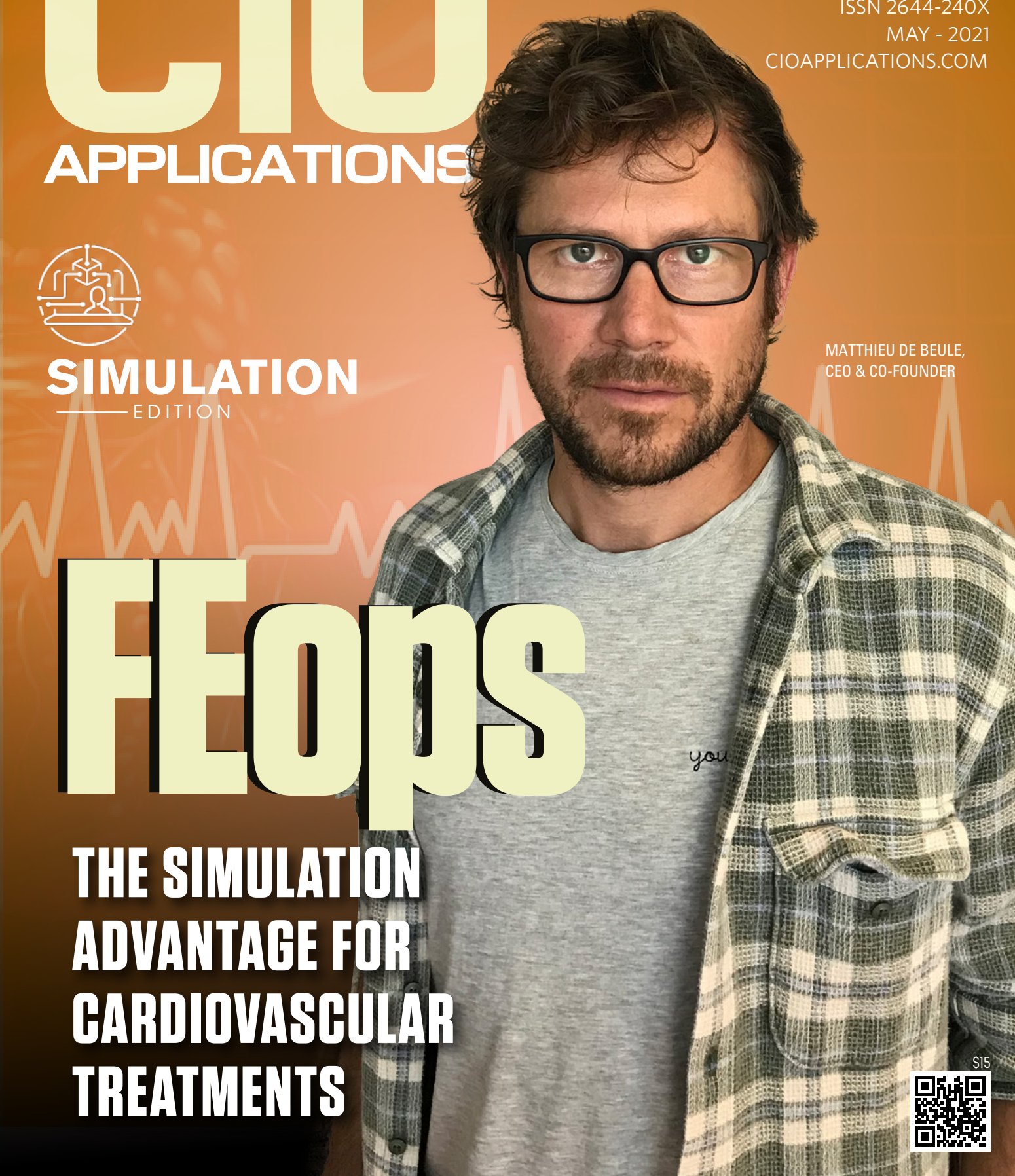
CIO APPLICATIONS

ISSN 2644-240X
MAY - 2021
CIOAPPLICATIONS.COM

SIMULATION EDITION



MATTHIEU DE BEULE,
CEO & CO-FOUNDER

FEops

THE SIMULATION ADVANTAGE FOR CARDIOVASCULAR TREATMENTS

S15

FEops

THE SIMULATION ADVANTAGE FOR CARDIOVASCULAR TREATMENTS

Founded in 2009 as a spinoff from Ghent University, FEops has developed the world's first and only patient-specific and AI-enabled simulation platform for structural heart interventions. The technology surpasses the granularity of basic anatomical measurements within the heart by combining digital twins (virtual copies of the heart or its substructures) with AI-enabled anatomical analyses. This generates data-driven insights aspiring to enhance and improve procedure planning and periprocedural guidance . With their flagship solution, FEops HEARTguide, prototypes of Heart Valves & Left Atrial Appendage Occlusion (LAAo) cardiovascular implants can be tested on a database of virtual patients. This also allows R&D teams to clearly understand the implant's working while in a particular patient's anatomy. Next to supporting the R&D of new generation heart implants, patient specific interventions can also be simulated pre-operatively based on the patient's digital twin in order to avoid complications.

Charting a Legacy in Cardiovascular Simulations

As there is a clear shift towards the use of minimally invasive approaches from open-heart treatments,

"We are also currently involved in lots of next-gen developments of structural heart devices with several companies of all sizes—from huge enterprises to startups

MATTHIEU DE BEULE,
CEO & CO-FOUNDER

physicians rely ever more on medical imaging to make very important decisions on factors such as implant size and positioning. This is not always straightforward since it can often become challenging to imagine how devices will interact with different patients. As Matthieu De Beule, CEO of FEops, puts it, "Patients' unique anatomy is where we come into play, because we use imaging in a functional way. The way we build standardized computer models of that patient's heart allows the physician to understand the case in an integrated and detailed manner. The doctor can thus assess the risk of complications preoperatively, to ultimately make procedures safer and more efficient."

FEops' solution is a fully cloud-based platform. By combining routine preoperative cardiac CT images with computer models of the implant, FEops HEARTguide predicts the interaction between e.g. the Transcatheter Aortic Valve Implantation (TAVI) device to treat aortic stenosis and the patient's unique anatomy, including post-implantation deformation, allowing physicians to assess the risk for paravalvular leakage and conduction abnormalities. FEops has already modeled close to 3000 structural heart cases with FEops HEARTguide, which is commercially available in Europe, UK, Canada and Australia for the TAVI and LAAo workflow. The company is currently in the process of getting an FDA clearance through a de-novo pathway for its LAAo workflow, which is expected in the second half of 2021.

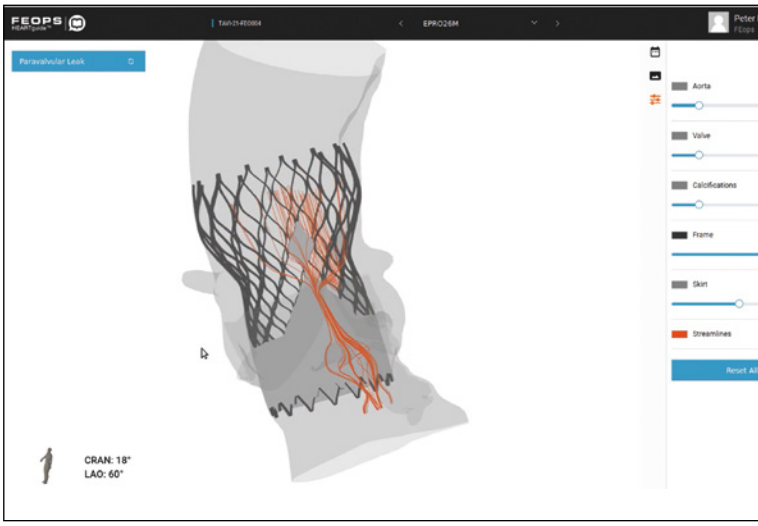
Accelerating Cardiovascular R&D

To FEops, the main strength of being a simulation specialist and digital health innovator comes from the advantage they offer value to clients end to end. In R&D, for instance, when a new device is being developed, the traditional approach of building prototypes can be very expensive. If preliminary lab tests are successful, animal experiments are carried out to determine if (or when) the device(s) go to clinical trials. Sometimes cadavers are also used, but all in all, it is a very lengthy and a rather risky process since only the final device integration can tell just how good the interaction with humans will be.

This is a space in which FEops has shifted the paradigm, having created validated digital models of the heart. Developers can now move forward without making a device prototype and can now test design iterations in real virtual patient models, early in the development cycle, reducing significantly the risk. If specific changes are made to a device, their potential impact on the patients can be observed. As De Beule puts it, "It is as close as you can get to a patient without even having to make a prototype. We are currently involved in several next-gen developments of structural heart devices with different companies of all sizes—from huge enterprises to startups all over the world."

Adequate Patient Selection is critical to a device success

The technology is also useful in the selection process of patients because the FEops platform predicts complications more precisely than the current medical device technologies out there. While running clinical trials, this is very useful, as one can make sure that the right device is being selected for the right patient or the right patient for the right device.



For instance, Transcatheter Mitral Valve Replacement (TMVR) is a potential therapeutic option for the treatment of severe mitral regurgitation. Early clinical experience supports the feasibility of TMVR but also highlights slow enrollment in TMVR studies due to a.o. physicians' concerns about the risk of left ventricular outflow tract (LVOT) obstruction. FEops responds to this clinical challenge with the development of its unique FEops HEARTguide TMVR workflow. It offers accurate simulation-based information about the effects of replacement device positioning and deformation within each patient's anatomy. This provides physicians with better insights into the replacement device's sizing and helps them identify the optimal position to avoid left ventricular outflow tract (LVOT) obstruction.

Overall, the digital twin model that FEops offers helps minimize chances of complication and maximize chances of procedural success. "The better you are informed upfront, the higher your chances are," adds De Beule.

Answering the Physician's Call with Cutting Edge Tech

FEops delivers unparalleled levels of insights in implant/patient interaction and is both intuitive and easy to use for clinicians and healthcare providers. The physicians or the field therapy specialists from device companies who assist physicians can upload the patient's images to the cloud. And once the data is obtained, the company can process the medical imaging and build the computer models. FEops HEARTguide can thereby run not only the simulations of different treatment scenarios, different device sizes and different positions but will also provide validated, AI-enabled anatomical analysis. The results are sent back to the cloud so that the physician or the therapy specialist can then use the secure portal to interactively interpret these 3D models together with the anatomical analysis to get a detailed understanding of the different possible treatment scenarios.

Technically, the platform is based on 2 techniques. The first one is FEops' proprietary simulation technology, based on finite element analyses. The technology was already being used for years in the automotive and aerospace industries, making FEops the first to bring that to the structural heart community. The cardiovascular model incorporates the material properties of all the different tissues involved in specific regions of the patient body and the device, enabling the user to study them in detail. The second technique brings in a validated, quality-controlled AI component. This is enhancing the scalability of FEops HEARTguide by e.g. providing an automated 3D reconstruction of the heart, starting from the DICOM images. Additionally the AI-enabled technology is providing detailed anatomical analysis

> **"The way we build standardized computer models of that patient's heart allows the physician to understand the case in an integrated and detailed manner**

Evolving the Way of Medical Innovation

Having worked with a plethora of different patients and gathered data on all of their cases, the company has expanded their intake to include trials from even larger sample sets. The PREDICT-LAA study is a physician-initiated study with Dr Ole De Backer and Dr Philippe Garot as PI's and is co-sponsored by Abbott and FEops. The final enrollment is expected in Q3 of this year.

FEops is also planning to extend its offering from the procedure planning phase to the procedural guidance phase, which means that physicians can use their technology preoperatively to plan and peri-operatively to guide their procedures. Together with the big imaging players, like GE, Philips and Siemens, FEops is working on technologies that allow users to visualize the simulation results during the intervention, which allows them to have clear landmarks during the intervention of where to land the specific device.

FEops' vision is to revolutionize structural heart interventions through data-driven use of cardiac imaging. This is already becoming very concrete with the launch of its novel AI platform, leveraged on their experience of having worked with close to 3,000 patients. This will help upload, process, and download medical images over the cloud in a secure way providing a full anatomical analysis on top of FEops' unique digital twin technology.

Physicians' feedback and early clinical data have revealed the potential of FEops HEARTguide to reduce cost and increase procedure efficiency. For example with his LAAo workflow FEops HEARTguide contributes in reducing procedure time, contrast volume and radiation exposure. It's no wonder that FEops is partnering with medical device manufactures worldwide to explore clinical and commercial synergies in bundling FEops's solution together with the manufacturer's medical device in clinical practice. These manufacturers value FEops as a commercialization partner to improve patient and physician adoption, reduce complications and optimize resources in the healthcare system by putting the right device, in the patient in the right location.

Combining a truly unique selling proposition with a promising business plan made FEops very successful in attracting venture capital money, in their two venture capital rounds, having raised 7.3 million Euro. Additionally, they have raised 5.9 million Euro in public funding, of which the last one was a grant of € 3.2 million from the European Innovation Council (EIC) accelerator program. The company is using the grant for accelerating the clinical evidence gathering and business implementation of FEops HEARTguide™ on a global scale.

With resources at hand and innovation at its heart, FEops is well on its way to revolutionizing the cardiovascular simulation space for all. CA

CIO APPLICATIONS

ISSN 2644-240X
CIOAPPLICATIONS.COM
MAY - 2021

FEops

TOP Simulation Solution Providers 2021

Recognized by CIO APPLICATIONS

FEops

TOP Simulation Solution Providers 2021

Recognized by CIO APPLICATIONS

The annual listing of 10 companies that are at the forefront of providing Simulation solutions and transforming businesses