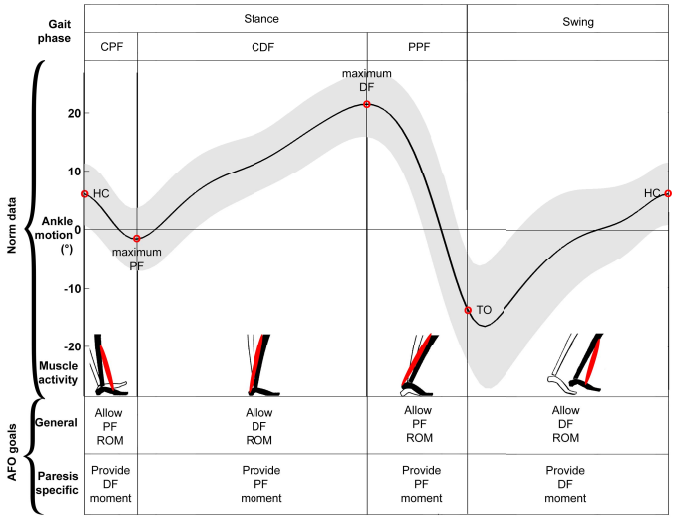


Fig. 1. Normal ankle motion and muscle activity including the AFO goals needed per gait phase to compensate for the paresis. AFO = ankle foot orthosis, CDF = controlled DF, CPF = controlled PF, DF = dorsiflexion, HC = heel contact, PF = plantarflexion, PPF = powered PF, ROM = range of motion, TO = toe off. General AFO goals are applicable to all paresis types (dorsiflexor paresis/ plantarflexor paresis/ combined paresis). Paresis specific AFO goals are applicable only to specific paresis types. Normal data from eight healthy adults (age 25 ± 1 years) who walked with standard shoes ("Performance X", extra wide, double depth, from Dr. Comfort [27]), were collected in our gait lab (average gait speed was 1.4 ± 0.1m/s). This ankle motion was comparable to what we found in the literature [6], the only difference being that our data were shifted 6° towards dorsiflexion.

The main requirements are: allow minimum 30° ankle ROM-the functional ankle ROM during normal gait [21]. The plantarflexion stiffness should be at least 0.003(Nm/°)/kg [8] to control plantarflexion ROM, and the dorsiflexion stiffness should be at least 0.021(Nm/°)/kg to both control dorsiflexion ROM (to a maximum of 28°) and provide a plantarflexion moment of at least 0.6Nm/kg. Following several design phases in which designs were scored on a theoretical ability to meet the relevant goals and requirements, a functional model, ADJUST, was developed (Fig. 2).

The first aim of the current study was to evaluate whether a proof of concept was obtained with ADJUST. To evaluate whether ADJUST met the requirements, we quantified its mechanical performance. To evaluate whether it met the goals, we quantified ankle kinematics and kinetics with ADJUST in a patient with combined plantarflexor and dorsiflexor paralysis, when they walked on a treadmill. The second aim of this study was to evaluate whether ADJUST was more beneficial than an existing AFO. Therefore, we also quantified ankle kinematics and kinetics with the patient's own AFO, when they walked on the treadmill.

II. Materials

A. Design

Fig. 2 shows ADJUST, which consists of two mirrored mechanical hinges, each containing a leaf spring to enable separate control of plantarflexion and dorsiflexion stiffness. The lateral hinge compensates for decreased plantarflexor function; the medial hinge, for decreased dorsiflexor function. The positions of both hinges can be changed without changing

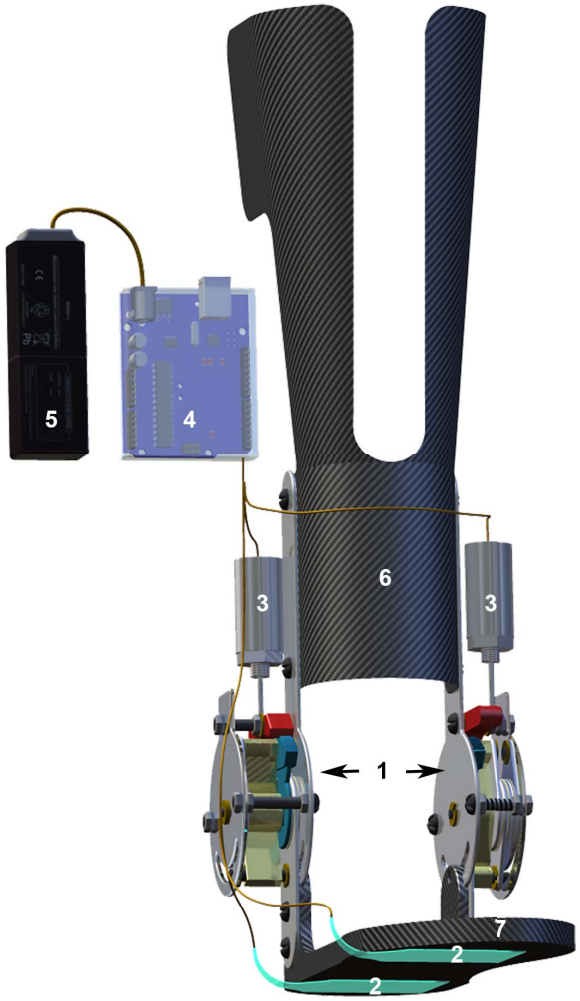


Fig. 2. ADJUST - right-leg version. 1 = lateral and medial mechanical hinge, 2 = force sensing resistors (FSRs), 3 = solenoids, 4 = cased Arduino board, 5 = battery, 6 = shank cover, 7 = footplate. The footplate is inserted into a shoe (not shown) and the FSRs are placed underneath the sole on the heel and the metatarsophalangeals. The battery powers the Arduino, the solenoids and the FSRs. Specifications of parts 2 - 7 can be found in the Appendix. ADJUST weighs 1.6kg.

their function. Each hinge contains a pawl and a ratchet made of hardened construction steel (Fig. 3). Because of how the teeth of the pawl and the ratchet are made, the alignment of ADJUST can change by the smallest mechanically possible increment of 5° ankle ROM. The maximum ankle ROM possible with ADJUST is 75°. This 75° can be divided into 75° plantarflexion ROM, 75° dorsiflexion ROM, or every ratio in between (in increments of 5°). The type of activity may require more dorsiflexion (when the wearer is walking uphill [22]) or more plantarflexion (when they are walking downhill [22]).

Other components of ADJUST include two force-sensing resistors (FSRs), two solenoids, an Arduino, a battery, a shank cover and a foot plate. Depending on the signal from the Arduino, which reads the FSRs, the solenoid is activated (Appendix). When that happens, the pawl unlocks from the ratchet, thus allowing the hinge to rotate freely in both directions (Fig. 3a). When inactivated, the pawl and the ratchet are locked, and rattling rotation is possible in only one direction while the hinge is locked in the opposite direction (Fig. 3b). To reduce friction, the connecting surfaces between the ratchet and the pawl are lubricated, and a polytetrafluorethylene disc is used between each rotational component.

Stiffness Calculation: The medial spring compensates for decreased dorsiflexion moments, which are needed during CPF and the swing phase (Fig. 1). The same spring is used to compensate for both moments, so that the highest moment determines its stiffness. However, since the medial spring counteracts the lateral spring during PPF (Fig. 4), it is preferable to use the lowest stiffness possible. The dorsiflexion moment needed during CPF is about five times higher than it is during the swing phase [22], [23] and the exact moment depends on several factors [8], [24]. We therefore estimated, based on the literature, that the moment needed during CPF was 0.15Nm/kg [22]. We used this moment (M_{df}), and the effects of body weight (BW) and plantarflexion ROM during CPF (α_{pf}), to estimate medial spring stiffness (k) according to equation 1:

$$k = \frac{BW * M_{df}}{\alpha_{pf}} \tag{1}$$

The lateral spring compensates for decreased plantarflexion moments, which are needed during CDF and PPF. According to Rouhani *et al.* [25], the maximum moment ($M_{pf\ MAX}$) that occurs during PPF [8] can be estimated from body weight (BW) and height (H) according to this equation:

$$M_{pfMAX} = 7.9\% BW * H$$

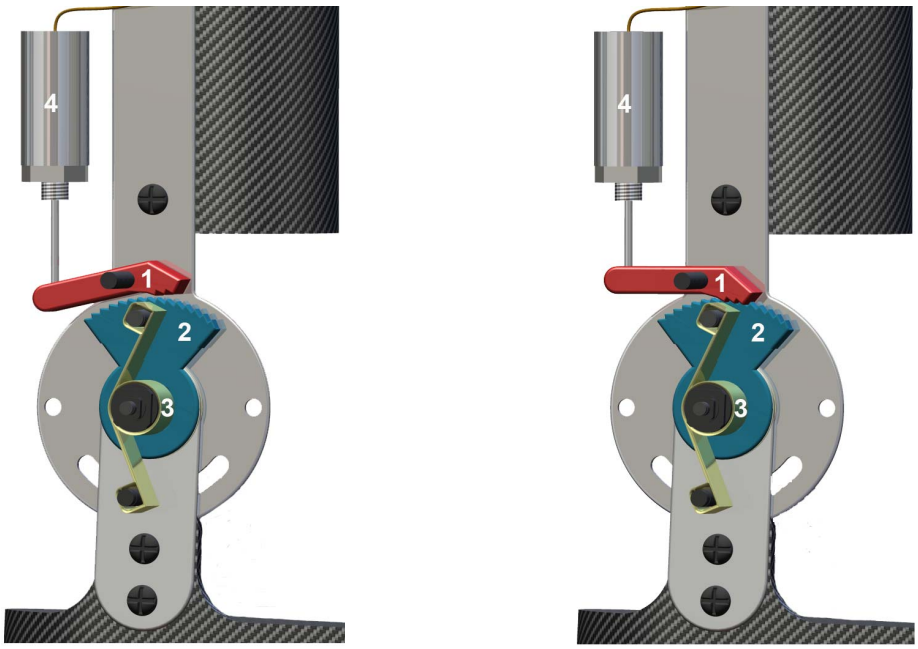
The lateral spring stores energy only during CDF (Fig. 4). During CDF, a maximum moment of 5.5%BW*H can be stored [25]. Therefore, a maximum plantarflexion moment can be provided:

$$\frac{5.5}{7.9} * 100\% = 70\%$$

Ankle stiffness during PPF has been found to have a linear relationship with gait speed [8]. We estimated lateral spring stiffness (k) based on body weight (BW), gait speed (V), the maximum possible energy storage (70%), and dorsiflexion ROM (α_{df}), according to equation 2:

$$k = \frac{V * BW * 70\%}{\alpha_{df}} \tag{2}$$

A total of four springs, two medial and two lateral, were manufactured from commercially available spring steel strips. The medial springs consisted of one and two spring steel strips (dimensions 7×1×70mm, E=210GPa, I=0.78mm^4). This resulted in a theoretical stiffness of 0.2Nm/° (flexible medial spring) and 0.5Nm/° (stiff medial spring), respectively. The lateral springs consisted of three and four spring steel strips (dimensions 15×1×70mm, E=210GPa, I=1.66mm^4) resulting in a theoretical stiffness of 1.6Nm/° (flexible lateral spring) and 2.1Nm/° (stiff lateral spring), respectively. Based on the stiffness requirement of 0.021(Nm/°)/kg, these available springs can be suitable for a person with a body weight of 76 to 100kg. Note that varying lateral spring stiffness makes it possible to change the onset of heel off. For example,



(a) (b)

Fig. 3. Unlocked (a) and locked (default) (b) mechanical hinge. 1 = pawl, 2 = ratchet, 3 = leaf spring, and 4 = solenoid. a) Solenoid is activated and unlocks the hinge to allow free rotation. b) Default setting with the solenoid inactivated and the hinge locked so energy can be stored in the leaf spring with anti-clockwise rotation of the footplate.

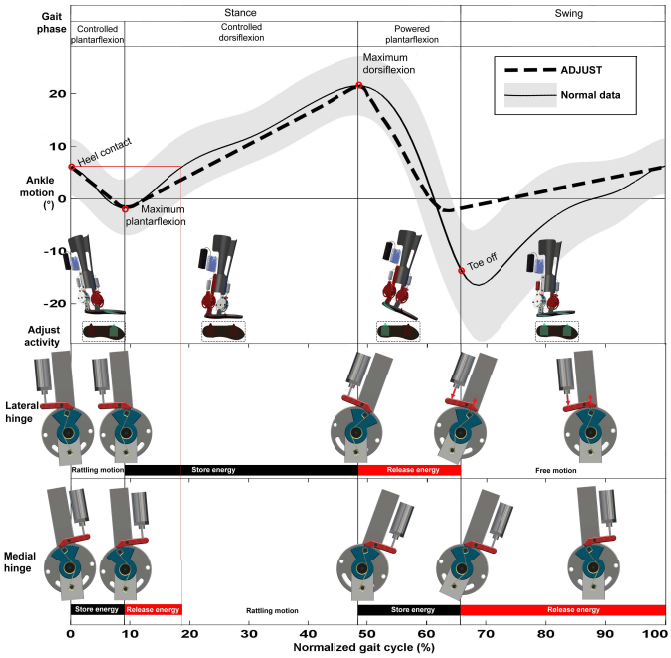


Fig. 4. Normal ankle motion and working mechanism of ADJUST per gait phase.

increasing lateral spring stiffness will advance the onset of heel off.

B. Working Mechanism

In Fig. 4, the working mechanism is depicted per gait phase. During the complete stance phase both solenoids are switched off, thereby locking both hinges. During CPF, energy is stored in the medial hinge while the lateral hinge allows rattling plantarflexion ROM. During CDF, energy is stored in the lateral hinge while the medial hinge allows rattling dorsiflexion ROM. During PPF, the lateral hinge releases its energy, while the medial hinge stores energy. During the swing phase, none of the FSRs registers contact with the floor, and the lateral solenoid is activated and unlocks the lateral hinge so its remaining energy is released. When that happens, the medial hinge also releases its energy, and the foot is lifted. When a patient walks on a level surface, only the lateral, and not the medial, solenoid is needed.

III. Methods

A. Mechanical Performance

We tested the mechanical performance of ADJUST with the Bi-articular Reciprocating Universal Compliance Estimator (BRUCE) [26]. The BRUCE records the ankle-joint configurations of a replicated human leg and the corresponding forces exerted by ADJUST on this leg [26]. A linear regression line of both the ascending and the descending stiffness profile is used to calculate mechanical stiffness around the ankle within the functional 10° plantarflexion ROM and 20° dorsiflexion ROM [26]. Mechanical stiffness was quantified when ADJUST was equipped with four stiffness configurations:

1) Stiff - stiff medial and lateral spring,
2) Stiff/flexible - stiff medial and flexible lateral spring,
3) Flexible - flexible medial and lateral spring,
4) Flexible/stiff - flexible medial and stiff lateral spring.

Mechanical stiffness can be influenced by the shoe. We therefore quantified all configurations with and without a standard shoe with a rocker sole (the “Performance X” line, extra wide, double depth, from Dr. Comfort [27]). We averaged mechanical stiffnessess with and without a shoe, and calculated standard deviations. We performed all mechanical tests

in accordance with the BRUCE protocol [26]. We estimated the mechanical stiffness (k) of the patient's own AFO shoe based on plantarflexion ROM during CPF (α_{pf}), dorsiflexion ROM during CDF (α_{df}), maximum plantarflexion moment during PPF ($M_{pf\ MAX}$), and body weight (BW) according to equation 3:

$$k = \frac{M_{pf\ MAX} * BW}{\alpha_{df} - \alpha_{pf}} \tag{3}$$

B. Case Study

One patient was selected from a larger study, registered at the Dutch Trial Register (TC = 5238). The Ethics Committee of the University Medical Center Groningen granted approval (2014/568). Prior to testing, the patient provided written informed consent. The selection criteria were body weight between 76 and 100kg, ankle-muscle paralysis (Medical Research Council scale (MRC) = 0 [28] of both plantarflexors and dorsiflexors, absence of ankle-muscle spasticity, and minimum passive ankle ROM of 30°. The latter three criteria were evaluated by an independent resident in Rehabilitation Medicine. The male patient selected (age 59, height 1.77m, shoe size 40) had a body weight of 76.7kg and bilateral paresis because of Hereditary Motor and Sensory Neuropathy (HMSN)/Charcot Marie Tooth. He has been using AFOs bilaterally for 22 years, and currently uses solid polypropylene dorsal AFOs with a full-length footplate. The first author (DW), and certified orthotist, placed a 6mm heel wedge (recommended for this patient by the independent resident in Rehabilitation Medicine) on the footplate to fit ADJUST to the patient's dominant leg. Which leg was dominant was verified by asking which leg the patient would use to kick a ball [29]. Passive ankle ROM was 25° plantarflexion and 5° dorsiflexion with the knee extended.

Kinematic and kinetic data were collected in the Gait Real-time Analysis Interactive Lab (GRAIL) [30]. The GRAIL has a 180° screen on which a standard virtual-reality environment was displayed. Kinematic data were obtained with 25 reflective markers, placed according to the lower extremity human-body model [31], and a 100Hz infrared motion-capturing system with 10 infrared cameras (Vicon Bonita B10 and Nexus version 1.8.5). Markers on AFOs and shoes were placed as close as possible to the specified anatomical locations. Kinetic data were obtained with two 1000Hz force plates, integrated into a dual-belt treadmill. Before the test started, the patient was secured with a safety vest. In total, five AFO conditions were tested in fixed order and at a fixed gait speed. These conditions were the patient's own AFO shoe and four ADJUST stiffness configurations with standard shoe [27]. A comfortable treadmill speed was determined with the patient's own AFO shoe by gradually increasing the speed until the patient indicated he had reached his comfortable speed. Thereafter, treadmill habituation started with ten minutes [32] of walking with the patient's own AFO shoe, and the eleventh minute was recorded. This test was repeated for the first (stiff) configuration of the ADJUST standard shoe. This configuration came second because it was the most stable configuration and we did not know whether the patient was able to walk with more-flexible configurations. The subsequent order of configurations was chosen so that the stiffness of only one hinge would change between configurations. For these configurations, the habituation time was one minute, after which the second minute was recorded. Between each test, the patient was allowed to rest. After the last configuration, the first was repeated to evaluate test-retest reliability. The test results were considered reliable whenever the means did not differ by more than one standard deviation.

All gait data were filtered in real time with a one-way, low-pass (Fc = 4Hz), second-order Butterworth filter and normalized to 100% gait cycle in D-flow software (3.18.2) [30]. Gait cycles, with a foot placement on only one of the force plates, were selected with the Gait Off-line Analysis Tool (GOAT) [30]. The first 25 gait cycles of each test were analyzed in Matlab (R2014a). Ankle kinematic and kinetic data were averaged for each gait phase. To get a sense of whether the ankle moments provided were adequate from the patient's perspective, we asked him about his experiences with each configuration.

TABLE I
MECHANICAL STIFFNESS OF ADJUST WHEN EQUIPPED WITH DIFFERENT SPRINGS. THE VALUE IN BOLDFACE DID **NOT** MEET THE REQUIREMENT

Configuration	Medial spring stiffness (Nm/°)	Lateral spring stiffness (Nm/°)
Stiff	0.7 ± 0.2	1.7 ± 0.7
Flexible	0.3 ± 0.0	$\mathbf{1.1} \pm 0.1$
Requirement	≥ 0.2	≥ 1.6

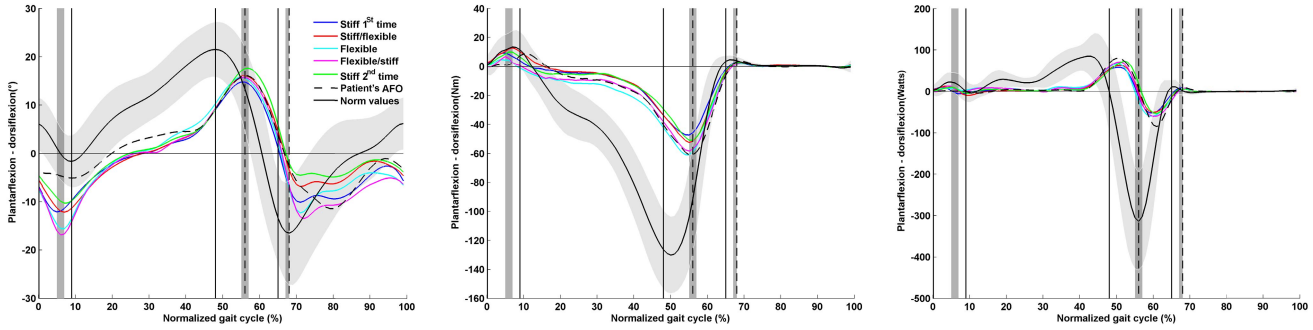
IV. RESULTS

A. Mechanical Performance

ADJUST's ankle ROM, quantified with the BRUCE [26], was in all configurations larger than 30°. Both the stiff medial and lateral springs, and the flexible medial spring, met the stiffness requirements (Table I). The estimated mechanical stiffness of the patient's own AFO shoe was 3.1Nm/° (calculated from Table II, according to equation 3).

B. Case Study

To determine whether ADJUST's kinetics are adequate for the patient, we multiplied the kinetic goals for moment (≥0.6Nm/kg) and power (≥0.5W/kg) by the patient's body weight of 76.7kg. The comfortable walking speed of 0.8m/s was lower than the 1.4±0.1m/s from our normal data. Because of differences in gait speed, in AFO conditions a longer stance phase [6] and a smaller ankle ROM during PPF [33], can be expected. Therefore, we had to correct the plantarflexion ROM goal for gait speed (to ≥ 18° [33]). Peak ankle power and moment are also expected to be lower in AFO conditions because of a lower gait speed [34]. However, we did not have to correct these goals, as they were derived from existing AFOs which were already based on walking at a lower speed of 0.9±0.2m/s [1]. The stiff ADJUST configuration was reliable on most outcomes except for plantarflexion ROM during PPF (Table II).



(a) (b) (c)

Fig. 5. Ankle motion (a), moment (b) and power (c) for all AFO conditions and normal data. Vertical lines (for the patient's own AFO and normal data) and grey areas (for ADJUST configurations) represent the transitions between gait phases. The transition from controlled plantarflexion to controlled dorsiflexion was the same for the patient's own AFO and normal data, while gait speed was lower in all AFO conditions.

TABLE II
ANKLE KINEMATICS AND KINETICS FOR ALL AFO CONDITIONS DURING STANCE. AFO = ANKLE FOOT ORTHOSIS, CDF = CONTROLLED DORSIFLEXION, CPF = CONTROLLED PLANTARFLEXION, M = MOMENT, MAX = MAXIMUM, P = POWER, PPF = POWERED PLANTARFLEXION, ROM = RANGE OF MOTION. BOLD VALUES DID **NOT** MEET THE GOAL

AFO condition	CPF ROM (°)	CDF ROM (°)	PPF ROM (°)	PPF Max M (Nm)	PPF Max P (W)
Stiff 1^{st} time	5 ± 2	27 ± 1	22 ± 2	46 ± 8	54 ± 8
Stiff 2^{nd} time	6 ± 2	28 ± 1	**17** ± 2	54 ± 8	54 ± 8
Stiff/flexible	7 ± 2	28 ± 2	20 ± 1	54 ± 8	54 ± 8
Flexible	8 ± 3	**31** ± 3	23 ± 3	61 ± 8	61 ± 8
Flexible/stiff	10 ± 2	**33** ± 2	22 ± 2	61 ± 8	61 ± 8
Patient's AFO	**1** ± 1	21 ± 2	19 ± 2	61 ± 8	84 ± 23
Goal	4 - 12	18 - 28	≥ 18	≥ 46	≥ 38

During CPF, differences were present between ADJUST and the patient's own AFO (Table II, Fig. 5). Both in the stiff and stiff/flexible configuration, plantarflexion was adequately controlled (Fig. 5a). In contrast, the patient's own AFO decreased plantarflexion ROM, while prolonging CPF. With flexible medial springs, a foot slap was visually and audibly present. During CDF, dorsiflexion ROM was adequate in the stiff and stiff/flexible configuration, and in the patient's own AFO. During PPF, the highest plantarflexion moments (Fig. 5b) were found in the flexible and flexible/stiff configuration and in the own AFO. These moments were lower than could be expected based on our normal data (115Nm) [34]. The maximum plantarflexion power (Fig. 5c) was adequate in all AFO conditions but was also lower than could be expected based on our normal data, even when corrected for gait speed (184W) [34]. Three configurations (stiff 1^{th} time, flexible and flexible/stiff) met the plantarflexion ROM goal. All AFO conditions provided dorsiflexion ROM during the swing phase (Fig. 5) to enable initial heel contact.

The patient noticed a foot slap in both the flexible and flexible/stiff configuration and found it unpleasant to walk with. After walking with all configurations, he preferred both the stiff and stiff/flexible configuration, as these did not result in a foot slap and they gave the stability he was used to with his own AFO. He did not notice any difference between these two configurations. He mentioned that having more flexibility might be more beneficial when walking hills or driving a car. He indicated that he still had to get used to ADJUST and did not yet feel as confident with it as when he walked with his own AFOs. He disliked the fact that ADJUST was heavier and bigger than his own AFO.

V. DISCUSSION

ADJUST was designed so as not to hamper ankle ROM, and to provide adequate plantarflexor and dorsiflexor moments. When equipped with stiff springs, it met the minimum ankle ROM and stiffness requirements and allowed normal ankle kinematics and kinetics. During CPF, ankle ROM with ADJUST was more normal than with the patient's own AFO. Flexible medial springs, which compensated for dorsiflexor paresis, were not suitable because they resulted in foot slap.

A. ADJUST Performance

To test the full capabilities of ADJUST, we chose a patient with complete paralysis of both plantarflexors and dorsiflexors (MRC=0 [28]). When ADJUST was equipped with stiff springs, it met the requirements and goals, and allowed more normal plantarflexion ROM during CPF than the patient's own AFO. This advantage of ADJUST over the patient's own AFO is especially important, because allowing a normal CPF will increase stability during stance [6]. When equipped with stiff springs, ADJUST also met the goals for CDF and PPF. However, both maximum moment and power were higher with the patient's own AFO, probably because of a greater stiffness. This indicates that, to improve the performance of ADJUST for this patient when he walked at this speed, the lateral spring should have been stiffer. Using a stiffer lateral spring can decrease dorsiflexion ROM during CDF within the normal range, increase maximum moment and power during PPF within the normal range, and can also advance the onset of heel off and thus of PPF (which would result in a more normal CDF duration). Plantarflexion ROM during PPF should not be taken into consideration, because it was found to be unreliable.

When stiffness is being optimized, metabolic cost [3] and gradual changes in stiffness should be considered.

When ADJUST was equipped with flexible medial springs, a foot slap was present. The minimum required stiffness to prevent foot slap should thus have been higher for this patient than is reported in the literature [8].

B. Improvements to ADJUST

To decrease the weight of ADJUST: 1) the medial hinge should be constructed as a smaller, free-rotating hinge in cases where a patient has functioning dorsiflexors, 2) several steel parts can be replaced with lightweight carbon and titanium, 3) the solenoids can be replaced by servomotors; alternatively, implementing a hydraulic locking mechanism [35] can make the use of heavy pawls, ratchets and solenoids obsolete, and 4) the one-size-fits-all adjustment possibilities in shank cover and footplate (see Appendix) should be excluded.

Flexible medial springs should not be used, because they resulted in foot slap. In a follow-up design, a more normal push-off power during PPF could be achieved when energy is also stored during CPF. When the energy that is stored during both CPF and CDF can be used during PPF, 91% instead of the currently 70% of normal push-off power might be possible. Spring functioning can be optimized, but cannot replace a normal push-off, which remains a limitation.

C. Study Limitations

Using commercially available spring steel strips limited the possibility of optimizing stiffness for this patient. However, as our main aim was to evaluate whether a proof of concept was obtained (and not to optimize spring stiffness) with our functional model, ADJUST, we believe that it was acceptable to use these springs.

The patient we selected had suffered paralysis of both plantarflexors and dorsiflexors. Additional results will be obtained when more patients are evaluated, and when patients with only plantarflexor paresis are evaluated, because they would need only the lateral hinge of ADJUST. Patients with only dorsiflexor paresis can use a simple elastic band that prevents foot slap during CPF, and provides clearance during the swing phase without hampering normal ankle ROM [1].

All tests were performed at a speed that was comfortable for the patient when walking with his own AFO. This speed might not have been optimal for walking with ADJUST, and this may have influenced our results. In addition, we did not evaluate push-off timing, which would be interesting in future research when optimizing metabolic cost during gait [9].

D. Future Research

A larger group of patients with varying degrees of flaccid ankle muscle paresis should be recruited to evaluate effects of ADJUST on gait. Outcome parameters of interest are ankle and knee kinematics and kinetics and metabolic cost [3]. Compensatory strategies may be more apparent in the knee than in the ankle [6]. Also, the effects of ADJUST on activities that require high ankle ROM, such as climbing stairs [5] and slopes [4], and getting up from or sitting down on a chair [36], should be evaluated in this larger group of patients. ADJUST's stiffness profile should be optimized for each gait phase and each patient. Comfortable walking speed should be determined with both ADJUST and the patient's own AFO, and the optimal push-off timing should be determined for ADJUST.

VI. Conclusion

When equipped with stiff springs, ADJUST met the minimum ankle ROM and stiffness requirements, and provided support for flaccid paretic plantarflexor and dorsiflexor muscles in a patient with ankle-muscle paralysis. Especially during CPF, it allowed more normal plantarflexion ROM than the patient's own AFO. Walking with ADJUST is feasible and could be profitable for patients with flaccid plantarflexor paresis and dorsiflexor paresis.

Appendix
Parts of ADJUST

1) Force Sensing Resistors: Two Force Sensing Resistors (FSRs, Interlink, type FSR-402, measuring range $\pm$ >10g till 10kg, resistance range $\pm$ >1 $M\Omega$ till < 3 $k\Omega$, active surface 38.1 × 38.1mm, lifespan $\pm$ >10.000.000 activations) were placed on the sole of the shoe (Fig. 6a). One FSR was placed underneath the heel; the other, underneath the metatarsophalangeales (mtp) (Fig. 6b). Both FSRs register shoe-to-floor contact. Contact means high resistance (maximum 1,023 units), whereas no contact means low resistance (minimum 0 units).

2) Solenoids: Two solenoids were used to control the pawls of each mechanical hinge. The heavy-duty solenoid (Intertec, type pushing ITSLZ 2560, current 6V/DC, diameter 25mm, start force 0.8N, peak force 22N, power 10W, weight 180g) was used for the lateral hinge. The low duty solenoid (Intertec, type pushing ITS-LZ-1949, current 6V/DC, diameter 20mm, start force 0.6N, peak force 11N, power 7W, weight 86g) was used for the medial hinge. Solenoids were connected to the Arduino via a Darlington (type BDT 65B, J85 50).

3) Arduino System: An Arduino Uno R3 programming board (ATMEL, type ATmega328, voltage 5V, recommended voltage 7-12V, voltage limits 6-20V, speed 16MHz, pins 14) was used to process input signals from the FSRs and to control the solenoids and OLED display module (Blue Yellow LED, interface IIC/12C, 0.96 Inch, voltage 2.2-5.5V, power 0.06W, dimensions 29.3×27.1mm, resolution 128×64pixels, pins 4). The complete Arduino system was housed in a transparent case (Fig. 6c). The battery unit that provided current to the Arduino system, FSRs and solenoids was of the lithium polymer type (Walkera, type 3S2P 3 cell, capacity 5200mAh, voltage 11.1V, dimensions 103×34×42mm, weight 317g). The complete Arduino system was inserted into a small bag that was placed on the patient's back.

When the patient walks on a level surface, the lateral solenoid receives a high signal from the Arduino when the input signal from both the heel and the metatarsophalangeal (mtp) FSR are below a certain threshold (Fig. 6d). When both signals are low (swing phase), the lateral solenoid presses the pawl to disconnect the hinge. Also, the solenoids should be turned off for as long as possible, because this has two advantages: (i) it saves energy, (ii) when the solenoids

Fig. 6. Parts of ADJUST: (a,b) FSR placement; lateral (a) and caudal (b) view, (c) Arduino system, (d, e) FSR signal; fixed threshold (±44% ON-time/GC) (d) and adapting threshold (±9% ON-time/GC) (e), (f, g) shank cover: not extended (27cm) (f) and extended (34cm) (g), (h,i) foot plate: with spacers (h) and with height adjustments (i). FSR = force-sensing resistors, GC = gait cycle, HC = heel contact, mtp = metatarsophalangeales, TO = toe off. c) 1 = Arduino Uno R3 programming board, 2 = OLED display module, 3 = lithium polymer battery, 4 = transparent case, 5 = ON/OFF switch, 6 = push button to change program. Type of information on the OLED display (top to bottom): the program selected (walking on a level surface), FSR signal (Toe or Heel), FSR input signal (currently 0 for both FSRs), threshold for each FSR (currently 600 for both FSRs). d, e) FSR data and solenoid activation while the patient is walking on a level surface. The resistance ranges from 0 to 1,023 units. The dotted lines indicate the thresholds for the heel FSR and the mtp FSR to identify the stance and the swing phases. h) Extendable footplate with 1 = heel part, 2 = carbon plate, 3 = toe part, 38 − 45 = spacers. Foot plates without and with spacers (with corresponding stiffness in Nm/°) are available in sizes: 36 (0.23), 38 (0.27), 40 (0.40), 41 (0.42), 43 (0.50), and 45 (0.55). i) Height adjustments (arrows) make it possible to change the height of the mechanical hinges by 1.5cm.

are off, both mechanical hinges are connected, and this produces optimal stability for the patient. Therefore, the threshold for distinguishing the stance phase from the swing phase should be as low as possible. The best-case scenario involves an input value of zero from both the heel FSR and the mtp FSR during the swing phase, and a maximum value of 1,023 for both FSRs during stance. Pilot testing showed that the input value never reached either zero or 1,023, and that the input signal from the heel FSR was different from the mtp FSR when the same force was exerted. Also, the input signal changed differently for each FSR when walking several minutes consecutively. Therefore, using a fixed threshold that was equal for both FSRs was not an option, and an adapting threshold ($|T_n|$) was calculated in real time, in accordance with equation 4:

$$|T_n| = \begin{cases} F * \text{FSR} + (1 - \text{Factor}) * T_{n-1}) & \text{if FSR} < (T_{n-1} + \text{Offset}) \\ T_{n-1} & \text{else} \end{cases} \tag{4}$$

This formula is based on a constantly changing input variable (FSR), a stored variable (T_{n-1}) and two fixed variables (offset and factor). FSR refers to the input signal from either the heel or mtp FSR. T_{n-1} refers to the previous ($_{n-1}$) threshold (T) for either the heel FSR or the mtp FSR. The offset and factor were defined after pilot tests and were set at 50 and 0.1, respectively. Fig. 6e shows the adapting threshold. The use of an adaptive threshold resulted in a reduction of 35% of solenoid ON-time over the fixed threshold of 600 (Fig. 6d).

4) Shank Cover: An extendable shank cover (Figs. 6f and 6g) was constructed to fit a variety of legs with ADJUST. It was composed of a combination of carbon and Kevlar, pre-impregnated with epoxy resin. Straps attached to the cover were made of Velcro. The soft layer inside the cover was made of foam. When the cover is extended (Fig. 6g), an additional Velcro strap is used to connect it to the shank.

5) Foot Plate: An extendable foot plate was fabricated from the same materials as the shank cover. The foot plate consisted of three parts, plus spacers that made it possible to adjust the size from 36 to 45 (Fig. 6h). A soft layer of foam was placed on top of the foot plate (not depicted in Figs. 6h and 6i). The stiffness of the footplate with each of the spacers was evaluated with BRUCE [26]. The height of ADJUST's mechanical hinges could be changed to enable alignment to the anatomical axis of the ankle [37] (Fig. 6i). Different heel wedges (0.6, 1.0, 1.6, 2.2mm) could be placed on the foot plate depending on the advice of the independent resident in Rehabilitation Medicine.

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