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Patient centered development and clinical evaluation of an ankle foot orthosis

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Chapter 1

General introduction

Patient centered development

The field of ankle foot orthoses (AFOs, [Box 1](#)) developments is a hot topic, with an average global filing rate of two AFO patents per month between 2008 and 2016[87]. Currently, at least 53 different AFOs are available in clinical practice (data from one of the largest company of orthopedic workshops in the Netherlands, OIM Holding BV). An important aspect of AFOs is that they should meet the users' needs[92]. When an AFO fits the needs of an individual, adherence to AFO use can improve[126]. Despite the amount of AFOs available, AFO users mentioned several drawbacks[12, 92]. For example, the mostly used solid dorsal AFOs decreases ankle range of motion (ROM)[121, 92]. When ankle ROM is decreased, it can be difficult to perform activities that require more ROM than level walking, such as climbing stairs[134] and slope walking[67]. Using hinged AFOs could be one solution to improve both climbing stairs[113] and slope walking[71]. However, the disadvantage of hinged AFOs is that they are unable to actively vary their stiffness into dorsiflexion and plantarflexion direction[8]. Normal ankle stiffness varies not only between directions but also throughout the gait cycle[104]. Ideally an AFO mimics the normal ankle stiffness profile. In some hinged AFOs, stiffness into dorsiflexion and plantarflexion can be varied (Neuro Swing[29], experimental AFO[62], and ankle hinge 17B66[82]). However, this stiffness can not be changed throughout the gait cycle. Other designs that have the potential to be implemented in AFOs have a varying stiffness throughout the gait cycle[47, 138], or are specifically designed for an activity such as slope walking[44]. None of these designs are currently available for AFO users, and we found no indication that these designs were developed to fit the AFO users' needs. These designs were most likely developed according to a conventional technology centered design process[128, 79]. Therefore, there is a distinct need for an improved AFO design that is developed according to a patient centered design process[53, 122].

This thesis describes a methodical user centered design process of a novel AFO. This process consists of three iterative core phases that are repeated several times to find the optimal solution for the user[124, 122]. These phases are: analysis, synthesis, and evaluation ([Figure 1](#))[124]. In this development a multitude of stakeholders were involved (patients/ specialists in Rehabilitation Medicine/ orthotists/ human movement scientists/ engineers), and a variety of research techniques used (focus group/ brainstorming/ explorative play/ designing/ usability testing/ clinical evaluation).

Analysis

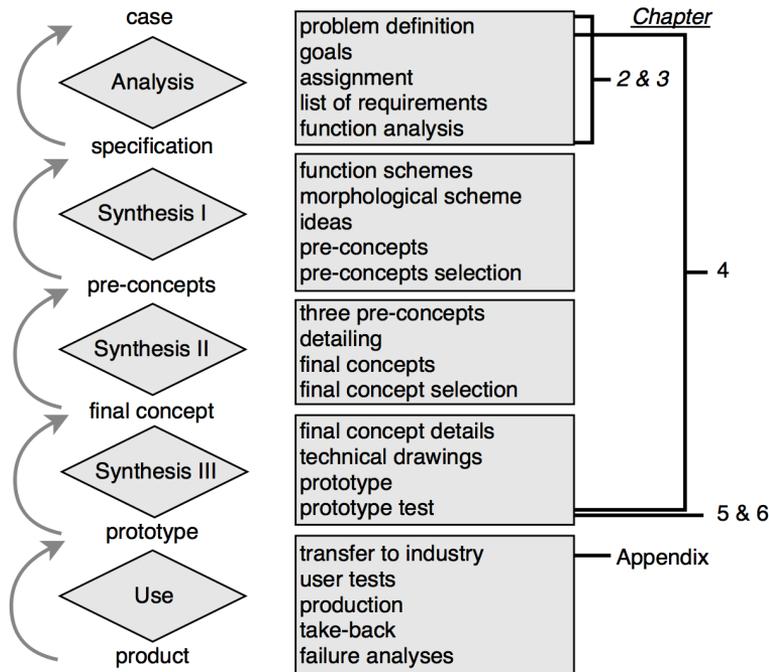
This iterative phase is intended to get insight in the needs of AFO users[53, 122, 124]. Key contents are: problem definition and patient needs ([Figure 1](#)).

Box 1. Ankle foot orthosis

A reusable externally applied device that encompasses the ankle and the whole or part of the foot, used to modify the structural and functional characteristics of the neuromuscular and skeletal system[54].

Main AFO function in flaccid vs. spastic paresis AFOs
prescribed for flaccid paresis should compensate for decreased muscle strength. AFOs prescribed for spastic paresis should manage spasticity[10].

Figure 1
Methodical design process[124] and chapter allocation



Problem Definition

When demarcating the target population for a novel AFO, a differentiation should be made between flaccid and spastic ankle muscle paresis[143, 10].

AFOs used for flaccid ankle muscle paresis should only compensate for muscle weakness while the presence of spasticity additionally requires an AFO to manage unpredictable increases in muscle strength[143, 10] (Box 1). This thesis focusses on patients with flaccid and not spastic ankle muscle paresis. Flaccid ankle muscle paresis can result from a multitude of pathologies such as spina bifida[2], hereditary motor and sensory neuropathy/Charcot Marie Tooth disease[40], and also from peripheral nerve trauma[89]. Walking with a flaccid dorsiflexor paresis can result in: foot drop during swing that causes tripping, an unstable loading response due to initial toe contact instead of heel contact, or a noticeable foot slap, that decreased stability during mid-stance due to reduced knee moment control[91]. Walking with a flaccid plantarflexor paresis can result in reduced power at the ankle during push-off that decreases walking speed[91]. Especially patients with severe flaccid ankle muscle paresis use AFOs to improve walking ability[100]. Outcomes on effects of AFOs can be structured according to the ‘International Classification of Functioning, Disability and Health’ (ICF) using the components ‘body functions’ and ‘activities’[136]. The component ‘participation’ was not considered at this stage since first a body function should be made possible

Box 2. In Chapter 2, a systematic review is described that evaluates effects of AFOs on body functions and activities in patients with flaccid ankle muscle paresis.

to be able to execute an activity before patients can participate in life situations. Extensive research has been performed on effects of AFOs on body function in patients post-stroke[15, 70, 115, 116]. However, since stroke is often characterized by spasticity[111], and the main AFO function differs between spastic and flaccid paresis[10] (Box 1), results of these studies may not be applicable to patients with flaccid ankle muscle paresis. Effects of AFOs on body functions and activities in patients with varying flaccid ankle muscle paresis were evaluated to demarcate the problem and to define the requirements for a novel AFO (Box 2).

Patient needs

Patient insights can become apparent especially in qualitative research designs as patients are not limited to fixed questions[72]. When allowing patients to interact to find common ground, important themes can be identified[34]. One way to allow interaction is to conduct a focus group discussion[34]. Only one focus group study was found that evaluated experiences with AFOs and this study included patients with multiple sclerosis[12] that often coincides with spasticity[4]. Therefore, these results may not be applicable to patients with flaccid ankle muscle paresis[10]. Other focus group studies that included patients with flaccid ankle muscle paresis to get insight in experiences with AFOs we could not find. Also, we found no focus group studies that provide insight in importance of activities and suggestions for improved AFO design in these patients. A focus group discussion was performed to get insight in the patient needs concerning the importance of activities and suggestions for improved AFO design in AFO users with flaccid ankle muscle paresis (Box 3).

Box 3. In Chapter 3, a focus group discussion is described that aimed to provide insight in experience with AFOs, importance of activities with AFOs, and suggestions for improved designs in people with flaccid dorsiflexor and plantarflexor paresis.

Synthesis

This iterative phase (Figure 1) builds on input from the analysis phase and continues with ideation[122, 53]. This phase is characterized by involving multiple disciplines to get the most original ideas[122, 124, 60]. A diverging range of solutions will be created until a minimum of ten pre-concepts are formed[124]. Up to this point everything is possible and no pre-concept should be excluded based on rationale[124]. Three concepts will be selected on their ability to meet the requirements and wishes. Business modelling[122] is an important aspect of this selection process since an easy and cost efficient production can facilitate the transfer to industry. After the concept selection the synthesis phase converges into creating a prototype[124] (Box 4).

Box 4. In Chapter 4, the development of a novel AFO, called ADJUST, is described. ADJUST provides support for flaccid plantarflexor paresis with and without dorsiflexor paresis while allowing normal ankle ROM. Mechanical performance of ADJUST was evaluated using the BRUCE. In a case study initial patient experiences were used to improve the design before the next patient tests. Feasibility of walking with ADJUST was evaluated using the GRAIL.

Evaluation

This iterative phase uses the prototype that was built in the synthesis phase, and continues with prototype tests, patient feedback, and the transfer to industry[124]. In this phase multiple patients are recruited to evaluate if the product could be successful in fulfilling its goal[122]. After each evaluation, comprising: patient feedback and mechanical- and clinical test outcomes, the prototype is refined and re-tested[122, 53]. Key contents of this phase are: mechanical- and clinical evaluation, and transfer to industry[53, 122, 124] (Figure 1).

Box 5. In Chapters 5 and 6, two clinical studies are described in which performance with ADJUST is evaluated and compared to patients' own AFO. Ten patients were evaluated. In Chapter 5, performance during level walking and on patients' satisfaction with both AFOs are described. In Chapter 6, performance during slope walking and functional tests (timed up and down stairs test, timed sit to stand test, and timed up and go test) are described.

Mechanical evaluation

To evaluate if the mechanical requirements are met, and if the product is safe to use, mechanical tests are performed[124]. Varying devices can be used to quantify AFO characteristics[63]. One example is the 'Bi-articular Reciprocating Universal Compliance Estimator' (BRUCE)[9]. The BRUCE is able to quantify ankle ROM and stiffness into dorsiflexion and plantarflexion[9]. An advantage of using the BRUCE to quantify mechanical characteristics, is that it enables comparisons to previously evaluated AFOs[58, 94]. When quantifying mechanical performance of a novel AFO the BRUCE was used (Box 4).

Clinical evaluation

To evaluate if a novel AFO fits the needs of a single user, a case study was performed first[122]. Patient experiences with the novel AFO were an important part of this study[122, 53]. Additionally, this study evaluates if walking with the novel AFO is feasible and has the potential to be beneficial. Walking ability was measured using the Gait Real-time Analysis Interactive Lab (GRAIL)[78]. The GRAIL consists of a 180 degrees screen on which an immersive virtual reality can be displayed, and a treadmill on which the projection of this reality can be continued[78]. The GRAIL was used when evaluating walking performance with a novel AFO (Box 4).

Based on the results of this case study, improvements to the novel AFO were made. Thereafter, more patients were recruited to evaluate effects of the novel AFO and patients' own AFO on level walking, and other functional activities that require more ROM than level walking (for example slope walking[67], Box 5). Patients experiences with the novel AFO play an important role in this study to evaluate if the AFO meets the patients' needs (Box 5). Results from both mechanical and clinical evaluations will be used to propose further improvements to the novel AFO (Box 6).

Box 6. In Chapter 7, the main results of the thesis are discussed and suggestions for future research proposed.

Transfer to industry

When making the transfer to industry, protecting a newly designed product is an important aspect[124]. At this stage the transfer to industry is already in progress. A collaboration agreement with an industrial partner is due to be signed. A patent application (Box 7) has been submitted as part of this agreement.

Box 7. The patent describing ADJUST, filed by Ottobock in collaboration with the University Medical Center Groningen is appended.