MASTER THESIS

DESIGN OF A BODY-WEIGHT CONTROLLED CLUTCH FOR THE DELIVERANCE OF ASSISTANCE WITH A PEADIATRIC ANKLE-FOOT ORTHOSIS

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Abstract

Ankle-foot orthoses (AFOs) greatly improve gait in patients with Cerebral Palsy (CP) by restoring ankle-foot biomechanics and minimising contractures. However, they restrict ankle ROM and poorly adapt to different terrains. This thesis thus aimed to develop an adaptable push-off mechanism to improve gait in children with CP.

A survey was conducted among the main stakeholders of CP, based on which a TRIZ analysis was performed to determine the most promising push-off design for the target group. Subsequently, four prototypes of a body weight controlled clutch (BWC) were created. Upon weightbearing, these clutch a slider that is connected to an assistance spring, and thereby store energy during stance while allowing full ankle ROM during swing. The prototypes were technically validated by determining their friction coefficient μ, an indication of successful slider clutching, and mathematically validated with a model to determine if 0.3 Nm/kg ankle torque can be generated.

The surveys indicated that future AFOs should better adapt to patients needs and their environment, should be more flexible and allow bigger ankle ROM. TRIZ subsequently concluded a BWC, in combination with a hinged AFO frame, to be most promising for the target group. Technical validation of the corresponding prototypes yielded friction coefficients as high as 0.98, sufficient for the target group, and the mathematical model indicated that 0.3 Nm/kg assistance torque can be reached for target users age 5 to 15, for spring stiffness $K = 6 – 18$ N/m and $\mu = 0.5 – 1.0$.

Too conclude, a body weight controlled clutch that can provide passive push-off assistance for children with CP was designed. Validation of corresponding prototypes indicated them to generate sufficient friction force and assistance torque. However, the BWC should be tested on patients to verify its performance in daily life.

Acknowledgement

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Special thanks to my colleagues at the CSIC-UPM institution for creating a fun and encouraging work environment. Especially to Gabri, for showing me around the lab, to Pablo, for answering content-related questions, and Karim, for helping with some of the experiments.

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Contents

1 Introduction

Cerebral Palsy (CP) is the most prevalent physical disability among children worldwide, affecting 1.5 to 2.5 per 1000 live births [1, 2]. CP is caused by damage to the brain or abnormal brain development before childbirth, during birth or during the first years of a child's life [3]. This results in permanent neurological disorders [2], which may cause problems with movement and coordination, speech and eating, the digestive system and cognitive development [3–5]. CP symptoms are highly variable between patients and CP encompasses a multitude of pathologies [4]. The whole body can be affected by the disability, or symptoms can be isolated to a specific area. In general, less severe cases will only experience motor impairment, while more severe cases also experience cognitive impairment [3]. Moreover, less severe cases will be affected only distally, while more severe cases experience increasing proximal involvement [3, 4].

There is a poor correlation between CP etiology, the area of the brain that is affected, and the corresponding physical, mental and physiological impairments [6]. Treatment plans and outcome predictions for CP are thus based on the child's capacity in the clinic [6]. Clinicians use classification systems to rate the child's level of impairment as a guide for potential treatments. As CP encompasses a multitude of symptoms, many classification systems have been developed over the years, rating characteristics such as type and nature of motor disorder, distribution of motor disorder, number of accompanying impairments, and therapeutic needs [6]. One of these classification systems is the Gross Motor Function Classification System (GMFCS), which assorts motor performance. The GMFCS classifies a child's motor function into five levels based on the quality of movement as well as the need for assistive devices. GMFCS level I indicates a high level of independence and GMFCS V indicates that the child is wheelchair dependent [6, 7].

Although CP is a static encephalopathy, secondary pathologies such as musculoskeletal deformities are often progressive [8]. Primary pathologic neurological signals produced by the damaged brain do not provide the right stimuli for the muscles to develop properly. This causes them to exert secondary pathological mechanical stimuli on surrounding tissues, causing joints and bones to progressively deform if proper treatment is not provided [7]. Contractures, for example, shortening and hardening of muscles and tendons that leads to decreased joint range of motion (ROM), are frequently seen in CP [9]. Thus, many individuals with CP develop pathological gait patterns which progress as they age and grow [10, 11]. Degeneration of the gait from true equinus to crouch gait is not uncommon (Table 1.1), and can eventually drive the child into a wheelchair. Children with CP should thus be monitored closely, for any detrimental changes to be prevented and treated early [12].

Tab. 1.1.: Overview of the most common gait disorders for CP, and their definitions [11, 13, 14].

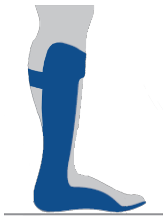
Gait disorder	Definition
Drop foot	Dorsiflexion does not occur properly, while plantar flexion remains normal.
True equinus	Plantarflexed ankle during stance with extended knee and hip joint.
Jump gait	Ankle equinus combined with a flexed knee and anterior pelvic tilt.
Apparent equinus	As the child gets older and heavier the ankle will exhibit normal dorsiflexion during stance, but knee flexion and pelvic tilt will become more severe.
Crouch gait	Excessive ankle dorsiflexion, combined with excessive knee and hip flexion during stance.

1.1 Problem Statement

To improve pathological muscle and joint patterns, current treatment options include physical therapy, assistive devices, medication and surgery [3, 15]. Ankle-foot orthoses (AFOs) are among the most frequently used types of assistive devices [16], as stabilizing the foot and ankle has been shown to positively influence knee and hip kinematics in patients with CP [16]. AFOs, for example, can counteract the excessive knee flexion seen in crouch gait and thereby reduce energy cost of walking, increase step length and improve stability and cadence [17, 18]. Depending on a patient's specific gait pathology clinicians will prescribe different types of AFOs [14] (Table 1.2).

Current AFOs mainly focus on restoring ankle-foot biomechanics and minimizing contractures [5]. They thereby restrict ankle ROM [17, 19] and thus reduce ankle plantar flexion torque and velocity [17, 20]. They provide assistance that is not perfectly timed with patient needs [21, 22], have limited modularity [23] and have poor adaptability to different tasks and terrains encountered during daily-life [24]. These limitations may cause an increased energy cost of walking, as well as unnatural walking patterns such as compensation work around the hip [25]. Moreover, patients may be reluctant to wear an AFO due to lack of comfort, cosmetic issues, and the inability to combine the device with preferred footwear and clothing [25, 26]. There is thus a need for new and more compliant AFO solutions that address the above-mentioned limitations, providing better adaptability to the patient's needs and the environment.

Tab. 1.2.: Overview of orthoses commonly used for CP, including their functionality and for which gait disorder they are most commonly used [14].

AFO type	Meaning	Description	Example
HAFO	Hinged	Allows plantar and dorsiflexion, while restraining all other ankle movement. Flexion can be limited by including stops. Used for drop foot, true equinus and jump gait.	
PLS-AFO	Posterior leaf spring	Resists plantarflexion movement and may assist during push-off. Used for drop foot, true equinus and jump gait.	
SAFO	Solid	Inhibits any ankle movement. Used for jump gait and apparent equinus to reduce ankle dorsiflexion.	
GRAFO	Ground reaction	An AFO with an anterior shell, which inhibits any ankle movement. Used for apparent equinus and crouch gait to reduce ankle dorsiflexion.	

1.2 Research Goals

This study falls within the context of the inGAIT project, a 3-year-long research project that aims to improve gait in children with CP by applying novel technologies to daily-life activities [27]. InGAIT plans to achieve this by exploring possible improvements to current AFO technologies. The general research goals of this project are:

- Define requirements for motor assistance of children with CP in daily-life activities.

- Design a modular device (AFO) as a potential solution to mitigate pathological gait in CP.
- Extract in-home metrics regarding patients' gait performance to give healthcare professionals more insight in patient capabilities and performance.

This study contributes to the first year of the inGAIT project and thus assists in achieving the project's first two goals. To do so, this study has the following goals:

1. Distribute and analyse questionnaires regarding current AFO designs for CP to identify the needs and requirements for new AFO designs.
2. Develop a mechanism that provides push-off power, which can be integrated in inGAIT's first prototype.

The questionnaires that were send to the target users included questions regarding AFO usability, aesthetics, functional and practical considerations, assistance type for different GMFCS levels and user expectancy towards a new design, within the context of daily-live activities. The second research goal emerged from the requirements defined for the inGAIT project, which were based on the questionnaire results and a panel meeting with practising clinicians.

1.3 Report Structure

This thesis follows the Design Thinking (DT) framework, which dictates that the designer should first understand the user within the context of the design challenge [28]. Literature research regarding CP was thus performed (Chapter **??**), and a survey regarding AFOs for CP was distributed among the target users, and analysed (Chapter 2). Following DT, the next step of the design process is to specify a meaningful and actionable problem statement [28]. Chapter 3 thus specifies the project requirements and goal. The third DT phase is ideation, which is when design generation takes place. Ideas were generated using TRIZ (Chapter 4) and elaborated upon via sketching (Chapter 5). Chapter 6 subsequently displays three concepts and selects the most promising one. Finally, DT demands creating cheap, quick and low-resolution prototypes for testing, to answer questions regarding the design. Chapter 7 thus elaborates on the created CAD model and corresponding physical prototype. Chapter 8 and 9 respectively use an experiment and a matlab model to validate the design. Finally, a discussion and conclusion are provided, including suggestions for future designs.

Survey

2

This chapter describes the study design of two questionnaires that were send out to the main stakeholders of Cerebral Palsy, as well as the conclusions that could be drawn from this investigation. The main stakeholders are the end-users and the healthcare professionals. End users include the patients (wearing the device) and the parents (assisting the children in donning and doffing). Healthcare professionals (e.g. physicians or orthotists) decide which AFO is most suitable for the child, and are in charge of manufacturing custom made orthotic bracing solutions. While designing an appropriate AFO it is thus crucial to include both end-user and healthcare professional requirements, needs and wishes.

A detailed description of the qualitative data analysis that was performed as part of this study can be found in Appendix A. Part of these results have been used for a journal manuscript submitted to the Journal of NeuroEngineering and Rehabilitation [29].

2.1 Methods

Two online surveys were developed within the framework of the inGAIT project [27] in three languages: English, Dutch and Spanish. One questionnaire was directed at healthcare Professionals in the area of CP (GP) and the other one at end-Users with CP to be answered by patients and their families (GU). The purpose of these surveys was to collect information regarding the points of improvements and strong suits of current orthoses. The surveys were approved by the research ethics board of the University of Twente (reference number 2021.91). All responses were anonymous.

The surveys contained closed questions (CQ) regarding respondents' demographics, AFO prescription, importance of design features, relevance of recording in-home metrics, and expectations towards a new device. The questionnaires also contained three open-ended questions (OE), which were analysed as part of this master thesis using content analysis [30] (Appendix A):

- *OE1:* "Which daily-life activities would benefit from improved gait performance in children with CP?"

- *OE2:* "What changes to the current exoskeletons are needed to improve walking in daily-life situations?"
- *OE3:* "What changes to the current AFOs are needed to improve walking in daily-life situations?"

2.2 Results

Eventually, 130 people responded to the questionnaire (94 GP and 36 GU). However, not all participants filled in the OEs (Appendix A). After data cleaning the response rate was 111 for OE1 (82 GP and 29 GU), 77 for OE2 (60 GP and 17 GU) and 92 for OE3 (70 GP and 22 GU). The closed questions indicated that the majority of the GP responses were from Spain (47.9%) and The Netherlands (33.0%), with mostly physiotherapists (53.2%), rehabilitation physicians (18.1%) and researchers (13.8%) responding. End-Users were primarily from Spain (55.6%) and The Netherlands (13.9%), with patients with GMFCS I (19.4%), II (36.1%), III (8.3%), VI (25.0%) and V (11.1%).[29]

Within the closed questions many healthcare Professionals (50%) reported that more information is required for them to feel confident when prescribing the correct AFO. The majority (79.3%) believes that patient performance in the clinic differs from real-life settings, and 98.9% thinks it is important to get more information about patients' walking performance in daily-life. Healthcare Professionals also indicated that preventing drop-foot, inhibiting foot slap and assisting push-off would be most beneficial for GMFCS levels I+ to III-. Where drop-foot prevention is more relevant for lower GMFCS levels and push-off assistance becomes more beneficial with more severe gait patterns, such as equinus and crouch gait.[29]

Regarding the importance of design features, both healthcare Professionals and end-Users indicated *ease of donning/doffing* and *comfort while wearing* the AFO to be most important. However, where healthcare Professionals would like to see *adaptability to walking terrain*, end-Users believe *replicability of normal walking patterns* to be more important. Finally, 46.53% of end-Users expect that it will require some effort to learn to use a new AFO system. However, the majority expects such a system to positively affect their gait performance (73.15%) and have improved social acceptance (70.27%).[29]

The results for the open-ended questions are summarised in Table 2.1. For OE1, respondents indicated that *General mobility* (68.5%), *Leisure* activities (39.6%) and mobility at *School* (31.5%) would benefit most from improved gait performance. Responses to OE2 illustrate that the main problems of using exoskeletons in daily life are their *Bulkiness* (45.5%), *User friendliness* (39.0%) and *Cost* (29.9%). Finally, for OE3, the main identified limitations of passive AFOs for use in daily-life are their *Adaptability* (51.5%), *Flexibility and ROM* (29.3%) and *Comfort* (28.3%).

Tab. 2.1.: Themes from the content analysis, with corresponding definition and the percentage of GP, GU and total respondents that mentioned this category. Categories are ordered from most to least frequent, based on the total number responses.

Theme	Definition	Percent		
		G_P	G_U	Total
	OE1: Daily-live activities that would benefit from an improved gait performance			
General mobility	Walking, stairs, running, jumping	70.7%	62.1%	68.5%
Leisure	Play, sports	45.1%	24.1%	39.6%
School	Mobility at school	35.4%	20.7%	31.5%
Equal social interaction	Keep up with able bodied peers	25.6%	6.9%	20.7%
Non-standard. terrain	Parks, playgrounds, nature	19.5%	17.2%	18.9%
Home	Mobility between and inside home rooms	18.3%	10.3%	16.2%
Other	-	2.4%	0.0%	1.8%
	OE2: Limitations of powered exoskeletons for daily-life use			
Bulkiness	Weight, volume	70.7%	62.1%	45.5%
User friendly	Ease of use	41.7%	29.4%	39.0%
Cost	Purchase and reparations costs	45.1%	24.1%	29.9%
Control	Control requirements and manipulation	29.3%	13.8%	28.6%
Adaptability	Patient's needs, environment	15.9%	17.2%	20.8%
Availability	Getting access to its use	35.4%	20.7%	11.7%
Flexibility and ROM	Possibility of movements, compliance	19.5%	17.2%	7.8%
Acceptance	Approval by end-user	18.3%	10.3%	6.5%
Durability	Lifetime	2.4%	0.0%	5.2%
Other	-	25.6%	6.9%	9.1%
	OE3: Limitations of passive AFOs for daily-life use			
Adaptability	Patient's needs, environment	55.7%	36.4%	51.1%
Flexibility & ROM	Possibility of movements, compliance	31.4%	22.7%	29.3%
Comfort	Avoid pressure, friction, abrasions	21.4%	50.0%	28.3%
Bulkiness	Wearability, weight, volume	12.9%	31.8%	17.4%
Energy cost	Energy cost of walking	20.0%	0.0%	15.2%
Metrics	Possibility of assessment while wearing	11.4%	4.5%	9.8%
User friendliness	Ease of use	10.0%	9.1%	9.8%
Cost	Purchase and reparation costs	7.1%	13.6%	8.7%
Durability	Lifetime	7.1%	4.5%	6.5%
Walking	Walking normal, functional	4.3%	9.1%	5.4%
Other	-	10.0%	13.6%	10.9%

2.3 Discussion

Most respondents were from Spain and The Netherlands, which could have had an effect on the results. Moreover, the majority of the responses were from healthcare Professionals (94 GP and 36 GU). On top of that, healthcare Professionals gave more elaborate answers to the OEs and thus mentioned more themes, as indicated by the fact that GP percentages are higher than GU ones for almost all categories (Table 2.1). Conclusions thus more heavily rely on GP opinion.

For OE1 and OE2, GP and GU showed the same order of importance for the three most frequently mentioned categories (Table 2.1). Respondents indicated that first *General mobility*, then *Leisure* and then *School* are daily-life activities that would benefit most from improved gait performance (OE1). The main points of improvement for exoskeletons, in ascending order, are *Cost*, *User friendliness*, and *Bulkiness* (OE2). However, results for OE3 show that healthcare Professionals think AFO *Adaptability* is more important then *Flexibility and ROM* and *Comfort*, while end-Users indicate *Comfort* to be the most important aspect. On top of that, the necessity of new AFOs that reduce *Energy cost* of walking was mentioned by 20% of Professionals, but not by the end-User group. This could be due to the fact that end-Users are not familiar with this concept.

2.4 Conclusion

The survey indicates that a new AFO should be especially suitable for general mobility, leisure activities and displacements at school. Moreover, the AFO should be comfortable (e.g less stiff and restraining, not harming the skin), capable of better adaptability to patient anatomy and the environment, and easy to don and doff. Healthcare Professionals especially see the importance of developing an AFO that adapts to different walking terrains, while patients and their families prefer establishing a more normal walking pattern. On top of that, healthcare Professionals also indicate that a new AFO should reduce the energy cost of walking. For lower GMFCS levels energy cost can potentially be reduced by incorporating drop-foot prevention, while higher GMFCS levels might require push-off assistance.

The conclusions of the survey were used as input for a technical meeting with clinicians in which the project requirements for inGAIT were defined. These were collected in a requirements document [31], based on which it was decided to focus this thesis on push-off support.

3 Requirements

Based on the inGAIT requirements document [31], which arose from the survey results and a panel meeting with practising clinicians, it was decided to design a push-off mechanism to support gait, which will eventually be part of the complete inGAIT prototype. Relevant requirements for the design of a push-off mechanism were selected from the requirements document (Table 3.1). Corresponding target values and units are specified, as well as the rank, the requirements' importance, M for *mandatory*, D for *desired* and O for *optional*. The ideal design should conform to all these requirements, of which the most important ones are indicated in blue. As it is desirable for the mechanism to be non-actuated (requirement 4), it was decided to focus on development of a passive mechanism, especially since this allows for easier fulfilment of requirements on AFO weight and size (e.g requirements 25 and 28–38).

InGAIT aims to design a modular and adaptable device that allows *"both adjustments to different patients' anthropometric measures and to patients' progression and capabilities (i.e. (1) adaptable in length/size; (2) possibility to adjust allowed range of motion (ROM); (3) adjustable (zero) alignment; and (4) possibility to adjust assistance provided)"* [31], as reflected in the requirements in Table 3.1. Adaptability can be interpreted in three ways: (1) as a control problem, where the AFO should adapt to different terrains, e.g. a flat surface vs. a slope; (2) as a fitting problem, where the AFO should be adjustable to different pilot sizes and anatomies; (3) as an assistance problem, where the AFO should be adaptable to different assistance needs, e.g. adjustable alignment and adjustable ROM. For inGAIT, adaptable control is optional (Table 3.1), and adaptability to pilot size and anatomy can be achieved by scaling the mechanism's components. The chosen design problem is thus: "Design of a passive push-off mechanism that provides adaptable assistance, for the first inGAIT prototype".

Tab. 3.1.: Requirements for the inGAIT push-off mechanism with corresponding target value and rank (level of importance) as defined by inGAIT, where rank is defined as (M) mandatory, (D) desired or (O) optional. In blue the 10 most important requirements for the design of a push-off mechanism are shown. Adaptability to pilot size and anatomy can be achieved by scaling the mechanism's components (requirement 2).

#	Requirement	Target value	Rank
	Functional requirements		
1	To be used for the defined purpose and target group	TRUE	M
2	The mechanism should be adjustable and valid for different pilot sizes (see requirement 1)	TRUE	M
3	The mechanism should be lightweight	TRUE	M
4	The mechanism should be non-actuated	TRUE	D
5	Environment: indoor, in a controlled environment (research environment)	TRUE	M
6	Environment: outdoor, in a non-controlled environment (daily-living)	TRUE	D
7	All risks associated with the use of the mechanism should be minimized as much as possible to an acceptable level	TRUE	M
8	The mechanism should allow walking on a slope	[-8, 8] %	M
9	The mechanism should allow walking on a steep slope	X < -8, X > 8 %	O
10	The mechanism should assist push-off	TRUE	M
11	The mechanism should prevent drop-foot	TRUE	D
12	The mechanism should inhibit foot-slap	TRUE	O
	Requirements on DoF and ROM		
13	Restrained DOF of the ankle with the possibility of a total restriction if desired	In/eversion	D
14	Required ROM of ankle plantarflexion, adaptable in intermediate values	>= 20 deg	M
15	Required ROM of ankle dorsiflexion, adaptable in intermediate values	>= 15 deg	M
16	Required ROM of ankle inversion/eversion (restrained)	±2 deg	D
17	Allowed ROM adaptable depending on user's needs and target group	TRUE	M
18	Zero alignment adjustable depending on user's needs	TRUE	D
19	APD assistance adjustable depending on user's needs and within limits specified in requirements 14, 15 and 16	TRUE	D
	Requirements on assistance		
20	Torque for assisting push-off (max value)	0.3 Nm/kg	D
21	Torque for preventing drop-foot during swing (max value)	0.05 Nm/kg	D
22	Torque for inhibiting foot-slap during initial contact (max value)	0.1 Nm/kg	O
23	The assistance smoothly adapts to the walking terrain	TRUE	O
24	The assistance smoothly adapts to changes in walking speed	TRUE	D
	Requirements on comfort and ergonomics		
25	The device should be worn in conjunction with normal shoes and clothes	TRUE	D
26	The maximum noise that may be generated by the system	35 dB	D
27	The system should be easy to use and easy to adjust	TRUE	M
	Requirements on size and weight		
28	Mass of the ankle mechanism	≤ 0.3 kg	D
29	Design space at the outside of the shank	≤ 0.03 m	D
30	Design space at the inside of the shank	≤ 0.01 m	D
31	Design space at the back to the thigh	0 m	D
32	Design space at the front of the thigh	0 m	D
33	Design space at the back of the shank	≤ 0.02 m	D
34	Design space at the front of the shank	≤ 0.01 m	D
35	Design space at the bottom of the foot	≤ 0.01 m	D
36	Design space at the upper part of the foot	≤ 0.01 m	D
37	Design space at medial and lateral sides of the ankle joint	≤ 0.05 m	D
38	Design space at the back of the heel	≤ 0.01 m	D
	Remaining requirements		
39	The inGAIT mechanism should allow an easy integration in different orthotic bracing	TRUE	D
40	Estimated lifespan	240 hours	D

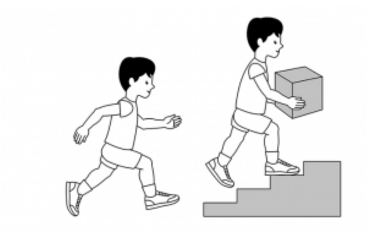
3.1 Target Group

The inGAIT project defines their target group to be the following [31]:

- Children aged 4 to 16 years diagnosed with CP
- GMFCS levels I, II and III
- Maximum weight of 60 kg
- No knee extension or ankle dorsiflexion contractures greater than 10 degrees
- At least 15 degrees of passive ankle plantarflexion ROM and 10 degrees of passive ankle dorsiflexion

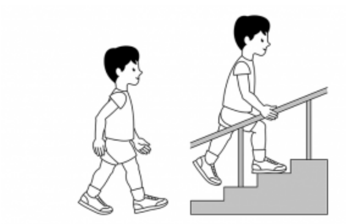
In accordance with the survey results, children with GMFCS level I to III (Table 3.2) are targeted, as healthcare Professionals indicated that these patients are most likely to benefit from a new AFO design [29]. However, as CP may cause contractures that limit knee and ankle ROM [9], GMFCS alone is not a sufficient indication for the target group. Care needs to be taken that knee extension and ankle dorsiflexion contractures are not greater than 10 degrees to ensure that patients are capable of walking with the AFO. On top of that, patients need to have sufficient passive ankle ROM to allow for push-off assistance, as push-off power is primarily transmitted by moving the ankle from dorsiflexion to plantarflexion right before toe-off.

Tab. 3.2.: Overview of the target group GMFCS levels and their definitions [32].



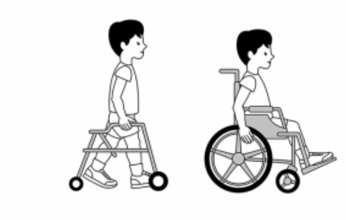
GMFSC Level I

- Can walk indoors and outdoors and climb stairs without using hands for support
- Can perform usual activities such as running and jumping
- Has decreased speed, balance and coordination



GMFSC Level II

- Has the ability to walk indoors and outdoors and climb stairs with a railing
- Has difficulty with uneven surfaces, inclines or in crowds
- Has only minimal ability to run or jump



GMFSC Level III

- Walks with assistive mobility devices indoors and outdoors on level surfaces
- May be able to climb stairs using a railing
- May propel a manual wheelchair (may require assistance for long distances or uneven surfaces)

4 TRIZ

TRIZ or *theory of inventive problem solving* is a Russian design method that allows for the systematic understanding and solving of technical problems. TRIZ consists of a plethora of tools, allowing users to tackle a multitude of different types of problems by guiding them in systematically generating creative ideas. Creating innovative solutions using TRIZ is based on finding and solving contradictions. According to the TRIZ discipline, contradictions arise when conflicting requirements are desired from a certain object or product. Instead of then adapting an existing solution to find a middle ground between contradictions, as is the usual way, TRIZ attempts to find a solution that eliminates the contradiction and fully satisfies both requirements.[33–35]

For this thesis an overview of the state-of-the-art of passive push-off mechanisms was created (Section 4.1) and three promising designs were subsequently chosen (Section 4.2) for further investigation with TRIZ (Section 4.3 and 4.4). To aid with the TRIZ process, a better understanding of the target group was obtained via interviews with a paediatric orthotist specialised in AFOs, and a father of a 9-year-old son with GMFCS level II CP. Moreover, a visit to the hospital allowed for the observation of gait of patients with CP.

4.1 State-of-the-art

Five types of passive push-off mechanisms were found in the literature: (1) bodyweight-controlled clutch, (2) ankle angle-controlled clutch, (3) ADR or Adjustable Dynamic Response, (4) spring-cam, and (5) leaf spring-cam.

4.1.1 Bodyweight-controlled Clutch

Bodyweight-controlled clutch (BWC) systems consist of an assistance spring that connects the shank to the heel (Figure 4.1). When bodyweight is put on the system's sole a mechanical sensor activates clutching of the assistance spring, ensuring that the spring has to elongate to perform dorsiflexion [36–38]. During the tibial progression of the stance phase the spring is then stretched, and the stored energy is released at toe-off when bodyweight is removed from the system's sole. During swing phase,

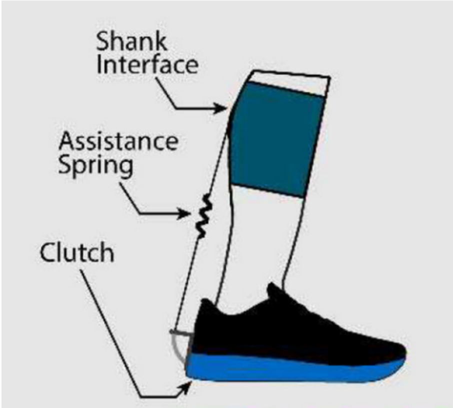


Fig. 4.1.: Schematic representation of a bodyweight-controlled clutch. The mechanism consists of an assistance spring that spans from the back of the heel to the shank interface. When weight is put on the clutch situated underneath the foot, the assistance spring will elongate during tibial progression, saving energy that can be released upon toe-off. When no weight is applied to the clutch the user can freely move the ankle [36].

as the bodyweight is not on the sole, the mechanical clutch is not engaged and the mechanism allows free movement of the foot. Thus, this type of system does not restrain the natural foot DoF and allows for walking up and down hills. However, patients with CP often have an unstable gait that requires restraining some ROM [5].

4.1.2 Ankle Angle-controlled Clutch

Ankle angle-controlled clutch systems behave similar to bodyweight-controlled systems, but with the main difference that clutching and unclutching of the spring is done with a mechanical sensor that detects a certain level of dorsi or plantarflexion of the ankle [22, 39–41]. These types of systems can only be used on level ground, as slopes alter ankle angle and cause the timing mechanisms to be activated at the wrong moment. Moreover, children with CP have difficulties controlling their ankle angles, and thus these types of mechanisms might not be suitable for them.

4.1.3 ADR

Adjustable dynamic response (ADR) mechanisms are currently the only commercially available solution for providing push-off assistance for patients with CP. ADRs can be installed in an AFO as a hinge and only allow one degree of freedom (DOF), dorsi and plantar flexion (Figure 4.3). They work with an anterior and posterior compression spring that provide continuous support. Whenever the patient dorsi or plantarflexes the ankle, energy is stored within the springs, causing them to exert a force on the ankle that pushes towards the zero alignment (neutral position) of the

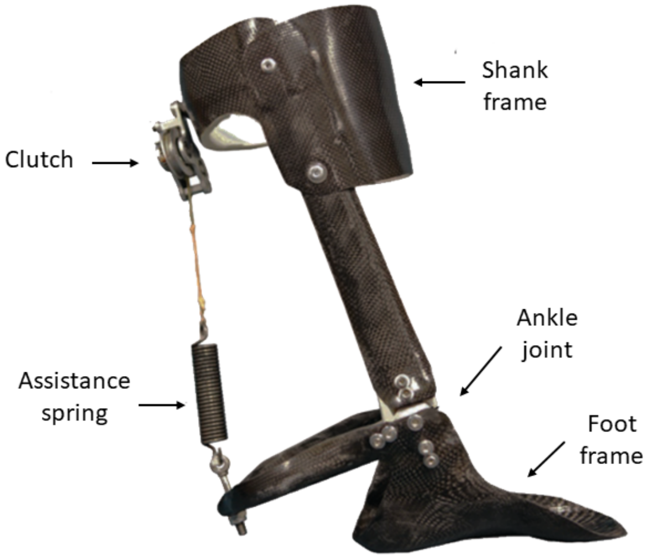


Fig. 4.2.: Example of an ankle angle-controlled clutch. The mechanism consists of an assistance spring that spans from the back of the foot frame to the clutch attached to the shank frame. When the user reaches specific ankle ankles the clutch locks, allowing the assistance spring to elongate upon tibial progression, saving energy that can be released upon toe-off [39]. Other ankle angle-controlled clutches have positioned the clutch around the ankle joint instead of at the shank [22, 40, 41].

springs. Thereby they resist rapid dorsiflexion, assist push-off, and resist drop-foot and foot slap [42]. The zero-alignment of an ADR can be changed by adjusting the balance between the two springs. ADR designs allow pretensioning or exchanging the springs [42–44]. The ROM can be restricted by using stiffer springs, but some devices also use dorsi and plantarflexion stops.

Although ADRs promise to support push-off, research indicates that they might not reduce energy cost of walking with respect to other AFOs [45], which is the goal of providing push-off power. This could be due to the fact that one of the ADR's biggest limitations is the difficulty to choose the appropriate spring module or desired stiffness for each individual patient [45]. Another reason could be the mechanisms poor adaptability to the challenging mobility tasks and terrain variations that occur in daily life [45]. On top of that, the ADR delivers continuous support. This might offer better stability, but it also offers support when it is not needed, and might unnecessarily restrain the user's ROM.

4.1.4 Spring-cam

The spring-cam mechanism developed by Sekiguchi et al. for stroke survivors allows energy to be stored in a spring when the user dorsiflexes the ankle [20]. Dorsiflexion causes the egg-shaped cam to increasingly compress the spring (Figure 4.4). Upon plantarflexion the spring is allowed to expand, and the energy saved in the spring is

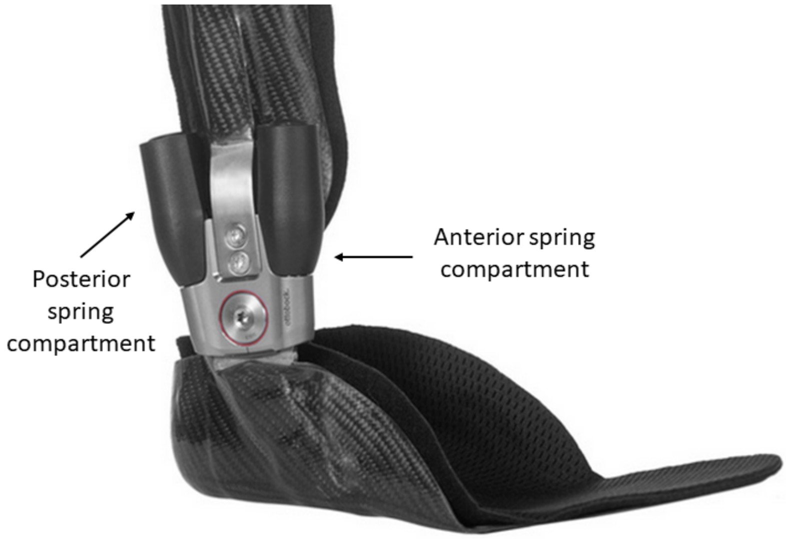


Fig. 4.3.: Example of an adjustable dynamic response AFO. The NexGear Tango by Ottoblock [42] is installed at the ankle joint of the AFO. When the user dorsi or plantar flexes the ankle, the anterior and posterior springs are elongated or compressed. This pushes the user towards the neutral angle of the ADR unit, and thereby supports toe-off and prevents dropfoot.

released. The spring can be pretensioned according to the user needs. Similar to the ADR mechanism, the spring-cam mechanism is incorporated in the ankle hinge, allowing only one DoF.

The shape of the cam profile determines the torque-angle curve of the ankle. This is one of the spring-cam's main advantages compared to the ADR, as choosing a more natural torque-angle curve will improve gait biomechanics [8]. Moreover, changing the cam could allow the mechanism to be more suitable for different activities, e.g. running and climbing stairs. The current design is unfortunately not suitable to wear inside a shoe, as the spring-cam mechanism is too bulky.

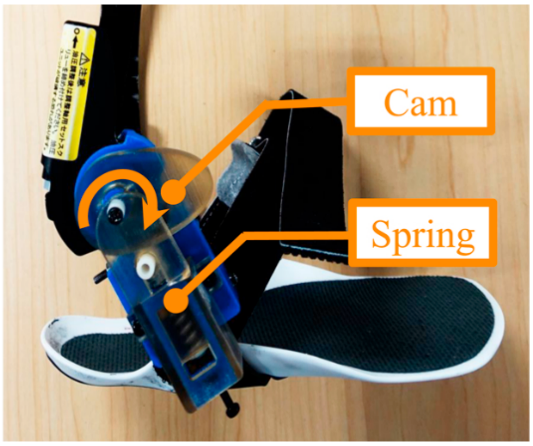


Fig. 4.4.: Spring-cam mechanism by Sekiguchi et al. [20]. Upon dorsiflexion the egg-shaped cam compresses the spring, saving energy that can be released later in the gait cycle.

4.1.5 Leaf Spring-cam

The leaf spring-based push-off mechanism developed for foot prosthesis by Shepherd et al. allows energy to be stored when the ankle rotates (Figure 4.5) [46]. During stance, tibial progression causes the cam to execute a counter clockwise movement, deforming the leaf spring and thereby saving energy. The shape of the cam was especially designed to have good walking performance but could potentially be adapted to support other movements. The leaf spring is supported by a slider. Changing the position of this slider alters the leaf spring stiffness. This is an advantage over the previous spring-cam design as it allows for quicker and easier adjustment of the prosthesis to patient needs. Prosthesis stiffness can thus be changed without interchanging springs, which would be required for the other spring-cam system, as well as the ADR and the bodyweight and ankle angle-controlled clutches.

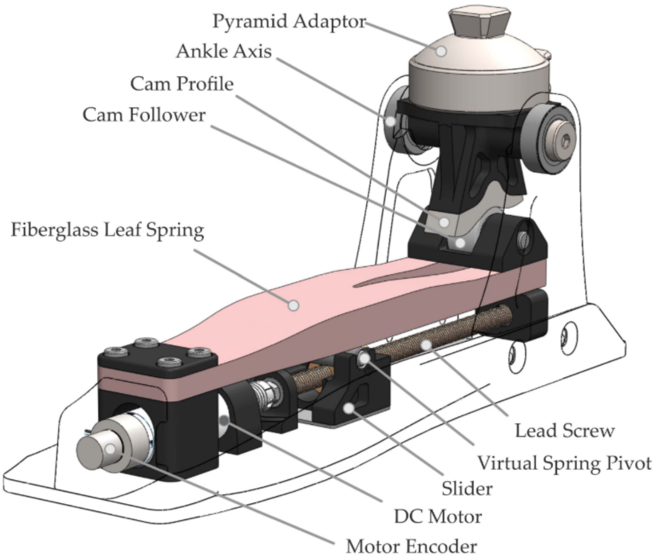


Fig. 4.5.: Leaf spring foot prosthesis by Shepherd et al. [46]. Tibial progression during the stance phase of gait causes the cam profile to rotate around the ankle axis. This deforms the fibreglass leaf spring, saving energy that can later be released during toe-off. Leaf spring stiffness can be changed by moving the virtual spring pivot, allowing the mechanism to adapt to patient needs without interchanging the spring.

4.2 Mechanism Selection

An overview was created, summarising how the push-off mechanisms described above already perform for the most important requirements defined in Chapter 3 (Table 4.1). The ankle angle controlled mechanism does not comply with the project's criteria at all, while the bodyweight controlled mechanism performs well under the given requirements. The bodyweight controlled mechanism was thus selected to be subjected to the TRIZ methodology. The ADR, spring-cam and leaf-spring mechanisms show a similar performance. Considering the fact that the leaf-spring mechanism has not yet been implemented in an AFO for CP, this mechanism was chosen for further investigation with TRIZ. Once adopted for CP patients, the leaf-spring has potential to outperform the ADR and spring-cam mechanisms. Finally, the ADR mechanism is interesting to look into, as it is the only solution that is currently on the market for our target group, and was thus also selected to be investigated with TRIZ.

Tab. 4.1.: Push-off mechanisms rated according to the most important project criteria defined in Chapter 3. Here, a rating of 0 indicates that the mechanism does not comply to the requirement, 3 indicates it moderately complies, and 5 indicates it complies very well.

	Requirements	*Mechanisms*				
		Body-weight controlled	**Ankle angle controlled**	**ADR**	**Spring-cam**	**Leaf spring-cam**
1	The mechanism should be adjustable and valid for different pilot sizes	5	4	4	3	3
2	The mechanism should be lightweight	5	2	3	4	1
3	The device should at least support walking in an indoor, controlled environment (research environment)	4	4	4	4	4
4	The mechanism should allow walking on a slope ([-8,8] deg)	5	0	2	2	4
5	Required ROM of ankle plantarflexion, adaptable in intermediate values (>= 20 deg)	5	3	4	5	4
6	Required ROM of ankle dorsiflexion, adaptable in intermediate values (>= 15 deg)	5	3	4	3	3
7	Allowed ROM adaptable depending on user's needs and within limits specified above	0	1	3	3	3
8	The system should be easy to use and easy to adjust	4	2	3	4	5
	Total	***33***	***19***	***27***	***28***	***27***

4.3 TRIZ Analysis

For each of the three selected push-off mechanisms, ADR, BWC and leaf spring, the main problem with respect to applying it within the inGAIT project was identified and suitable TRIZ tools were selected for solving it. As the TRIZ analysis starts with an existing product two pipelines, containing specific TRIZ tools, can be used (Appendix B):

1. Eliminate specific negative effect or improve ineffective result:
   a) Innovation Situation Questionnaire (ISQ)
   b) RCA+
   c) Technical contradiction
   d) Contradiction matrix
   e) 40 inventive principles
   f) Assessment and selection

2. Discover problems and improve system's functionality:
    a) Function analysis
    b) Function model
    c) Su-field model
    d) 76 inventive standards
    e) Assessment and selection

Pipeline 1, *eliminate specific negative effect or improve ineffective result*, can be executed on push-off mechanisms that do not have any adaptability with respect to assistance yet and can in this case serve to introduce this adaptability to the design. It can also be used to improve a current mechanism's ability to adapt to user needs. Pipeline 2, *discover problems and improve system's functionality*, should be executed on a design that already has some adaptability to ensure that the outcome of the TRIZ process yields an adaptable mechanism, as per the goals of the thesis.

TRIZ Problem I: ADR mechanism provides insufficient push-off support

As discussed in Section 4.1, ADRs might not reduce energy cost off walking compared to other AFOs [45]. This indicates that the push-off power that the ADR generates is insufficient, which could be improved by changing the system's assistance adaptability. Thus, this problem was further investigated with pipeline 1 (Appendix B).

TRIZ Problem II: Bodyweight controlled clutch lacks ROM control

The bodyweight controlled push-off mechanism especially lacks in the possibility of having an adaptable ROM, or any way of limiting the ROM for that matter, while it performs well on the other project criteria (Table 4.1). Similar to the ADR, the bodyweight controlled push-off mechanism was thus subjected to pipeline 1 (Appendix B).

TRIZ Problem III: A leaf spring powered push-off mechanism

As the leaf spring push-off mechanism has only been implemented in prosthesis, the first step would be to adapt it for implementation in an AFO design. It was thus subjected to pipeline 2 (Appendix B).

4.4 Results

Here the identified TRIZ contradictions (in italics), as well as the corresponding solution that was selected with TRIZ can be found. A detailed explanation of how these contradictions and their corresponding solution were determined can be found in Appendix B.

1. ADR mechanism provides insufficient push-off support
    a) *Weak spring:* Instead of putting springs in a heavy metal casing, use up all this space only with springs, such that there can be stronger springs within the same mechanism volume.
    b) *High spring stiffness:* Measure the patient's torque-angle curve of the ankle, and design a spring that matches that curve, for creating optimal push-off support.
    c) *Zero alignment of the foot is set to 0-15 deg dorsi flexion:* Have the mechanism be able to turn around the joint, so that the user can easily set the zero alignment.
2. Bodyweight controlled clutch lacks ROM control
    a) *Preventing free plantarflexion during stance:* Include a joint with plantarflexion stop in the AFO.
    b) *Set spring tension:* Mechanism to adjust spring pretension.
    c) *Prevent free dorsi/plantar flexion during swing*: Incorporate the mechanism in a rigid mechanism that constrains the ankle.
3. A leaf spring powered push-off mechanism
    a) *Insufficiently supports foot:* Add a foot support arch to the insole.
    b) *Strut weights down leg:* Trim the battery, motor encoder and DC motor, and possibly the lead screw and virtual spring pivot.
    c) *Strut insufficiently plantarflexes ankle:* Use different cam profiles depending on the activity.

4.5 Discussion and Conclusion

As the inGAIT project aims to be innovative it was decided to discard the ADR from the potential solutions. Moreover, there seems to be an inherent shortcoming to the ADR, where two springs acting in parallel might not be able to give the needed support [45]. The bodyweight controlled clutch and leaf spring thus remain potential solutions for the inGAIT project. As Dr. Shepherd and Dr. Rouse, designers of the leaf spring AFO, have much more expertise in this area, it was decided to collaborate with them, and to look into the bodyweight controlled clutch ourselves.

Based on the TRIZ analysis, the BWC can be improved by adding a rigid AFO structure, as this will allow stabilisation of the ankle joint and thus better ROM control. On top of that stops (e.g. for preventing plantarflexion) can be added to the AFO to further control the ankle joint. Finally, adding the possibility of adjusting the assistance spring pretension could be beneficial (e.g. for having higher or lower resistance force of the spring at the desired phase of gait).

Ideation

5

The TRIZ process concluded that a bodyweight-controlled clutch that can be combined with a rigid AFO structure with flexion stops should be designed. To restrict the scope of the design problem, this thesis focuses on the design of the BWC only. Other collaborators of the inGAIT project worked on the AFO itself, including ankle ROM restriction, and spring and shoe attachment. Moreover, the TRIZ process concluded that it would be desirable to allow adjustment of the assistance spring's tension to match the patients assistance needs. However, before an adjustable assistance spring can be tested and validated, a functioning AFO and clutch need to be designed. This restricts the design problem to the design of a bodyweight controlled clutch.

Three possible ways of implementing a BWC were found (Figure 5.1). The potential of each of these three bodyweight clutching mechanisms for use within the inGAIT project was explored during the ideation process (Section 5.1, 5.2 and 5.3).

1. Clutching a slider situated underneath the foot, similar to the design of Yandel et al. [36].
2. Pushing down a lever underneath the foot upon weightbearing which causes the assistance spring to be clutched mechanically, like the design by Liu et al. [37].
3. Placing a pneumatic system underneath the foot which mechanically clutched the assistance spring upon weightbearing. Hirai et al. [47] for example, use a pneumatic system to lock the ankle joint of an AFO, when the foot is in the air.

5.1 Slider

Ideation was performed for the design of a bodyweight controlled clutch that uses a flexible slider situated underneath the foot (Figure 5.2). Whereas Yandell et al. used a solid heel "*to prevent the grippers from clutching the slider at heel contact and before foot flat*" [36], it would be beneficial to make use of this space. Especially in small children's feet it might be problematic to create sufficient slider surface area for proper clutching action. Removing the solid heel would free up extra design space for the slider. Moreover, removing the solid heel makes the design more lightweight, which is again crucial for smaller children.

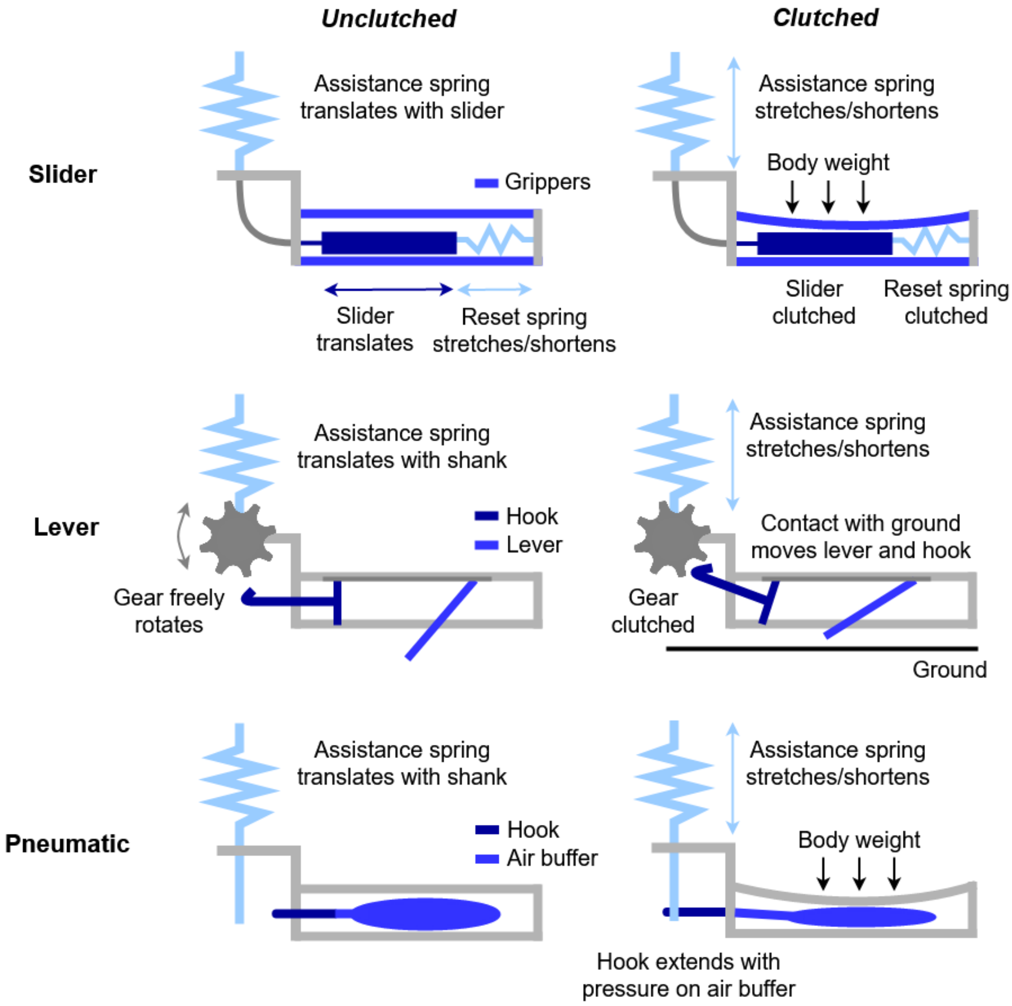


Fig. 5.1.: Schematic representation of the working principles of a slider based, lever based and pneumatic BWC. For a slider based BWC, a slider is clutched upon weight-bearing, thereby locking the assistance spring into place, forcing it to elongate and store energy during dorsiflexion. Upon toe-off, as weight is removed from the slider, the energy is released and the assistance spring is allowed to translate with the slider. The lever based design locks the assistance spring into place when a lever is mechanically moved upon contact of the BWC with the ground. For the pneumatic system an air buffer is compressed upon weightbearing. The air subsequently forces a hook to extend and thereby clutches the assistance spring [36, 37, 47].

Yandell et al. tested one slider size, a square of 5 by 7 cm. It would thus be interesting to look into the potential of using different slider shapes and sizes, especially since designing for small children's feet leaves a limited design space for the slider. In case insufficient clutching area is achieved for our target group, it would be beneficial to sacrifice some of the plantar or dorsiflexion ROM to ensure that sufficient grip force is generated. The slider would then only have limited space to move within the gripper boundaries. On top of that the clutching mechanism could be based on mechanical force instead of friction force, e.g. using a sawtooth profile. Using a sawtooth profile, however, will complicate proper mechanism detachment during the swing phase of gait. Springs might need to be introduced for separating the slider from the grippers. Another problem with using a sawtooth profile is the fact that this type of system might not function properly if the sole bends. In this case it would be better to not include the sawtooth profile at the toes, and to ensure that the rest of the mechanism cannot bend.

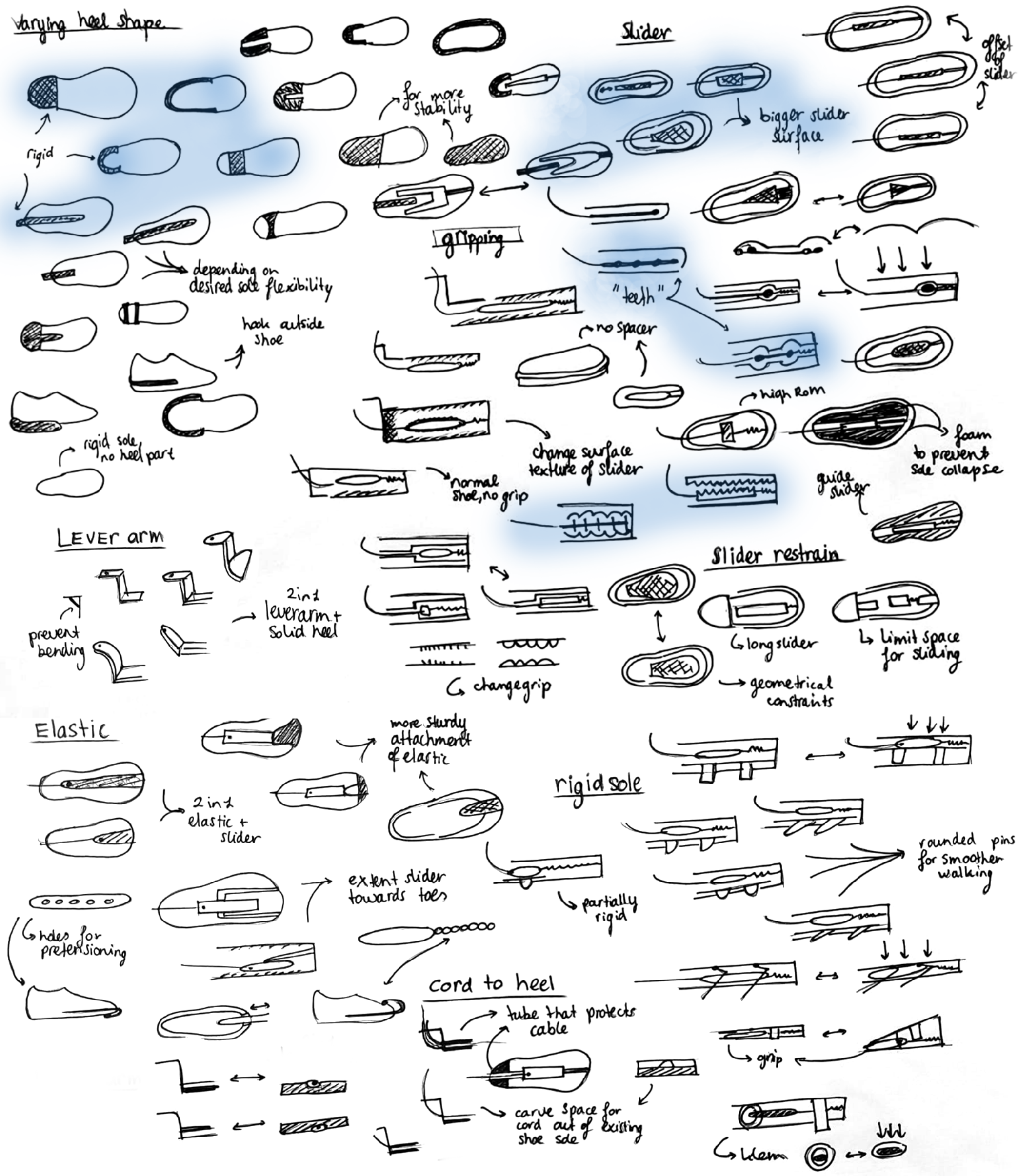


Fig. 5.2.: Ideation for a slider based BWC. Highlighted in blue are the idea of varying (top left) solid heel shape and (top right) slider size, to create a bigger surface area for the slider. This is especially crucial if we are to get sufficient slider surface area for small children's feet. On top of that, (lower middle) the idea of increasing the friction force of the clutch, e.g. by using a saw-tooth profile, is highlighted.

5.2 Lever

Ideation was performed for the design of a bodyweight controlled clutch that uses a rigid lever for clutching the assistance spring (Figure 5.3). This shows that the lever can be situated inside the shoe sole, underneath the shoe sole or on the AFO. For all designs, clutching and releasing timing is critical. In case the clutching device only spans part of the sole, multiple clutches should be considered, to ensure that the spring force is only released at toe-off.

For placing the lever inside the shoe sole, rigid protrusions that extend past the bottom of the sole can be used. Upon loading these protrusions move the lever and lock the spring in place. A flexible arch along the length of the shoe sole can be used as well. Upon loading, the arch deforms and locks the spring in place. On top of that, interlocking discs with a sawtooth profile can be used. When no weight is put on the mechanism, springs ensure that the teeth do not interlock, allowing the cylinder that holds the discs to rotate freely, ensuring unrestricted ankle motion.

For placing the lever underneath the shoe sole, a flexible arch can be used as well. Loading flattens the material, thereby clutching a hook that is attached to the assistance spring. Another option is creating a lever that pivots about the back of the heel. However, placing a lever underneath the shoe might make the mechanism more prone to wear and tear, and increases the chances that dirt interferes with the system. Finally, the lever can be attached to the AFO frame. This would be beneficial as it eliminates the need for custom shoes or shoe alterations.

5.3 Pneumatic

Ideation was performed for the design of a clutch based on a pneumatic system (Figure 5.4). This shows that the mechanism could be situated underneath or inside the sole, and consist of one or multiple air buffers. When weight is put on the air buffer, the air travels through a tube, moving a lever which in turn clutches the assistance spring. Having the air buffers on the outside of the shoe, in contact with the ground, might cause quick wear and tear, while placing the air buffers inside of the sole protects them better.

During a committee meeting the potential of using a pneumatic system was discussed. Unfortunately the conclusion was that such a system would probably not be strong enough to provide the necessary clutching force. This option was thus disregarded for further investigation.

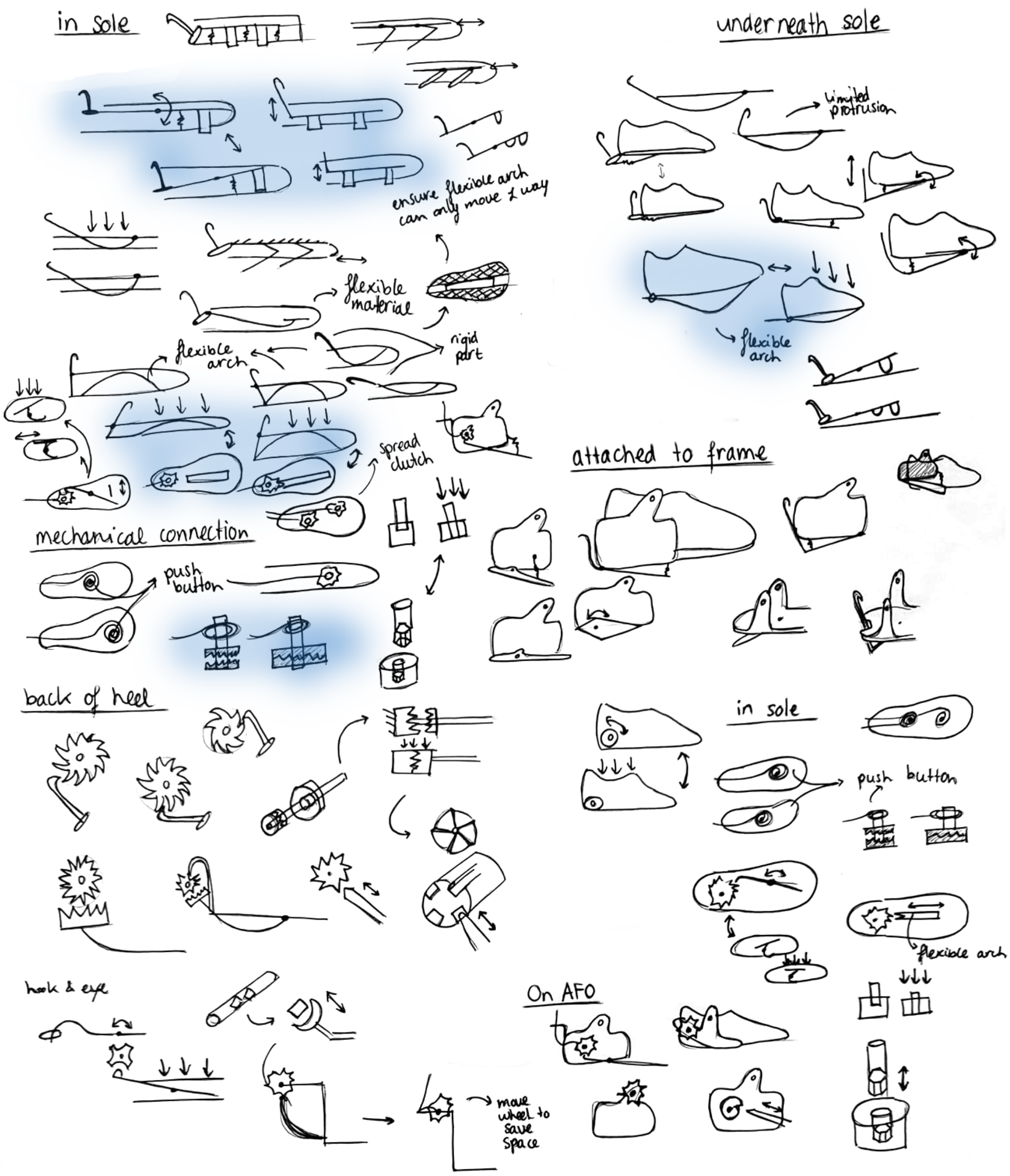


Fig. 5.3.: Ideation for a lever based BWC. Highlighted in blue are the idea of (top left) using rigid protrusions inside the shoe sole that extend past the sole, and using a flexible arch (left middle) inside the shoe sole or (top right) underneath the shoe sole to clutch the assistance spring. Finally, (lower left) interlocking discs with a saw-tooth profile that interlock upon weightbearing are highlighted.

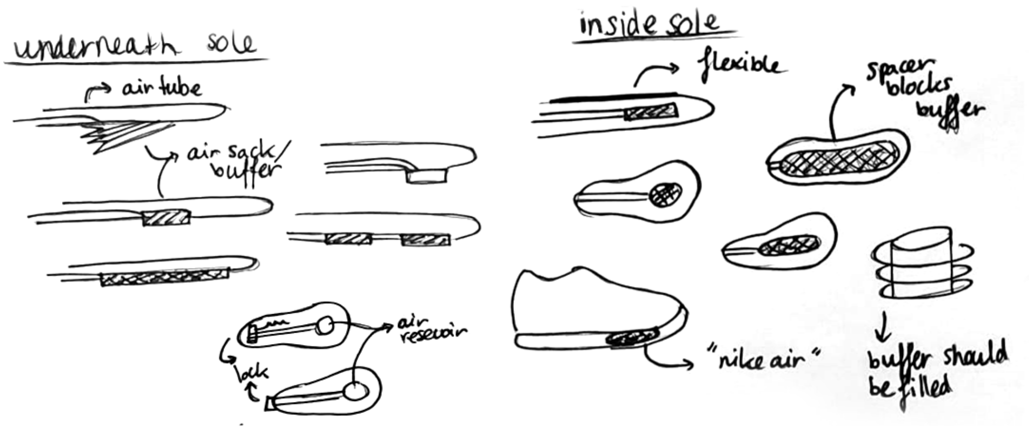


Fig. 5.4.: Ideation for a pnuematic based BWC, showing the possibility of placing an air-buffer underneath or inside the shoe sole.

6 Conceptualisation

Based on the ideation phase (Chapter 5), three concepts were generated. These were subsequently rated for their potential use within the inGAIT project (Table 6.1) based on the requirements specified in Chapter 3 and some additional design aspects. Moreover, BWCs have the disadvantage that there is a cord spanning from the heel to the shank, which might hinder users in their activities of daily life. Descending stairs, for example, can be difficult if an AFO extends too far past the back of the heel and/or shank. It would thus be desirable to place the cable as close to the user's body as possible, ensuring that the space at the back of the heel is kept clear from material.

6.1 Concept 1

Concept 1 (Figure 6.1) is based on Yandell's clutch design [36]. A slider situated underneath the foot is clutched in place during the stance phase of gait as the user puts bodyweight on it, allowing energy to be saved in an assistance spring during tibial progression. During swing, when no weigth is applied to the clutch, the user can freely move the ankle. Unlike Yandell's design there is no solid heel. This maximises possible slider surface area and allows clutching of the slider before foot-flat if the slider is situated accordingly.

Three holes are included in the spacer, one at the back and two at the side of the heel (Figure 6.1). These serve to guide the attachment string that connect the slider to the assistance spring. When guiding the attachment string through the hole at the back of the heel, the BWC takes up more space there and might thus interfere with activities of daily life. Another option is guiding the attachment string through the holes at the side of the heel, which minimises the amount of material at the back of the heel and calf. In this case it is preferable to use two strings, as this ensures that the user only experiences pulling forces in the sagittal plane, and no inversion/eversion forces are transmitted to the AFO. The goal is to choose the location where these cords enter the clutch in such a way that the minimal moment arm is obtained that still provides the user with the required assistance force. Creating multiple wire guides allows for experimentation with different moment arms within a single prototype.

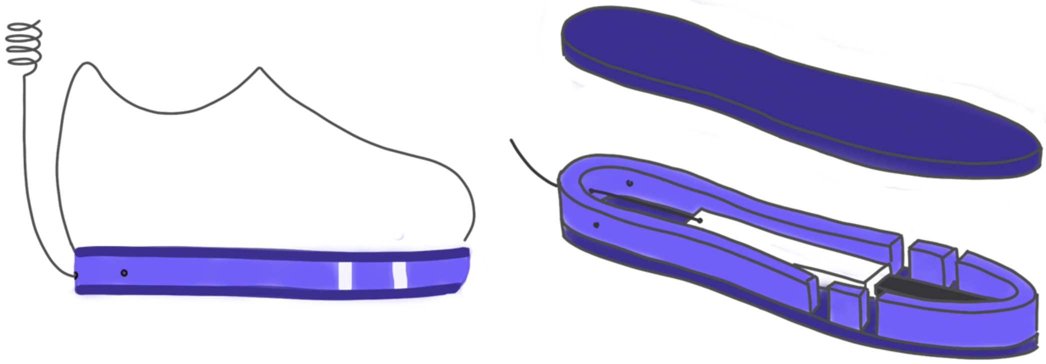


Fig. 6.1.: Concept 1, a slider based BWC, consists of two grippers (dark blue), separated by a spacer (light blue) that contains toe gaps to allow roll-off. The slider (white) is connected to the assistance spring with an attachment string which can be guided out of the spacer via the back or the sides of the heel. When weight is applied to the clutch the generated friction locks the assistance spring, allowing energy storage.

The main challenges of a slider based clutch are attaching the clutch to the shoe, ensuring smooth movement of the cables and the slider, and preventing slider slippage, e.g. via increasing slider friction by increasing the number of slider and gripper layers. However, a slider based clutch can potentially be lightweight and thin, and once proof of concept is achieved, the possibility of incorporating the option of pretensioning the spring, as concluded to be beneficial by TRIZ, can be investigated.

6.2 Concept 2

Concept 2 consists of a bendable arch inside the shoe sole, which flattens upon loading and thereby locks a gear at the heel of the sole (Figure 6.2). The gear is mounted on a rotating pin. Thus, when the gear is clutched, this pin cannot rotate. The assistance spring's cord is wound around the pin. If the pin is not clutched the user can freely move his ankle, while the assistance spring cord is kept under tension by a torque spring. Clutching the gear in turn clutches the assistance spring. Similar to concept 1, concept 2 allows for tuning of the moment arm, by choosing where the assistance spring cords leave the mechanism.

The main problems of an arch based clutch are creating a sole that is strong enough to contain the arch, ensuring smooth movement of the cables and the fact that a thick, stiff and possibly uncomfortable heel component is needed. However, an arch based clutch would be easier to attach to the shoe compared to a slider based clutch, and the clutching of the assistance spring and resetting of the system arch can be done with one component.

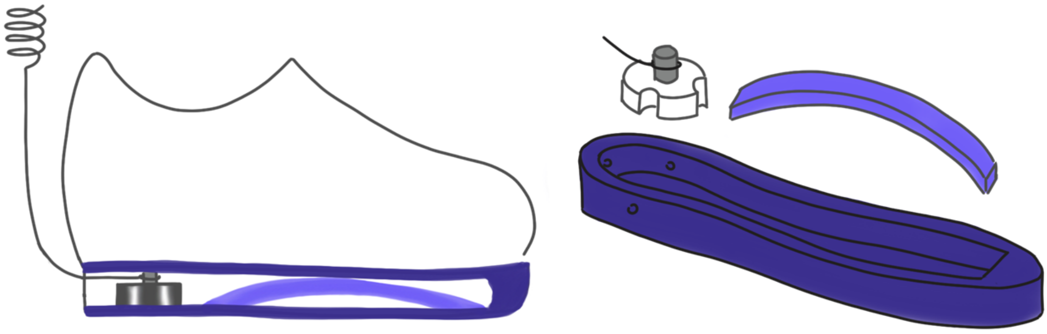


Fig. 6.2.: Concept 2, a BWC with flexible arch (light blue) that deforms upon weightbearing, locking the gear (white). This prevents the pin (grey) from rotating, thereby clutching the assistance spring and allowing energy storage. When no weight is applied on the clutch, the gear and pin rotate freely while a torque spring keeps the attachment string under tensions.

6.3 Concept 3

Concept 3 consists of a rotating pin inside the shoe sole, around which the assistance spring cord is wound. If no weight is put on the pin it can rotate freely, and thus the user can freely move his ankle. The assistance spring cord is then kept under tension by a torque spring. The pin consists of two parts with a sawtooth profile that mechanically interlock when weight is put on them. This prevents the pin from rotating upon loading, and thereby clutches the assistance spring.

Unlike the slider and the arch based clutch, that stretch across the length of the foot, a pin based clutch only clutches when weight is put on a specific part of the shoe sole. Thus, the pin clutch needs to be placed carefully for the mechanism to work. If it is concluded that for optimal mechanism functioning the pin clutch should be situated in the midfoot area, this might lead to a thick and uncomfortable midfoot component for the user. Moreover, measures should be taken to keep the two pin components apart when no weight is applied, e.g. by incorporating a spring.

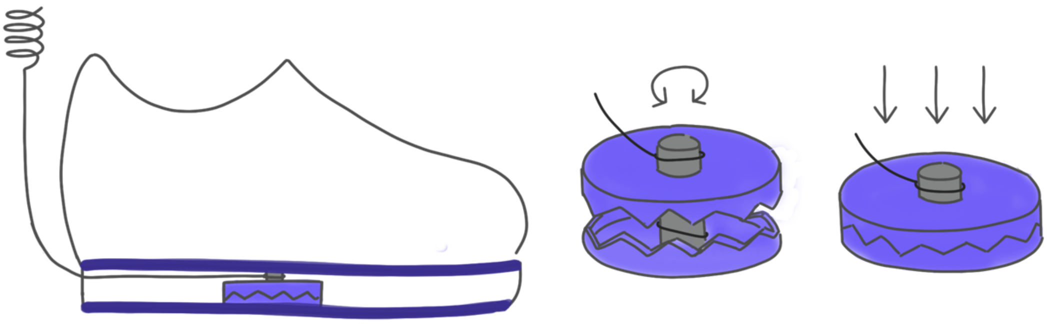


Fig. 6.3.: Concept 3, BWC with two gears that interlock upon weightbearing, preventing the pin (grey) from rotating and allowing energy to be stored in the assistance spring. When no weight is applied to the clutch a spring prevents the gears from interlocking, allowing the pin to rotate freely, allowing free ROM of the ankle.

6.4 Concept Selection

To select the most promising concept for further development for the inGAIT project, the concepts were ranked according to relevant requirements from Chapter 3 as well as 5 additional design aspects (Table 6.1). Each design aspect and requirement were given a weight. Overlapping requirements or requirements for which all three concepts scored equally were excluded from the ranking. From Table 6.1 it can be concluded that it would benefit the inGAIT project the most, to design a slider based clutch.

Tab. 6.1.: Concept rating based on five design aspects that are relevant for BWCs, as well as the requirements defined in Chapter 3. Requirements for which all concepts scored equally, as well as overlapping requirements were excluded from the ranking. Here a rating of 1 indicates that the concept poorly adheres to the corresponding requirement, 3 that it moderately adheres and 5 that it adheres very well. A weight of 2 was given to mandatory requirements, and a weight of 1 to optional requirements.

	Relevant design criteria	Weight	Concept		
			1	2	3
	Design aspects to consider				
	Simplicity	2	5	4	3
	Ease of attaching AFO to shoe with bodyweight clutch	2	1	3	4
	Unclutched clutch friction	2	4	5	2
	Clutch from heelstrike/foot flat up untill toe off	2	5	4	2
	Comfort related to sole flexibility	2	5	3	2
	InGAIT requirements				
2	The mechanism should be adjustable and valid for different pilot sizes	2	3	4	5
3	The mechanism should be lightweight	2	5	2	3
8	The mechanism should allow walking on a slope	2	3	4	4
18	Zero alignment adjustable depending on user's needs	1	2	4	4
25	The device should be worn in conjunction with normal shoes and clothes	1	3	2	2
26	The maximum noise that may be generated by the system	1	5	3	3
27	The system should be easy to use and easy to adjust	2	3	4	4
35	Design space at the bottom of the foot	1	4	3	3
39	The inGAIT mechanism should allow an easy integration in different orthotic bracing	1	4	2	3
40	Estimated lifespan	1	3	4	2
	Total		***89***	***84***	***75***

7 Prototyping

A CAD design was created for the bodyweight controlled clutch (Figure 7.1). It consists of a top and bottom gripper, slider and reset spring. The spacer has a ring width of 10 mm and a thickness of 5 mm, and contains a notch for the reset spring. Compared to the BWC by Yandell et al. [36], the solid spacer material underneath the heel has been significantly reduced, creating a bigger area that can be used for clutching, and allowing more flexibility with regards to when in the gait cycle bodyweight will start clutching the slider. The design by Yandell et al. [36] only starts clutching from foot flat, while our design can potentially start clutching from heel strike, depending on where the slider is placed. Attachment points for Velcro straps were added to the spacer design, allowing for temporary attachment of the clutch to the shoe and thus making it easier to test and reuse the physical prototype. The final clutch design should be attached directly to the shoe sole, to prevent sliding of the clutch with respect to the shoe, increasing the efficiency of force transmission.

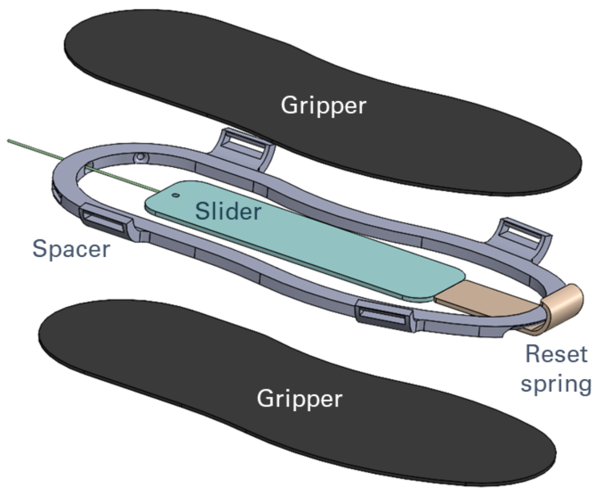


Fig. 7.1.: CAD design of the BWC, consisting of a spacer that separates the top and bottom gripper, allowing a slider to move freely between the grippers when no weight is applied to the clutch. The slider is connected to a reset spring, which ensures that the slider remains in position upon movements of the ankle joint.

The BWC CAD was designed for a size EU-34 sports shoe so that it could be combined with the inGAIT AFO prototype (Figures 7.2). The AFO contains a compartment at the back of the shank in which a compression spring is positioned. A lid on top of this spring is connected to the attachment strings. Thus, when tensions is put on the strings during tibial progression, the spring compresses and energy is stored. To allow exploring the possibility of minimising the amount of material at the back of the heel, as discussed during the conceptualisation phase (Chapter 6), the clutch contains three rope guides. One at the apex of the heel, to verify general functioning of the clutch, and two at the side of the heel, to verify if guiding the attachment strings along the side of the foot has potential. The rope guides serve to ensure a smooth transition of the attachment string from inside the clutch to the assistance spring, and prevent wear. They were designed separately from the AFO frame. For future designs, it would be beneficial to incorporate the rope guides into the AFO frame.

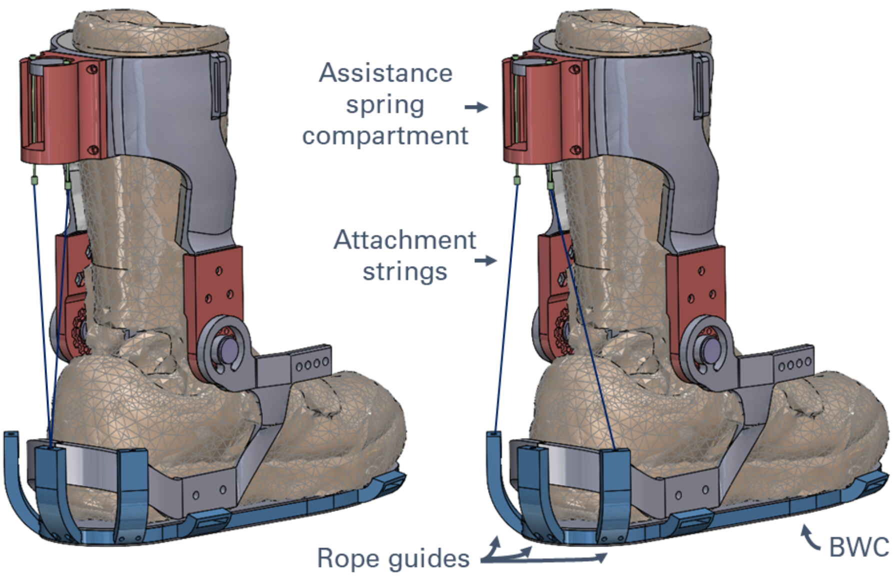


Fig. 7.2.: CAD design of the BWC and inGAIT AFO. Including multiple string guides at the back at the heel allows for testing different attachment string configurations with the same prototype.

Two spacer prototypes of the BWC were created: (1) a completely rigid spacer (3D printed PLA, 5 mm high); and (2) a flexible spacer (fast resetting foam, 9.5 mm high), see Figure 7.3. Both spacers had a ring width of 10 mm, with a 40 mm wide notch at the toes to pass the reset spring through, and a hole at the back of the heel for guiding the attachment string (Figure 7.3). To allow toe roll-off during walking, the rigid spacer was made with a 20 mm wide gap at the metatarsophalangeal joint.

Each spacer prototype could be fitted with one of two different sliders (50x130 mm): (1) a slider made of nylon strapping webbing (1.5 mm thick), and; (2) a slider made of neoprene rubber (2 mm thick), see Figure 7.3. Thus, four different physical prototypes could be combined with the inGAIT AFO for testing (Figure 7.4). All of them included double layered grippers, of which a latex layer faced the inside of the clutch and a leather layer the outside (Figure 7.4).

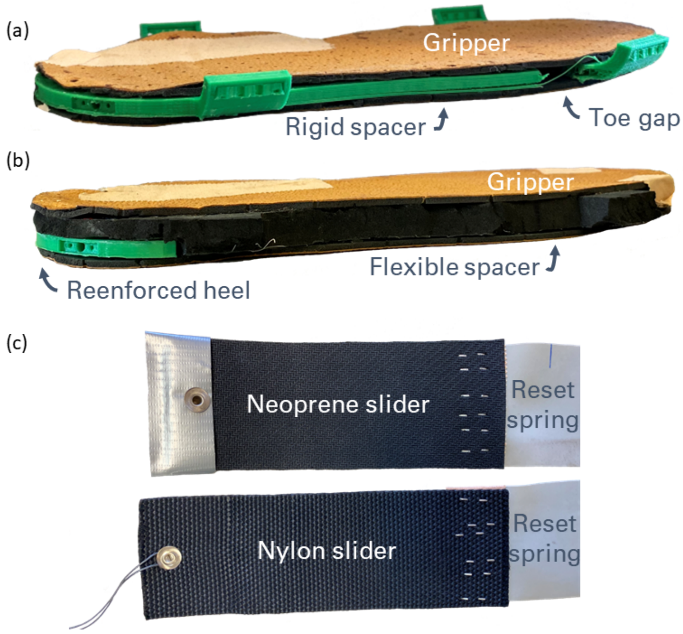


Fig. 7.3.: BWC prototypes: (a) rigid spacer with toe gap, (b) flexible spacer with rigid heel re-enforcement, and (c) two different slider designs, (top) neoprene rubber and (bottom) nylon strapping webbing .

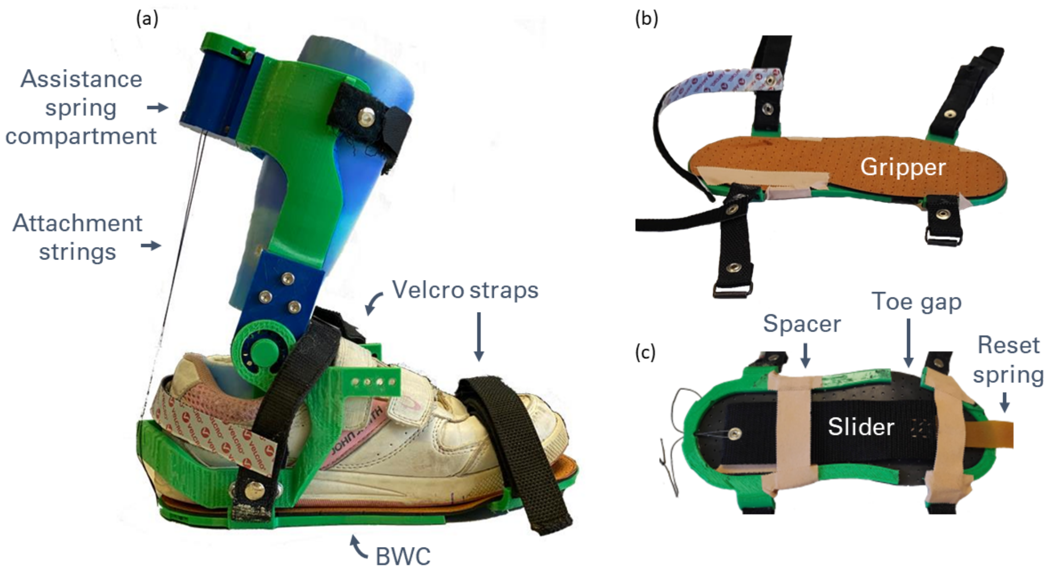


Fig. 7.4.: Physical prototype of the BWC combined with the inGAIT AFO (a). A top view of the BWC showing the velcro straps and the top gripper (b). A bottom view of the BWC without bottom gripper, that shows the slider and reset spring (c). A toe gap was added to the spacer to allow proper toe-off.

8 Technical Validation

To technically verify the BWC prototypes defined in Chapter 7, this chapter evaluates the clutching properties of the sliders (neoprene and nylon) in combination with the different spacers (rigid and flexible). To do so, masses of 0 to 45kg were applied to the clutch, simulating the normal forces that the target group defined in Chapter 3 can exert on the clutch.

8.1 Background

The BWC's clutching properties depend on the friction coefficient, μ, between the slider and the grippers during clutch loading, which can be calculated with Equation 8.1.

$$\mu = \frac{F_{fric}}{F_N} \tag{8.1}$$

where, F_{fric} is the friction force, the maximum force that can be applied on the slider before it starts slipping, and F_N is the normal force acting on the clutch due to the user's body-weight. It is worth noting that the friction coefficient does not depend on surface area. We assume Coulomb friction (Equation 8.1) which does not contain the area [48]. However, a certain minimum area is required for the (maximum) friction coefficient of a system to be obtained.

The friction coefficient μ generally ranges from 0 to 1, where lower values indicate low clutching efficacy [36, 48]. In our prototype, we can assess an effective friction coefficient which value depends not only on the slider and gripper materials, but also on the spacer´s height relative to slider thickness. For example, a thinner spacer combined with a thicker slider will make it easier for the slider and gripper to form a firm connection, resulting in a higher effective μ. However, for proper unclutching during the swing phase, when the clutch is not loaded, it is also important that the space between the grippers is sufficiently large to allow free movement of the slider. For simplification, we will refer to this effective friction coefficient as friction coefficient, μ.

8.2 Materials & Methods

A test bench was created for assessing the prototypes' μ coefficient for different normal force values (Figure 8.1). For each spacer–slider combination, the clutch was loaded with weights ranging from 15 to 45 kg in steps of 5 kg (Table 8.1). These weights were used to simulate the normal forces that the target users can exert on the clutch. Due to the diverse characteristics of patients with CP while walking, it is important to assess the clutching during different key events of the stance phase. Thereby, the different loading weights were tested at three locations (Table 8.1 and Figure 8.1): mid-foot (to simulate mid-stance), heel (to simulate heel strike) and toes (to simulate push-off). Unlike other contributions [36], we also included the heel loading test as it would allow us to evaluate the potential of our BWC to start clutching immediately after heel strike, not delaying it to foot-flat.

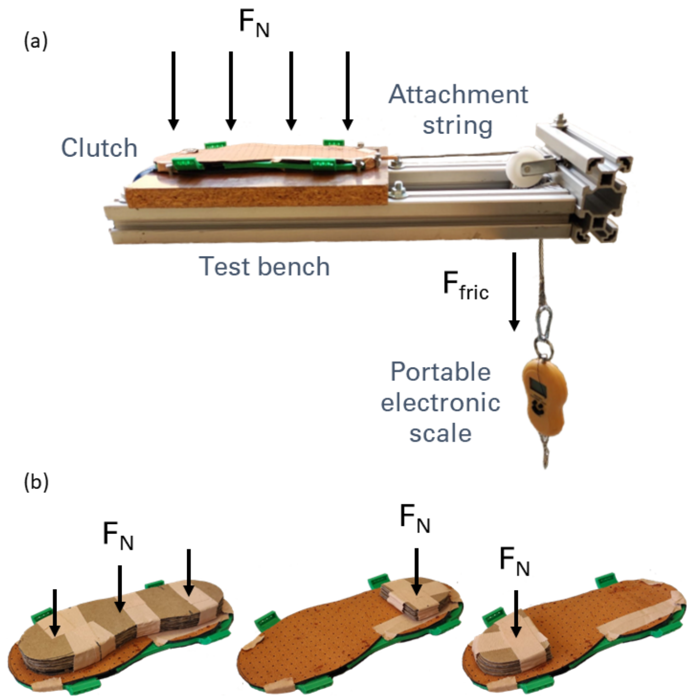


Fig. 8.1.: Experimental setup: (a) The clutch was fixed to the test bench and loaded with weights, simulating the F_N applied by the final users. The attachment string of the slider was guided through a pulley and connected to a portable electronic scale, which was used to measure the maximum F_{fric} until the slider slipped. (b) Different plateaus were placed on the clutch to ensure that the loading weight acted on the mid-foot, heel or toes.

To estimate μ for all parameter combinations in Table 8.1, we determined the maximum holding force (F_{fric}) in each case. The F_{fric} was obtained by applying pulling forces to the attachment string connected to the slider (Figure 8.1). This allowed us to simulate the force exerted on the slider by the assistance spring during the tibial progression of the stance phase. The pulling forces were manually exerted and measured via a portable electronic scale. They were progressively increased

Tab. 8.1.: Overview of interchangeable experimental parameters

Parameters	Values
Spacer	Rigid, flexible
Slider	Nylon, neoprene
Normal weight (kg)	0, 15, 20, 25, 30, 35, 40, 45
Weight location	Mid-foot, heel, toes

Tab. 8.2.: Obtained friction coefficients with RMS fit

Spacer	Slider	μ *mid*	*heel*	*toe*
Rigid	Nylon	0.98	0.88	0.33
	Neoprene	0.48	0.42	0.01
Flexible	Nylon	0.54	0.54	0.25
	Neoprene	0.30	0.33	0.01

until the slider slipped (visually observed). The display of the portable electronic scale was filmed to determine the maximal manually applied holding force. Each measurement was executed three times. The F_{fric} was estimated by averaging the three registered values.

For each clutch configuration F_{fric} was plotted as a function of F_N, and a linear regression fit was performed. The resulting slopes were used to estimate the averaged μ for mid-foot, heel and toes loading. For the linear regression fits, as we did not have data points below 15 kg of normal weight, we assessed F_{fric} when no load (0 kg) was applied on the clutch, i.e. $F_N = 0\ N$, and used these values as intercept points. This allowed us to satisfy the physical constraint that F_{fric} cannot be negative when $F_N = 0\ N$.

8.3 Results

The obtained values of μ for each clutch configuration are presented in Table 8.2. These correspond to the slopes of the linear regression fits for F_{fric} versus F_N datapoints (Figure 8.2). The μ for mid-foot and heel loading are quite similar for all spacer-slider combinations (Table 8.2 and Figure 8.2), although the clutching surface for heel loading was much smaller. The slider was not long enough to properly reach the toe area and thus the μ was much lower for these cases. For the neoprene slider the μ at the toes was so low (0.01 and 0.00, for rigid and flexible spacer respectively) that it can be said that no clutching took place.

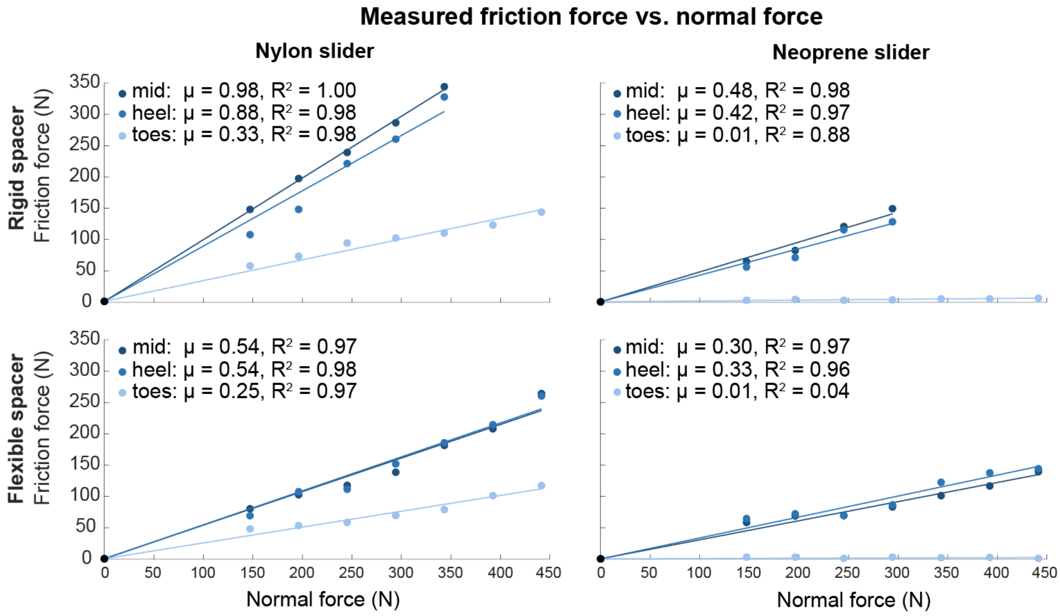


Fig. 8.2.: Obtained values when assessing the maximum F_{fric} pulling from the slider for a fixed F_N applied on the clutch. The position of F_N was tested at three locations (mid-foot, heel and toes). A linear fit was applied to the data points to find the corresponding μ and R^2 coefficients.

8.4 Discussion

From all tested spacer–slider combinations, the highest clutching efficacy was obtained for the 5 mm rigid spacer combined with a nylon slider. Even though the flexible spacer was made from flexible fast resetting foam, it performed worse than the rigid spacer, as indicated by the lower μ. This can be explained by the fact that the flexible spacer was twice as thick as the rigid spacer, and thus made clutching more difficult.

The nylon slider performed better than the neoprene slider in combination with both the rigid and flexible spacer, as shown by the higher μ coefficient between gripper and nylon slider material than between gripper and neoprene slider material. Moreover, the nylon slider was able to withstand the forces that it was subjected to during the experiment, while the neoprene slider failed when loaded with 15 kg (e.g. rigid spacer with neoprene slider, Figure 8.2). The slider of the final design should be able to carry the maximum user weight of 60 kg and withstand the pulling forces applied by them. In that sense, the nylon slider seems to be strong enough to withstand this load, although we did not test it in this experiment, as we only reached up to 45 kg.

As the prototypes were manually loaded, the obtained μ values are not as accurate as they could have been if a robotic actuator would have been used, which we did not have access to. Moreover, only a limited amount of slider-spacer combinations were tested. For future work it could be beneficial to test a higher variety of different materials and spacer thicknesses. Finally, μ was 0.33 maximum for toe loading, and as the force is transferred to the ankle upon toe-off it is uncertain if proper push-off assistance will occur. Thus, experiments with real subjects should be conducted. If the friction coefficient at the toes turns out to be insufficient, the slider should be moved forward or made longer to increase the clutched surface area during toe loading, thereby increasing μ.

8.5 Conclusion

The technical validation shows that a sufficient friction coefficient can be reached with relatively cheap, lightweight and easy to find materials to ensure proper clutching of the slider. However, the clutch's validation is not complete yet. The next step is verifying if the clutch does indeed satisfy the requirements defined in Chapter 3. To do so, the BWC should be tested both on healthy users and patients with CP. This allows determining if the mechanism is valid for different pilot sizes (Table 3.1, requirement 2), and if it is functional in the specified environment (requirements 5, 6, 7 and 8). Measures for proper functioning of the clutch are correctly performed clutching and unclutching, as well as users not feeling any dorsiflexion stiffness during swing. Finally, further testing should verify if an assistance torque of 0.3 Nm/kg can be reached (requirement 20).

9 Mathematical Validation

The technical validation of the BWC in Chapter 8 indicated that high friction coefficients can be reached with cheap and readily available materials. However, further verification of the clutch is required to determine if it satisfies the requirements defined in Chapter 3. Thus, a model was created in Matlab to calculate the forces that the BWC should provide to reach the required 0.3 Nm/kg assistance torque around the ankle (Table 3.1, requirement 20). The model was subsequently used to determine if, and for what lever arm position and assistance spring stiffness, this requirement would be reached, and to see if sufficient friction force can be generated by the clutch to support the needed assistance force.

Eventually the model can be used for choosing a suitable lever arm position and assistance spring stiffness combination for different user weights and sizes. Prototypes designed based on the model can subsequently be tested on real subjects to further investigate if the BWC satisfies the requirements defined in Chapter 3.

9.1 Mathematical Model

The goal of the mathematical model is to find lever arm positions (x,y) with respect to the heel of the foot that allow the BWC to provide the required 0.3 Nm/kg assistance torque T_{req} around the ankle (Figure 9.1). Which lever arm positions satisfy this requirement depends on the user's weight and size, the inGAIT AFO's dimensions, the assistance spring stiffness and the friction coefficient of the clutch.

The model takes the user's mass and height as an input, and calculates the dimensions of relevant anatomical segments, e.g. the length of the shank, using Winter approximation [49] (Figure 9.1). If user mass and height are not provided, these are calculated based on age, with Henry Dreyfuss' ergonomy tables. The dimensions of a suitable AFO are subsequently determined based on user size. Some AFO dimensions, however, e.g. the size of the assistance spring compartment, do not depend on user size, but are fixed and defined by the inGAIT AFO prototype. Finally, the assistance spring stiffness and clutch's friction coefficient are inputs for the model as well. These should be strategically chosen to obtain relevant lever arm positions. Assistance spring stiffness, for example, should be as low as possible, to not impede tibial progression during the stance phase. Moreover, the friction coefficient should be a realistic value, e.g. such as the ones obtained for the technical validation in Chapter 8.

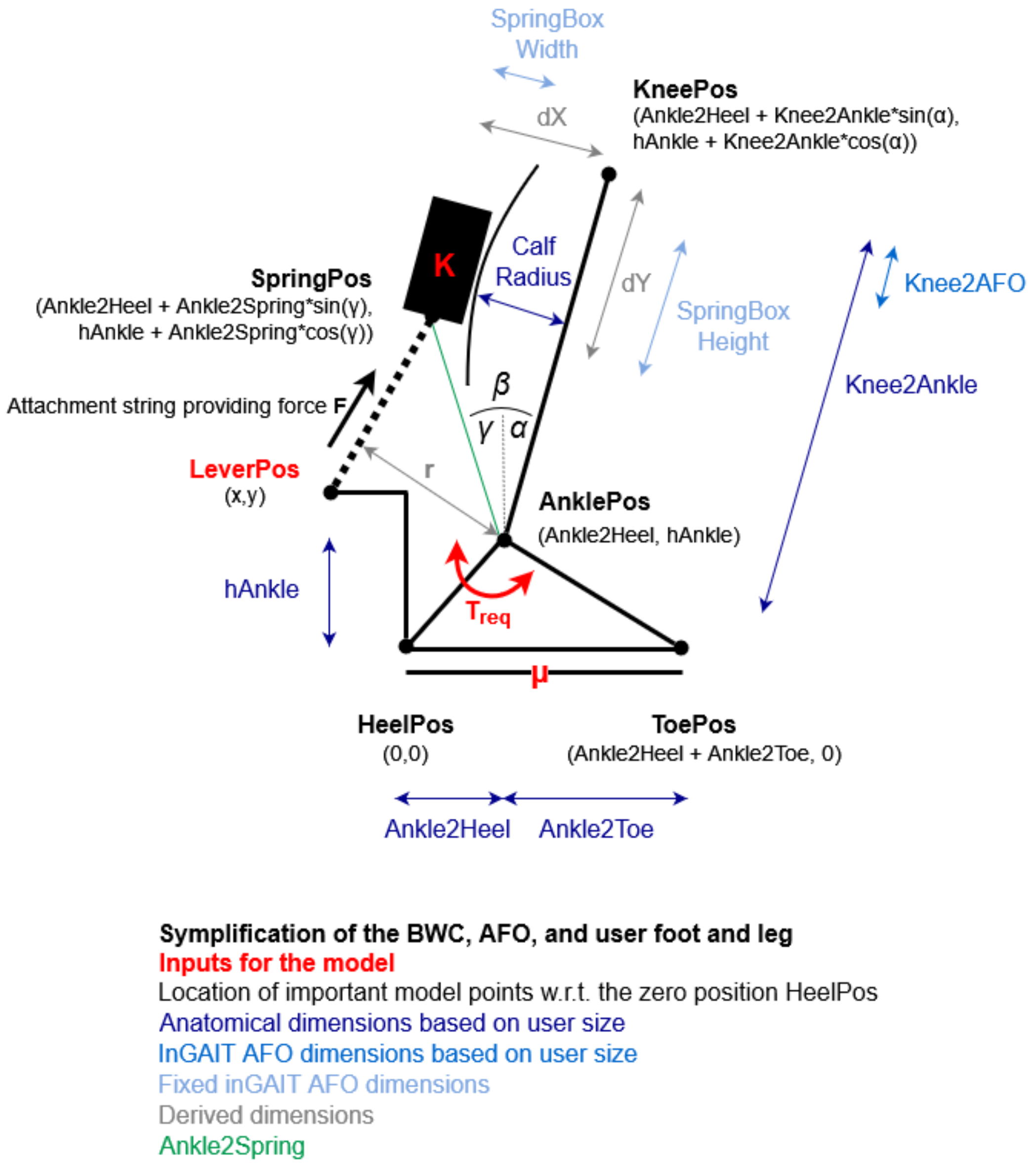


Fig. 9.1.: The mathematical model verifies if the BWC is able to provide the required torque T_{req} of 0.3 Nm/kg for a specific user. To do so, either the user's age, or height and mass needs to be provided. Based on Henry Dreyfuss' ergonomy tables and using Winter approximation [49], relevant anatomical dimensions can then be determined, as well as corresponding AFO dimensions. Subsequently, by choosing the assistance spring stiffness K and the friction coefficient μ of the BWC in the model, a relevant LeverPos can be found. This is done by calculating the difference in force (F_{diff}) exerted on the attachment string, between what is required (F_{req}) and what can be provided by the assistance spring (F_{ass}), for different leverarm positions.

The model calculates the force difference F_{diff} between the required force F_{req} and the force that can theoretically be provided by the assistance spring F_{ass} (Equation 9.1) for different lever arm positions. If F_{diff} is positive, the assistance spring can provide the required force to generate a torque of 0.3 Nm/kg around the ankle for the corresponding lever arm position.

$$F_{diff} = F_{ass} - F_{req} \tag{9.1}$$

where F_{diff} is the difference in force between what can be provided by the assistance spring F_{ass} and the required force F_{req}.

To determine F_{diff}, F_{ass} and F_{req} need to be determined. Let us first derive F_{req}, which depends on the required torque T_{req} of 0.3 Nm/kg, the user's mass and the moment arm between the ankle joint and the attachment string (Equation 9.2).

$$F_{req} = \frac{T_{req} * m}{r} \tag{9.2}$$

where F_{req} is the required force in N, T_{req} is the required torque in Nm/kg, m is the user's mass in kg, and r the moment arm between the ankle joint and the attachment string in m (Figure 9.1).

Whereas T_{req} and the user's mass are given model inputs, the moment arm is defined as the distance from the ankle joint (AnklePos) to the line described by the attachment string, which spans from LeverPos to SpringPos (Figure 9.1). The moment arm can thus be calculated using the formula for the distance between a point and a line (Equation 9.3).

$$r = \frac{|Ax_0 + By_0 + C|}{\sqrt{A^2 + B^2}} \tag{9.3}$$

where r is the moment arm in m, x_0 and y_0 are the coordinates of the AnklePos in m, and A, B and C are parameters describing the line through LeverPos and SpringPos (Figure 9.1). If this line is defined as $y = ax + b$, then $A = a$, $B = -1$, and $C = b$.

To determine the moment arm, AnklePos, LeverPos and SpringPos should thus be known. LeverPos is a model input that has to be chosen by the modeller, while AnklePos and SpringPos can be derived from the geometry of the BWC, AFO and user foot and leg. For this purpose relevant anatomical landmarks and dimensions were defined (Equation 9.4, Figure 9.1).

$$\begin{aligned}
HeelPos: &\quad (0, 0) \\
ToePos: &\quad (Ankle2Heel + Ankle2Toe, 0) \\
AnklePos: &\quad (Ankle2Heel, hAnkle) \\
KneePos: &\quad (Ankle2Heel + Knee2Ankle * sin(\alpha), \\
&\qquad hAnkle + Knee2Ankle * cos(\alpha))
\end{aligned} \tag{9.4}$$

where the position of the back of the heel (HeelPos) is taken as the model's origin, and the front of the toes (ToePos), ankle joint (AnklePos) and knee joint (KneePos) are subsequently determined by the horizontal distance between heel and ankle joint (Ankle2Heel), the horizontal distance between the ankle joint and toes (Ankle2Toe), the distance between the ankle joint and the ground (hAnkle), the distance between knee and ankle joint (Knee2Ankle) and the angle α between the vertical and the shank in degrees (Figure 9.1). Here the shank is defined as the line between the knee and ankle joint, and all distances are given in m.

With AnklePos known, only SpringPos needs to be determined to be able to calculate the moment arm. However, before the location of the SpringPos relative to the HeelPos can be determined, the SpringPos location relative to the KneePos needs to be known. This is calculated by finding the distances between the KneePos and SpringPos, perpendicular (dX) and parallel (dY) to the shank (Equation 9.5, Figure 9.1).

$$\begin{aligned} dX &= SpringBoxWidth + CalfRadius \\ dY &= SpringBoxHeight + Knee2AFO \end{aligned} \tag{9.5}$$

where dX and dY are the perpendicular and parallel distance between KneePos and SpringPos with respect to the shank in m, SpringBoxHeight and SpringBoxWidth are the dimensions of the assistance spring compartment as set for the inGAIT AFO in m, the CalfRadius in m for different ages was taken from literature [50, 51], and the distance between the knee joint and the top of the AFO (Knee2AFO) in m is described by Equation 9.6.

$$Knee2AFO = \frac{90}{420} * Knee2Ankle \tag{9.6}$$

where Knee2AFO is the distance between the knee joint and the top of the AFO as defined for the inGAIT AFO prototype in m, and Knee2Ankle is the length of the shank of the corresponding user in m.

Knowing the SpringPos location with respect to the KneePos allows for calculating Ankle2Spring, the length of the imaginary line between the AnklePos and SpringPos (Equation 9.7, Figure 9.1), as well as the angle β between the shank and this imaginary line (Equation 9.8, Figure 9.1). This finally allows for the calculation of the SpringPos with respect to the HeelPos (Equation 9.9), and thus for determining the moment arm.

$$Ankle2Spring = \sqrt{dX^2 + (Knee2Ankle - dY)^2} \tag{9.7}$$

where Ankle2Spring is the length of the imaginary line between AnklePos and SpringPos in m, dX and dY are the perpendicular and parallel distance between KneePos and SpringPos with respect to the shank in m, and Knee2Ankle is the length of the shank in m.

$$\beta = tan^{-1}(\frac{dX}{Knee2Ankle - dY}) \tag{9.8}$$

where β is the angle between Ankle2Spring and the shank in degrees, dX and dY are the perpendicular and parallel distance between KneePos and SpringPos with respect to the shank in m, and Knee2Ankle is the length of the shank in m.

$$\begin{aligned} SpringPos : (&Ankle2Heel + Ankle2Spring * sin(\gamma), \\ &hAnkle + Ankle2Spring * cos(\gamma)) \end{aligned} \tag{9.9}$$

where the coordinates of SpringPos are given in m, Ankle2Heel is the horizontal distance between heel and ankle in m, Ankle2Spring is the length between AnklePos and SpringPos in m, hAnkle is the height of the ankle joint to the ground in m, and $\gamma = \alpha - \beta$ in degrees. With α the angle between the shank and the vertical, and β the angle between the shank and the imaginary line between AnklePos and SpringPos (Figure 9.1).

Now that all components to calculate F_{req} are known, the assistance spring force F_{ass} needs to be determined. This depends on the spring stiffness K, which is an inherent property of the spring and an input to the model, and the amount of spring compression, which is determined by user and AFO size, as well as the level of ankle dorsiflexion (Equation 9.10). Care needs to be taken that F_{ass} does not exceed the friction force F_{fric} that can be generated by the BWC, as that would cause the slider to slip and no energy to be stored in the assistance spring. Moreover, if no compression occurs, energy cannot be stored in the spring and F_{ass} is 0.

$$F_{ass} = \begin{cases} K * \Delta l, & \text{for } F_{ass} \leq F_{fric} \text{ and } \Delta l < 0 \\ 0, & \text{otherwise} \end{cases} \tag{9.10}$$

where F_{ass} is the force that can be generated by the assistance spring in N, K is the spring stiffness in N/m, Δl is the amount of assistance spring compression in m, and F_{fric} is the amount of friction force that can be generated by the clutch (Equation 9.11).

$$F_{fric} = F_N * \mu \tag{9.11}$$

where F_{fric} is the maximum pulling force that the slider can be subjected to before slippage occurs, F_N is the normal force on the BWC, as determined by the user's weight, and μ is the BWC's friction coefficient.

The model assumes that the assistance spring starts compressing from 0° ankle dorsiflexion, and that the user has normal ankle ROM and can thus dorsiflex the ankle up until 10°, as was required from the target group in Chapter 3. Spring compression Δl is then determined by calculating the length of the attachment string, the distance between LeverPos and SpringPos, for 0° and 10° (Equation 9.12), as an increase in attachment string length is proportional to a decrease in assistance spring length, and thus to spring compression.

$$\Delta l = \sqrt{SpringPos_x|_{0^\circ} - x)^2 + (SpringPos_y|_{0^\circ} - y)^2} - \sqrt{SpringPos_x|_{10^\circ} - x)^2 + (SpringPos_y|_{10^\circ} - y)^2} \tag{9.12}$$

where Δl is the level of spring compression in m, which is the difference in attachment string length at 0° and 10° dorsiflexion, with the attachment string spanning from LeverPos (x,y) to SpringPos.

Too conclude, the mathematical model takes the required torque (T_{req}), the coordinates (x,y) of the LeverPos, the friction coefficient μ, the spring stiffness K and the user's age or height and mass as an input, to determine if the assistance force (F_{ass}) that the can be delivered by the assistance spring exceeds the required force (F_{req}) for the corresponding parameters.

9.2 Methods

The difference in force, F_{diff}, between what the assistance spring can deliver, F_{ass}, and what is required, F_{req}, was calculated for a multitude of LeverPos locations within a predefined solution space, while varying the model's other input parameters. The forces were calculated at the target group's maximal dorsiflexion angle of 10°, as this is the angle at which the assistance force will act.

The solution space spans from -Ankle2Heel to Ankle2Heel in the x-direction, and from 0 to 2*hAnkle in the y-direction (Figure 9.2), and has a resolution of 99 data points in both x- and y-direction. As indicated in Chapter 6 the back of the heel should be kept clear of material as much as possible. Using a solution space, rather than a single LeverPos coordinate, allows us to visualise what would be valid LeverPos locations within a reasonable area. This, in turn, aids us in determining a trade-off for the optimal LeverPos location with respect to limiting size and providing the necessary functionality. By choosing part of the solution space to be to the right of the HeelPos, the possibility of guiding two attachment strings past the side of the shoe could be explored (Figure 9.3).

The solution space was evaluated for different configurations of the model's other input parameters, namely age, spring stiffness K, friction coefficient μ and required torque T_{req}. The solution space was evaluated for age 5, 10 and 15, in accordance with the target group of 4 to 16-year-olds (Chapter 3). As Yandell et al. used K values of 6.1, 13.2, 17.7 N/mm for their AFO in their first case study [36] it was decided to evaluate the solution space for K = 6, 12 and 18 N/mm. The technical validation (Chapter 8) showed friction coefficients ranging from 0.25 to 0.98 for the Nylon slider, which was concluded to be the most promising one, while Yandell et al. obtained friction coefficients of 0.79 and 0.58, for their prototype. It was thus decided to evaluate the solution space for μ values of 0.5, 0.75 and 1. Finally, to investigate the possibility of guiding two attachment strings past the side of the shoe and having a smaller lever arm, values of 0.1, 0.2 and 0.3 Nm/kg were investigated for T_{req}.

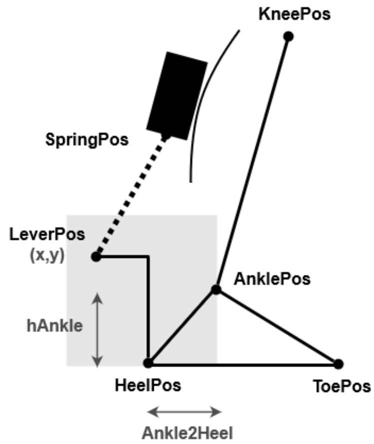


Fig. 9.2.: Graphical representation of the solution space for the LeverPos, spanning from -Ankle2Heel to Ankle2Heel in the x-direction, and from 0 to 2*hAnkle in the y-direction.

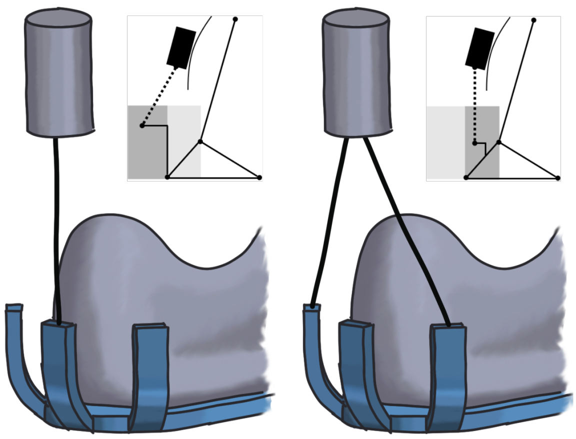


Fig. 9.3.: If the LeverPos is in the left half of the solution space, behind the heel, the attachment string should be guided past a single lever arm at the back of the heel. If it is in the right half, in front of the heel, the attachment string should be guided along the sides of the shoe via a lever arm at either side.

9.3 Results

Firstly, an overview was created on how the values for F_{req} and F_{ass} influence F_{diff} (Figure 9.4). This shows that along the line from AnklePos to SpringPos, where the moment arm approaches zero, F_{req} goes to infinity. When moving away from this line F_{req} rapidly decreases as the moment arm increases. The force that the spring can supply, F_{ass}, on the other hand, increases as the moment arm increases. The force difference, F_{diff}, is thus only positive in the left half of the solution space, indicating that for the given parameters the LeverPos should be positioned behind the heel.

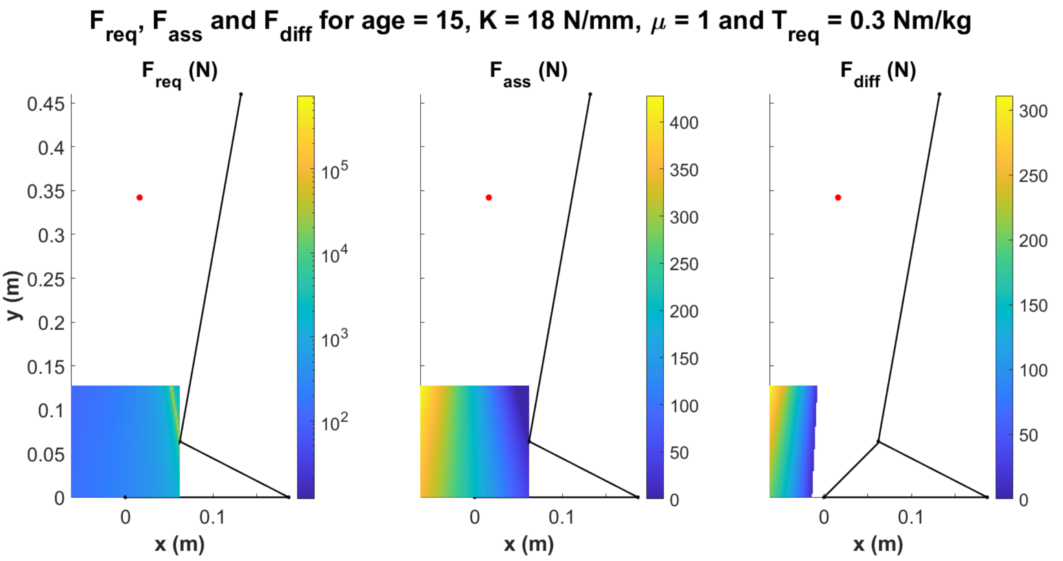


Fig. 9.4.: Overview of how F_{diff} is obtained from F_{req} and F_{ass}, with the red dot representing the SpringPos. Where F_{req} decreases as the moment arm increases, F_{ass} increases as the moment arm increases, resulting in positive F_{diff} values only in the left half of the solution space.

Evaluating the solution space for different ages shows that older children have a wider area in which the LeverPos can be positioned to obtain T_{req} (Figure 9.5). This is mainly caused by the fact that for younger children LeverPos locations starting from the left most boundary of the solution space are no longer valid. These children are too light to create sufficient friction force to clutch the slider when bigger lever arms and thus higher pulling forces are concerned. Similarly to increasing age, increasing K and μ also increases the number of possible LeverPos locations (Figure 9.6 and 9.7). For small K, T_{req} is reached only for the top left corner of the solution space. Increasing K causes smaller lever arms to become valid as well, as this increases the amount of energy that can be stored in the assistance spring for a certain level of compression. Increasing μ does not allow smaller lever arms. On the contrary, it allows bigger lever arms to be valid as well, as increasing μ increases the force that can be exerted on the slider before slippage occurs.

All results taking $T_{req} = 0.3$ Nm/kg (Figure 9.5, 9.6 and 9.7) show that the LeverPos needs to be positioned behind the heel. However, when accepting a T_{req} of 0.2 or even 0.1 Nm/kg, valid LeverPos coordinates can be found in front of the heel (Figure 9.8), indicating that guiding the attachment string past the side of the shoe to save space at the back of the heel could still be an option for lower T_{req}.

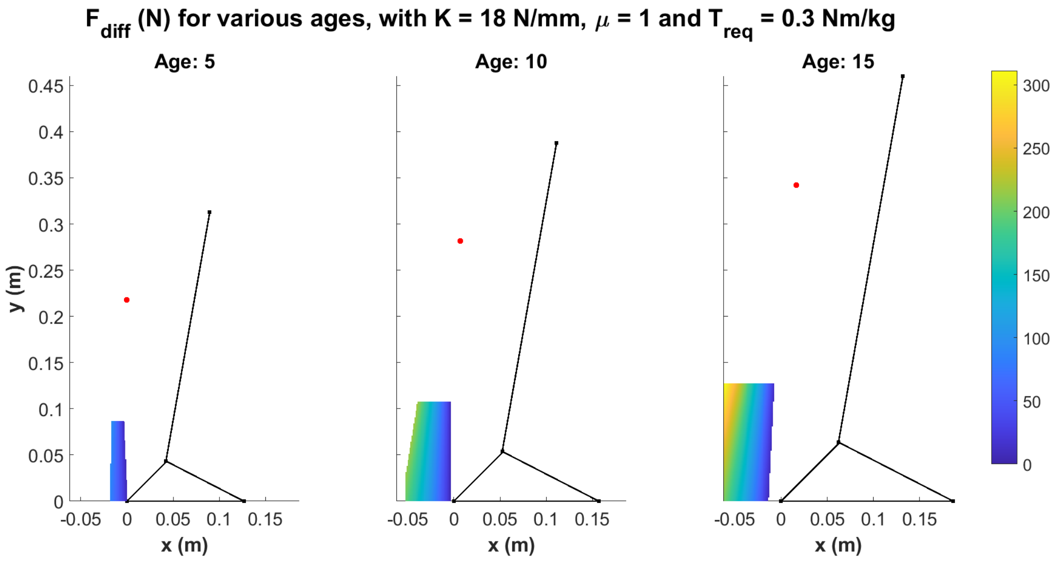


Fig. 9.5.: Possible LeverPos locations for users age 5, 10 and 15, for K = 18 N/mm, μ = 1 and T_{req} = 0.3 Nm/kg, with the red dot representing the SpringPos. The younger the user, the lower the number of possible LeverPos locations, especially reducing the options at the left side of the solution space. For the shown parameters the LeverPos should be placed behind the heel.

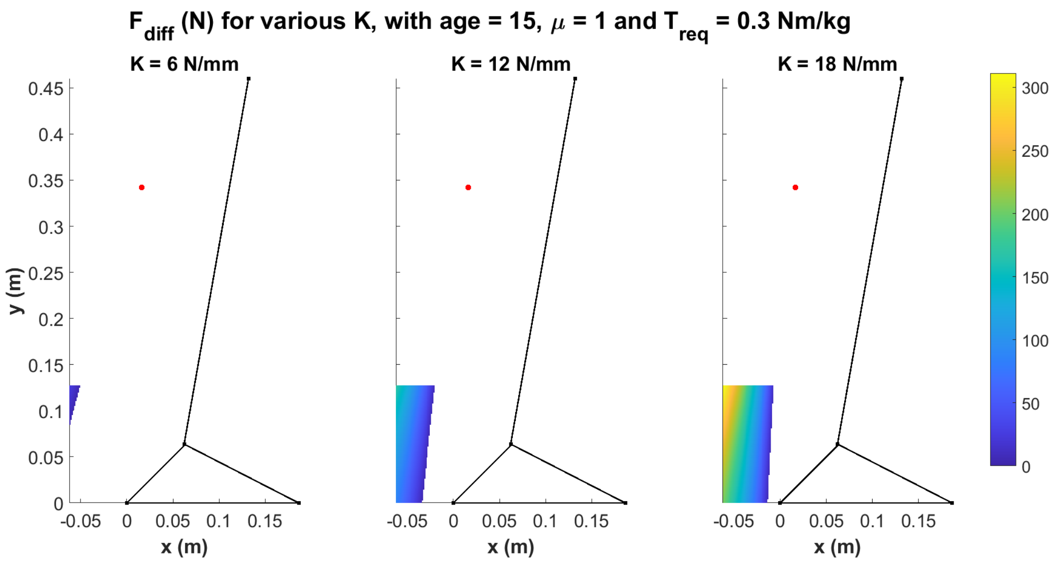


Fig. 9.6.: Possible LeverPos locations for an assistance spring with K = 6, 12 and 18 N/mm, for age = 15, μ = 1 and T_{req} = 0.3 Nm/kg, with the red dot representing the SpringPos. As K increases, the number of possible LeverPos locations grows, starting from the top left of the solution space. For the shown parameters the LeverPos should be placed behind the heel.

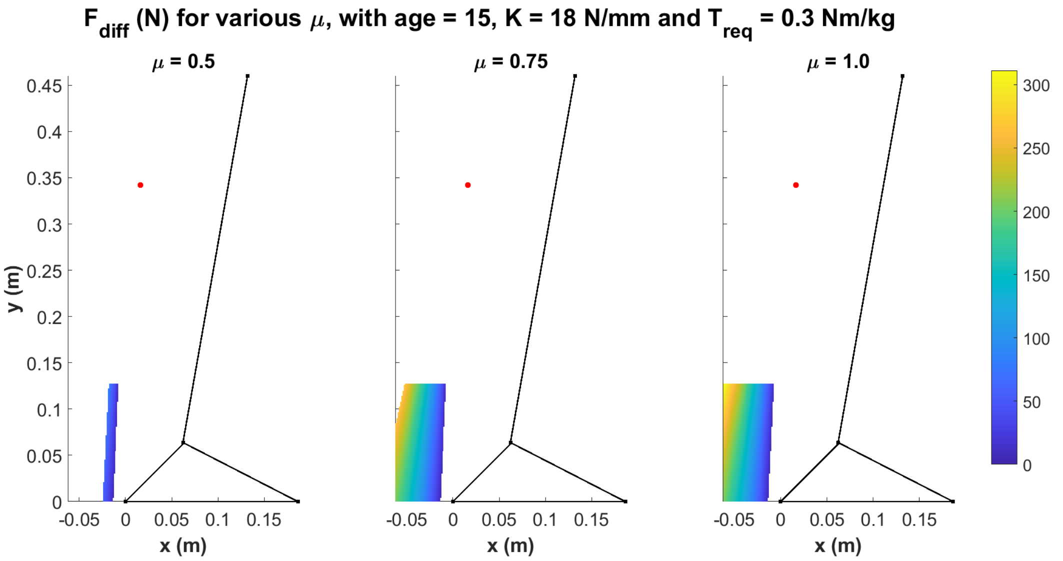


Fig. 9.7.: Possible LeverPos locations for μ = 0.5, 0.75 and 1.0, for age = 15, K = 18 N/mm and T_{req} = 0.3 Nm/kg, with the red dot representing the SpringPos. As μ increases, the number of possible LeverPos locations grows as bigger lever arms are allowed, while the minimum lever arm remains the same. For the shown parameters the LeverPos should be placed behind the heel.

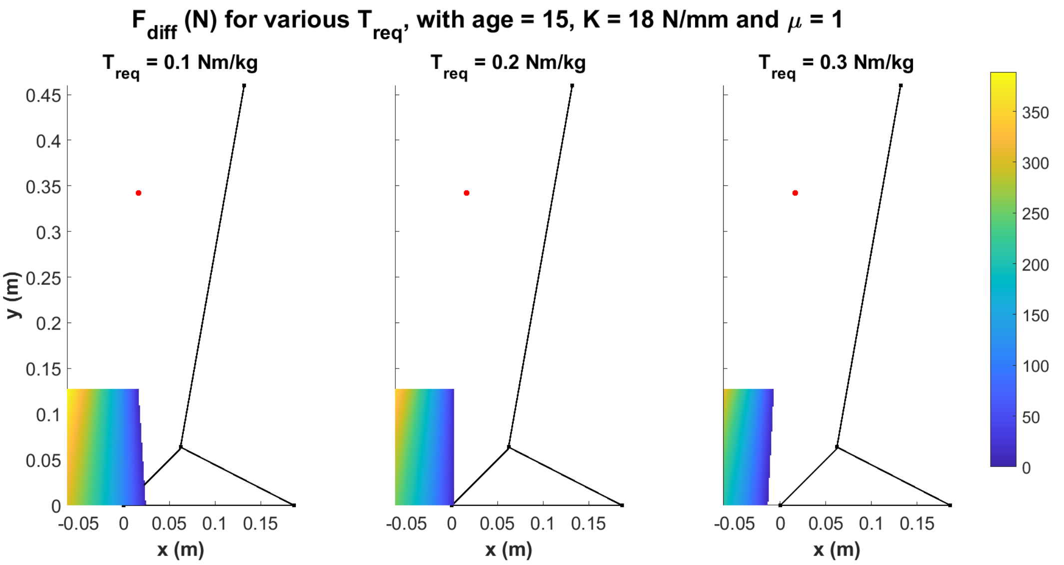


Fig. 9.8.: Possible LeverPos locations for T_{req} = 0.1, 0.2 and 0.3 Nm/kg, for age = 15, K = 18 N/mm and μ = 1.0, with the red dot representing the SpringPos. As T_{req} decreases, the number of possible LeverPos locations grows, allowing the LeverPos to be placed in front of the heel. For some parameters guiding the attachment string past the side of the shoe via a lever arm at either side, thus results in valid LeverPos locations.

9.4 Discussion

The optimal LeverPos solution has the smallest possible lever arm while still satisfying the requirement of providing T_{req}, as this reduces the amount of space that the BWC takes up at the back of the heel. In Figures 9.5 to 9.8 this is thus the line of rightmost valid LeverPos locations. Moreover, LeverPos should be chosen to minimally restrict the user when executing activities of daily life. It should thus be placed a little above ground level, to allow smooth heel strike and walking on uneven terrain. On top of that, the assistance spring should have minimal K, ensuring minimal interference with the tibial progression of the stance phase of gait. Unfortunately, a trade-off should be made when setting the values for K and LeverPos, as using a softer spring requires a bigger lever arm, and vice versa. Finally, μ should be sufficiently high to prevent the slider from slipping. However, for the given input parameters a μ of 0.5 is sufficient when choosing a LeverPos with minimal lever arm (Figure 9.7).

The mathematical model is an idealised representation of the real life situation and thus only gives a rough idea if obtaining T_{req} is possible for the given parameters. The model assumes infinitely stiff AFO components that do not experience unwanted movement with respect to each other or the user. However, in real life, energy will dissipate due to system compliance. Moreover, the model assumes that spring compression occurs from 0° to 10° dorsiflexion, but as gait is dynamic it is highly unlikely that maximum compression will occur every gait cycle. In addition, if the user walks on slopes or uneven terrain these ankle angles will not be met, generating different moment arms, and thus different T_{req}. Finally, the model is based on average child dimensions, and results might thus deviate from situations where real patients are concerned. Thus, to take the above mentioned problems into account some buffer should be built into the mechanism (e.g. higher r or K) to ensure that sufficient force is supplied even if conditions are non-ideal. On top of that, for further validation of the BWC, a physical prototype should be tested on patients to determine if T_{req} is reached.

9.5 Conclusion

According to the mathematical model, the required assistance torque of 0.3 Nm/kg can theoretically be reached for the target users if the LeverPos is situated behind the heel (Figures 9.5 to 9.7). Even if μ is only 0.5, T_{req} is reached for sufficiently large K (Figure 9.7). If a lower T_{req} is allowed, the attachment string can be rerouted along the sides of the shoe to obtain an even smaller moment arm. However, for T_{req} = 0.3 Nm/kg, age = 5 – 15, K = 6 – 18 N/m and μ = 0.5 – 1.0, rerouting is not necesary.

10 Discussion

A survey regarding current AFOs for Cerebral Palsy was conducted among the main stakeholders of CP. Corresponding results were used as input for a technical meeting with clinicians, to define the inGAIT project requirements. Based on which the goal of the thesis became the design of a passive push-off mechanism that provides adaptable assistance, for the first inGAIT prototype (Chapter 3). To achieve this, passive push-off mechanisms were found in literature: body weight-controlled clutch, ankle angle-controlled clutch, adjustable dynamic response, spring-cam and leaf spring-cam. TRIZ subsequently concluded the BWC, in combination with a rigid AFO frame and the possibility to pretension the assistance spring, to be most promising for inGAIT. Ideation then focused on slider, lever and pneumatic based BWCs, resulting in slider, flexible arch and interlocking gear based concepts. Four slider based prototypes were subsequently created, with a flexible or rigid spacer and a neoprene or nylon slider. Technical validation of these prototypes indicated that high friction coefficients μ and thus good clutching capacity can be achieved with relatively cheap and readily available materials. Finally, a mathematical model of the BWC confirmed that the required torque around the ankle of (0.3 Nm/kg can theoretically be generated for the target group if the position of the lever arm and the assistance spring stiffness are chosen accordingly.

10.1 Requirements Fulfilment

As it was decided to focus this thesis solely on the design of a push-off mechanism and not on the accompanying AFO, some of the requirements defined in Chapter 3 are no longer relevant. These are requirements pertaining to the ankle's ROM (requirement 13–17) and to the AFO's design space (requirement 29–32, 34 &36). However, the design space at the back of the shank and heel (requirement 33 & 38), bottom of the foot (requirement 35), and medial and lateral sides of the ankle joint (requirement 37) is still relevant for the BWC. Conforming to the desired dimensions at the back of the shank and heel, 2 and 1 cm respectively, is problematic as the BWC inherently needs to occupy some of this space. This can be reduced by decreasing assistance spring radius, trimming spring box material and using a smaller lever arm, although the latter requires a stiffer assistance spring to provide the same torque. When the lever arm is placed behind the heel, as advised by the mathematical model, the sides of the ankle will be kept clear of material, conforming to requirement 37, even though rerouting the attachment string close to the sides of the shoe should still fulfil the 5 cm protrusion limit. Finally, the desired maximal clutch height of 1 cm was achieved for the prototype with a rigid spacer (9.7 mm) but not for the one with a flexible spacer (15.4 mm). However, as the friction coefficient of the flexible spacer was quiet low, maximum 0.48 (Chapter 8), it will be beneficial do decrease spacer and thus prototype height.

The proposed BWC design conforms to some of the requirements. It can be produced based on each individual's shoe size and shape, and the lever arm location can be chosen according to the user's needs (requirement 2). The clutch is non-actuated (requirement 4) and lightweight (requirement 3), 60 to 70 g. Thus, staying below the desired weight of 0.3 kg (requirement 28) mostly depends on the accompanying AFO. In comparison, Yandell's design, including shank interface, weights 459 g, of which 263 g are for the clutch and lever arm. For our design, the weight of the lever arm can be reduced by integrating it into the AFO frame.

Unfortunately, the mechanism cannot provide the required torque to prevent drop-foot (requirement 11 & 21) or inhibit foot-slap (requirement 12 & 22), and due to the size of the spring box it might be difficult to wear in conjunction with normal clothing (requirement 25). However, this can be solved by decreasing the radius of the assistance spring and trimming spring box material. Normal shoes can be used, although they would require serious alteration to attach the BWC and AFO (requirement 25). Moreover, the BWC will be difficult to integrate with other orthotic bracing solutions (requirement 39), as the it requires a shank interface to which the spring box can be attached. Finally, no special attention was given to ensure adjustable zero alignment (requirement 18), or adaptable plantar/dorsiflexion assistance (requirement 19) even though providing adaptable assistance was part of the thesis' goal, as this first requires having a functioning push-off mechanism. The zero alignment of the current prototype is set by the length of the attachment strings and the placement of the slider with respect to the clutch. Adaptability of assistance can thus be introduced by allowing temporary shortening or lengthening of the attachment string, and by facilitating changes in reset spring pretension to allow control over the slider location.

The mathematical validation indicated that for age = 5 – 10, K = 6 – 18 N/mm and μ = 0.5 – 1.0 the required assistance torque of 0.3 Nm/kg (requirement 20), can theoretically be provided for the set solution space. However, to verify if this requirement can actually be met, the BWC should be tested on real subjects. The same holds for requirements 5–8, 23, 24 and 26, as of now it can only be speculated if these criteria are met. The BWC is controlled by the user's body weight and should thus inherently adapt to different walking speeds (requirement 24), and function on gentle slopes (requirement 7). Since Yandell et al. had promising results with their clutch [36], our clutch should at least be able to function properly in a controlled environment (requirement 5). However, as our design restrains the ankle's ROM and might collide with objects in the user's surrounding, functioning might be problematic in uncontrolled environments and for different walking terrains (requirement 6 & 23). Allowing some ankle inversion/eversion and placing the lever arm higher up, preventing collisions, might improve this. On top of that, walking on steep slopes (requirement 8) forces the ankle into higher levels of dorsiflexion [52]. As our target users are likely to have limited ankle ROM, they might be incapable of further flexing the ankle to reach sufficient spring compression to generate push-off assistance in this situation. Finally, the BWC's assistance spring is expected to be the most noisy component (requirement 26), as the slider and grippers are made of soft materials.

10.2 Design Improvements

To be able to test the BWC on real subjects and to verify its functioning, some alterations need to be made to the prototype presented in this thesis. First of all, the inGAIT AFO needs to be fabricated from strong, rigid and lightweight material, not 3D printed PLA, that can withstand the forces that the BWC will subject it too, as well as efficiently transfer the assistance force to the ankle. The grippers should be made out of a single piece of rubber, and stronger attachment strings, that can carry at least 60 kg, should be used. The BWC should be glued to the shoe instead of put in place by Velcro, to prevent it from sliding with respect to the shoe, reducing energy dissipation. The lever arm should be integrated with the inGAIT AFO (Figure 10.1), as this will prevent the attachment string from pushing it towards the heel. Finally, once the above alterations have been verified to work on real subjects, adjustable assistance should be improved, e.g. by allowing easier attachment string length changes, interchangeable assistance springs, or pretensioning of the assistance and reset springs.

10.3 Future Steps

After improvements to the current prototype have been implemented, further testing is needed. First of all it should be verified that the BWC and AFO can withstand 60 kg of loading. Then user tests need to be performed, first with healthy subjects and subsequently with patients, to verify that the assistance spring is loading and returning force properly, and that the reset spring is returning the slider to the initial position. Various terrains and walking speeds should be investigated, as well as

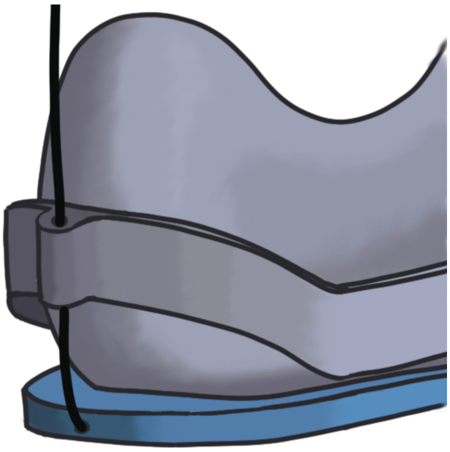


Fig. 10.1.: Integrating the lever arm into the inGAIT AFO will prevent the attachment string from deforming it and pushing it towards the heel.

the effect of the assistance spring stiffness on tibial progression, as K should be sufficiently low not to hinder tibial progression. Finally, it should be verified that the mechanism can provide T_{req} and that it reduces energy cost of walking, which can be done my measuring EMG signals of the calf muscles with and without AFO.

As the bodyweight controlled clutches found in literature were designed for healthy adults as performance enhancers [36–38], it will be interesting to further investigate how such mechanisms perform for children with CP, especially since these subjects have limited ankle ROM and ankle control. Moreover, our design is an adaptation of Yandell's BWC [36], with the main differences being a bigger slider, 50x130 mm instead of 50x70 mm, and the removal of spacer material underneath the heel. Increasing spacer size ensures that sufficient friction force can be generated by the clutch, even when used by small children, and during a bigger part of the stance phase. Removing spacer material at the heel makes the design more lightweight and allows the slider to move all the way to the back of the foot. This allows setting the default slider position more towards the heel, enabling clutching to take place earlier, which is beneficial in case of delays in the system. Finally, where Yandell´s design consists of a clutch that is connected to a shank interface via a cable, only counteracting ankle dorsiflexion during the stance phase of gait, our design also includes a hinged AFO, which only allows plantar and dorsiflexion. As our target group consists of children with CP and not healthy individuals, care needs to be taken that the AFO provides the primary need of this patient group, restoring the ankle´s biomechanics. If this is not achieved, providing push-off power will not be as effective. .

11 Conclusion

Based on a survey regarding current AFOs for cerebral palsy and a TRIZ analysis, a first prototype for a slider based bodyweight controlled clutch was made, and mathematically and technically validated. Although the created prototype should be able to supply the required torque if the moment arm and assistance spring stiffness are chosen properly, the materials used for the clutch were not strong enough to withstand the forces that it will be subjected to. Further development of the design is thus needed to test the BWC on patients and to verify its functioning.

The thesis' goal of designing a passive push-off mechanism that provides adaptable assistance, for the first inGAIT prototype was partially met. A prototype that can provide push-off support was created, however, it does not provide adaptable assistance.

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A

Qualitative Analysis of Open-ended Questions

A.1 Background

In the case of an AFO the end-users include the patients (wearing the device) and the parent (assisting the children in donning and doffing). However, healthcare Professionals (e.g. physicians or orthotists) are also important stakeholders. They decide which AFO is most suitable for the child, and are in charge of manufacturing custom made orthotic bracing solutions. While designing an appropriate AFO it is thus crucial to include both end-user and healthcare professional requirements, needs and wishes.

Questionnaires are a cost-effective, simple and quick tool for gathering information directly from stakeholders. They are thus a useful method for creating a deeper understanding of their needs. A questionnaire can contain closed or open-ended questions. Closed questions are multiple choice (e.g. yes/no, Likert scale) and require quantitative analysis (e.g. statistical analysis, frequency analysis). Open-ended questions (OE), on the other hand, allow respondents to answer in an open text format where they can recollect their complete knowledge. Therefore, these require qualitative analysis methods.

Qualitative analysis condenses non-numeric data (e.g. interview transcripts, survey responses, video and audio recordings) by localising key words and phrases, and categorising them into broader themes [53]. This allows researchers to search for similarities, variations and patterns within a data set, and enables them to extract meaningful knowledge. Choosing the right qualitative analysis approach is essential in obtaining relevant conclusions.

Methods like descriptive phenomenology, grounded theory or discourse analysis can be used for qualitative analysis when research requires high interpretation levels, such as uncovering patterns in social problems, cultural context and people's perception [54–56]. If researchers wish to stay close to the data or high level interpretation is not needed, thematic or content analysis can be performed [57]. While thematic analysis condenses the data to a number of recurrent themes, content analysis goes a step further and includes (quantitative) frequency analysis of these themes [30, 58]. These analyses can be done inductively, by allowing the data to determine the themes, as well as deductively, by defining some preconceived themes that are expected to arise or that fit the research questions [57]. Both thematic and content analysis are popular tools in health care studies [59–61] where highly structured questions gather respondent's views and not their more complex life experiences.

A.2 Method

A.2.1 Study design

Two online surveys were developed within the framework of the inGAIT project [27] in three languages: English, Dutch and Spanish. One questionnaire was directed at healthcare Professionals in the area of CP (GP) and the other one at end-Users with CP to be answered by patients and their families (GU). The purpose of these surveys was to collect information regarding the points of improvements and strong suits of current orthoses. The surveys were approved by the research ethics board of the University of Twente (reference number 2021.91). All responses were anonymous.

The surveys contained closed questions regarding respondents' demographics, AFO prescription, importance of design features, relevance of recording in-home metrics, and expectations towards a new device. The questionnaires also contained three open-ended questions, which were analysed within the present master thesis:

- *OE1:* "Which daily-life activities would benefit from improved gait performance in children with CP?"
- *OE2:* "What changes to the current exoskeletons are needed to improve walking in daily-life situations?"
- *OE3:* "What changes to the current AFOs are needed to improve walking in daily-life situations?"

A.2.2 Data Analysis of the Open-ended Questions

Responses to the OE questions were analyzed using content analysis [30]. Irrelevant answers (e.g. "I don't know") were removed prior to starting the analysis. Data were imported into ATLAS.ti 9 (ATLAS.ti GmbH, Berlin, Germany), and responses were reread multiple times to identify the key thoughts, impressions and concepts. Inductive coding was used to sub-categorize the responses, and the resultant subcategories were grouped into emergent broader themes (categories) through discussion. After finalization of categories and subcategories, all responses were reassessed again to ensure that all data was subjected to the same inclusion criteria when assigning words and phrases to the different categories. Category and subcategory frequencies were assessed. Responses could be labelled with more than one category.

A.3 Results

A.3.1 Respondents

The survey for professionals in the field of CP (GP) was answered by people working in the healthcare sector (e.g. physiotherapists, rehabilitation physicians, surgeons, occupational therapists, orthopaedists), but also by researchers, equipment vendors and orthotists. The target population for the GU survey were primarily CP patients. In case patient could not answer the questionnaire (e.g. too young to understand the questions, severe cognitive impairment), parents or legal caregivers could respond instead.

Eventually, 130 people responded to the questionnaire (94 GU and 36 GP). However, not all participants filled in the OEs. After removing irrelevant answers as described in the section Data Analysis, participation for the GP and GU groups respectively was 91.5% and 91.7% for OE1, 67.0% and 50.0% for OE2, and 76.6% and 61.1% for OE3 (Table A.1). The coding process after data cleaning revealed that in some cases, respondents had either misinterpreted the question (e.g. talking about AFOs for OE2, while this question was referred to changes in exoskeletons) or simply given a response that did not answer the question (e.g. answering “getting around unassisted” for OE1, while the participant was asked to name an activity). These responses were also removed from the analysis, yielding a final response rate of 87.2% and 80.6% for OE1, 63.8% and 47.2% for OE2, and 74.5% and 61.1% for OE3, for GP and GU respectively (Table A.1).

A.3.2 Open-ended Question 1

A total of 12 categories and subcategories were identified during content analysis of OE1 (Table A.2). For OE1, 68.5% of respondents (70.7% GP and 62.1% GU) indicated that *General mobility* in daily-life would benefit from an improved gait performance of the patient. This category encompasses activities or subcategories such as *Walking*, *Stairs*, *Running*, and any other movements that require coordinated motor function of the whole body. Responses to OE1 indicated a need for allowing

Tab. A.1.: Number and percentage of respondents that answered the OEs.
There were a total of 130 (94 Gu and 36 GP) respondents. During data cleaning irrelevant responses (e.g. "I don't know" or "?") were removed. During coding it was discovered that twelve respondents mentioned that all activities of daily life would benefit from improved gait performance in children with CP, responding "all", "all activities" and "daily activities" for example. However, as the question was aimed at uncovering which specific activities were most important to improve gait for in children with CP these responses do not provide more insight and were not considered in the analysis. Moreover, 11 respondents mentioned the goals of improving gait such as "walk normally", "getting around unassisted" or "minimize energy consumption". This does not answer the OEs, and thus these answers were discarded from the analysis as well.

	After data cleaning			After coding		
	All	GP	GU	All	GP	GU
OE1	119 (91.5%)	86 (91.5%)	33 (91.7%)	111 (85.4%)	82 (87.2%)	29 (80.6%)
OE2	81 (63.1%)	63 (67.0%)	18 (50.0%)	77 (59.2%)	60 (63.8%)	17 (47.2%)
OE3	94 (72.3%)	72 (76.6%)	22 (61.1%)	92 (70.8%)	70 (74.5%)	22 (61.1%)

the patient to behave as typically developing children (e.g. "the child has to be able to move in a playful way to the extent what is possible given the child's motor skills: running, climbing, jumping, etc"). Within *General mobility*, *Walking* is deemed as the most important subcategory getting 48,6% of responses (normalized with the participation of both groups), with statements like "ambulation", "displacements"', or "getting from A to B". After *Walking*, *Stairs* and *Running* got normalized response rates of 12.6% and 9.9%, respectively.

The second most frequent category identified based on the answers to OE1 was *Leisure*, with a response rate of 39.6% (45.1% GP and 24.1% GU). It encompasses *Play* (25.2%), *Sports* (16.2%), and all other activities associated with free time that require full body motor function. Some respondents also indicated the importance of having a functional gait pattern in specific locations categorized as *School* (31.5%), *Home* (16.2%) or *Non-standardized Terrains* (18.9%). The latter indicates places with uneven terrain such as parks, playgrounds or nature. Finally, the category *Equal social interaction* (20.7%) was identified, relating to the ability to keep up with able bodied peers and family members.

A.3.3 Open-ended Question 2

A total of 12 categories and subcategories were identified during content analysis of OE2 (Table A.3). Responses for OE2 showed that the first and main problem of powered exoskeletons to be used in daily-life settings is their *Bulkiness* (45% GP, 47.1% GU, 45.5% normalized), including subcategories of *Weight* (31.2%) and *Volume* (27.3%). The second most frequent category was *User friendliness* (39.0%), followed by *Cost* (29.9%), *Control* (28.6%), and *Adaptability* (20.8%) of the device. For *Control*, participants primarily referred to the exoskeleton software and "better controllers with more biomechanical insight".

Categories with lower frequencies were *Availability* (11.7%), the possibility of getting access to an exoskeleton, and *Flexibility & ROM* (7.8%), in which both GP and GU groups would like to have a device with "more joints" and a "better (i.e. less robotic) ROM". Finally there were two categories, *Acceptance* (6.5%) and *Durability* (5.2%), that were only mentioned by the professionals.

Tab. A.2.: Identified themes with corresponding definitions, frequency and percentage of participants that referred to them in their response to OE1: Which daily-life activities would benefit from improved gait performance in children with CP?

Theme	**Definition**	**Frequency**		**Normalized(%)**		
		GP	GU	GP	GU	Total
	n			*82*	*29*	*111*
General mobility	Activities and movements that require coordinated motor function of the whole body: physical activity, jumping, running, cycling, sleeping, standing, climbing, stairs, sitting	58	18	**70.7**	**62.1**	**68.5**
Walking	Walking or displacements (from one place to another)	43	11	**52.4**	**37.9**	**48.6**
Stairs	Climbing and descending stairs	11	3	**13.4**	**10.3**	**12.6**
Running	Running	7	4	**8.5**	**13.8**	**9.9**
Leisure	Leisure activities that require full body motor function (e.g. play, sports, hobbies, trips, holidays)	37	7	**45.1**	**24.1**	**39.6**
Play	Physical play activities such as playing outside or at a playground	24	4	**29.3**	**13.8**	**25.2**
Sport	Sports (e.g. soccer) and physical education	13	5	**15.9**	**17.2**	**16.2**
School	Displacements to and from, around, and inside the school	29	6	**35.4**	**20.7**	**31.5**
Equal social interaction	Ability to keep up with able bodied peers and family members, e.g. during play or trips	21	2	**25.6**	**6.9**	**20.7**
Non-standardised terrain	Places with uneven terrain such as parks, streets, playgrounds or nature	16	5	**19.5**	**17.2**	**18.9**
Home	Displacements around and inside the house	15	3	**18.3**	**10.3**	**16.2**
Other	All other activities that were mentioned, e.g. playing with sand when the device has hinges	2	0	**2.4**	**0.0**	**1.8**

A.3.4 Open-ended Question 3

A total of 17 categories and subcategories were identified during content analysis of OE3 (Table A.4). Responses for OE3 revealed that the most important problem of current AFOs based on end-User opinion is the lack of *Comfort* (21.4% GP, 50% GU), stating phrases like “breathability” and “softer materials”. According to Professionals, the predominant limitation of current AFOs is the *Adaptability* of these devices to both patient’s needs (e.g. type and level of assistance) and environment (e.g. type of walking surface) (55.7% GP, 36.4% GU).

Overall, accounting for normalized responses based on the participation of both stakeholder groups, *Adaptability* was the most frequent category (51.1%). This was followed by *Flexibility* & ROM (22.7%), indicating that current AFOs are too stiff and restraining, and *Comfort* (28.3%). Other identified categories were *Bulkiness* (17.4%), *Weight* (8.7%) and *Wearability* (9.8%), where combining clothes and AFOs was regarded as specifically difficult.

The necessity of new AFOs that reduce *Energy cost* was mentioned by 20% of Professionals, but not by the end-User group. Finally, other identified categories were *Metrics* (9.8%), with answers like “Possibility to test different AFO models with quantitative metrics to evaluate which solution is the best for a specific patient”, *User friendly* (9.8%), *Cost* (8.7%), *Durability* (6.5%) and the improvement of general *Walking* (5.4%). In the latter, some respondents highlighted the necessity to improve *Functional* walking, while others stressed the desire of generating *Normal* walking patterns with AFOs.

A.4 Discussion

Respondents had a multitude of different nationalities, however, most respondents were from Spain and The Netherlands, which could have had an effect on the results. Moreover, many people filled in OE1, while response to OE2 and OE3 was significantly lower. This is probably due to the fact that exoskeletons are a very specific topic that especially end-Users did not know much about. As for OE3, responses might have been lower as people got tired of the survey and did not wish to continue.

For almost all categories for all the OEs GP percentages are higher than GU ones. This was caused by the fact that Professionals gave more elaborate answers and therefore their responses were labelled to correspond to more categories. This caused the conclusion to rely even more on GP opinion compared to GU opinion, as the GP group was already three times larger than the GU group.

Finally, for OE1 and OE2, healthcare Professionals and end-Users agreed on the order of the top three categories, (1) *general mobility*, (2) *leisure* and (3) *school*, and (1) *bulkiness*, (2) *user friendliness* and (3) *cost*, respectively. For OE3, however,

Tab. A.3.: Identified themes with corresponding definitions, frequency and percentage of participants that referred to them in their response to OE2: What changes to the current exoskeletons are needed to improve walking in daily-life situations?

Theme	**Definition**	**Frequency**		**Normalized(%)**		
		GP	GU	GP	GU	Total
	n			*60*	*17*	*77*
Bulkiness	Desire to have a lighter and smaller exoskeleton that is easier to wear and use, as well as more portable and easier to transport	27	8	**45.0**	**47.1**	**45.5**
Weight	The weight of the exoskeleton or parts of the exoskeleton (e.g. batteries) should be decreased	22	2	**36.7**	**11.8**	**31.2**
Volume	The size and volume of the exoskeleton should be decreased	14	7	**23.3**	**41.2**	**27.3**
User friendly	Exoskeletons should be more user friendly, comfortable, easier to use and more simplistic	25	5	**41.7**	**29.4**	**39.0**
Cost	The cost, price or reimbursement (e.g. by health insurance) of exoskeletons is a concern	20	3	**33.3**	**17.6**	**29.9**
Control	The exoskeleton software should ensure better balance control, gait patterns, autonomy, robustness, troubleshooting, consistency and foot placement	19	3	**31.7**	**17.6**	**28.6**
Adaptability	The exoskeleton should be able to better adapt to a patient's anatomy and gait (pattern, stride, speed), as well as to different terrains, to provide a more versatile device that is suitable for a multitude of daily life activities	14	2	**23.3**	**11.8**	**20.8**
Availability	A better/higher availability of exoskeletons for patients is needed	7	2	**11.7**	**11.8**	**11.7**
Other	Any other necessary improvements to exoskeletons that were mentioned, e.g. battery life	5	2	**8.3**	**11.8**	**9.1**
Flexibility & ROM	Desire to have a more flexible device with more freedom of movement, e.g. by including more joints	4	2	**6.7**	**11.8**	**7.8**
Acceptance	Exoskeletons should be more socially accepted and be socially attractive, partly achieved by having an aesthetically pleasing design	5	0	**8.3**	**0.0**	**6.5**
Durability	Durability	4	0	**6.7**	**0.0**	**5.2**

healthcare Professionals indicated *Adaptability*, *Flexibility and ROM*, and *Comfort* to be the top three priorities in descending order. End-Users, on the other hand, indicated *Comfort* to be the highest priority, with *Adaptability* second and *Bulkiness* third. This difference can be explained by the fact that healthcare Professionals think AFOs are more comfortable than end-Users perceive them to be, or by the by the fact that healthcare Professionals are more knowledgeable in the area of AFO functionality, and might thus put more emphasis on this.

A.5 Conclusion

The main points of improvement for exoskeletons, in ascending order, are reducing *Cost*, making them more *User friendly*, and reducing *Bulkiness* (Table A.3). Although these are also valid points to tackle when designing an AFO, the analysis described in this chapter indicates that current AFOs primarily lack *Adaptability*, have limited *Flexibility & ROM*, and lack *Comfort* (Table A.4). A new AFO design would thus benefit from better adaptability to patient anatomy and environment, should be less stiff and restraining and should not harm the foot, ankle and lower leg. Finally, the analysis indicated that AFOs are most often used in daily-life activities of *General mobility* (in which Walking pays a significant role), *Leisure* and *School* (Table A.2). A new design for an AFO should thus be especially suitable for walking, to allow the child to execute displacements at home, outside the house and at school.

Tab. A.4.: Identified themes with corresponding definitions, frequency and percentage of participants that referred to them in their response to OE3: What changes to the current AFOs are needed to improve walking in daily-life situations?

Theme	Definition	Frequency GP	Frequency GU	Normalized(%) GP	Normalized(%) GU	Normalized(%) Total
	n			*70*	*22*	*90*
Adaptability	AFOs should adapt to patient and environmental need better	39	8	**55.7**	**36.4**	**51.1**
Patient assistance	AFOs should deliver optimal gait patterns and assistance to the patient depending on the capabilities and needs of the individual patient	22	4	**31.4**	**18.2**	**28.3**
Environment	AFOs should be able to adapt to the environment. situation and terrain	9	0	**12.9**	**0.0**	**9.8**
Flexibility & ROM	Current AFOs are too stiff and restraining	22	5	**31.4**	**22.7**	**29.3**
Comfort	AFO wear should be more comfortable and not cause skin irritation (blisters, pressure zones, chafing), e.g. by consisting of more breathable and softer materials	15	11	**21.4**	**50.0**	**28.3**
Bulkiness	Desire to have a lighter and smaller AFO that is easier to combine with shoes and clothing	9	7	**12.9**	**31.8**	**17.4**
Wearability	AFOs should be easier to wear underneath clothing and within shoes	4	5	**5.7**	**22.7**	**9.8**
Weight	AFOs should be as light as possible, to improve ease of walking	5	3	**7.1**	**13.6**	**8.7**
Energy cost	Energy cost of walking should be reduced during AFO wear	14	0	**20.0**	**0.0**	**15.2**
Other	Any other necessary improvements to AFOs that were mentioned, e.g. better Velcro	7	3	**10.0**	**13.6**	**10.9**
Metrics	Information or measurements should be available regarding AFO use and choice	8	1	**11.4**	**4.5**	**9.8**
User friendly	AFOs should be simple, easy to use and easy to don/dof	7	2	**10.0**	**9.1**	**9.8**
Cost	AFOs should cost less	5	3	**7.1**	**13.6**	**8.7**
Durability	Durability	5	1	**7.1**	**4.5**	**6.5**
Walking	AFO wear should improve a child's walking ability	3	2	**4.3**	**9.1**	**5.4**
Functional	AFOs should improve functional walking ability	1	2	**1.4**	**9.1**	**3.3**
Normal	AFOs should aid replicability of a normal walking pattern	2	0	**2.9**	**0.0**	**2.2**

TRIZ Analysis

B

B.1 TRIZ Problem I: ADR mechanism provides insufficient push-off support

As discussed in Chapter 4, ADRs might not reduce energy cost off walking compared to other AFOs. This indicates that the push-off power that the ADR generates is insufficient. This problem was further investigated with the first TRIZ pipeline: *eliminate specific negative effect or improve ineffective result* (see Chapter 4).

B.1.1 Information Situation Questionnaire

Table B.1 shows the information situation questionnaire (ISQ) for the ADR mechanism.

B.1.2 RCA+

Figure B.1 shows the RCA+ diagram for the ADR mechanism. Note that there are two main causes for the fact that the ADR provides insufficient support, insufficient push-off torque, and asynchronous support.

B.1.3 Technical Contradictions

The RCA+ yielded the technical contradictions in Figure B.2, which have mixed AND and OR relationships. To select the most promising technical contradiction to solve, a top-down approach was used. Looking at Figure B.1 there is an OR relationship between *"ADR mechanism provides insufficient push-off torque"* and *"Asynchronous push-off support timing"*. These two branches were ranked on severity and being more likely to happen. Table B.2 shows that it would be more promising to improve the fact that the *"ADR mechanism provides insufficient push-off torque"*. Further investigating that branch, an OR relationship can be found between *"Mechanism doesn't adapt to changes in terrain"*, *"Insufficient energy stored in spring"* and *"ADR returns foot to the predetermined natural position"*. Here the AND relationship with

Tab. B.1.: Information situation questionnaire for the ADR mechanism.

Question	Answer
Describe the existing innovative situation in free words	We would like to develop a new AFO with ADR mechanism. However, current ADR provide insufficient push-off support.
Describe a system (product) which must be improved (limit it to those parts which can be changed by you)	ADR mechanism
Describe a key problem extracted	Insufficient push-off support
Describe a goal of improvement (desired result)	Improve the push-off support
Present a list of principal demands and requirements to the future solution (5-10 requirements). Try to be as specific as possible	1. The mechanism should be adjustable and valid for different pilot sizes (age 4-16, max 60kg) 2. The mechanism should be lightweight 3. The device should at least support walking in an indoor, controlled environment (research environment) 4. The mechanism should allow walking on a slope ([-8,8] deg) 5. Required ROM of ankle plantarflexion, adaptable in intermediate values (>= 20 deg) 6. Required ROM of ankle dorsiflexion, adaptable in intermediate values (>=15 deg) 7. The system should be easy to use and easy to adjust 8. The system should be worn with normal clothing/shoes
Are there any known solutions to solve the problem/challenge presents? If yes, mention them and specify why each of them cannot be used in your situation	1. Add a motor to generate push-off *This is too expensive, too heavy and causes issues with limited battery life.* 2. Use less stiff springs *This increases ROM and push-off torque generated by the user but alters ankle biomechanics. No net reduction in energy cost of walking is achieved.* 3. Use a motor for better timing of release of the energy saved in the spring *This would make the device heavier and more expensive.*
Are there any ideas of improvement that have been proposed? Describe ideas which haven't been already obtained (if any). Specify against each idea why it cannot be used.	-

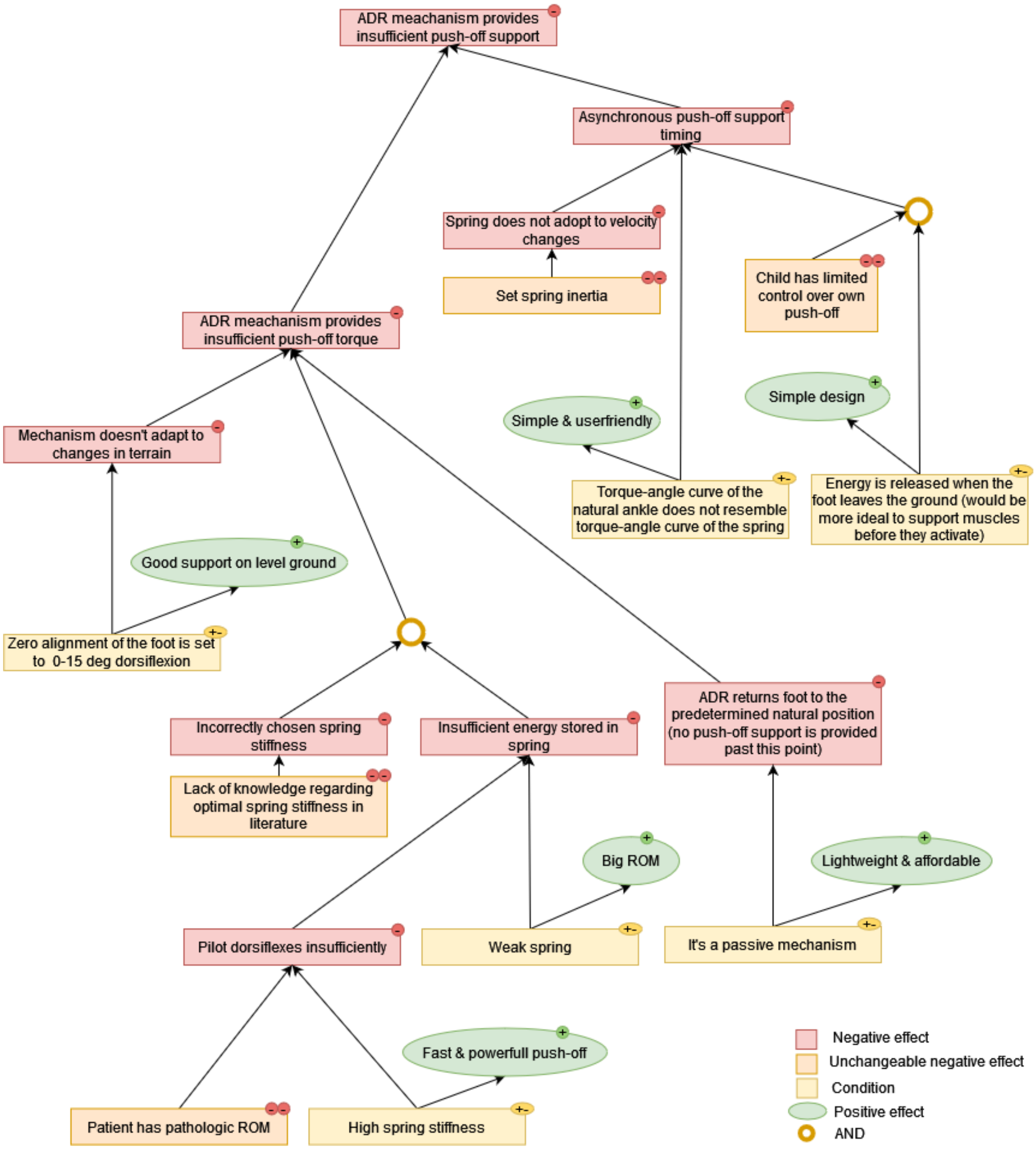

Fig. B.1.: RCA+ diagram of the ADR mechanism.

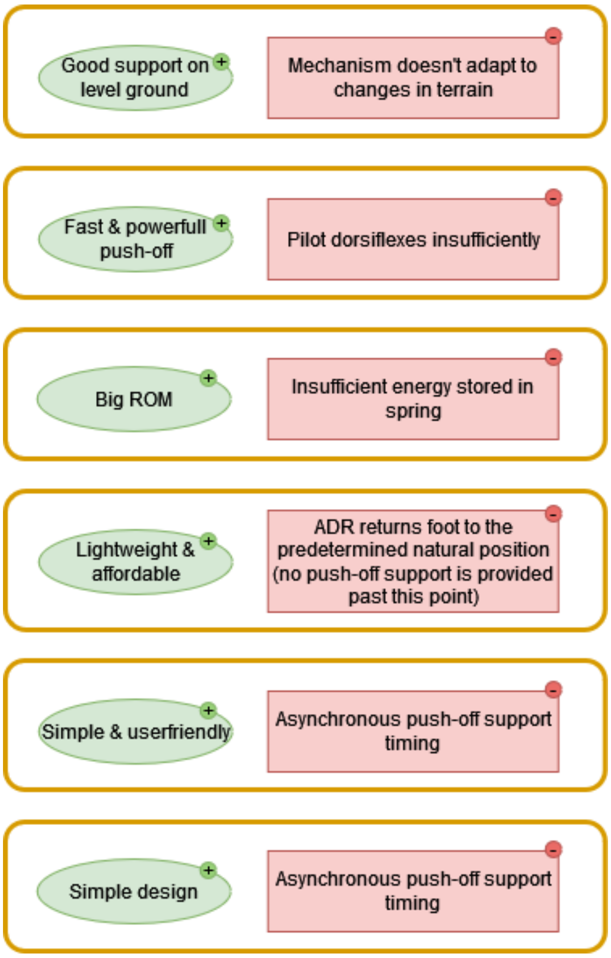

Fig. B.2.: Technical contradictions from the RCA+ for the ADR mechanism.

Tab. B.2.: Ranking of the two main ADR branches

Which is worse or happens more often					
	Problem	**1**	**2**	**Score**	**Rank**
1	ADR mechanism provides insufficient push-off torque		1	1	1
2	Asynchronous push-off support timing	-1		-1	2

"Incorrectly chosen spring stiffness" is disregarded as this pathway does not lead to a technical contradiction. Table B.3 shows the ranking of importance for these three negative effects. Since *"Insufficient energy stored in spring"* is ranked as the most crucial the OR relationship between *"Weak spring"* and *"High spring stiffness"* was evaluated in Table B.4.

B.1.4 Contradiction Matrix

Although TRIZ dictates that the technical contradiction with rank 1 should be solved. It was decided to also investigate the top 3 technical contradictions: *(1) weak spring, (2) high spring stiffness* and *(3) zero alignment of the foot is set to 0-15 deg dorsiflexion*. Especially because solving the third contradiction would be in accordance with the

Tab. B.3.: Ranking of the OR relationship of the left RCA+ branch.

Which is worse or happens more often					
Problem	**1**	**2**	**3**	**Score**	**Rank**
1 Mechanism doesn't adapt to changes in terrain		-1	1	0	2
2 Insufficient energy stored in spring	1		1	2	1
3 ADR returns foot to the predetermined natural postion	-1	-1		-2	3

Tab. B.4.: Ranking of the OR relationship of the left RCA+ branch

Which is worse or happens more often				
Problem	**1**	**2**	**Score**	**Rank**
1 Weak spring		1	1	1
2 High spring stiffness	-1		-1	2

project requirements. Table B.5 shows which of the 40 inventive principles were selected to be investigated further for each of the contradictions.

B.1.5 40 Inventive Principles

The inventive principles from Table B.5 were applied to the three contradictions, and ideas were generated. Subsequently ABC filtering was applied, where (A) indicates *worth considering*, (B) *doubtful*, and (C) *not worth considering*. For each of the three technical contradiction the goal was to have 7 to 8 ideas worth considering. Ideas marked with (*) are not novel and can already be found on the market. These are thus not worth considering.

Weak spring:

3) *Local quality*
   - Use heavier/stronger springs and try to trim down material from the metal casing. (A)
   - Use a nonuniform spring, which allows free movement for small ROM, but provides more power. (A)
   - Use 2 springs with different stiffnesses in series. One weaker one and one stronger one. (*)
   - Use multiple springs with different stiffnesses in series. (B)

Tab. B.5.: Selected inventive principles with contradiction matrix

Contradiction		Positive effect		Negative effect		Principles
1	**Weak spring**	Big ROM	(21) stability (32) adaptability / versatility	Insufficient energy stored in spring	(24) efficiency of functioning	3, 10, 19, 12, 13
2	**High spring stiffness**	Fast & powerful push-off	(14) speed (15) force/moment (18) power	Pilot dorsiflexes insufficiently	(24) efficiency of functioning	35, 13, 2, 28, 19
3	**Zero alignment of the foot is set to 0-15 deg dorsiflexion**	Good support on level ground	(21) stability	Mechanism doesn't adapt to changes in terrain	(32) adaptability / versatility	40, 35, 15, 30

- Have a bend in the metal frame that makes it harder for the spring to compress/extend around, changing the springs properties. (B)
- Have a screw inserted in the frame that can be screwed against the spring, to bend the spring and change the springs properties. (C)
- Measure the patient's torque-angle curve of the ankle, and design a spring that matches that curve, for creating optimal push-off support. (A)
- Instead of using two weak circular springs, use two stronger leaf springs for push-off support. (C)

10) *Prior action*
- Pretension spring so that it will be able to store more energy. (*)
- Allow a higher ROM to the user so that more tibial progression occurs, and the person can safe and release more energy from a passive spring. (C)
- Put in a stiffer spring in the ADR casing. (*)

19) *Periodic action*
- Use multiple weaker springs in parallel. (B)
- Time the release of the spring energy in such a way that it releases right before the patient's muscles activate to generate push-off energy. (A)
- Ensure that the energy release from the springs takes just as long as that of the Achilles tendon. (B)
- Release all energy stored in the spring in the moment where the zero position has not been reached yet, so that all energy can be used. (C)
- Let the user push a button right before push-off to signal the mechanism that it should start providing push-off power. (C)

12) *Equipotentiality*
- Allow the whole mechanism to be lowered or raised with respect to the ankle joint, to ensure different pretensioning of both springs at the same time. (A)
- Offer different foot crutches depending on the patient need, so that the springs are activated/loaded differently for different patients. (B)
- Have movable foot crutches, so that material from the ADR mechanism can be removed and will leave space for bigger/stronger springs. (B)
- Have the set screws detect different pressures of spring tension, so that they will automatically move and adapt to patient needs/terrain changes. (B)

13) *Other way around*
- Turn the mechanism upside down. (C)
- Have the metal foot crutch push the spring in the middle, so that one spring can be used for both dorsiflexion and plantarflexion support. (B)
- Let the mechanism move during the gait cycle, so that it can adapt to different walking terrains. (A)
- Use knee force as well for storing energy in springs. (C)

- Instead of putting springs in a heavy metal casing, use up all this space only with springs, such that there can be stronger springs within the same mechanism volume. (A)

High spring stiffness:

35) *Parameter or property change*
    - Use a non-linear spring, so that it's easier to overcome the first part of the tibial progression phase. (A)
    - Use a motor to change pre-tension of the spring during tibial progression. (C)
    - Have the user push their leg forward into dorsiflexion. (C)
    - Use a motor to push the user towards dorsiflexion. (C)
    - Have the user be pushed by another person to support with tibial progression. (C)
    - Allow a bigger range of replacement springs, such that smaller children can also use the device. (A)
    - Have a flexible casting, such that it will deform if the pressure on the springs gets too high, and tibial progression will still occur. (B)
    - Have the set screws detect different pressures of spring tension, so that they will automatically move and adapt to patient needs/terrain changes. (B)
    - Exchange the springs for pneumatic springs. (A)
    - Fill the casing with a vacuum, to change spring compression properties. (B)
    - Let the spring heat up due to the pressure caused by tibial progression, and let the spring be sensitive to heat such that it becomes easier to deform it when it heats up. (C)
    - Measure the patient's torque-angle curve of the ankle, and design a spring that matches that curve, for creating optimal push-off support. (A)
13) *Other way around*
    - Use a spring that is less stiff. (*)
    - Turn the mechanism upside down, such that spring deformation will occur in a slightly different manner. (B)
    - Instead of providing push-off, provide drop foot support, as this will allow the user to better dorsiflex the foot, and thus to save energy in the springs. (C)
    - Instead of having a hollow casting with a spring in the inside, have a spring around a metal pin, the new "casing". (A)
    - Have the casing move up or down with respect to the ankle joint, for better pretensioning of both springs as the same time. (B)
2) *Taking away*

- Design a smaller casing, which requires smaller springs. (A)
- Have movable foot crutches, so that material from the ADR mechanism can be removed and will leave space for longer, less stiff springs. (B)
- Have the springs attached higher up the child's leg, such that the device feels lighter, and the springs can be made longer and less stiff. (A)

28) *Principle replacement*
    - Use a motor to provide the push-off support and eliminate the need of saving energy in a spring. (C)
    - Let the user pull his/her legs with power from the arms. (C)
    - Use a leg exoskeleton instead of an AFO. (C)
    - Use magnets to drive tibial progression. (C)
    - Let the user push a button when tibial progression resistance force of the spring is too high, such that tension can be released from the spring. (C)

19) *Periodic action*
    - Use 2 springs with different stiffnesses in series. One weaker one and one stronger one. (*)
    - Use multiple springs with different stiffnesses in series. (B)
    - Use a motor to move up the tension spring during the phase of gait where tibial progression should be supported. (C)

Zero alignment of the foot is set to 0-15 deg dorsiflexion:

40) *Composite structures*
    - AFO from composite material, that is flexible and forms with shape of the terrain. (B)
    - Use multiple layers of springs, to have different support properties dependent on the ankle angle. (B)

35) *Parameter or property change*
    - Use vacuum chamber instead of springs, when terrain gets hilly air can be added to the chamber to change the zero alignment. (B)
    - Have the mechanism be able to turn around the joint, so that the user can easily set the zero alignment. (A)
    - Have two motors in the ADR that control the pretension of the frontal and dorsal springs. (C)
    - Have a sensor in the device that will detect forces on the springs that indicate that someone is not walking on level ground, so that a motor can change the ADR settings. (C)
    - Allow the whole mechanism to be lowered or raised with respect to the ankle joint, to ensure different pretensioning of both springs at the same time. (A)

- Fill the casing with a material that becomes more viscous upon impact, such that sudden unexpected changes of the ROM are not allowed, and stability is provided. (B)
- Use non-linear springs to allow certain ROM non-rigid stops. (A)
- Use multiple smaller springs with different properties, and individually pretension them to select the right spring properties. (B)
- Have two stop blocks, one for dorsiflexion and one for plantar flexion, of which the position can be changed. (A)
- Pretension the springs in such a way that the right ROM is allowed. (*)
- Attach the springs to the lower leg and foot crutches directly, without using a casing. (A)
- Have multiple holes cut out of the lower leg crutch in which the springs can be fitted. (C)
- Have the spring attach to a chain with multiple hooks, which can be attached to a pin on the lower leg crutch, allowing pretension of the spring as desired. (C)

15) *Dynamization*
   - If there is a sudden change in ADR load, let the mechanism disconnect such that the person can freely move the ankle. If normal walking pattern/level ground is detected, switch it on again. (B)
   - Have the set screws detect different pressures of spring tension, so that they will automatically move and adapt to patient needs/terrain changes. (C)
   - If high force is detected activate ROM stop to prevent further movement. (B)
   - Have movable foot crutches, so that material from the ADR mechanism can be removed and will leave space for bigger/stronger springs. (B)
   - Have a motor change the position of the setscrews according to the required ROM needed at a certain phase of the gait cycle. (C)

30) *Thin films and flexible shells*
   - Instead of using a heavy metal shell use two pneumatic springs, that provide the ADR functionality on their own. (A)
   - Make the casing flexible. (C)
   - Make the casing height variable. (A)

B.1.6 Assessment and Selection

ABC filtering was applied, see Section B.1.5. Ideas marked with (A) were subsequently submitted to a *Multi-Criteria Decision Matrix (MCDM)* (see Table B.6) based on the requirements specified in the ISQ (see Table B.1). Ideas landscaping was then applied to incorporate ideas cost and complexity (see Figures B.3, B.4 and B.5), and

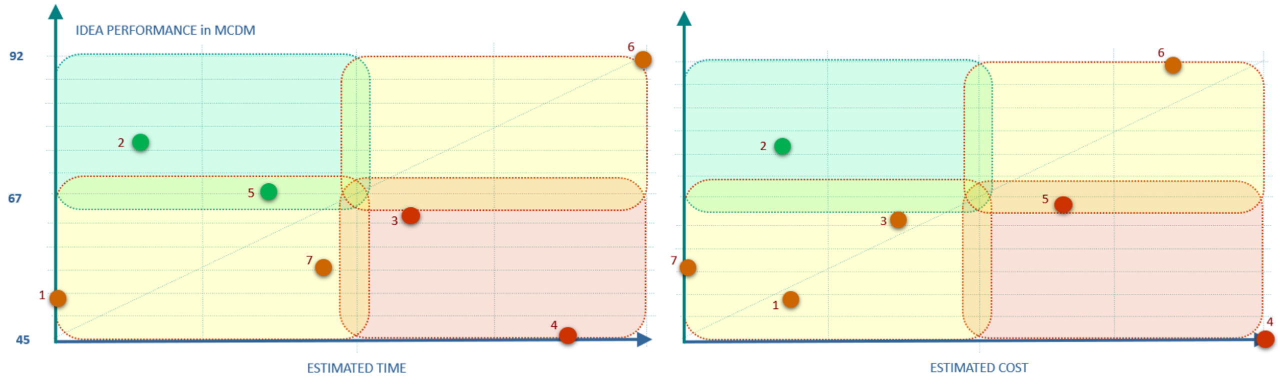

Fig. B.3.: Ideas landscapes for “weak spring”. Idea 3,4 and 6 are not worth considering.

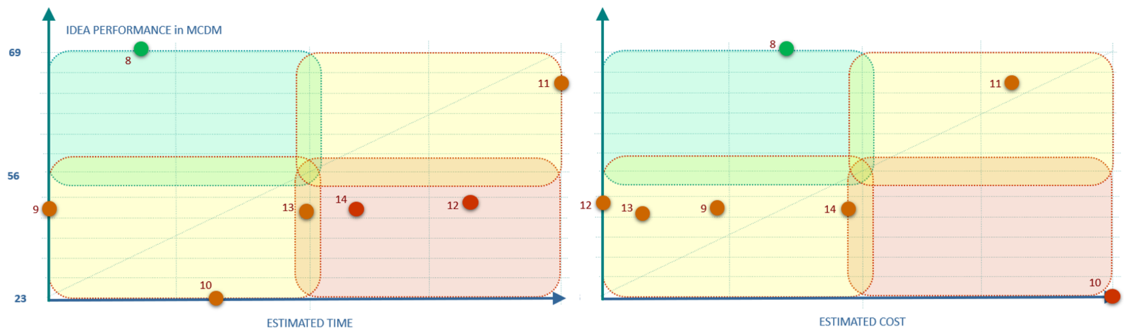

Fig. B.4.: Ideas landscape for “high spring stiffness”. Idea 10 and 14 are not worth considering.

the most promising ideas were selected for each contradiction. Ideas from Table B.6 that were not deemed to be worth considering in the ideas landscaping were marked lighter grey in Table B.6. Promising ideas were subsequently subjected to a MCDM based on TRIZ criteria (see Table B.7). This yielded the following ideas to be worth considering for ideation:

1. *Weak spring:* Instead of putting springs in a heavy metal casing, use up all this space only with springs, such that there can be stronger springs within the same mechanism volume.
2. *High spring stiffness:* Measure the patient’s torque-angle curve of the ankle, and design a spring that matches that curve, for creating optimal push-off support.
3. *Zero alignment of the foot is set to 0-15 deg dorsi flexion:* Have the mechanism be able to turn around the joint, so that the user can easily set the zero alignment.

Tab. B.6.: MCDM of the ADR mechanism ideas based on the ISQ.

	Ideas	The mechanism should be adjustable and valid for different pilot sizes (age 4-16, max 60kg)	The mechanism should be lightweight	The device should at least support walking in an indoor, controlled environment (research environment)	The mechanism should allow walking on a slope ([-8,8] deg)	Required ROM of ankle plantarflexion, adaptable in intermediate values (>= 20 deg)	Required ROM of ankle dorsiflexion, adaptable in intermediate values (>=15 deg)	The system should be easy to use and easy to adjust	The system should be worn with normal clothing/shoes	total
	Weight	*5*	*3*	*5*	*3*	*4*	*4*	*4*	*3*	
Weak spring	1 Use heavier/stronger springs, and try to trim down material from the metal casing.	2	5	2	0	0	0	2	3	52
	2 Use a nonuniform spring, which allows free movement for small ROM, but provides more power.	1	2	4	1	2	2	4	2	72
	3 Measure the patient's torque-angle curve of the Achilles tendon, and design a spring that matches that curve, for creating optimal push-off support.	4	2	4	0	0	0	3	2	64
	4 Time the release of the spring energy in such a way that it releases right before the patient's muscles activate to generate push-off energy.	0	2	4	1	0	0	3	2	47
	5 Allow the whole mechanism to be lowered or raised with respect to the ankle joint, to ensure different pretensioning of both springs at the same time.	2	0	2	3	3	3	2	2	67
	6 Let the mechanism move during the gait cycle, so that it can adapt to different walking terrains.	4	0	2	5	4	4	3	1	92
	7 Instead of putting springs in a heavy metal casing, use up all this space only with springs, such that there can be stronger springs within the same mechanism volume.	2	5	2	0	0	0	2	5	58
High spring stiffness	8 Use a non-linear spring, so that it's easier to overcome the first part of the tibial progression phase.	2	2	4	1	2	2	2	2	69
	9 Allow a bigger range of replacement springs, such that smaller children can also use the device.	2	2	2	1	0	0	2	2	43
	10 Exchange the springs for pneumatic springs.	0	2	0	0	0	0	2	3	23
	11 Measure the patient's torque-angle curve of the Achilles tendon, and design a spring that matches that curve, for creating optimal push-off support.	4	2	4	0	0	0	3	2	64
	12 Instead of having a hollow casting with a spring in the inside, have a spring around a metal pin, the new "casing".	0	5	0	0	0	0	3	5	42
	13 Design a smaller casing, which requires smaller springs.	0	4	1	0	0	0	3	4	41
	14 Have the springs attached higher up the child's leg, such that the device feels lighter and the springs can be made longer and less stiff.	0	4	2	0	0	0	3	2	40
Zero alignment of the foot is set to 0-15 deg dorsiflexion	15 Have the mechanism be able to turn around the joint, so that the user can easily set the zero alignment.	3	0	2	5	3	3	2	1	75
	16 Allow the whole mechanism to be lowered or raised with respect to the ankle joint, to ensure different pretensioning of both springs at the same time.	3	0	2	4	3	3	2	1	72
	17 Use non-linear springs to allow certain ROM non-rigid stops.	1	2	3	1	1	1	2	2	51
	18 Have two stop blocks, one for dorsiflexion and one for plantar flexion, of which the position can be changed.	3	0	2	1	5	5	2	2	82
	19 Attach the springs to the lower leg and foot crutches directly, without using a casing.	0	5	0	0	0	0	2	4	35
	20 Instead of using a heavy metal shell use two pneumatic springs, that provide the ADR functionality on their own.	0	5	0	0	0	0	3	2	33
	21 Make the casing height variable.	3	0	1	1	4	4	3	2	73

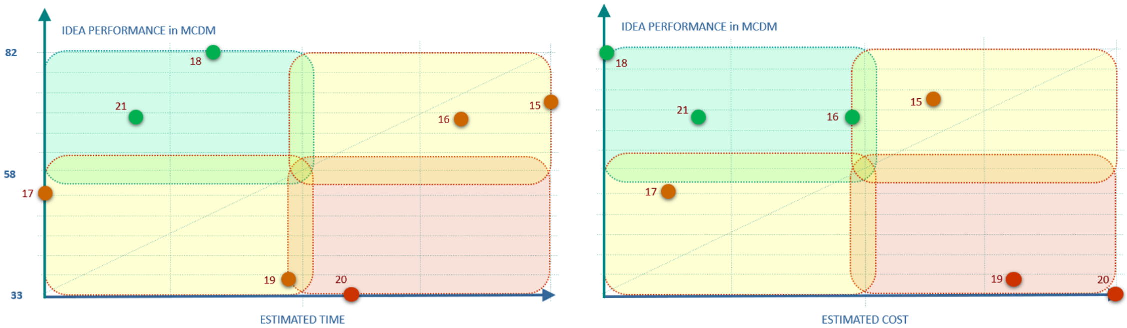

Fig. B.5.: Ideas landscape for "zero alignment of the foot is set to 0-15 deg dorsiflexion". Idea 19 and 20 are not worth considering.

Tab. B.7.: MCDM of the ADR mechanism ideas based on TRIZ criteria.

		Ideas	Solves a problem in full: a desired result is fully achieved, no compromise.	Eliminates a contradiction in a "win-win" way. Nobody and nothing suffers.	Has the highest degree of costs-effectiveness, or preferably, free (or "ideal").	Produces no harmful side effects.	Provides extra benefits.	total
		Weight	*5*	*4*	*3*	*2*	*1*	
Weak spring	1	Use heavier/stronger springs, and try to trim down material from the metal casing.	3	5	3	5	0	54
	2	Use a nonuniform spring, which allows free movement for small ROM, but provides more power.	3	4	3	5	2	52
	5	Allow the whole mechanism to be lowered or raised with respect to the ankle joint, to ensure different pretensioning of both springs at the same time.	1	2	2	4	1	28
	7	**Instead of putting springs in a heavy metal casing, use up all this space only with springs, such that there can be stronger springs within the same mechanism volume.**	**5**	**5**	**3**	**3**	**3**	**63**
High spring stiffness	8	Use a non-linear spring, so that it's easier to overcome the first part of the tibial progression phase.	3	3	3	5	2	48
	9	Allow a bigger range of replacement springs, such that smaller children can also use the device.	2	1	3	4	1	32
	11	**Measure the patient's torque-angle curve of the Achilles tendon, and design a spring that matches that curve, for creating optimal push-off support.**	**4**	**4**	**2**	**5**	**3**	**55**
	12	Instead of having a hollow casting with a spring in the inside, have a spring around a metal pin, the new "casing".	1	3	3	3	3	35
	13	Design a smaller casing, which requires smaller springs.	1	3	3	5	2	38
Zero alignment of the foot is set to 0-15 deg dorsiflexion	**15**	**Have the mechanism be able to turn around the joint, so that the user can easily set the zero alignment.**	**4**	**4**	**2**	**5**	**2**	**54**
	16	Allow the whole mechanism to be lowered or raised with respect to the ankle joint, to ensure different pretensioning of both springs at the same time.	3	4	2	4	1	46
	17	Use non-linear springs to allow certain ROM non-rigid stops.	2	2	3	4	0	35
	18	Have two stop blocks, one for dorsiflexion and one for plantar flexion, of which the position can be changed.	2	2	3	3	0	33
	21	Make the casing height variable.	3	2	3	4	2	42

Tab. B.8.: Information situation questionnaire for the bodyweight controlled clutch.

Question	Answer
Describe the existing innovative situation in free words	We would like to develop a new AFO with bodyweight controlled push-off mechanism. However, current bodyweight controlled clutches do not provide ROM restrictions.
Describe a system (product) which must be improved (limit it to those parts which can be changed by you)	Bodyweight controlled clutch
Describe a key problem extracted	Insufficient ROM restriction
Describe a goal of improvement (desired result)	Improve ROM adaptability
Present a list of principal demands and requirements to the future solution (5-10 requirements). Try to be as specific as possible	1. The mechanism should be adjustable and valid for different pilot sizes (age 4-16, max 60kg) 2. The mechanism should be lightweight 3. The device should at least support walking in an indoor, controlled environment (research environment) 4. The mechanism should allow walking on a slope ([-8,8] deg) 5. Required ROM of ankle plantarflexion, adaptable in intermediate values (>= 20 deg) 6. Required ROM of ankle dorsiflexion, adaptable in intermediate values (>=15 deg) 7. The system should be easy to use and easy to adjust 8. The system should be worn with normal clothing/shoes
Are there any known solutions to solve the problem/challenge presents? If yes, mention them and specify why each of them cannot be used in your situation	1. Use a stiffer spring *This would only alter dorsiflexion ROM during stance, as it inhibits tibial progression. It does not provide additional stability during walking.*
Are there any ideas of improvement that have been proposed? Describe ideas which haven't been already obtained (if any). Specify against each idea why it cannot be used.	-

B.2 TRIZ Problem II: Bodyweight Controlled Clutch Lacks ROM Control

Table 4.1 shows that the bodyweight controlled push-off mechanism especially lacks in the possibility of having an adaptable ROM, or any way of limiting the ROM for that matter, while it performs well on the other project criteria. Similar to the ADR, the bodyweight controlled push-off mechanism was thus subjected to the first TRIZ pipeline indicated in Chapter 4: *eliminate specific negative effect or improve ineffective result*.

B.2.1 Information Situation Questionnaire

Table B.8 shows the ISQ for the bodyweight controlled clutch.

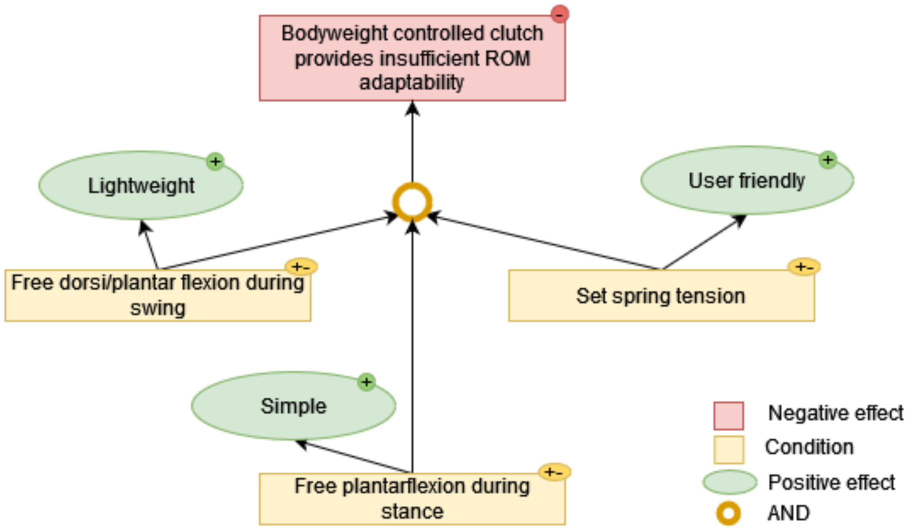

Fig. B.6.: RCA+ diagram of the bodyweight controlled clutch mechanism.

B.2.2 RCA+

Figure 11 shows the RCA+ diagram for the bodyweight controlled clutch. Note that, on top of dorsi and plantar flexion, the bodyweight controlled clutch also allows inversion and eversion, and induction and adduction. As the project requirements [14] do not specify any need for having adaptability of ROM in this direction, only that it would be desirable to allow two degrees of inversion and eversion, these were not included as a problem within the RCA+.

B.2.3 Technical Contradictions

The RCA+ yielded the technical contradictions in Figure B.7, which were subsequently ranked in Table B.9 to B.12, according to the three TRIZ criteria: (C1) *Includes the lowest number of components*, (C2) *Includes easier to change components*, and (C3) *Aligns with business strategy*. According to the ranking it would be most beneficial to incorporate a way of limiting plantar flexion during stance, subsequently having adaptable spring tension would be worth looking into, and thirdly it would be beneficial to incorporate dorsi and plantar flexion limitations during the swing phase of walking, see Table B.12.

B.2.4 Contradiction Matrix

Although TRIZ dictates that the technical contradiction with rank 1 should be solved. It was decided to also investigate the other 2 contradictions, as solving multiple contradictions will lead to a more robust design. Table B.13 shows which of the

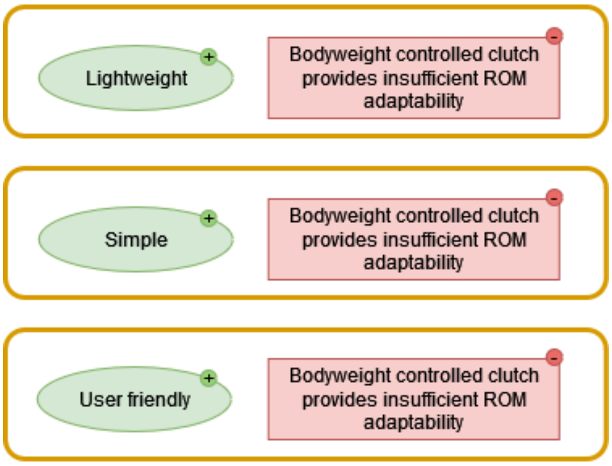

Fig. B.7.: Technical contradictions from the RCA+ for the bodyweight controlled clutch.

Tab. B.9.: Ranking of the technical contradictions of the bodyweight controlled clutch, according to criteria 1: *includes the lowest number of components*.

C1: Includes the lowest number of components					
	Problem	**1**	**2**	**3**	**Score**
1	Free dorsi/plantar flexion during swing		-1	-1	-2
2	Free plantar flexion during stance	1		0	1
3	Set spring tension	1	0		1

Tab. B.10.: Ranking of the technical contradictions of the bodyweight controlled clutch, according to criteria 2: *includes easier to change components*.

C2: Includes easier to change components					
	Problem	**1**	**2**	**3**	**Score**
1	Free dorsi/plantar flexion during swing		0	-1	-1
2	Free plantar flexion during stance	0		0	0
3	Set spring tension	1	0		1

Tab. B.11.: Ranking of the technical contradictions of the bodyweight controlled clutch, according to criteria 3: *Aligns with business strategy*.

C3: Aligns with business strategy					
	Problem	**1**	**2**	**3**	**Score**
1	Free dorsi/plantar flexion during swing		1	1	2
2	Free plantar flexion during stance	-1		1	0
3	Set spring tension	-1	-1		-2

Tab. B.12.: Ranking of the technical contradictions of the bodyweight controlled clutch.

Total score						
	Problem	**C1**	**C2**	**C3**	**Score**	**Rank**
1	Free dorsi/plantar flexion during swing	-2	-1	2	-1	3
2	Free plantar flexion during stance	1	0	0	1	1
3	Set spring tension	1	1	-2	0	2

Tab. B.13.: Selected inventive principles with contradiction the matrix, for the bodyweight controlled clutch.

Contradiction		Positive effect		Negative effect		Principles
1	**Free plantar flexion during stance**	Simple	(45) complexity of a system	Insufficient ROM adaptability	(32) adaptability / versatility	29, 28, 1, 24
2	**Set spring tension**	User friendly	(34) convenience/usability	Insufficient ROM adaptability	(32) adaptability / versatility	10, 25, 1, 26, 5
3	**Free dorsi/plantar flexion during swing**	Lightweight	(1) weight of moving object, (2) weight of immobile object	Insufficient ROM adaptability	(32) adaptability / versatility	15, 29, 35, 28, 3, 19

40 inventive principles were selected to be investigated further for each of the contradictions.

B.2.5 40 Inventive Principles

The inventive principles from Table B.13 were applied to the three contradictions, and ideas were generated. Subsequently ABC filtering was applied, where (A) indicates *worth considering*, (B) *doubtful*, and (C) *not worth considering*. For each of the three technical contradiction the goal was to have 7 to 8 ideas worth considering. Ideas marked with (*) are not novel and are thus not worth considering.

Preventing free plantar flexion during stance:

29) *Use of gas and fluids*
- Have a bag of air under the foot. When weight is put on it the air flows towards the back of the heel, preventing plantarflexion. (C)
- Have a bag of water under the foot. When weight is put on it water flows to the back of the heel, preventing plantarflexion. (C)
- Blow air out of the back of the device to prevent leg from moving backward. (C)
- Surround the device with water, as this will slow down any plantar flexion movement. (C)
- Have the spring in an inflatable bag, that fills with air when dorsiflexion is initiated and prevents some resistance against plantarflexion. (C)

28) *Principle replacement*
- Include a rigid plantarflexion stop block. (C)
- Include the spring mechanism in an AFO with plantarflexion stop. (C)
- Include a rubber plantarflexion stop, for damping the stopping motion. (A)
- Have an adjustable plantarflexion stop: (A)
  - Have a plantarflexion stop in the form of a screw, that can be moved deeper or less deep into the AFO shell. (A)

- Have a movable 'bridge' at the back of the heel, that can be moved up or down, depending on where you want the plantarflexion to be stopped. (A)

- Include a joint with plantarflexion stop in the AFO. (A)
- Put the spring in a rigid tube. So that it cannot buckle and will have a plantarflexion stop. (B)
- Put the spring in a telescopic tube so that it can be made longer or shorter, according to the patient needs. (B)
- Use a pneumatic spring, which cannot buckle and thus provides a plantarflexion stop. (A)
- Include an ankle-joint that restrains a lot of the ankle's degrees of freedom. (C)
- Activate a magnet that prevents plantarflexion, during the stance phase. (C)
- Pressure on the foot heats a thermal locking mechanism, preventing plantarflexion. (C)
- A motor locks plantarflexion during stance. (C)

1) *Segmentation*
   - Include a second spring to constrain plantar flexion movement. (A)
   - Use two elastics to the side of the device to restrain plantar flexion. (B)
   - Incorporate an ankle hinge that only allows dorsiflexion movement when weight is put on the foot. (A)
   - Upon clutching not only the spring but also some plantarflexion restraining string gets clutched. (A)

24) *Intermediary*
   - Include a motor that moves a plantarflexion stop as desired. (C)
   - Have the user exert a force with his/her hands to prevent plantarflexion. (C)
   - Have the spring deactivate when the user performs plantar flexion when the spring is clutched. (B)

Set spring tension:

10) *Prior action*
   - When switching or attaching springs, the physicians should make sure that the spring is pretensioned properly, by adjusting the length of the cord connected to the spring. (*)
   - Mechanism to adjust spring pretension: (A)
     - Have a crank at the back of the leg with witch the spring can be pretensioned. (A)
     - Use screw to pretension spring. (A)
   - Choose a spring with a suitable stiffness. (*)

- Use a non-linear spring that matches the ankle torque-force profile. (A)

25) *Self-service*
    - A spring in the nose of the mechanism automatically resets the system. The front spring / calf spring ratio should be tuned in accordance with the calf spring stiffness. (*)
    - A motor measures spring tension and can vary spring stiffness throughout the gait cycle. (C)
    - Have the mechanism switch springs according to terrain differences or based on where in the gait cycle the user is. (C)
    - An infrared sensor scans the terrain and predicts what type of springs stiffness would be necessary for optimal AFO support. (C)
    - If the tension in the spring gets too high, give some room for movement by reducing spring pretension. (B)

1) *Segmentation*
    - Have a necklace system, where you can select the ring that you want to hook onto the AFOs leg crutch, to select spring pretension. (A)
    - Have a spring cord with removable elements, so that you can remove rings of metal for higher tension. (B)
    - Have the spring build up out of two different springs with different stiffnesses. (A)
    - Have multiple attachment points for the spring, such that the user can choose which one would provide the best spring tension. (A)
    - Have a carabiner like system that clutches the cord that the spring is attached to, that allows a continuous range of different spring pretensions. (A)
    - Have a telescopic distal spring attachment that can be made shorter and longer, depending on the force required. (B)
    - Have a segmentable spring, that can be made shorter or longer by connecting or removing extra pieces of spring. (B)

26) *Use copies and models*

5) *Merging*
    - Yandell et al. [3] merged the mechanism compared to Liu et al. [7]. Where the spring is now attached to the mechanical sensor at all times. (*)
    - Have the foot plate be elastic and safe the energy. (C)

Prevent free dorsi/plantar flexion during swing:

15) *Dynamization*
    - Ensure that the attachment point of the calf spring can be moved up and down. (B)

- Have a non-elastic cord in parallel with the spring that stops dorsiflexion. (B)
- Incorporate the mechanism in a rigid mechanism that constrains the ankle. (A)
- Incorporate the mechanism in a classic, DoF restraining AFO. (A)
- Include dorsi and plantar flexion stops. (A)
- Have a mechanical lock that locks the foot in place when the user moves their foot too fast. (B)
- Hold the foot in the optimal position for initiating push-off during swing. (B)
- Have a spring activate if the foot drags along the ground, that lifts the foot. (C)
- Have a set swing phase position, in which the foot is situated during each swing phase that can be manually adjusted to the patient. (B)

29) *Use of gases and liquids*
   - Have a joint filled with air, if you flex too much the air gets compressed and the ankle cannot move in that direction anymore. (C)
   - Have a joint filled with water, if you flex too much the water gets compressed and the ankle cannot move in that direction anymore. (C)
   - Blow air out of the device to prevent the foot from doing extensive dorsi or plantar flexion. (C)
   - Surround the device with water, as this will slow down any foot flexion. (C)
   - Have the spring in an inflatable bag, that fills with air when dorsi or plantar flexion is initiated and prevents some resistance against dorsi or plantarflexion. (C)

35) *Parameter or property change*
   - Include an ankle joint in the design with dorsi/plantarflexion stops. (A)
   - Have a bag of water around the foot, that freezes during swing such that the ankle cannot move. (C)

28) *Principle replacement*
   - Have the user hold his/her leg during the swing phase. (C)
   - Have the user hold cords connected to their hands, such that they can influence foot position during swing phase. (C)
   - Activate a magnet that prevents too much dorsi and plantarflexion during the swing phase. (C)
   - A motor locks excessive dorsi and plantarflexion during swing. (C)
   - Use nonrigid cords to partially restrain ankle ROM. (A)

3) *Local quality*
   - Use a nonuniform / nonlinear spring, to have the spring force more resemble the human anatomy. (B)

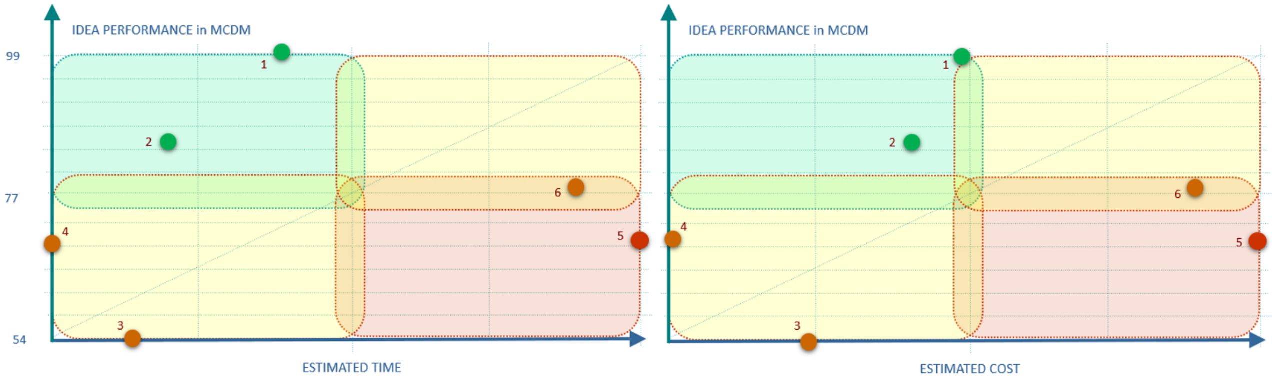

Fig. B.8.: Ideas landscapes for "preventing free plantarflexion during stance". Idea 5 and 6 are not worth considering.

- Make up a spring of multiple parts. Have them confined by movable sticks, such that the spring pushes against different positions and different spring tension is created upon dorsi and plantar flexion. (B)

19) *Periodic action*
    - Restrain the ankle during swing only. (B)

B.2.6 Assessment and Selection

ABC filtering was applied, see Section B.2.5. Ideas marked with (A) were subsequently submitted to a *Multi-Criteria Decision Matrix (MCDM)* (see Table B.14) based on the requirements specified in the ISQ (see Table B.8). Ideas landscaping was then applied to incorporate ideas cost and complexity (see Figures B.8 to B.9), and the most promising ideas were selected for each contradiction. Ideas from Table B.14 that were not deemed to be worth considering in the ideas landscaping were marked lighter grey in Table B.14. Promising ideas were subsequently subjected to a MCDM based on TRIZ criteria (see Table B.15). This yielded the following ideas to be worth considering for prototyping:

1. *Preventing free plantarflexion during stance:* Include a joint with plantarflexion stop in the AFO.
2. *Set spring tension:* Mechanism to adjust spring pretension.
3. *Prevent free dorsi/plantar flexion during swing:* Incorporate the mechanism in a rigid mechanism that constrains the ankle.

Tab. B.14.: MCDM of the bodyweight controlled clutch ideas based on the ISQ.

	Ideas	The mechanism should be adjustable and valid for different pilot sizes (age 4-16, max 60kg)	The mechanism should be lightweight	The device should at least support walking in an indoor, controlled environment (research	The mechanism should allow walking on a slope ([-8,8] deg)	Required ROM of ankle plantarflexion, adaptable in intermediate values (>= 20 deg)	Required ROM of ankle dorsiflexion, adaptable in intermediate values (>=15 deg)	The system should be easy to use and easy to adjust	The system should be worn with normal clothing/shoes	total
	Weight	5	3	5	3	4	4	4	3	
Preventing free plantarflexion during stance	1 Have an adjustable plantarflexion stop.	5	3	3	3	4	0	4	3	99
	2 Include a joint with plantarflexion stop in the AFO.	4	3	3	2	3	0	3	3	83
	3 Use a pneumatic spring, which cannot buckle and thus provides a plantarflexion stop.	2	2	2	1	1	0	3	3	54
	4 Include a second spring to constrain plantar flexion movement.	3	4	2	2	2	0	2	3	68
	5 Incorporate an ankle hinge that only allows dorsiflexion movement when weight is put on the foot.	3	2	3	2	3	0	1	3	67
	6 Upon clutching not only the spring but also some plantarflexion restraining string gets clutched.	3	3	3	2	3	0	3	3	78
Set spring tension	7 Mechanism to adjust spring pretension.	4	3	3	3	2	2	4	3	94
	8 Use a non-linear spring that matches the Achilles torque-force profile.	2	4	4	1	1	1	3	3	74
	9 Have a necklace system, where you can select the ring that you want to hook onto the AFOs leg crutch, to select spring pretension.	4	3	3	3	3	3	4	4	105
	10 Have the spring build up out of two different springs with different stiffnesses.	2	4	3	1	1	1	3	3	69
	11 Have multiple attachment points for the spring, such that the user can choose which one would provide the best spring tension.	4	3	3	3	3	3	4	3	102
	12 Have a carabiner like system that clutches the cord that the spring is attached to, that allows a continuous range of different spring pretensions.	4	2	3	4	2	3	3	2	91
Free dorsi/plantar flexion during swing	13 Incorporate the mechanism in a rigid mechanism that constrains the ankle.	3	1	3	1	2	2	2	2	66
	14 Incorporate the mechanism in a classic, DoF restraining AFO.	3	1	2	1	1	1	2	2	53
	15 Include dorsi and plantar flexion stops.	3	2	3	2	3	3	3	3	87
	16 Include an ankle joint in the design with dorsi/plantarflexion stops.	3	2	3	2	3	3	3	3	87
	17 Use nonrigid cords to partially restrain ankle ROM.	3	4	3	2	3	3	3	4	96

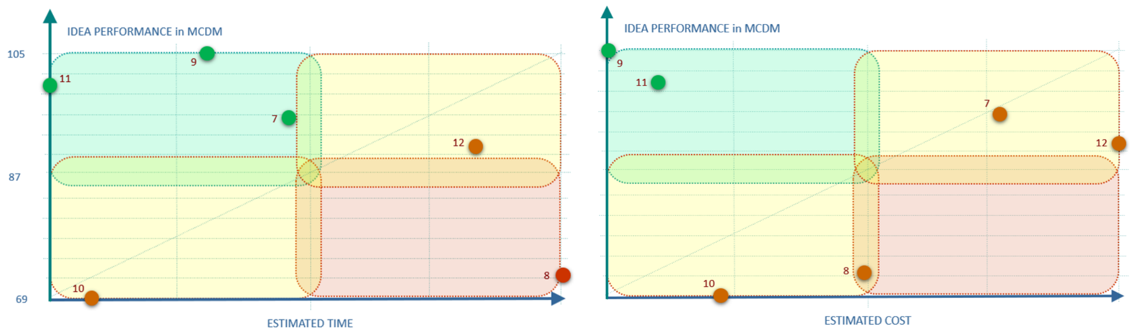

Fig. B.9.: Ideas landscape for "set spring stiffness". Idea 8 and 12 are not worth considering.

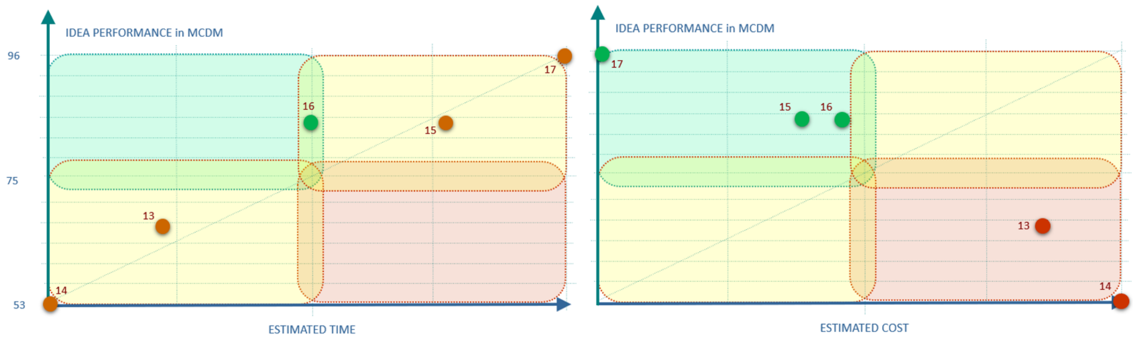

Fig. B.10.: Ideas landscape for "Prevent free dorsi/plantar flexion during swing". Idea 14 is not worth considering.

Tab. B.15.: MCDM of the ADR mechanism ideas based on TRIZ criteria.

	Ideas	Solves a problem in full: a desired result is fully achieved, no compromise.	Eliminates a contradiction in a "win-win" way. Nobody and nothing suffers.	Has the highest degree of costs-effectiveness, or preferably, free (or "ideal").	Produces no harmful side effects.	Provides extra benefits.	total
	Weight	*5*	*4*	*3*	*2*	*1*	
Preventing free plantarflexion during stance	1 Have an adjustable plantarflexion stop.	4	3	4	4	0	52
	2 Include a joint with plantarflexion stop in the AFO.	**4**	**4**	**4**	**4**	**2**	**58**
	3 Use a pneumatic spring, which cannot buckle and thus provides a plantarflexion stop.	2	1	2	2	0	24
	4 Include a second spring to constrain plantar flexion movement.	2	1	1	4	0	25
Set spring tension	**7 Mechanism to adjust spring pretension.**	**4**	**3**	**4**	**4**	**2**	**54**
	9 Have a necklace system, where you can select the ring that you want to hook onto the AFOs leg crutch, to select spring	4	3	4	3	2	52
	10 Have the spring build up out of two different springs with different stiffnesses.	2	2	1	2	0	25
	11 Have multiple attachment points for the spring, such that the user can choose which one would provide the best spring	4	3	4	3	2	52
Free dorsi/plantar flexion during swing	**13 Incorporate the mechanism in a rigid mechanism that constrains the ankle.**	**4**	**4**	**4**	**3**	**3**	**57**
	15 Include dorsi and plantar flexion stops.	3	3	4	2	3	46
	16 Include an ankle joint in the design with dorsi/plantarflexion	3	3	3	4	2	46
	17 Use nonrigid cords to partially restrain ankle ROM.	2	2	2	4	1	33

B.3 TRIZ Problem III: A Leaf Spring Powered Push-off Mechanism

The leaf spring mechanism was subjected to the second TRIZ pipeline, *discover problems, and improve system's functionality*, using the following TRIZ tools: *function analysis, function model, Su-field model, 76 inventive standards,* and *assessment and selection*.

B.3.1 Function Analysis

Figure B.11 shows that the push-off mechanism as incorporated in a foot prosthesis consists of a *motor encoder, DC motor, slider, virtual spring pivot, lead screw, fiberglass leaf spring, cam follower, cam profile, ankle axis* and *pyramid adaptor*. However, as the goal is to design an pros, the function analysis was performed with the prospective of attaching the leaf spring-cam to a leg. The leaf spring's main function then becomes creating a plantarflexion moment around the ankle. The *ankle* can thus be considered as the system's target. When adapting the prosthesis to an orthosis, the mechanism components remain the same but are now contained in a leg *strut*. An *insole* was added to support the foot. This insole is worn inside of a shoe. Supersystem components thus include the *foot*, the *leg*, and the *shoe*. All

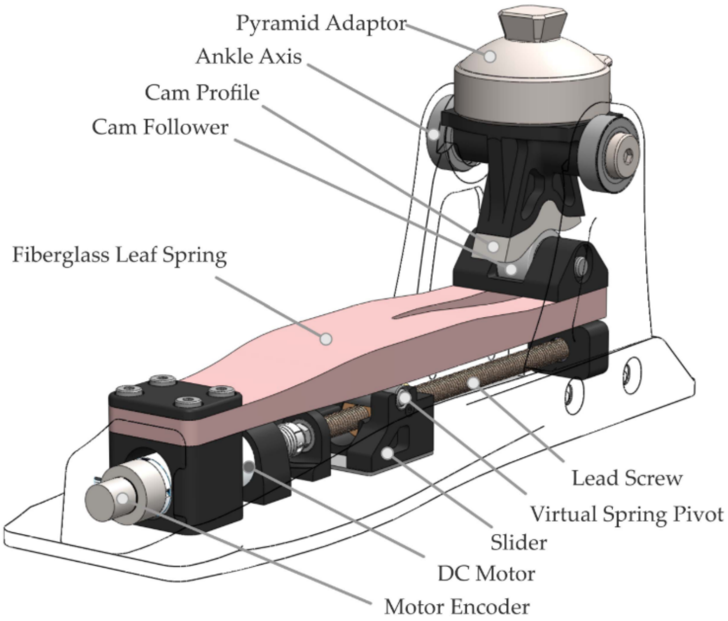

Fig. B.11.: Leaf spring foot prosthesis by Shepherd et al. [46]

physical interactions between identified components can be found in the *matrix of interaction* (see Table B.16). The components are also displayed in the *function model* (see Figure B.12).

B.3.2 Function Model

A function model was created for the leaf spring mechanism (see Figure B.12). In this figure the analysis of functional interactions is also concluded. After finding the positive interactions, negative interactions were added to the matrix of interactions (see Table B.16) and the functional model (see Figure B.12). For the identified positive functions, the possibility of failure was explored and depicted in the functional model.

B.3.3 Su-field Model

Before a Su-field model could be formulated, the most important problems of the leaf spring mechanism were found using *binary problem ranking*, see Table B.17 and B.18. Subsequently, the three main problems that occur with leaf spring AFO designs were selected for further investigation with the *76 inventive standards*. Figure B.13 shows the Su-field models of these problems. All problems operate in the mechanical domain.

Tab. B.16.: Matrix of interactions.

	Ankle	Strut	Slider	Lead screw	DC motor	Motor encoder	Battery	Virtual spring pivot	Fiberglass leaf spring	CAM follower	CAM profile	Ankle axis	Insole	Leg	Foot	Shoe
Ankle		X														
Strut			X	X	X	X	X	X	X	X	X	X		XX		
Slider				X				X								
Lead screw					X											
DC motor						X	XX									
Motor encoder							XX									
Battery																
Virtual spring pivot									X							
Fiberglass leaf spring										X						
CAM follower											X					
CAM profile													X			
Ankle axis													X			
Insole															X	X
Leg																
Foot																
Shoe																

Tab. B.17.: Binary problem ranking.

Problem	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total
1 Strut weights down leg		0	1	1	1	1	1	1	0	1	0	1	1	0	9
2 Strut insufficiently plantar flexes ankle	0		1	1	1	1	1	1	0	1	0	1	1	0	9
3 Strut excessively drags slider	-1	-1		-1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-13
4 Lead screw uncontrollably moves slider	-1	-1	1		0	0	0	0	-1	-1	-1	-1	-1	-1	-7
5 DC motor uncontrollably turns lead screw	-1	-1	1	0		0	0	0	-1	-1	-1	-1	-1	-1	-7
6 Motor encoder uncontrollably controls DC motor	-1	-1	1	0	0		0	0	-1	-1	-1	-1	-1	-1	-7
7 Motor encoder drains battery	-1	-1	1	0	0	0		0	-1	-1	-1	-1	-1	-1	-7
8 DC motor drains battery	-1	-1	1	0	0	0	0		-1	-1	-1	-1	-1	-1	-7
9 Fiberglass leaf spring insufficiently pushes CAM follower	0	0	1	1	1	1	1	1		1	-1	1	-1	-1	5
10 CAM follower uncontrollably deforms leaf spring	-1	-1	1	1	1	1	1	1	-1		-1	-1	-1	-1	-1
11 CAM follower inefficiently moves CAM profile	0	0	1	1	1	1	1	1	1	1		1	-1	-1	7
12 CAM profile uncontrollably pushes CAM follower	-1	-1	1	1	1	1	1	1	-1	1	-1		-1	-1	1
13 CAM profile insufficiently rotates insole	0	-1	1	1	1	1	1	1	1	1	1	1		-1	8
14 Insole insufficiently supports foot	0	-1	1	1	1	1	1	1	1	1	1	1	1		10

Tab. B.18.: Problem ranking in descending order of importance.

#	*Problem*	*Score*
1	**Insole insufficiently supports foot**	**10**
2	**Strut weights down leg**	**9**
2	**Strut insufficiently plantar flexes ankle**	**9**
4	CAM profile insufficiently rotates insole	8
5	CAM follower inefficiently moves CAM profile	7
6	Fiberglass leaf spring insufficiently pushes CAM follower	5
7	CAM profile uncontrollably pushes CAM follower	1
8	CAM follower uncontrollably deforms leaf spring	-1
9	Lead screw uncontrollably moves slider	-7
9	DC motor uncontrollably turns lead screw	-7
9	Motor encoder uncontrollably controls DC motor	-7
9	Motor encoder drains battery	-7
9	DC motor drains battery	-7
14	Strut excessively drags slider	-13

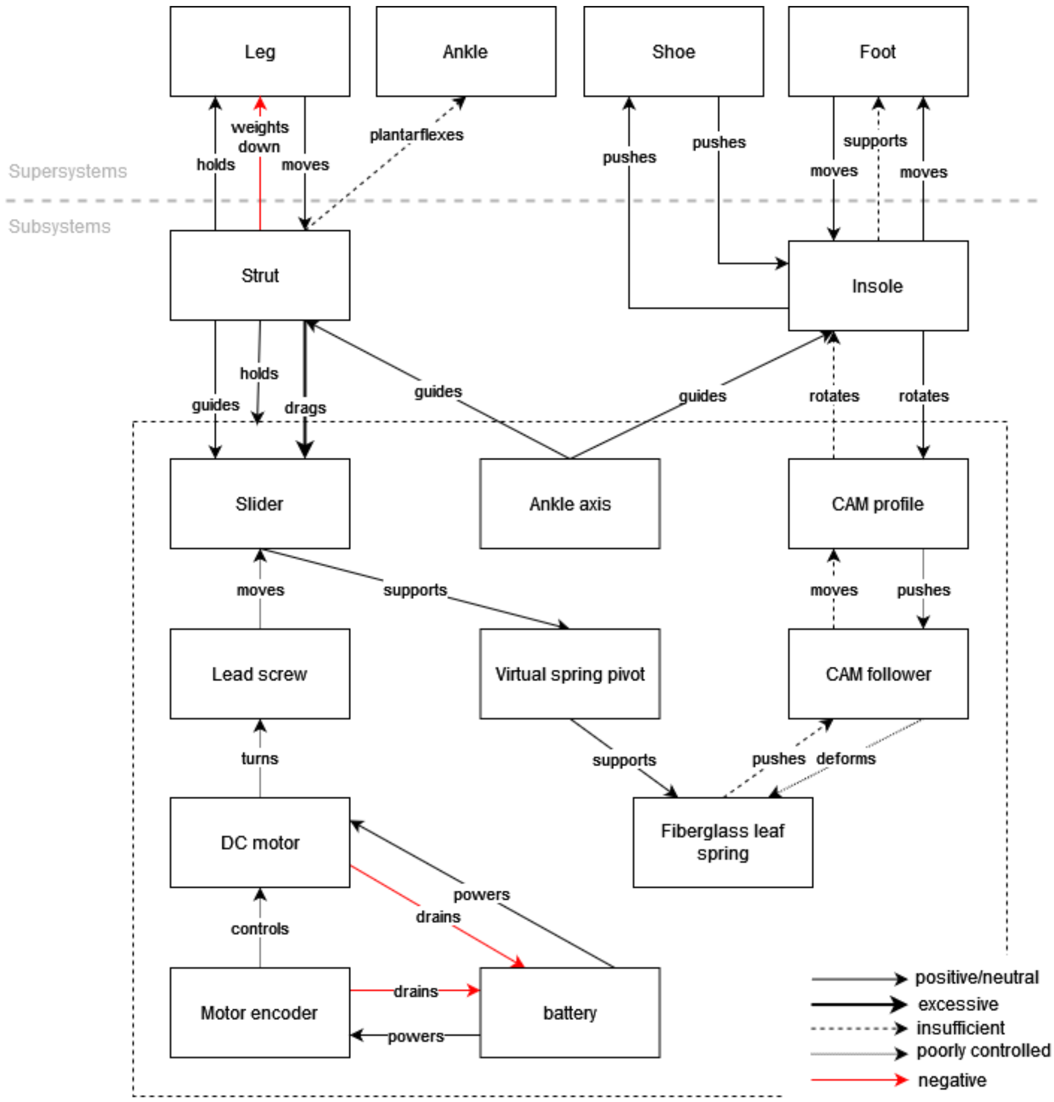

Fig. B.12.: Function model.

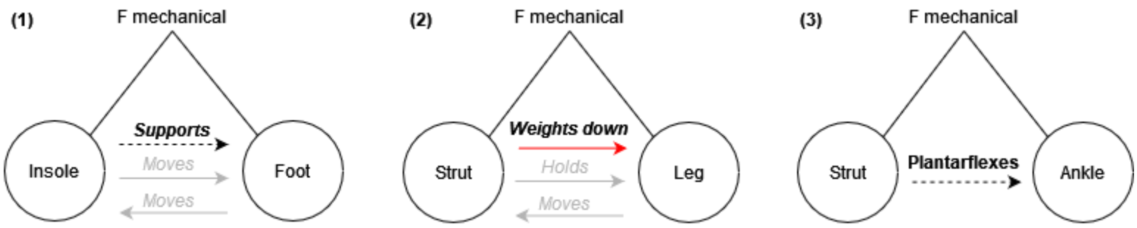

Fig. B.13.: Su-field models of the three main leaf spring AFO problems.

B.3.4 76 Inventive Standards

The 76 inventive standards were implemented on the three identified Su-field models in Figure B.13, and ABC filtering was applied.

Insole insufficiently supports foot:

Inventive standards were chosen based on the nature of the problem at hand. The goal is to improve support of the foot. This fits the pathway "*improve effect of insufficient interaction or improve controllability*". It is allowed to introduce new components to the system and thus inventive standards 1-1-2, 1-1-3, 1-1-4 and 1-1-5 were investigated. Furthermore, it would be desirable to "*provide optimal action*" as well, and thus inventive standard 1-1-6, was also investigated.

1-1-2 *Introduce foreign additives*

- Add AFO shell around lower leg that resembles the current CP AFO designs. (A)
- Introduce an AFO foot piece to support foot deformations. (A)
- Add possibility for restraining ROM. (A)
- Add a ridge to the insole so that the foot will not slide to the sides. (A)
- Electrically stimulate the muscles of the foot, so that they have a healthy firing pattern and do not deform the foot. (C)

1-1-3 *Attach substance to existing substance*

- Convert the insole to a below the shoe support, to create a broader base of support. (B)
- Create a click-on frame underneath the shoes, so that the user can wear their own insoles with the device. (A)
- Create a supporting structure around the shoe, that puts pressure on the foot to stay in place. (B)
- Add a foot support arch to the insole. (A)

1-1-4 *Use existing environment*

- Make the leaf spring stiffer and thus more stable. (B)
- Wear AFO without a shoe (direct contact with ground, no flexible sole to cause instability). (C)

1-1-5 *Change existing environment*

- Remove possibility for inversion/eversion action. (A)
- Add dorsiflexion/plantarflexion stop. (A)

1-1-6 *Using maximum action and removing excess*

- Give a patient the AFO with highest level of ROM, and gradually remove ROM if the gait cycle appears to be instable. (C)

- Give the child a very restraining foot AFO together with the leaf spring AFO. As long as the child's gate seems to be impeded by the restrains, keep removing material from the foot AFO. (C)

Strut weights down leg:

Following the pathways of the 76 inventive principles this problem can either be seen as "*elimination of a harmful interaction between two substances*", namely the strut and the leg, or it can be seen as "*elimination of a harmful interaction between a substance and a field*", namely the gravitational force and the strut. Principles 1-2-1, 1-2-2 and 1-2-4, or 1-2-3 and 1-2-5 should then be used, respectively. Principles 1-2-3 and 1-2-5 are not valid for this problem. Principles 1-2-1, 1-2-2 and 1-2-4 propose the introduction of a new substance or field, which in this case will have to relate to increasing push-off power (e.g., by providing motorized push-off force). If more push-off power is provided the device will feel lighter to the user. However, instead of adding more components to the device it was opted to execute trimming, as this was deemed the easiest way to reduce (experienced) device weight.

Figure B.12 shows a hierarchical function model of the leaf spring AFO. The components with the lowest functional ranking are the battery and the motor encoder. The battery is more expensive and was thus selected for the trimming process first (see Table B.19). Moving up in the function hierarchy the DC motor and the fiberglass leaf spring can be found. The fiberglass leaf spring provides the main functionality of the AFO and thus cannot be trimmed. A level higher the lead screw, virtual spring pivot and cam follower can be found. The trimming analysis was stopped for the functional hierarchy level of the cam profile, slider, and ankle axis as none of these are trimmable.

Trimming suggests removing the motorized control of the slider position, as this will allow the battery, motor encoder, DC motor and potentially even the lead screw to be removed (see Table B.19). Moreover, the slider and virtual pivot point can be merged into one component, as well as the fiberglass leaf spring and the cam follower.

Strut insufficiently plantar flexes ankle:

A similar approach to "*insole insufficiently supports foot*" can be taken, and thus principles 1-1-2, 1-1-3, 1-1-4, 1-1-5 and 1-1-6 were investigated.

1-1-2 *Introduce foreign additives*

- Add motor for providing push-off torque. (C)

Tab. B.19.: Overview of components and why they can be trimmed.

Component	Function	Trimming tasks			
		An object can be trimmed if its function is not needed	An object can be trimmed if its function can be delivered by another system object	An object can be trimmed if its function can be delivered by a supersystem object	An object can be trimmed if its function can be delivered by an object which receives a function
Battery	Power motor encoder; power DC motor	X	X	Electricity could be generated by mechanical work from the AFO wearer	X
Motor encoder	Control DC motor	X	X	X	Get DC motor with integrated encoder
Fiberglass leaf spring	Push cam follower	X	X	X	X
DC motor	Turn lead screw	X	X	The AFO user / clinician can turn the lead screw	X
Lead screw	Move slider	X	X	Slider can be moved by AFO user/clinician	X
Cam follower	Move cam profile; deform fiberglass leaf spring	X	X	X	The fiberglass leaf spring can be produced such that its distal end matches the cam profile
Virtual spring pivot	Support fiberglass leaf spring	X	Slider can support fiberglass leaf spring directly	X	Slider can be slightly changed so that it is more suitable for supporting the leaf spring
Cam profile	Rotate insole; push cam follower	X	X	X	X
Slider	Support virtual spring pivot	X	X	X	X
Ankle axis	Guide strut; guide insole	X	X	X	X

- Add motor for controlling release of spring force at the optimal moment. (C)
- Use different cam profiles depending on the activity. (A)
- Have multiple cam profiles that can be switched with a motor, for optimal support.
- Add a second spring. (C)

1-1-3 *Attach substance to existing substance*

- Add a substance on the ankle axis to reduce friction between strut and insole, to improve push-off power. (A)
- Let the patient pull a string at the back of the ankle to manually power push-off. (C)
- Add a coating to the leaf spring that hardens the spring and ensure for a higher energy efficiency. (C)

1-1-4 *Use existing environment*

- Walk on stiff ground so that push-off power is optimally used. (A)
- Use stiff shoes, so no push-off power is absorbed by the sole of the shoe. (A)

- Remove shoe, such that there is direct contact between the sole and the ground. (B)
- Use a more efficient leaf spring so that more of the stored energy is given back to the patient. (A)
- Let the patient push the spring a little further so that more energy can be stored. (C)

1-1-5 *Change existing environment*

- Spray out a substance that make the underground stiff. (C)
- Spray out a substance that increases the grip with the shoe on the ground so all energy saved in the spring can be put towards push-off. (C)
- Let the patient do muscle strengthening exercises such that a lower push-off support from the device suffices. (B)

1-1-6 *Using maximum action and removing excess*

- Use a huge leaf spring and trim down the spring according to the patient needs.

B.3.5 Assessment and Selection

ABC filtering was applied, see Section **??**. Ideas marked with (A) were subsequently submitted to a *Multi-Criteria Decision Matrix (MCDM)* (see Table B.20) based on the project requirements specified in Table B.1 and B.8. Ideas landscaping was then applied to incorporate ideas cost and complexity (see Figures B.14 and B.15), and the most promising ideas were selected for each contradiction. Ideas from Table B.20 that were not deemed to be worth considering in the ideas landscaping were marked lighter grey in Table B.20. Promising ideas were subsequently subjected to a MCDM based on TRIZ criteria (see Table B.21). The MCDM and trimming process yielded the following solutions for the three selected contradictions:

1. *Insufficiently supports foot:* Add a foot support arch to the insole.
2. *Strut weights down leg:* Trim the battery, motor encoder and DC motor, and possibly the lead screw and virtual spring pivot.
3. *Strut insufficiently plantarflexes ankle:* Use different cam profiles depending on the activity.

B.4 Conclusion

The TRIZ process yielded the following potential solutions for the three problems defined in Section 4.3:

1. ADR mechanism provides insufficient push-off support

Tab. B.20.: MCDM of the leaf spring mechanism ideas based on project requirements

	Ideas	The mechanism should be adjustable and valid for different pilot sizes (age 4-16, max 60kg)	The mechanism should be lightweight	The device should at least support walking in an indoor, controlled environment (research environment)	The mechanism should allow walking on a slope ([-8,8] deg)	Required ROM of ankle plantarflexion, adaptable in intermediate values (>= 20 deg)	Required ROM of ankle dorsiflexion, adaptable in intermediate values (>=15 deg)	The system should be easy to use and easy to adjust	The system should be worn with normal clothing/shoes	total
	Weight	*5*	*3*	*5*	*3*	*4*	*4*	*4*	*3*	
Insole insufficiently supports foot	1 Add AFO shell around lower leg that resembles the current CP AFO designs.	3	2	2	2	2	2	2	1	64
	2 Introduce an AFO foot piece to support foot deformations.	3	2	3	4	2	2	3	2	82
	3 Add possibility for restraining ROM.	4	4	3	2	4	4	3	3	106
	4 Add a ridge to the insole so that the foot will not slide to the sides.	4	3	3	4	2	2	2	2	86
	5 Create a click-on frame underneath the shoes, so that the user can wear their own insoles with the device.	5	4	3	4	2	2	3	4	104
	6 Add a foot support arch to the insole.	3	4	3	4	2	2	2	3	87
	7 Remove possibility for inversion/eversion action.	4	4	3	4	2	2	3	3	96
	8 Add dorsiflexion/plantarflexion stop.	3	3	3	2	4	4	3	3	98
Strut insufficiently plantarflexes ankle	9 Use different cam profiles depending on the activity.	3	3	4	5	2	2	2	2	89
	10 Add a substance on the ankle axis to reduce friction between strut and insole, to improve push-off power.	1	5	3	3	1	1	3	3	73
	11 Walk on stiff ground so that push-off power is optimally used.	1	3	2	2	1	1	4	2	60
	12 Use stiff shoes, so no push-off power is absorbed by the sole of the shoe.	2	3	3	3	1	1	4	2	73
	13 Use a more efficient leaf spring so that more of the stored energy is given back to the patient.	2	4	3	3	1	1	3	2	72

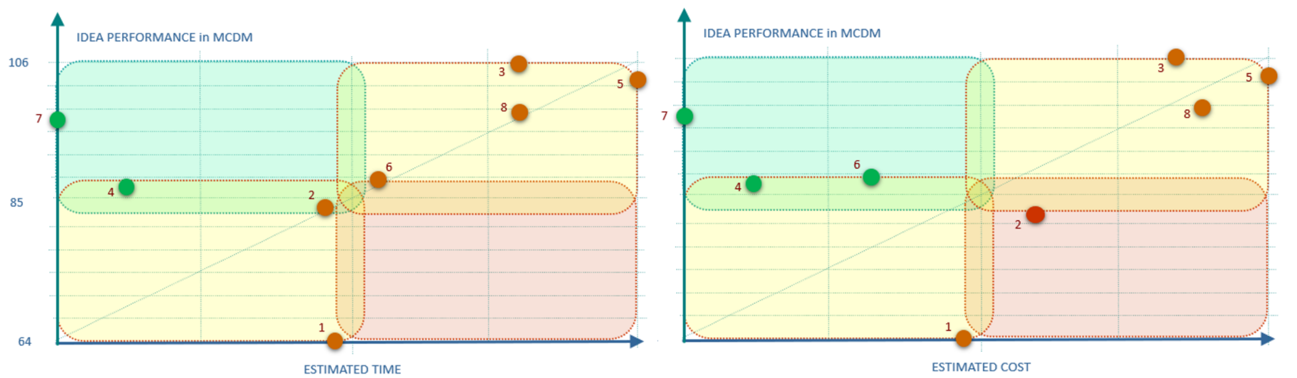

Fig. B.14.: Ideas landscapes for "insole insufficiently supports foot". Idea 1 and 2 are not worth considering.

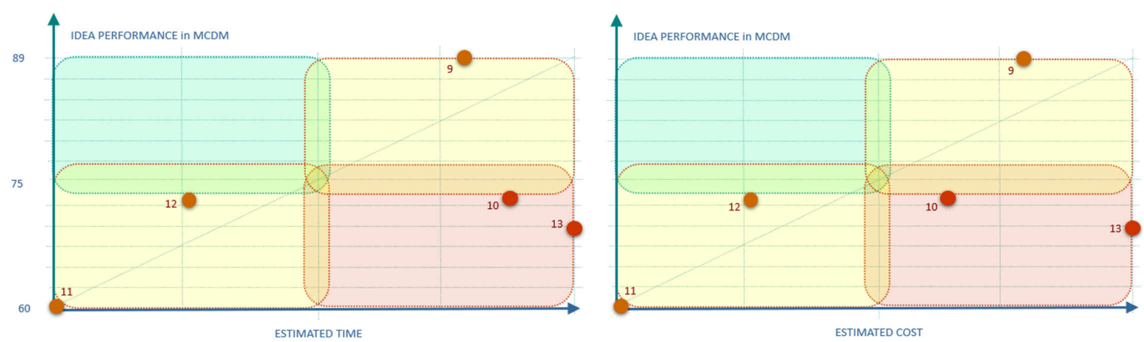

Fig. B.15.: Ideas landscape for "strut insufficiently plantarflexes ankle". Idea 10 and 13 are not worth considering.

Tab. B.21.: MCDM of the leafspring mechanism ideas based on TRIZ criteria.

	Ideas	Solves a problem in full: a desired result is fully achieved, no compromise.	Eliminates a contradiction in a "win-win" way. Nobody and nothing suffers.	Has the highest degree of costs-effectiveness, or preferably, free (or "ideal").	Produces no harmful side effects.	Provides extra benefits.	total
	Weight	*5*	*4*	*3*	*2*	*1*	
Insole insufficiently supports foot	3 Add possibility for restraining ROM.	1	4	3	4	4	42
	4 Add a ridge to the insole so that the foot will not slide to the sides.	2	4	4	4	0	46
	5 Create a click-on frame underneath the shoes, so that the user can wear their own insoles with the device.	5	3	2	2	3	50
	6 Add a foot support arch to the insole.	**4**	**4**	**4**	**4**	**0**	**56**
	7 Remove possibility for inversion/eversion action.	1	4	5	4	4	48
	8 Add dorsiflexion/plantarflexion stop.	1	4	3	4	4	42
Strut insufficiently plantarflexes ankle	**9 Use different cam profiles depending on the activity.**	**3**	**4**	**2**	**3**	**4**	**47**
	11 Walk on stiff ground so that push-off power is optimally used.	2	2	5	1	0	35
	12 Use stiff shoes, so no push-off power is absorbed by the sole of the shoe.	1	1	4	2	0	25

a) *Weak spring:* Instead of putting springs in a heavy metal casing, use up all this space only with springs, such that there can be stronger springs within the same mechanism volume.

b) *High spring stiffness:* Measure the patient's torque-angle curve of the ankle, and design a spring that matches that curve, for creating optimal push-off support.

c) *Zero alignment of the foot is set to 0-15 deg dorsi flexion:* Have the mechanism be able to turn around the joint, so that the user can easily set the zero alignment.

2. Bodyweight controlled clutch lacks ROM control
   a) *Preventing free plantarflexion during stance:* Include a joint with plantarflexion stop in the AFO.
   b) *Set spring tension:* Mechanism to adjust spring pretension.
   c) *Prevent free dorsi/plantar flexion during swing*: Incorporate the mechanism in a rigid mechanism that constrains the ankle.
3. A leaf spring powered push-off mechanism
   a) *Insufficiently supports foot:* Add a foot support arch to the insole.
   b) *Strut weights down leg:* Trim the battery, motor encoder and DC motor, and possibly the lead screw and virtual spring pivot.
   c) *Strut insufficiently plantarflexes ankle:* Use different cam profiles depending on the activity.

As the inGAIT project aims to be innovative it was decided to discard the ADR from the potential solutions. Moreover, there seems to be an inherent shortcoming to the ADR, where two springs acting in parallel might not be able to give the needed support [45]. The bodyweight controlled clutch and leaf spring thus remain potential solutions for the inGAIT project. As Dr. Shepherd and Dr. Rouse, designers of the leaf spring AFO, have much more expertise in this area, it was decided to collaborate with them on this area, and to look into the bodyweight controlled clutch ourselves.

Colophon

This thesis was typeset with $\LaTeX\,2_\varepsilon$. It uses the *Clean Thesis* style developed by Ricardo Langner. The design of the *Clean Thesis* style is inspired by user guide documents from Apple Inc.

Download the *Clean Thesis* style at `http://cleanthesis.der-ric.de/`.

Declaration

I declare that this thesis was composed by myself, that the work contained herein is my own except where explicitly stated otherwise in the text, and that this work has not been submitted for any other degree.

Parts of this work have been submitted to the Journal of NeuroEngineering and Rehabilitation, and to the XLIII Jornadas de Automática 2022.

Enschede, August 29, 2022

Marleen van Hoorn