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Patient centered development and clinical evaluation of an ankle foot orthosis

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Document Version

Publisher's PDF, also known as Version of record

Publication date:

2017

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

van der Wilk, D. (2017). *Patient centered development and clinical evaluation of an ankle foot orthosis*. Rijksuniversiteit Groningen.

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Summary

Patients with flaccid ankle muscle paresis regularly use ankle foot orthoses (AFOs) to improve their walking ability. AFOs generally allow sufficient ankle range of motion (ROM) for normal walking. Patients can be hampered when using their AFO to perform activities of daily living (ADL) that require a different ankle ROM compared to level walking. It is essential for an AFO to meet the needs of its users since this will improve adherence to AFO use. There are no AFOs known that are designed based on the needs of users: a patient centered approach. Improving AFO design can best be done using a patient centered and methodological design process (*Chapter 1*). In this design process, three core phases iterate and multiple stakeholders are involved to optimize AFO design to the needs of the patient. These core phases are analysis, synthesis, and evaluation. In the analysis phase, the problem is demarcated and the patient needs defined. In the synthesis phase, the information acquired during analysis is used to create a prototype. In the evaluation phase, the prototype is mechanically and clinically evaluated. This phase also incorporates the transfer to industry. After evaluation, the three core phases should iterate to further improve the prototype. The aim of this thesis is to describe a patient centered development and clinical evaluation of an AFO to provide support for flaccid ankle muscle paresis.

To demarcate the problem in the analysis phase, a systematic review was performed (*Chapter 2*). This review evaluated effects of AFOs on body functions and activities in patients with flaccid ankle muscle paresis. Twenty-four studies were included, of which 16 had level III evidence (quasi-experimental design), and 8 had level IV evidence (observational design). These studies included a total of 394 patients. We concluded that patients with dorsiflexor paresis benefit most from a simple AFO such as an elastic AFO, that provides clearance during swing without decreasing: physical comfort, ankle ROM, and unimpaired power at the ankle during push off. Patients with plantarflexor paresis (with and without dorsiflexor paresis) benefit most from dorsal AFOs as it decreased oxygen cost during walking, increasing power at the ankle during push off, and increased comfortable walking speed. However, dorsal AFOs also decreased physical comfort and ankle ROM, and hampered squatting. Literature evaluating ventral and hinged AFOs was scarce. Simple solutions are available for people with dorsiflexor paresis and especially people with plantarflexor paresis are hampered by their AFO. The focus for improved AFO design should be on patients with plantarflexor paresis with and without dorsiflexor paresis (in case of combined paresis).

To define the patient needs in the analysis phase, in *Chapter 3* a focus group discussion was described. This discussion aimed to get insight in AFO users' ideas on the importance of activities and suggestions for an improved AFO design. Eight experienced AFO users (four women and four men) with flaccid plantarflexor and dorsiflexor paresis participated. Thematic analysis with inductive approach was used to develop key codes and themes from the literal transcription of the discussion. Three main themes were identified: walking and standing ability, AFO characteristics and activities (such as walking stairs and slopes). AFO users found level walking the most important ADL that was generally facilitated by dorsal AFOs. Standing up from a chair was second most important and was generally difficult with dorsal AFOs. The use of hinged AFOs could improve performing this ADL according to patients who had experience using these type of AFOs. However, the use of these AFOs can also decrease stability during walking. AFO users' opinion was that improved AFO design

should find a balance between stability and flexibility dependent on the paresis severity of an individual and the type of ADL. This design should firstly function during level walking.

In the synthesis phase a prototype was created, called ‘ADJUST’ (*Chapter 4*). ADJUST was designed to provide support for flaccid paretic plantarflexor and dorsiflexor muscles without limiting normal ankle ROM. ADJUST two hinged mechanisms, in which springs can be inserted, enable independent stiffness variations into plantarflexion and dorsiflexion. The hinged mechanisms were designed to allow a more efficient use of the patients’ ankle motion to store energy, when compared to existing AFOs.

In the evaluation phase, ADJUST was mechanically and clinically evaluated (*Chapter 4*). Mechanical performance was evaluated using the ‘Bi-articular Reciprocating Universal Compliance Estimator’ (BRUCE). All minimum mechanical requirements were met when both hinges of ADJUST were inserted with stiff springs. Clinical feasibility of walking with ADJUST was tested in a case study and compared to patient’s own AFO. This case study was performed on the treadmill of the ‘Gait Real-time Analysis Interactive Lab’ (GRAIL). It was concluded that walking with ADJUST is feasible and could be profitable when compared to patients’ own AFO. Suggestions from the patient were used to implement changes to ADJUST. These suggestions concerned the choice of spring stiffness and to cover ADJUSTs’ medial hinge to prevent injury on the collateral ankle. These changes were implemented prior to consecutive patient tests.

Clinical evaluation continued by quantifying effects of ADJUST and patients’ own AFO on kinematics & kinetics during level walking, AFO satisfaction (*Chapter 5*), ankle & knee kinematics during slope walking, and time to perform large ankle ROM activity tests: timed up and go test, timed up stairs test, timed down stairs test, and timed sit to stand test (*Chapter 6*). Ten patients (four women and six men) with flaccid plantarflexor and dorsiflexor muscle paresis were recruited. All participants own AFOs were non-hinged. Kinematics & kinetics were measured while participants walked on the treadmill of the GRAIL system. Based on ankle kinematics a gait phase was subdivided into: controlled plantarflexion (heel contact till maximum plantarflexion), controlled dorsiflexion (maximum plantarflexion till maximum dorsiflexion), powered plantarflexion (maximum dorsiflexion till toe off), and swing (toe off till heel contact).

In *Chapter 5*, AFO satisfaction was quantified using relevant questions from the D-QUEST. During level walking, ADJUST increased both controlled plantarflexion ROM and controlled dorsiflexion ROM in six participants, and decreased these ROMs in three participants. ADJUST had varying effects on maximum ankle power during powered plantarflexion that increased in three, and decreased in three participants. Nine participants were satisfied with ADJUSTs’ adjustment possibilities into dorsiflexion and plantarflexion that their own AFO lacked. Five patients were dissatisfied with ADJUSTs’ weight and size of especially the medial hinge.

Walking up and down slope with ADJUST generally increased ankle ROM (*Chapter 6*). During walking up slope, ADJUST increased controlled plantarflexion ROM in nine participants, and increased controlled dorsiflexion ROM in five participants. During walking down slope, ADJUST increased both controlled plantarflexion ROM and controlled dorsiflexion ROM in six participants. Especially

the increase in controlled plantarflexion ROM during down slope walking improved both ankle and knee kinematics. Time to perform large ankle ROM activity tests was not different between AFOs.

In *Chapter 7* the findings of this thesis are discussed and opportunities for future research proposed. To fulfill all requirements, ADJUSTs' weight and the size should be decreased, and individual automatic adjustments of ADJUSTs' initial alignment and stiffness configuration should be realized. After fulfilling all requirements a larger patient group should be recruited to confirm ADJUSTs' quality and to finalize the patient driven development.