Synthesis of passive lightweight orthoses considering human-machine interaction

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Abstract

With increasing age, the probability of neurological diseases such as strokes, cancers, meningitis and Parkinson's also increase. A stroke, for instance, often leads to damage to the central nervous system and therefore subsequent problems within the musculoskeletal system occur. Such movement restrictions are currently treated with the help of orthoses. However, commercial passive orthoses have the disadvantage that not all functions are covered, e. g. supporting all phases of the gait cycle. Full functionality can only be ensured with heavier active orthoses. The aim of this contribution is to develop a new hybrid user-centered/lightweight-design approach with which fully functional, passive lightweight orthoses can be designed and developed effectively in the future. Therefore, the methodology according to PAHL/BEITZ is expanded by including user-specific functions and attributes. The developed approach is applied on an ankle-foot-orthosis.

Keywords

Lightweight design, Orthosis, Design methodology, User-centered design, Modell order reduction

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1. Introduction

In Germany, more than 200,000 first strokes and over 70,000 recurrent strokes occur annually [1; 2]. A stroke often leads to damage of the central nervous system, which is responsible for signal transmission and processing between brain and muscles, among other things. This results in disturbances of the musculoskeletal system, which in turn can result in pathophysiological movement execution [3]. For example, one of the most important movement sequences for humans is walking i. e., the gait. If the damage to the central nervous system is such that the lower leg musculature is impaired, plantar- and dorsiflexion (lowering and lifting of the forefoot) cannot be performed or can only be performed to a limited extent, resulting in an increased risk of stumbling and falling. Active and passive ankle-foot-orthoses (AFOs) are currently used to treat such movement restrictions. Active AFOs use external energy, which is stored in accumulators and batteries, to replace the missing force or moment by e. g. servomotors [4]. Since this results in additional weight for the patient, passive AFOs are often preferred. Passive AFOs are light, but have the disadvantage that only dorsiflexion (lifting of the forefoot) can be supported due to limited controllability. The great potential of passive orthoses was confirmed by a trend analysis by Bos et al. [5] from 2016, which analyzed the future developments of orthoses based on past and – at that time – current publications. Within this, it was shown that in the group of passive orthoses, compliant mechanisms are favored by shifting the support work to other, intact muscle groups.

According to Shorter et al. [6], since an AFO performs support work in a task-oriented way, passive AFOs should be expanded in the future to include the function of plantar flexion support. A solution would be a light, mobile and compact orthosis, which fulfills this additional function and at the same time keeps the required energy consumption of the patient due to additional weight as low as possible [7]. In order to be able to exploit both the functional extension and the entire lightweight potential, the user-specific and weight-optimizing properties should be integrated into the product development process (PDP) [8; 9]. Furthermore, the user's motion behavior should be mapped throughout the PDP to enable gait simulations for target (healthy) and actual (damaged) gait cycles [10]. Developed concepts and their iterative changes must be constantly evaluated and virtually incorporated into the prediction of user behavior. However, such a user-centered (UC) and lightweight design (LD) methodology, with which passive orthoses can be effectively and purposefully designed and pre-designed, does not exist in the state of the art. The research question is therefore: How can fully functional, lightweight, passive orthoses be developed in the future by coupling LD and UC methods in virtual product development?

According to Klein et al. [7], LD does not require a new specific PDP. It is sufficient to incorporate the basic idea of LD into existing and successful processes i. e. considering lightweight attributes [11]. Hence, in his dissertation, Posner [12] presented a method kit for LD which integrates various methods into the classic design methodology and can be called up in a product-focused manner. For medical aids, lightweight design aspects are only included as attributes and considerations in current design processes. The combination of user-centered and lightweight features and methods has already been successfully applied in the development process of medical devices in some scientific contributions. Duarte et al. [13] developed a lightweight back orthosis which was designed using the design theory of Pahl/Beitz et al. [14]. Furthermore, the authors postulated that in the early phase of designing orthoses, the cyclic movement sequences of the impaired muscle parts should be first identified [15]. Borstell et al. [16] described the conceptual design of an additively manufactured orthosis to support the thumb using the application "contra-bass". The major advantage of this approach is the structured overview of all load cases provided by the respective muscle groups. However, it is not always trivial to find a cyclic movement for a specific muscle group, e.g. rowing for the back muscles. For the lower leg muscles, the human gait can be used as a cyclic motion. For this, Shorter et al. [6] defined support phases that take into account the dorsiflexors and plantarflexors. With reference to Shorter's work, Collins et al. [17] described a method for developing passive AFO that can support dorsiflexion. Here, the authors already used implicitly UC methods to consider ergonomic features. However, in their approach are still certain functions unconsidered, like the supporting of the whole plantar flexion. According to Boese et al. [18], however, it is imperative to analyze the UC- and LD-specific requirements already in the planning phase and, if possible, to consider all of them by UC methods. Afterwards, the individual requirements can be modified or extended. In the concept phase of medical aids, the integration of the user then becomes mandatory. For this purpose, Regufe et al. [19] presented a UC approach for the design of medical devices, which can produce a large number of technical solutions for joint mechanisms. The advantage of this approach is, that it allows structuring the information identified in the design phase and the resulting solutions. However, the process is relatively time consuming. A faster way for UC/L design of orthoses is presented by Kubasad et al. [20]. The fast test- and simulation-driven method based on Ramsey et al. [21] finds iteratively an optimal user interaction design by trial-and-error. However, a disadvantage is that the brute-force approach makes it very restrictive. As a result, many mandatory usabilities cannot be considered. To address these issues, we present an approach to UC/L-fair conception, which is strongly oriented towards the methods according to Kubasad et al. and Regufe et al. This attempts to combine the advantages of both approaches. For this purpose, UC lightweight aspects are integrated into the classical design process to achieve a structured methodology adapted to medical devices for the fully functional design of passive orthoses.

2. Methods and preliminary results

As described in the previous chapter, the classical linear design process for lightweight products needs to be reviewed with UC methods in order to realize all functions in a passive orthosis. For a better understanding of this extended conceptual design approach, the procedures of the individual subdisciplines LD and UC product development are described in the next chapter.

2.1 Pahl-Beitz design process with lightweight design adaptations

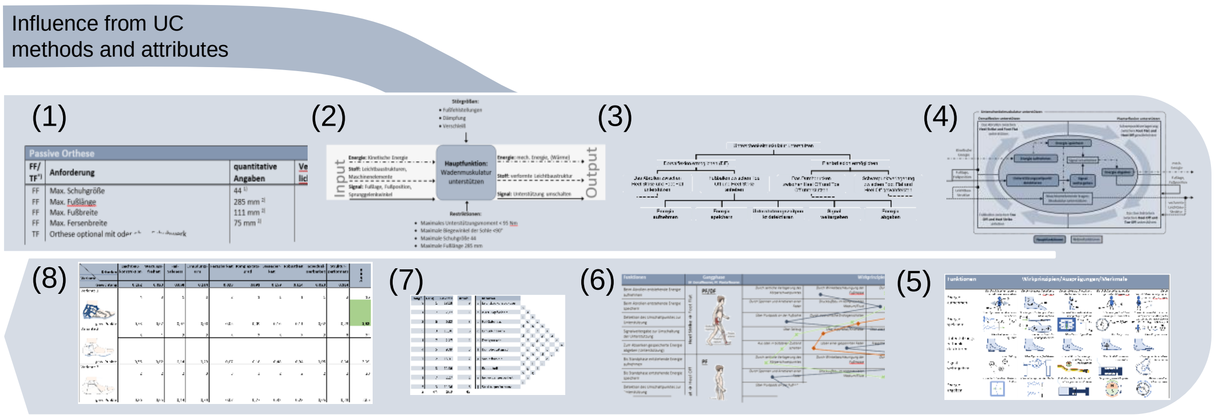


Figure 1: Procedure of the conceptual design process of medical aids under consideration of LD aspects

In the methodology presented in Figure 1, the conceptual design process according to Pahl/Beitz et al. [14] is considered under aspects of LD. In a list of requirements (1), the various functions and properties are defined as fixed and partial requirements. The premises on which the developed product is based on are collected, converted into functions and properties and initially entered in an unstructured list [22–25]. Already within the list of requirements, properties such as "minimum weight" and "design space" were considered. Additionally, the important functions for fully functional passive orthoses during and between the moments of the gait cycle (see Figure 2) were adopted as fixed requirements according to SHORTER et al. As a UC product, functions for individual use such as "orthosis optionally usable with or without footwear" or "adaptation of the support performance to the patient's body weight" have also been integrated into the list of requirements.

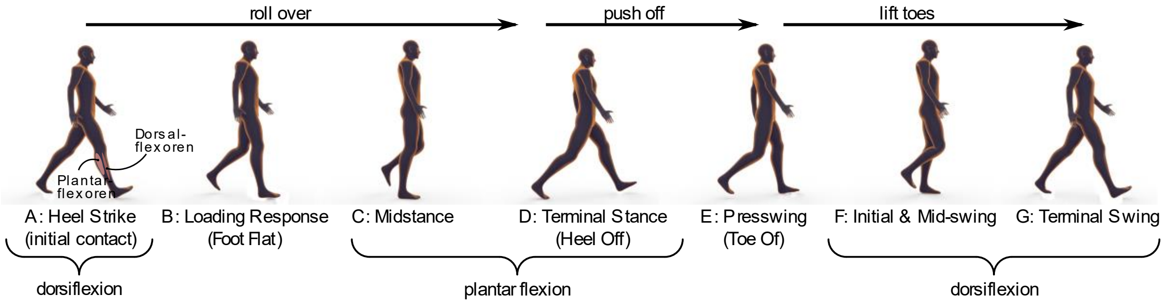


Figure 2: Explanation of the different Phases during gait cycle

To be able to assign various sub-functions to the main function "supporting lower leg muscles", bottom-up principles such as the black box (2) in Figure 1 were applied and a logical relationship between stationary and transient input and output variables was initially created. Here, the UC lightweight development of medical aids had an influence on the material and sensory levels. Furthermore, LD-related restrictions and disturbance variables of orthoses were identified and taken into account [26; 27]. Subsequently, a sensible and compatible linking of partial functions within a functional structure had to be realized.

A functional structure (3) in Figure 1 makes it easier to find solutions, since the top-down structuring can simplify processing (see Figure 3). On the first level is the main function, which is subdivided into the two sub-functions of the lower leg muscles (allowing plantar- and dorsiflexion). These have been assigned to the functions of SHORTER et al. On the bottom level are the basic functions, which are the same and obligatory for each higher-level sub-function of the third level. These are "absorb energy", "store energy", "detect support timing", "transmit signal" and "release energy." Then, the identified basic functions were brought into a functional context through a targeted search for inter-dependencies. Establishing a function relationship (4) in Figure 1 helps to structure and connect the various sub-functions to each other. For a clear cause-effect relationship, the black box representation is extended. The partial functions are defined as a cycle and integrated into the main function as the last level. The input variables are first initialized to have a starting value at e.g. signal and substance. The output variables reference back to the main function, as they become the input variable in after each motion phase. In the cycle itself, the kinetic energy resulting from the passivity is absorbed and stored. The stored energy is used to modify light structures and thereby support weakened muscles. Moreover, work has to be done for signal processing, which leads to further energy consumption. For this purpose, the support times that were detected at the beginning and signals have to be passed on. For energy absorption, different variants of energy harvesting opportunities in passive AFO have been investigated, which are mostly based on the combination of mass and acceleration of different parts of the body. Solutions for passive energy storage are largely mechanically based, although quasi-passivity can also be achieved with the aid of closed-loop energy conversion options [28; 29].

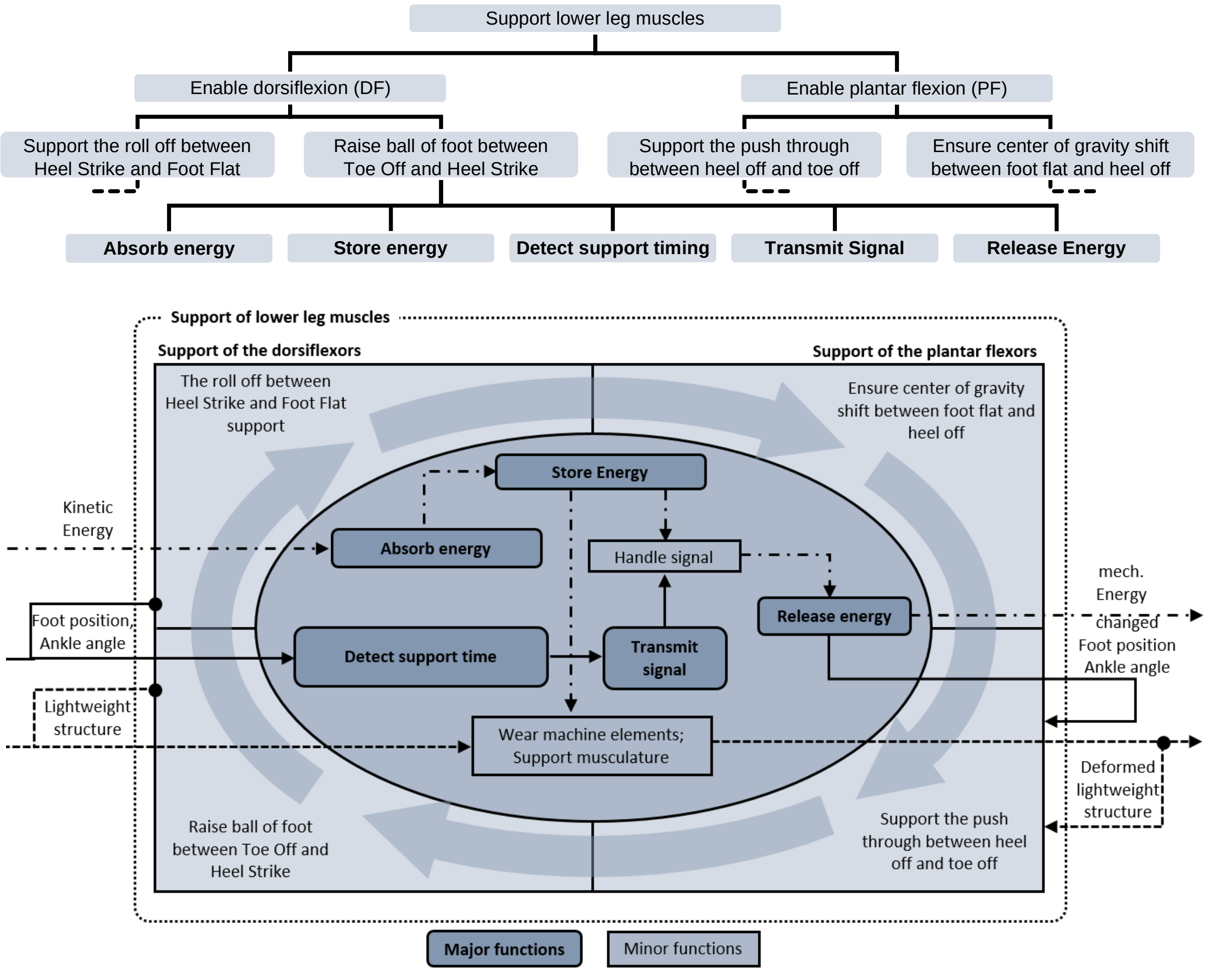
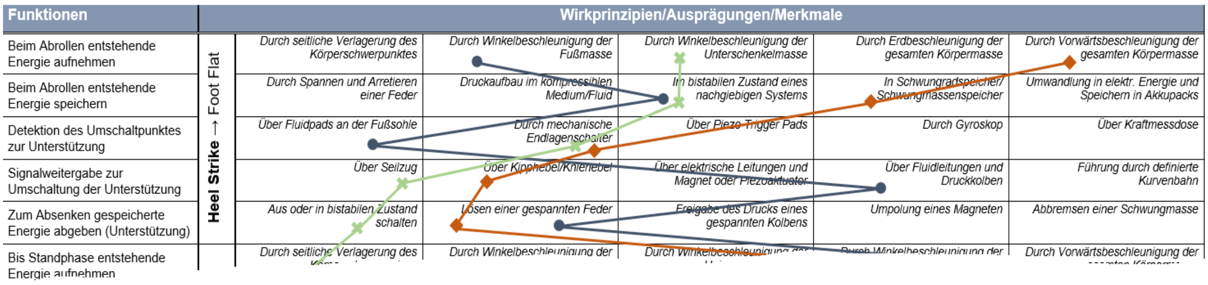


Figure 3: Integration of the sub-functions into the black box and definition of the relationships between the individual basic functions

With the help of an effect map (5) in Figure 1, different solution alternatives can be systematically elaborated for the individual sub-functions. The various manifestations are entered in a table, thereby generating an overview with simplified sketches, explanations and formulas. The support times can also be realized passively with the aid of pressure or position changes or quasi-passively via closed-loop sensors. The signal transport happens accordingly by mechanical force transmitters or electrical lines. The energy output depends on the selected energy storage and can be solved using a wide range of different actuators.



Funktionen		Wirkprinzipien/Ausprägungen/Merkmale				
Beim Abrollen entstehende Energie aufnehmen	Heel Strike → Foot Flat	Durch seitliche Verlagerung des Körperschwerpunktes	Durch Winkelbeschleunigung der Fußmasse	Durch Winkelbeschleunigung der Unterschenkelmasse	Durch Erdbeschleunigung der gesamten Körpermasse	Durch Vorwärtsbeschleunigung der gesamten Körpermasse
Beim Abrollen entstehende Energie speichern		Durch Spannen und Arretieren einer Feder	Druckaufbau im kompressiblen Medium/Fluid	Im bistabilen Zustand eines nachgiebigen Systems	In Schwungradspeicher/ Schwungmassenspeicher	Umwandlung in elektr. Energie und Speichern in Akkupacks
Detektion des Umschaltpunktes zur Unterstützung		Über Fluidpads an der Fußsohle	Durch mechanische Endlagenschalter	Über Piezo Trigger Pads	Durch Gyroskop	Über Kraftmessdose
Signalweitergabe zur Umschaltung der Unterstützung		Über Seilzug	Über Kipphebel/Kniehebel	Über elektrische Leitungen und Magnet oder Piezoaktuator	Über Fluidleitungen und Druckkolben	Führung durch definierte Kurvenbahn
Zum Absenken gespeicherte Energie abgeben (Unterstützung)		Aus oder in bistabilen Zustand schalten	Lösen einer gespannten Feder	Freigabe des Drucks eines gespannten Kolbens	Umpolung eines Magneten	Abbremsen einer Schwungmasse
Bis Standphase entstehende Energie aufnehmen		Durch seitliche Verlagerung des	Durch Winkelbeschleunigung der	Durch Winkelbeschleunigung der	Durch Winkelbeschleunigung der	Durch Vorwärtsbeschleunigung der

Figure 4: Impression of the morphological box

The morphological box (6) in Figure 1 according to ZWICKY et al. [14] is an established method in PDP for the structured conceptual design of overall solutions. Furthermore, the morphological box lends itself to experimentation by combining different active principles, since a large number of possible solution characteristics (in this case 3,2x10^6) can be achieved here.

Since the individual sub-functions are repeated in each phase, suitable features should always be chosen when going through the morphological box to generate compatible solutions (see Figure 4). Furthermore, in order to obtain lightweight UC solutions, the choice of the expressions for each feature at each run according to the lightweight and UC solution orientation must be questioned. In the following, a run through the morphological box populated with the previous defined principles in the effect map is shown.

The first concept is a solution with compliant mechanisms and bistable switching states and is based on the work of Bos et al. [30]. The energy used is stored in springs, which are made of the mechanisms own body's mass. The signal is transmitted intrinsically via the force action trajectories of the compliant areas. Concept 2 is a mechanical variant which is based on the work of Kishnan et al. [31] and Yakimovich et al. [32]. It realizes the passivity by tensioning classical spiral and torsion springs. The signals are detected via pressure pads or pivoted levers and transmitted, for example, by means of cable pulls. Energy is released by enable the previously tensioned and locked springs. In a third concept, a creative solution was chosen to generate a new innovative product. For this reason, a further mechanical solution with, for instance, flywheel accumulators or compression chambers as energy storage options was selected for the present passive AFO problem.

With the aid of a preference analysis (7) in Figure 1, the product-specific properties and functions defined in the requirements can be converted into evaluation criteria. These are then compared in pairs to obtain a weighting for future evaluation methods. As a result, the criteria "lightweight design"=18.18 (LD-Criteria) and "controllability"=15.91 (UC-Criteria) received the highest weighting factors.

At the end of a conceptual design phase, the concept ideas were evaluated. Since these rarely have enough quantifiable data in new designs, the qualitative evaluation methods should be carried out as objectively as possible. The method used in this work is the score rating (8) in Figure 1. Within the evaluation phase, the individual concepts are evaluated with a score range (0-4) with regard to the criteria that were calculated in the previous step. Afterwards, the concept that could achieve the highest score is selected.

2.2 Conceptual UC design methods

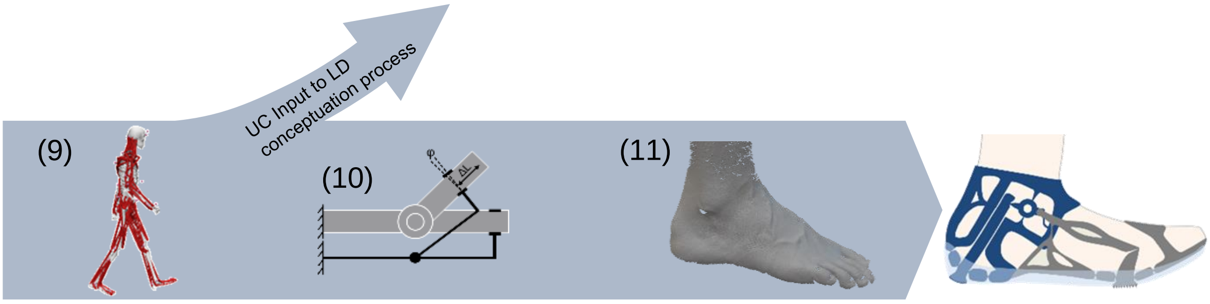


Figure 5: Conceptual design methods of medical aids under consideration of further UC aspects

Since the development of lightweight orthoses is strongly UC, the classical conceptual design process is extended by further methods of UC development, which are shown in Figure 5 [33; 34].

In order to obtain initial data for design and dimensioning, and to identify the required biomechanical support due to the loss of muscle function, motion studies (9) must be carried out with a representative selection of test subjects [35]. In this process, the affected areas are first measured and then motion capture images are created within a measurement cell using IR motion capturing. Simultaneously, EMG measurements also identify the exact timing of muscle activations. Force plates synchronously provides quantifiable support reactions during gait. In a musculoskeletal simulation, accelerations and support reaction forces are determined with the data obtained. These serve as input data for further design methods [36].

To get a first impression of the interrelated machine elements with the areas to be supported, a system map (10) was integrated in the development process. In it, kinematic relationships are determined and sketched with mechanical substitute models. In addition, initial approximate calculations and dimensioning are carried out.

To ensure that the joint axes and effective trajectories of the orthosis to be developed are as colinear as possible with the impaired body part, the free-form surfaces of the orthosis must be designed to fit precisely. A virtual image of the impaired limb can be generated with the aid of optical 3D measurement methods. Strip light projection methods (11) and photogrammetry are used for this purpose [37].

3. Explanation of the resulting concept

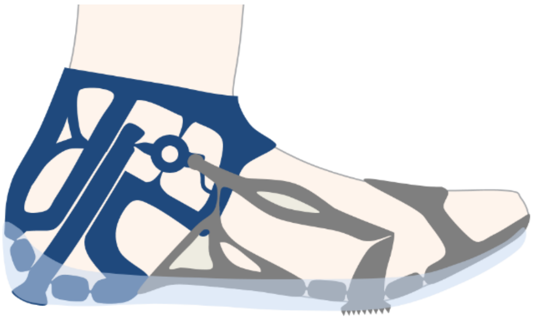


Figure 6: According to score rating, best concept for UC lightweight orthosis

After applying the methodology described in the previous chapter, three different variants of an orthosis were designed, which best fulfilled both LD and UC criteria. The first concept turned out to be the most promising in the systematic evaluation. Designed as a topology-optimized orthosis, this concept showed up to have the greatest potential to achieve minimal weight. Furthermore, the design space for topology optimization was perfectly defined with the help of the preceding 3D scan, which should also lead to a user-individual fit of the orthosis.

As shown in Figure 6 the first concept is a compliant system that is intended to realize energy storage through a bi,- tri- or multi-stable mechanism located parallel to the ankle joint. The mass-own leaf spring first release the stored energy after a force to the heel is applied (heel strike). This causes the front part of the mechanism, which is actually supported by the dorsiflexors, to move in a rotational motion relative to the ground about the ankle joint axis (Foot Flat). As the gait cycle progresses, the body's center of gravity moves forward. As a result, the forefoot rotates proximally, causing the spring to re-tension at the ankle joint. After reaching the rear end position, the heel is automatically lifted unconsciously by the forward acceleration of the body and the limited extensibility of the ligaments in the foot (heel off). As a consequence, the forefoot moves distally again. Force must now be applied through the plantar flexors to further accelerate the body. Since it is assumed that the plantar flexors of a person who needs an AFO are restricted, this leads to the maximum torque (~90 Nm) which must be supported by the mechanism [35]. For this, a solution still has to be found that takes into account the rotational movements working acyclically at the support times. After acceleration by the foot, the foot must be lifted (Toe Off). The force to lift the whole foot is mainly provided by the gluteus maximus. However, to avoid the so-called foot drop during the swing phase, the dorsiflexors are used subconsciously. Therefore, the energy used to keep the forefoot up during the swing phase must also be provided by the mechanism. In the draft, a solution is shown how an increased adhesion (by e.g. increasing the effective area) with the ground is built up using a kind of Velcro to generate an opposing force when the ball of the foot is lifted off the ground. This force could be sufficient (~25 Nm) to tension a spring (possibly the same spring) and switch the mechanism to another stable state [35]. After the foot is lifted off, it is swung forward to finally strike the heel again (heel strike) and let the cycle start from the beginning.

4. Discussion

Using the example of an AFO, the present approach demonstrates how orthoses can be designed in the future by coupling different UC and LD methods. In this respect, it was shown by means of a comprehensive literature review and by using own example that classic design methods based on the Pahl/Beitz design methodology can also be used for medical products. Furthermore, the approach was used to design a flexible lightweight orthosis which considers the complete gait cycle. In addition, the possible switching times for compliant orthoses were identified. Furthermore, a draft was made, which can serve as a blueprint for future developments of compliant AFOs. Among other things, this describes a possible design with corresponding switching kinematics, executed as a topology-optimized product.

5. Conclusion and further scheduled studies

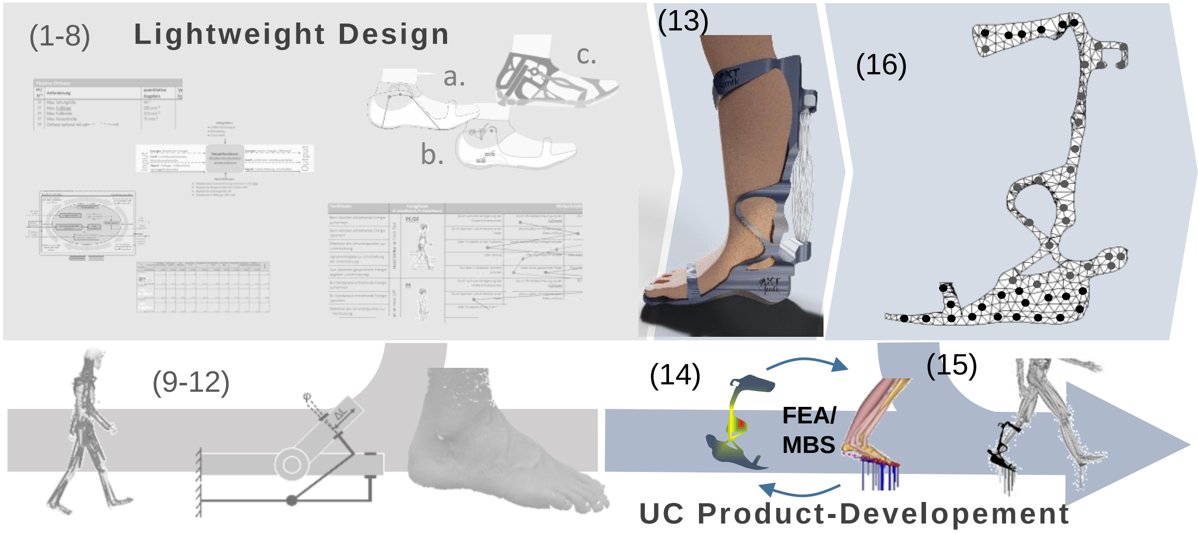


Figure 7: Further methods to synergistic conceptualization between UC and LD of passive AFO

This contribution first provided a detailed state of the art description of current UC and LD methods. Afterwards, the previously explained methods for UC lightweight product development were combined using the example of an AFO. From this, a structured approach for medical device design was developed. During the sketching of the concept, the enormous increase in the degree of complexity due to the support timings working acyclically to the angular acceleration stood out. Since the acyclic control of the compliant orthotic solution is a complex task for compliant mechanisms, the load cases for switching the multistable mechanism must be known exactly. For this purpose, stress distributions similar to those of Chu et al. [38] should be determined individually for the subject. For reaching the higher level of complexity, for instance, materials with different elastic moduli could be used by an asynchronously working parallel mechanism attached to the inner side of the orthosis.

Furthermore, it could be shown through the concept evaluations that the presented methodology is very well suited for the realization of functional concepts. However, the solution space could be further narrowed down by more objective evaluation methods.

In the further course of the PDP, the selected concept must first be further elaborated (see Figure 7). Then the stiffness curves must be optimized in such a way that the structural response of the orthoses corresponds to the user-specific support with known deformation. This will be identified by musculoskeletal simulation of the recorded gait motion data to determine required moment-angle trajectories. For this purpose, a reduced weight truss-FEA (14) is initially coupled with a human model MBS (15). However, since weight-reduced topology optimization results are also to be covered within the development strategy in the future, a model-order reduced FEA is needed in the design methodology (16).

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