Chapter 4

Development of an ankle foot orthosis with support of flaccid paretic plantarflexor and dorsiflexor muscles

Submitted

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Abstract

ADJUST, a novel ankle foot orthosis (AFO) that allows normal ankle range of motion (ROM) while providing support for flaccid ankle muscle paresis was developed. ADJUST consists of two leaf spring hinges to independently control plantarflexion and dorsiflexion stiffness. To evaluate if ADJUST meets the minimum mechanical requirements, its ankle ROM and stiffness were quantified. To evaluate if ADJUST meets the minimum ankle kinematic and kinetic goals for normal gait, a patient with both plantarflexor and dorsiflexor paralysis walked with ADJUST and with his own AFO. ADJUST when equipped with stiff springs met all requirements and goals. Ankle ROM during stance and swing was within normal range when ADJUST was equipped with stiff springs. Ankle ROM during stance was outside normal range with own AFO and with ADJUST when equipped with flexible springs. Power at the ankle met the minimum goal but was lower with ADJUST compared to the own AFO. The optimal stiffness configuration that would result in a higher power at the ankle with a normal ankle ROM was not yet reached for this patient. Walking with ADJUST seems feasible and could be profitable in patients with flaccid ankle muscle paresis.

Keywords  Ankle foot orthosis, ankle range of motion, ankle muscle paresis, patient centered
Introduction

An ankle foot orthosis (AFO) can improve, but also hamper performing daily life activities in people with flaccid ankle muscle paresis\cite{121}. Most used solid AFOs have a single stiffness, while the optimum varies per body weight, gait phase, gait speed, and depends on the paresis severity\cite{69,121,8}. These AFOs also limit ankle range of motion (ROM)\cite{121} which hampers performing high ankle ROM activities of daily living (ADL) such as walking on slopes\cite{71} and stairs\cite{98}, or normal gait\cite{91}.

When focusing on normal gait as a main activity\cite{11}, stance phase can be divided into three phases relevant to ankle muscle functioning \cite{104} (Figure 1). These phases are different from the often used rocker phases as these rocker phases are not directly relevant to ankle muscle functioning\cite{91}. 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) \cite{104}. During CPF, plantarflexion ROM is needed to regain stability\cite{91}. Most AFOs limit plantarflexion ROM and thereby decrease stability\cite{121,91}. During CDF, dorsiflexion ROM is needed so that the tibia inclines in a controlled manner by the plantarflexors while the ground reaction force (GRF) progresses forward\cite{91}. AFOs that limit plantarflexion ROM during CPF, can also increase tibia inclination at the beginning of CDF\cite{91}. Increased tibia inclination often coincides with increased knee extensor demands and thus increased metabolic cost\cite{91}. In AFOs that limit dorsiflexion ROM\cite{121}, more time is needed to bring the body forward, and as a result gait speed decreases\cite{91}. During PPF, power is generated at the ankle to propel the body forward by an active plantarflexion ROM and moment\cite{91}. In AFOs that limit plantarflexion ROM\cite{121}, plantarflexion power can be decreased which in turn can increase metabolic cost to maintain a certain gait speed\cite{141}.

Three AFOs are known that partly overcome these problems. Two of these AFOs are currently used in clinic and make use of adjustable dorsiflexion and plantarflexion springs (Neuro Swing, Fior&Gentz\cite{29}, and ankle hinge 17B66, Ottobock\cite{82}). However, similar to solid AFOs, these AFOs can only store energy when the ankle dorsiflexes beyond the AFOs neutral alignment (that is the angle between shank/calf cover and footplate when no external moment is applied\cite{8}). This characteristic may be another reason that despite using an AFO that should compensate for plantarflexor paresis, plantarflexion power with AFOs is still lower compared to normal data\cite{8,121}. Another AFO that is able to change its neutral alignment to allow a more efficient way of harvesting energy, is the ‘unpowered exoskeleton’\cite{17}. However, this exoskeleton does not assist during CPF and swing, has not been tested on patients with flaccid ankle muscle paresis and is currently in its developmental stage\cite{17}. An ideal AFO should not hamper normal ankle ROM, and should provide adequate dorsiflexor and plantarflexor moments to compensate for the ankle muscle paresis\cite{121,8}. This AFO should function primarily during normal gait, but also during other ADL\cite{11}.

In this study, the development of a novel AFO is described, following the ‘methodical design process of biomedical products’\cite{124}. This process consists of several phases starting with the problem definition, goal formulation, listing of requirements, several design phases, and ending with a newly designed product\cite{124}. This process included a patient centered approach\cite{122}. Different problems can be identified when comparing dorsiflexor to plantarflexor paresis\cite{91}. In case of
Figure 1
Normal ankle motion and muscle activity including the AFO goals needed per gait phase to compensate for the paresis

<table>
<thead>
<tr>
<th>Gait phase</th>
<th>Stance</th>
<th>Swing</th>
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<td>CPF</td>
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AFO = ankle foot orthosis, CDF = controlled dorsiflexion, CPF = controlled plantarflexion, DF = dorsiflexion, HC = heel contact, PF = plantarflexion, PPF = powered plantarflexion, 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 only applicable to specific paresis types. Normal data of eight healthy adults (age 25 ± 1 years) who walked with standard shoes (‘performance X’, extra wide, double depth, Dr. Comfort[21]), were collected in our gait lab (average gait speed was 1.4 ± 0.1m/s). This ankle motion was comparable to literature[91] with the only difference that our data were shifted 6° towards dorsiflexion.

dorsiflexor paresis, the AFO should enable initial heel contact[91]. During CPF, plantarflexion ROM should be allowed without resulting in foot slap so that stability can be maintained[91]. During swing, the foot should be lifted to prevent foot drag and tripping[91]. In case of plantarflexor paresis, the AFO should control dorsiflexion ROM during CDF[91]. When dorsiflexion is controlled, forward progression of the GRF is controlled and no excessive knee extensor demands are needed[91]. During PPF, ankle power should be generated[91] to maintain gait speed without increasing metabolic demands[141]. The goals that are needed per paresis type and per gait phase, are schematically presented in Figure 1.
These goals 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[121])
   (c) provide ≥0.5W/kg* maximum plantarflexion power (existing AFOs[121])

4. During swing
   (a) provide dorsiflexion motion to enable initial heel contact

* = 95% confidence interval

The main requirements needed are: allow minimum 30° ankle ROM that is the functional ankle ROM during normal gait[49], minimum plantarflexion stiffness should be 0.003Nm*kg/°[104] to control plantarflexion ROM, and minimum dorsiflexion stiffness should be 0.021Nm*kg/° to control dorsiflexion ROM (to maximum 28°) and to provide a plantarflexion moment (of minimum 0.6Nm/kg). Following several design phases in which designs were scored on theoretical ability to meet the goals and requirements, ADJUST was developed (Figure 2). To evaluate if ADJUST met the requirements, its mechanical performance was quantified. To evaluate if ADJUST met the goals, ankle kinematics and kinetics with ADJUST and with patients’ own AFO were evaluated in a patient with combined plantarflexor and dorsiflexor paralysis, when walking on a treadmill.

Materials

Design

Figure 2 depicts ADJUST that consists of two mirrored mechanical hinges each containing a leaf spring to enable separate control of plantarflexion and dorsiflexion stiffness. The lateral hinge is used for compensating decreased plantarflexor function, and the medial hinge for compensating decreased dorsiflexor function. The position of both hinges can be changed without changing its function. Each hinge contains a pawl and ratchet made of hardened construction steel (Figure 3). Inherent to the construction of the teeth of the ratchet and pawl, alignment of ADJUST can change in the smallest mechanically possible steps 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 steps of 5°). The type of activity may require re-alignment in more dorsiflexion (when walking uphill[67]) or plantarflexion (when walking downhill[67]).

Other components of ADJUST are two force sensing resistors (FSRs), two solenoids, an Arduino, battery, shank cover and foot plate. Dependent on the signal from the Arduino that reads the FSRs, the solenoid will be activated (see Appendix). When activated, the pawl unlocks from the ratchet, allowing the hinge to rotate freely in both directions (Figure 3a). When inactivated, the pawl and ratchet are locked and
1 = lateral and medial mechanical hinge, 2 = force sensing resistors (FSR), 3 = solenoids, 4 = cased Arduino board, 5 = battery, 6 = shank cover, 7 = footplate. The footplate is inserted in a shoe (not depicted) and the FSRs are placed underneath the sole on the heel and the metatarsophalangeals. The battery powers the Arduino, solenoids, and FSRs. Specifications of parts 2-7 can be found in the Appendix. Weight of ADJUST is 1.6kg.

rattling rotation is only possible in one direction while locking the hinge in opposite direction (Figure 3b). To reduce friction, the connecting surfaces between ratchet and pawl are lubricated, and between each rotational component a polytetrafluorethylene disc is used.
Fig. 3
Mechanical hinge

(a) Unlocked hinge  (b) Locked hinge (default)

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.

Stiffness calculation

The medial spring is used for compensating decreased dorsiflexion moments, that are needed during CPF and swing (Figure 1). The same spring is used to compensate both moments, thus the highest moment determines its stiffness. However, since the medial spring counteracts the lateral spring during PPF (Figure 4) it is preferred to use the lowest stiffness possible. The dorsiflexion moment needed during CPF is about five times higher compared to swing[140, 67] and the exact moment depends on several factors[104, 38]. The moment needed during CPF was therefore estimated from previous literature, which is 0.15Nm/kg[67]. This moment ($M_{df}$), and the effects of body weight ($BW$) and plantarflexion ROM during CPF ($\alpha_{pf}$) were used to estimate medial spring stiffness ($k$) according to equation (1):

$$k = \frac{BW \times M_{df}}{\alpha_{pf}} \quad (1)$$

Two medial springs were fabricated from commercially available materials. These springs consisted of one and two spring steel strips (dimensions 7x1x70mm, E=210GPa, I=0.78mm$^4$) with a theoretical stiffness of 0.2 and 0.5Nm/°, respectively.

The lateral spring is used for compensating decreased plantarflexion moments that are needed during CDF and PPF. According to Rouhani et al.[103], the maximum moment ($M_{pf\ MAX}$) that occurs during PPF[104] can be estimated from body weight ($BW$) and body height ($BH$) according to:

$$M_{pf\ MAX} = 7.9\%BW \times BH$$

The lateral spring only stores energy during CDF (Figure 4). During CDF a maximum moment of 5.5%BW*BH can be stored[103]. Therefore, a maximum
plantarflexion moment can be provided of:

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

Ankle stiffness during PPF was found to have a linear relationship with gait speed[^104]. Lateral spring stiffness ($k$) was estimated based on body weight ($BW$), gait speed ($V$), possible energy storage ($70\%$), and dorsiflexion ROM ($\alpha_{df}$) according to equation (2):

$$k = \frac{V \times BW \times 70\%}{\alpha_{df}}$$ (2)

Two lateral springs were fabricated from the same commercially available materials as the medial springs. The lateral springs consisted of three and four spring steel strips (dimensions 15x1x70mm, $E=210$GPa, $I=1.66$mm$^4$) with a theoretical stiffness of 1.6 and 2.1Nm/$^\circ$, respectively. Based on the stiffness requirement of $0.021$Nm*$kg/^\circ$, these available springs can be suitable for a person with body weight 76 to 100kg. Note that by varying lateral spring stiffness, the onset of heel off and thereby the onset of PPF can be changed. For example, increasing lateral spring stiffness will advance the onset of heel off.

**Figure 4**

Normal ankle motion and working mechanism of ADJUST per gait phase

<table>
<thead>
<tr>
<th>Gait phase</th>
<th>Stance</th>
<th>Swing</th>
</tr>
</thead>
<tbody>
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<td>CPF</td>
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</tr>
</tbody>
</table>

CDF = controlled dorsiflexion, CPF = controlled plantarflexion, DF = dorsiflexion, HC = heel contact, PF = plantarflexion, PPF = powered plantarflexion, TO = toe off.

**Working mechanism**

In **Figure 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 swing phase none of the FSRs registers contact, the lateral solenoid is activated and unlocks the lateral hinge to allow releasing its remaining energy. When this energy is released, the medial hinge can release its energy to lift the foot. During level walking only the lateral- and not the medial solenoid is needed.

Methods

Mechanical performance

Mechanical performance of ADJUST was tested using the 'Bi-articular Reciprocating Universal Compliance Estimator' (BRUCE)[9]. The BRUCE registers ankle joint configurations of a replicated human leg and corresponding forces exerted by ADJUST on this leg[9]. A linear fit of both the ascending and descending stiffness profile is used to calculate mechanical stiffness around the ankle within the functional 10° plantarflexion ROM and 20° dorsiflexion ROM[9]. Mechanical stiffness was quantified when ADJUST was equipped with four stiffness configurations: stiff - stiff medial and lateral spring, stiff/flexible - stiff medial and flexible lateral spring, flexible - flexible medial and lateral spring, and flexible/stiff - flexible medial and stiff lateral spring. Mechanical stiffness can be influenced by the shoe and therefore all configurations were quantified with and without standard shoe with rocker sole (shoe line ‘performance X’, extra wide, double depth, of Dr. Comfort[21]). Mechanical stiffnesses with and without shoe were averaged and standard deviations calculated. All mechanical tests were performed according to the BRUCE protocol[9].

Mechanical stiffness ($k$) of the patients’ own AFO shoe was estimated based on plantarflexion ROM during CPF ($\alpha_{pf}$), dorsiflexion ROM during CDF ($\alpha_{df}$), maximum plantarflexion moment during PPF ($M_{pf\ MAX}$), and body weight ($BW$) according to equation (3):

$$k = \frac{M_{pf\ MAX} \cdot BW}{\alpha_{df} - \alpha_{pf}}$$

(3)

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. Selection criteria were, body weight between 76 and 100kg, ankle muscle paralysis (Medical Research Council scale (MRC) = 0[39] 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 selected male patient (age 59yrs, body height 1.77m, shoe size 40) had a body weight of 76.7kg and bilateral paresis due to Hereditary Motor and Sensory Neuropathy (HMSN)/Charcot Marie Tooth. He has been using AFOs bilateral 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 (advised for this patient by the independent resident in Rehabilitation Medicine) on the footplate to fit ADJUST to his dominant leg. Which leg was
dominant was verified by asking which leg he would use to kick a ball[24]. Passive ankle ROM was 25° plantarflexion and 5° dorsiflexion with extended knee.

Kinematic and kinetic data were collected in the Gait Real-time Analysis Interactive Lab (GRAIL)[78]. The GRAIL has a 180° screen on which a standard virtual reality environment was displayed. Kinematic data were obtained using 25 reflective markers, placed according to the lower extremity Human body model[118], 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 using two 1000Hz force plates, integrated in a dual-belt treadmill. Before test started the patient was secured by a safety vest. In total, five AFO conditions were tested in fixed order and at a fixed gait speed. These conditions were own AFO shoe and four ADJUST stiffness configurations with standard shoe[21]. Comfortable treadmill speed was determined with the own AFO shoe by gradually increasing speed until the patient indicated he had reached his comfortable speed. Thereafter, treadmill habituation started with ten minutes[117] of walking with the own AFO shoe and the eleventh minute was recorded. This test was repeated for the first (stiff) configuration of ADJUST standard shoe. This configuration was chosen as second as it was the most stable configuration and we did not know if 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, 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 was reliable whenever means did not differ more than one standard deviation.

All gait data were filtered real time using a one-way, low-pass (Fc = 4Hz) 2nd order Butterworth filter and normalized to 100% gait cycle in D-flow software (3.18.2)[78]. Gait cycles with a foot placement on only one of the force plates were selected using Gait Off-line Analysis Tool (GOAT)[78]. 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 an impression if the ankle moments provided were adequate from the patients’ perspective, he was asked about his experiences with each configuration.

Results

Mechanical performance

ADJUSTs ankle ROM, quantified using the BRUCE device[9], was in all configurations larger than 30°. All stiff medial and lateral springs and the flexible medial spring met the stiffness requirements (Table 1). Estimated mechanical stiffness of the own AFO shoe was 3.1Nm/° (calculated from Table 2, according to equation (3)).
# Table 1

Mechanical stiffness of ADJUST when equipped with different springs

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Medial spring stiffness (Nm/°)</th>
<th>Lateral spring stiffness (Nm/°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stiff</td>
<td>0.7 ± 0.2</td>
<td>1.7 ± 0.7</td>
</tr>
<tr>
<td>Flexible</td>
<td>0.3 ± 0.0</td>
<td>1.1 ± 0.1</td>
</tr>
<tr>
<td>Requirement</td>
<td>≥ 0.2</td>
<td>≥ 1.6</td>
</tr>
</tbody>
</table>

Bold values did not meet the requirement.

# Table 2

Ankle kinematics and kinetics for all AFO conditions during stance

<table>
<thead>
<tr>
<th>AFO condition</th>
<th>CPF ROM (°)</th>
<th>CDF ROM (°)</th>
<th>PPF ROM (°)</th>
<th>Max M (Nm/kg)</th>
<th>Max P (W/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stiff 1\textsuperscript{st} time</td>
<td>5 ± 2</td>
<td>27 ± 1</td>
<td>22 ± 2</td>
<td>0.6 ± 0.1</td>
<td>0.7 ± 0.1</td>
</tr>
<tr>
<td>Stiff 2\textsuperscript{nd} time</td>
<td>6 ± 2</td>
<td>28 ± 1</td>
<td>17 ± 2</td>
<td>0.7 ± 0.1</td>
<td>0.7 ± 0.1</td>
</tr>
<tr>
<td>Stiff/flexible</td>
<td>7 ± 2</td>
<td>28 ± 2</td>
<td>20 ± 1</td>
<td>0.7 ± 0.1</td>
<td>0.7 ± 0.1</td>
</tr>
<tr>
<td>Flexible</td>
<td>8 ± 3</td>
<td>31 ± 3</td>
<td>23 ± 3</td>
<td>0.8 ± 0.1</td>
<td>0.8 ± 0.1</td>
</tr>
<tr>
<td>Flexible/stiff</td>
<td>10 ± 2</td>
<td>33 ± 2</td>
<td>22 ± 2</td>
<td>0.8 ± 0.1</td>
<td>0.8 ± 0.1</td>
</tr>
<tr>
<td>Own AFO</td>
<td>1 ± 1</td>
<td>21 ± 2</td>
<td>19 ± 2</td>
<td>0.8 ± 0.1</td>
<td>1.1 ± 0.3</td>
</tr>
<tr>
<td>Goal</td>
<td>4 - 12</td>
<td>18 - 28</td>
<td>≥ 18</td>
<td>≥ 0.6</td>
<td>≥ 0.5</td>
</tr>
</tbody>
</table>

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.

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## Case study

The comfortable walking speed of 0.8m/s was lower than the 1.4±0.1m/s from our normal data. Due to differences in gait speed, in AFO conditions a longer stance phase can be expected\[91\] and a smaller ankle ROM during PPF\[66\]. Therefore, plantarflexion ROM goal had to be corrected for gait speed (to ≥ 18°\[66\]). Peak ankle power and moment are also expected to be lower in AFO conditions due to a lower gait speed\[109\]. However, these goals did not have to be corrected as they were derived from existing AFOs which were already based on walking at a lower speed of 0.9±0.2m/s\[121\]. The stiff ADJUST configuration was reliable on most outcomes except for plantarflexion ROM during PPF (Table 2).

During CPF, differences were present between ADJUST and own AFO (Table 2, Figure 5). Both in the stiff and stiff/flexible configuration, plantarflexion was adequately controlled. In contrast, the 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 own AFO. During PPF, maximum plantarflexion power was adequate in all AFO conditions but lower than could be expected based on our normal data, even when corrected for gait speed (2.4W/kg)\[109\]. The highest plantarflexion moments were found in the flexible and flexible/stiff configuration and in the own AFO. These moments were also lower than could be expected (1.5Nm/kg)\[109\]. Three configurations (stiff 1\textsuperscript{st} time, flexible and flexible/stiff) met the plantarflexion ROM goal. All AFO conditions provided dorsiflexion ROM during swing (Figure 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 feel as confident yet as walking with his own AFOs. He disliked that ADJUST was heavier and bigger than his own AFO.

### Figure 5

Ankle motion for all AFO conditions and normal data

Vertical lines (for the 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 equal for own AFO and normal data while gait speed was lower in all AFO conditions.

### Discussion

ADJUST was designed to not hamper ankle ROM and to provide adequate plantarflexor and dorsiflexor moments. ADJUST, when equipped with stiff springs, met the minimum ankle ROM and stiffness requirements and allowed normal ankle kinematics and kinetics. During CPF, ankle ROM with ADJUST was more normal compared to the patients’ own AFO. Flexible medial springs (used to compensate for dorsiflexor paresis) were not suitable as they resulted in foot slap.

### ADJUST performance

To test the full capabilities of ADJUST we chose a patient with complete paralysis of both plantarflexors and dorsiflexors (MRC=0[39]). When ADJUST was equipped with stiff springs it met the requirements and goals, and allowed more normal plantarflexion ROM during CPF when compared to the own AFO. This advantage of ADJUST over patients’ own AFO is especially important as allowing normal CPF
will increase stability during stance\cite{91}. ADJUST equipped with stiff springs also met the goals for CDF and PPF. However, both maximum moment and power were higher with the own AFO, probably because of a higher stiffness. This indicates that, to improve performance of ADJUST for this patient walking at this speed, the lateral spring should have been stiffer. Using a stiffer lateral spring can decrease dorsiflexion ROM during CDF within normal range, increase maximum moment and power during PPF (which is desirable when looking at normal data), and can also advance the onset of heel off and thus onset of PPF (which would result in a more normal CDF duration). Plantarflexion ROM during PPF should not be taken into consideration as it was found to be unreliable. When optimizing stiffness, metabolic cost\cite{8} and gradual, instead of stepwise, changes in stiffness should also 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, when compared to literature\cite{104}.

**Improvements to ADJUST**

To protect patients from injury on the medial side of the contralateral ankle, ADJUSTs medial hinge should be made smaller and should be covered with a soft layer. If possible, the medial hinge should be constructed as a smaller and free rotating hinge in case a patient has functioning dorsiflexors. This will decrease the weight of ADJUST, which was a limitation of the current design. The medial solenoid should be left out during walking as this also decreases weight. Flexible medial springs should not be used as they resulted in foot slap.

**Study limitations**

One patient was selected with 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 as 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 swing without hampering normal ankle ROM\cite{121}.

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 which may have influenced our results.

**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\cite{8}. Compensatory strategies may be more apparent in the knee compared to the ankle\cite{91}. Also, effects of ADJUST on activities that require high ankle ROM such as walking stairs\cite{98}, -slopes\cite{71} and standing up/sitting down on a chair\cite{35} should be evaluated in this larger group of patients. Comfortable walking speed should be determined with both ADJUST and own AFO.
Conclusion
ADJUST when equipped with stiff springs, met the minimum ankle ROM and stiffness requirements and was able to support flaccid paretic plantarflexor and dorsiflexor muscle function in a patient with ankle muscle paralysis. Especially during CPF, ADJUST allowed more normal plantarflexion ROM when compared to the own AFO. Walking with ADJUST is feasible and could be profitable in patients with flaccid plantarflexor paresis with and without dorsiflexor paresis.

Acknowledgement
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Appendix: Parts of ADJUST

Force Sensing Resistors

Two Force Sensing Resistors (FSRs, Interlink, type FSR-402, measuring range ± 10g till 10kg, resistance range ± 1 MΩ till < 3 kΩ, active surface 38.1 x 38.1mm, lifespan ± 10,000,000 activations) were placed on the sole of the shoe (Figure 6a). One FSR was placed underneath the heel and the other underneath the metatarsophalangeal (mtp) (Figure 6b). Both FSRs register shoe to floor contact. Contact means high resistance (maximum 1023 units), no contact means low resistance (minimum 0 units).

Solenoids

Two solenoids were used to control the paws 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).

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 29.3x27.1mm, resolution 128x64pixels, pins 4). A transparent case contained the complete Arduino system (Figure 6c). The battery unit that provided current to the Arduino system, FSRs and solenoids was a lithium polymer battery (Walkera, type 3S2P 3 cell, capacity 5200mAh, voltage 11.1V, dimensions 103x34x42mm, weight 317g). The complete Arduino system was inserted in a small bag that was placed on the back of a patient.

During level walking, the lateral solenoid receives a high signal from the Arduino when the input signal from both heel- and mtp FSR are below a certain threshold (Figure 6d). When both signals are low (swing phase), the lateral solenoid pushes the pawl to disconnect the hinge. Also, the solenoids should be turned off for as long as possible as this has two advantages (i) this saves energy, (ii) when the solenoids are off both mechanical hinges are connected meaning optimal stability for the unstable patient. Therefore the threshold to distinguish stance phase from swing phase should be as low as possible. Best case scenario means an input value of zero for both heel- and mtp FSR during swing phase and a maximum value of 1023 for both FSRs during stance. Pilot testing showed that the input value never reached either zero or 1023, also the input signal was different for the heel FSR compared to 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 no option, and an adapting threshold ($|T_n|$) was calculated real time according to the equation:
\[ |T_n| = \begin{cases} 
F \cdot \text{FSR} + (1 - \text{Factor}) \cdot T_{n-1} & \text{if } \text{FSR} < (T_{n-1} + \text{Offset}) \\
T_{n-1} & \text{else}
\end{cases} \quad (4) \]

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 or mtp FSR. The offset and factor were defined after pilot tests and were set at 50 and 0.1, respectively. Figure 6e displays the adapting threshold. When compared to Figure 6d (with a fixed threshold of 600), the use of an adaptive threshold resulted in a reduction of 35% of solenoid ON-time.

**Shank cover**

An extendable shank cover (Figure 6f&g) 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 (Figure 6g), an additional Velcro strap is used to connect it to the shank.

**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 enabled extending from size 36 till size 45 (Figure 6h). A soft layer of foam was placed on top of the foot plate (not depicted in Figure 6h&i). Stiffness of the footplate with each of the spacers was evaluated with BRUCE[9]. The height of the mechanical hinges of ADJUST could be changed to enable alignment to the anatomical axis of the ankle[27] (Figure 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.
Figure 6
Parts of ADJUST

a) FSR placement-caudal  b) FSR placement-lateral

c) Arduino system

d) FSR-Fixed threshold
(±44% ON-time/GC)

e) FSR-Adapting threshold
(±9% ON-time/GC)

f) Shank cover (27cm)

g) Extended shank cover (34cm)

h) Foot plate with spacers

i) Foot plate with height adjustments

FSR = force sensing resistors, GC = gait cycle, HC = heel contact, mtp = metatarsophalangeals,
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 down), the program selected (Level walking), 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 during level walking.  The resistance
ranges between 0 and 1023 units.  The dashed lines indicate the thresholds for heel- and mtp FSR
to identify stance- and swing phase.  h) Extendable footplate with 1 = heel part, 2 = carbon plate,
3 = toe part, 38-45 = spacers.  Foot plates with and without spacers (with corresponding stiffness
in Nm/°) are available in sizes: 36 (0.23), 38 (0.27), 0.40 (0.40), 41 (0.42), 43 (0.50), and 45 (0.55).
i) Height adjustments (arrows) allows changing the height of the mechanical hinges by 1.5cm.
Biographic sketches

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