



Success Story / **Validated simulation for prosthetic feet**

# Virtual crash tests for 3D-printed prosthetic feet

With the introduction of the new Medical Device Regulation (MDR), the approval of orthopedic devices will become more difficult. For the first time, a digital process chain will be established that enables preventive quality assurance of individualized prostheses and orthoses by validating a virtual load test of a 3D-printed prosthetic foot.



„With Simq's support and expertise, we can pioneer this at Mecuris. Incorporating simulation-based quality assurance into the digital creation of personalized orthopedic devices can add real value for patients.“

Franziska Glas / Quality Assurance & Simulation / Mecuris GmbH

## The task

The project "Validated simulation of a 3D-printed prosthetic foot" brings together experts from the fields of biomechanics, orthopedic technology, 3D printing, certification, validation, and simulation.

Together, we verify that the calculation of the strains of the real and virtual testing yield the same results. This is a crucial step in validating the simulation. The project makes it possible to digitally test patient-specific designed orthopedic products before they are 3D printed and made available to patients in the shortest possible time.

## The solution

In cooperation with a physician or orthopedic technician, patient-specific parameters are determined and automatically integrated into CAD models via the Mecuris Solution platform. The medical devices are manufactured in certified 3D printing centers and checked by experts before they are used (**Figure 1**).

In cooperation with Simq GmbH, an initial finite element analysis of the Mecuris prosthetic foot "NexStep" was already developed in 2016 with the boundary conditions of the static test of the test standard DIN EN ISO 10328 (**Figure 2**).

This standard describes the requirements on the mechanical stability of lower limb prostheses and represents a prerequisite for the sale of the Mecuris prosthetic foot.



Figure 2: Finite element analysis „NexStep“

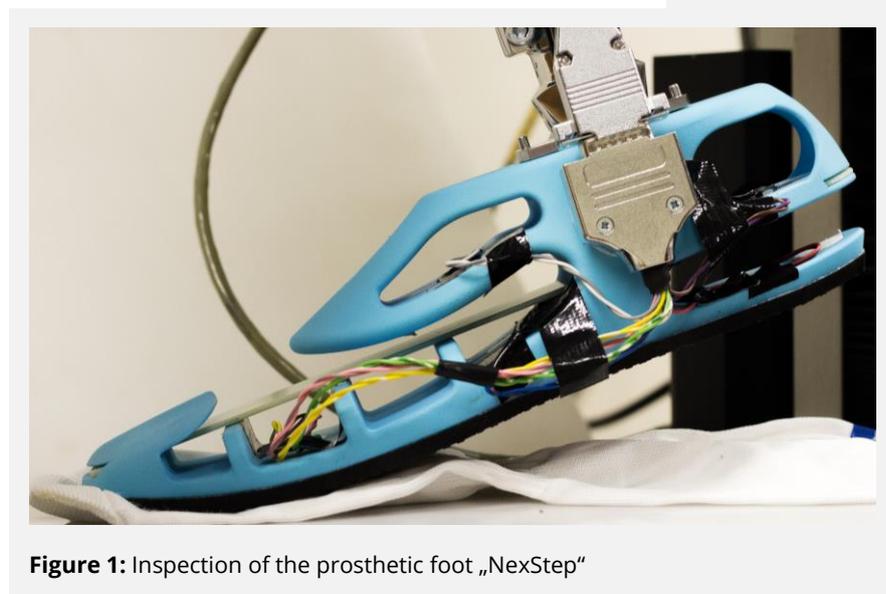


Figure 1: Inspection of the prosthetic foot „NexStep“

## The result

Mecuris is supported by Simq in setting up the internal simulation of patient-specific designed products. The focus so far was on improving the material models and parameters to correctly represent the load behavior of the prosthetic foot. From the first comparisons of real and virtual strains in the "validated simulation" project, potential improvements could already be identified, and iterations planned. An initial challenge has already been mastered based on the tests: The fundamental

feasibility was demonstrated: strain gauges are suitable for implementing the process of metrological validation of numerical simulation methods for additively manufactured medical devices. In order to find suitable measures that further increase the accuracy between real and virtual deformation, thus the safety of the medical device and consequently of the patient, Simq is a central partner in the project. Currently, Mecuris and Simq are working together in a project group (SIGMA3D) to develop a solution for simulation in orthotic applications.

## Your contact



**Dr.-Ing. & M.Sc. Sven Herrmann**  
Director Consulting & Seminars

+49 8092 7005 712  
sherrmann@simq.de

## About the customer

Mecuris combines a variety of 3D technologies in the intuitive to use Mecuris Solution Platform. This platform enables orthopedic technology to step into the digital age - easy and economically. Mecuris is supported by Simq in setting up the internal simulation of patient-specific products. Up to recently regarding prosthetic feet and orthotic blanks, from now on providing insights for the latter.



## About Simq

The company was founded in 2014 and is part of the CADFEM Group. Simq's products and services enable medical device manufacturers, clinicians and medical staff to practically apply numerical simulation and use it for more effective and safer patient care.

Simq is committed to the standardization and broader application of in silico medicine as part of the Avicenna Alliance, thereby ensuring safe, affordable and cost-effective healthcare.



**Simq is a certified simulation service provider and software manufacturer in the field of medicine and medical technology and is one of the pioneers of in silico medicine.**