Chapter 7

General discussion
CHAPTER 7. GENERAL DISCUSSION

Analysis
This thesis aimed to describe a patient-centered development and clinical evaluation of an ankle foot orthosis (AFO) to provide support for flaccid ankle muscle paresis. When AFOs do not fit the user’s needs, adherence to AFO use can decrease[126, 12]. Between 2010 and 2014, on average € 36.5 million was invoiced within the category leg/foot orthoses in the Netherlands[36]. An estimated 50%[135] of these costs can be attributed to AFOs, and with an adherence rate of only 20%[126], a considerable amount of money is wasted each year. Therefore, it is essential for an AFO to fit the needs of users[92].

Target group
In the sagittal plane, flaccid ankle muscle paresis can be subdivided into three paresis types: dorsiflexor, plantarflexor, and combined paresis[91, 10]. In current literature (Chapter 2) the focus has been on compensating for foot drop and foot slap, both resulting from dorsiflexor paresis. Although these symptoms are inconvenient and can cause tripping and falls[91], this clearance problem during swing can be easily overcome by using a simple elastic band to connect the foot to the shank (Chapter 2). Clearance can also be provided by solid AFOs. However, these AFOs introduce side effects such as: limiting ankle range of motion (ROM), and decreasing both unimpaired push-off power[127], and physical comfort[92]. Consequently, patients with only dorsiflexor paresis benefit more from elastic AFOs (Chapter 2).

Much less attention was paid to compensating the more challenging plantarflexor paresis. Compensating for a plantarflexor paresis requires large moments at the ankle to control dorsiflexion motion and to provide powered plantarflexion[104]. In contrast to prosthetics in which space and weight are almost unlimited due to the absence of a limb, implementing such large moments in a small and lightweight device surrounding the still present limb is thus a mechanical challenge. This high mechanical load can explain why AFO users mentioned that their AFO sometimes broke (Chapter 3). In case of combined paresis, a novel AFO should thus firstly compensate for plantarflexor paresis, and secondly for dorsiflexor paresis. The target group we defined for ADJUST is patients with flaccid plantarflexor paresis with and without flaccid dorsiflexor paresis.

Requirements for ADJUST
According to AFO users, AFOs should primarily function during level walking and a novel AFO should provide both stability and flexibility depending on the individual needs[92] and the type of ADL (Chapter 3). An AFO should also be: comfortable, easy to don and doff, lightweight[92, 77], durable, fit in normal shoes, and in a novel design all features should be combined (Chapter 3). We did not find studies evaluating which requirements a novel AFO should fulfill based on a patient-centered approach. Therefore, requirements were formulated during our analysis phase (Table 1, left column). Based on these requirements ADJUST was developed.

Evaluation
The quality of ADJUST was determined by checking, which requirements are fulfilled (Table 1). ADJUST met the requirements for mechanical stiffness, and for ankle motions, -moments, and -powers when a patient walked with ADJUST (Chapter 4).
Table 1
Evaluating requirements fulfilled by ADJUST

| Requirement                                      | Fulfilled?
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Provides support for flaccid plantarflexor paresis</td>
<td>Yes, but further improvements can be made by: A. Individually optimizing the stiffness configuration, B. Automatically exploring the optimal initial alignment for an individual, C. Automatically exploring the optimal initial alignment for an ADL, and D. Making the energy storing mechanism more efficient.</td>
</tr>
<tr>
<td>2 Provides support for flaccid dorsiflexor paresis</td>
<td>Yes, see 1A-D.</td>
</tr>
<tr>
<td>3 Allows normal ankle ROM</td>
<td>Promising, see 1A &amp; 1B.</td>
</tr>
<tr>
<td>4 Outperforms existing AFOs on ankle ROM</td>
<td>Promising, see 1A &amp; 1B.</td>
</tr>
<tr>
<td>5 Outperforms existing AFOs on power generated at the ankle during powered plantarflexion</td>
<td>Promising, see 1A &amp; 1C.</td>
</tr>
<tr>
<td>6 Enables standing up from a chair, climbing stairs, and slope walking</td>
<td>Yes, see 1A &amp; 1B.</td>
</tr>
<tr>
<td>7 Combines all features in one design</td>
<td>For the most part, but also 1B &amp; 1C should be implemented.</td>
</tr>
<tr>
<td>8 Retail price should be ≤€ 550 for prefab or ≤€ 1750 for a custom made product</td>
<td>The costs of the parts are within the price range, however the retail price was not yet defined by a partner in the industry.</td>
</tr>
<tr>
<td>9 Weighs ≤0.4 kg (comparable to[142])</td>
<td>No, but making a single adjustable prototype to fit several individuals (one size fits all) made ADJUSTs’ weight not representative for a final product. Excluding adjustment options, merging both hinges and using different materials such as plastic covers will decrease weight.</td>
</tr>
<tr>
<td>10 Fits in own shoes</td>
<td>No, the hinges should be downsized.</td>
</tr>
<tr>
<td>11 Fits underneath own clothing</td>
<td>No, see 10.</td>
</tr>
<tr>
<td>12 Comfortable, skin redness should not persist &gt;30 min.</td>
<td>Not yet, a custom made foot plate and shank cover should solve this. These parts can be 3D printed to ensure an optimal fit[129].</td>
</tr>
<tr>
<td>13 Donning and doffing takes ≤1 min.[92]</td>
<td>Unknown, a certified orthotist fitted ADJUST to the participants leg.</td>
</tr>
<tr>
<td>14 Durable, remains to function for ≥2 years</td>
<td>Unknown, should be evaluated by a partner in the industry before taken into production.</td>
</tr>
</tbody>
</table>

AFO = ankle foot orthosis, ROM = range of motion, kg = kilogram, min. = minute.

It was therefore concluded that ADJUST provided support for plantarflexor and dorsiflexor muscle function while allowing normal ankle ROM. During clinical evaluations it became apparent that this support was not always adequate for all participants, indicated by the ankle and knee motion, and ankle power that were not always within normal range during level- (Chapter 5) and slope walking (Chapter 6). Other requirements (price, ergonomic, spatial, and time) were not the first priority when developing ADJUST but are important when constructing a second prototype.

According to participants, the most important improvement with ADJUST compared to their own AFO, were its adjustment possibilities in stiffness and alignment that better fitted their needs (Chapters 5 and 6). Especially when performing a demanding ADL in terms of ankle ROM, such as walking down slope, participants experienced the beneficial effects of ADJUST (Chapters 5 and 6). ADJUSTs’ design seems superior to the patients’ own AFOs with participants mentioning (Chapter 5):

[With ADJUST] I experience a better roll-over. I might even be able to walk without a walking stick. (Participant 2)
It feels good to experience (some) ankle motion. [ADJUST] provides support during slope walking. (Participant 8)
These developments are very promising! I am curious to see what will be next. (Participant 7)

These participants also mentioned that the most important improvements for ADJUST should be its weight and the size of its hinges (particularly the medial hinge). They suggested that adjustments in stiffness and alignment should occur automatically (Chapter 5):

I hope [ADJUST] will be improved so that it will be light weight and fit in my own shoes. (Participant 4)
[ADJUST] should fit underneath trousers. (Participant 3)
It is too difficult to adjust the alignment and stiffness [of ADJUST]. (Participant 2)

Comparison with competitors
When compared to existing AFOs, promising results were found: ADJUST allowed more normal plantarflexion ROM during controlled plantarflexion in most patients (Chapters 4, 5, and 6), and in some patients ADJUST provided more ankle power during powered plantarflexion (Chapter 5). ADJUST, similar to existing AFOs, enabled standing up from a chair, climbing stairs and slope walking (Chapter 6).

Conventional AFOs that are designed to provide separate support to plantarflexor and dorsiflexor muscles can only vary its stiffness into plantarflexion and dorsiflexion direction and not per gait phase (Neuro Swing[29], ankle hinge 17B66[82], and the klap-EVO[8, chap. 7]). These AFOs are also unable to effectively use the ankle ROM to store energy due to their characteristic of a neutral alignment: that is the angle between foot plate and shank cover when no external moment is applied[8]. Due to this characteristic, energy can only be stored in a conventional energy storing AFO when the ankle is flexed beyond its neutral alignment (Figure 1).

We found one patented[138] AFO that was designed to effectively use the controlled dorsiflexion ankle ROM, and that varies its stiffness per gait phase[17]. Similar to ADJUSTs’ lateral hinge, this ‘unpowered exoskeleton’ (Figure 2) makes use of a ratchet mechanism to enable storing energy during the complete controlled dorsiflexion ankle ROM. This exoskeleton showed profitable results in healthy adults: the device took over plantarflexor muscle function and reduced metabolic walking cost by 7%[17]. However, this exoskeleton does not fit underneath clothing or in normal shoes (Figure 2), and only provides support for plantarflexor muscles. Patients generally suffer from combined plantarflexor and dorsiflexor paresis. Unlike ADJUST, this exoskeleton was not tested in patients, and due to the lack of dorsiflexor support it is also not suitable to be used in patients.

Challenges and opportunities
To meet all requirements ADJUST should be improved by decreasing its weight and size, and adding individual alignment plus stiffness adjustments that should occur automatically.

Decreasing the weight and size of ADJUSTs’ medial hinge can be done by implementing its function into the lateral hinge. Excluding redundant parts would
At heel contact the heel sensor registers contact and the lateral solenoid is disengaged, thereby the lateral pawl is engaged to the lateral ratchet. The medial pawl and ratchet were already engaged. During controlled plantarflexion, plantarflexion motion is allowed by rattling motion of the lateral hinge while energy builds up in the medial hinge to control this motion. At maximum plantarflexion the function of the two hinges reverses. During controlled dorsiflexion, dorsiflexion motion is allowed by rattling motion of the medial hinge while energy builds up in the lateral hinge to control this motion until maximum dorsiflexion is reached and the heel leaves the floor to start powered plantarflexion. Theoretically the medial hinge should be disengaged during controlled dorsiflexion, however pilot testing showed this was not needed. During powered plantarflexion, the lateral hinge releases its energy while the medial hinge stores energy. During swing that starts at toe off, none of the sensors registers contact, the lateral solenoid is activated to disengage the pawl from the ratchet. The medial hinge can then release its energy to lift the foot.

decrease ADJUSTs’ total weight by ±360g Future tests should evaluate if ADJUST could be used unilateral. The size of ADJUSTs’ lateral hinge can be decreased by using the complete length of the shank cover to distribute the material needed to provide support for plantarflexor muscles. Decreasing ADJUSTs’ weight can additionally be done by: replacing steel parts with carbon and titanium (minus...
±290g), excluding the ‘one size fits all’ adjustment possibilities in footplate and shank cover (minus ≥110g), and using a polymer instead of steel hinge cover (minus ±50g). However, ADJUSTs’ total weight would then be ±800g, therefore still not meeting the requirement (Table 1). The requirement of 400g was based on an existing device: the AFO with oil damper[142]. This AFO only supports dorsiflexor muscles[142]. Supporting plantarflexor muscles requires larger moments that can add weight to an AFO. This increase in weight when only supporting plantarflexor muscles[17] instead of only dorsiflexor muscles[142] is also illustrated by the unpowered exoskeleton that weighs 500g. Therefore, 800g when both dorsiflexor and plantarflexor muscles are supported could be acceptable, and patient tests must prove if this weight is indeed acceptable. More reductions are feasible when a fluids (hydraulic or pneumatic) system is implemented (Figure 3). Previous research has shown that using hydraulics in AFO design is feasible[28, 14]. Another advantage of using a fluids design such as the one in Figure 3, is that stepless energy storing is possible, and also that energy can be stored during controlled plantarflexion. Future studies should evaluate if this fluids device could be used to provide adequate support for both plantarflexor and dorsiflexor muscles.

Besides the weight and size reductions, adjustments in alignment should occur automatically in the ADJUST. Automatic alignment adjustments to slope walking are already described in prosthetic design[44, 139]. Possibly this mechanism can be implemented in AFO design to find an optimal alignment for each individual. To further improve power at the ankle during powered plantarflexion, the energy storing system should be optimized by implementing a step-less mechanism such as a disc brake. Improving power can additionally be done by storing the energy during controlled plantarflexion and using this energy to lift the foot during swing, instead
Figure 3
Fluids alternative

1 = heel sensor, 2 = heel cylinder, 3 = pressure chamber, 4 = electric valve, 5 = forefoot cylinder, 6 = spring. At heel contact, the heel sensor (1) is activated and the electric valve (4) is closed. During controlled plantarflexion, the piston in the heel cylinder (2) moves up and pressure builds in the pressure chamber (3). During controlled dorsiflexion, the piston moves down and more pressure is added to the pressure chamber (3). When the heel leaves the floor the electric valve (4) opens and pressure is released into the forefoot cylinder (5) during powered plantarflexion. During swing, the spring (6) lifts the foot. Of extracting energy during powered plantarflexion. Storing energy during controlled plantarflexion is theoretically feasible using the fluids design (Figure 3).

One of the bigger challenges will be to find an optimal stiffness configuration for each individual. This configuration is (at least) dependent on factors such as: the optimization outcome (e.g. ankle ROM/power /energy cost), the type of ADL (Chapter 2), paresis type[91], body weight[91], step length[1], walking speed[104], gait phase[104], and degree of inclination during slope walking[67]. Literature that focused on finding the optimal AFO stiffness for an individual is scarce and only patients with spastic paresis were evaluated when optimizing energy cost of walking. This literature included AFOs that have a single ankle stiffness instead of a separate stiffness into plantarflexion and dorsiflexion direction[8, chap. 6]. The literature that did evaluate AFOs with separate plantarflexion and dorsiflexion stiffness, included conventional AFOs (Neuro Swing[29]) that can not change its stiffness and alignment per gait phase[57, chap. 5]. This literature emphasized that there is not one optimal stiffness, but this stiffness configuration should be determined individually. Future research that focusses on finding an individual stiffness configuration should at least consider all these factors. To get insight in individual causal relations between factors, future research should consider big data processing.

ADJUST was designed for patients with flaccid ankle muscle paresis and may not be suitable for spastic paresis. The presence of spasticity (one type of increase in muscle tone at rest; characterized by increased resistance to passive stretch, velocity...
dependent and asymmetric about joints’[25]) cannot be controlled by ADJUST. Developing an AFO for patients with spastic paresis would be based on a different AFO function: to manage increased muscle tension instead of compensating for weakness[10].

It can be stated that with the ADJUST, an AFO was developed that is suitable for a large group of patients. This assumption was enhanced by the fact that a large partner in the industry: Otto Bock showed interest in ADJUST and invested in a patent (see appendix: Patent).

**Thesis limitations**

The most important limitation is that only a limited number of patients participated in our studies. However, by involving a multitude of stakeholders of which most were patients, comparing our results to qualitative literature in each design phase[122, 53], and by following all steps in the methodological design process[124], an AFO was developed that meets the most important patients needs.

This thesis focussed on level- and slope walking. The second most important activity mentioned by AFO users: rising from a chair was only evaluated by timing five times standing up and sitting down on a chair (Chapter 6). Quantifying lower extremity kinematics and kinetics, and administering a questionnaire that evaluates functional limitations when standing up and sitting down on a chair[102] could have provided additional insight in effects of ADJUST when compared to patients’ own AFO. In a future study, after implementing design optimizations, rising from a chair should be evaluated in more detail.

The shortcomings of ADJUST could have influenced our results. ADJUSTs’ heavy weight possibly hampered participants to walk up stairs and up slope (Chapter 6). The non-optimal stiffness configuration and -energy storing system could have resulted in a non-optimal power output at the ankle during powered plantarflexion (Chapters 5 and 6). When optimizing ADJUSTs’ design these limitations should be diminished.

**Future research**

Further improvements to ADJUST should be made including: a decrease in weight and size, automatic adjustment of the initial alignment and stiffness configuration per individual and per ADL, and optimizing the energy storing mechanism. After these improvements are implemented, future studies should focus on finding an optimal stiffness configuration and alignment per individual. When focusing on level walking, a future study should recruit one participant with plantarflexor and dorsiflexor paralysis and by tuning the alignment and stiffness, should try to find for example an optimum power output within a normal ankle ROM. At a later stage, besides body functions and activities, also participation should be evaluated. When a novel prototype is realized that fulfills all requirements, a clinical evaluation with a larger patient group has to be performed to confirm the quality of ADJUST and to finalize the patient driven development.