INDIVIDUAL OPTIMIZATION OF A NEW 3D-PRINTED PROSTHETIC FOOT

Mecuris GmbH creates individual prosthetic feet by combining virtual analysis with Additive Manufacturing (AM). optiSLang, ANSYS and Solidworks are applied for parametric simulations.

Introduction

Replacing the functions of a human ankle is challenging as it is an intricate mechanism. Naturally, prosthetic feet aim to mimic the biomechanical characteristics of the intact limb. The design process of such devices is often supported by finite element (FE) simulations to improve their functionality. It is now possible to create individual prosthetic feet by combining virtual analysis with additive manufacturing (AM). By implementing a set of parameters in the design, prosthetics can be adapted to weight and mobility.

For every final prosthetic design, a new evaluation of load and safety would be needed. However, these calculations may be replaced with a comprehensive metamodel to monitor the influence of the specific parameter changes. A robustness study can ensure that the same functionality and safety is provided for each patient.

Vision

At Mecuris GmbH, we aim to supply each patient with an individual aid (see Fig. 1). Therefore, throughout the design process of prosthetics and orthotics, we have to make sure that patients and orthopedic technicians are involved in the development of the final product. This influence provides individual performance and aesthetics considering certain safety boundaries.

Selective Laser Sintering (SLS) has significantly improved in the past few years, and now allows the production of highly durable products. Prosthetic feet have to withstand a fatigue test (2 million load cycles) to be certified. Furthermore, AM allows great geometric freedom, such that adjustments of geometric parameters in the CAD model can be realized in manufacturing.

Development and Testing

The development of prosthetic feet at Mecuris GmbH is carried out considering a single size and body weight. Naturally, when these patient parameters change, the function and safety of the aid deviates.

A few ISO norms can characterize prosthetic feet, including ISO 10328, which contains the previously mentioned durability test for critical heel and toe loading. Other norms aim to simulate a gait cycle on a test bench to provide deeper functional understanding.

Fig. 1: Patient fitting and rehabilitation with a 3D-printed Mecuris prosthetic foot. The foot displayed is inserted into a cosmetic shell

FE-simulations can model the ISO 10328 with reasonable complexity and computational time. Still, the parametric FE-simulation of two different load cases poses challenges.

A combination of physical and virtual testing facilitates the development of a safe and well-functioning prosthetic foot.

Particularly important is the rollover-shape (ROS) of the design that determines how smooth the patient walks and is closely linked to other performance parameters. FE-simulation of the ISO 10328 (see Fig. 2.) load cases can predict the ROS, with significantly less computational effort than the FE-simulation of the whole gait cycle.

Metamodels

Once the prototype fulfills most design requirements, a broader parametric study is necessary to evaluate parameter adjustments from safety (certification) and functionality aspects. The study presented in this paper considered so-called patient parameters (size, bodyweight) and free parameters (three geometric values). The patient's influence reflected in the patient parameters and the free parameters were used in the optimization.

Firstly, the parameter ranges were defined and implemented in a robust parametric CAD model. The parametric model was built up using Solidworks Professional 2017. The next step involved an automatic FE-simulation setup applying "named selections" to maintain references. We used ANSYS Workbench 19.2 as an FE-solver in this study. In the FE-model of the physical test bench, non-linear contacts and plasticity were considered. The Design of Experiments (DoE) was further complicated by creating stable references in the FE-simulation, dealing with meshing and convergence problems.

The design sampling was carried out with the optiSLang 7.2 add-in in the ANSYS Workbench environment. Advanced Latin Hypercube Sampling with 50 and 150 design points were used for heel and toe loading respectively. Besides the previously mentioned five inputs, 3 functional and 11 safety outputs were defined (total). The approximation quality of the metamodels reached a Coefficient of Prognosis (CoP) value of 95% or more in most cases.

Fig. 2: ISO 10328 test stand and modeling of the two load cases with the subject prosthetic foot. All construction components are included in the FE-simulation (equivalent stress is shown)

Promisingly, the free parameters had a high influence on the outputs, indicating that functional adaptation is possible. For example, heel thickness influenced 46% of the heel deformation at heel loading (heel strike) and body weight was only the second most important parameter with a CoP of 36% (see Fig. 3).

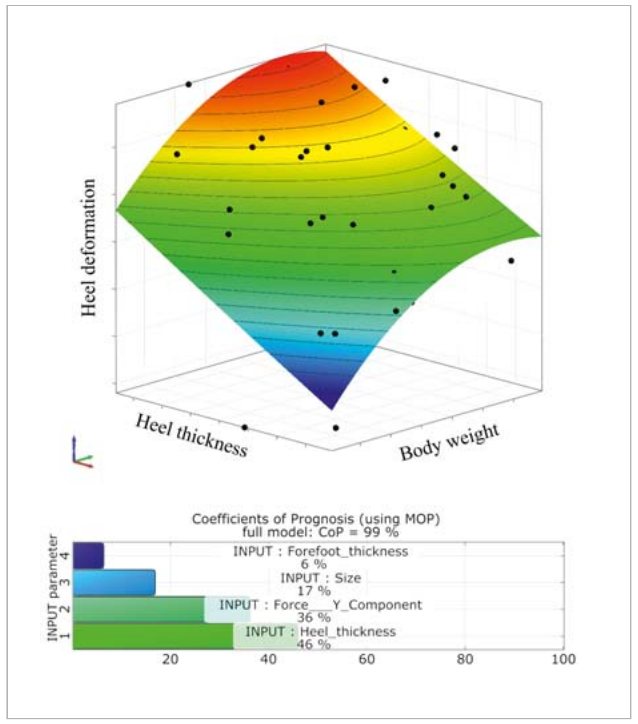

Fig. 3: Metamodel of Optimal Prognosis for Heel Deformation. The model shows high accuracy with only roughly 50 design points

Functional Robustness

Traditionally, robustness is associated with manufacturing imperfections. However, in this study, we sought to achieve a parametric design that allows functional adaptation based on patient parameters. This was not possible with only one robust design, since both patient parameters (foot size and bodyweight) range widely and their distribution was unknown due to lacking broad data.

Therefore, a new idea was necessary: to set certain safety limits, and optimize the free parameters for each size-body weight combination in the restricted domain. The optimization aimed to replicate the functional parameter values of the already existing reference design. This was reflected in a single combined objective function, since manual multi-objective optimization in each case would be too time-consuming. To perform these optimization tasks, we switched to optiSLang 7.2 standalone, where the already available metamodels were imported. Figure 4 shows the optimization system setup.

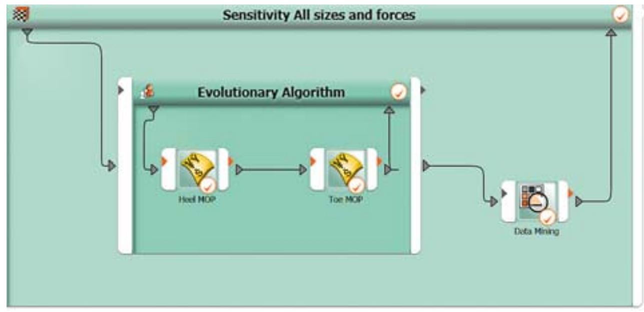

Figure 4: A nested system where the inner optimizer adjusts the free parameters and the outer sampling system changes the patient parameters. An evolutionary algorithm is used to approximate the global optima

The optimized designs closely followed the prescribed functional parameter values. However, the prediction of a full ROS with only two load cases raised difficulties, even when a fully-developed reference existed.

Therefore, functional validation of three optimized designs with varying patient parameters was carried out. We used a previously developed FE-simulation tool which provides the full ROS of the prosthetic foot. The comparison of three validation designs to the reference design revealed similar (promising) ROS performance for all designs (see Fig. 5).

In conclusion, the prosthetic foot developed for a single patient was extended to a range of patients using freely adjustable geometric parameters. The means of this adaptation included modeling the two load cases of the ISO 10328 standard, performing a design study with these FE-simulations, and optimization on the metamodels. The idea of additively manufacturing prosthetic feet allowed to replace the traditional robustness evaluation with a patient-specific optimization, thus reaching the ideal functionality in each design.

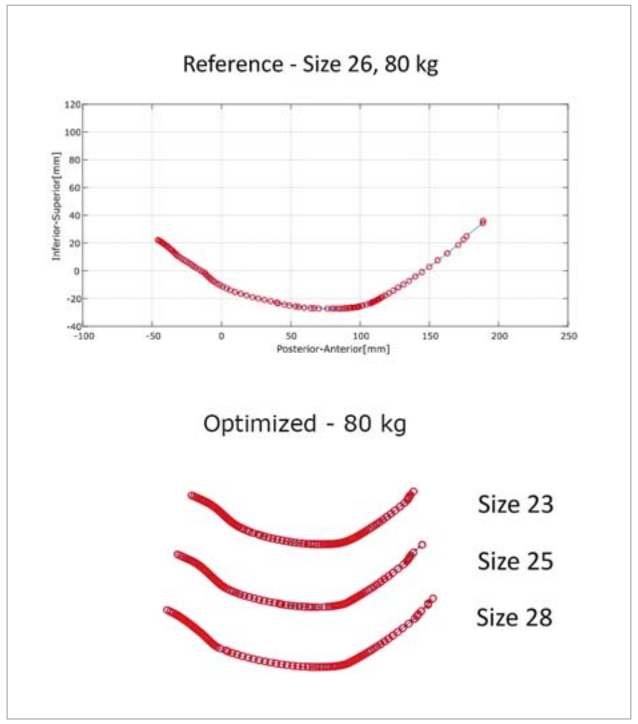

Figure 5: The rollover-shapes of the reference design and three optimized designs for the same body weight but varying foot sizes

Optimization time

The computation of the two design studies (heel and toe loading) lasted roughly 3 and 7 days respectively. The computer used for the calculation was equipped with 8 cores and 16 GB RAM. The optimization time for all size-body weight combinations (56 cases) lasted roughly 2 hours. This calculation only has to be performed once, and later the optimized free parameters can be picked for the given patient data.

User Testimonial

Patient testing and feedback are essential for prosthetic foot development. Our testimonial received two variants of the product to evaluate different daily use cases.

We designed and manufactured two versions, one for Nordic Walking and another for performing domestic chores (e. g. carrying heavy objects). These activities require different functional properties from the prosthetic foot. In the first case, we allowed more flexibility and a smooth rollover-shape. For the second purpose we optimized the foot for an increased body weight, taking the extra load into consideration.

“The prosthetic knee harmonizes well with both feet. [...] One foot is a soft variant for usage at home, the other is a stiff variant for outdoor usage and fast walking. My subjective impression confirms the different behavior of the feet.”

Michael Kramer, Rehatreff, 1 | 2019 (translated from German)

Outlook

All simulation models in this study were validated against physical measurements for the reference design and proved to be accurate. Thus, the most significant question for this optimization tool appears in quantifying patient preferences that can serve as input for the optimization objective.

Additionally, further improvements of the metamodels are possible by exploring more design points or making mesh refinements to avoid noisy results. Moreover, the ROS FE-simulation setup that validated the optimized designs might be directly used for the DoE. It can provide deeper understanding of functionality but it raises computational effort significantly.

There is a German patent pending of the prosthetic foot with the number: DE 10 2019 100 584.1

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