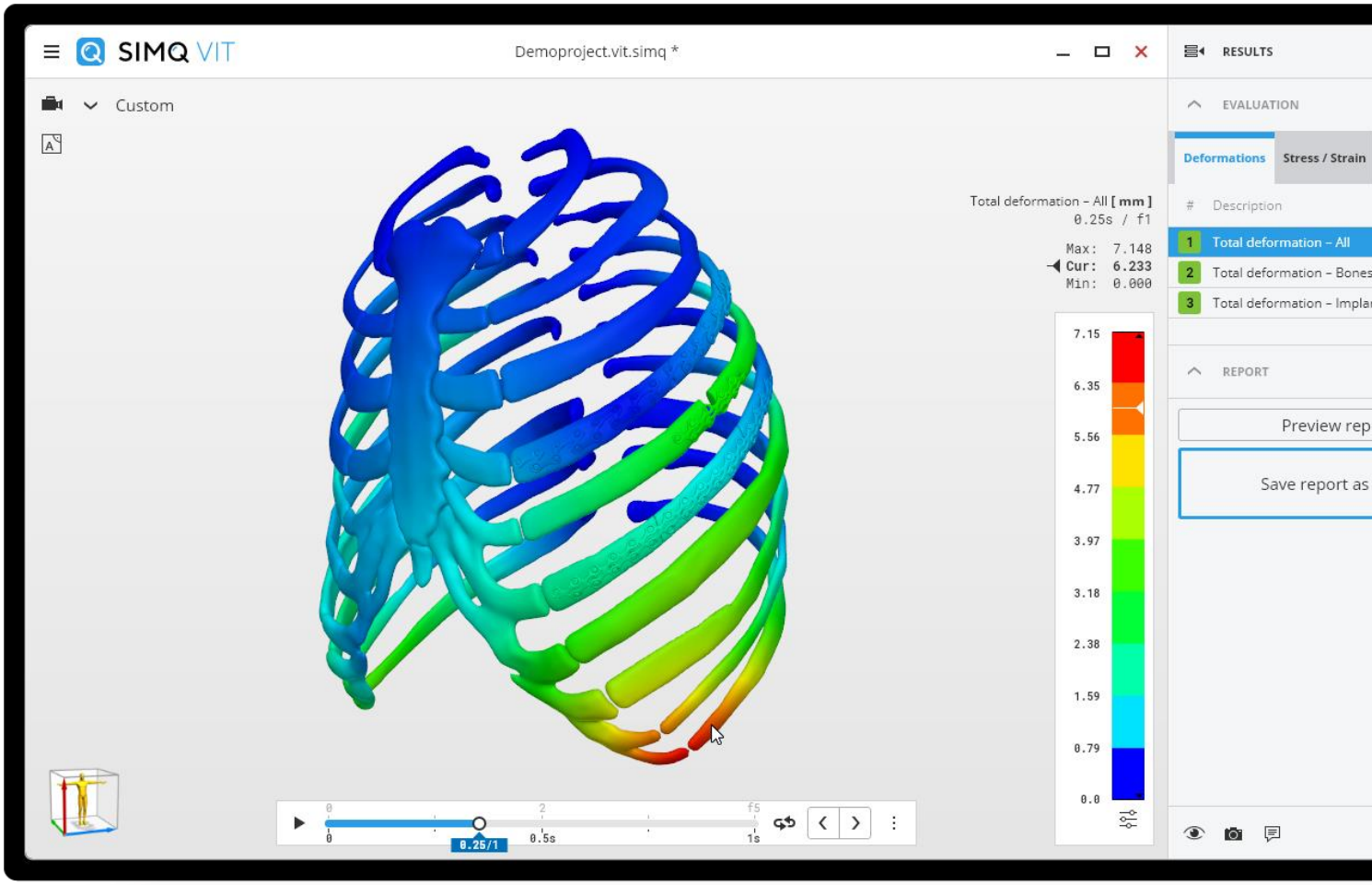

Success Story / **Virtual implant testing with simulation**

Digital verification of patient-specific implants

The use of computer simulations continues to be strengthened by regulatory authorities. One goal here is to regulate mass customization in medicine more closely. FDA and MDCG want medical device manufacturers to take more responsibility for customized implants. This is where Simq VIT comes in, providing its users with quick and easy access for digital verification of patient-specific implants based on biomechanical analysis. The standardized workflows generate an automated simulation report and technical documentation based on FDA guidelines.

"With Simq VIT, we can incorporate safety-relevant information into the design and check it against the state of the art as early as the design phase of the patient-specific implants with just a few clicks. In this way, we manage the balancing act between complying with regulatory requirements and helping patients as quickly as possible. "

Thomas Koett /
Development Engineer Implants / KLS Martin Group

The task

Standard products follow a standardized, tested and documented approval process. For patient-specific implants, this has not been possible so far. To close this gap and make liability and documentation for patient-specific implants future-proof, an additional process step must be introduced.

This is to verify and visualize the design of the patient-specific implant (PSI) and then discuss the design with the physician. By digitally verifying the design, the safety and performance of the implants for each patient **(Fig.1) will be** easily and quickly determined with the software.

The solution

With Simq VIT, we can provide medical device manufacturers and physicians with the best possible support and digitally verify patient-specific implants quickly and easily.

The software uses finite element methods, such as those used in the automotive industry. Based on the planning data and the individual patient anatomy, an algorithm uses objective criteria to check how well the implant fits, what forces are acting, and the stress levels for bone, graft and implant. Based on the simulation results, it is possible, for example, to quickly see whether all the planned screws are needed and to make further improvements to the implant geometry.

Fig. 1: Selection of available workflows in Simq VIT

The Simq VIT software is based on the Simq platform and offers a complete solution for customers: Through the partnership with Ansys, customers do not have to worry about additional hardware or licenses. Furthermore, with the pay-per-use model, simulations can also be sent off in parallel.

Lean workflows, all validated with industry partners and universities, make it possible to set up complex biomechanical simulations for different anatomical regions in a very short time **(Fig. 2a).**

The libraries with load cases and the material of the bolts can be continuously extended based on the customer's requirements **(Fig. 2b).**

The security of patient data is guaranteed - if required, the customer still has the option of retaining data sovereignty with an on premises solution.

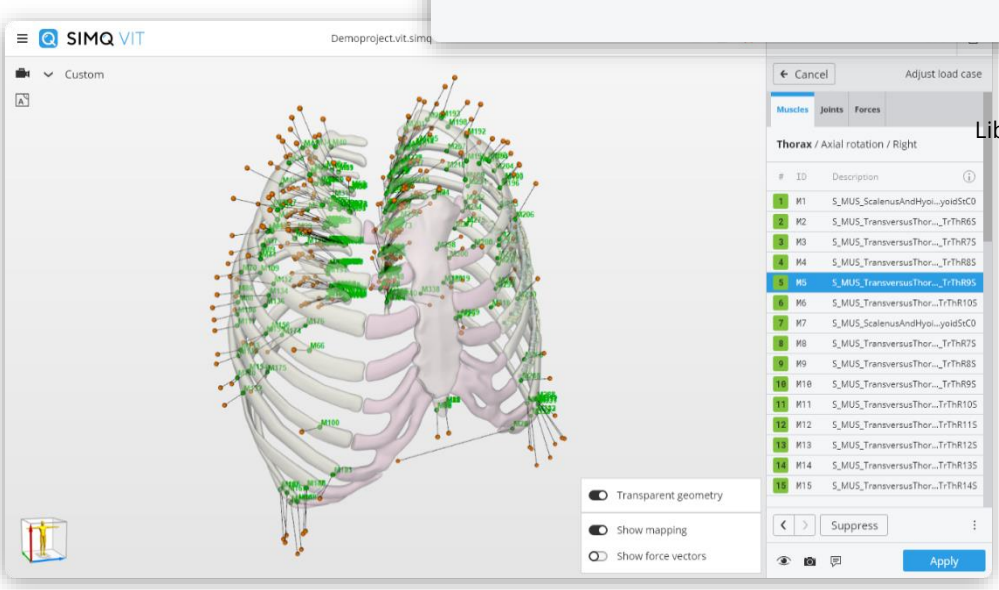

Fig. 2a: Displaying the force vectors for the thorax workflow

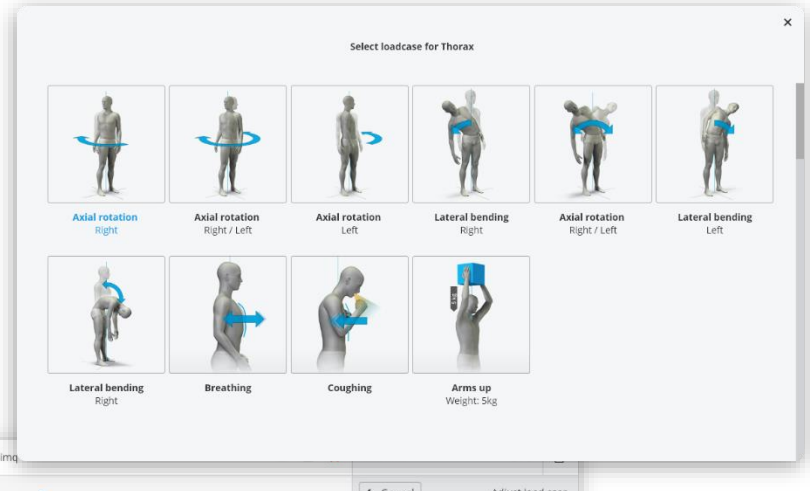

Fig. 2b: Library of the different load cases for the Thorax Workflow

The result

With Simq VIT, KLS Martin is ready for the future. Thanks to the predefined workflows in Simq VIT, which are developed together with the customer and adapted to the corresponding requirements, KLS Martin can set up highly complex biomechanical simulations within minutes and design better and patient-specific verified implants. Meanwhile, more than 10 implant designers from KLS Martin use Simq VIT on a daily basis.

Arbitrarily scalable thanks to the infrastructure provided by Simq VIT: no licenses are sold here. Customers get everything from a single source from Simq and are always maximally flexible with a pay-per-use model. Another benefit is the ability to work in parallel and run multiple simulations simultaneously without incurring additional licensing costs, HPC costs or the like.

The objective results of the simulation serve the engineer as a basis for discussion with the treating physician.

In addition to the resulting reduced liability risk, improved safety and quality of the implants, KLS Martin saves a lot of time through automated reports.

Thus, an approximately 40-page automatically generated report, adapted to the latest FDA guidelines, proving the safety and quality of the implant specifically for each individual patient, can be generated after each simulation and used for technical documentation and post-market surveillance.

This means that KLS Martin will continue to meet the new regulatory requirements for custom implants in the future, and KLS Martin patients can look forward to safe implants that are optimized for them.

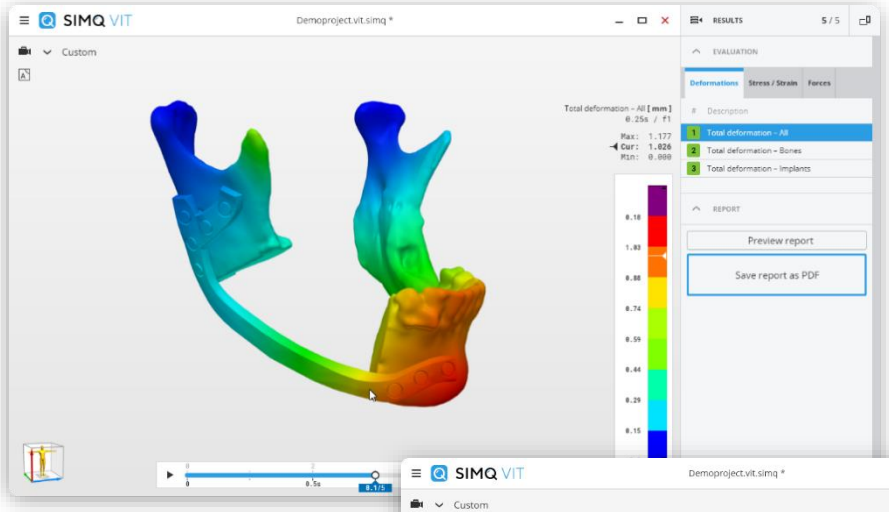

Fig. 3: Mandible

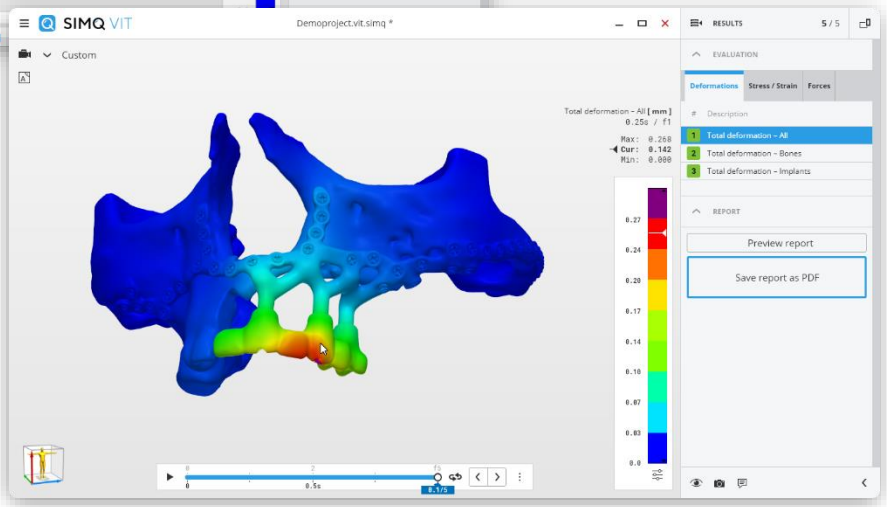

Fig. 4: Maxilla

Your contact

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About the customer

The KLS Martin Group is an internationally active group of companies for innovative medical technology in almost all areas of surgery. With their innovative medical technology solutions such as implant systems, high-frequency surgical devices, surgical lasers, sterilization containers, surgical lights, surgical instruments as well as individual OR solutions, they have set new standards many times.

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
software producer in the field of medical and medical technology and is one of the
among the pioneers of in silico medicine.