Design of an intelligent orthosis in support of the locomotor system

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I statutory declaration

I hereby declare that I have authored this thesis independently, that I have not used other than the declared sources and resources, and that I have explicitly marked all material which has been quoted either literally or by content from the used sources.

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Linz, 19th June 2019

II acknowledgment

First of all I would like to thank my thesis advisors Univ.-Prof. Mag.art. Mario Zeppetzauer / Univ.-Prof. Mag.art. Elke Bachlmair at the University of Art and Design Department of Industrial Design for their design support.

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At last I would like to thank OA Mag. Dr. Rainer Hochgatterer for his time to be interviewed and for sharing great inputs from the medical point of view with many years of experience in the treatment of patients.

III introduction

The "intelligent orthosis" project started in september 2018 in cooperation with the MCI Management Center Innsbruck - Department of Mechatronics and shows a new solution to a future approach of how an intelligent orthosis can make everyday life easier for cerebral palsy patients.

The aim of the project is to define an optimal solution strategy for active and passive support of an intelligent orthosis. A first concept of a human centred product design is presented, based on an observed gait analysis of a specific user, an existing diagnosis and an expert talk. The focus is on individual needs, like custom settings or to think about a more patient-oriented product, which are gaining more and more importance.

Concerning product design, the results of this study show that it is crucial to take into account user interaction and preferences, and also the inclusion of new technologies in order to achieve the most important goal of this study – to achieve improvement in treatment of patients and gain more acceptance from the patient side.

content:

IV exposé

problem definition:

The main problem of the target group is the muscle weakness/drop foot, which leads to a deviating gait pattern and a decrease of walking speed. While working with a cerebral palsy patient, who volunteered for the project, a further problem was identified – namely reduced muscle activity of the legs. Due to frequently minimal lifting, the foot is angled inside, which causes an unstable ground contact.

questions:

- What are the main causes of the deviating gait pattern?
- How can a patients gait pattern be enhanced?

current state of research and relating knowledge:

In recent years, several publications of active or motorised orthosis have been published, featuring various motor mechanisms. "Twisted actuator strings" are gaining popularity in the scientific field and are used for several robotic applications. [1] Recently a research work with the title "Bio-inspired Active Soft Orthotic Device for Ankle Foot Pathologies" [2] was published, showing a new approach of a soft orthotic device.

questions:

- How could the motor be attached to the leg and where exactly is the optimal position to gain a portable product?
- Where are the optimal lifting points positions on the foot, to achieve a lift support and where they have to be located to correct the toe-out angle?

reference literature and methods:

The observational gait analysis is an effective problem-solving strategy to determine the main functional problem. It is often used as a basic technique and there is no need of complex technical aids. [3]

"observed gait analysis RLANRC-System" (Dr. Jacquelin Perry)
Götz-Neumann, K. [Ed.] (2011): *"Gehen verstehen. Ganganalyse in der Physiotherapie."* 3rd edition.

issues of the thesis:

- What are the main causes of the deviating gait pattern?
- How can a patients gait pattern be enhanced?
- How could the motor be attached to the leg and where exactly is the optimal position to gain a portable product?
- Where are the optimal lifting points positions on the foot, to achieve a lift support and where they have to be located to correct the toe-out angle?
- What are the specific accomplishments of the different gait phases?
- What is the solution strategy for active and passive support of an intelligent orthosis?
- Which kind of support is necessary and what is giving support efficiently?
- What are future expectations for the intelligent orthosis?

expectations:

- To find a targeted solution strategy for an intelligent orthosis

time schedule:

17.10.	Intermediate presentation (MCI Management Center Innsbruck-department of mechatronics)
7.11.	Research finish
8.11.	Skype meeting / Research presentation
21.11.	FINAL presentation MCI / functional prototype
21.12.	Ideation

aim of the project:

To design an intelligent orthosis in support of the locomotor system, which provides good usability on a daily basis. Additionally, to create a minimalistic design that is more affordable compared to previous orthosis. The orthosis should be more adaptable by providing customizable features and by supporting the locomotor during the walk. A further aim is to enhance the walking speed of the user and to give him or her the possibility to choose custom settings via smart phone.

V abstract

The "intelligent orthosis" project started in september 2018 in cooperation with the MCI Management Center Innsbruck - department of mechatronics and shows a new solution to the approach of how an intelligent orthosis can make everyday life easier for cerebral palsy patients in the future. The main problem of the target group is the muscle weakness/drop foot, which leads to a deviating gait pattern and a decreased walking speed. During the project, contact was established with a cerebral palsy patient, who volunteered for the project. Through this contact with this "specific user", a further problem was identified – namely reduced muscle activity of the leg. Due to the minimal lifting in the „swing phase" of the leg, many patients´ feet are angled inside which causes unstable ground contact.

Together with a group of students [4] from MCI's bachelor class, the first technical and functional principles were selected, which focused on these two problems. In summary these are the drop foot and the foot's angulation before ground contact (toe-out angle correction). This mechanism of correction must be activated in a few hundreds of milliseconds during the swing phase (foot has no ground contact) in order not to restrict the patient while walking. The hip position is only detected by sensors and is not actively supported by a further motor. The user receives passive feedback from vibration motors. Due to this passive, non-motor support, the patient has the possibility to correct the deviation by himself (training function). Various sensors (gyroscope, acceleration sensor, pressure sensor, encoder,...) can be used to evaluate the angle of the hip and knee position. For example, an encoder detects the hip position. The project was limited to the reference leg (patient's right leg). The product is operable by a smart phone app and enables the patient to choose individual settings for active motor support or to switch on/off the passive feedback.

In course of an observational gait analysis (RLANRC-system - 8 gait phases) a third problem could be analysed, due to an intensive muscle research, namely a balance problem results from muscle weakness, especially in the monopod phase. Two additional air cushion pockets (foot sole area and calf area) counteract the patient's sense of equilibrium in a sensory way through targeted air support. The intelligent orthosis presents a good mixture of an active motor support and a training function (passive feedback). By an intensive investigation on the cause problems of the foot lift weakness, a purposeful solution strategy could be defined. The conclusions of the research, the problem definition, the analysis and the subsequent expert talk were fundamental for the new design. On the one hand, this is made possible by patent-oriented methods and, on the other hand, by production methods that will be used in the future in order to have the product manufactured fast and affordable. Furthermore, the design ensures a improved attachment to the leg, a user-friendly handling and the courage to distinguish itself from conventional medical products.

Das Projekt „intelligente Orthese" hat im September 2018 in Kooperation mit dem MCI - Management Center Innsbruck - Mechatronik gestartet und zeigt ein neues Konzept bzw. neuen Lösungsansatz, wie man künftig den Alltag für Zerebralparese Patienten durch eine neue intelligente Orthese erleichtern kann. Das Hauptproblem der Zielgruppe ist die Muskelschwäche/Fußheberschwäche, die zu einem abweichenden Gangbild und einer starken Verlangsamung der Gehgeschwindigkeit führt. Während dem Projekt wurde ein intensiver Kontakt zu einem Zerebralparese Patienten hergestellt, der sich freiwillig zur Verfügung gestellt hat. Durch den Austausch mit unserem „specific User" konnte ein weiteres Problem festgestellt werden, welches aus der eingeschränkten Muskelaktivität resultiert. Durch die geringe Anhebung des Beines in der „Schwung-Phase" ist bei vielen Patienten die Ausrichtung des Fußes nach innen geneigt und sorgt für einen unsicheren Bodenauftritt des Fußes.

Gemeinsam mit einer Studentengruppe [4] aus den Bachelor Jahrgang des MCI wurden erste technische Funktionsprinzipien ausgearbeitet, die sich speziell auf diese zwei Probleme fokussiert haben. Zusammenfassend sind diese die Fußheberschwäche und die Ausrichtung des Fußwinkels vor dem Bodenkontakt. Der korrigierende Mechanismus muss in wenigen hundert Millisekunden während der Schwungphase (Fuß hat keinen Bodenkontakt) erfolgen, um den Patienten nicht beim Gehen einzuschränken. Die Hüftposition wird nur mittels Sensoren detektiert und nicht aktiv unterstützt durch einen weiteren Motor. Der User erhält über Vibrationsmotoren ein passives Feedback. Durch diese passive, nicht motorische Unterstützung, hat der Patient die Möglichkeit selbst die Abweichung zu korrigieren (Trainingsfunktion). Verschiedene Sensoren (Gyroskop, Beschleunigungssensor, Drucksensor, Encoder...) können die jeweilige Abwinkelung der Hüfte und des Knies evaluieren. Zum Beispiel detektiert ein Encoder die Position der Hüftstellung. Das Projekt beschränkte sich auf das Referenzbein (rechtes Bein des Patienten). Das Produkt soll mittels Smartphone App bedienbar sein und dem Patienten künftig die Möglichkeit geben, individuelle Einstellungen für die aktive Motorunterstützung vorzunehmen bzw. ein passives Feedback ein oder auszuschalten.

Im Zuge einer beobachtenden Gehanalyse (RLANRC-system - 8 Gangphasen) und einer intensiven Muskelrecherche konnte ein drittes Problem analysiert werden, nämlich ein aus der Muskelschwäche resultierendes Gleichgewichtsproblem, speziell in der Einbein-Stand-Phase. Zwei zusätzliche Luftkissenpockets (Fußsohlenbereich und Wadenbereich) wirken durch gezielte Luftunterstützung dem Gleichgewichtsgefühl des Patienten sensorisch entgegen. Die intelligente Orthese zeigt eine gute Mischung aus aktiver Motorunterstützung und einer Trainingsfunktion (passives Feedback). Durch die intensive Auseinandersetzung mit den Ursachen-Problemen der Fußheberschwäche, konnte eine gezielte Lösungsstrategie definiert werden. Die Erkenntnisse der Recherche, der Problemdefinition, der Analyse und des anschließenden Expert Talks waren fundamental für ein neues Design. Dieses erschließt sich auf der einen Seite aus Patentien orientierte Methoden und auf der anderen Seite aus zukünftig verwendende Produktionsmethoden, um das Produkt günstig und schnell fertigen zu lassen. Im Weiteren sorgt das Design für eine verbesserte Anbringung am Bein, eine usergerechte Handhabung und den Mut sich von herkömmlichen medizinischen Produkten abzugrenzen.

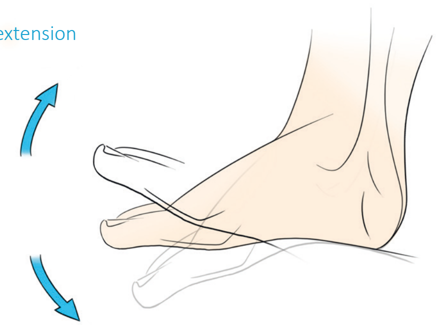
RESEARCH - 1 terminology / requirements

RESEARCH - 1 terminology / requirements

1.1 locomotor / passenger

The locomotor (pelvis and legs) and the passenger (upper body half and pelvis) subdivide the body during the walk in two functional units. The pelvis is the connecting element of both units and belongs to the locomotor and as well to the passenger unit. [5] 70% of the overall mass is the passenger load and is carried by the locomotor (30% of the overall mass). [6] Head, neck, torso, pelvis and arms are part of the passenger unit and abbreviated as "HAT" (Elftmann 1954). [7]

The locomotor unit includes the pelvis and the lower extremities as anatomical segments and among others the sacroiliac joint, the hip-, knee-, upper and lower ankle- and metatarsal phalangeal joints. The knuckle parts of the locomotor consist of pelvis, femur, tibia, fibula, feet and toes and serve as a lever for the movement functions. Standing stability, locomotion, shock absorption and saving energy are the four functions of the locomotor unit. Despite constantly changing postures, stability is ensured in an upright position. A driving force is generated which makes the locomotion possible. The shock absorption dampens the impact of the body weight on the ground. Functional movement saves energy and reduces muscle work. [8] The five metatarsophalangeal joints are also known as "MTP" in short form which can only be rotated around two axes. (flexion/extension, spreading/tightening) [9];[10] The sacroiliac joint connects the spine at sacrum bone level with the basin blades and is located between the sacrum and the right and left ilium. [11]



[figure 1]

The extension of the foot is called dorsal extension and indicates the movement upwards. Plantar flexion refers to the flexion of the foot and shows the movement downwards. [12]

1.2 definition of the upper and lower limbs of orthoses

orthoses for upper extremities are divided in:
- finger & hand
- wrist, forearm
- elbow joint, upper arm
- shoulder joint
- whole arm

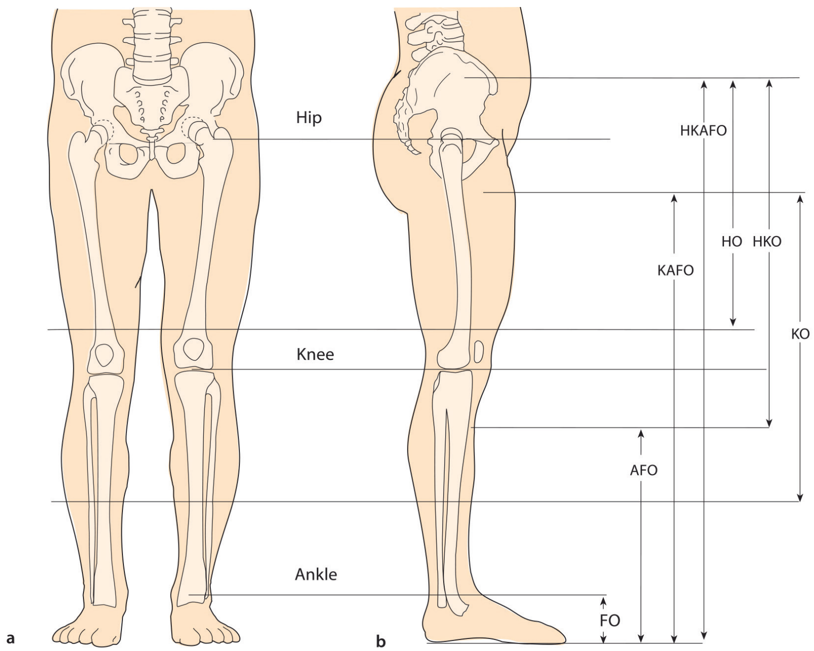
orthoses for lower extremities are divided in:
- toes & foot
- ankle joint, lower leg
- knee joint
- thigh
- hip joint
- whole leg

Furthermore, there is an additional subdivision for footrests. [13]

1.2.1 ISO standard for orthoses

According to "ISO 8549-3" (1989), all orthoses are classified internationally. A "thigh orthosis" has so far described the treatment of the entire leg from the thigh to the foot (not the thigh only). The international standard defines this fitting method as "KAFO" (Knee-Ankle-Foot-Orthosis) instead of thigh orthosis. A KAFO orthosis describes the narrowing body segments and/or joints. [14]

In 2003, the "ISO standard 8551" was published, for the purpose to avoid misleading terms by specifying a general description of the patient and by defining information which has an influence on orthotic care. Supply Chain: Description of Person- Clinical Goals- Functional Requirements- Biomechanics / Design. [15]



Nomenclature of lower extremity orthotic treatment. [figure 2]

1.3 distinction of palsy- supportive-, and segments orthoses

Hohmann & Uhlig have simplified the terminology for orthoses in two systems by separating paralysis orthoses and relief orthoses.

Paralysis orthoses (customized or body shape models) are function-supplementing and also supporting, motion-influencing orthoses for multiple-joint limb areas. The required partial fixation is defined by static-rigid basic elements of the orthosis.

Relief orthoses (customized or body shape models) are motion-limiting. The load absorption (e.g. pelvis-leg skeleton) is influencing the orthoses for multiple-joint limb areas differently. The fixation of the stable load is defined by a static-rigid basis and joint elements of the orthosis.

Segment orthoses (hybrid form) (customized or body shape models) influence the biomechanics of individual movement elements (joints) and body regions. Depending on their function, they have motion-controlling, load-regulating functions, direction-influencing and growth controlling tasks. In different combinations and limitations, the basic elements of these orthoses have both static (stabilizing) and dynamic (elastic) characteristics. [16]

1.4 ergonomic requirements of the body

body measurements
/ man (m) (age 26-40, 5th percentile / without clothes)
/ woman (w) (age 26-40, 5th percentile / without clothes)
[status 1999] [17]

(bh) body height
(vertical distance from stand space to the highest point of the head (vertex))

m: 1665 mm
w: 1544 mm

(th) trochanterion height
(vertical distance from stand space to right trochanterion)

m: 840 mm
w: 775 mm

(ch) crotch height
(vertical distance from stand space to the distal part of ramp inferior of Os pubis)

m: 765 mm
w: 712 mm

(ish) Iliac spine height
(vertical distance from stand space to highest point of iliac spine on the right side)

m: 994 mm
w: 922 mm

(ph) patella height, top
(vertical distance from stand space to upper end of right patella)

m: 480 mm
w: 422 mm

(tw) total weight
(person weighs in standing position; weight transfer is consistent on both legs)

m: 63,4 kg
w: 50,7 kg

(mbd) maximum body depth
(maximum horizontal distance between front side and back side of the torso)

m: 261 mm
w: 245 mm

(wd) waist depth, omphalion
(The horizontal distance of the abdominal wall in the same high of the navel)

m: 190 mm
w: 155 mm

calf circumference and ankle circumference
(cc) calf circumference: biggest circumference of the lower leg between knee joint and ankles
(ac) ankle circumference: smallest circumference of the lower leg between knee joint and ankles

m: (cc): 331 mm (ac):218 mm
w: (cc): 321 mm (ac):218 mm

knee circumference and knee circumference, maximal flexion
(kc) knee circumference is the maximum circumference in the area of knee joint
(kcf) knee circumference is the maximum flexion of the lower leg against the femur

m: (kc): 348 mm; (kcf): 393 mm
w: (kc): 333 mm; (kcf): 370 mm

(bc) buttock circumference
(buttock is the maximum horizontal circumference over the hips and buttock during standing)

m: (bc): 906 mm
w: (bc): 897 mm

(ffb) foot-to-foot breadth
(maximum horizontal distance between the outside of feet)

m: 485 mm
w: 481 mm

(hb) hip breadth
(maximum horizontal distance between the outsides of the hips)

m: 345 mm
w: 341 mm

(kkb) knee-to-knee breadth, standard
(maximum horizontal distance between fibula head (standing position)

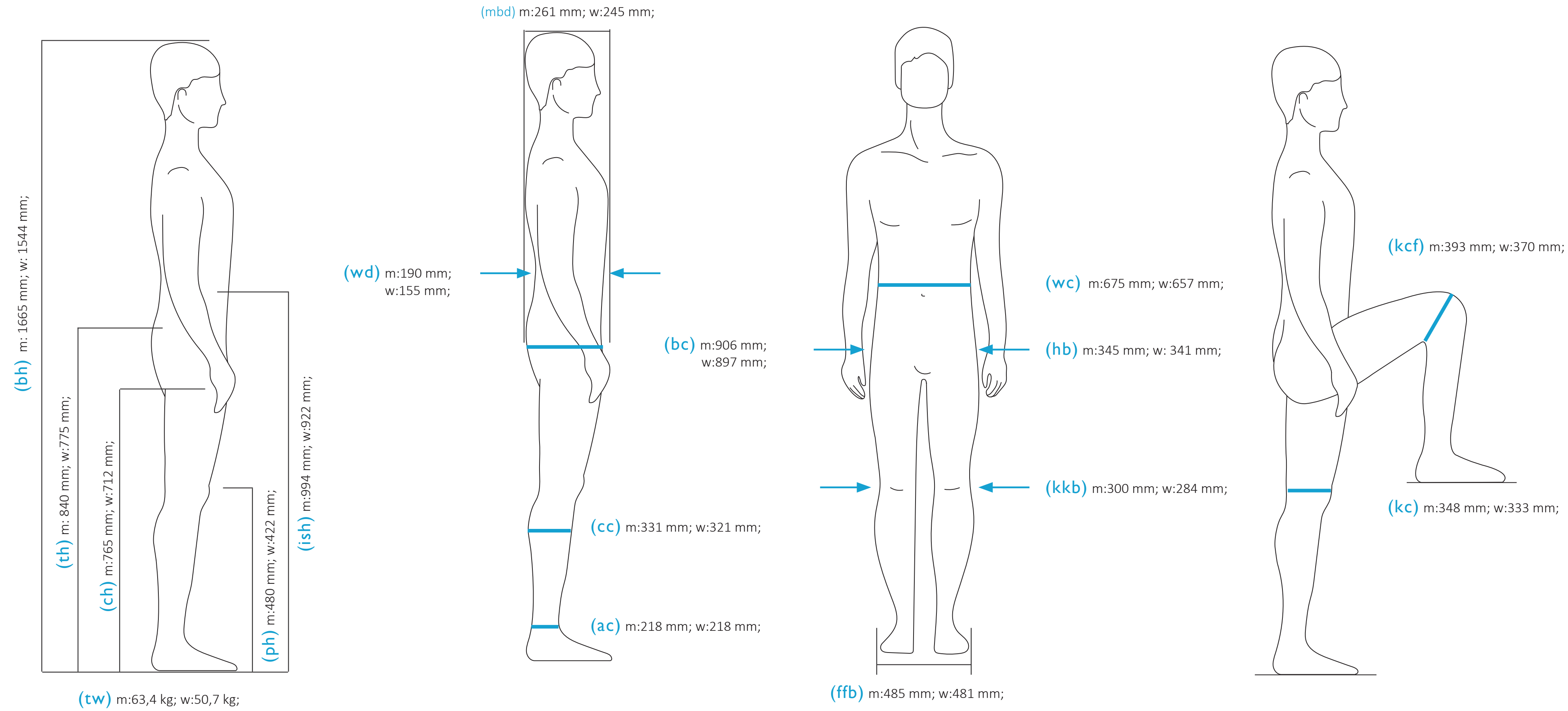
m: 300 mm
w: 284 mm

(wc) waist circumference
(buttock circumference is the maximum horizontal c. over the hips and buttock during standing)

m: 675 mm
w: 657 mm

[17]

RESEARCH - I terminology / requirements



[figure 3]

1.4 ergonomic requirements of the body

body measurements
/ man (m) (age 26-40, 5th percentile / without clothes)
/ woman (w) (age 26-40, 5th percentile / without clothes) [status 1999] [18]

lateral and medial malleolus height

(la) vertical distance of stand place to the widest protruding point of lateral ankle (outside)
(ma) medial ankle (inside)

m: (la): 63 mm (ma): 83 mm
w: (la): 58 mm (ma): 77 mm

foot length and forefoot length

(fl) foot length the distance parallel on the longitudinal axis from the heel backside to the top of the longest toe (first or second)
(ffl) forefoot longitude the maximum horizontal distance of the forefoot place of the lower leg to the widest protruding tiptoe of the right foot.

m: (fl):244 mm (ffl):178 mm
w: (fl):224 mm (ffl):166 mm

(fb) foot breadth (Maximal horizontal distance of metatarsal medial to metatarsal lateral, messured: standing position)

m: 92 mm
w: 83 mm

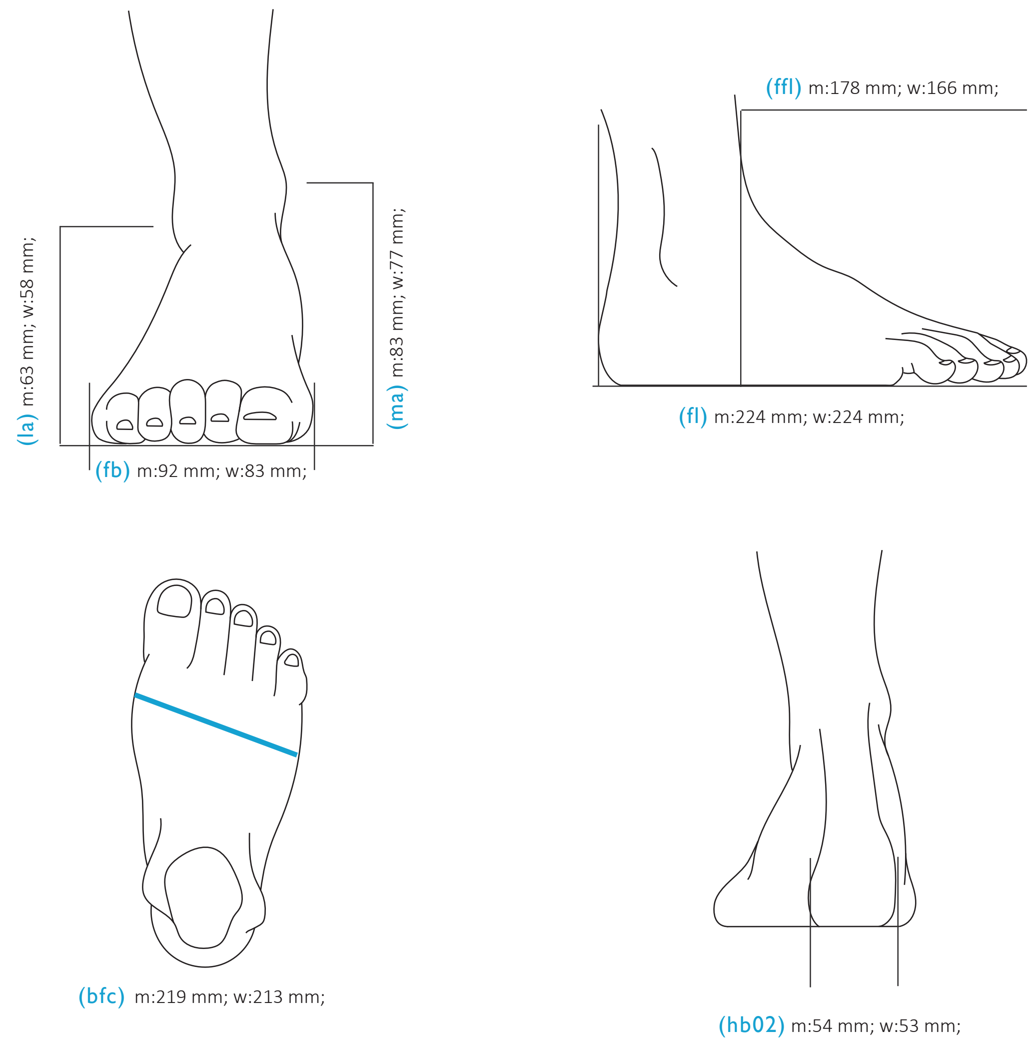
(bfc) ball of foot circumference (Maximal circumference over the ball of foot. Messured: standing position)

m: 219 mm
w: 213 mm

(hb02) heel breadth (Maximal horizontal distance between external surfaces of the heel)

m: 54 mm
w: 53 mm

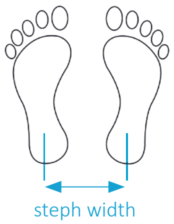
[18]



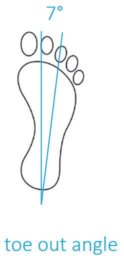
[figure 4]

2.1 definition of gait cycle / step length / step width

The term gait cycle is defined as the period of time between two continuous initial ground contacts of the same leg (reference leg). 0 % point of the gait cycle indicates the moment of ground contact at the beginning and the following ground contact of the same leg marks the end of the gait cycle. The time immediately before the end is referred to the 100 % point. At the same time, the other leg (contralateral leg) performs the identical movements (as the reference leg), but shifted by half of a gait cycle. The step width defines the distance between the heel centers of the feet and the step length indicates the distance between the heel contact of one leg until the heel contact of the contralateral leg. [19]



[figure 5]



[figure 6]

[figure 7]

The distance (while walking) is measured perpendicular to the line of locomotion and is normally in the range of 5-13 cm. During the quiet stand the longitudinal axis of the foot is rotated 7° outwards in relation to the locomotion line. This slight toe out angle of the foot also exists during the walk. [20]

2.1.1 measurement of the gait cycle

Characteristic specifications for walking are speed (m/min or m/sec), length of the gait cycle (m), cadence (steps per minute), joint angle, torque requirements, muscle activity and their normal timing. [21] Supplementary the following information may be provided:

- length of 2 steps/ 4 heel contacts (stride length)
- time for 2 steps in sec (stride time) [22]

The default value for normal walking is about 120 steps per minute. [23] During the walk the average speed varies about 74 m/min for women and about 82 m/min for men. [24] With a normal gait the speed is approx. 5 km/h with 82-84 m/min. [25]

2.2 stance & swing phases

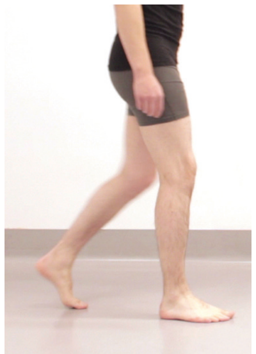
The gait cycle is split into two different phases (stance phase & swing phase). On the one hand, the stance phase is the period of the gait cycle in which the foot is on the floor and begins with the heel contact on the ground (also termed as initial contact). On the other hand, the swing phase (swing) describes the period in which the foot is in the air. The swing is also mentioned for forwarding the leg. This phase starts with the so-called initial swing. During this period the foot lifts off the ground (toe-off, i.e. toes lifted off). The stance and swing phase are divided into further subphases: 5 stance phases and 3 swing phases. Usually they accomplish the weight transfer, the one-leg stand and the forward movement of the swing leg. [26]

Weight transfer is the most ambitious tasks within the gait cycle due to the rapid transfer of body weight to the leg which just recently finished the forward motion and is currently in an unstable state. [27] On closer inspection, the transfer takes place in the stance phase and occurs in the initial contact and in the loading response (the shock absorption phase). [28]

By lifting off the contralateral leg, the one-legged position begins and continues until its initial contact. The body is moved over the supporting leg (reference leg) which carries the sole responsibility for the support of the weight and the maintenance of the forward motion for this period. The heel lifts off the ground and the body weight relocates towards the metatarsopalangeal joints. [29]

Through the mid stance phase, the terminal stance phase and the pre-swing phase, the second task of the stance phase is performed: one-legged position. The pre-swing phase occupies a special position and ends the one-legged position and initiates at the same time the transition to the swing leg (forward motion). [30] The duration of the monopod is a good indication of the supportability of the limb. [31]

The preparation for suitable positioning of the reference leg (forward motion of the swing leg) already starts at the end of the stance phase (pre-swing). After the swing leg is lifted off the ground, the unloaded leg swings forward in front of the body. This forward motion is completed with the extension of the knee joint and the leg is prepared for the upcoming initial contact. [32]



a initial double limb stance

[figure 8]

b single limb stance

[figure 9]

c terminal double limb stance

[figure 10]

Furthermore there is an additional subdivision of the stance phases into three sections due to the constant change of single and double supported phases (a, b, c). If both limbs have ground contact, this indicate the double supported stance phase. If only one leg has contact with the ground this refers to the single supported stance phase. [33]

With the a initial double limb stance the gait cycle begins and both legs have contact with the ground, after the initial contact and loading response have been completed. (reference leg: right in figure 8; 9; 10) The b single limb stance section starts, when the contralateral leg releases from the ground for the swing phase. The reference leg is in Mid- and Terminal stance. In this interval, there is only one leg (here: right leg) on the floor and the entire body weight rests on one limb. The c terminal double limb stance begins with the first heel contact of the contralateral leg or contralateral initial contact and corresponds to the early pre-swing of the reference leg (right leg). This section continues until the original standing leg (reference leg) lifts off and becomes the swing leg. [34]

The distribution in percent of ground contact periods (simplified):

stance phases:		
	a initial double limb stance	10 %
	b single limb stance	40 %
	c terminal double limb stance	10 %
swing phases:		40 %

[35]

The exact duration of the stance and swing phase varies with walking speed. At a comfortable walking speed of 80 m/min, 62 % are distributed over the stance phases and 38 % over the swing phases. A slower walking speed increases the double supported gait periods (e.g. in hemiplegic patients). [36]

2.3 RLANRC-system (8 phases of gait)

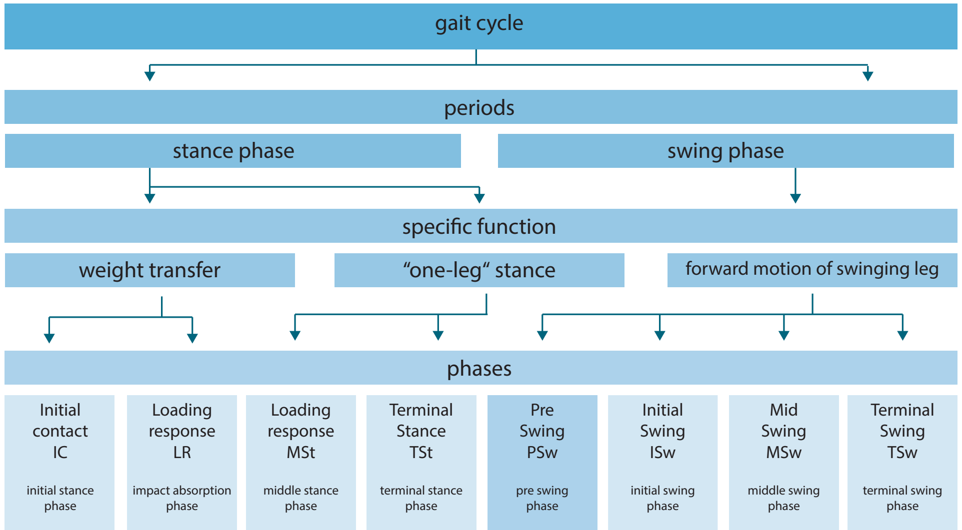
The systematic gait analysis was developed in the sixties at Rancho Los Amigos National Rehabilitation Center, a large renowned rehabilitation clinic in Los Angeles (USA). Dr. Jacquelin Perry, who joined the Institute in 1955 and headed Pathokinesiology until the early 1990s, created a system of observational gait analysis. At this time the usual clinical examination methods were only inadequately suitable for detecting dysfunctions during walking. Today, the Pathokinesiological Institute of the RLAMC uses the observational gait analysis as a basic technique. [37]

These reasons led to the founding of the "Observational Gait Instructor Group (O.G.I.G.)" in Los Angeles in 1998, along with Dr. Perry and team members from the Rancho Los Amigos National Rehabilitation Center and the University of Southern California. The observational gait analysis is an effective problem-solving strategy that directly addresses the anatomical-structural damage, the functional limitations and potential disabilities of the patient. This application is not created for analyzing tiny changes in joint angles, even the trained eye and experienced observer can only perceive angle changes in joints with an accuracy of about 5°. This tool includes the knowledge of the mechanics of normal walking habit, knowledge of deviations and their possible primary and secondary causes, as well as a clear terminology for the exact description of the normal and pathological gait pattern. Through this basis, the observational gait analysis is a solving strategy, which enables the therapist to identify and determine the main functional problem. This method allows to identify the causes of the deviations, to select suitable treatment approaches and to determine a individual adaption to the needs of the patient. The independence of time and space represents considerable benefits and there is no need for additional preparations, further therapists or complex technical aids. [38]

Compared to conventional terminologies of the gait, the RLANRC system uses neutral terms such as initial, middle and terminal phases to name the different gait phases and ensures good understanding and clarity. Two functionally important moments of the gait cycle are designated by their own names, e.g. loading response and pre swing. [39]

It is worth mentioning that the sole study of handbooks and the use of gait analysis forms, without appropriate training can quickly lead to incorrect assessments. [40] In the course of the thesis the observational gait analysis was used as a starting point. The observed results and the knowledge of an additional patient´s diagnosis was later compared with medical expertise (expert talk).

(see annex XIII - expert talk on page 152-159)



[figure 11]

2.4 specific accomplishments of gait phases

IC Initial contact - 0 % gait cycle

This phase indicates the short moment when the heel touches the ground. The joint positions at this time determine the shock absorption behavior of the leg and the leg is positioned in such a way that the stance phase can begin with the heel rocker. [41] The preparation for shock absorption, forward motion and stability are among the specific accomplishments. [42]

LR Loading response - 0-12 % gait cycle

The loading response phase begins with initial ground contact and ends with the lifting of the contralateral leg. The body weight is suddenly transferred to the outstretched leg. This is the first double supported stance phase (initial double limb support IDLS). [43] Specific accomplishments include shock absorption, controlled knee joint flexion which provides shock absorption & knee joint stability, guaranteed stability despite weight transfer, maintenance of forward motion, heel rocker function and hip joint stabilization, which ensures upright position of the torso. [44]

MSt Mid stance - 12-31 % gait cycle

The mid-stance phase begins with the lifting of the contralateral leg (toe-off) and ends with the lifting of the heel of the reference leg. The body‘s center of gravity is perpendicular to the forefoot. The forward motion over a fixed foot, the controlled forward motion of the tibia and the maintenance stability of the leg and torso are the specific performances in the mid stance. [45]

TSt Terminal stance - 31-50 % gait cycle

The terminal stance phase begins with the heel lift of the reference leg and ends with the initial contact of the contralateral side. The Terminal stance section completes the one-legged stand. The special accomplishments in this phase are: The forward motion of the body over the supporting leg (standing leg), the controlled dorsal extension at the ankle with release of the heel from the ground and the hyperextension in the hip joint. [46]

PSw Pre-swing - 50-62 % gait cycle

With the initial contact of the contralateral side, the pre-swing phase begins and ends with the lifting of the reference leg (toes lifted, toe-off) and is the second terminal double limb stance. The specific accomplishments in PSw are: The preparation of the reference leg for initial swing, foot release from the ground, leg forward motion, passive knee joint flexion (40°) and plantar flexion of the ankle joint. [47]

ISw Initial-swing - 62-75 % gait cycle

Initially, the reference leg is raised (toe-off). If the ankle joint, the standing leg and the reference leg cross over, the initial swing phase is completed. The most important factors in this phase are: releasing the foot from the ground, the forward motion of the reference leg, the hip joint flexion (15°) and the knee joint flexion (60°). [48]

MSw Mid-swing - 75-87 % gait cycle

If the tibia of the standing leg crosses the tibia of the reference leg, the mid-swing phase begins, and ends when the tibia of the swinging leg is vertical positioned to the ground. The specific accomplishments are: Continuing moving the reference leg forward, ensure sufficient distance between foot and floor (at the reference leg), increasing hip flexion (to 25°) and dorsal extension of the ankle to neutral zero position. [49]

TSw Terminal-swing - 87-100 % gait cycle

At the beginning the tibia of the reference leg is positioned vertical to the ground. If the reference leg touches the ground, the terminal swing is completed. (initial contact) The specific accomplishments are: to complete the forward motion of the reference leg, to prepare the reference leg for the stance. [50]

IC - Initial contact

LR - Loading response

MSt - Mid stance (early)

MSt - Mid stance (late)

TSt - Terminal stance

PSw - Pre-swing

ISw - Initial-swing

MSw - Mid-swing

TSw - Terminal-swing

gait phases overview demonstrated on an healthy subject.

[figure 12-20]

right leg = reference leg
left leg = contralateral leg

RESEARCH - 2 gait cycle

Gait phases overview demonstrated on an healthy subject.

stance phase 60%						swing phase 40%		
weight transfer		one-leg-stand		forward motion of swinging leg				

IC - Initial contact	LR - Loading response	MSt - Mid stance (early)	MSt - Mid stance (late)	TSt - Terminal stance	PSw - Pre-swing	ISw - Initial swing	MSw - Mid swing	TSw - Terminal swing
~1 sec	~0,37 sec	~0,05 sec	~0,05 sec	~0,10 sec	~0,05 sec	~0,05 sec	~0,40 sec	~0,05 sec
0%	0-12%	12-31%		31-50%	50-62%	62-75%	75-87%	87-100%
double limb support	double limb support	single limb support		single limb support	double limb support			

[figure 21]

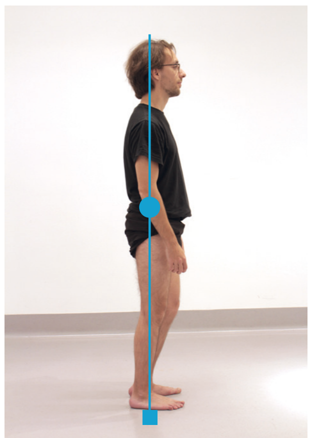
2.5 ground reaction force vector

Each body segment has an own center of gravity (center of mass). The functional balance between the alignment of the body segments and the muscle activity on the joints is necessary to achieve stability in an upright position. If the center is located exactly above the supporting joint, the stability is functional and economical and is also called "passive stability" (Völker 1992).

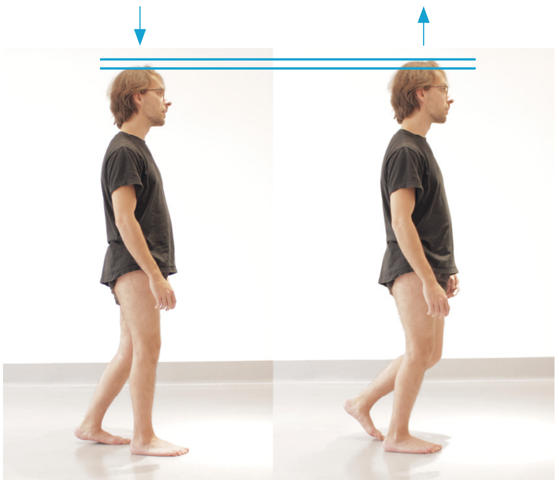
The following three anatomical conditions of the body are representing a significant challenge to maintain stability (Perry 1992):

- The size and weight difference between passenger and locomotor; the passenger weight (70% of the total mass) is carried by the locomotor (30% of the total mass)
- The multisegmented, supporting lower limb
- The rounded joint contours of the lower extremities

Three forces acting on the joints: body weight, ligament tension and muscle activity. The ground reaction force vector, or body vector, determines the effect of body weight for the stability (every moment of standing and walking). As soon as the weight of the body reaches the ground, forces of equal strength (newton's 3rd law) are exerted, but in the opposite direction (to the body). [51]



[figure 22]



Without modulating mechanisms the body would be lifted 9.5 cm, which would quickly lead to exhaustion. [54]

[figure 23]

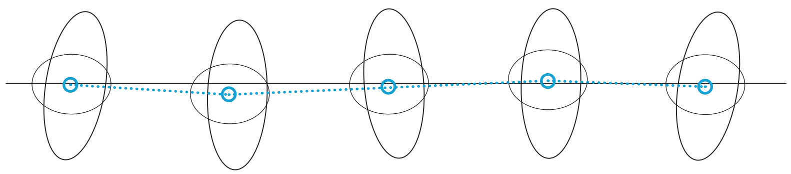
2.5.1 determinants of gait

The "Determinants of Gait"- the determining factors of walking were originally described by Saunders (1953). The concept is still in use today and was only minimally modified by Inman et al (1981) and Rose und Gamble (1994).

Six specific movement sequences can contribute to an improvement in walking efficiency. Since the focus of this thesis is on the lower extremities and not directly on the hip, only the following three factors are highlighted:

- coordinated ankle and knee joint mechanism
- controlled dorsal extension in mid stance
- heel lift in terminal stance and heel contact in initial contact

With a combination of this six specific movement sequences (Determinants of gait), transverse and vertical displacements can be reduced to less than 50 % of its deflection (Inman et al. 1981, Perry 1992). These can considerably reduce the required energy for walking. [52]



[figure 24]

Lateral shifts of the HAT within a gait cycle. Maximum shift to the right in the right and maximum shift to the left in the left monopod (mod. according to Perry 1992). Head, neck, torso, pelvis and arms are part of the passenger unit and abbreviated as "HAT" (Elftmann 1954). [53]

2.6 rocker functions & impact absorption

As already mentioned, the main task of the locomotor is to advance the body. The forward fall of the body weight is used as the main driving force and the mobility at the base of the supporting limbs plays an important role in the process which is made possible by the central system of heel, ankle and metatarsal phalangeal joints. The three contiguous rocker functions allow the passenger to fall forward and convert the downward body weight into forward motion. The resulting forward motion is guided by controlling muscle activity. [55]

heel-rocker function

The weight stored during weight transfer due to the body weight falling forward on the standing leg produced swing is obtained by the function of the heel-rockers and take place in the initial contact and load response (0-12 % gait cycle). Due to the eccentric muscle work of the pretibial musculature the "falling down" of the foot is slowed down. [56]

ankle-rocker function

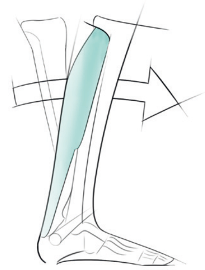
The Ankle-rocker function describes the controlled dorsal extension by selective muscle control in the ankle joint. By contraction of the calf muscles, the tibia becomes a stable foundation for the extension on the knee joint, while at the same time the forward movement of the lower leg and the continuation of the leg is being enabled. The ankle-rocker function takes place in 12-31 % of the gait cycle (mid stance). The forward motion of the tibia is stabilized by the m.soleus muscle and at the same time, together with the m.gastrocnemius muscle, in conjunction with eccentric muscular work, effects the controlled dorsal extension of the foot. (Inman 1981, Tittle 1985, Perry 1992) [57]

forefoot-rocker function

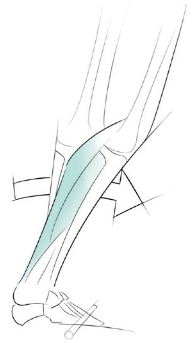
The forefoot-rocker function allows further forward movement of the leg with increasing controlled dorsal extension in the ankle joint. The heel is lifted off the ground and takes place during the terminal stance (31-50 % gait cycle). The m.gastrocnemius and m.soleus work together with about 80 % of their maximum force on the speed reduction of the tibial motion into the dorsal extension (Rohen 1984, Perry 1992). In this phase, their muscle activity is three times higher than in mid-stance. [58]

If the heel touches the ground after falling in initial contact, the result is a sudden load on the front leg of about 60 % of the body weight in 0.02 seconds (Saunders 1953, Whittle 2002). The shock-absorbing reaction of the ankle, knee and hip joints is necessary to absorb this force. [59]

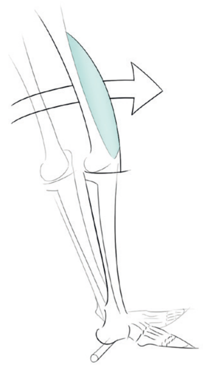
heel-rocker function
[figure 25]



ankle-rocker-function
[figure 26]

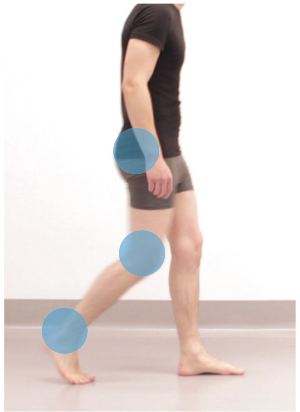


forefoot-rocker function
[figure 27]



Shock-absorbing mechanism on the knee joint: controlled flexion on the knee joint through eccentric activity of the m.quadriceps. [60]

[figure 28]



Three shock absorption joint regions. [61]

[figure 29]

2.7 preview of relevant muscles

Which muscles are active in different gait phases? And where (hip, knee, ankle) are these muscles located? Which muscles are necessary for walking?

hip-joint area:

m.adductor magnus
m.biceps femoris *(ischio-crural muscules)*
m.semimembranosus *(ischio-crural muscles)*
m.semitendinosus *(ischio-crural muscules)*
m.tensor fasciae latae
m.glutaeus maximus
m.glutaeus medius
m.rectus femoris
m.iliacus
m.adductor longus
m.gracilis
m.satorius
[62]

knee-joint area:

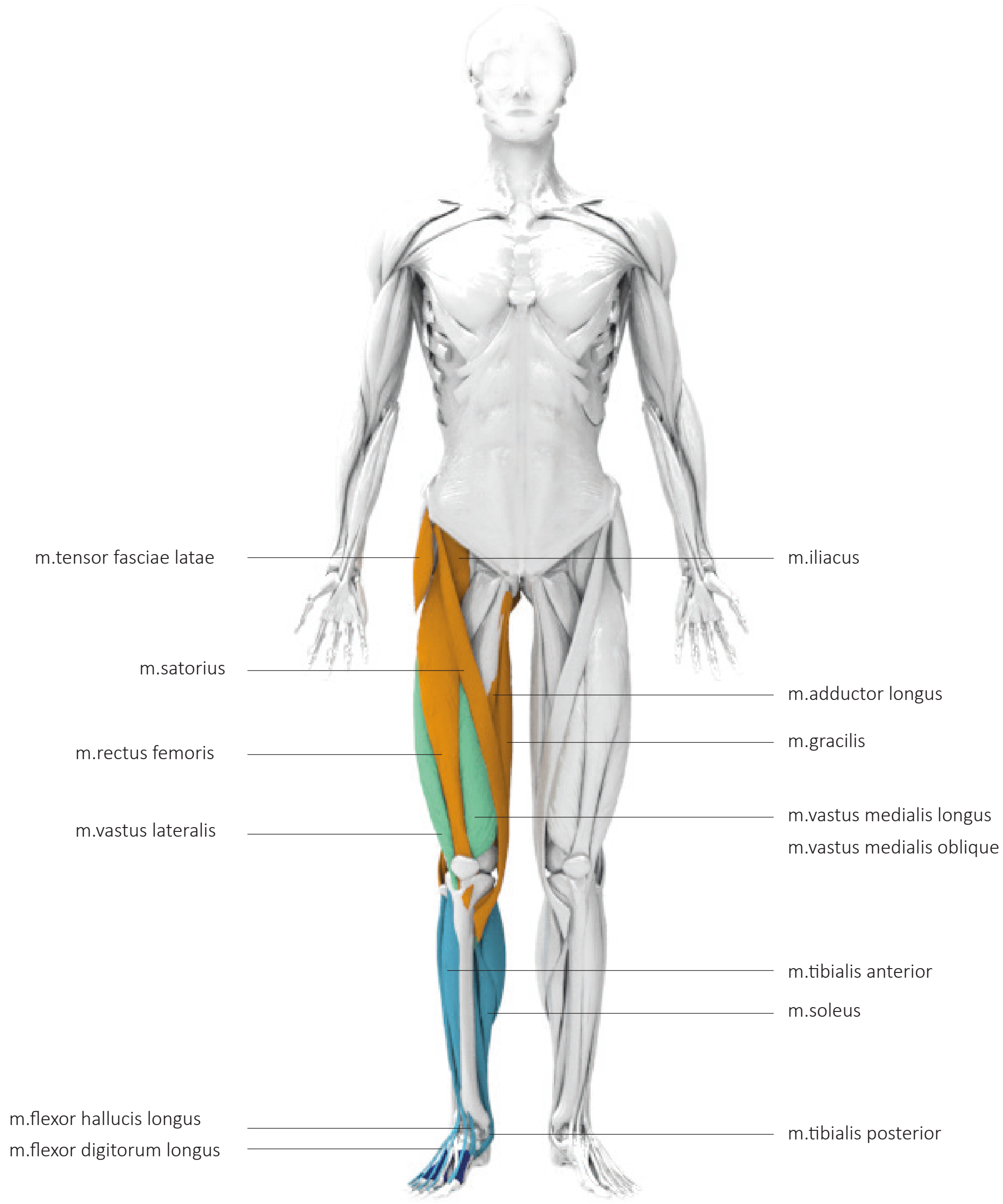
m.popliteus
m.vastus intermedius *(M.quadriceps)*
m.vastus medialis longus *(M.quadriceps)*
m.vastus medialis oblique *(M.quadriceps)*
m.vastus lateralis *(M.quadriceps)*
m.rectus femoris *(M.quadriceps)*
m.biceps caput breve
m.gracilis
m.sartorius
m.biceps caput longum
m.semimembranosus
m.semitendinosus
[63]

ankle area:

m.flexor hallucis longus
m.flexor digitorum longus
m.soleus
m.gastrocnemius
m.tibialis posterior
m.tibialis anterior *(pretibial muscles)*
m.extensor digitorum longus *(pretibial muscles)*
m.extensor hallucis longus *(pretibial muscles)*
m.peroneus longus
m.peroneus brevis
[64]

metatarsophalangeal joints (MTP joints):

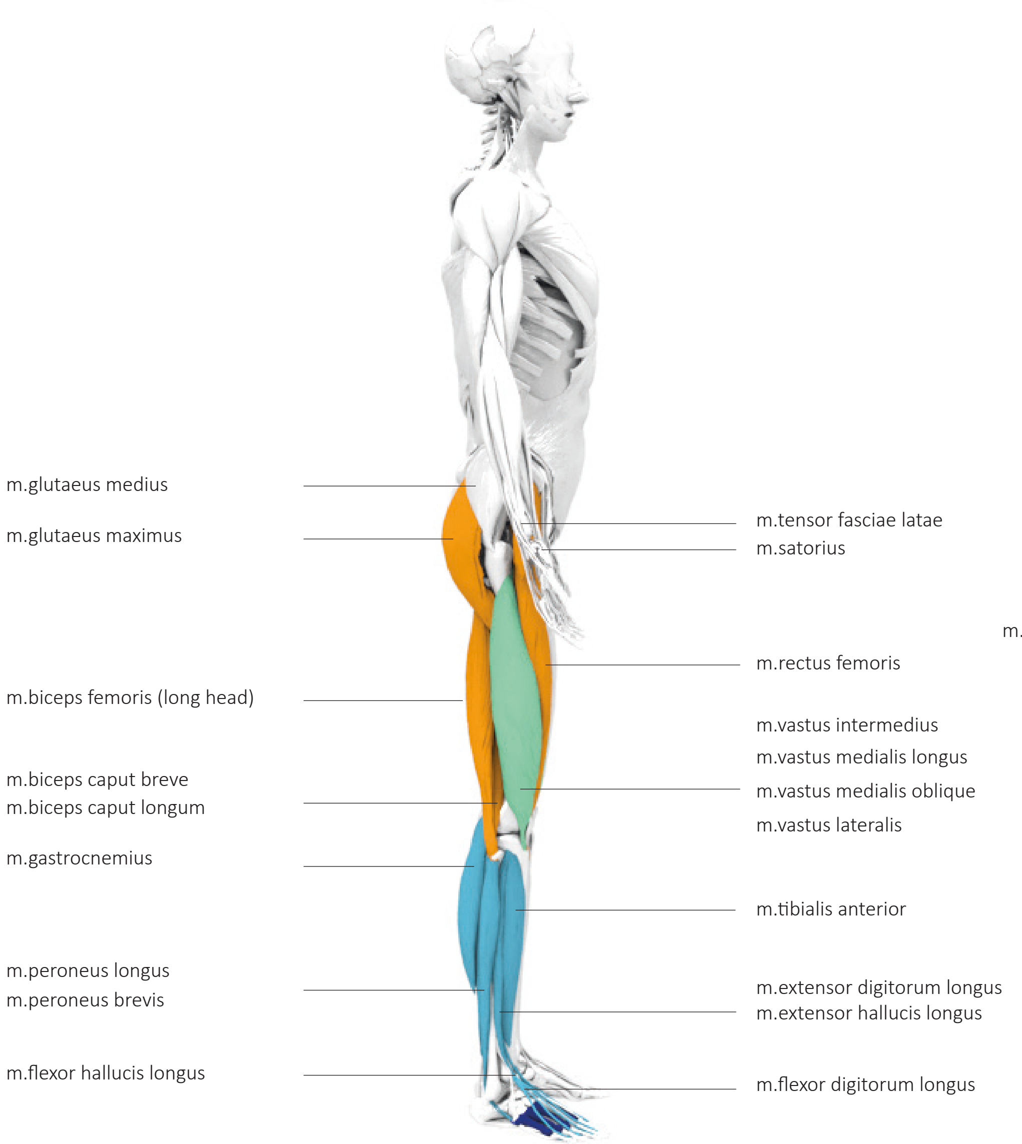
[65]

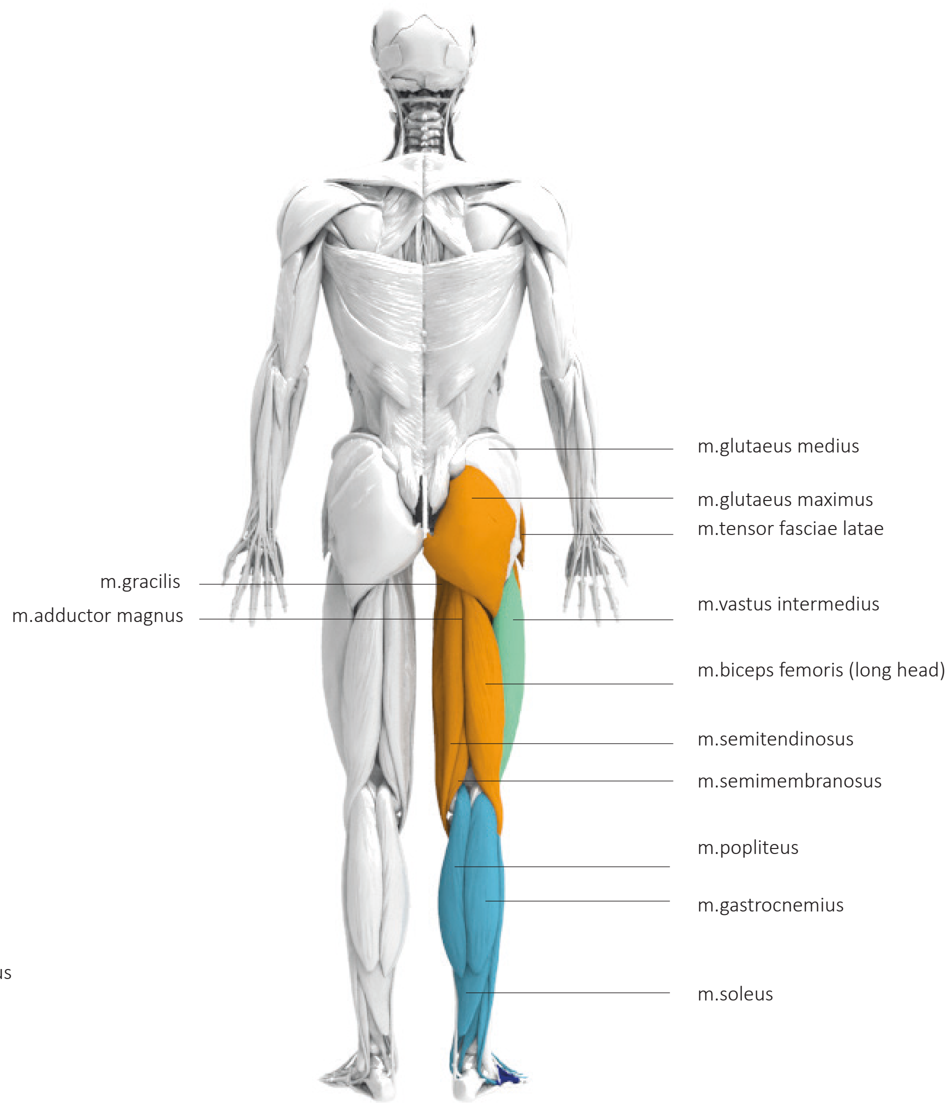


[figure 30-32] *muscle person*
"BodyParts3D, © The Database Center for Life Science licensed under CC Attribution-Share Alike 2.1 Japan."

RESEARCH - 2 gait cycle

2.7 preview of relevant muscles





[figure 30-32] *muscle person*
"BodyParts3D, © The Database Center for Life Science licensed under CC Attribution-Share Alike 2.1 Japan."

2.7 preview of relevant muscles

[figure 33]

[figure 36] important phases
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2.7 preview of relevant muscles

[figure 34]

[figure 36] important phases)
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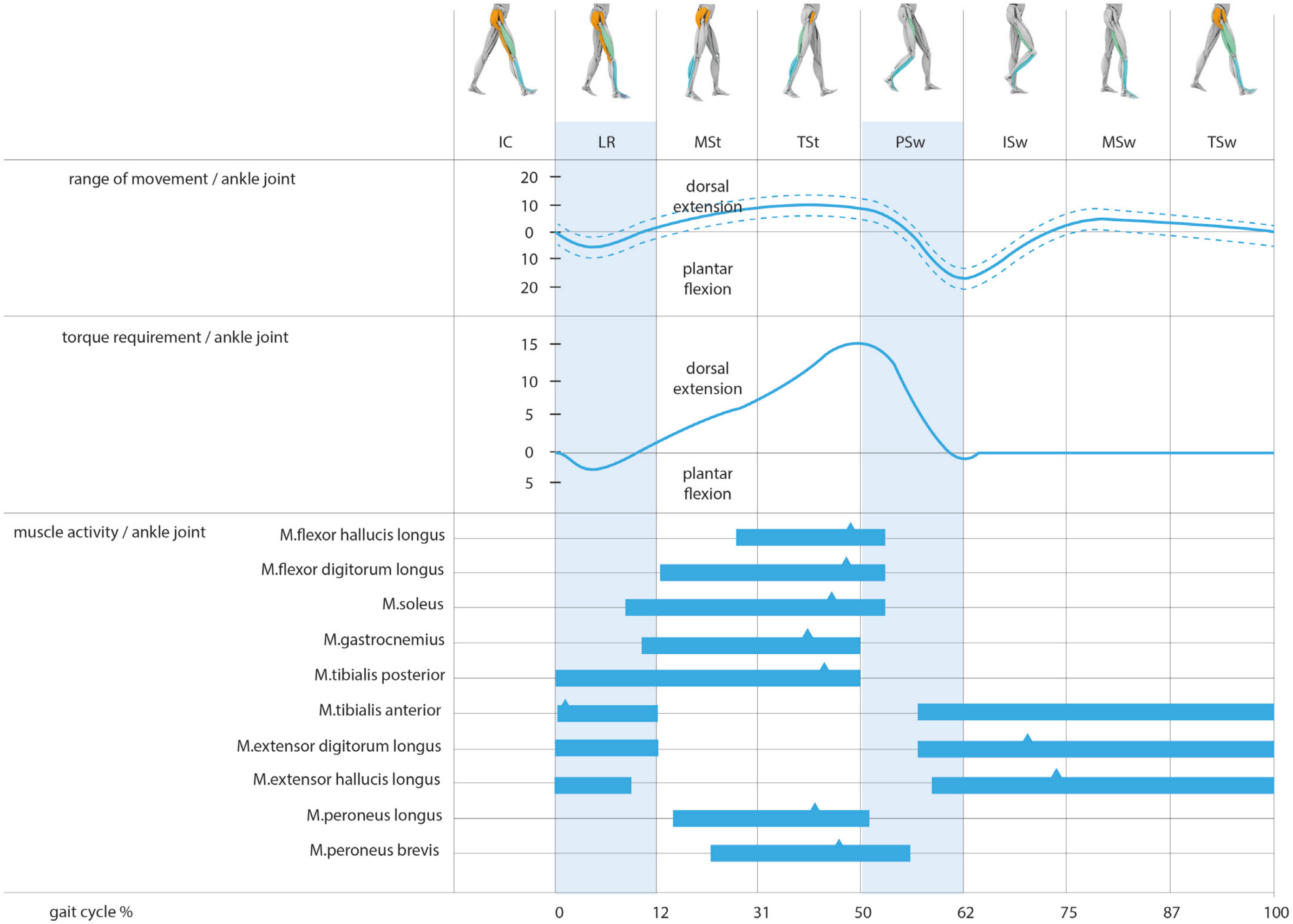
2.7 preview of relevant muscles



[figure 35]

[figure 36] important phases
"BodyParts3D, © The Database Center for Life Science licensed under CC Attribution-Share Alike 2.1 Japan."

RESEARCH - 2 gait cycle

2.8 important phases

(MSt - early) (MSt - late)

phase of weight transfer (Initial contact IC)

phase of weight transfer (Loading response LR)

phase of "one-leg-stand" (Mid stance MSt)

phase of "one-leg-stand" (Terminal stance TSt)

phase of moving swinging leg along (Pre-swing PSw)

phase of moving swinging leg along (Initial-swing ISw)

phase of moving swinging leg along (Mid-swing MSw)

phase of moving swinging leg along (Terminal-swing TSw)

[figure 36] important phases
"BodyParts3D, © The Database Center for Life Science licensed under CC Attribution-Share Alike 2.1 Japan."

ANALYSIS - 3 analysis of causes

ANALYSIS - 3 analysis of causes

3.1 cerebral palsy (ICP)

In relation to the population, the formation of an ICP is about 1-7 out of 1000 newborns. Boys are affected more frequently (55-66%) than girls. [66]

Cerebral palsy (ICP) is mostly a spastic disorder of the neural and muscle system that occurs to children. It is characterized by disturbances of the neural and muscle system in the areas of the muscle tension (tone), muscle strength, coordination and motion sequences. Most common are spastic hybrids, in which the muscle tensions are generally increased. The causes leading to infantile cerebral palsy are very varied. Oxygen deficiency, umbilical cord complications, infections, brain hemorrhages and accidents can lead in the whole course of pregnancy cause to infantile cerebral palsy (most frequently in the course of birth). The symptoms can be individually severe. Spastic symptoms occur in 75% of all cases. [67]

- Hemiplegia (32%):	The extremities of one half of the body are affected, the arms usually more than the legs.
- Diplegia (40%):	The legs are more affected than the arms.
- Tetraplegia (2%):	In tetraplegia, all extremities are paralyzed and the motor and mental development are considerably delayed. Only about 10% of all patients are able to walk.
- Bilateral hemiplegia:	All four extremities are spastically paralyzed, the arms more than the legs.
- Triplegia:	Three extremities are spastic paralyzed.

[68]

In these listed diseases, the long flexor muscles and adductors in particular are affected by paralysis and the joints become stiff due to spasticity. [69]

3.2 persons coucerned

"Walking is a complex interaction of joint mobility, selective muscle action and position sensibility which enables the individual to progress in the desired direction at a chosen speed. Each of these elements of gait, however, can be disrupted by a wide variety of pathologies." (Jacquelin Perry, M.D., Sc. D. (hon) Professor emeritus, Orthopaedics, University of Southern California.)

What other diseases show similar symptoms to cerebral palsy patients?

Furthermore, other diseases are listed with similar sequelae to cerebral paresis patients:

A moderate form of CMT/HMSN patients suffering from motion and sensory nerve disease. These affected motor nerve fibres are responsible for controlling motion and are often more severely affected than other nerve fibres (sensoric). The consequences of this disease are often severe paralysis of the peroneal nerve (lower leg muscles). Slight spastic symptoms on the legs and muscle tension may also result. [70]

Rheumatoid arthritis leads to mobility and powerlessness limitations. [71]

MS multiple sclerosis is a well known disease that causes muscle weakness and stiffness. [72]

ALS Amyotrophic lateral sclerosis usually begins at the age between 50 and 70 and almost exclusively affects the motor neural system. Among other things, the motor system is also diseased and leads to muscle twitching, muscle atrophy and muscle weakness (paresis) in arms and legs. Disease of the motor system nerve cells in the cerebral cortex and their connections to the spinal cord, leads both to muscle paralysis and to an increase in muscle tone (spastisce paralysis) with an increase in reflexes. [73]

The Guillan-Barré syndrome, an autoimmune disease, is manifested in the patient by general weakness, especially muscle weakness, insecure walking, signs of paralysis in the legs. [74]

In Morbus Parkinson disease, the main motoric symptoms for an impaired locomotor system are divided into four main groups: Brady kinesis or akinesis, Tremor, Rigor and postural instability. The gait becomes small-stepped and shuffling. Sometimes movement inhibitions appear as well. [75]

1 brady kinesis or akinesis
Slowdown of motion sequences and immobility

2 tremor
Tremor is an involuntary, rather regular, rhythmic movement of body parts. The tremor usually begins on one side of the hand, then the leg, the head and the chin can also be affected.

3 rigor
Usually the neck and shoulder muscles are affected first by the stiffening of the musculature. At the beginning these complaints could be confused with rheumatismor muscle tension. The muscle stiffness, or an increased state of tension of the muscles, can be pronounced differently in different parts of the body.

(4 postural instability)
The postural instability is not within the intended target group for this product. [76]

Hemiplegia discribes the loss of all sensomotoric functions in one body half. Over 70 % of the patients are over 60 years old. Among many other symptoms paralysis or spastic patterns may develop. [77]

summary of the target group

Many different diseases result in a limitation of the walking ability. In general the target group for the "intelligent orthosis" should in principle be able to walk. This means the potential users can be narrowed down roughly and refer only to the lower extremities:

- able to walk or slight limitations to walk
- slight muscle weakness
- slight spastic paralysis
- slight loss of control of the locomotor system

3.3 specific user

3.3.1 description

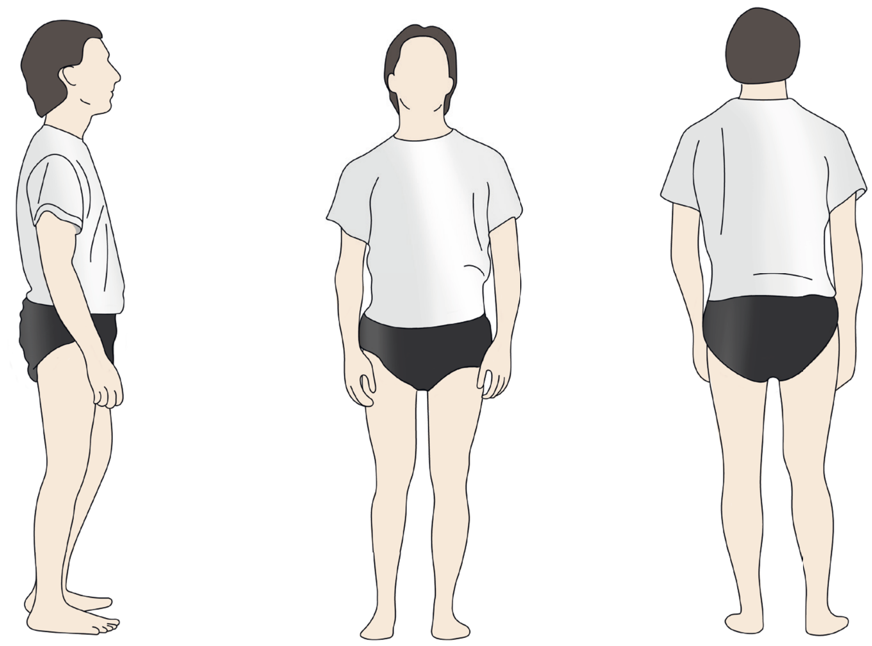
The specific user is 30 years old and has cerebral paresis (spastic diplegia) since birth due to early childhood brain damage after premature birth. In the area of the lower extremities, the disease led to typical gait patterns and malpositions. Coordination and fine motor skills are limited. [78]

In his spare time, he wears steel-cap shoes because they give him a stronger sense of stability. The shoes he prefers to wear are from the brand "Engelbert-Strauss" and look very simple at the first sight and the reinforcement inside the shoes cannot be seen.

Although he was prescribed a DAFO orthosis (prepreg technique), he does not like to wear it. Without a qualified training, the risk of getting accustomed to a wrong gait pattern is high. The reasons are various. On one hand he does not want to attract attention and on the other hand he cannot walk faster. His hopes for the future are that he will no longer stand out because of his gait pattern and he wants to be able to accelerate his walking speed. Walking and standing causes great difficulties in everyday life. He quickly feels exhausted due to impairments on his hips, gluteal muscles and partial paralysis of the femur. If he is standing on one leg, he has difficulty to keep balance.

The user tends to turn the foot too far inwards. The hips and gluteal muscles are restricted in their movements. The specific user would like to wear an orthosis at home as well as in his everyday life.

[79];[231] (see annex XII- diagnosis on page 151)

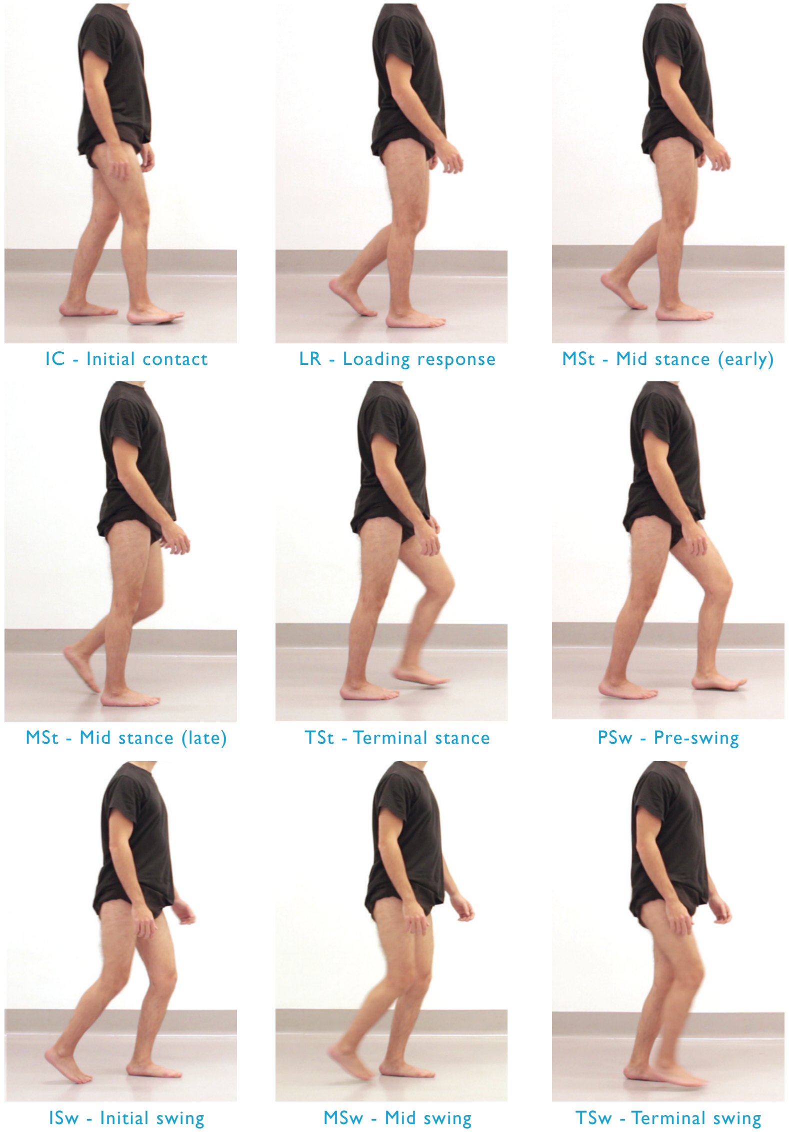


[figure 37]

3.3.2 body measurements

shoe size:	40
body height:	1,70 m
body weight:	57 kg
hip diameter: (belt position)	86-87 cm
femur:	44-45 cm
over the knee:	41-40 cm
under the knee:	34-35 cm
above the ankle joint:	23-24 cm
foot lenght till the waistband:	90 cm

3.3.3 gait analysis



gait phases overview demonstrated on cerebral palsy patient.

[figure 38]

right leg = reference leg
left leg = contralateral leg

3.3.4 pathological deviations of specific user - knowledge

This observerd gait analysis, inspired by the "observed gait analysis RLANRC-System" (Dr. Jacquelin Perry) was performed by the specific user. It clearly shows the need of support. On the next page in (figure 39) "gait analysis conclusio - user specific" the conclusio of the gait analysis is shown. In the background (figure 39), another person is deposited with normal gait speed. Important to know is, that the depositing person is not comparable in time, because the person in the background has a faster walk in real time. These first results were the starting point to find out the main causes of the deviations. The focus was only on one unique gait cycle. In general the gait pattern or gait cycle of cerebral palsy patients are highly variable.

The aim of the gait analysis is not, to evaluate exact deviations of degrees, the focus is to find out in which gait phase lifting support is needed. The second focus was on the observation of the toe-out angle in the lower area of the foot, which was only observed in the frontal perspective.

In conclusion, the results show the low average walk speed of 109 steps/min.

The default value for normal walking is about 120 steps per minute. [80] Arised from observation this deviation causes long stance phases. The uncertain hand movements during the walk (especially in the "one-legged-position") show a slight disturbance of equilibrium.

The stride length provides information on the functionality of the locomotor or the duration of swing phases or rather contralateral the duration of the monopod. The normal average stride length is about 1,4 m (persons without physical limitation). [81]

The dorsal extension was not present in the Pre-Swing phase and in the Initial Swing. The specific user had difficulties lifting the leg. Especially in the phases TSt, PSw and ISw an active motor support could counteract the deviation (drop foot). Retrospectively to the "determinants of gaits" factors, it can be recognize clearly: the height differences of the head/body. The observed person had difficulties to walk forward in a straight line. He often deviated sideways. From the beginning of the PSw phase til the end of the MSw phase a correction of the toe-out angle could be supportiv for the user to achieve a stable ground contact. This sequence of the three mentioned phases often takes place within a few hundreds of milliseconds.

origination of measurement

The indicated values were determined by two persons using a stop timer on their mobile phone. The two resulting values were compared and the mean value was determined (e.g. 1) 2.97 sec.). For the stride time this measurements were repeated 5 times. At the final stage, the average value was calculated from several results. This method tries to counteract the reaction delay caused by "manual stopping" and avoids large deviations.

stride time

(time of two steps per seconds [82]
/ 4 heel contacts per seconds)
right = reference leg; left = start swing leg;

1) 2,97 sec.
2) 2,49 sec.
3) 2,35 sec.
4) 2,49 sec.
5) 2,98 sec.

average stride time: 2,65 sec.

stride length

(distance of two steps [83]
/ 4 heel contacts)
right = reference leg; left = start swing leg;
messured from middle point of the heel to the next middle point of the heel

1) 195 cm
2) 191 cm
3) 188 cm
4) 183 cm
5) 197 cm

average stride length: 190,8 cm = 1,908m

walking speed

distance of 10 meters (required time in seconds) [84]
right = reference leg; left = start swing leg;

1) 10,33 sec. (18 steps)
2) 10,33 sec. (18 steps)
3) 10,15 sec. (18 steps)
4) 10,30 sec. (18 steps)
5) 10,15 sec. (18 steps)
6) 10,20 sec. (18 steps)
7) 9,58 sec. (18 steps)

average: 10,14 sec. (18 steps)

walking speed (m/sec) = distance (m) / time (sec)
= m/sec x 60 = m/min [85]

walking speed: 59,17m/min

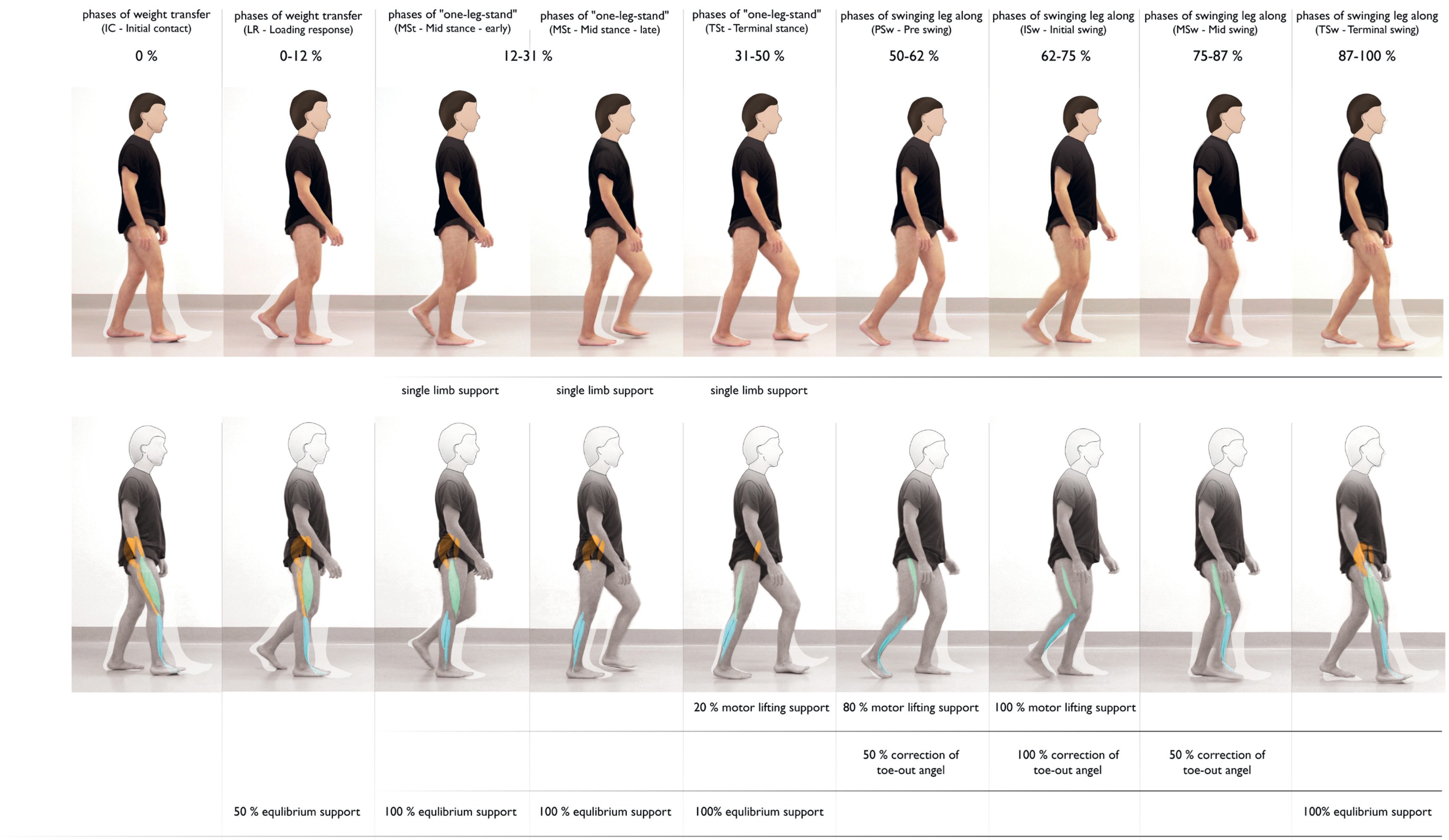
cadence (stepfrequency / steps per minutes [86]

right = reference leg; left = start swing leg;
measured by heel contacts

1) 107 steps/min
2) 110 steps/min
3) 110 steps/min

average cadence: 109 steps/min

gait analysis - Design of an intelligent orthosis in support of the locomotor system



[figure 39]

INCEPTION POINT & COOPERATION -
4 MCI Management Center Innsbruck - department of mechatronics

4.1 concept idea

The "Medical Device Project" started at the MCI - Management Center Innsbruck - department of mechatronics and shows a new solution to the approach of how an intelligent orthosis can make everyday life easier for cerebral palsy patients in the future.

The main problem of the target group is muscle weakness, which leads to a varying gait pattern and a low walking speed. Through contact with a cerebral palsy patient, who voluntary provided for the project, a first analysis of problems was established because of the limited muscle activity:

- One focus was mentioned for the problem of low-lifting of the leg during the swing phase.
- One further focus was the toe-out angle (outside rotation) of the foot, which results in an unstable ground contact.

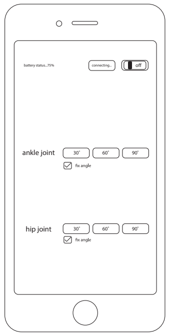
Together with a bachelor student group and with the mentoring of FH-Prof. Yeongmi Kim, PhD. first technical function principles could be tested and a first sensory package was defined. With active motor support at the hip area the students tried to counteract the low-lifting leg through lifting the thigh.

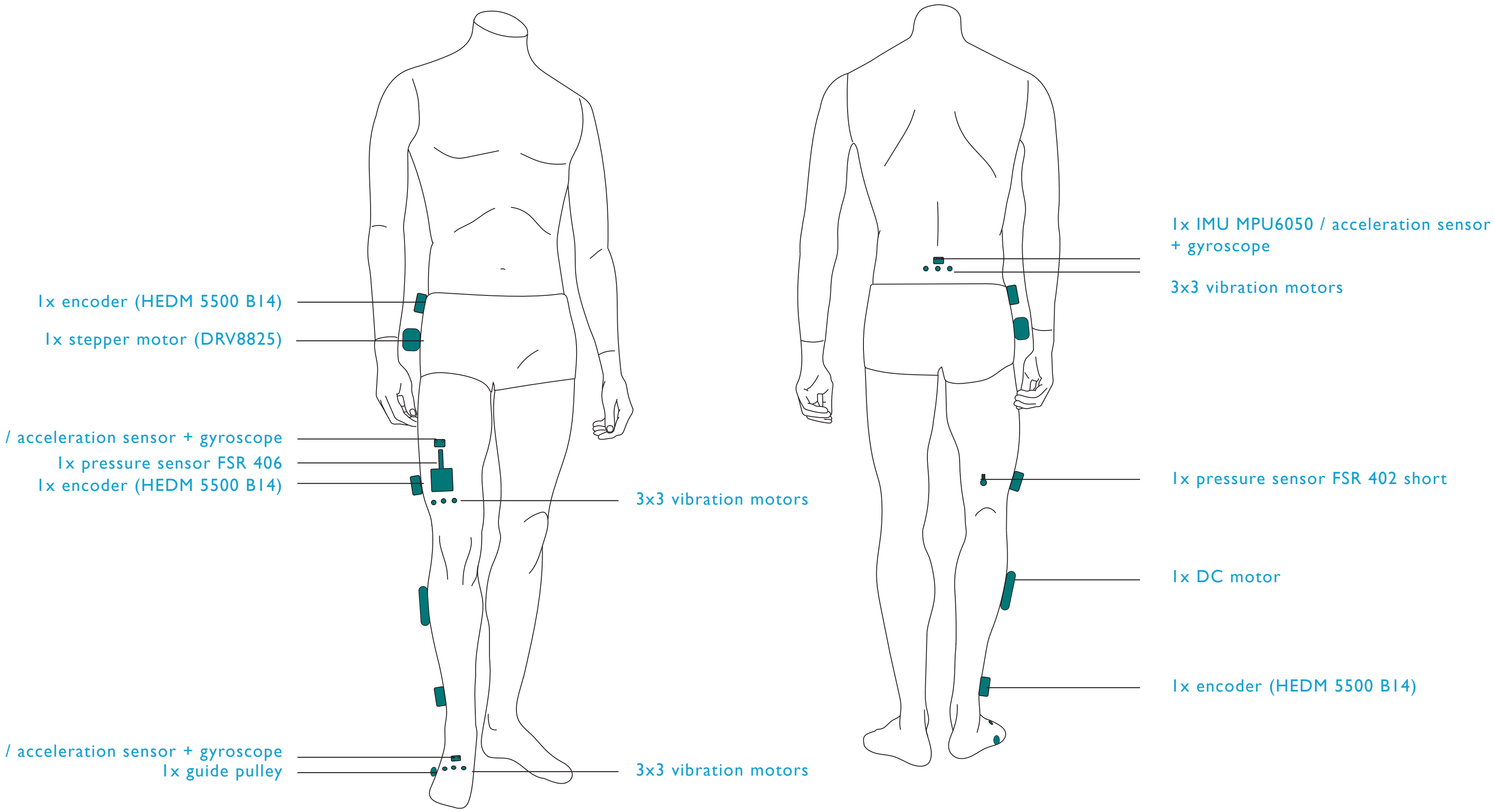
A DC motor with a "Passive Returning Mechanism for Twisted String Actuators" [87] mechanism was implemented for correcting actively the toe-out angle. The twisted rope made the corrected angle direction possible. [88]

The hip position was not corrected actively by a further motor, but the actual position could be detected in four different levels by an encoder. The hip angle can be activated by a strong motor (stepper motor).Within three vibration motors the user could perceived passive feedback, to give him the signal for correcting the hip position itself (for example perceive vibration on the left side means to lift the position on the left side higher until the signal stops). First of all the right leg - the reference leg of the patient was restricted. With the aid of two further pressure sensors and with an encoder the knee angle could be detected, too. [89]

Subsequently the intention of an app, gives the user the possibility for custom settings to control the active motor support. The conception shows a mixture of active motor support and allows to choose a training mode (passive feedback for self-correction). This means on one side the patient can switch on the active motor support in case being already exhausted (individual needs can be set) and on the other side the support can be switched to a passive mode if the active support is actually not needed. The vibration motors on the hip, knee and upper side of the foot were suggested to give the user signals like "lift up the thigh higher", "keep moving the foot more in outside direction" or "correct the hip on the left or right side more" (training mode). [89]

4.2 sensor package overview





sensor package overview and app idea
[figure 40];[figure 41]

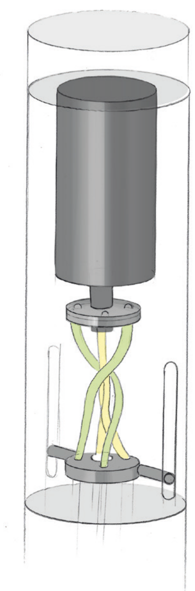
4.3 ankle-stabilisation

At the final presentation of the medical device project on the MCI Management Center Innsbruck - department of mechatronics, Mattias Abfalterer, Sandrino Achenrainer und Alexander Figl presented a first functional prototype with a "twisted string actuator" for outwards angle correction.

The inventor´s name of the "twisted cord actuator" is Kremer, S.R. [90] Usman M. / Seong H. / Suthar B. / Hawkes E. / Gaponov I. / Ryu, J-H. published in 2017 the "Passive Returning Mechanism for Twisted String Actuators" scientific paper. [91]

"The twisted string actuator is an actuator that is gaining popularity in various engineering and robotics and applications." (Usman Muhammad 2017)

This simple motor principle shows a great potential for the future. Many publications were released in the last years, especially in the scientifc field of robotics. Research scientists try to optimize this principle continuously.



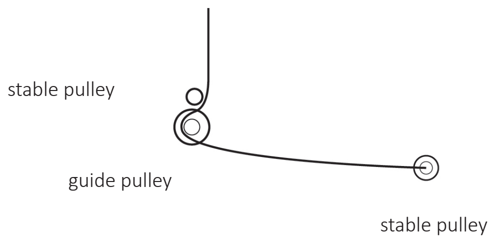
"twisted string actuator" principle [figure 42]

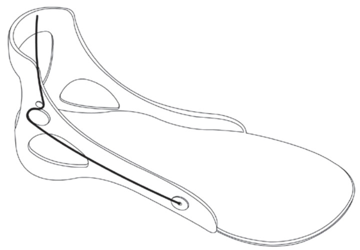
presentation material- final presenation [figure 43-48]

5.1 actor position

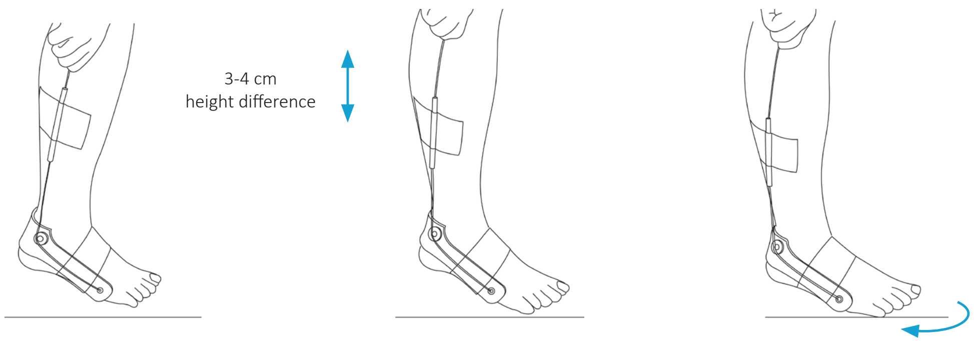
How could the motor be attached to the leg and where exactly is the optimal position to gain a portable product? Where are the optimal lifting points situated on the foot to achieve a lifting support and where they have to be located for gaining a toe-out angle correction?

At the beginning a more simplified principle with only one guide pulley, one stable pulley and the aid of adhesive tape (without an active motor) was tried out (figure 49; 50; 51-53;). To achieve an external rotation of the ankle joint, the position of the actuator has to be placed on the side of the fibula (figure 69). The deflection of the rope has to be as straight as possible near the bottom and may have a slight difference in height.





rope path- in shoe
[figure 49];[figure 50]



strong inside rotation angle

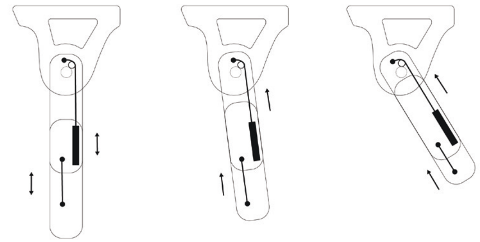
pulling mechanism

toe-out angle arround from-20° to 10° is corrected

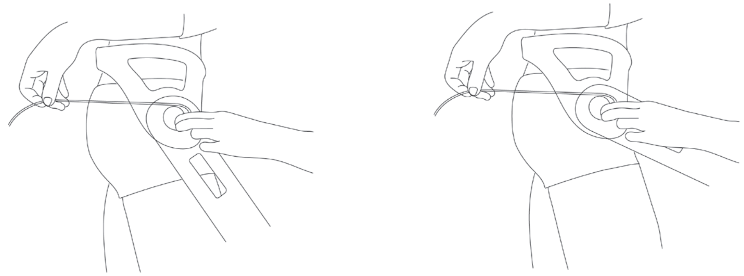
[figure 51-53]

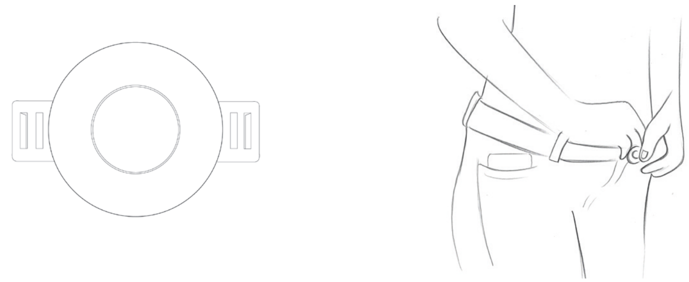
5.2 hip area

Further a simplified function principle with a rope (without an actuator) was tested to achieve a shortening of two plastic elements, because the thigh is also shortening by lifting activity (figure 54-56; 57-58;). The figures 59-60 show a first idea of a quick closure which enables opening the belt by one hand.



hip mechanism application
[figure 57-58], [figure 54-56]

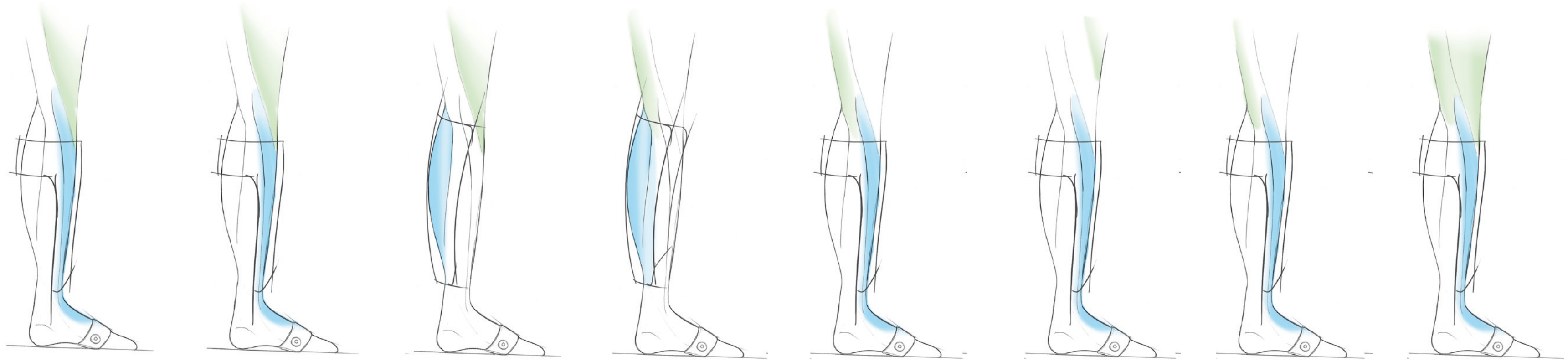




quick closure idea application
[figure 59];[figure 60]

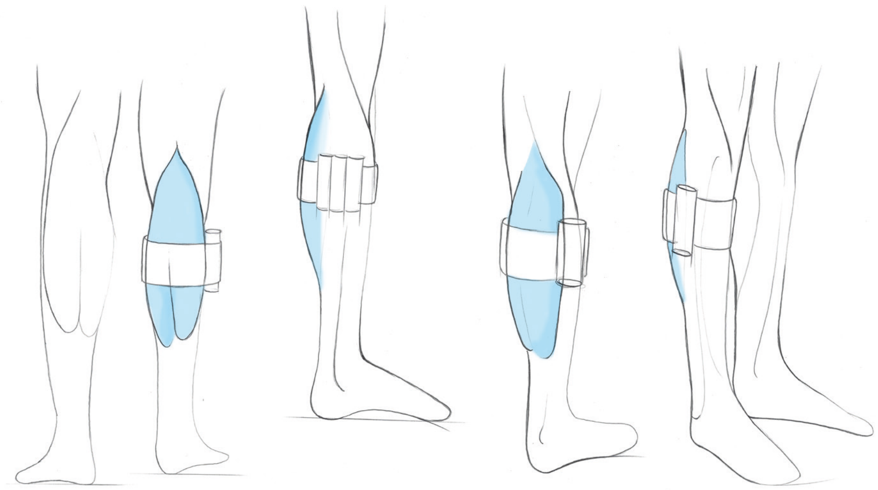
IDEATION - 5 training & support system

The illustrations (figure 61-68; 70-71;) presenting ideas of supporting the lower leg area. One fundamental idea was to look for a selective support by taking into account the different gait phases with their specific accomplishments.

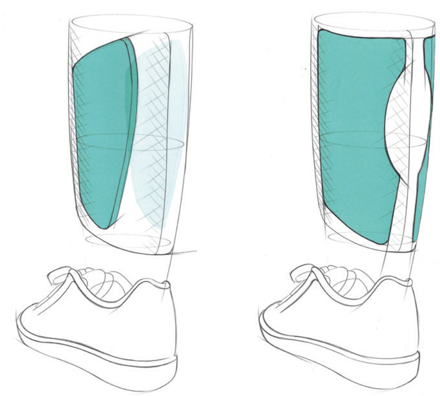


Initial contact | Loading response | Mid stance | Terminal stance | Pre-swing | Initial-swing | Mid-swing | Terminal-swing

[figure 61-68]



actor postions
[figure 69]



idea of air cushions support
[figure 70-71]

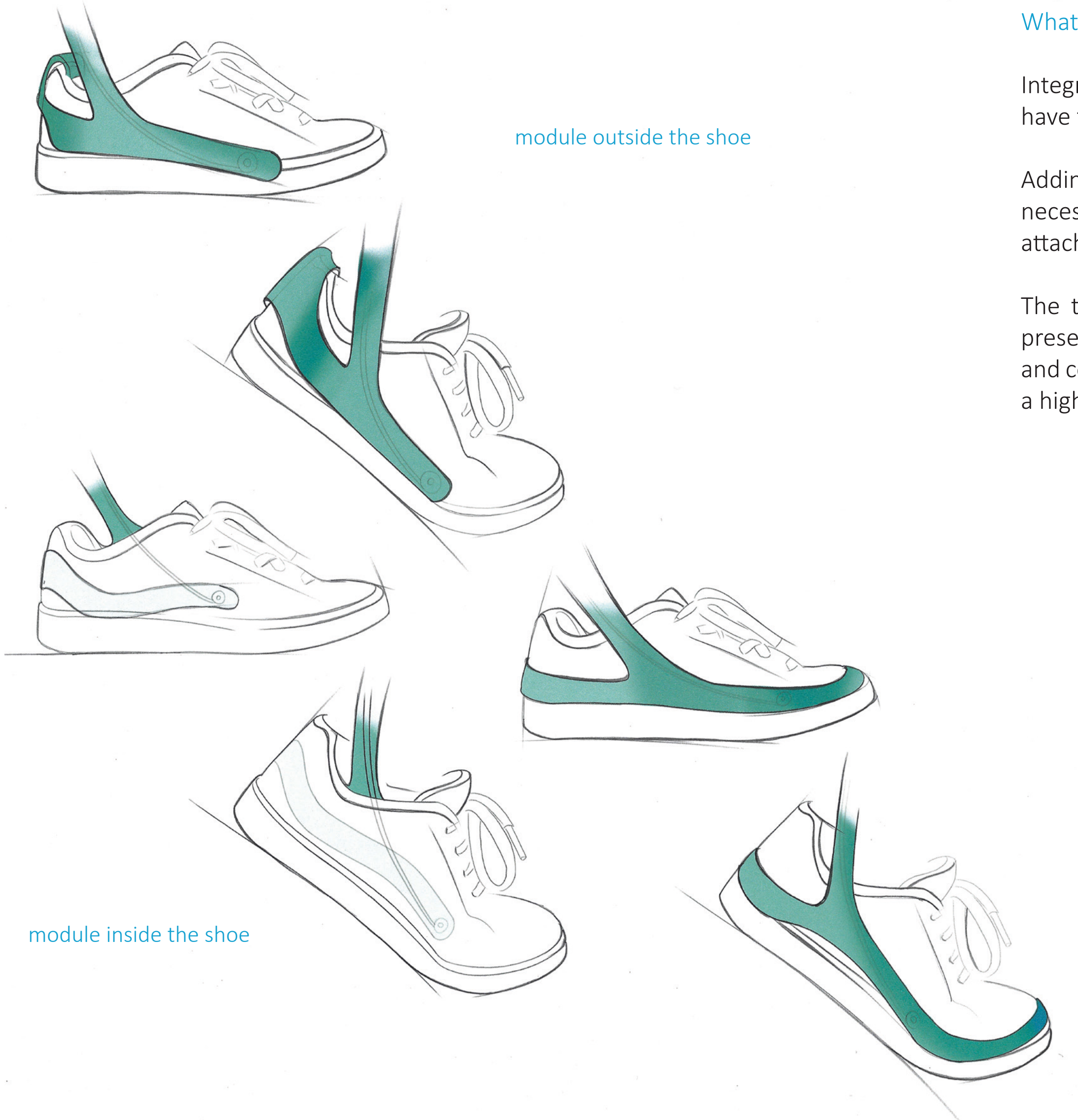
5.4 correction of toe-out angle

What are the advantages and disadvantages of the three different versions?

Integrating the module inside the shoe presents some disadvantages: little flexibility, you have to wear the shoe for the correction (difficult to manage in everyday life).

Adding the module outside of the shoe presents further disadvantages, because it is necessary to take into account the way the shoe is shaped. In everyday life, this method of attachment could be dangerous.

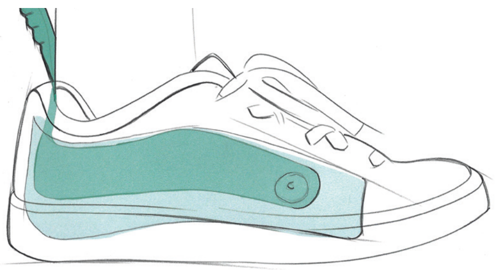
The third way to add the module is in combination with a compression stockings. It presents high flexibility for the user. This version also allows a correction without shoes and could therefore also be used in indoor environments. In addition, this version provides a high flexibility for the use to wear any shoe model.



module outside the shoe

module inside the shoe

[figure 72]



[figure 73]

module inside in combination with compression stockings

first ideation sideview and perspective
[figure 74];[figure 75]

EXPERT TALK - 6 expert talk interview - conclusio

The interview took placed on the 14th december together with Mr. OA Mag.Dr.Rainer Hochgatterer. Subsuming the expert talk the main reason of the deviations of gait is situated in the lower ankle and is named weakness of the foot extensors or drop foot. A weakness of the foot extensors means, the patient is impaired with the dorsal extension in the lower ankle. [92]

"To counteract drop foot and what the patient could need is, as soon as the patient leaves the ground behind, he would need a support which makes the following movement." (dorsal extension movement demonstrated), Mr. OA Mag. Dr. Rainer Hochgatterer.

"If the patient is not spastic, people with slipped disc in the lower segments suffer from paresis forefoot. A motion to react the dorsal extension which supports the flexion could support the right ground contact for making the normal gait possible. The three mentioned analysis of problems (weakness of the foot extensors, toe-out angle of the foot and balance problems) which result from the observed gait analysis are frequently established according to Mr. OA Mag. Dr. Rainer Hochgatterer."

1) You have just received a short overview of the project, how do you rate the three problem analyses (drop foot, medial alignment of the foot and balance problem)? Are these problems common in cerebral palsy patients?

"Of course, these problems can often be identified. To a certain extent, these problems are very similar, but each patient is very different depending on where the patient was operated on and how spasticity is manifested. These are people who are able to walk. What I am not quite sure of yet: The foot lifter weakness is only in the lower area and has nothing to do with the upper hip area. So the question is whether the patient would benefit more if he had "support" in the lower area? (...) I like the construction here in the picture very much because it looks very portable. Where I am not sure yet is how to transfer the force to the thigh and whether it could work? If I wanted to lift the thigh with this construction, there would be a lot of leverage. The patient can lift this by himself, what he cannot do is to lift the foot in the lower area. Originally, this was thought of for foot lift weakness, right?" [93]

5) In your opinion, where is the optimal position from which to lift the thigh? Is the intended position of the hip joint on the trochaneus and above the hip joint pivot point in your opinion already optimally selected?

The concept idea, to lift over the hip the thigh was viewed from Mr. OA Mag.Dr.Rainer Hochgatterer with scepticism: "For this lift-support much force is needed.", Mr. OA Mag. Dr. Rainer Hochgatterer. In his opinion a kind of "stretch-jean" which is preloaded in the outstrechted state seems more appropriate to him than a joint on the side with a motorised elevation. [94]

"I think a rubber band placed at the top of the thigh helps the patient rather than a mechanism from the outside because the muscles tenses." Mr. OA Mag. Dr. Rainer Hochgatterer. The only benefit, which Mr. OA Mag. Dr. Rainer Hochgatterer can see, is through the guide on the side of the support device with which the lifting muscles are controlled. [95]

"But if in extreme cases we speak of a paralyzed patient and want to move something here, it is not able to be conceived and will certainly not work. And even when I think of my leg, it is difficult.", Mr. OA Mag. Dr. Rainer Hochgatterer. "With the lower actuator, you will need less force, I think a spastic can lift the foot here (above) on his own. Regarding the problem of the strong internal alignment of the foot, if the machanism with the rope pull works in this way, it is certainly good that the foot is turned outwards." (...) Mr. OA Mag. Dr. Rainer Hochgatterer.

2) Do you like the idea that the patient can choose individual settings and has the possibility to control gait deviations himself?

For Mr. OA Mag. Dr. Rainer Hochgatterer a product of this type without individual settings will not work, because every patient is individual. The portability, how much force can be loaded on the orthosis and the associated energy supply for a long continuous use are important factors for Mr. OA Mag. Dr. Rainer Hochgatterer, which should be taken into account. Important to keep in mind is the theme of "skin compatibility" and "breathability". [96]

"I think these are points that often present problems during the implementation." Mr. OA Mag. Dr. Rainer Hochgatterer.

3) How do you feel about the additional sensory support of air cushions in the calf area? Can you imagine that the air gives patients a better feeling of safety, especially when standing on one leg? (no supporting forces and ideally without additional pump)

The idea to implement air pockets for sensory support is in Mr. OA Mag. Dr. Rainer Hochgatterer opinion reasonable and could work, because of the similar effects with "tape" or a knee stocking, which do not make the knee more stabil. [97] "For example, a knee sock does not objectively make the knee more stable, it only feels more

[figure 76]

stable. In my opinion, this can work. In addition, the air cushions would have to be tried out in more detail with a spastic, because a spastic has no physiological movement sequence, but is a pathological movement stereotype." [98]

"In conclusion to be a pathological motion sequence type means, the spastic patient cannot control the direction of the muscle movement and everytime it results differently." [99]

4) If yes, would you consider another position (e.g. shinbone, only on the back) more optimal for support? (at the moment the positions of the m.soleus (both sides), m.gastrocnemius caput lateral and m.gastrocnemius caput medial were considered)

"The most comfortable position for the patient might be between the ankle and the area where the m.gastrocnemius starts. Directly on the muscle belly, these would probably be too much.- From my intuition, I would say that the position would be most comfortable with the archiliss tendon, because this is where most proreceptors are. Here we are at a level where most muscles meet. Of course, it also depends on the muscle belly of the patient, there are patients where the muscle belly is lower. In principle, it has to be thin and wearable." Mr. OA Mag.Dr. Rainer Hochgatterer.

6) Would you place the splint on the patient's ankle inside the shoe (shoe-in shoe) or as an add-on element? Where do you see possible problems here?

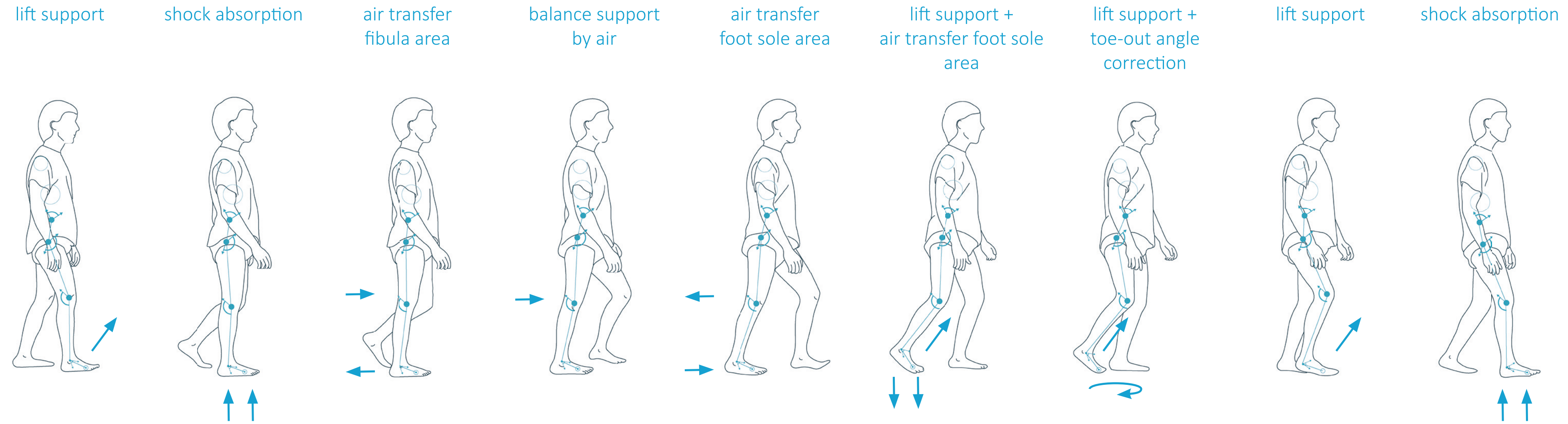
Mr. OA Mag. Dr. Rainer Hochgatterer liked the shoe-in-shoe concept, because of patients preference to wear normal shoes and every kind of change on the shoe is much work. The use of different sensors to detect different positions sounds interesting to Mr. OA Mag. Dr. Rainer Hochgatterer. Mr. OA Mag. Dr. Rainer Hochgatterer seemed to like the idea of feedback to the vibration motors for the training mode as well. [100]

[230] (see annex XIII- expert talk on page 152-159)

SOLUTION STRATEGY - 7 analysis of requirements

7 analysis of requirements

What is the solution strategy for active and passive support of an intelligent orthosis?
Which kind of support is necessary and what is giving support efficiently?



[figure 77]

calculation of total force in initial contact:

If the heel touches the ground after falling in initial contact, the result is a sudden load on the front leg of about 60 % of the body weight in 0.02 seconds (Saunders 1953, Whittle 2002). [101]

Ftotal = mass centre point x g
Ftotal = 63,4 kg x 9,81 m/s² = 621,95 N

force on one leg:
m0 = 60 % of 621,95 N = 373,17 N

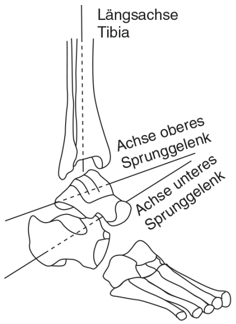
overview of the activations types:

- lift support
- toe-out angle correction
- shock absorption (air cushion pocket sole)
- air transfer (air pocket sole -> air pocket muscles)
- balance support (air)
- air transfer (air pocket muscles-> air pocket sole)

7.1 center point of ankle motion

Where is the center point of the ankle motion joint located?

Within the scope of developing an artificial joint replacements it is under consideration, which rotational motions of observed motion underlie the hindfoot. It is assumed that the movements of the upper and lower ankle joint take place as a hinge around fixed axes. However, the axes of both joints are not parallel. [102]



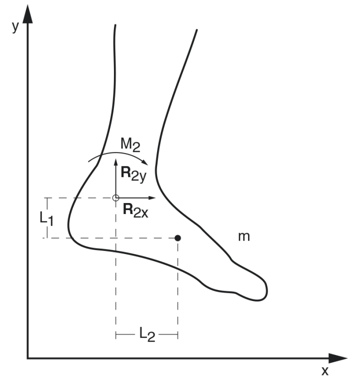
Rotational axes that are important for the movement of the hindfoot: Axle of the upper ankle joint, axis of the lower ankle joint and longitudinal axis of the tibia. (Debrunner and Jacob 1998) [103]

[figure 78]

In order to establish the relationship between reaction force and reaction torque with the joint load, the force transmitted from the tibia to the talus in the ankle joint is subsequently calculated from the knowledge of R2 and M2. For this purpose, a model assumption must be made as to which muscle generates the moment M2. It is assumed that the tensile force of the tendon of the anterior tibialis, which causes dorsiflexion of the foot, runs in the y-direction at a distance D from the axis of rotation. The moment M2 =-m-g-L2, which acts proximal on the foot, is thought to be generated by a pair of forces F and F*. F attacks the axis of rotation of the tibia and talus. F* is the tensile force of the tendon; its line of action runs at a distance D from the axis of rotation. F* points in positive direction, F points in negative y-direction; the amounts of F and F* are equal. Expressed by the pair of forces, the torque M2 (relative to the centre of gravity of the foot) is. [104]

(figure 79): Free, motionless foot. Reaction force R2 and reaction torque M2 act on the foot from the lower leg. Model for determining the ankle joint load when the foot is kept free and motionless. [105] The value of muscle torque during the first 10% of the gait cycle of drop foot persons is 0.2±0.1Nm/kg compare to a healthy subject: −0.26±0.06Nm/kg. [106]

On closer examination of muscle weakness patients, one might assume that the traction force of the tendon will be lower here.



[figure 79]

$$M_2 = -L_2 \cdot |\mathbf{F}| + (L_2 - D) \cdot |\mathbf{F^*}|$$

[figure 80] reaction torque

7.2 weight proportion

In order to determine the joint forces for the torque and the required tensile force of the ankle joint, the center of gravity of the body segment, the moment of inertia, the mass for a static movement, is needed. The inertia force plays a decisive role for the dynamic movement.

How much is the weight of the foot? (m1 mass)

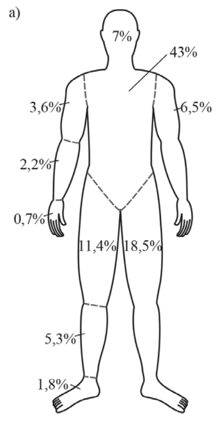
The mass of the whole body can be determined by weighing, individual segments of the body cannot be weighed and one is dependent on the weighing of preparations. Alternatively, the mass can be determined from the absorption of gamma rays or X-rays (see e.g. Zatsiorski et al 1986, Wicke et al, 2008/9). By the volume of individual segments and with their mean density the segment mass can be determined. Segment volumes are determined by immersion in a vessel filled with liquid and measurement of the displaced liquid volume or with the aid of a spatial, optical surface measurement. [107]

mass of segments of the human body

According to Clauser (1986) cited by Nigg (1994), the foot is 1.5% and the lower leg 4.0% of the body mass. According to Dempster (1955) the foot is 1.4% and the lower leg 4.5%. [108]

Assuming the person weighs of 63.4 kg (age 26-40 5th percentile / without clothes) [109] and the mass in % of the foot assumed to 1.5%, the resulted mass is 0.95 kg (static mass).

m1 = 0,95kg (0,95kg x 9,81m/ ² = equivalent to 9,319N)



[figure 81]

How much weight is the leg? (m2 mass)

From the taken percentage mass fractions of the body parts in figure 81 is obtained by adding 11.4% (thigh), 5.3% (lower leg), and 1.8% (foot) the mass 2 with a total of 18.5% for the right or left leg. [110]

Assuming the person weighs "63.4 kg (age 26-40 5th percentile / without clothes)" [111]

m2 = 11.73kg (is equivalent to = 115N mass of the leg)

What moment of inertia will act on the foot?

moment of inertia

The segments of the human body (head, torso, thigh, lower leg, etc.) are geometrically irregular in shape. In order to calculate their moments of inertia, they can be replaced approximately by geometrically simple bodies of similar dimensions, for example the head by a sphere or the forearm by a cylinder. [112] Drillis and Contini determined the lengths of the segments of the human body in 1966. [113]

Altitude of prominent points or joints (when standing upright with the arm hanging down) additional width of shoulders and pelvis and width and length of foot (Drillis and Contini 1966, cited after Winter 1990). Knee joint 0.285m altitude; ankle joint 0.039m altitude. [114]

In orthopaedic biomechanics, these moments of inertia are of particular importance, since the movement of the segments during walking and running can be regarded as a flat movement in the sagittal plane. The relative radius of inertia of the foot about axes perpendicular to the sagittal plane and passing through the centres of gravity of the segments. [115]

According to *Winter (2005),* derived from Dempster (1955), the relative radius of inertia of the foot is 0.475 [m/m]. As an example of the application, the moment of inertia of the lower leg of an adult person, mass 60 kg and height 1.70 m is calculated. According to *Clauser* data, the lower leg has a mass of 4.0% of the body weight, equal to 2.4 kg. A relative segment length for the lower leg of 0.285 - 0.039 = 0.246. For a body height of 1.70 m, the lower leg has a length of 0.246 x 1.70 = 0.418 m. With the relative radius of inertia (winter data) of 0.302, the moment of inertia around the center of gravity of the lower leg is (0.302 x 0.418)² x 2.4 = 0.0382 [kg x m2]. [116]

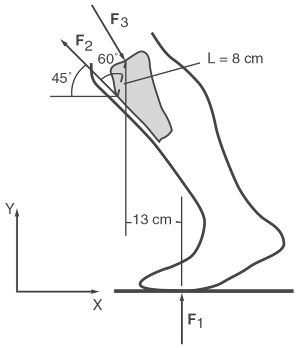
calculation of the moment of inertia of the foot

Person m = 63.4 kg Body height 1.70 m; Assuming the foot is a mass of 1.5 % of body weight, equal to 0.95 kg. The ankle joint altitude value of 0.039 (Drillis and Contini 1966, cited after Winter 1990). For a height of 1.70 m, the foot has a length of 0.0663 m. With the relative radius of inertia (winter data) of 0.475, the moment of inertia around the centre of gravity of the foot is (0.475 x 0.0663)² x 0.95 = 0.00094 [kg x m2]. [117]

However, it should also be considered that the cerebral paresis patients spasticity represents an unknown variable in the assessment of the forces, since the movements and also the force displacement here can be very different and one must also think of larger forces for the product.

loading of the tibio-femoral joint

With reference to the figure 82 an example was calculated, which resulted in 1576,6 N for F3 assumed for a person with a mass of 60 kg. This figure 82 shows the strain on the tibio-femoral joint and points to the posture of the leg when climbing stairs. [118]



[figure 82] loading of the tibio-femoral joint.

7.3 pressure distribution between the foot and the foot ground on plain contact surface

Between the human body and the external environment, or between bones that meet in a joint in the body, one rarely finds flat contact surfaces. Even with a flat contact surface between the foot and the floor, the pressure p = dF/dA is not the same at every point of the contact surface. [119]

If the pressure on a contact surface is not the same everywhere, this is referred to as pressure distribution. The proportion dF of the total applied force, which is transmitted by each individual surface piece dA of the contact surface, the pressure dF/dA on each surface piece dA, differs from place to place. In the case of the foot, it is clear why the pressure is not the same at every point. The distribution of pressure is determined by the architecture of the skeleton and by lining of soft fabrics of different thickness and mechanical properties. [120]

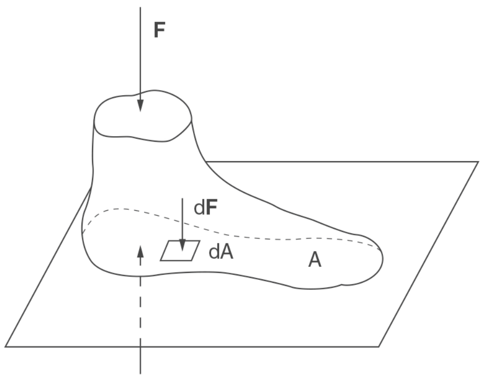
If a pressure distribution exist on a contact surface, such as between the sole of the foot and the ground, the pressure distribution is not considered in detail for special application for reasons of simplicity, but a quantity derived from the pressure distribution: the so-called center of pressure. [121]

p = F/A

In this formula, the force F is expressed in Newtons and the area A in square meters. The unit of pressure [N/m2] is called Pascal [Pa]. The terms pressure and compressive stress have the same meaning. Assuming a body mass of 60 kg and an assumed foot area of 160 cm2 , 18750 Pa is obtained (corresponds to 0.1875 bar). [122]

$$p_{mittel} = \frac{1}{2} \cdot 60 \cdot 10 / 0,016 \; N/m^2 = 18750 \; Pa$$

[figure 83]

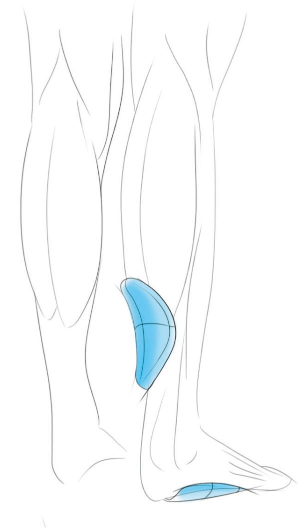


[figure 84]

SOLUTION STRATEGY - 7 analysis of requirements

As already shown on page 46 (figure 77) selective support by shifting air volume provides sensory support for the user. Two different pockets (pocket sole + pocket muscles) were created on a 3D foot with the aid of a 3D program. In order to guarantee that the air expands constantly, an already inflated and smaller pocket is additionally considered.

Due to the additional content, the size of pocket muscles increases, but the free volume in which the air can spread remains the same. A silicone tube is sufficient to connect the two pocket elements.

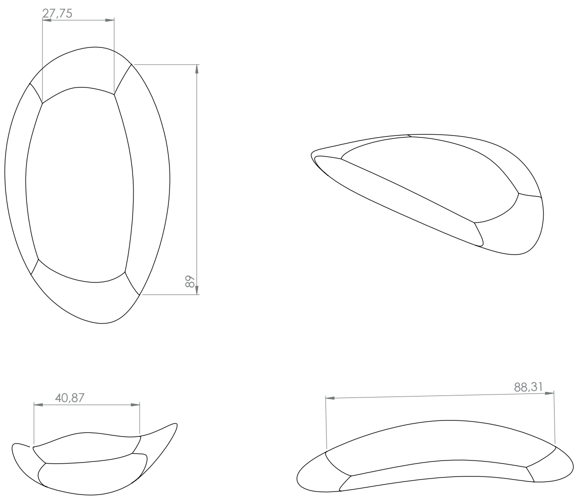


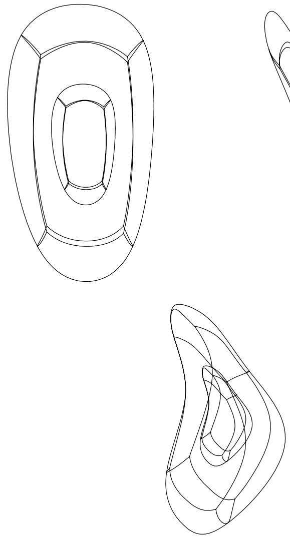
pocket sole (on the sole of the foot):

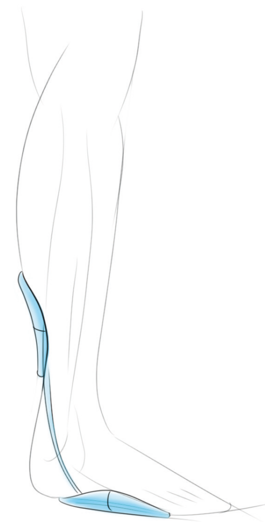
volume:
58606.384 (+/- 0.012) cubic millimeters
contemplated on shoe size between 40-42.

pocket muscles (between area of archiliss tendon and m.gastrocnemius):

volume:
58606.384 (+/- 0.012) cubic millimeters.
volume of 58606,384 (+/- 0.012) cubic millimeters (identical with pocket sole).







[figure 85] pocket sole;[figure 86];[figure 87] *pocket muscles;*[figure 88]

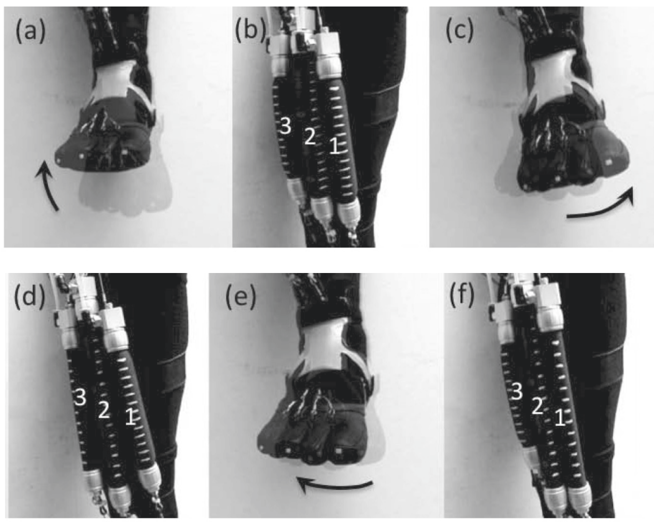
7.4 bio-inspired active soft orthotic device for ankle foot pathologies

"We describe the design of an active soft anklefoot orthotic device powered by pneumatic artificial muscles for treating gait pathologies associated with neuromuscular disorders. The design is inspired by the biological musculoskeletal system of a human foot and a lower leg, and mimics the muscle-tendon-ligament structure." [123]

"In patients with neuromuscular disorders, such as stroke, cerebral palsy (CP), amyotrophic lateral sclerosis (ALS), and multiple sclerosis (MS), pathologies of the ankle-foot can result in abnormal gaits over time. Drop foot is one example. Due to the damage of the long nerves or of the brain/spinal cord, the anterior muscles of the lower leg, which work for dorsiflexion, become weaker while the posterior muscles become stiffer. As a result, the foot drops in swing phases causing toe strikes instead of heel strikes." [124]

Three pneumatic artificial muscles assist dorsiflexion (12° dorsiflexion from a resting position and 20° dorsiflexion from plantarflexion), and as well inversion and eversion. An advantage of the pneumatically actuation is that the electrical power consumption ot the prototype is relatively low. Including electronics and batteries the prototype weighs in total 950g and is made of soft plastics and composite materials with light, flexible, robust, conformable and wearable properties. (rubber, neoprene and nylon) [125]

"Actively assisted ankle motions: (a) Dorsiflexion (b) with all three muscles actuated; (c) Inversion (d) with only muscle 1 actuated; (e) Eversion (f) with only muscle 3 actuated." [128]



[figure 89] *"Bio-inspired Active Soft Orthotic Device for Ankle Foot Pathologies"*

The presented design shows a solution of an soft orthotic device without limiting the 3D motion of the foot, because common ankle-foot orthosis (AFO) forces the joint angle. In addition such passive orthosis prevent the foot from dropping during the swing phase but they were not designed to support the user to exercise and train the weak muscles. As a result of the long-term use the user will get physically dependent on these orthosis which lead to neural adaptations over time that gradually reduce the muscle activity. [126]

"While the system consumes very little power and could run on batteries for several hours, it still relies on air source connection for the pneumatic muscles. Thus, one immediate area of future work is to investigate solutions that allow complete untethered operation. Available options include portable air compressors and compressed air canisters." [127]

7.5 disadvantages of other actuators

"Recently, a lot of work has been carried out in order to create artificial muscle that is similar to the characteristics of human muscle, such as: pneumatic McKibben actuator, electroactive polymer actuators as artificial muscles, piezoelectric muscle-like actuator, shape memory alloys and many other technical solutions." [129]

"Pneumatic actuators deal with high forces and displacement, the distribution of control signals takes a huge amount of space in addition they are noisy and have a significant hysteresis work ratio. In comparison electroactive polymer actuators endure large forces for small displacement and a large activation voltage is necessary for this actuators. Shape memory actuators are easy to control, compact, have high energy density and good mechanical properties, but compare to other actuators expensive. Additional they have a slow dynamic response and poor fatigue properties. Piezoelectricmuscle-like actuators are suited only for very small forces and displacements. It is extremely difficult to control because of problems with a very high hysteresis and memory effect." [130]

7.6 twisted-string actuators (TSA)

"Twisted string actuators are widely used in different areas of robotics, however, their lifetime remains one of the main concerns for robotics. Many modern robotic applications require compliant, lightweight, simple, and reliable actuation systems." [131] "A linear twisted-string actuator is designed to produce movement in a humanoid robot arm that is close to the movement of a human arm with similar requirements of speed and force." [132]

"A twisted string actuator (TSA) is a simple, compact and efficient actuation system which has been in use for over a thousand years in different areas of engineering. Twisted strings were employed for powerful machines and devices like pump drills, ballistae and catapults, windlasses and many more." [133]

Many publications of "Twisted-string actuators" topics have appeared in recent years. The scientists Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. released in 2017 a publication about the "A Study on Life Cycle of Twisted String Acutators: Preliminary Results". They focused specially on the Life Cycle of a twisted string relate to its material properties and operation conditions (comparison of 2 different materials: conventional Dyneema braided string & D-Pro string with chafe resistant coating) and provide preliminary results of an extensive experimental study. Load, stroke and the number of strings play an important role in life cycle. [134]

"In the nearest future, we are planning to conduct a similar experimental investigation on the lifetime of the strings made of materials and with different coatings. Material techniques to improve the chafe resistance and reduce heating of strings are also under consideration to improve the lifetime. We have also observed that the string exhibits slightly different behavior when twisted across or against the braiding direction,which can also be an important factor for string life cycle." [135]

They observed a slightly different behavior of the sting exhibits if the twist is across or against the braiding direction, which can also be a relevant factor for string life cycle. In the nearest future they want to investigate how different string braiding techniques influence the life cycle, compare the performance of the strings of different radii and lengths and to find out how to increase the life cycle by various using lubrication and string coating methods. [136]

7.6.1 dual-twisted string actuator (TSA)

The scientific researchers (Jeong, S.H / Shin, Y.J / Kim, K-S. 2017) presented in their publication in 2017 a further developed principle of "the Active Dual-Mode Twisting Actuation Mechanism". [137]

In summary an optimised version was published which is based on a new twist actuation mechanism, by a new mechanical Design, to split the mechanism into a speed mode (fast & small forces) with a large radius braiding and into a force mode (slow & large force) with a small braiding radius. [138]

7.6.2 potential / future advantages of twisted-string actuators

Pneumatic or hydraulic actuators are difficult to miniaturize for a robotic hand and require a large compressor. [139] "Therefore, most robotic hands use electric motor-based driving systems, mainly because they are easier to miniaturize than other driving mechanisms and ensure the best performance compromise." [140]

The heat generation of the DC motor needs also consider further. Another benefit to use an electric motor-based system is, the backdriveability. Compared to other systems, DC motors are quiet. Innovatively publications show a high potential to optimise the Twisted-string actuator mechanism in the future. To improve the material and the performance to reach an ideal motor-system for robotic applications. Another important aspect is the price factor for this motor-system which is, in comparison to pneumatic muscles for example, propitious.

SOLUTION STRATEGY - 8 design strategy, concept & process

8.1 tape drawing

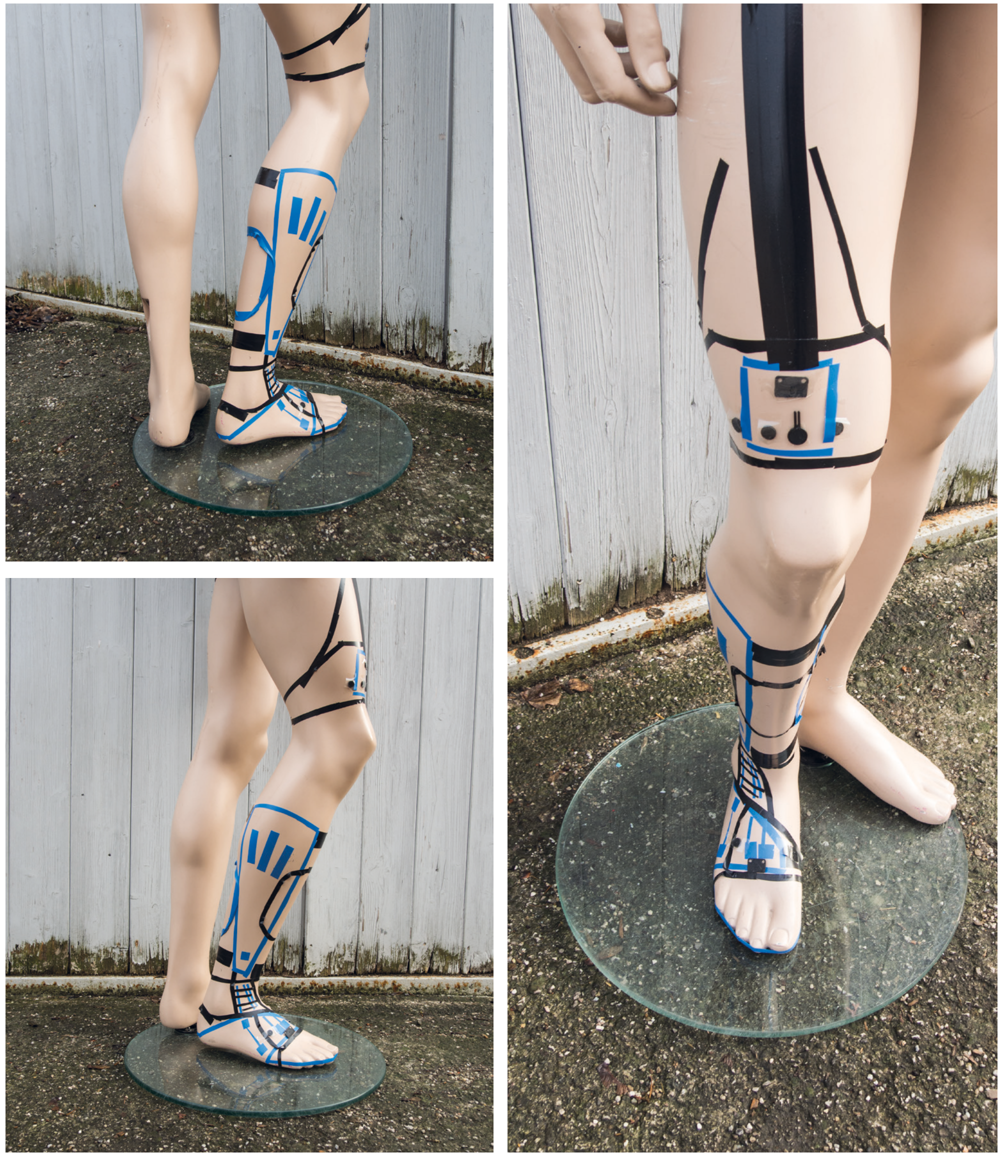
"Modelers and designers work hand-in-hand to provide precision adjustments to the design, using tape as a shared language." [141]

"You can turn ideas around so fast. With all the technology we've got, rapid pro taping is still the fastest medium to get where we want to go, explains Larry Pelowski, a Master Modeler, Exterior Design. It's pretty much universal between design and modeling. It's just an invaluable tool." [142]

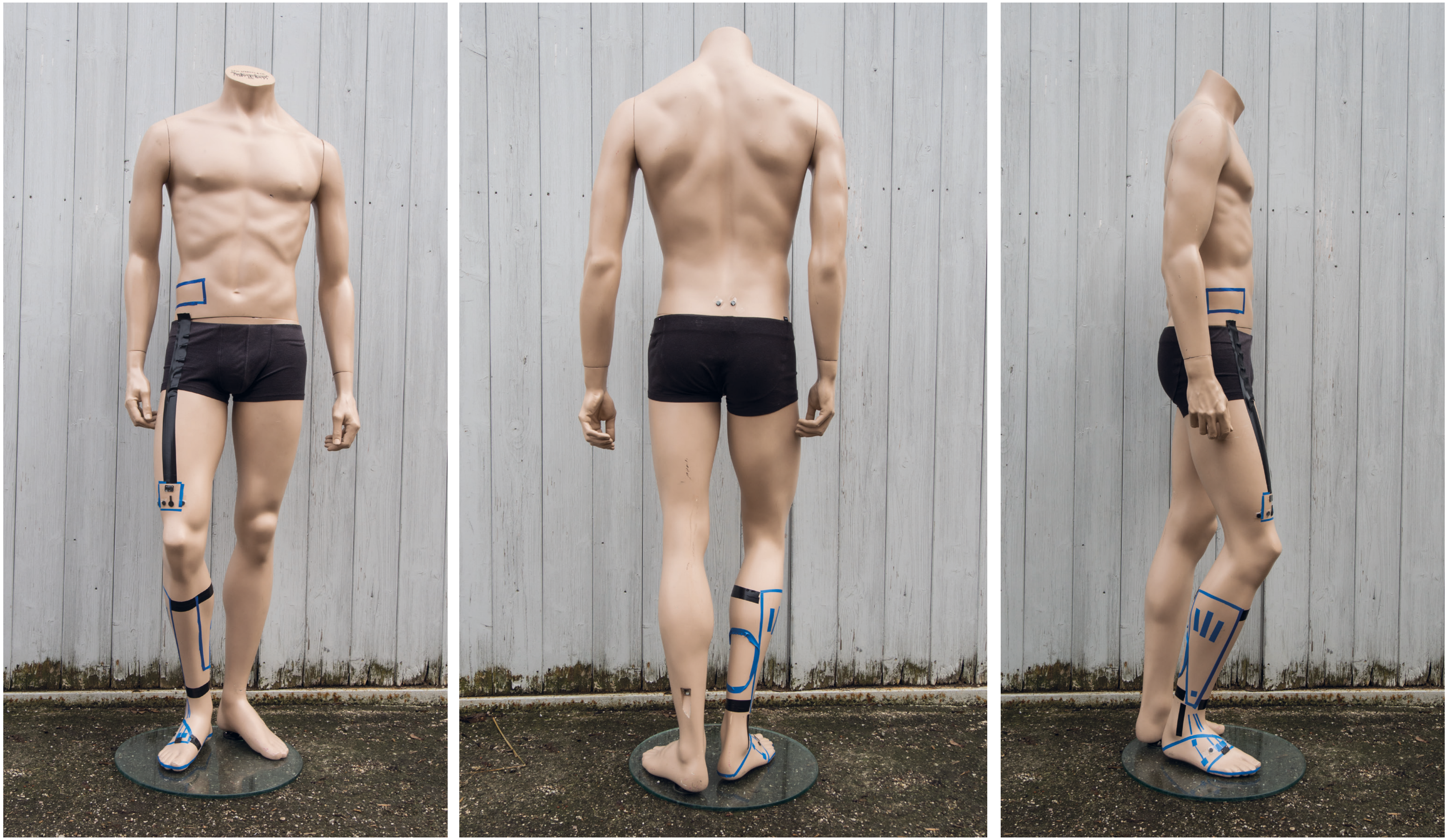
Tape drawing is often used for form finding on clay models in the automotive industry. In this project, tape drawing was used to distinguish stable zones from flexible zones and was new interpreted. This tool was useful to identify the "important areas" quickly and to keep the shaping as small as possible.

tape drawing of orthosis areas on a mannequin:

- The thin blue lines show the zones, defined in the following design process for stable zones. The intelligent orthosis need to be fixed at the leg in this area to reach stability.
- The wide blue lines indicate the air element and the three future actors. In these zones there is more space needed and these four elements are fix components.
- The boundaries by thin black lines are showing possibilities to save on the one hand area and show on the other hand where the element or textile could be completed in the future. (these framework boundaries present conditions for the design shape)
- Thick black lines are supposed for elasticity and retaining functions. In these zones freedom of movement needs to be required.



[figure 90-95] *tape model*



[figure 90-95] *tape model*

8.2 package definition

motor package:

How much is the weight of the foot?
m1 = 0,95 kg (0,95 kg x 9,81 m/ ² = equivalent to 9,319 N) + for cerebral paresis patients spasticity represents an unknown variable in the assessment of the forces

How much weight is the leg?
m2 = 11.73 kg (is equivalent to = 115 N mass of the leg)

Which dimensions of force can be assumed during dynamic movements?
5 kg of effective mass during dynamic movements were assumed in this project. To think of a motor for 70-100 Nm in future development. (depending on the spastic factor and body weight of the person)

- Nm for lifting the foot: 70-100 Nm are assumed in this project.
In the US.Patent No.7,650,204 B2 of an "Active control of an ankle-foot orthosis" (Dariush, B. 2006) about 0.5-0.75 seconds with 100 Nm [143] was mentioned to effect Plantarflexion/Dorsiflexion though with another motor system.

- Nm for toe out the angle: In this movement a lower value of Nm 70 can be assumed because the movement is only rotating sidewards.

Which number of strings are assumed?
Referring to the publication of "A Study on Life Cycle of Twisted String Actuators: Preliminary Results": four strings for the twisted actuator are fitting with this application. The strings should be made out of a Dyneema PRO material. [144]

What is the motor size of the brushless DC motor?
In the further process three small twisted actuators are used. The one for the toe-out angle correction, with less torque, is smaller than the other two actuators, to save weight. For the volume size a fictive size was presumed. (Ø16 for motor 1 and 2)

supplementary components:

- elastic band (hip- knee area)
- air cushion pockets (pocket sole & pocket muscles)
- textile & foam components (stable zones & flexible zones)
- base frame as a connecting element
  (textile & base frame for motor implementation)

functional elements:

- three fixed points on the foot (one for toe-out angle correction; two for lifting)
- three ropes
- six rope guidance

three fixed points on the foot:
According to the "Bio-inspired Active Soft Orthotic Device for Ankle Foot Pathologies" publication the fixed lifting points on the foot on this location works. In this project the Inversion/Eversion is not follow up further. [145]

defined degrees of ankle
"The study evaluated 10 subjects with drop foot (DF) whose results were compared to a group of 10 healthy controls (C). In the DF group, the subjects walked almost 47 % slower and performed 60 % less steps per minute compared to the C group. The main problem in the DF group was insufficient ankle dorsiflexion in the 0–10% of the gait cycle. Mean values in the groups during the first 10 % of the gait cycle were as follows: DF (−10.42 ± 5.7°) and C (−2.37 ± 1.47°), which affected the substantial differences in the values of muscle torque: DF (0.2 ± 0.1 Nm/kg) and C (−0.26 ± 0.06 Nm/kg)." [146]

DF group
"Angle (°) / Swing phase
–15.19±3.1 (min±SD)
0.52±2.11 (max±SD)" [147]

"Torque (Nm/kg) /Swing phase
– 0.01±0.13 (min±SD)
0.11±0.1 (max±SD)" [148]

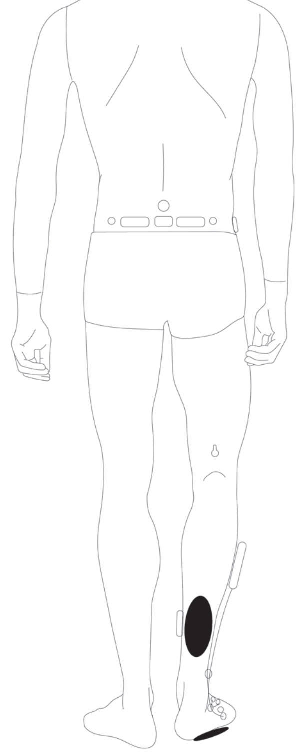
mean values in the groups in the 10% of gait cycle:
"DF (-10.42 ± 5.7°) and C (-2.37 ± 1.47°), which
causes substantial differences in the values of torques:
DF (0.2 ± 0.1 Nm/kg) and C (-0.26 ± 0.06 Nm/kg)." [149]

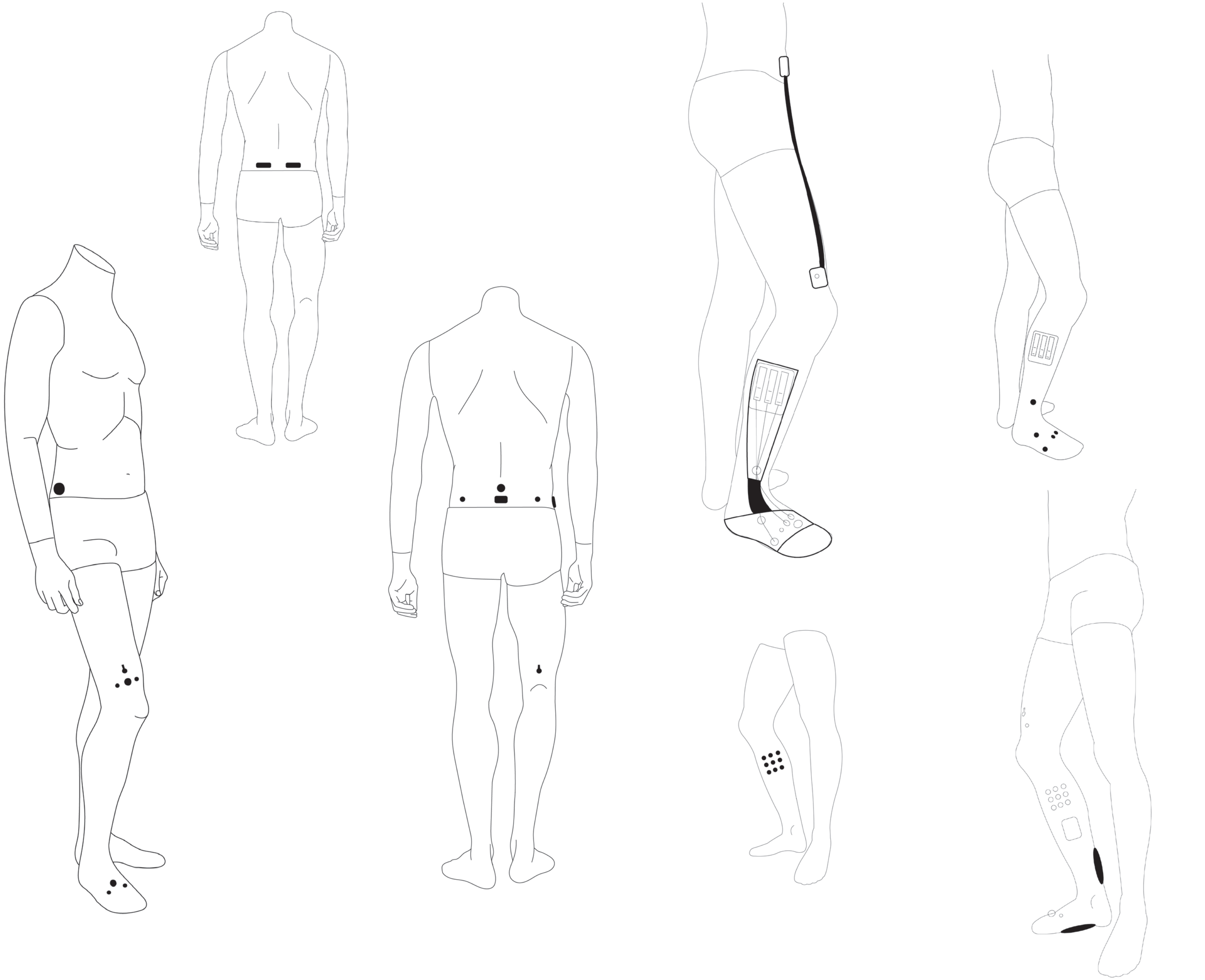
According to the mentioned study of drop foot subjects this degress of the angle are assumed:

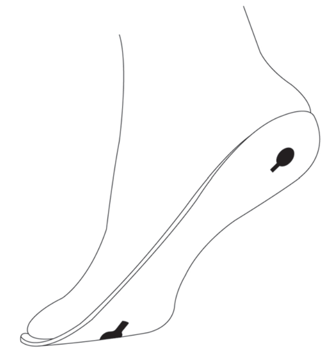
- drop foot lifting support: "–10.42±5.7°" [150]

The value of degrees to correct the toe-out angle was estimated:
- toe-out angle correction:-10°± 10° (estimated value)

SOLUTION STRATEGY - 8 design strategy, concept & process







[figure 96-103]
[figure 105]

[figure 104] *sensor package definition*

8.2.1 sensor package definition

This is the estimated sensor package for the further process. For the design the package dimension is important.

[figure 106] IncOder™ inductive angle encoders

/ potential sensors	/ expected functions	/ dimensions / size
hip & knee area:		
1x IncOder™ inductive angle encoders	/ detecting the hip position	/ Ø=58 mm h=16.5 mm [151]
2x Seeed 316040001 Mini Vibration Motor 3V 2.0mm Circular	/ vibration feedback ("to correct left or right side")	/ Ø=10 mm h=22 mm [152]
1x nRF52832 Multiprotocol Bluetooth 5 accelerometer + gyrosensor	/ bluetooth connection instead of cables / detecting walking speed / detecting users walking direction and turns	/ 6 x 6 mm [153]
1x battery pack	/ energy supply	
1x arduino nano (future package)	/ to collect data	/ 18 x 45 mm [154]
2x Interlink Force-Sensing Resistor FSR 402 Short	/ to detect knee bend angulation	/ Ø=18.29 mm h=0.46 mm [155]
2x Seeed 316040001 Mini Vibration Motor 3V 2.0mm Circular	/ vibration feedback ("lift up the thigh higher")	/ Ø=10 mm h=22 mm [156]
1x nRF52832 Multiprotocol Bluetooth 5 accelerometer + gyrosensor	/ bluetooth connection instead of cables / detecting motion speed of the thigh / detecting thigh position	/ 6 x 6 mm [157]
ankle area:		
1x battery pack	/ supply of energy for actuators	
2x Interlink Force-Sensing Resistor FSR 402 Short	/ pressure sensors detect the foot ground contact	/ Ø=18.29 mm h=0.46 mm [158]
2x Seeed 316040001 Mini Vibration Motor 3V 2.0mm Circular	/ vibration feedback ("correct the hip on the left or right side more")	/ Ø=10 mm h=22 mm [159]
1x nRF52832 Multiprotocol Bluetooth 5 accelerometer + gyrosensor	/ bluetooth connection instead of cables / detecting walking speed / detecting users walking direction and turns	/ 6 x 6 mm [160]
1x arduino nano + motorcontroller (future package)	/ data collection and actuator control	/ 18 x 45 mm [162]


[figure 107] Seeed 316040001 Mini Vibration Motor 3V 2.0mm circular


[figure 108] Bluetooth 5 / NRF52832


[figure 109] Force-Sensing FSR402 Short


[figure 110] MPU6050 Gyro, Accelerometer

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In the following chapters, a closer examination of the "base frame" is shown. The base frame has the task to connect the compressions textile and the actuators. In the future, a customized or a custom-made product will ensure a more *patient-oriented adaptation,* a *more efficient* and *cheaper production.* The possible production methods become more precise analyzed and first materials are selected on the basis of their *material properties* and *manufacturability.*

The material selection of the compression stockings has not been followed up in detail since commercial stockings have proven to be *skin-friendly* and *functional.* On page 78-79 an extended method is shown of how *generative design* can enable selective textile reinforcements in future to *optimize conventional compression materials.*

8.3 customization

Nowadays there is already a tendency existing towards customizing products. In product design, marketing and in the production process field this type of products are named as Customized Products [163] or Custom-made products. [164]

"*Mass customization* allows a customer to design certain features of a product while still keeping costs closer to that of mass-produced products. In some cases, the components of the product are modular. This flexibility allows the client to mix-and-match options to create a semi-custom final product." [165] Cleverism writes that: "Mass customization is an important business concept, which numerous brands are adopting these days." [166] "The customer is now becoming part of the *"product development"* process." [167]

In brief there is a difference between the term "personalization" and "customization". [168] "Personalization is a means of meeting the customer‘s needs more effectively and efficiently, making interactions faster and easier and, consequently, increasing customer satisfaction and the likelihood of repeat visits," according to TechTarget. [169] For example, Amazon personalizes its home page for each user. [170] "Customization, by definition, is "the action (by a user) of modifying something to suit a particular individual or task." [171]

B. Joseph Pine II describes in his book "Mass customization: The New Frontier in Business Competition (Harvard Business Review Press, 1992)" four primary types of mass customization. [172] According to this concept which present a new level of mass production, the "intelligent orthosis" is a "collaborative customization" [173] in the future. This means, "companies work in partnership with clients to offer products or services uniquely suited to each client." [174]

With the "specific user" Univ.-Prof. Dipl.-Ing. Johannes Braumann (Laboratory for Creative Robotics at the University of Art and Design) and I already created a first 3D scan of both legs with the *"Artec 3D scanning"* Tool and Software. The result could be evaluated very quickly (about one hour) and also mapping textures of the skin were generated by the hand scanner which produce periodically a laser pattern to detect shape information. Missing polygons were patch after scanning to improve the 3D model by using the associated software. In the future this scanning process show great potential to customizable orthosis based on 3D printing technology. Till now (depending on which type of orthosis) this medical products were expensive products and needed much time to adapt for the patient to get *patient-oriented.*

The consideration of variable parameters are highly important to enable a flexible design process. At least the product is not only patient-ortiented it also presents a more economical, more efficient and faster fabrication.

basic concept of an improvement for a customize & production method:

1) 3D scan of the leg (it can be considered to include already the chosen compression stockings in the scanning process)

2) definition of parameters trough algoritmic analysis of body measurements from scan-data

3) individual parameter adaption

4) automatic 3D-model generation from parameter data

5) control loop with FEM-analysis

6) individual material selection

7) manufacturing with generative / additive production method

[figure 111] Artec 3D Scanning Range
[figure 112] 3D scan of specfic user

8.4 production methods

The injection moulding process allows a low-cost manufacturing, but only in serial production, and this requires an expensive tool. Thus excludes this processing method for the application, since an individualization in combination with the high-cost of the molding tool, is not profitable. Basically thermoforming are frequently used for orthoses. Through hot air or warm water, the material is made formable and will adapted to the patient and provides a stable hold. [175] In spite of many advantages of individual adaption by deformable material, the realisation time (considered in total time)- due to this post-processing time, is an essential factor against traditional thermoforming to fit in this application compaired to an additive 3D-Printing method in combination with a 3D-scan.

3D-printing benefits in the orthopaedic sector are resulting the fact that plaster casts no longer need to be used. The required data is obtained with the use of 3D scanning technologies and occur without direct body contact.The outcome is an almost perfectly adapted orthosis that can also be designed according to the patient's aesthetic requirements (choice of shade, decorations, accessories). The products can now be manufactured more quickly, individually designed and adapted to patient requirements. [176] 3D printing technology is a process that is increasingly being used in technical orthopaedics. Using this modern technology, three-dimensional components can first be digitally designed and then engineered in layers. This also applies to the Pohlig Print Orthoses®. In the context of the so-called selective laser sintering process (SLS), pulverized material is bonded together by laser radiation. In this way, mechanically and thermally resilient Print Orthoses® can be manufactured. [177]

A futher benefit to select the 3D-Printing technology is the reason that the orthosis concerns to be an asymmetrical product. The muscleposition, musclesizes and the whole leg can be unique on each patient. For example the m.gastrocnemius can be very different from patient to patient (reffering to the expert talk with Mr. OA Mag.Dr.Rainer Hochgatterer). (see annex XIII- expert talk)

Currently, selective laser sintering (SLS printing), which is also very popular among our customers, is the most widespread method in medical 3D printing (bio-print production). [178]

"The additive manufacturing product is not always better for the user than products made using traditional production and fitting methods. Thus, for each product, the actual potential for improvement for the user must be weighed against traditional fitting methods and standards in a cost-benefit analysis." [179]

Particularly in the manufacture of aids, i.e. medical devices, it is on the one hand, essential to preoccupy the strict regulatory requirements- e.g. the biocompatibility of the materials, the long-term service properties, risk analyses, fracture simulations and required functionalities- on the other hand, the functional and therapeutic benefits, the design and the wearability of the aid is decisive important for the user. [180] After various tests to verify print quality, mechanical load-bearing capacity, component accuracy and the required design options, the authors (Kienzle, C. / Schäfer, M. / Pohlig GmbH 2018) and their experience from recent years currently shortlist four additive methods for the manufacture of orthopaedic aids: [181]

- "Fused Deposition Modelling (FDM)" [182]
- "Continuous Liquid Interface Production (CLIP)" [183]
- "Multi Jet Fusion (MJF)" [184]
- "Selective laser sintering (SLS)" [185]

In the SLS process, a layered powder build-up occurs. The generated 3D mould became fused to a homogeneous bond by a high temperature process with a laser system. In terms of material mechanics, composite quality and colour design options, this production process is predestined for the manufacture of aids. Common materials are polyamides, thermoplastic polyurethan and metals. [186] The SLS procedure, which has been established and proven over many years be regarded as suitable for the production of technical end components from plastics such as PA11 and PA12. [187] It enables a variety of design options, provides mechanical high quality 3D-prints in high precision and enables the successful realization of a wide range of orthopedic end products in prosthetics and orthotics. [188]

Despite all the enthusiasm, however, the new digital processes must not conceal the fact that the technologies used here also have deficiencies and are still far from being able to cover the broad spectrum of orthopaedic everyday care. [189] The weight-bearing structures of joint-guided orthoses must also assert themselves against lightweight and significantly more stable fibre composite materials. This has to be occur especially against the background of a cost-benefit-analysis. [190]

The 3D printed shape needs to fit on the lower leg with the implemented actuators (to facilitate wearability motors). The actuator components will define the most expensive components of the intelligent orthosis. To reach a preferably affordable product the base frame needs to be as cheap as possible.

8.5 materials selection

traditional used materials for orthoses:

wood (poplar): prosthesis shafts, fitting parts such as prosthesis joint (good strength; low weight; pleasant wearing characteristics; complex processing; poor post-processing possibilities; protection against moisture)

leather: orthosis sleeves, prosthesis shafts, feedings (large selection; pleasant wearing properties; comparatively high raw material costs; limited cleaning possibilities; contact allergy risk)

felt: pads, pelottes (high resistance; poor processing)

fabric: bodice, bandages (large selection; good processing; easy adaptation; low strength)

metal (aluminum alloys, stainless steel alloys): splints, clamps, fitting parts such as orthotic joint (high strength; good possibility of modification; high weight; time-consuming processing; contact allergy risk)

thermoplastics: polyethylene PE; polypropylene PP; polyethylene terephthalate PET; low temperature thermoplastics NTT): corsets, positioning shells, test sockets for orthoses (medium to high strength; good processing; good adaptation; partial embrittlement; shrinkage; creep flux)

flexible foam (polyethylene PE; ethylene vinyl acetate EVA; polyurethane PUR): upholstery, lining, footbeds, neckties, positioning beds (large selection; good processing; easy adaptation; variable combination; low strength)

silicones: dynamic orthoses (variable combinable; shore hardness; good skin compatibility; good e.g., adhesive properties; high weight; high costs; complex processing)

fibre-reinforced plastics (carbon fiber CF; glass fiber GF with suitable matrix e.g. acrylic resin, epoxy resin): orthoses, insoles, prosthesis components, spring feet (variably combinable; high strength with low weight; poor possibility of modification; elaborate processing; high costs)
[191]

new printable plastics:

"PA11, PA12 PA12CF, TPU and metals." [192]

The polyamide 12 (PA12, "nylon") used in both processes (HP Multi Jet Fusion and laser sintering) enables the manufacture durable, biocompatible and acid-resistant orthoses. In addition, it is easy to post-process, which makes it possible to design the orthopaedic aids according to the preferences of the patients. A decisive advantage of the powder bed process is that almost all shapes and geometries are achievable. Additionally, only a few days (mainly 3- 5 working days) are needed for the production, which can mean a noticeable shortening of the processes in orthopaedics. [193]

CRP technology has investigated in a collaborative research project with MHOX Design the application for *generative manufactured orthoses* by using the "Windform material®“ and addivitve manufacturing and Windform GT technology. The Windform GT material is suitable well for this application due to its elasticity, impermeability and resistance. It is a polyamid-based material reinforced with glass fibres, which exhibits optimum bending properties without breaking, even over a long period of time. The additive manufacturing and the 3D printing, combined with the windform materials, mean a breakthrough of new application limits. [194]

A further big advantage of the plastics usage is the possibility to supplement additives to gain for example better properties of UV stability or to reach an antistatically material. It is quite conceivable to add in the future reflecting pigments to the material. [234];[235] This would enable the product to be more recognisable in the dark.

material selection criteria:

Based on the material properties of PA12, a detailed material table was generated where the following relevant properties and requirements were considered:

density (ISO 1183 g/cm³) for the weight properties; E-modul (ISO 527 in MPa (N/mm²)); 3D-Printing / SLS (YES/NO) for the quick and flexible process; tensile strength (ISO 527-1/2 in MPa) for stability; impact toughness ISO 179 in kJ/m² (Charpy 23°C) for do not break on impact.

However, some properties were difficult to discover (see annex VI list of material selection) only complete values could be incorporated and compared in two diagrams.

SOLUTION STRATEGY - 8 design strategy, concept & process

The listed values for impact toughness (charpy 23°) were assumed as the value 100 even the material do not break or the value is indicated over 100. A further categorisation takes place for 0-3 reffering to the 3D-printability. 0 means the material is not available; 1 indicates that it is theoretically possible to print; 2 is given if the material is available, but not frequently in use or complicated in processing; 3 is mentioned for an easy processing and if the material is frequent in use.

diagramm01: (rough selection)
density ISO 1183 g/cm³(x-axis), E-modul ISO 527 in MPa (y-axis) and 3D-Printing / SLS + categories 0-3 (size of the circle)

The material PPS+40GF is not printable and has been excreted. PES+30GF, PSU+30GF and the Windform®XT 2.0 have been eliminated in a further step by limiting the E-modul boarder to 6500. PVDF is also excluded because of the limitation for the density property to 0.9-1,45.

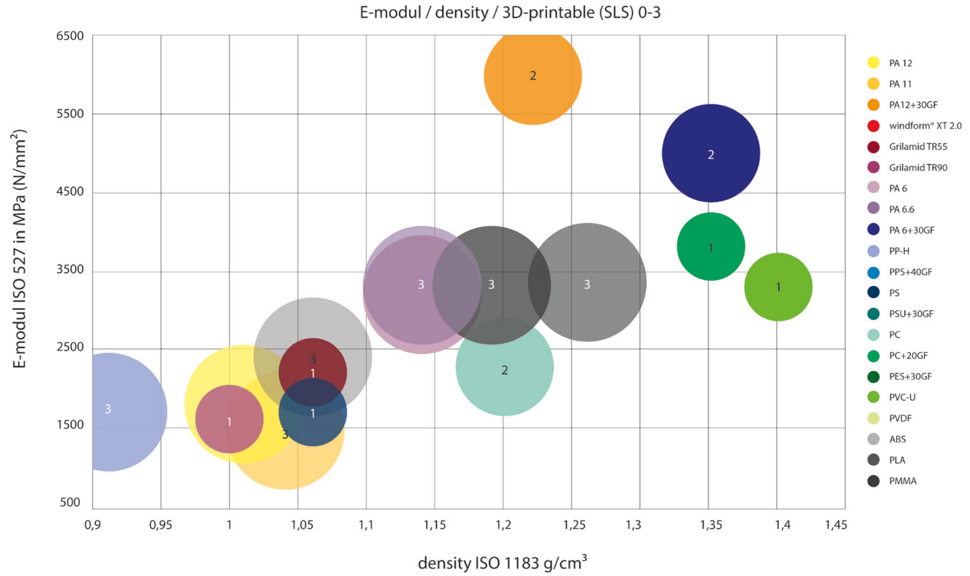
PA 12, PA 11, ABS, PA 6, PA 6.6, PMMA and PLA show in the area of a density around 1 to 1,3 good printabilty and good e-modul results. PA12+30GF, PA6 + 30GF with a printabilty of 2 have a high e-modul and densitiy properties.

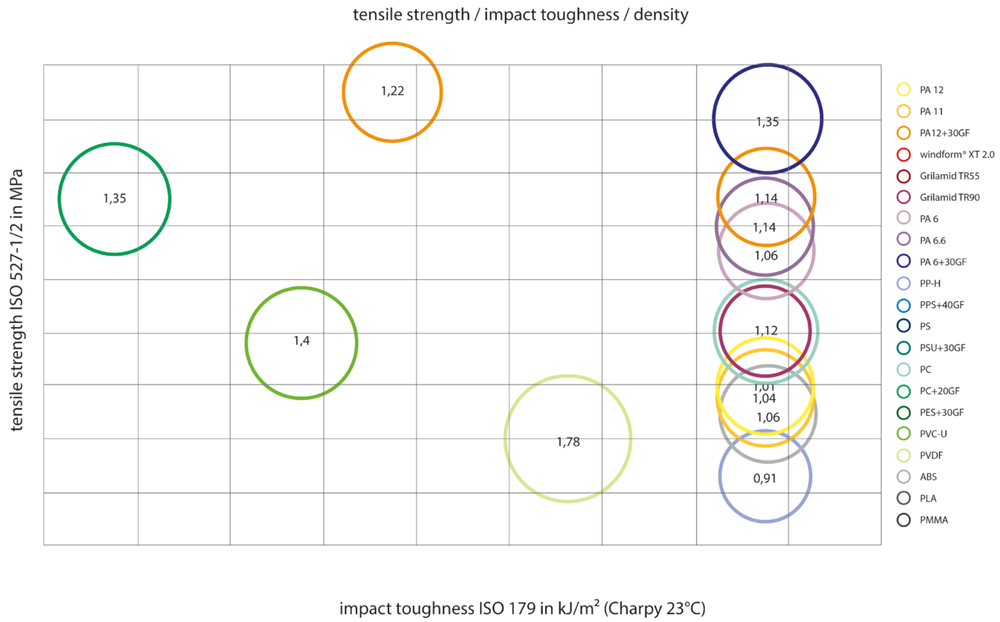
diagramm 02: (detailed selection)
impact toughness ISO 179 in kJ/m² (Charpy 23°C) (x-axis), tensile strength ISO 527-1/2 in MPa (y-axis) and density ISO 1183 g/cm³ (circle outline)

On diagram 02 PES+30GF was excreted by limiting the y-axis to 115. By limiting the impact toughness to the value of minimum 60 PS, PMMA, PLA, PPS+40GF, Windform®XT 2.0 and PSU+30GF have been outselected. Many materials like PA 6, PA 6.6, ABS, Grilamid TR55, Grilamid TR90, PA 6+30GF and PC are shown at the value of 100.

For the intelligent orthosis the production method of laser sintering (SLS) made out of the material PA 12 is selected. Which shows optimally properties for the Tensile strength, Elastic, Acid Resistant properties and other required characteristics. An extension to chose the Windform material®, PA 6, PA 6.6 or fibreglass-reinforced composites (shown in the material selection table) if more stability is required due to a higher body weight is possible. The 3D-printing technology enables an easy change of material and color. This lead to another advantage for a flexible operation in the future.

(see annex VI list of material selection on page 105-108)





[237]
[figure 194]
[figure 195]

iO DESIGN

9.1 brand description

The imaginary brand with the two initial letters "iO" is the abbreviation for "intelligent orthosis". The original idea for the reduction to two initial letters arised during the research phase when ISO 8549-3 of 1989 classified internationally designations for all orthoses. [195] According to international standards, a "thigh orthosis" converts into a »KAFO« (»Knee-Ankle-Foot-Orthosis«). This abbreviations described the enclosed body segments and/or the joints. [196]

The short form "iO" does not describe any body segments, however, it is generally intended to refer to orthosis with motor support and sensor technology, whether bandage or ankle foot orthosis (AFO). Equivalent foot orthoses with motor support can be found under the following terms like "active orthosis".[197] *"Active Ankle Foot Orthosis (AAFO)"* [198] or as an further example under: *"computer controlled knee-ankle-foot orthosis (Intelligent Orthosis).*" [199]

Since this orthosis in this project also consists a combination of different sensors, the "active" term became the term of "intelligent". Using the abbreviations "AAFO" means (Active Ankle Foot Orthoses)" [200] The two letters "iO" are used as common abbreviations in different spellings and can show a variety of meanings:

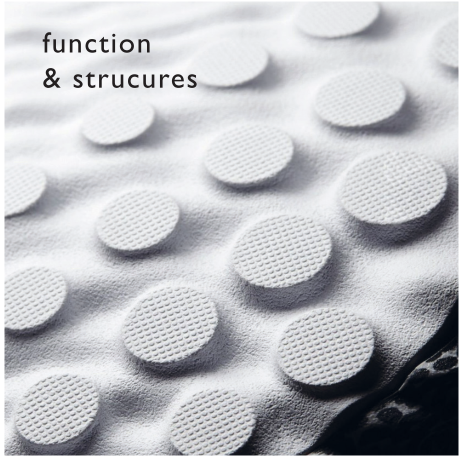
i.o. means "in order" in English and is also assigned the same meaning with the spelling "i.O." in German. This designation in the German spelling could also mean "in Oldenburg".[201] Probably the best-known abbreviations such as "IO, I/O" stand for "Input/Output" and the spelling ".io" refers to a domain suffix. [202]

Far reaching the spelling "Io" denotes the moon or satellite of the planet Jupiter. Also the description of an object-oriented programming language indicates this abbreviation. In addition various electro devices are called "I/O modules" or "I/O boards" or "IOC (I/O Controller)".[203]

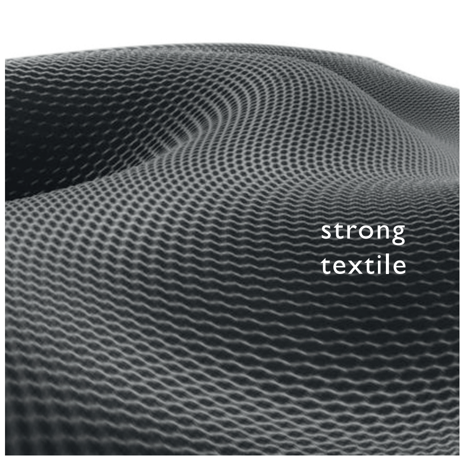
The designation "IO" for an intelligent orthosis is not a novum and was already used in the publication entitled "Newly designed computer controlled knee-ankle-foot orthosis (Intelligent Orthosis)."[204]

[figure 114] iO logo icon; [figure 115] creating iO logo; [figure 116]; [figure 117]

[figure 118]



[figure 119]

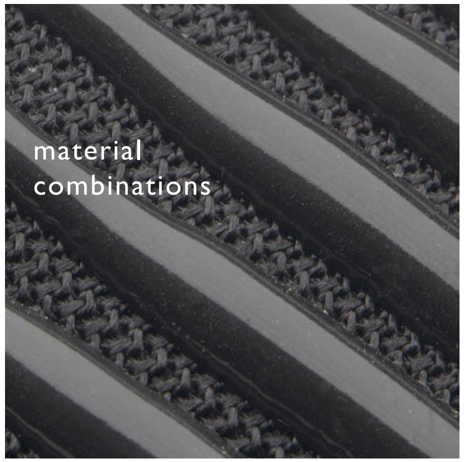


[figure 120]

[figure 121]

[figure 122]

[figure 123]



[figure 124]

[figure 125]

[figure 126]

[figure 127]

[figure 128]

[figure 129]

[figure 130]

[figure 131]

[figure 132]

[figure 133]


[figure 134]


[figure 135]

[figure 136]


[figure 137]


[figure 138]

[figure 139]


[figure 140]

[figure 141]

9.3.1 iO design language & market position

application areas:

Orthoses are used in a wide range of applications. On one hand to *heal injuries quickly* or on the other hand *as an aid in everyday life,* for example to counteract a drop foot. No matter for which application the orthosis may be used, *weight* plays an important role for making an aid device long-term wearable for the user. The patient-specific needs are very important and each client is individual. These factors play an essential role for the product design. The product positioning is less in the use of orthoses in recovery therapy but much more in the every day use which provides support and optimisation of the gait pattern - *almost like a fitness device.*

impression and design:

The appearance of the intelligent orthosis is deliberately sporty. The goal behind is showing self-confidently to point out the performance. In addition, the product convinces with a simple and portable design.

In case of various sports articles, the question of whether the accessory is visible or not is less important. On the other hand, on orthoses products, many opinions polarize, some patients do not have a problem if the orthosis is visable, others prefer not to show it at all. The design of the "intelligent orthosis" presents an approach in the middle. A new design away from usual medicine devices. The product creates the impression of a *"sports accessory"* and makes the handling for the patient due to its simple design easier and less problematic.

market position and trends:

Since the intelligent orthosis is a new product, market positioning is not particularly necessary at this point. Due to the product research of various FO orthoses with different material designs it can be observed that the *trend increasingly goes torwards to "soft orthotic / textile orthotic"* and the individuality and optimal adaptation to the user is becoming more and more meaningful.

Major sports shoe manufacturers such as NIKE and Adidas are frequently exhibiting new textiles which let shoes appearing lighter and "socklike". For example the shoe "Air Vapormax Flyknit Moc- Triple Black" [205] published in 2017 or "Deerupt S shoe" released by Adidas. [206]

usability:

The combination of textile and a stable plastics frame achieves a more user friendly product and scores with a simple attachment on the leg. A *washable textile,* an easily removable motor inside a basic frame, a targeted active support in the specific gait phases and cost-effective and patent-precise production will show *many advantages* for the user in the future.

UX INTERFACE DESIGN

10.1 user & interface

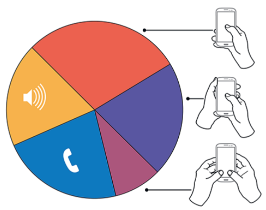
"People can use mobile devices when they're standing, walking, riding a bus, or doing just about anything. Users have to hold a device in a way that lets them view its screen, while providing input." [207]

"The users who we observed touching their phone's screens or buttons held their phones in three basic ways:

- one handed —49%
- cradled —36%
- two handed —15%"

[208]

"Summary of how people hold and interact with mobile phones." [209] (figure 142)



[figure 142]

one handed

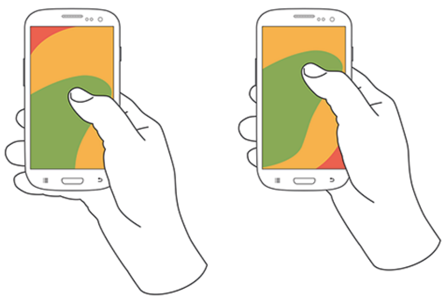
The 49% of users who use just one hand typically hold their phone in a variety of positions (left-handers do the opposite) two of them are shown in (figure 143), but other ways of holding a mobile phone with one hand are possible. Like in figure 143 shown, the thumb joint is higher in the image on the right because some users seemed to consider their hand position on the reach they need. [210]

"For example, they would hold the phone so they could easily reach the top of the screen rather than the bottom." [211]

"One-handed use—with the

- right thumb on the screen —67%
- left thumb on the screen —33%"

[212]



[figure 143] "Two methods of holding a touchscreen phone with one hand"

cradling in two hands

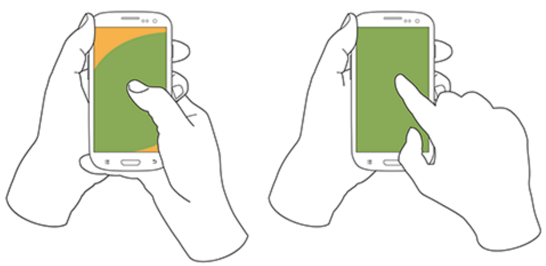
Using two hands to hold a mobile phone, but only one hand to touch the screen or buttons, is referred to as Cradling shown in figure 144. [213] "The 36% of users who cradle their mobile phone use it in two different ways: with their thumb or finger." [214]

"Cradling—with a

- thumb on the screen —72%
- finger on the screen —28%"

[215]

"Anecdotally, people often switched between one-handed use and cradling. I believe this was sometimes for situational security—such as while stepping off a curb or when being jostled by passersby—but sometimes to gain extra reach for on-screen controls outside the normal reach." [216]



[figure 144] "The two methods of cradling a mobile phone"

two-handed use

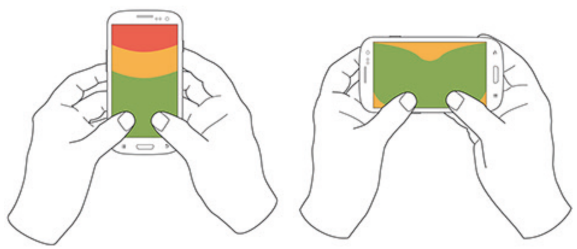
"We traditionally associate two-handed use with typing on the QWERTY thumbboards of devices like the classic Blackberry or on slide-out keyboards." [217] 15% of mobile phone users holding the mobile phone in a two-handed way. (figure 145) Users cradle their mobile phone in their fingers and use both thumbs providing input like they would use a desktop keyboard. [218]

"Two-handed use—when holding a phone

- vertically, in portrait mode—90%
- horizontally, in landscape mode—10%"

[219]

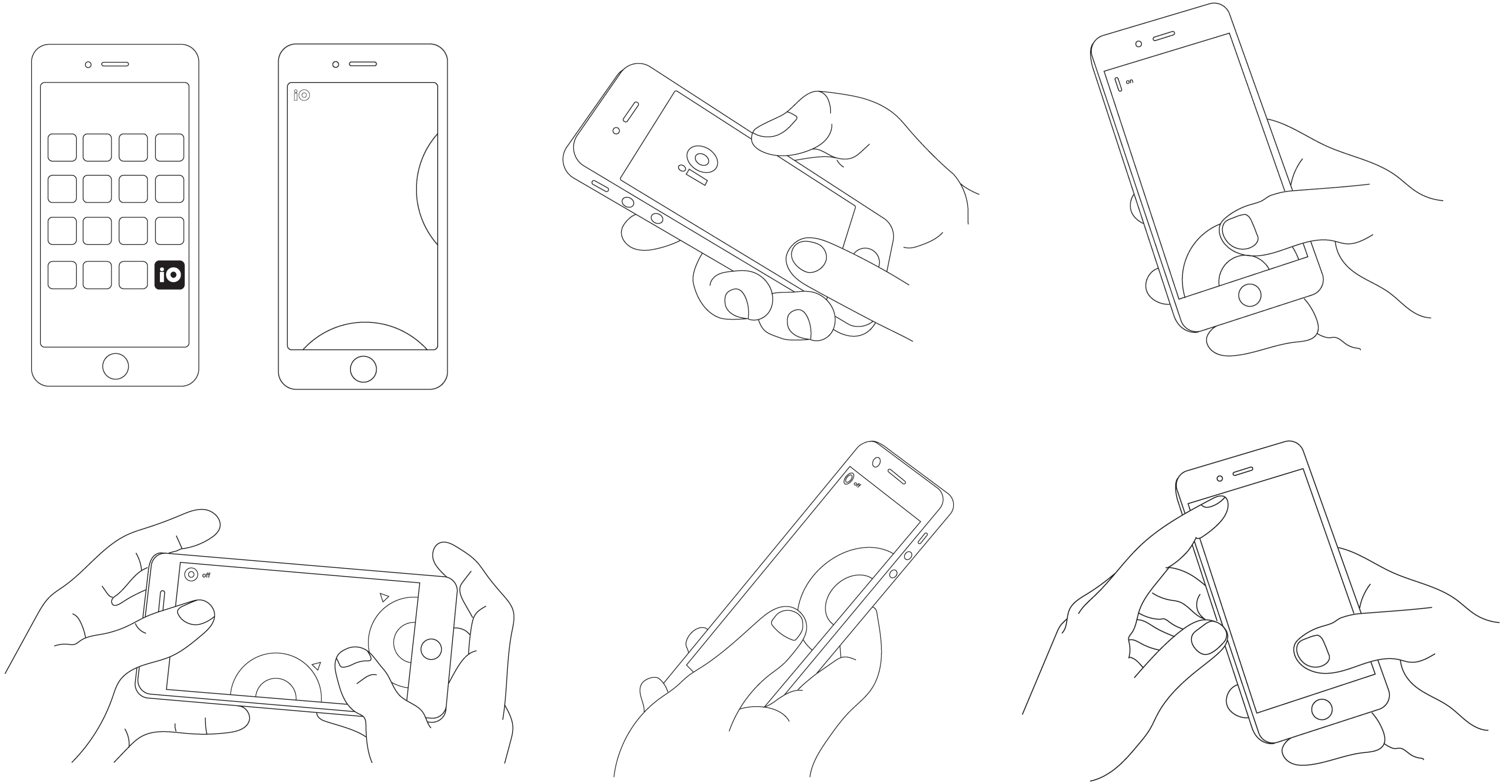
"People often switched between two-handed use and cradling, with users typing with both thumbs, then simply no longer using one hand for input and reverting to using just one of the thumbs consistently for interacting with the screen. However, not all thumb use was for typing. Some users seemed to be adept at tapping the screen with both thumbs or just one thumb. For example, a user might scroll with the right thumb, then tap a link with the left thumb moments later." [220]



[figure 145] "Two-handed use when holding a phone vertically or horizontally"

UX INTERFACE DESIGN

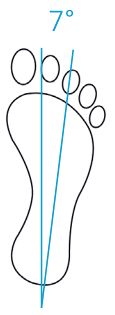
10.1.2 user journey



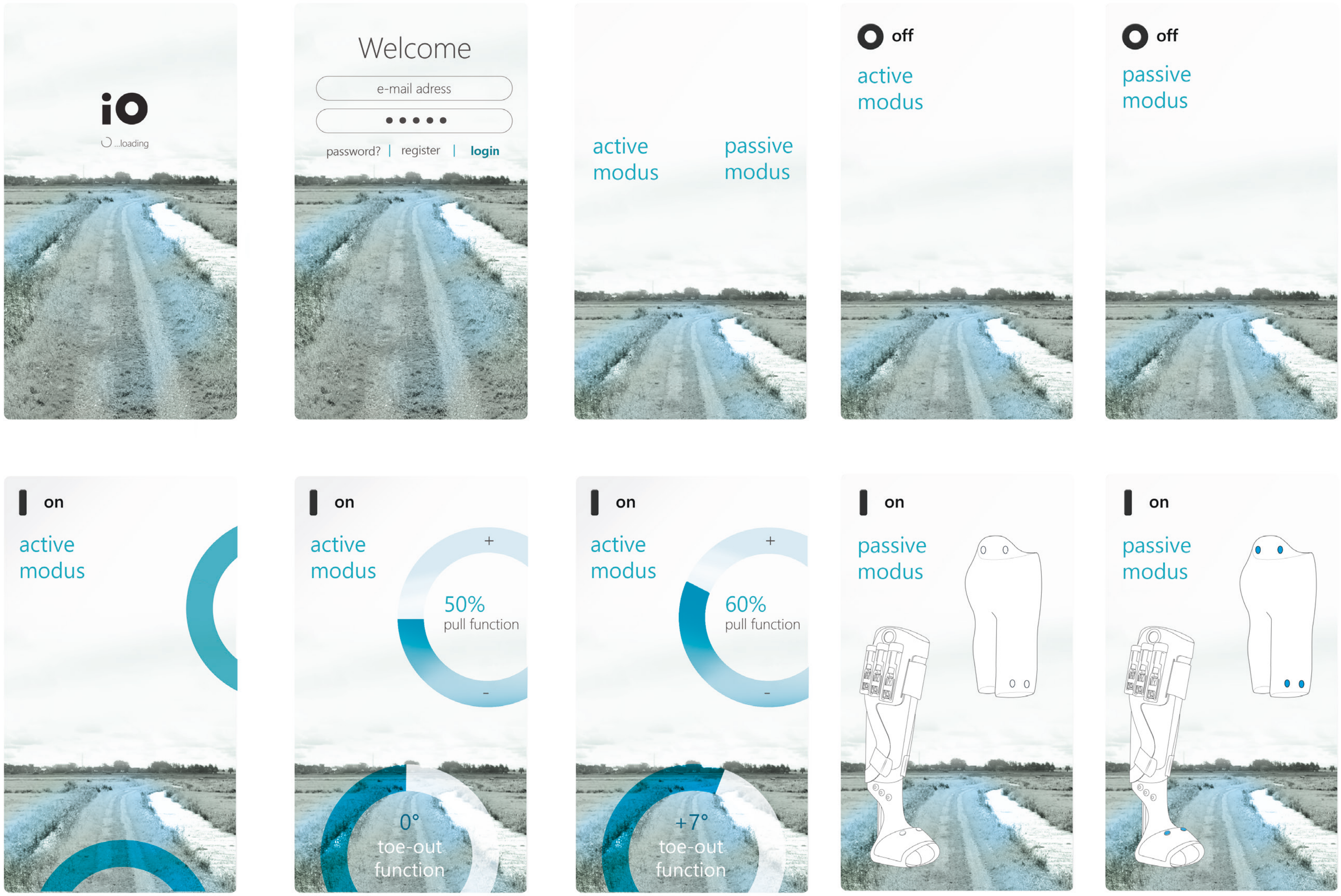
[figure 146] "user-journey"

UX INTERFACE DESIGN

10.1.3 interface design



7° toe out angle
[figure 6]



[figure 147] "interface design"

10.1.3 interface design

The user interface design consists of two different "function modes" and they can be switched by drag and drop to the side.

The first mode shows the *active motor function,* where two navigation circles display the individual setting options. As shown in the wireframe (figure 148), *the pull function* can be set by percentage (%) in the upper navigation circle in order to counteract the drop foot. The lower navigation circle allows the *"toe-out function" setting* and is specified by angle in degrees (°).

The blue area indicates the actual setting position and is further displayed as a text inside the circle. By drag and drop to the side the *second passive function mode* (figure 148) appears, in which the individual vibration motors can be activated or deactivated.

[figure 148] application interface design

iO PRODUCT DESIGN

11.1.1 textile design / generative design

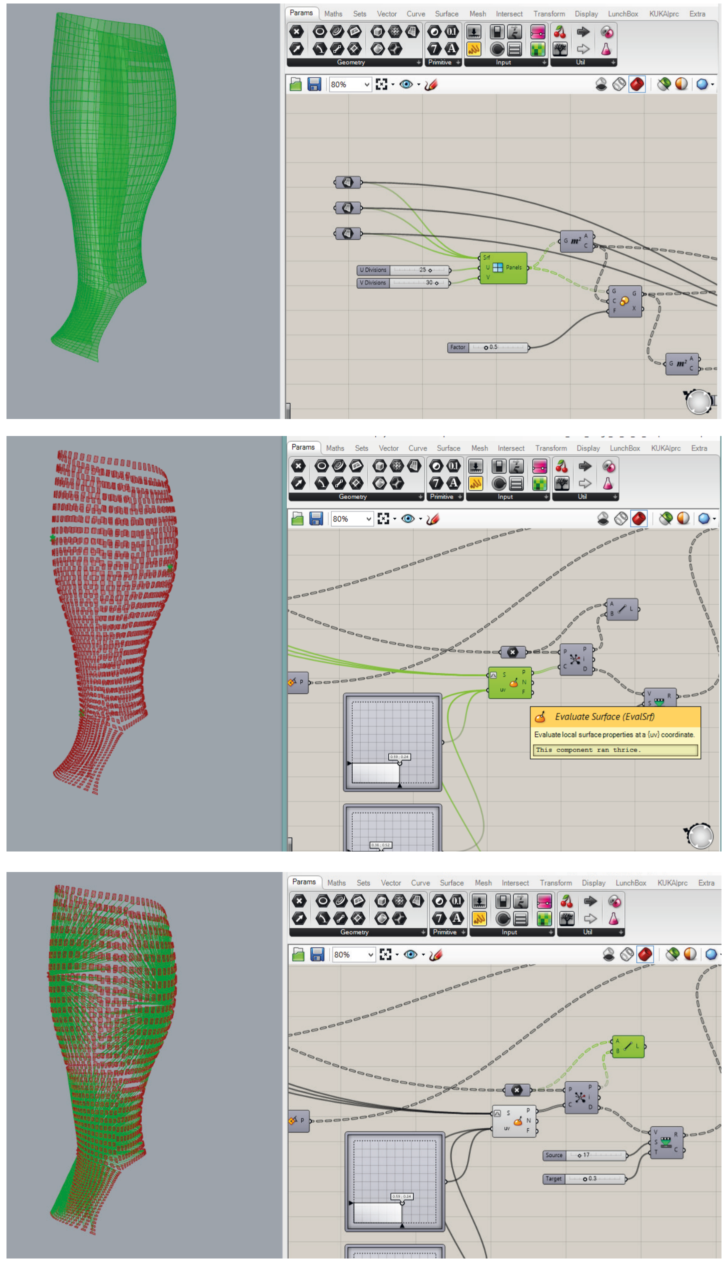
Generative design enables parametrically defined structures. The targeted parameterization of textile design was particular interest for this approach. With this method, different areas can be defined, e.g. where elements follow each other more closely or where there is more space between the elements or a rotation takes place.

"Algorithms can also lead to geometries. For instance, if an integrated editor is used within CAD or another modeling software, a 3D geometry is created by manipulating the standard set of primitives provided by the software or procedurally defined by a sequence of instructions. For instance, a line can be defined by two points, a start and an end; points in turn can be defined by their coordinates {x,y,z}. For example, a vase model can be defined as a revolution of a profile curve around an axis, and more complex objects can be obtained by establishing a set of rules." [221]

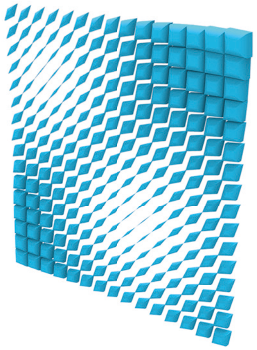
With the *"grasshopper"* plug-in for Rhinoceros (3D-program) and with the aid of an existing tutorial [222] the "generative design" for textiles was created. This method of defining a "closest point", structures and elements are aligned and applied to the design. Another "SCALE factor" could be used to perform different scaling modifications.

The resulting structural definition could be applied to *conventional compression textiles,* because they established as suitable, are *skin-friendly* and *provide a good fit.* These compression stockings are usually termed as MKS (medical compression stockings). Elastic threads are incorporated in the textile and ensure a consistant pressure. [223] The "flat knitting process" permits MKS-textiles to be tailor-made and can be manufactured in high compression classes. The compression stocking classes are classified according to strength by A,1,2,3,4. [224]

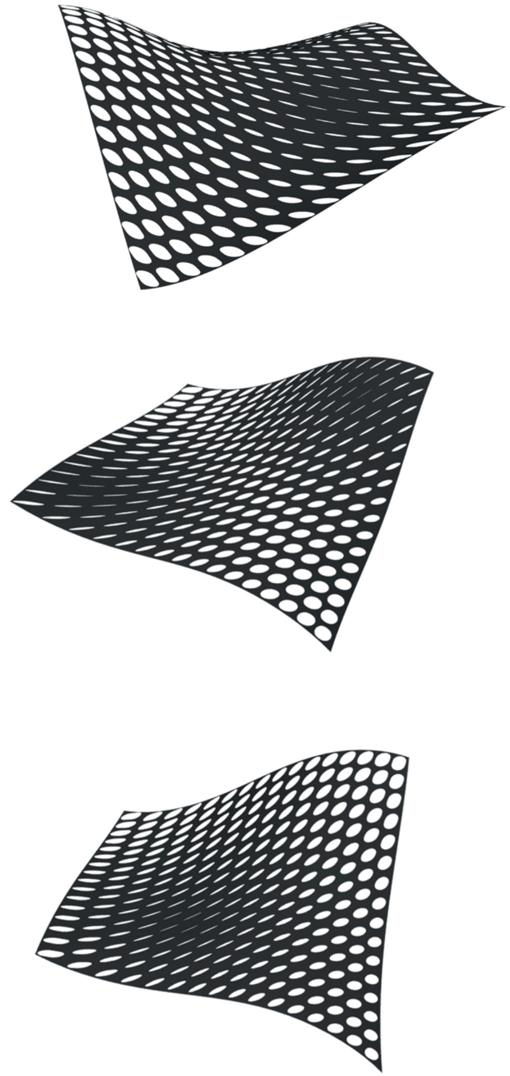
A strong (3) to very strong (4) compression textile would be conceivable for this application. As a further consideration the compression stockings can be included to the customization-process.

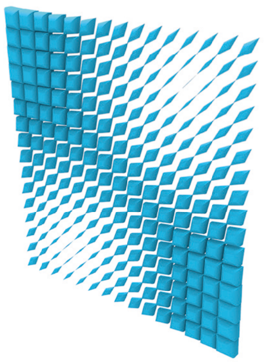


[figure 149-151] "screenshots generative design"



2-point MD-slider position 1





2-point MD-slider position 2

[figure 152-153] "MD-slider positions";[figure 154] "generative textile design";[figure 155] "generative textile variations";

iO PRODUCT DESIGN

11.1.2 textile & foam components

The textile elements (compression stockings) presenting a mixture of textile and stabil foam components in particular zones. Blue-coloured stitching or customized-coloured stitching are used as a highlight.

[figure 156] "textile & foam"
[figure 157] "shape-finding ideation"

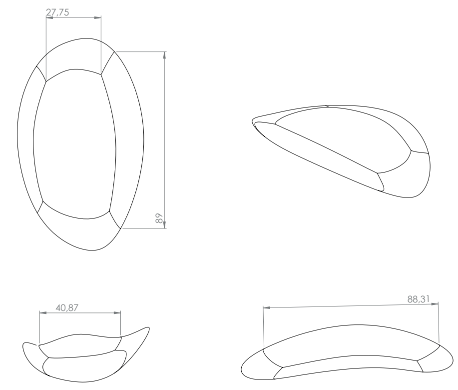
[figure 158] "mixture foam & textile"

11.1.3 iO sensory support by air cushion

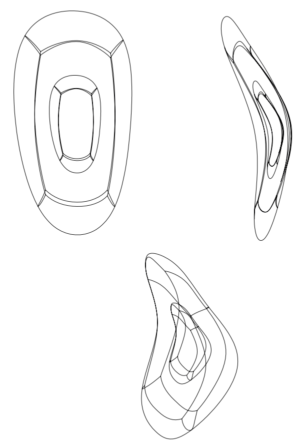
As already mentioned the air is pumped upwards from the pocket soles of the foot *(pocket sole)* during the ground contact and provides sensory support during the one-leg stand *(pocket muscles)*. As soon as the user lifts his leg and moves into the swing phase, the air returns to the sole pocket *(pocket sole)* of the foot and provides at the same time an additional shock absorption, as described on page 46;50.

These additional air cushions are integrated in the compression stockings. But there is also the possibility to separat them from the textile, in case the user wants to wash their stockings.

pocket sole

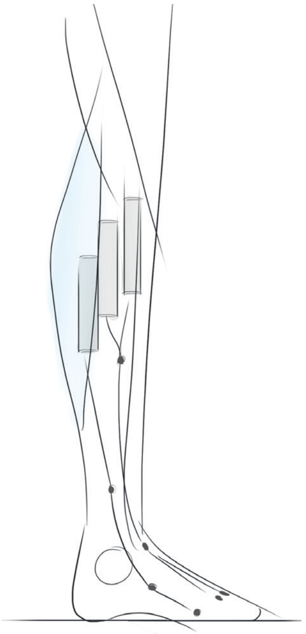


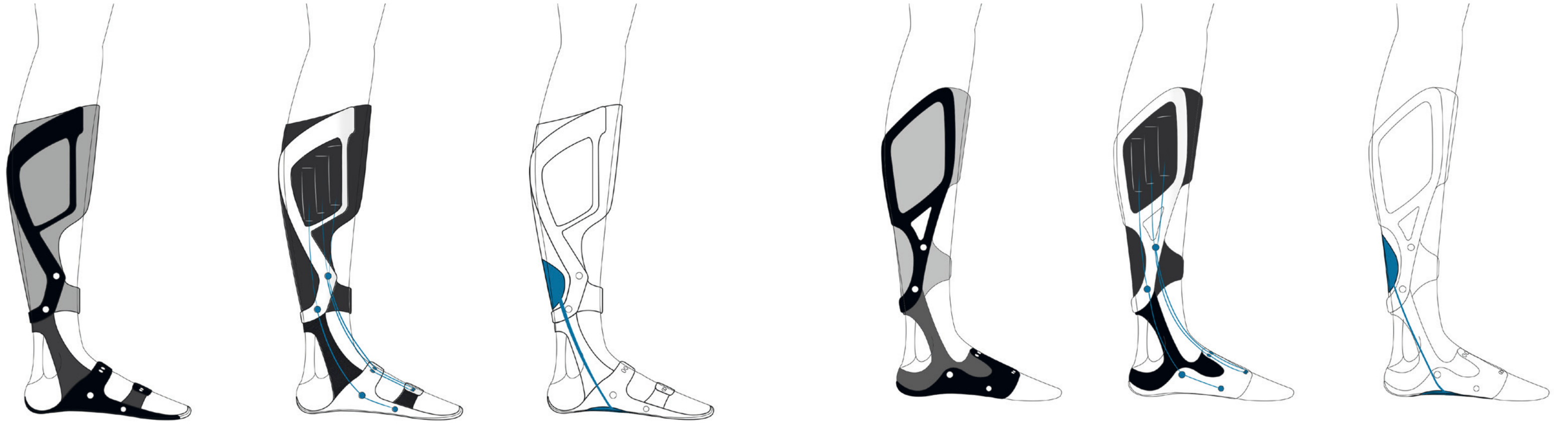
pocket muscles

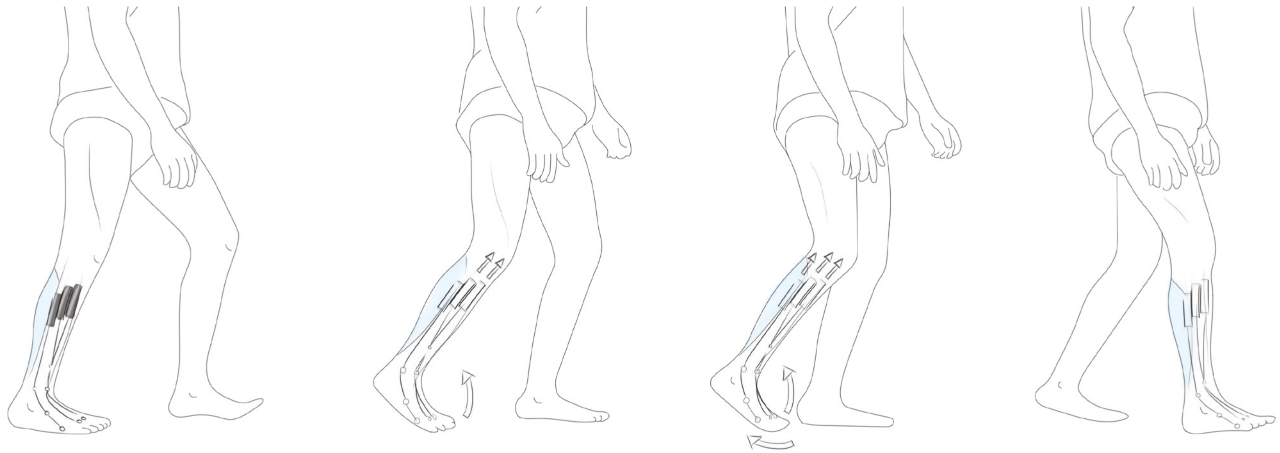


[figure 85] *pocket sole* ;[figure 87] *pocket muscles;*[figure 159] "muscle & air cushions";[figure 160] "gait phases & air cushions"

11.1.4 iO motor enclosure design







[figure 161] *"drawing inspiration"*;[figure 162-163] *"drawing inspiration02"*;[figure 164] *"solution-drawing"*

iO PRODUCT DESIGN

11.1.4 iO motor enclosure design

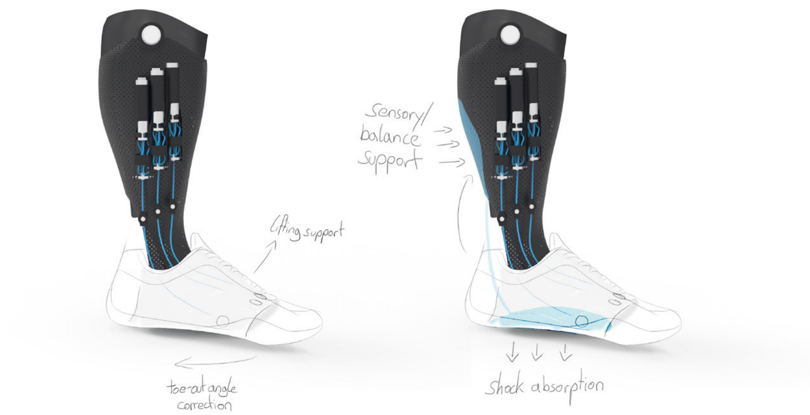
How are the three motors arranged? How does the motor housing look like? Do this motor need ventilation slots? How could the motor be attached to the leg and where exactly is an optimal position to gain a portable result?

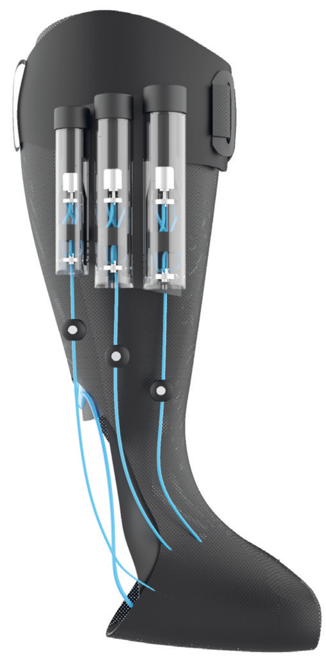
The figure 165 demonstrates first trials of different arrangements. The black and white component serves as a spaceholder to keep a fixation point for the basic frame.

The first idea was to integrate the three actuators in a box. In the next steps the box was redesigned as a tube-case. Three extra case components are created.

The actuator size was selected fictitiously.

- 1st actuator size Ø16mm
- 2nd actuator size was scaled by 0.90 for optical reasons
- 3rd actuator size was scaled to by 0.80 for aesthetical and functional reasons.
  This actuator need less power because the ankle-joint is only rotating sidewards.
  (see page 56)





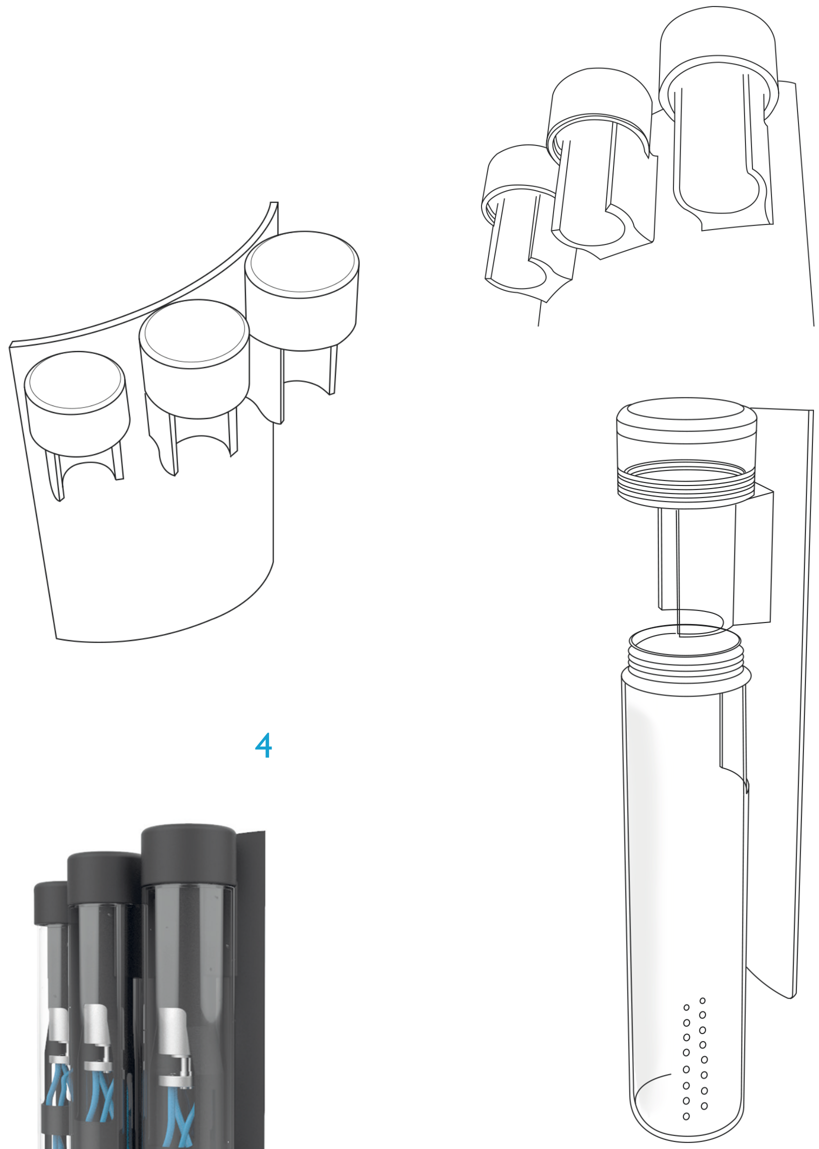
[figure 165] "motor-package options";[figure 166] "brainstorming";[figure 167] "sideview"

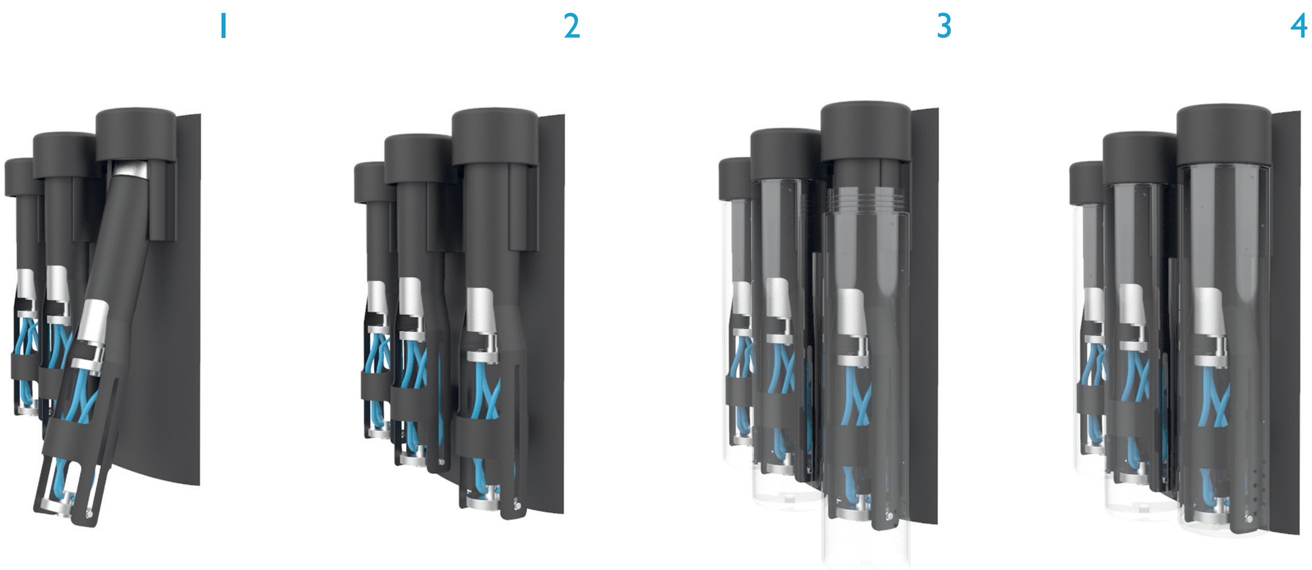
iO PRODUCT DESIGN

11.1.4.1 actuator attachment

The idea of tube casing:

At first the tube-casings are arranged on a removed surface from the 3D body. The clamp is used for lateral fixation. (1)(2) (figure 168) The transparent tube form is pushed into the fixture from bottom to top and closed with a positive fit by grooves. (3)(4) (figure 168) Ventilation slots are necessary due to the high heat development of the motor. (figure 169)





[figure 168] *"actuator attachment"*;[figure 169] *"actuator attachment illustration"*

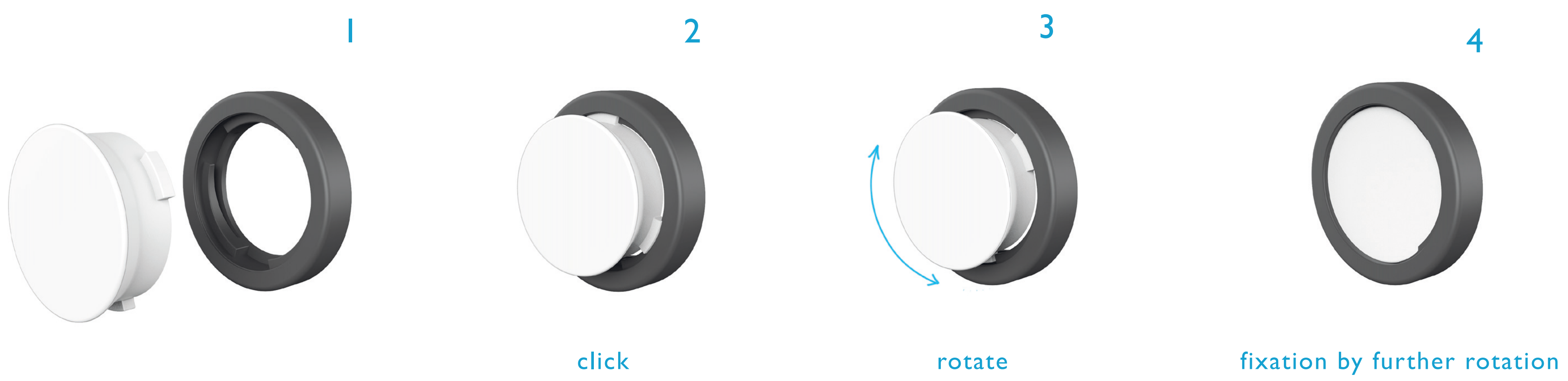
iO PRODUCT DESIGN

11.1.4.1 actuator attachment

How could the actuators be attached to the basic frame?

The bayonet joint consists out of two parts. [225];[226] It was considered: One part, for example, the *white element* is integrated into the textile (stable foam component). The opposite part, the *black element* is contained in the basic frame. These two elements can be closed by a rotary movement. Through a slanted edge in the inner part the mechanism fixes. This procedure allows the user an easy attachment to the leg.

frame closure Ø35mm



[figure 170] *"quick-closure attachment"*;[figure 171] *"backview"*

11.1.4.1 actuator attachment

- small quick closure

The attachment according to the same method can be applied to the respective attraction points on the upper foot surface and on the side of the foot. Due to the round shape, the rope can be easily positioned and fastened inside.

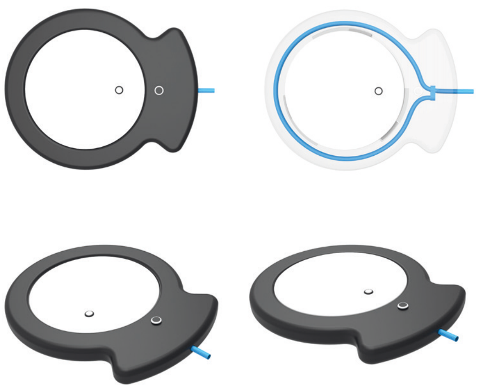
- rope closure

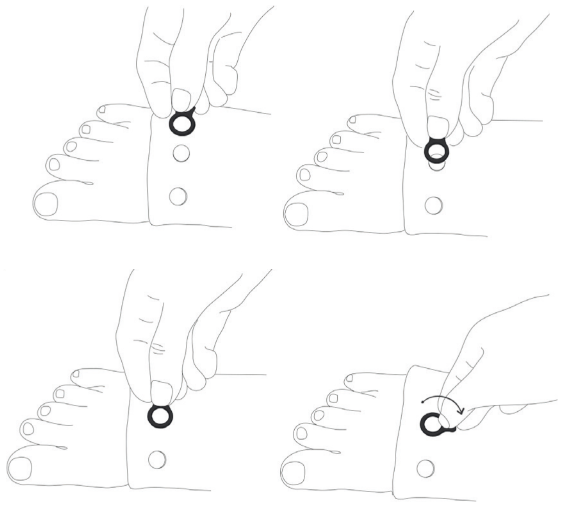
The "rope closure" element was inspired by a commercially available guide element for ropes from Seilflechter. [227]

rope closure

[figure 174] *"rope closure"*

small quick closure 3x Ø small dimension





[figure 172] *"small quick-closure"*;[figure 173] *"small quick-closure illustration"*;[figure 175] *"frontview"*; [figure 176]

11.1.5 iO base frame

The base frame is available in two different colours, *black and white.* These colours can be combined easily with any clothing due to their neutrality. As mentioned in the process method explantation on page 62, a different colour selection is possible without any problems.

[figure 177]

[figure 178] *"base frame preview"*

11.1.5.1 ergonomic aspects in order to high adjustment and parametric details of the base frame

On page 12-14 the ergonomic requirements of body measurements are listed. These measurements are important for the *compression stockings size* for men and women. In summary six important variable parameters (including the material selection as a parameter) are defined for the base frame. As mentioned on page 61-63 the weight can be various from patient to patient and so the parameter 01,02 and 03 focusing on the weight adaption and stability.

parameter 01, 02 and 03 "weight and stability adaption":
First the use of a fibreglass-reinforced composite can provides higher stability properties. Another parameter to gain better stability results, is to adapt the *wall thickness*. The mentioned compression stocking classes (page 78), according to the strength can be chosen for personal requirements.

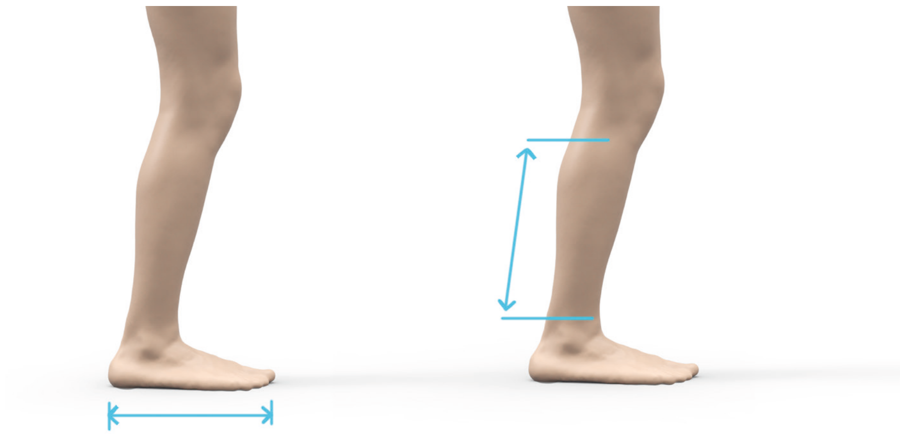
parameter 04 "size adaption":
The shoe size and also other important values for different high adjustments (listed on page 14) can be selected individually.

parameter 05 " various diameters of the leg":
Three different circle diameters can be evaluated to develop the individual base frame. (shown in figure 180)

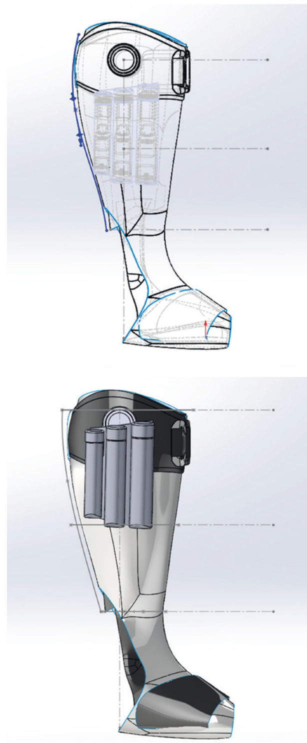
parameter 06 "shape contour of the leg":
The shape contour of the leg is a further specific parameter that needs to be measured to achieve an ideal result (figure 180).

In conclusion the specific parametric details for an individual adaptation to the base frame are:

parameter 01	- material selection
parameter 02	- wall thickness adaption
parameter 03	- classes of compression stockings
parameter 04	- shoe size & high adjustment variabilities
parameter 05	- specific characteristics of the diameters of the leg identified by three different circles
parameter 06	- unique shape contour of the leg



[figure 179] *"variable measurements"*



[figure 180] *"parametric details"*

[figure 181] *"3D-printing"*

1 attach

2 click

3 rotate

4 fixation by further rotation

5 fixation by lashings

[figure 182] *"sequence of base frame fixation"*

iO PRODUCT DESIGN

Design of the intelligent orthosis (without base frame).

[figure 183] *"visualisation compression stockings"*

iO PRODUCT DESIGN

Design of the intelligent orthosis (with base frame).

[figure 184] *"visualisation orthosis"*

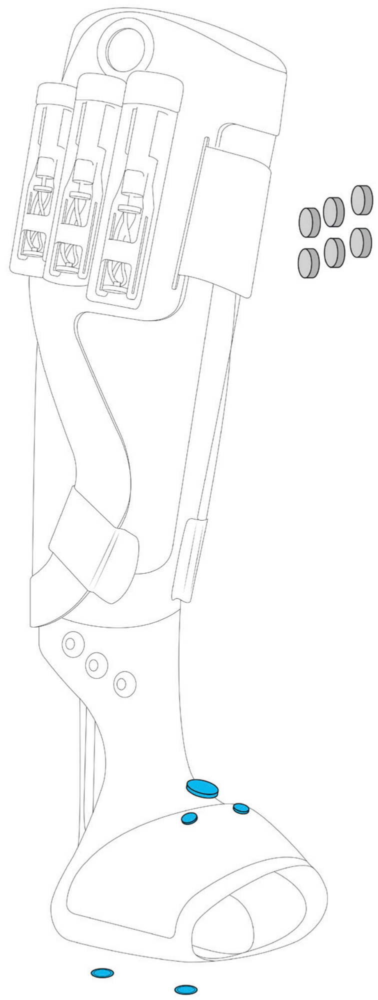
iO PRODUCT DESIGN

Additional velcro straps provide an extra fixation on the leg:

[figure 185] *"visualisation orthosis with additional velco straps"*

iO PRODUCT DESIGN

Design of the intelligent orthosis (assembly view).



battery pack option

1x nRF52832 Multiprotocol Bluetooth 5 accelerometer + gyrosensor [160]

2x Seeed 316040001 Mini Vibration Motor 3V 2.0mm Circular [159]

2x Interlink Force-Sensing Resistor FSR 402 Short [158]

[figure 186] *"sensor assembly view"*

iO PRODUCT DESIGN - 11.2 hip/knee area

11.2.1 ergonomic aspects in order to high adjustment of the hip area

The on page 12-13 listed ergonomic requirements of body measurements presented two different important values for the product:

(ish) Iliac spine height
minus
(ph) patella height, top.

The result of this subtraction is the relevant size for the hip/knee compression stocking.

The (ish) iliac spine height show without clothes and on persons (male) with the age 26-40 (from the percentile 1-99) a range of 954mm-1181mm. For women with the same age (percentile 1-99) a range of 892mm-1090mm without clothes. [228]

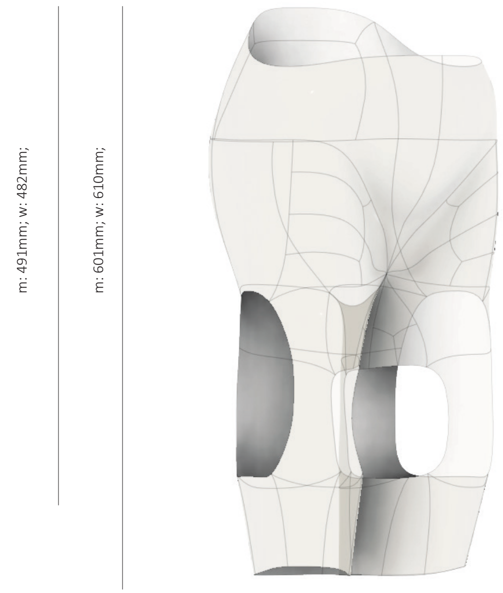
Compared to the patella height,top the range of 463mm-580mm is defined for men at the age 26-40 (percentile 1-99) without clothes. For women in the age of 26-40, without clothes the measurments for the patella height, top are from 410mm-480mm. [229]

- The resulting sizes for men are:

1 percentile:	491mm
5 percentile:	514mm
50 percentile:	546mm
95 percentile:	583mm
99 percentile:	601mm

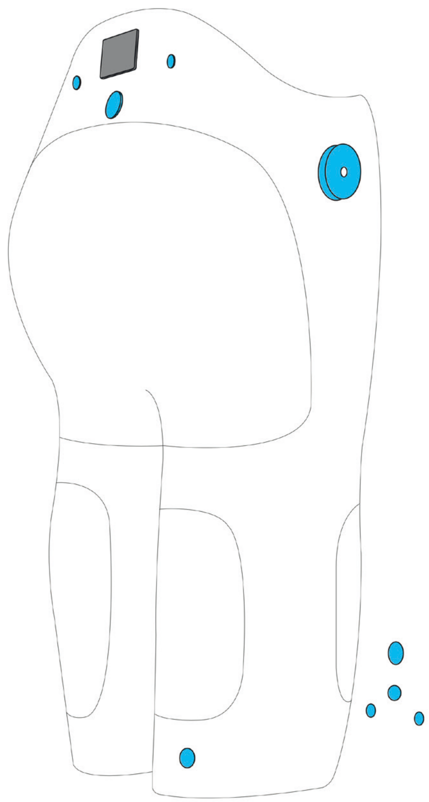
- The resulting sizes for women are:

1 percentile:	482mm
5 percentile:	500mm
50 percentile:	550mm
95 percentile:	593mm
99 percentile:	610mm



[figure 187] *"hip textile 01"*
[figure 188] *"hip textile 02"*

11.2.2 textile, foam components & sensors (assembly view)



battery pack option

2x Seeed 316040001 Mini Vibration Motor 3V 2.0mm Circular [152]

1x nRF52832 Multiprotocol Bluetooth 5 accelerometer + gyrosensor [153]

1x IncOder™ inductive angle encoders [151]

1x nRF52832 Multiprotocol Bluetooth 5 accelerometer + gyrosensor [153]

2x Seeed 316040001 Mini Vibration Motor 3V 2.0mm Circular [152]

2x Interlink Force-Sensing Resistor FSR 402 Short [155]

[figure 189] *"hip textile 03 & sensors"*
[figure 190] *"hip textile 04 & sensors assembly view"*

12 iO PERSPECTIVE / VISION

What are expectations for the intelligent orthosis in the future?

The perspectives of the intelligent orthosis in support of the locomotor system present a wide range.

The usage of the "twisted string actuators" shows great potential to be optimised in further scientific works. Further topics could be first, *to minimize the size of the actuators* and second to make it *more affordable.*

In principle these mechanism fits into the application device of the intelligent orthosis. In the course of the scientific research, future questions arose regarding the twisted actuator mechanism in recently released scientific papers for the topics of optimization of the *coating and different string braiding techniques.* [232] As already mentioned the focus of this project has been placed on design. The result presented an approach for a new design to make "twisted actuators" *portable for the user.*

Individual settings, a training function and the possibility to switch on the active motor support in case the user is already exhausted are great advantages. In addition the *patient-oriented processing method* generated an affordable quick orthosis. The presented process on page 60-63 to obtain a cheap orthosis without contact and elaborate plaster cast show a big improvement to common methods. The editing processing as done before on previous orthoses is no longer necessary. These mentioned factors show good prospects, for a product that will be worn *in everyday life* because of the higher comfort.

Various sensors can be optimated to a smaller size or to a more accurrent detection. Also further developments on the app function can be considered, in order to obtain specific information about gait behaviour, and to clarify with an orthopaedist or physiotherapist in a more accurate way. An additional protocol can reveal possible improvements in muscle activity. In contrast to passive orthoses the foot is not only supported by not falling down. [233] Over a long-term-use the active support can improve the muscle activity and can be used as a training device outside the clinic.

The evaluated Design, which differs from typical medical products presents a more attractive version for users. A futher benefit is the simple attachtment solution on the leg. This orthosis is easily compatible with daily clothes. Related to the compression stocking a further step could be to develop a low-cost production or series production (combination of compression textiles and foam components for stability) and to improve the mesh arrangement through generative design (to control particulary a denser course page 78-79). An additional further development could be to find out a solution that makes the electronic components removable from the textile part, to guarantee washability of the entire product.

3D-printing technology is constantly optimized and shows a fast, accurate and flexible manufacturing method for the product (despite current gaps to replace other production methods).

The final vision is to start tests in order to optimize the product, shape, sensors and technical function according to the aestetics of iO.

13 iO VISUALISATION

[figure 191] *"visualisation two phases"*

Design of an intelligent orthosis in support of the locomotor system

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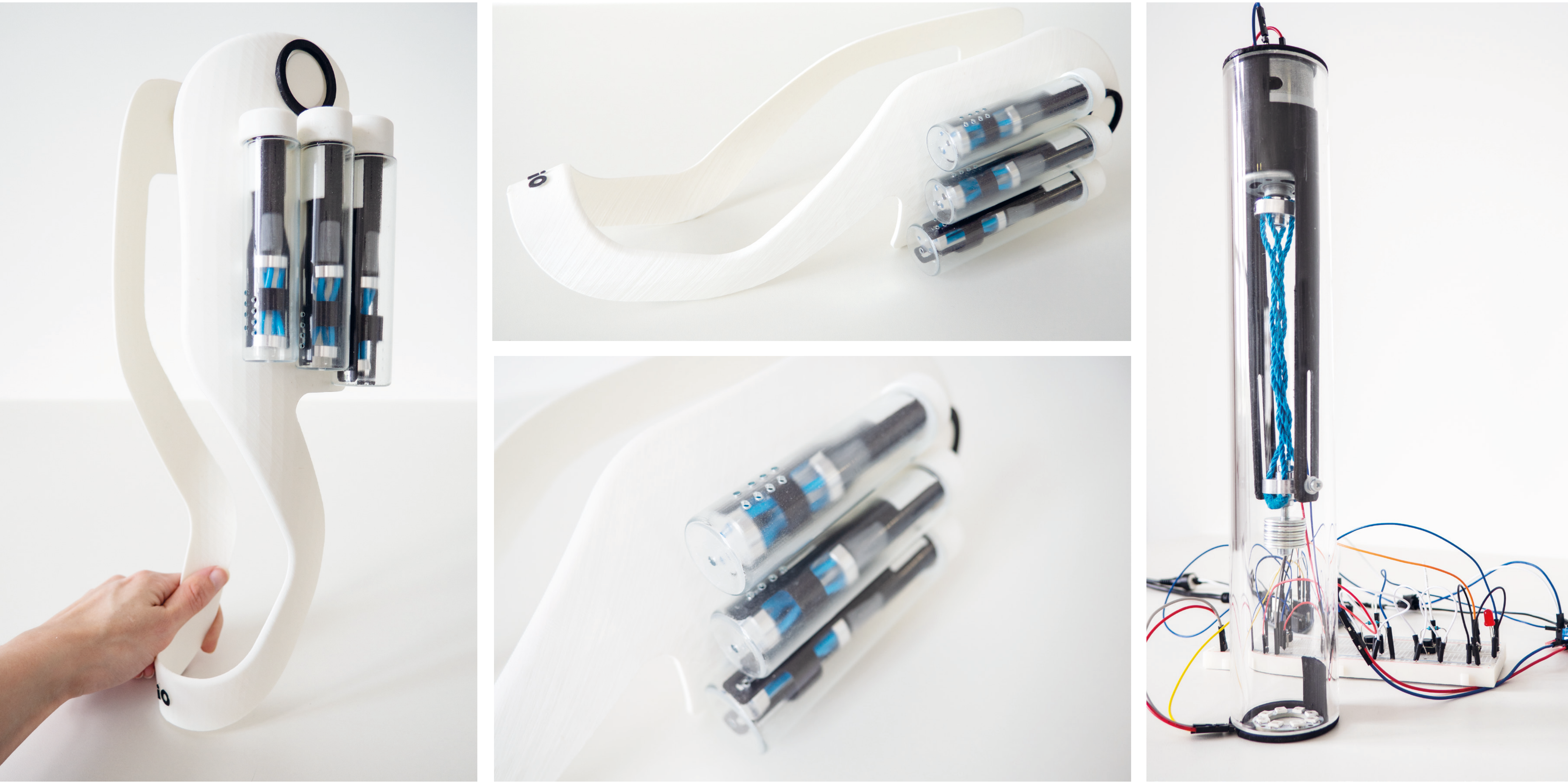
[figure 192] *"final visualisation"*

The video is attached on the enclosed CD.

[figure 193] *"video preview"*

15 iO DESIGN MOCK UP



[figure 200] *iO design mock-up*

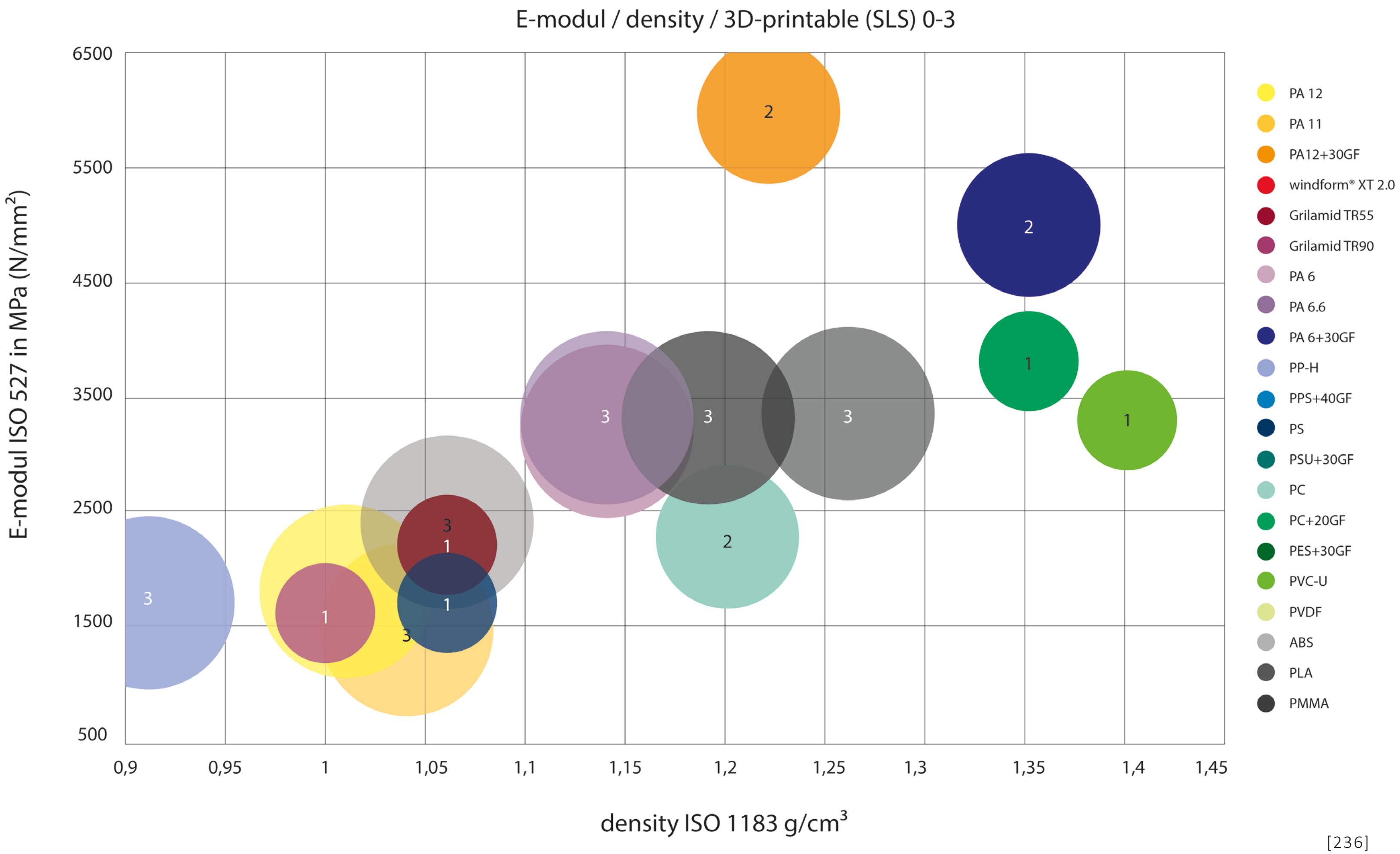
VI list of material selection

VI list of material selection

	plastics		density	E-modul	price	3D-printing / SLS		tensile strength	bending strength	long-term service temperature	impact toughness	UV resistance	acid resistant
			Dichte ISO 1183g/cm³	E-modul ISO 527 in MPa (N/mm²)	Preis l/kg	YES/NO		Zugfestigkeit ISO 527-1/2 in MPa	Biegefestigkeit ISO 178 in MPa	DG-Temp in °C	Schlagzähigkeit ISO 179 in kJ/m² (Charpy 23°C)	UV -Beständigkeit	Säureresitent
1	PA 12		1,01	1800	1,8	YES		50	68	(-50°C til +80°C)	100	middle	middle
2	PA 11		1,04	1500	(-)	YES		48	57,5	(-70°C til +80°C)	100	(-)	good
3	PA 12+30GF		1,22	6000	(-)	YES		105	(-)	(0°C til +110°C)	80	middle	middle
4	windform® XT 2.0		1,09	8928	(-)	YES		83,84	133	(-)	22,43	(-)	(-)
5	Grilamid TR55		1,06	2200	(-)	NO		75	(-)	(+80°C til +100°C)	100	(-)	middle
6	Grilamid TR90		1	1600	(-)	NO		60	(-)	(+80°C til +100°C)	100	(-)	middle
7	PA 6		1,14	3200	1,88	YES		80	121	(-40°C til +90°C)	100	(-)	(-)
8	PA 6.6		1,14	3300	1,6	YES		85	110	(-30°C til +100°C)	100	(-)	(-)
9	PA 6+30GF		1,35	5000	(-)	YES		100	(-)	(-30°C til +110°C)	100	(-)	(-)
10	PP-H		0,91	1700	0,75	NO		33	(-)	(0°C til +100°C)	100	middle	good
11	PPS+40GF		1,65	6500	(-)	NO		90	200	(0°C til +220°C)	16	middle	good
12	PS		1,06	1700	0,79	YES		55	103	(-10°C til +70°C)	6	middle	good
13	PSU+30GF		1,49	7380	(-)	NO		108	155	(-)	28,4	middle	good
14	PC		1,2	2300	1,24	YES		60	97	(-100°C til +115°C)	100	middle	(-)
15	PC+20GF		1,35	3800	(-)	NO		85	(-)	(-30°C til +130°C)	65	(-)	(-)
16	PES+30GF		1,6	10200	(-)	NO		140	195	(-)	45	(-)	good
17	PVC-U		1,4	3300	(-)	NO		58	85	(-15°C til +60°C)	75	middle	good
18	PVDF		1,78	2100	(-)	YES		40	78	(-50°C til +120°C)	89,4	good	good
19	ABS		1,06	2400	0,76	YES		45	75	(-40°C til +80°C)	100	middle	middle
20	PLA		1,26	3350	0,86	YES		73		(-)	13,5	good	(-)
21	PMMA		1,19	3300	(-)	YES		70	105	(-40°C til +70°C)	20	(-)	(-)

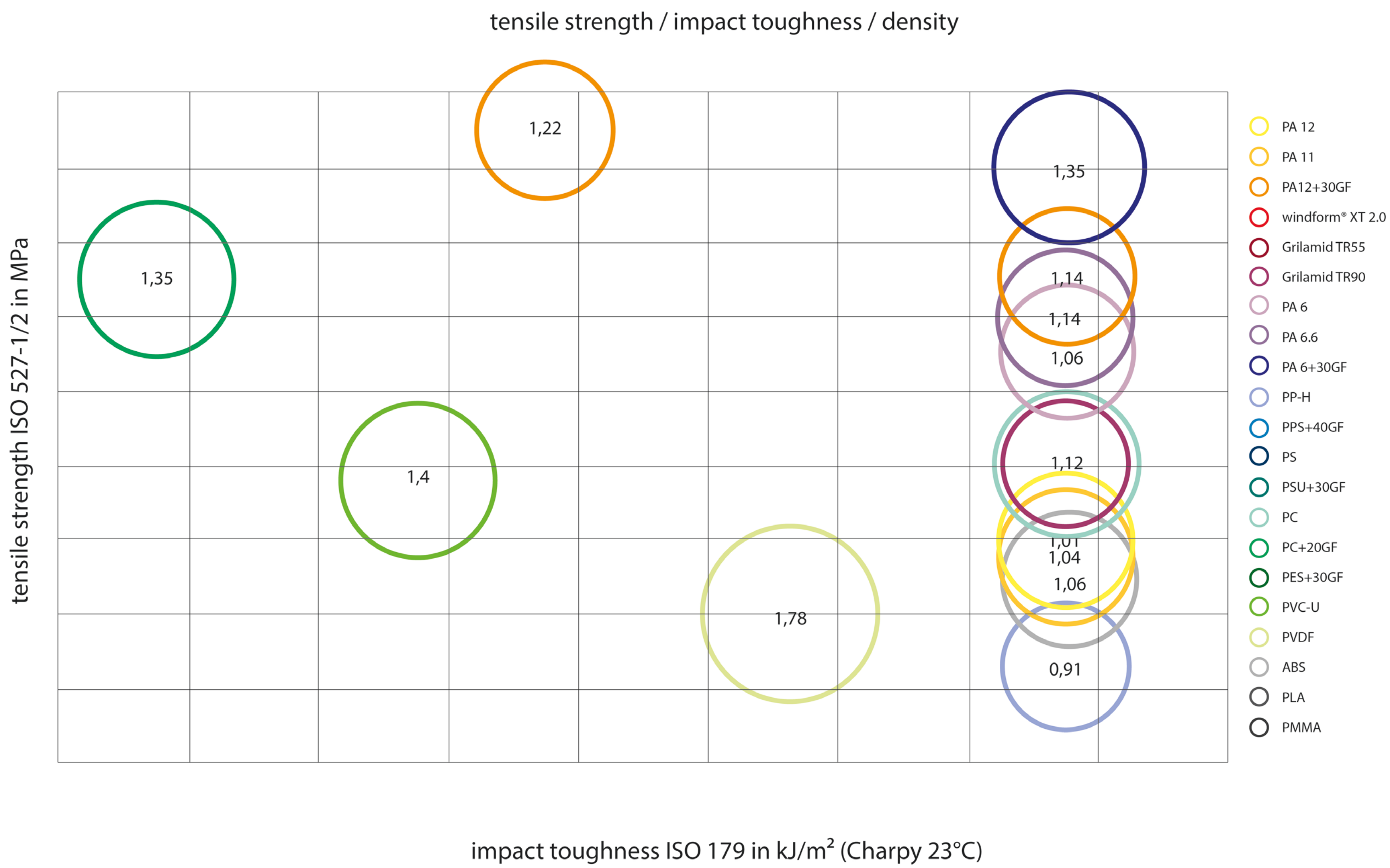
[236]

diagram 01 (E-modul / density / 3D-printable (SLS) 0-3)



[236]
[figure 194]

diagram 02 (tensile strength / impact toughness / density)



[236]
[figure 195]

VII list of abbreviations

VII list of abbreviations

[1] c.f. (Usman Muhammad 2017) video comment
Usman M. / Seong H. / Suthar B. / Hawkes E. / Gaponov I. / Ryu, J-H. [Eds.] (2017):
"Passive Returning Mechanism for Twisted String Actuators."
URL: https://www.youtube.com/watch?v=J26y1nn7JMM [access:19.02.2019]

[2] c.f. (Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. 2011)
Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. [Eds.](2011):
"Bio-inspired Active Soft Orthotic Device for Ankle Foot Pathologies."
URL: https://ieeexplore.ieee.org/abstract/document/6094933 [access:14.03.2019]

[3] c.f (Götz-Neumann, K.2011) p.92-p.93 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[4] (Abfalterer, Mattias / Achenrainer, Sandrino / Figl, Alexander / Frei, Max / Heinrich, Nils / Neubauer, Vanessa /Payr, Johannes / Rieger, Marcel /
Robertshaw, Clare Gwenyth / Seiler, Felix / Wimmer, Doris/ advisor: FH-Prof. Yeongmi Kim, PhD (2018): "Medical Device Project."
MCI Management Center Innsbruck - Department of Mechatronics)
project material and results of the cooperationproject at MCI Innsbruck

[5] c.f (Götz-Neumann, K.2011) p.24 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[6] c.f (Götz-Neumann, K.2011) p.27 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[7] c.f (Götz-Neumann, K.2011) p.25 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[8] c.f (Götz-Neumann, K.2011) p.27 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[9] c.f. (Befunddolmetscher 2016) [own translation] [access:27.02.2019]
Befunddolmetscher - Die Erklärungshilfe für Ihren medizinischen Befund[Ed.](2016): "Metatarsophalangealgelenk.CT Fuß." [15.02.2016]
URL: https://befunddolmetscher.de/ct/fuss/10129/Metatarsophalangealgelenk [access: 27.02.2019]

[10] c.f. (Thieme - via medici) [own translation] [access:27.02.2019]
Thieme - via medici[Ed.]: "Weitere Gelenke des Fußes."
URL: https://viamedici.thieme.de/lernmodule/anatomie/weitere+gelenke+des+fu%C3%9Fes [access: 27.02.2019]

[11] c.f. (Kuhs, C.2017) [own translation] [access:27.02.2019]
Kuhs, C.[Ed.](2017): "Wenn der Stoßdämpfer im Rücken schmerzt." [16.11.2017]
URL: http://www.spiegel.de/gesundheit/diagnose/iliosakralgelenk-wie-sie-dem-schmerz-im-ruecken-entgegen-wirken-a-1178248.html [access: 14.02.2019]

[12] c.f. (Befunddolmetscher 2016)
Befunddolmetscher - Die Erklärungshilfe für Ihren medizinischen Befund [Ed.](2016): "Dorsalextension/Plantarflexion. CT Fuß." [11.03.2016]
URL: https://befunddolmetscher.de/ct/fuss/10486/DorsalextensionPlantarflexion-x0yhttps:/ [access:14.02.2019]

[13] c.f. (Hohmann, D. / Uhlig, R. 2004) p.7 [own translation]
Hohmann, D. / Uhlig, R. [Eds.](2004): "Orthopädische Technik."

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[14] c.f. (Specht, J. / Schmitt, M. / Pfeil, J. 2008) p.3 [own translation]
Specht, J. / Schmitt, M. / Pfeil, J. [Eds.](2008): "Technische Orthopädie. Orthesen und Schuhzurichtungen."

[15] c.f. (Specht, J. / Schmitt, M. / Pfeil, J. 2008) p.2 [own translation]
Specht, J. / Schmitt, M. / Pfeil, J. [Eds.](2008): "Technische Orthopädie. Orthesen und Schuhzurichtungen."

[16] c.f. (Hohmann, D. / Uhlig, R. 2004) p.8 [own translation]
Hohmann, D. / Uhlig, R. [Eds.](2004): "Orthopädische Technik."

[17] c.f. (Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr 1989) (bh): p.1856;p.1947;(th): p.1865;p.1956;(ch):P:1866, p.1957;(ish):p.1864;p.1955;(ph):p.1871;p.1962;(tw):p.2072;p.2073;(mbd):p.1872;p.1963;(wd):p.1875,p.1966;(cc);(ac):p.1938;p.2029;(kc);(kcf):p.1937;p.2028;(bc):p.1935;p.2026;(ffb):p.1877;p.1968;(hb):p.1884;p.1975;(kkb):p.1885;p.1976;(wc)p.1935;p.2026 [own translation]
Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr [Ed.](1989):
"Handbuch der Ergonomie - mit ergonomischen Konstruktionsrichtlinien und Methoden."

[18] c.f. (Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr 1989) (la);(ma):p. 1870;p.1961;(fl);(ffl):p.1929;p.2020;(fb):p.1930;p.2021;(bfc):p.1939;p.2030;(hb02):p.1931;p.2022; [own translation]
Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr [Ed.](1989):
"Handbuch der Ergonomie - mit ergonomischen Konstruktionsrichtlinien und Methoden."

[19] c.f (Götz-Neumann, K.2011) p.9 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[20] c.f (Götz-Neumann, K.2011) pp.9-10 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[21] c.f (Götz-Neumann, K.2011) p.7 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[22] c.f (Götz-Neumann, K.2011) p.20-21 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[23] c.f (Götz-Neumann, K.2011) p.20 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[24] c.f (Götz-Neumann, K.2011) p.8 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[25] c.f (Götz-Neumann, K.2011) p.19 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[26] c.f (Götz-Neumann, K.2011) p.10 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[27] c.f (Götz-Neumann, K.2011) p.16 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[28] c.f (Götz-Neumann, K.2011) p.11 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

VII list of abbreviations

[29] c.f (Götz-Neumann, K.2011) pp.16-17 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[30] c.f (Götz-Neumann, K.2011) p.11 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[31] c.f (Götz-Neumann, K.2011) p.16 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[32] c.f (Götz-Neumann, K.2011) p.17 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[33] c.f (Götz-Neumann, K.2011) p.16 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[34] c.f (Götz-Neumann, K.2011) p.16 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[35] c.f (Götz-Neumann, K.2011) p.18 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[36] c.f (Götz-Neumann, K.2011) p.18 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[37] c.f (Götz-Neumann, K.2011) p.92 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[38] c.f (Götz-Neumann, K.2011) p.93 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[39] c.f (Götz-Neumann, K.2011) pp.10-11 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[40] c.f (Götz-Neumann, K.2011) p.94 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[41] c.f (Götz-Neumann, K.2011) p.12 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[42] c.f (Götz-Neumann, K.2011) p.17;p.44 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[43] c.f (Götz-Neumann, K.2011) p.12 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[44] c.f (Götz-Neumann, K.2011) p.12:p.45 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

VII list of abbreviations

[45] c.f (Götz-Neumann, K.2011) p.12;p.46 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[46] c.f (Götz-Neumann, K.2011) p.13;p.17;p.47 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[47] c.f (Götz-Neumann, K.2011) p.13;p.17;p.48 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[48] c.f (Götz-Neumann, K.2011) p.13;p.50; [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[49] c.f (Götz-Neumann, K.2011) p.13;p.51 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[50] c.f (Götz-Neumann, K.2011) p.13;p.17;p.52 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[51] c.f (Götz-Neumann, K.2011) pp.27-28 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[52] c.f (Götz-Neumann, K.2011) p.37 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[53] c.f (Götz-Neumann, K.2011) pp.25-26 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[54] c.f (Götz-Neumann, K.2011) p.37 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[55] c.f (Götz-Neumann, K.2011) pp.29-30 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[56] c.f (Götz-Neumann, K.2011) pp.30-31 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[57] c.f (Götz-Neumann, K.2011) pp.31-32 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[58] c.f (Götz-Neumann, K.2011) pp.32-33 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[59] c.f (Götz-Neumann, K.2011) p.34 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[60] c.f (Götz-Neumann, K.2011) p.35 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[61] c.f (Götz-Neumann, K.2011) p.34 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

VII list of abbreviations

[62] c.f (Götz-Neumann, K.2011 / Templates Builder 2018) p.77 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."
Templates Builder[Ed.]: "Posterior Muscle Of Lower Extremities." [02.04.2018]
URL: https://anatomyclass99.com/q/posterior-muscle-of-lower-extremities.asp [access: 14.02.2019]

[63] c.f (Götz-Neumann, K.2011 / Templates Builder 2018) p.61 [own translation]
Götz-Neumann, K. [Ed.](2011): „Gehen verstehen. Ganganalyse in der Physiotherapie.“ 3rd edition.
Templates Builder[Ed.]: „Posterior Muscle Of Lower Extremities.“ [02.04.2018]
URL: https://anatomyclass99.com/q/posterior-muscle-of-lower-extremities.asp [access: 14.02.2019]

[64] c.f (Götz-Neumann, K.2011 / Templates Builder 2018) p.61 [own translation]
Götz-Neumann, K. [Ed.](2011): „Gehen verstehen. Ganganalyse in der Physiotherapie.“ 3rd edition.
Templates Builder[Ed.]: „Posterior Muscle Of Lower Extremities.“ [02.04.2018]
URL: https://anatomyclass99.com/q/posterior-muscle-of-lower-extremities.asp [access: 14.02.2019]

[65] c.f (Götz-Neumann, K.2011 / Templates Builder 2018) p.61 [own translation]
Götz-Neumann, K. [Ed.](2011): „Gehen verstehen. Ganganalyse in der Physiotherapie.“ 3rd edition.
Templates Builder[Ed.]: „Posterior Muscle Of Lower Extremities.“ [02.04.2018]
URL: https://anatomyclass99.com/q/posterior-muscle-of-lower-extremities.asp [access: 14.02.2019]

[66] c.f (Moosecker, J. / Fries, A. / Institut für Sonderpädagogik / Universität Würzburg)
Moosecker, J. / Fries, A. / Institut für Sonderpädagogik / Universität Würzburg [Eds.]: "Infantile Zerebralparese (ICP)."
URL: https://www.intakt.info/informationen-und-recht/diagnose-behindert/infantile-zerebralparese/ [access: 01.03.2019]

[67] c.f. (ottobock)
ottobock [Ed.]: "Infantile Zerebralparese (ICP)."
URL: https://www.ottobock.at/neurorehabilitation/infantile-zerebralparese/ [access:14.02.2019]

[68] c.f. (ottobock)
ottobock [Ed.]: "Infantile Zerebralparese (ICP)."
URL: https://www.ottobock.at/neurorehabilitation/infantile-zerebralparese/ [access:14.02.2019]

[69] c.f. (ottobock)
ottobock [Ed.]: "Infantile Zerebralparese (ICP)."
URL: https://www.ottobock.at/neurorehabilitation/infantile-zerebralparese/ [access:14.02.2019]

[70] c.f. (DGM Deutsche Gesellschaft für Muskelkranke e.V.)
DGM Deutsche Gesellschaft für Muskelkranke e.V. [Ed.]:
"Neurale Muskelatrophie (HMSN/CMT). Die Hereditär motorisch-sensorischen Neuropathien (HMSN) oder Charcot-Marie-Tooth Erkrankungen (CMT) oder Neuralen Muskelatrophien."
URL: https://www.dgm.org/muskelerkrankungen/neurale-muskelatrophie-hmsncmt [access:14.02.2019]

[71] c.f. (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) 2016)
Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) [Ed.](2016):
"Leben und Alltag mit rheumatoider Arthritis."[27.07.2016]
URL: https://www.gesundheitsinformation.de/leben-und-alltag-mit-rheumatoider-arthritis.2222.de.html?part=lebenundalltag-eh [access:14.02.2019]

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[72] c.f (Leitner, A. / Fuchs, S. / Wild, J. 2019) [own translation][access: 14.02.2019]
Leitner, A. / Fuchs, S. (medical review)/ Wild, J. (editorial treatment)[Eds.](2019): "Multiple Sklerose (MS)." [January 2019]
URL: https://www.netdoktor.at/krankheit/ms-7417 [access: 14.02.2019]

[73] c.f. (DGM Deutsche Gesellschaft für Muskelkranke e.V.)
DGM Deutsche Gesellschaft für Muskelkranke e.V.:[Ed.]: "Amyotrophe Lateralsklerose (ALS)."
URL: https://www.dgm.org/muskelerkrankungen/amyotrophe-lateralsklerose-als [access:14.02.2019]

[74] c.f. (Redaktion Gesundheitsportal 2017)
Redaktion Gesundheitsportal [Ed.](2017): "Guillain-Barré-Syndrom." [31.10.2017]
URL: https://www.gesundheit.gv.at/krankheiten/immunsystem/autoimmunerkrankungen/guillain-barre-syndrom_ [access:14.02.2019]

[75] c.f. (Parkinson aktuell- UCB Pharma GmbH) [own translation][access: 14.02.2019]
Parkinson aktuell- UCB Pharma GmbH [Ed.]: "Bewegungsstörungen bei Morbus Parkinson."
URL: https://www.parkinson-aktuell.de/was-ist-parkinson/symptome-fuer-parkinson/bewegungsstoerungen-bei-parkinson [access:14.02.2019]

[76] c.f. (Parkinson aktuell- UCB Pharma GmbH) [own translation][access: 14.02.2019]
Parkinson aktuell- UCB Pharma GmbH [Ed.]: "Bewegungsstörungen bei Morbus Parkinson."
URL: https://www.parkinson-aktuell.de/was-ist-parkinson/symptome-fuer-parkinson/bewegungsstoerungen-bei-parkinson [access:14.02.2019]

[77] c.f. (Heilpaed) [own translation][access: 14.02.2019]
Heilpaed [Ed.]: "Hemiplegie."
URL: https://www.heilpaed.ch/heilpaedphysio/hemiplegie.htm [access:14.02.2019]

[78] c.f. diagnosis / (see annex XII - diagnosis) [own translation]

[79] textual constitution of a conversation with the specific user, a volunteered person for the project. [Innsbruck, 20.10.18]

[80] c.f (Götz-Neumann, K. 2011) p.20 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[81] c.f (Götz-Neumann, K. 2011) p.20 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[82] c.f (Götz-Neumann, K. 2011) p.21 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[83] c.f (Götz-Neumann, K. 2011) p.21 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[84] c.f (Götz-Neumann, K. 2011) p.21 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[85] c.f (Götz-Neumann, K. 2011) p.21 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

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[86] c.f (Götz-Neumann, K. 2011) p.21 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[87] (Usman M. / Seong H. / Suthar B. / Hawkes E. / Gaponov I. / Ryu, J-H. 2017)
Usman M. / Seong H. / Suthar B. / Hawkes E. / Gaponov I. / Ryu, J-H. [Eds.] (2017):
"Passive Returning Mechanism for Twisted String Actuators."
URL: https://www.youtube.com/watch?v=J26y1nn7JMM [access:19.02.2019]

[88] Abfalterer, Mattias / Achenrainer, Sandrino / Figl, Alexander / advisor: FH-Prof. Kim, Yeongmi, PhD (2018): "Ankle-Stabilisation."
presentation material-final presentation. Medical Device Project MCI Management Center Innsbruck- department of mechatronics

[89] Abfalterer, Mattias / Achenrainer, Sandrino / Figl, Alexander / Frei, Max / Heinrich, Nils / Neubauer, Vanessa /Payr, Johannes /
Rieger, Marcel / Robertshaw, Clare Gwenyth / Seiler, Felix / Wimmer, Doris/ advisor: FH-Prof. Kim, Yeongmi, PhD (2018): "Medical Device Project.")
MCI Management Center Innsbruck- department of mechatronics)

[90] (Kremer, S. R. (1989). U.S.Patent No. 4,843,921.)
Kremer, S. R. (1989). U.S.Patent No. 4,843,921. "twisted cord actuator."
URL: https://patentimages.storage.googleapis.com/30/15/d5/b84f4f8dba7f0f/US4843921.pdf [access:19.02.2019]

[91] (Usman M. / Seong H. / Suthar B. / Hawkes E. / Gaponov I. / Ryu, J-H. 2017)
Usman M. / Seong H. / Suthar B. / Hawkes E. / Gaponov I. / Ryu, J-H. [Eds.] (2017):
"Passive Returning Mechanism for Twisted String Actuators."
URL: https://www.youtube.com/watch?v=J26y1nn7JMM [access:19.02.2019]

[92] c.f. (Hochgatterer, Rainer 2018)
commentary: The recording of the interview as an audio file is located on the enclosed CD. (see annex XIII- expert talk)

[93] (Hochgatterer, Rainer 2018)
commentary: The recording of the interview as an audio file is located on the enclosed CD. (see annex XIII- expert talk)

[94] c.f. (Hochgatterer, Rainer 2018)
commentary: The recording of the interview as an audio file is located on the enclosed CD. (see annex XIII- expert talk)

[95] c.f. (Hochgatterer, Rainer 2018)
commentary: The recording of the interview as an audio file is located on the enclosed CD. (see annex XIII- expert talk)

[96] c.f. (Hochgatterer, Rainer 2018)
commentary: The recording of the interview as an audio file is located on the enclosed CD. (see annex XIII- expert talk)

[97] c.f. (Hochgatterer, Rainer 2018)
commentary: The recording of the interview as an audio file is located on the enclosed CD. (see annex XIII- expert talk)

[98] (Hochgatterer, Rainer 2018)
commentary: The recording of the interview as an audio file is located on the enclosed CD. (see annex XIII- expert talk)

[99] (Hochgatterer, Rainer 2018)
commentary: The recording of the interview as an audio file is located on the enclosed CD. (see annex XIII- expert talk)

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[100] c.f. (Hochgatterer, Rainer 2018)
commentary: The recording of the interview as an audio file is located on the enclosed CD. (see annex XIII - expert talk)

[101] c.f (Götz-Neumann, K. 2011) p.34 [own translation]
Götz-Neumann, K. [Ed.](2011): "Gehen verstehen. Ganganalyse in der Physiotherapie."

[102] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.103 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[103] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.104 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[104] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.251 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[105] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) pp.250-251 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[106] c.f. (Wiszomirska I./Blazkiewicz M./Kaczmarczyk K./Brzuszkiewicz-Kuzmicka G./Wit A. 2017)
Wiszomirska I./Blazkiewicz M./Kaczmarczyk K./Brzuszkiewicz-Kuzmicka G./Wit A. [Eds.] (2017):
"Effect of Drop Foot on Spatiotemporal, Kinematic, and Kinetic Parameters during Gait." [11.04.2017]
URL: https://www.hindawi.com/journals/abb/2017/3595461/ [access:26.02.2019]

[107] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.231 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[108] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.233 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[109] c.f. (Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr 1989) p.2072 [own translation]
Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr [Ed.](1989):
"Handbuch der Ergonomie - mit ergonomischen Konstruktionsrichtlinien und Methoden."

[110] c.f. (Richard, H.A. / Kullmer, G. 2013) p.7 [own translation]
Richard, H.A. / Kullmer, G. [Eds.] (2013): "Biomechanik - Grundlagen und Anwendungen auf den menschlichen Bewegungsapparat."

[111] c.f. (Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr 1989) p.2072 [own translation]
Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr [Ed.](1989):
"Handbuch der Ergonomie - mit ergonomischen Konstruktionsrichtlinien und Methoden."

[112] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.229 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[113] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) pp.233-234 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[114] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.234 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

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[115] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) pp.235-236 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[116] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.236 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[117] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.236 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[118] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.459 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[119] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) pp.16-17 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[120] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.16 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[121] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.20 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[122] c.f. (Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. 2012) p.16;p.18 [own translation]
Brinckmann, P. / Frobin, W. / Leivseth, G. / Drerup, B. [Eds.] (2012): "Orthopädische Biomechanik."

[123] (Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. 2011) p.1
Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. [Eds.](2011):
"Bio-inspired Active Soft Orthotic Device for Ankle Foot Pathologies."
URL: https://ieeexplore.ieee.org/abstract/document/6094933 [access:14.03.2019]

[124] (Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. 2011) p.1
Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. [Eds.](2011):
"Bio-inspired Active Soft Orthotic Device for Ankle Foot Pathologies."
URL: https://ieeexplore.ieee.org/abstract/document/6094933 [access:14.03.2019]

[125] c.f.(Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. 2011) p.1-2;p.3;p.5;
Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. [Eds.](2011):
"Bio-inspired Active Soft Orthotic Device for Ankle Foot Pathologies."
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[126] c.f.(Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. 2011) p.1
Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. [Eds.](2011):
"Bio-inspired Active Soft Orthotic Device for Ankle Foot Pathologies."

[127] (Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. 2011) p.7
Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. [Eds.](2011):
„Bio-inspired Active Soft Orthotic Device for Ankle Foot Pathologies.“
URL: https://ieeexplore.ieee.org/abstract/document/6094933 [access:14.03.2019]

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[128] (Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. 2011) p.3
Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. [Eds.](2011):
"Bio-inspired Active Soft Orthotic Device for Ankle Foot Pathologies."
URL: https://ieeexplore.ieee.org/abstract/document/6094933 [access:14.03.2019]

[129] (Urukalo, D. / Jovanovic, M. D. / Rodic, A. 2017) p.2
Urukalo, D. / Jovanovic, M. D. / Rodic, A. [Eds.] (2017): "Modeling, Development and Control of Linear Twisted-String Actuator."
URL: https://uni-obuda.hu/journal/Urukalo_Jovanovic_Rodic_75.pdf [access:02.03.2019]

[130] (Urukalo, D. / Jovanovic, M. D. / Rodic, A. 2017) p.2
Urukalo, D. / Jovanovic, M. D. / Rodic, A. [Eds.] (2017): "Modeling, Development and Control of Linear Twisted-String Actuator."
URL: https://uni-obuda.hu/journal/Urukalo_Jovanovic_Rodic_75.pdf [access:02.03.2019]

[131] (Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. 2017) p.1
Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. [Eds.] (2017): "A Study on Life Cycle of Twisted String Actuators: Preliminary Results." [11.09.2017]
URL:https://www.researchgate.net/publication/320076454_A_Study_on_Life_Cycle_of_Twisted_String_Actuators_Preliminary_Results
[access:02.03.2019]

[132] (Urukalo, D. / Jovanovic, M. D. / Rodic, A. 2017) p.3
Urukalo, D. / Jovanovic, M. D. / Rodic, A. [Eds.] (2017): "Modeling, Development and Control of Linear Twisted-String Actuator."
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[133] (Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. 2017) p.1
Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. [Eds.] (2017): "A Study on Life Cycle of Twisted String Actuators: Preliminary Results." [11.09.2017]
URL: https://www.researchgate.net/publication/320076454_A_Study_on_Life_Cycle_of_Twisted_String_Actuators_Preliminary_Results
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[134] c.f (Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. 2017)
Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. [Eds.] (2017): "A Study on Life Cycle of Twisted String Actuators: Preliminary Results." [11.09.2017]
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[135] (Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. 2017) p.7
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[136] c.f (Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. 2017) p.7
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URL: https://www.researchgate.net/publication/320076454_A_Study_on_Life_Cycle_of_Twisted_String_Actuators_Preliminary_Results
[access:02.03.2019]

[137] c.f. (Jeong, S.H / Shin, Y.J / Kim, K-S. 2017), article
Jeong, S.H / Shin, Y.J / Kim, K-S. [Eds.] (2017): "Design and Analysis of the Active Dual-Mode Twisting Actuation Mechanism."
URL: https://www.researchgate.net/publication/320723443_Design_and_Analysis_of_the_Active_Dual-Mode_Twisting_Actuation_Mechanism
[access:02.03.2019]

[138] c.f. (Jeong, S.H / Shin, Y.J / Kim, K-S. 2017), video on youtube
Jeong, S.H / Shin, Y.J / Kim, K-S. [Eds.] (2017): "Design and Analysis of the Active Dual-Mode Twisting Actuation Mechanism." [14.11.2017]
URL: https://www.youtube.com/watch?v=QBQMZsSQJQM [access:02.03.2019]

[139] c.f. (Jeong, S.H / Shin, Y.J / Kim, K-S. 2017), article p.1;
Jeong, S.H / Shin, Y.J / Kim, K-S. [Eds.] (2017): "Design and Analysis of the Active Dual-Mode Twisting Actuation Mechanism."
URL: https://www.researchgate.net/publication/320723443_Design_and_Analysis_of_the_Active_Dual-Mode_Twisting_Actuation_Mechanism
[access:02.03.2019]

[140] (Jeong, S.H / Shin, Y.J / Kim, K-S. 2017), article p.1;
Jeong, S.H / Shin, Y.J / Kim, K-S. [Eds.] (2017): "Design and Analysis of the Active Dual-Mode Twisting Actuation Mechanism."
URL: https://www.researchgate.net/publication/320723443_Design_and_Analysis_of_the_Active_Dual-Mode_Twisting_Actuation_Mechanism
[access:02.03.2019]

[141] (Orensten, E. 2014)
Orensten, E. [Ed.](2014): "The Language of Tape Design - A look at the age-old technique of using full scale clay models and tape in the automotive design process." [03.02.2014]
URL:https://coolhunting.com/design/the-language-of-tape-design/ [access:22.02.2019]

[142] (Orensten, E. 2014)
Orensten, E. [Ed.](2014): "The Language of Tape Design - A look at the age-old technique of using full scale clay models and tape in the automotive design process." [03.02.2014]
URL:https://coolhunting.com/design/the-language-of-tape-design/ [access:22.02.2019]

[143] c.f. (Dariush, B. 2006 U.S.Patent No.7,650,204 B2) commentary: Values from diagram. p.9
Dariush, B. (2006) U.S.Patent No.7,650,204 B2. "Active control of an ankle-foot orthosis."
URL: https://patentimages.storage.googleapis.com/9c/eb/d1/87842f325dd859/US7650204.pdf [access:19.02.2019]

[144] c.f (Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. 2017)
Usman, M. / Seong, H. / Suthar, B. / Gaponov, I. / Ryu, J-H. [Eds.] (2017): "A Study on Life Cycle of Twisted String Actuators: Preliminary Results." [11.09.2017]
URL: https://www.researchgate.net/publication/320076454_A_Study_on_Life_Cycle_of_Twisted_String_Actuators_Preliminary_Results
[access:02.03.2019]

[145] c.f. (Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. 2011)
Park, Y-L. / Chen, B-R. / Young, D. / Stirling, L. / Wood, R.J. / Goldfield, E. / Nagpal R. [Eds.](2011):
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URL: https://ieeexplore.ieee.org/abstract/document/6094933 [access:14.03.2019]

[146] (Wiszomirska I./Blazkiewicz M./Kaczmarczyk K./Brzuszkiewicz-Kuzmicka G./Wit A. 2017) abstract
Wiszomirska I./Blazkiewicz M./Kaczmarczyk K./Brzuszkiewicz-Kuzmicka G./Wit A. [Eds.] (2017):
"Effect of Drop Foot on Spatiotemporal, Kinematic, and Kinetic Parameters during Gait." [11.04.2017]
URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5405572/ [access:26.02.2019]

[147] (Wiszomirska I./Blazkiewicz M./Kaczmarczyk K./Brzuszkiewicz-Kuzmicka G./Wit A. 2017) ,table 3
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[151] c.f (zettlex 2018)
[152] c.f (utronix limited)
[153] c.f (Nordic - semiconductor)
[154] c.f (Arduino)
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[156] c.f (utronix limited)
[157] c.f (Nordic - semiconductor)
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commentary: Only project-relevant information was taken from the diagnosis.

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[236] c.f. (material sources) [access:17.03.2019]
material sources URL listed on page 146-148
(see annex VI - list of material selection on page 105-108)

[237] c.f. (material sources) [access:17.03.2019]
material sources URL listed on page 146-148
(see annex VI - list of material selection on page 105-108)

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XI statement of agreement

XI.1 specific user

date: 14th december 2018
participants: Thomas Gärtner, Viktoria Frank

I hereby declare, Thomas Gärtner (born on 27th may in 1988) that the on the 26th october 2018 generated images and video materials (gait analysis) and the 3D-scan of my legs have the permission to be used, reprinted and published as a part of the diploma thesis of Viktoria Frank with the title:

"Design of an intelligent orthosis in support of the locomotor system."

Linz, 14th december 2018

signature:

(Thomas Gärtner)

XI statement of agreement

XI.2 expert

Interview- "Design of an intelligent orthosis in support of the locomotor system"
(cerebral palsy patients)

date: 14th december 2018
interview participants: OA Mag. Dr. Rainer Hochgatterer, Viktoria Frank

I hereby declare, Rainer Hochgatterer (born on 29th july in 1977), that I did the interview listed below on 14th december 2018 and Viktoria Frank has the permission to use and to reprint the interview in english as part of her diploma thesis with the title:

"Design of an intelligent orthosis in support of the locomotor system."

Linz, 14th december 2018

signature:

(Rainer Hochgatterer)

XII diagnosis

XII diagnosis

We hereby prescribe for the named patient:
1 pair of dynamic lower leg orthoses in prepreg technique after plaster cast, tibial condylar support on both sides, full-contact foot-mount in extensive anatomical correction of the upper ankle joint, lower ankle joint, longitudinal curvature and hindfoot (neutral position),

facultative: 1 pair of orthotic shoes, shoe adaptation with roll-off sole on both sides.

diagnosis:

- bilateral cerebral palsy (G80.1G) in terms of spastic diplegia (GMFCS Level II)
- condition after intertrochanteric derotation/varisation osteotomy right 1999 with hip dysplasia
- hip subluxation right with distinct secondary cup dysplasia and coxa antetorta
- condition after toe correction and adductor tenotomy 1997 leg length difference
- condition after intramuscular extension of the m.adductor longus and gracilis right (08/2007) (M62.40Z)
- condition after premature birth

explantation:

Correction, stabilisation, mobilisation, extension of the radius of action, improvement and maintenance of the independent standing and walking ability, dynamic contracture prophylaxis, tonus influence, refer to diagnostic.

By named children a spastic diplegia relating to because of brain damage after premature birth with typical gait pattern and typical misalignments in the area of the lower limbs. Furthermore, there is a significant coordination disorder and fine motor skills of hands. As a result the ability to write considerably slow and the typeface insecure.

[231]

XIII expert talk

project description:

The "intelligent orthosis" project started about 2 months ago in cooperation with the MCI Management Center Innsbruck - department of mechatronics and shows a new solution to the approach of how an intelligent orthosis can make everyday life easier for cerebral palsy patients in the future.

The main problem of the target group is the muscle weakness/ drop foot weakness, which leads to a deviating gait pattern and a decreased walking speed.Through intense contact with a cerebral palsy patient, who volunteered for the project, a further problem was identified because of the resulting limited muscle activity. Due to the minimal lifting of the foot in the “swing phase”, the foot is angled inside for many patients which causes an unstable ground contact.

Together with a group of students from MCI‘s bachelor class, the following technical functional principles were selected, which focused on these two problems.

In summary these are drop foot and the foot’s angulation before ground contact. Drop foot can be compensated by the support of a motor in the hip area and by a motor that lifts the thigh. For the alignment of the foot angle, a rotary motor principle was used, which uses ropes to rotate the foot to the outside.

This mechanism must activate in the few seconds during the swing phase (foot has no ground contact) in order not to restrict patients while walking. The hip position is only detected but not actively supported by a further motor.

The project is currently limited to the reference leg only. (patient‘s right leg)

In the course of observational gait analysis (RLANRC-system - 8 gait phases) and intensive muscle research, a third problem could be analyzed, namely the balance problem, especially in the monopod stance phase (late LR loading response MSt mid stance, TSt terminal stance).

concept description: The product should be operable by an app and allow the patient to make custom settings for active motor support. This additional visual support enables the patient to see his current condition and the lift angle of the thigh and also the angle of inclination of the foot. By various sensors (gyroscope, acceleration sensor, pressure sensor,...) the intelligent orthosis detects the appropriate angulation of the knee by the position of the pressure sensors on the knee or by an encoder on the hip position.

The orthosis should provide a good balance of active motor support and training support. I.e. if the patient is exhausted, he can adjust motor activity to his current needs and otherwise can minimize the support, should he have enough energy at this moment and not need any support from the motor.

For these reasons of "passive support", vibration motors on the hip, knee and upper side of the foot were considered in order to send signals to the patient e.g. "lift knee even higher", "tilt foot even further outwards", "correct hip position". This passive, non-motor support gives the patient the possibility to control the adjustment by himself. (training function)

An integrated "air cushion component" in the posterior to lateralfibula (m.soleus (both sides), m.gastrocnemius caput lateral and m.gastrocnemius caput mediale) should support equilibrium in the one-leg stance phases and when standing, as well as ensure safe standing stability. The air support is intended to make the patient feel safer and also to consume less energy for balance.

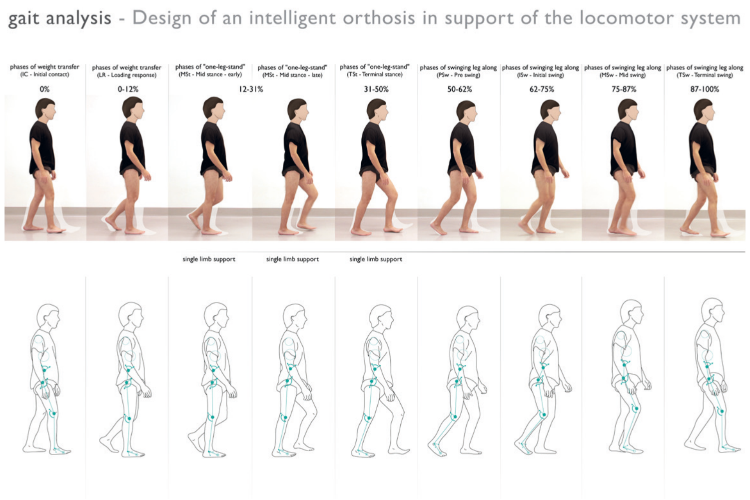
description of the design implementation:

in the attachment are located:

- an overview of the research analysis & solution strategy
- video of the gait deviation
- diagnosis of the patient
- overview of muscles
- preview of the concept - first concept drawings

XIII expert talk

overview of the solution strategy

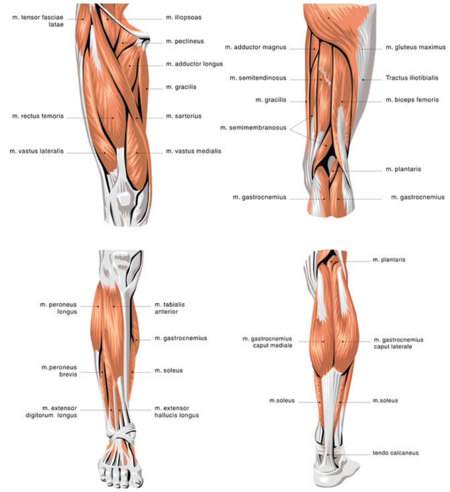


[figure 199]

video of the gait deviation

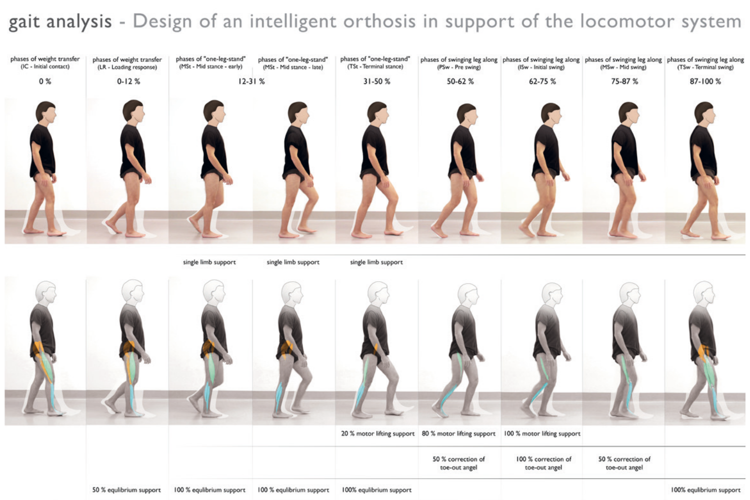
[figure 197]

overview of muscles



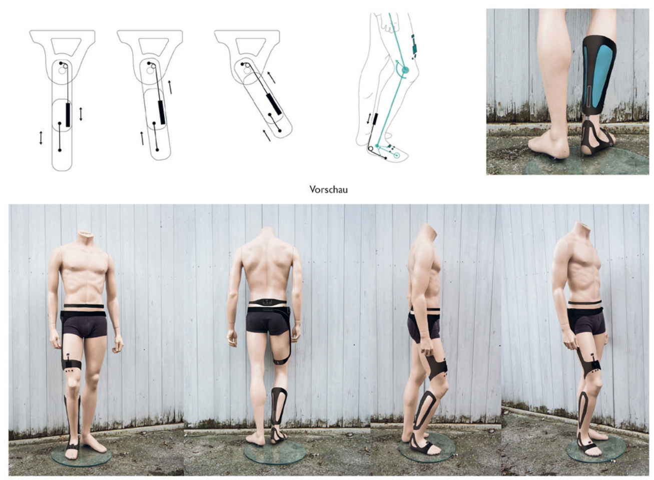
[figure 196]

overview of the research analysis



[figure 39]

first concept drawings



[figure 198]

diagnosis of the patient

[231]

[see annex XII diagnosis on page 151]

XIII expert talk

Interview - Design of an intelligent orthosis in support of the locomotor system (cerebral palsy patients)

interview questions:

1) You have just received a short overview of the project, how do you rate the three problem analyses (drop foot, medialalignment of the foot and balance problem)? Are these problems common in cerebral palsy patients?

2) Do you like the idea that the patient can choose individual settings and has the possibility to control gait deviations himself?

3) How do you feel about the additional sensory support of air cushions in the calf area? Can you imagine that the air gives patients a better feeling of safety, especially when standing on one leg? (no supporting forces and ideally without additional pump)

4) If yes, would you consider another position (e.g. shinbone, only on the back) more optimal for support? (at the moment the positions of the m.soleus (both sides), m.gastrocnemius caput lateral and m.gastrocnemius caput medial were considered)

5) In your opinion, where is the optimal position from which to lift the thigh? Is the intended position of the hip joint on the trochaneus and above the hip joint pivot point in your opinion already optimally selected?

6) Would you place the splint on the patient's ankle inside the shoe (shoe-in shoe) or as an add-on element? Where do you see possible problems here?

Interview performed on 14th december 2018 with OA Mag. Dr. Rainer Hochgatterer – Specialist in orthopaedics and orthopaedic surgery; head of knee and sports outpatient department; Clinic for Orthopaedics at the Kepler Universitätsklinikum GmbH Med Campus III.

A Viktoria:
B OA Mag. Dr. Rainer Hochgatterer:
(...)

1) "You have just received a short overview of the project, how do you rate the three problem analyses (drop foot, medial-alignment of the foot and balance problem)? Are these problems common in cerebral palsy patients?"

A: *(presenting the patient's diagnosis) "The presented diagnosis is difficult to read for laymen. About the toe foot there is a lot to be found in books. You believe that the foot lift weakness is connected with the ankle joint (archiliss tendon) and less with the m. quadriceps in the thigh?."*

B: *"Drop foot doesn't automatically mean the patient cannot lift his leg. Drop foot means that the dorsal extension is limited in the lower part of the foot and the patient cannot lift the leg when walking (movement shown - foot cannot be pulled up). Furthermore, it cannot roll over the heel, because the patient first steps using the forefoot. Here we are talking about a so-called "stepper walk"."*

"According to the diagnosis, a correction of the toe foot was carried out and through this correction, the rear structure of the foot is loosened and the front structure is reinforced or not. - This varies from case to case."

A: *"Thank you very much for the explanation. Here I would like to show you the gait analysis picture next." (presenting the gait analysis image)*

B: *"In this case, the toe was slightly overcorrected, because the picture shows a flat foot, the toe walker would not be able to walk on the ground with the heel. The patient gets his heel on the ground here. The archiliss tendon seems to be long enough here, it may be that the patient cannot control the anterior shin muscles due to his spasticity and therefore cannot lift the foot. This is the area where the patient needs help and where the Peronaeus (corrected) splint is used in practice."*

A: *"Okay. The root problem here is rather in the lower ankle area."*

B: *"Yes. The problem is situated in the lower ankle area. Assuming the patient is not a spastic, who else has forefoot lift paresis? These are patients who have had an intervertebral disc incerted in the lower segments, this presses on the nerve and these are the three muscles in front that enable this function. If these are weak and the posterior muscles are too short, the problem is that the patient cannot lift the foot forward."*

A: *"ok thank you very much. In the interview questions, drop foot was considered to be the lifting of the entire leg." (...)*

B: *"No, drop foot is only the limitation of the dorsal extension. (presenting movement - foot area (toe area) in front is tightened upwards) To counteract drop foot and what the patient could need is, as soon as the patient leaves the ground behind, he would need support which makes the following movement. (Dorsal extension movement demonstrated) The support is intended to allow the foot to be lifted forward and to support flexion so that the patient can perform properly - for normal gait."*

A: *"Thank you very much for explaining what is important in drop foot." (...)*

A: *(presenting the 8 gait analysis template as a picture) "I performed an 8 gait analysis and compared it to a person with a normal gait pattern and then observed exactly which muscle is active. With the help of the "Gehen verstehen" book and with the help of a 3D program I have listed these in detail. Based on this research I have analyzed the deviations more precisely, here as an example you can see that about 10° diffraction of the hip for the optimal lifting of the thigh is missing."*

B: *"aha, yes the flexion in the hip to stretch the knee."*

A: *"Exactly (...) and here shock absorption would possibly be helpful and in the pre-swing phase, the foot, which is turned strongly inwards, should be straightened again. In the next drawing, you can see the biomechanics* *of these gait phases. On the basis of this result, which was only based on observation, I have tried out the optimal positions with cable pulls for thigh lifting, where an actuator could pull on the rope in the future.*

This mechanism shortens the device in the upper muscle with an additional elastic band to achieve a further shortening. For the external rotation of the foot, the actuator is positioned laterally and the „tightening at the right moment“ has already been tested. In the next picture, you see first how the basic structure could be thought of, very reduced and solved with a simple rope pull. In this project, we deal with the topic of "tightening/lifting" and the active correction of the outer rotation of the foot (below).

(...) The third side effect is a kind of air cushion (in blue) that has no supporting function/force. These are only supposed to provide a sensory function and a better feeling of safety for the patient."

B: *"Aha. Okay. How exactly did you come up with this solution? Why should these air cushions provide an extra sense of security?"*

A: *"I tested the air cushions on my leg with a mini bellow and noticed that light air pressure adds clear stability. Also by the exchange with Thomas, I found out that he voluntarily likes to wear steel cap shoes from Engelbert-Strauss. It was interesting for me to learn that he feels more secure. This was the inspiration for the air cushions. In addition, I could observe during the gait analysis that the hands often rocked back and forth. I thought that the air would always fill up in the one-leg position."*

B: *"You mean the patient steps on the air below and it pushes it up?"*

A: *"right, exactly."*

B: *"It‘s already on sale. There is an orthosis from the company Air-cast (corrected) called "air heel" for the ankle joint or for the archiliss tendon, where there is an air cushion in the lower area and the air is transferred to the archiliss tendon area. This marbles the archilis tendon - if you would like to see this product."*

A: *"Yes. Thank you very much for the advice. I am very grateful for any input. Aircast also has a knee orthosis that has mini bellows integrated to operate the bellows after the product has been attached. The air in the bellows provides better support for the orthosis. This was another inspiration for the intelligent orthosis. For question 1), these three areas were derived from analysis (observation)."*

B: *"...and whether these are frequently observed?"*

A: *"Precisely."*

B: *"Of course, these problems can often be identified. To a certain extent, these problems are very similar, but each patient is very different depending on where the patient was operated on and how spasticity is manifested. These are people who are able to walk. What I‘m not quite sure of yet: drop foot is only in the lower area and has nothing to do with the upper hip area. So the question is whether the patient would benefit more if he had “support“ in the lower area? (...) I like the construction here in the picture very much because it looks very portable. What I‘m not sure of yet is how to transfer the force to the thigh and whether it could work? If I wanted to lift the thigh with this construction, there would be a lot of leverage. The patient can lift this by himself, what he cannot do is to lift the foot in the lower area. Originally, this was thought of for drop foot, right?"*

A: *"Yeah, exactly, right."*

B: *"This mechanism will support the patient to a certain extent, but it‘s true: “The more I lift here, the less has to be lifted down."*

A: *"Yes, that‘s how the concept was originally conceived."*

B: *"For the lower area the next question is if I think of a mechanism with an actuator that pulls the foot upwards or doesn‘t let it tip down in front, if the material remains stiff enough at this point, one could also solve the problem."*

A: *"Yes. In any case, there is also the possibility not only to turn the foot (below) but also to pull it straight up. We have currently thought of the concept in such a way that this actuator in the hip area can compensate for the slight elevation of the foot (entire leg). With the planned rope pull that pulls at the „last moment“ (when the foot has already been lifted slightly). Of course, the patient can lift the foot independently, but not quite as high as it should be due to the low muscle strength."*

B: *"If I may imagine this mechanism like this, with a glass bottle (glass bottle in hand) The weight of this bottle is max. 1kg and I lift the weight with this movement upwards... Compared to the thigh the weight is about 10kg and you would use exactly the same lever. Try to lift it with one hand." (glass bottle was passed on)*

B: *"For this lifting, you need much strength. Correct?"*

A: *"Yes. We are in the process of assessing the forces and thinking of an actuator that is strong enough."*

B: *"The question is whether you develop a product where you "only" support an active movement a little or where you think of "dressing" as you say, makes a difference to just lifting your leg."*

A: *"Exactly."*

B: *"With the lower actuator, you‘ll need less force, I think a spastic can lift the foot here (above) on his own. Regarding the problem of the strong internal alignment of the foot, if the mechanism with the rope pull works in this way, it is certainly good that the foot is turned outwards. (...)*

The next question regarding the equilibrium problem is how to influence it. If the patient is able to walk, this problem is more likely to be compensated."

A: 2) "Do you like the idea that the patient can choose individual settings and has the possibility to control gait deviations himself?"

B: *"I think it will not work without individual settings because every patient is individual."*

A: *"Exactly. That was the idea that you don't fix the foot, which is turned strongly inwards, but that the patient can adjust how far the foot is turned inwards. A stronger rope pull compensates this misalignment."*

B: *"Exactly, I really like the idea of this and individual settings need to be made. I don't know if these topics will still be dealt with in the next questions, the following points are always important for this product: logically the wearability, how much the orthosis can withstand, the energy supply, if the orthosis is worn all day long (...) if I imagine how long my GoPro battery lasts (...) what is not to be neglected is the skin compatibility, the orthosis must hold well on the skin, but must not rub and should remain breathable. The question is if the patient wears the orthosis the whole morning (...) I think these are points that often present problems during the implementation."*

A: *"That's right. The choice of material has not yet been taken into account in this design example but will be examined in more detail below. The project is still at the beginning or in the middle of the process."*

B: *"I like the solution with the rope pull very much, there are exoskeletons where one uses hydraulic muscles or which work with rope pull mechanisms. The fact is: „The smaller the better", otherwise, the orthosis will never be put on because you cannot wear it for long."*

A: *"We are currently working on reducing the complexity of the subject to a minimum and applying the mechanics with a simple rope pull at the right moment. If it is still possible, the orthosis could also be worn under the trousers. In my opinion, this would be very attractive for the patient."*

B: *"Yes."*

A: *"...and to think about how a toilet visit would work with this product, so that it could be easily removed in such cases."*

B: *"Yes, sure."*

A: 3) "How do you feel about the additional sensory support of air cushions in the calf area? Can you imagine that the air gives patients a better feeling of safety, especially when standing on one leg? (no supporting forces and ideally without additional pump)"

B: *"The third question with the air cushions certainly makes sense, as we know, it has a similar effect as tape or as orthoses have, which in principle give the patient a safe feeling but do not really stabilize. For example, a knee sock does not objectively make the knee more stable, it only feels more stable. In my opinion, this can work. In addition, the air cushions would have to be tried out in more detail with a spastic, because a spastic has no physiological movement sequence, but is a pathological movement stereotype."*

A: *"What does that mean exactly?"*

B: *"This means that the spastic's muscle (...) if you say to a patient: „Stretch your leg out" they cannot stretch it out completely and next time the movement will look completely different. A spastic cannot control in which direction the muscle moves. He will stretch out the leg, but the movement is not always the same, because the problem is, so to speak, in the development and design of the movement."*

A: *"I also noticed in the timer recording of the steps per minute that the steps were not always the same speed."*

A: 4) "If yes, would you consider another position (e.g. shinbone, only on the back) more optimal for support? (at the moment the positions of the m.soleus (bds.), m.gastrocnemius caput lateral and m.gastrocnemius caput medial were considered)"

A: *"I have the m.soleus area (blue area) in the fibula area in mind, possibly the position becomes even narrower. The first time I tried it on my leg, I found the position to be the most comfortable."*

B: *"Will probably be a good position, otherwise, I would not know any position because the shin front would not fit. A position at the back would be better. The most comfortable position for the patient might be between the ankle and the area where the m.gastrocnemius starts. Directly on the muscle belly, these would probably be too much."*

A: *"Ah ok, that would be this area" (the presented picture was marked with the pencil)*

B: *"The question is whether this function should be combined with a compensating stocking, because it provides good grip and you would also have more resistance so that the air cushion can empty again, as an elastic principle."*

A: *"The air cushions have an additional valve which opens during movement when the patient wants to move and the pressure increases, as a result, the valve opens and lets the air out again. The big advantage is that when the patient is moving, the air cushions are flat."*

B: *"and how does the air get into the air cushion?"*

A: *"The air is pumped up over the sole of the foot, after each step it is passed upwards through a silicone tube into the cushion."*

B: *"If the patient is barefoot, is the air always supplied fresh into the shoe?"*

A: *"The idea was that the material is textile and is located directly at the foot (in the lower area). There is air in the sole of the foot, which is guided upwards along the foot through two silicone tubes. The air pocket, which contains a smaller pocket because the air does not expand evenly, fills the rest of the air pocket."*

B: *"Does the same air always circulate here or does new air always come into the air cushion?"*

A: *"The air cushion will always contain some residual air and above a certain overpressure, the valve will release the air. In a conversation with Thomas, it became clear that standing for a long time causes problems and theoretically it would be possible to pump in the air if necessary. The air cushions remain very reduced. In principle, can you imagine the implementation of possibly placing the position even further downwards?"*

B: *"From my intuition, I would say that the position would be most comfortable with the archiliss tendon, because this is where most pro-receptors are. Here we are at a level where most muscles meet. Of course, it also depends on the muscle belly of the patient; there are patients where the muscle belly is lower. In principle, it has to be thin and wearable."*

A: *"The air cushion will not inflate more than 1cm - even less to feel just sensory support."*

A: 5) "In your opinion, where is the optimal position from which to lift the thigh? Is the intended position of the hip joint on the trochaneus and above the hip joint pivot point in your opinion already optimally selected?"

A: *"The biggest question is where the optimal position to lift the thigh is? If you look at the currently conceived holding apparatus and the actuator is positioned here (...) (as illustrated in the picture presented) We have asked ourselves the question, do we have to position this lifting point, rather in the middle, or would they place this lifting point more in the direction of the knee, as shown in the picture? Of course, there is an additional foam between the skin."*

B: *"I will say that the upper part, which looks like a belt and when the joint is here, it's a relatively long load arm, a short lever arm. If the fulcrum is here at the hip (...) and the rope contracts here, nothing will change in the stretched position (...) because you would need an enormous force here. That's what I'm saying now. However, if the position is already in slight flexion and the position is already slightly pre-stressed here, it could be that it can be somewhat supportive.*

(...) one would have to try this with a spastic, who holds muscularly in a way against whether something happens here at all. The danger here is whether the holding device will simply "only" twist here. This looks very good on this picture and that's exactly what we would like, but we know for example in patients who have a total hip endoprosthesis that is luxated (the joint jumps out) and who then receive an orthosis for 6 weeks that it is quite large and uncomfortable to wear. In reality, it is very uncomfortable to wear and never fits under your trousers.

(...) You don't get the strength to lift your thigh. From my point of view, it is completely unrealistic, it stands or falls with the wearing comfort if the orthosis is uncomfortable to wear, it does not attract a patient." (...)

B: *"The question is, when it comes to supporting just a little - at the right moment, if you're not thinking of a stretch jean the further you go in that direction (upwards), supported and prestressed when stretching out, with a thick elastic fabric in the pants. (...) Inside there could be a rope pull that pulls between thigh and belt or a band that pulls together, but not a lever outside (...). I think a rubber band placed at the top of the thigh helps the patient rather than a mechanism from the outside because of the muscles tension." (...)*

A: *"In principle, we imagined this to be similar, but where a rubber band is fixed on the side, which also allows an adjustable height. I.e. patients with a longer thigh can adjust the height with the band."*

B: *"What material do you want this holding device to be made of? What exactly is the idea here?"*

A: *"Made of a flexible plastic, the idea was also to make the orthosis cheap."*

B: *"But there's a joint in here?"*

A: *"Yes. Possibly like a ball-and-socket joint that can rotate in any direction and move."*

B: *"I see. Okay."*

A: *"In addition to the basic structure, a textile is planned on the upper side."*

B: *"The way the holding device here on the thigh is conceived, it will not work."*

A: *"Do you think it's necessary to think of a larger area when lifting?"*

B: *"For example, the lever arm is assumed to be as long as my forearm, if the center of rotation is here and the upper arm (...) and I want to lift my leg now, I need a lot of force if it would just lift over the belt (...) The scaffold will bend and the leg will not move. I am now asserting this on the basis of this sketch. It will be difficult to solve. (...) In the ankle joint, the function will definitely work, I am not worried about that. I think that lifting in the hip area is rather the problem."*

A: *"So the basic element in the thigh area does not have to lift the whole leg, assuming the patient manages to lift the foot himself, but lacks the strength at the last moment (see comparison gait analysis), where the leg is to be lifted even further, the engine would start here, the strength would not be so high. The patient is not able to lift the whole leg, but the strength is missing in the last moment (see comparison gait analysis), where the leg is to be lifted even further, the engine would start here, the force would not be so high."*

B: *"Short experimental example: (leg is lifted, Viktoria should press on the back of the leg as a motor) On the basis of this example, a lot of force is needed to move the thigh in a relevant way. The question is: Does it help the spastic because he is „guided" by it? If the spastic does not make any movements but is guided by them, in this direction this holding apparatus could have an effect. But if in extreme cases we speak of a paralyzed patient and want to move something here, it is inconceivable and will certainly not work. And even when I think of my leg, it is difficult."*

A: *"Yes, sure. Whether the engine would create enough power is questionable."*

B: *"Yes, whether the motor can do that and whether the holding device (corrected) made of plastic will bend. These are criteria where we have a lot of experience in orthopedics. (...)If the orthosis is moved permanently, it has to withstand an incredible amount of stress so that it does not break."*

A: *"All right. Thank you very much. I recently watched a Youtube video showing tips on how to apply a hip orthosis correctly. In this video, it was said that the optimal area for the hip joint is at the trochanter (corrected), but above the fulcrum of the hip joint."*

B: *"Yeah, that's right, that's right. If you look at the hip in detail, here's the daughter aunt and here's the fulcrum."(Picture of hip bone shown) "Here is a bearing surface where there's not much soft tissue over it."*

A: *"Great, which means the position was properly considered for the joint position."*

B: *"Yes. It's got to be the hip pivot or it won't work. The question is also whether it needs a joint, whether a simple connection in the front thigh area is sufficient."*

A: *"Ok. In summary, you see this connection on the front of your thigh as on the side?"*

B: *"Yes. I'm afraid the holding device (...) the rope pulls the belt forward, but if you put something here (shown on the side) the holding device twists."*

A: *"For the moment, one can only assume that the holding device is stable enough. At the moment it is still a concept idea."*

B: *"It's okay."*

A: 6) "Would you place the splint on the patient's ankle inside the shoe (shoe-in shoe) or as an add-on element? Where do you see possible problems here?"

A: *"The idea was to create a textile shoe with punctual reinforcement and a shoe-in-shoe concept. The rope is fixed to the point. (Shown on presented pictures) An imaginary folding mechanism in the calf area was thought of to be able to slip better into the shoe. If the orthosis gets too warm, the upper element can be folded back and provides additional comfort."*

B: *"What do you need the hinge for? I thought the air hose was here? Why do I need a hinge to connect two soft objects?"*

A: *"You can imagine it like a bend strip. The element is only slightly out-I'll have to close it."*

B: *"Do you mean a tape that curls up?"*

A: *"That's right. I have already tested the buckling function with a simple model. Of course, the air hoses and the rope autromatically bend with the buckling mechanism."*

B: *"I see. Okay."*

A: *"I've thought a lot about whether this element should be on the outside of the shoe, which can be very dangerous."*

B: *"No, that is not a good idea, and it's extremely impracticable. Patients want to wear normal shoes, everything that has to be done on the shoe itself is tedious work."*

A: *"Another idea was that because the first target group to be considered was in their early 30s, they would be able to wear an Adidas shoe."*

B: *"Yes, sure, that must look cool, too."*

A: *"Exactly. But whether this orthosis can be worn completely under the trousers, together with the actuators, is still questionable."*

B: *"You only need a motor at the top, don't you?"*

A: *"No, in two positions, ankle and thigh area/hip. As indicated on the drawing provided."*

B: *"So the engine is here?"*

A: *"Yes, exactly."*

B: *"What is this element?" (points to the battery belt)*

A: *"Here was the idea of carrying the battery with an extra belt strap."*

B: *"Why do not you position the engine here?" (points to the rear hip area where the vibration motors are located)*

A: *"In the beginning, the motor was also planned here, but in the other position you need a shorter rope path, so in the end this position was chosen. Currently this mechanism was thought of with two additional pulleys."*

B: *"What battery life do you have in mind?"*

A: *"Whew. The battery theme depends very much on how much power you need, in this concept only the optimal position of the battery is considered."*

B: *"Okay. All right."*

A: *"Of course, we consider how the patient can remove the orthosis and recharge the battery. These are currently two separate independent systems."*

B: *"What does this actuator do again?"*

A: *"This one pulls his foot out in the pre-swing phase."*

B: *"Ahh, yeah, sure."*

A: *"Two, same principles around a pulley. And here's the fixation point."*

B: *"Ahh. Okay."*

A: *"In the lower area, the rope pull can certainly be easily incorporated into a textile with additional reinforcement."*

B: *"But where you still have to watch out, the pulley can only work if both parts don‘t shift on the skin."*

A: *"That‘s right, the wire rope must run past the outside, pretty straight."*

B: *"Of course, it‘s on the outside. But when I put on my clothes here, the question is what exactly happens, whether the two things do not just slip."*

A: *"I see - we have already tested this, the foot also lifts itself slightly upwards, but in principle this deflection, which must be very straight and as horizontal as possible, makes this desired movement possible."*

B: *"Have you already been able to test the function with your test subjects?"*

A: *"No. Unfortunately not yet."*

B: *"Does this one have poor spasticity, too?"*

A: *"As far as I know, less. We have talked before about how poor spasticity can occur with this condition."*

B: *"Something else you might want to consider - only as input - the spastics, even if they have partly thin legs (...) give me your hand briefly... One fights against "something like that". (Arm pulls on hand and steers in all directions - Viktoria holds hand still) (...) These are the forces you fight against. You don‘t know exactly what the patient is doing and everyone is different again and the movements they are doing they are doing with a lot of strength. If one would dimension the motor, even if it is about the last lift (plucking) (...) Better more power than less power."*

A: *"Okay, good. Seeing as the product will be an intelligent orthosis and include a sensory package where pressure sensors are attached and acceleration sensors with gyroscope - i.e. we know how fast and where the patient moves - these sensors are located in 3 different positions (hip, knee and ankle) so the product will know how the user is behaving right now."*

B: *"Great."*

A: *"That‘s why you can also act here by saying that when the knee is raised, the rope pulls more...you can do a lot with programming."*

B: *"Great."*

A: *"That one can also make individual adjustments to the user. (...) We have not talked about the vibration motors yet, they are placed in three different positions. Assuming the patient uses the intelligent orthosis in switched-off mode, he can still set a training mode. (...) If the vibration motors at the knee, for example, vibrate, this means that the patient has to lift the foot even further until the vibration signal stops."*

B: *"So if the leg is in the right position, the engine will not vibrate anymore?"*

A: *"That‘s right. This was thought of as a "feedback solution". With the hip position, no change is actively corrected by a motor, of course, the hip position is another big problem. Through an encoder, we know the hip position, this sensor can measure these values. Here, for example, only the vibration button on the left vibrates, which would mean for the user to raise the hip further. This is also meant by the individual adjustment and should also give the patient the possibility to actively control the gait deviations. (...) Another scenario is, for example, if the user is tired, he has the possibility to activate the motor for additional help."*

B: *"Great idea. If the product actually works like this. All these things (...), whether it will be feasible sometime - logically with the energy supply (...) with the feasibility so that it will be pleasant to wear - but that goes here in the right direction. (...) ...and it must be efficient. The concept certainly goes in the right direction here. (...) and the structure (...) one may not underestimate this in any case with the Spastik (...) here I can press with my whole strength against it, I have no chance, in order to move something. But I think for slight spasticity – someone who is slightly spastic, bringing it in a normal direction, is certainly good.(...) Everything that is pleasant to wear will be worn later. You don‘t like to put on something yourself that gets uncomfortable after an hour. This is also important for the topic "what patients prefer", they only use things that are pleasant and not those that are better and meaningful - it has to be pleasant."*

A: *"These factors were also among the basic problems with our test subject, who was prescribed a DAFO orthosis according to prepreg technique - and does not want to wear it. This was also the spark for this project. And also, for this reason, I was contacted as a design student, who specifically dealt with the form and reduced the concept to the essential. (...) Thank you very much Mr. Hochgatterer for the intense conversation, I was able to learn a lot of new things and am grateful for your input, which comes from many years of experience with the patients."*

B: *"I also wish you all the best with your project."*

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