A NEW METHOD FOR PASSIVE ANKLE FOOT ORTHOSIS DESIGN – INTEGRATION OF MUSCULOSKELETAL AND FINITE ELEMENT SIMULATION

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ABSTRACT

Motor disorders are diseases affecting the muscle function of the human body. A frequently occurring motor disorder affects the lower leg muscles resulting in a pathological gait called foot drop. Patients have a higher risk of stumbling and falling. The most common treatment is the use of a passive ankle-foot-orthosis (AFO). However, the compensation of foot drop is only limited due to the non possible support of all rotational directions of the ankle joint. Therefore, a newly developed concept for a passive AFO is currently in work. To ensure a best possible treatment of the patient, the provided support by the AFO and required support by the patient have to be in accordance. Thus, in this contribution a method is presented that integrates model order reduced finite element analysis for computing the provided support of the AFO and musculoskeletal human models for representing the patients' gait behaviour. With the method, the design of the force generating structures of the AFO can be realized regarding the patients' requirements. The presented method is further evaluated with a specific use case. The main focus lies here in the principal functionality of the method and the provision of valid results.

Keywords: User centred design, Design methods, Product modelling / models, Orthosis, Musculoskeletal human model

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1 INTRODUCTION

Being able to perform movements is a crucial prerequisite for humans to participate in daily life. Actions like walking, grabbing things or speaking are only possible due to the interplay of the many muscles in our body. The muscles are regulated by our natural control centre, the brain, and are activated by signals via the spinal cord and nerves. However, this signal transmission process can be damaged due to multiple reasons like stroke, tumor, traumata and more resulting in a motor disorder (Younger, 1999). Most common are paralysis, which implies the complete loss of muscle functions, and paresis, a partly loss of the muscle functions, which is equal to the weakening of the muscle's maximal force that can be applied to the human body. A frequently occurring motor disorder for humans affects the lower leg muscles. The lower leg muscles can be divided in two groups (Figure 1a). The muscles at the tibia are the dorsiflexors, who are responsible for lifting the foot up (dorsiflexion). The second group are the plantarflexors located mainly at the calf of the lower leg and are responsible for lowering the foot (plantarflexion). During normal gait of humans (see Figure 1b), the dorsiflexors are activated mainly in the swing phase to lift the toes for ground clearance and at the heel contact of the foot to provide a controlled lowering of the foot. The plantarflexors on the other hand are active in the stance phase until the foot is lifted from the ground to push off and accelerate the body forward (Neptune *et al.*, 2001). If the nerve (Ischias) that is responsible for the regulation of the lower leg muscles is damaged, a motor disorder known as foot drop can be the result (Stewart, 2008). Patients suffering from this disease show a pathological gait pattern, slower gait speed and a higher risk of stumbling and falling (Stewart, 2008; Kluding *et al.*, 2013). This is mainly caused by paralysis or paresis of the dorsiflexors making it impossible for the patients to lift their toes during walking. In addition, the plantarflexors are also often damaged to a patient-specific extent due to the regulation of the muscles from the same nerve.

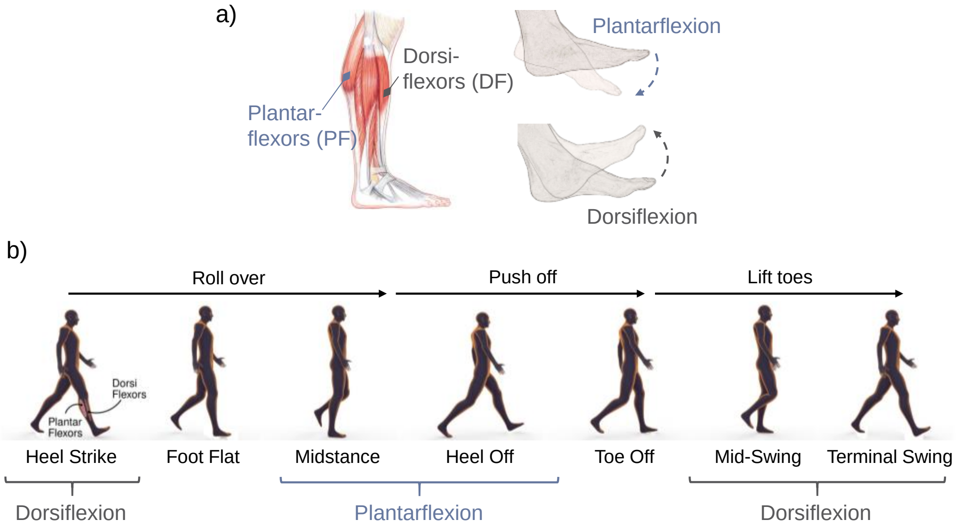

Figure 1: Overview of the lower leg muscles and their function, a) Location of plantar- and dorsiflexors and corresponding actuated movement; b) Activation timing of plantar- and dorsiflexors during gait cycle

The most common treatment of foot drop is by an ankle-foot-orthosis (AFO). AFOs are externally applied medical devices that are designed to help patients to walk easier and "more normally" (Blaya and Herr, 2004). They should provide stability to the ankle joint, be light and allow rotation of the ankle (Carberry *et al.*, 2011; Shorter *et al.*, 2011; Yamamoto *et al.*, 2005). The main functional requirement is support of both rotational directions, the dorsi- and plantarflexion during gait (Shorter *et al.*, 2011; Carberry *et al.*, 2011). There are two basic types of AFOs. The first ones are active AFOs (Blaya and Herr, 2004; Sawicki and Ferris, 2009) that are able to supply an adjustable support for dorsi- and plantarflexion during gait resulting in a better gait quality and performance (Russell Esposito *et al.*, 2018; Deberg *et al.*, 2014). The drawbacks of these devices are their weight-heavy (normally in kg ranges up to 5 kg) and bulky design and unfavorable energy consumption, which limits them to the use in laboratory settings with external power supply and the control of computers (Deberg *et al.*, 2014; Jackson and Collins, 2015; Russell Esposito *et al.*, 2018). The second type are passive AFOs

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(Deberg *et al.*, 2014; Yamamoto *et al.*, 2019). These devices are equipped with passive mechanical elements (e.g., springs, dampers) to assist patients. The foot drop is mainly prohibited by a restriction of the ankle movement (Russell Esposito *et al.*, 2018; Deberg *et al.*, 2014). Their major advantage is the small weight (usually less than 1 kg (Russell Esposito *et al.*, 2018)), which offers the possibility of a mobile use. While gait improvements have been demonstrated as well, a deviation to healthy gait and the results of active AFOs is existing (Jackson and Collins, 2015) due to the non-possible support of the plantarflexion with current passive foot drop-treating devices. However, there are innovative concepts like the one presented by Collins *et al.* (2015), who use a spring in combination with a ratchet-clutch mechanism to reduce the metabolic cost of a healthy subject during walking. The applicability of this solution for foot drop patients is unfortunately not possible due to the required full strength of the lower leg muscles. Nevertheless, this solution shows that a plantarflexion assistance of passive AFOs is feasible.
Thus, a newly developed concept for a passive AFO being able to support both ankle rotational directions is currently in work (Scherb *et al.*, 2022b). The passive AFO should be designed to consider lightweight as well as user-centered design requirements (Steck *et al.*, 2022). On the one hand, the technical realization of the AFO and its necessary components has to be developed. Therefore, a concept that can detect different gait phases and switch the support between plantar- and dorsiflexion is required. On the other hand, the required support by the user and the provided support by the AFO have to be in accordance to ensure an appropriate treatment for the patient. Normally, this is done by performing user tests to request user (dis-)comfort (Linnenberg and Weidner, 2022; Mills *et al.*, 2012). However, there are some issues and limitations with user tests such as a very cost- and time-consuming design review process, the purely qualitative feedback from the users or ethical restrictions (Fritzsche *et al.*, 2021; Ferrati *et al.*, 2013; Molz *et al.*, 2022). Thus, digital human models and more precisely musculoskeletal human models (MHM), which are mainly based on multi body simulation, are increasingly used in recent years to investigate the effects of orthoses and similar devices on the human body. MHMs allow to study the effects on biomechanical parameters like muscle activations (Miehling *et al.*, 2018; Molz *et al.*, 2022). Furthermore, the pathological situation of patients can be recreated in MHMs (Scherb *et al.*, 2022a). Combining this with the design of the passive AFO and adjustment of the AFO's structures for force generation according to the required amount and timing of assistance for the patient, an optimized treatment of the patient's pathological gait could be reached. The main goal here is to demand a certain contribution of the weakened plantar- and dorsiflexors (if applicable) in order to prevent a further damage of the muscles due to inactivity. Therefore, the AFO should only provide the assistance that the muscles cannot provide themselves, referred to as assistance-as-needed (Afschrift *et al.*, 2014). The gait behaviour and the required assistance for the patients can be represented by MHMs, while the load and reaction of the force generating structures can be modelled with a finite element model (FE model). Based on a conducted systematic review (Scherb *et al.*, 2023), it was established that there are studies for investigating the effects of AFOs on the human body with MHMs (Arch *et al.*, 2016; Yamamoto *et al.*, 2019), but none of them combines their investigations with a finite element simulation of the AFO. Finite element simulations of AFOs are mainly used for topology optimizations of the foot and cuff plates or stress analysis (Jamshidi *et al.*, 2010; Chu *et al.*, 1995). However, investigating the design of the force generating structures of the AFO and them affecting the biomechanics of the patient by combining the finite element and musculoskeletal simulation could be really helpful to optimize the design of the force generating structures for a best possible patient treatment.

2 AIM AND RESEARCH QUESTIONS

Therefore, a method to couple both simulation environments that is capable of introducing the results of each simulation as boundary conditions into the respective other one resulting in a holistic consideration of all requirements of the passive AFO is shown in this paper. The method should allow the design of the force generating structures in accordance with the gait behaviour of the patients, which consequently enables an optimal support by the AFO for the patient and accordingly a best possible treatment of foot drop. Therefore, the research question that should be answered in this contribution is (1) how a method for the design of a passive AFO that accounts for a best possible treatment of foot drop patients has to be set up. Additionally, on a simplified use case the transferability of data between musculoskeletal simulation and finite element simulation should be investigated and the possible influence on the biomechanics of the MHM by adjustments in the finite simulation should be shown, which is the main principal function of the method.

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3 COUPLING OF MHM AND FEA FOR THE DESIGN OF A PASSIVE AFO

3.1 General approach

The first step for realizing a method to integrate musculoskeletal simulation with finite element analysis (FEA) is to become aware of the required data for exchange between both simulation environments (see Figure 2). The required exchange data is defined by the underlying differential equations each numerical approach (MHM and FEA) is based on.

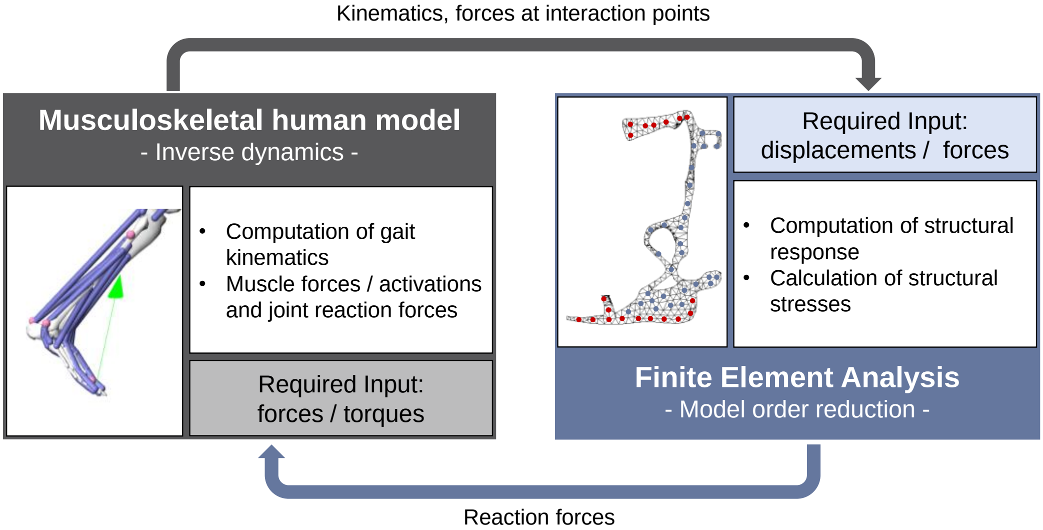

Figure 2: Overview of the required data for exchange between MHM and FEA; red dots indicate required nodes at contact or force application, blue dots indicate required nodes for improved approximation of solution

For the musculoskeletal human simulation, the approach of inverse dynamics is used. Therefore, the MHMs get a tracked motion and external forces on the human body as their inputs. Based on the tracked data, the MHMs are able to determine the coordinates of each human joint during the gait (kinematics). Combining this with the external forces on the human body, like the gravity, ground reaction forces etc., the occurring internal forces in the human body can be computed (muscle activations, joint reaction forces and more). The FEA requires displacements and forces on the corresponding model as input. Thus, the determined kinematics of the patient and the applied force on the device (e.g. force applied by patient, ground force) are transferred from the MHM. In the FEA, the stresses and accordingly the response of the structures responsible for the provided support is calculated. The response of the support structures expresses itself as a force that is applied on the body part of the patient (referred to as reaction force). Therefore, this reaction force can be introduced in the MHM as an external force and is used to compute the biomechanical effect of the assistance on the human body. In order to enable the performance of this integration process via FEA within a feasible calculation time, a special procedure for FEA called "model order reduction" (MOR) is used. MOR is characterized by the reduction of considered nodes to a minimal number for the solution of an existing problem (Craig and Bampton, 1968; Arras and Coppotelli, 2015). The preservation of nodes at a location of contact or force application (marked red in Figure 2) and further nodes for the improvement of the approximation (blue dots in Figure 2) is important.
After identifying the principal data required for exchange between MHM and FEA, the actual concept for coupling both simulation programs in order to be able to design a passive AFO can be realised (see Figure 3). The musculoskeletal simulation is based on motion captured gait data of healthy subjects. The motion capture is used to create a MHM of the subjects (healthy model). By weakening the maximum forces that the plantar- and dorsiflexors can apply to varying severities (resulting from foot drop as a consequence of muscle paralysis/paresis), exemplary MHMs of patients suffering from a foot drop can be replicated, which serve as the patient/user basis for simulative design of the passive AFO. Using these patient models (in combination with the motion captured gait data), an initial analysis is executed resulting in the ankle kinematics during gait, the force applied by the weakened muscles in the lower leg and the external forces acting on the foot. The target muscle activation is the most important

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outcome. This results actually from analysing the healthy model with the motion captured gait data, but is also used in the analysis with the patient model, e.g. for determining the desired applied force by the weakened lower leg muscles. Thus, the target muscle activation serves as the optimization target for evaluating the success of the assistance provided by the specific design of the AFO to the patient MHM. The other calculated data (ankle kinematics, force applied by patient and external force) is transferred via the interface as boundary conditions into the finite element simulation. In the next step, the supporting structures of the orthosis model have to be adjusted according to the required assistance by the patient, i.e. according to the weakened muscle situation of the patient, in order to obtain the desired muscle activations from the healthy situations as optimization criterion. The structure adjustment implies actions like e. g. the selection of materials and the dimensioning of the structure. The material distribution will be done in hybrid form via catalogs and optimization techniques. First, with the help of design catalogs, a new type of actuator kinematics will be substituted by compliant mechanisms. Second, both foot and calf plate will be lightened by FEA design methods like topology optimization with a stiffness objective function. Afterwards, the resulting design of the AFO could be analysed by FEA, but due to too large computation times, MOR is used. Before starting the simulation, the considered nodes have to be specified as joint nodes and approximation nodes by MOR. The execution of MOR-FEA results then in occurring displacements, stresses and forces in the supporting strcutures during the applied ankle motion during gait. The resulting forces are interpreted as the forces applied by the AFO to support the patient. Accordingly, they are imported to the MHM and are applied as external forces at the patient model. This analysis provides the muscle activation with assistance that is obtained by the previously adjusted specific design of the supporting structures. As already mentioned earlier, the evaluation of their design is done by a comparison of the resulting muscle activation with the target muscle activation, as it is hypothesized that a best possible treatment is realized, when the plantarflexor muscle activation of the patients with assistance matches the plantarflexor muscle activation of the healthy subjects. If the muscle activation with assistance differs too much from the target muscle activation, a new adjustment of the supporting structures (e.g. select new material, newly dimensioning) is necessary, whose exact realization is subject to our future work. With the adjusted structure a renewed execution of the MOR-FEA and simulation of the adjusted assistance and resulting muscle activation is then done. This process is repeated until the muscle activation with assistance matches the target muscle activation according to a predefined optimization target range. Accordingly, the final design of the supporting structures of the passive AFO indicates to be the optimal selection for treating the patient with a specific severity of foot drop.

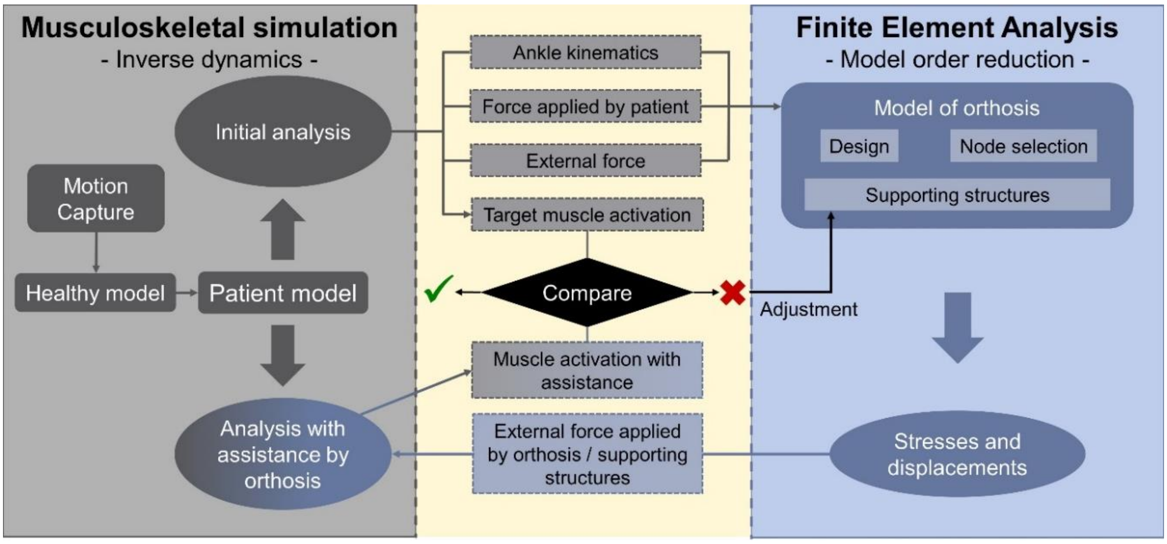

Figure 3: Conceptual approach for the coupling of MHM and FEA

3.2 Use case

As a first step, the functionality of the interface between both simulation programs and the possibility to influence the biomechanics of the MHM by adjustments in the finite simulation should be evaluated, which represents the main function of the method. The design and optimization of a passive AFO for treatment of foot drop and especially the realization of a possibility to switch the support

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between both ankle rotational directions during gait by the passive AFO would be too complex at this stage. Therefore, a special use case is chosen with required assistance of only one rotational direction to enable a good traceability of the previously described steps of the method and an easy evaluation of the provided results. In the investigated use case, a MHM (Miehling, 2019) in the musculoskeletal simulation software OpenSim (Delp *et al.*, 2007) is put in a position with a 90° hip flexion and 90° knee angle in the right leg. The other joint coordinates remain in their default values (Figure 4). The investigated motion is a steady plantarflexion up to 20° in 1s and again backwards to the starting position in 1s. The 20° plantarflexion were chosen due to determination of this value as maximal value during gait (Lund *et al.*, 2015).The other joint coordinates remain constant at their position during the motion. The motion is dynamically analysed by the MHM to receive the healthy muscle activations. In the next step, a patient (or weakened) model should be created that accounts for a very weak muscle situation, but not a complete functional loss of force. Therefore, the maximal applicable force of the dorsiflexors (coloured grey in Figure 4) is decreased by 90 % resulting in a remaining possible dorsiflexors strength of 10 %. Consequently, the activation of weakened dorsiflexors increases for performing the motion due to the loss of force. The goal is to assist the dorsiflexors at lifting the foot in such a way that the activation of the patient dorsiflexors decreases and gets similar to the healthy dorsiflexors activation (target muscle activation). The assistance should be realized by a structure that is assumed to be attached between the tibia and the foot of the model. After stretching the structure during lowering of the foot (plantarflexion), the stiffness of the material should return the structure back in its initial start position and accordingly applies force on the foot that pulls the foot upwards and therefore assists the dorsiflexors. The situation of the lower leg is remodelled in ANSYS with the flexible structure attached between two rigid approximations with the same dimensions and weights of the respective bones (tibia and foot) and the model fixed in the knee. The structure is modelled as a rod with a diameter of 1 cm. After choosing a material of the structure, the simulation of the occurring stresses in the structure is started in combination with the transferred boundary conditions from the musculoskeletal simuation (motion, gravity). Then, the node stresses are converted into the occurring axial force at the point of attachment of the structure on the foot. This force is imported into the weakened MHM and applied at the equal point as external force on the foot. Finally, the result is the muscle activation of the weakened model's dorsiflexors with assisted force from the structure on the foot. The implementation, exchange of data and actuation and control of OpenSim and ANSYS is done via MATLAB (Mathworks Inc.) that functions as a bilateral interface. The material of the support structure has to be a material with low stiffness to enable a deformation just by the force applied from the foot. Therefore, the structure is assumed to be an isotropic material with a density of $1350\frac{\mathrm{kg}}{\mathrm{m^{\wedge}3}}$. In order to investigate different effects on the resulting dorsiflexors' muscle activation, a parameter analysis with varying values for the Young's modulus of the material is performed. The different chosen values are 1 MPa, 2,5 MPa, 5 MPa, 7,5 MPa and 10 MPa. In the executed transient structural simulation only linear elastic material behaviour is considered.

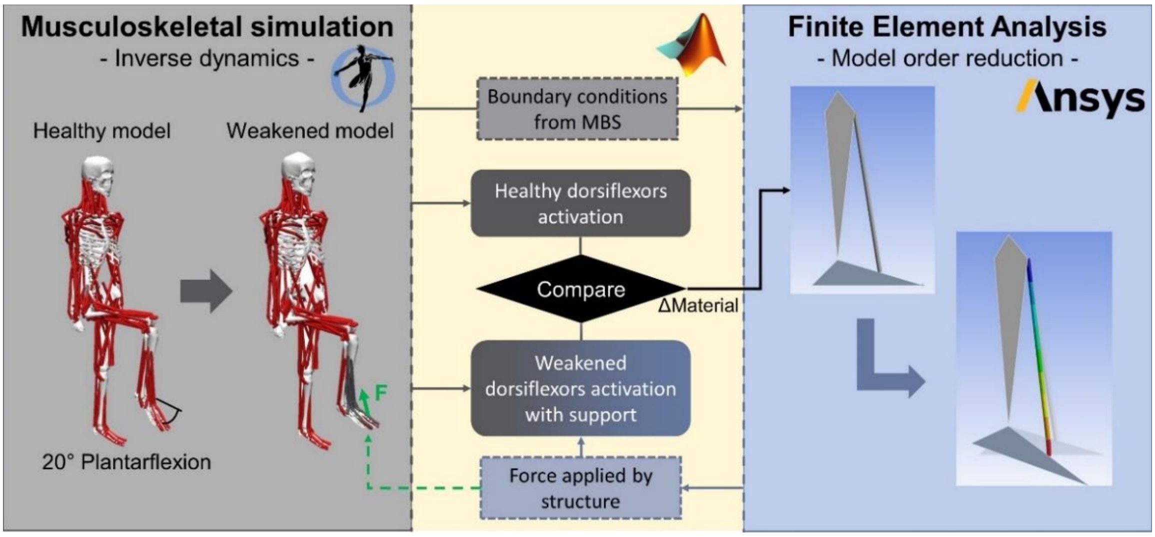

Figure 4: Investigated use case for the support of dorsiflexors at lifting foot by integration of a structure with varying stiffness

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4 RESULTS

The execution of the dynamic analysis of lowering and lifting the foot with the healthy model results in a very low required muscle activation of the dorsiflexors. In Figure 5 the tibialis anterior muscle is exemplary shown as the strongest dorsiflexor. The activation of the muscle remains under 10 % during the full motion. By analysing the motion with the patient (weakened) model, a high increase of the activation can be seen up to around 80 % at the end of the motion. The assistance provided by the structure on the weakened model results in an enabled decrease of the muscle activation, which is strengthened with increasing Young's modulus of the material. The main decrease is reached in the middle of the performed motion, when the foot is at 20° plantarflexion and the structure is accordingly maximally stretched. The assistance of the structures with 7,5 and 10 MPa even results in a no longer required contribution of the tibialis anterior (muscle activation is decreased to 0 %) at this time of the motion. However, it can also be seen that the activation of the dorsiflexors at the beginning and end of the motion is nearly unchanged with the support of the structure compared to weakened situation without support, which implies a large deviation from the healthy model, i.e. the target situation.

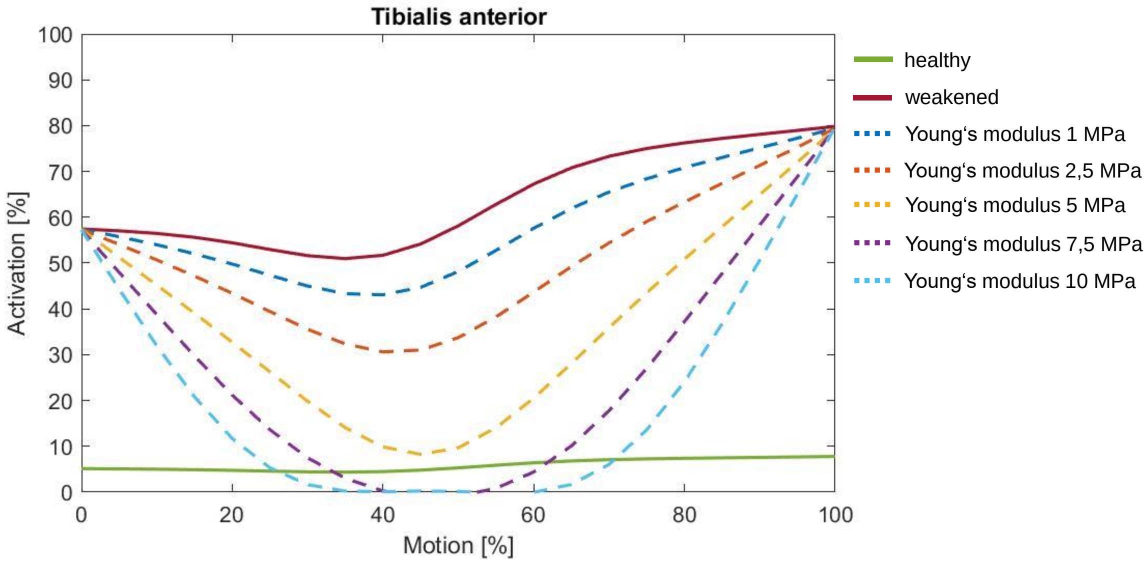

Figure 5: Activation of the tibialis anterior in the healthy and weakened situation (solid lines) and depending on the provided force from varying material adjustments of the support structure (dashed lines)

5 DISCUSSION & CONCLUSION

The aim of the provided contribution was to present a method for the design of a passive AFO by coupling MHM and FEA in order to account for a best possible treatment of patients and to evaluate the results of the method based on a simple use case. The use case itself depicts a simple motion of one coordinate with no ground contact. Therefore, the only acting external force is the gravity on the lower leg. The main load during the motion acts on the dorsiflexors. At the beginning of the motion, the dorsiflexors are activated to hold the foot in the upper position of the 90° angle between foot and tibia. Then, the lowering of the foot is realized by reducing the applied force of the dorsiflexors. By that, the passive support of gravity is used and the activation of the plantarflexors is not necessary. At the lowest point of the motion (20° plantarflexion), the activation of the dorsiflexors, i.e. the force that is applied by them, has to be increased again to lift the foot back up in the starting position. Looking at the resulting activation of the tibialis anterior (Figure 5), this behaviour can be seen nicely at the weakened situation and also indicated at the healthy situation. Furthermore, the rise in activation by a factor of 10 in the weakened situation compared to the healthy situation due to the weakening of dorsiflexors maximal applicable force with factor 10 is shown (e.g. at the beginning with an tibialias anterior activation of 5.5 % at healthy situation and 55 % at the weakened situation). Analysing the support of the inserted structure between foot and tibia, it is evident that at the beginning no assistance is provided due to the non-changing muscle activation for all variations, which is explained by the missing deformation in the structure. After the start of motion and accordingly the begin of the deformation of the structure, the required activation of the dorsiflexors decreases, which means that the applied contribution for the controlled lowering of the foot is increasingly taken over by the structure. The point with highest stress in the structure and accordingly highest force applied on the foot is reached at the maximal degree of the ankle joint coordinate (in this case at 20° plantarflexion). At this point the activation of the tibialis anterior reaches a minimum due to the support of the structure as well. In the lifting phase of the foot, the deformation of structure is again decreasing resulting in a decreasing stress in the structure and accordingly a decreasing force applied on the foot. The necessary effect is that the muscles need to provide more force to lift the foot and their muscle activation increases. To the end of the motion, the structure approaches its starting position and therefore provides decreasing assistance on the foot. The muscles compensation of the missing assistance by the structure results in a similar high muscle activation as in the regular weakened situation. Thus, the principal behaviour of the structure and accordingly the effects on the human body seem to be comprehensible, which can be compared in reality to the behaviour of an elastic band (e.g. THERABAND) between the tibia and foot. Furthermore, the calculated effect of the varying Young's modulus depicting a higher force applied on the foot and a resulting decreased muscle activation at a higher Young's modulus is also plausible due to the higher occurring stresses in the structure. The decrease of the tibialis anterior activation up to 0 % for the Young's modulus of 7,5 MPa and 10 MPa indicates no required support from the muscle for this time range of the motion. Thus, there is no load acting on the dorsiflexor muscles at this time during the motion, which could ultimately cause a further impairment of the muscles' situation, the medical professional has to be aware of. Therefore, with the possibility to provide the results of different effects, a selection from the different stiffness variations of the structure can be made due to the desired effects on the weakened muscles.

However, there are some limitations and simplifications existing in the investigated use case. First, a simplified use case with just a 2D motion and required assistance of one rotational direction was investigated. The only existing external force in the use case was the gravity and in total only small torques and forces act on the lower leg, which can be seen at the low required muscle activation of the tibialis anterior in the healthy situation. Patients suffering of foot drop are most limited during walking. At walking, forces of 1 times the body weight are applied on the foot and torques of 1.5 times the body weight act on the ankle joint. In addition, the foot is at some times at the ground and at some time in the air. Therefore, for the use of the method to design passive AFOs these and further complex boundary conditions have to be defined in the interface and have to be transferred between both simulation programs. Second, there were no non-linear effects considered in the FEA. The stretch of the assumed structure material would definitively cause some non-linear effects that should be considered in the FEA. For simplicity reasons and the fact that the executed use case is not one that should be investigated in reality, this was neglected in this execution. For the simulation of a situation that should be realized, a consideration of the non-linear effects is indispensable to ensure a valid transfer of the calculated result and elaborated effects to the real situation. Lastly, the use case and the interface were modelled in such a way that the created node stress in the structure was immediately converted in the acting forces and that the forces were acting at their corresponding time step on the human. Thus, no time delays or existing dampers were considered in the simulation. This could be pretty useful, as the results show, to guarantee an appropriate assistance for the users' requirements during the whole motion. In the end, an increasing complexity in the modelled support device and the simulated transfer of the provided support to human will be required for the design of a passive AFO.

Nevertheless, the investigated use case showed that the introduced method for coupling MHM and FEA principally works. It is possible to exchange and transfer data, especially the required boundary conditions for each simulation program, and also to use this data in the respective calculation. Furthermore, it was proven that an effect of the human body can be computed depending on the chosen parameter variation in the design of the supportive device. Based on this effect, the optimized design configuration of the device can be identified to assist the human in the most sufficient way. However, so far just the basic functionality of the method is proven. The validity of the method to identify the best design configuration of a passive AFO that provides the best possible treatment for a foot drop patient has to be evaluated in the next steps.

6 SUMMARY AND OUTLOOK

In this contribution, a method was shown that is capable of integrating MHMs und FEA for the design of a passive AFO to account for the best possible treatment of foot drop patients. The method itself considers the underlying differential equations of both simulation types and uses the results of each simulation as the introduced boundary condition for the respective other one. The main focus of the contribution was to describe the method and check the basic principle function of the method. This was shown with a use case of a simple 2D motion of the ankle joint. The use case has proven that the required muscle force and muscle load of a patient can be adjusted based on material variations in the finite element simulation. This effect enables the optimal design of the force generating structures in accordance with the requirements and considered motion of the user. With these results, the method can further be aligned to its actual purpose, the design of a passive AFO. For this, the issue of walking for foot drop patients will be approximated more closely. Thus, the weakened situation of foot drop patients will be considered and the ankle joint kinematics and dynamics will be introduced in the simulation. Furthermore, a mechanism that enables the switch between the support of dorsi- and plantarflexion will have to be considered in the simulation. Due to the apparent high complexity of the FEA simulation of a regular passive AFO model, a truss model derived from the passive AFO model is planned to be used for evaluation in the next step. Parallel to this, the investigation of the suitable method for receiving the MOR model of the passive AFO is pursued that will serve as a further evaluation step and ultimately as validation for the presented method. All simulated results are also planned to be verified by performing tests with a prototype that will be developed.

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