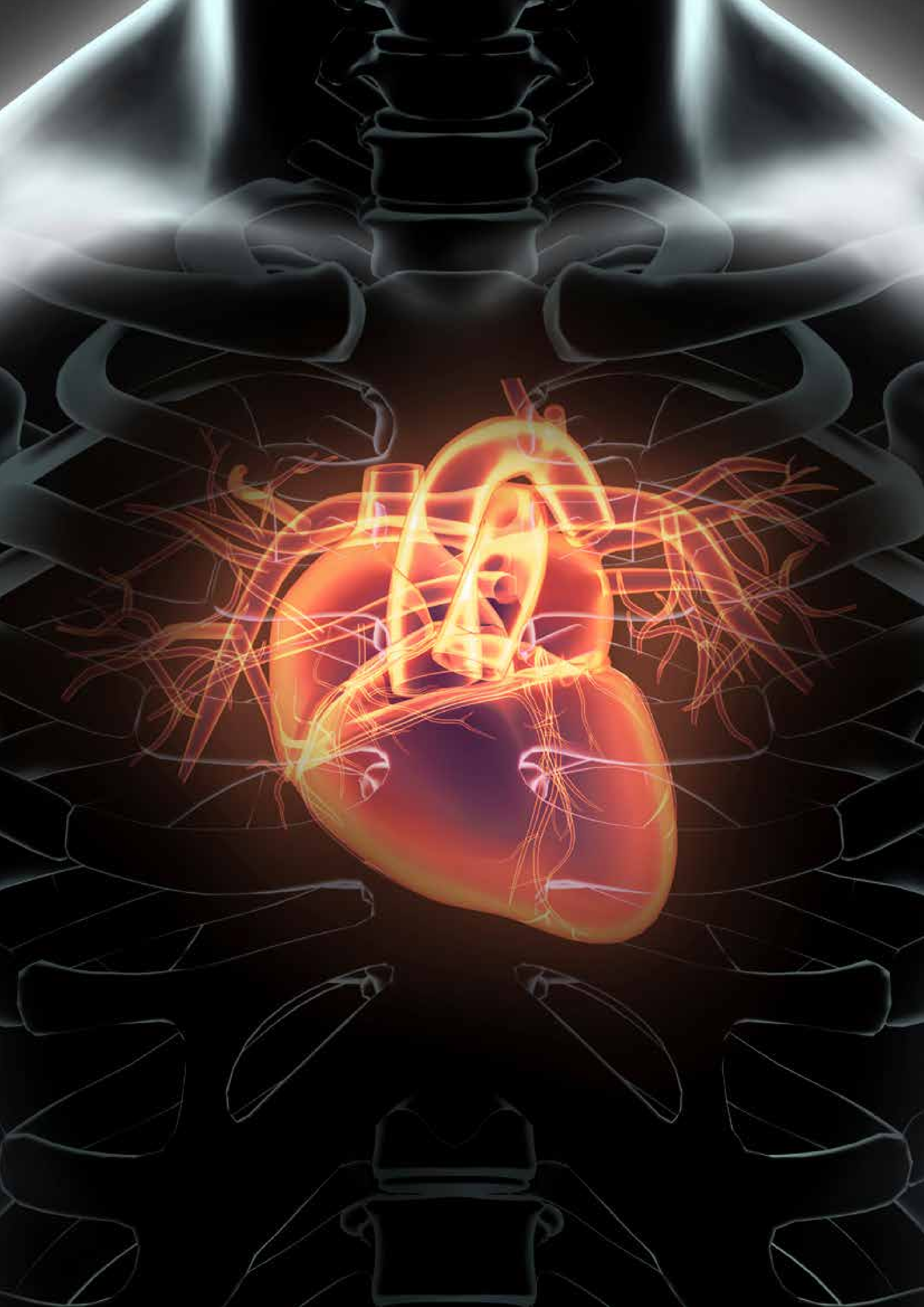

Prime the pump

Introducing simulation-led design exploration to centrifugal blood pump development

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Kuninori Masushige and Yuka Takahashi – Siemens PLM Software

The use of computer-aided engineering (CAE) significantly reduces workload, while ensuring reliability and improving medical device designs, an area where the development span is long and the authentication process is strict. Engineering simulation is now being widely recognized and is being adopted by regulatory authorities, manufacturers and suppliers around the world. One such example is the recent workshop on blood damage studies via modeling of a blood pump, organized by the US Food & Drug Administration (FDA), to set best practices and promote the use of simulation in device design. With increasing visibility and acceptance, CAE is now at the forefront of medical device design and is being actively deployed in bringing the latest products to market.

One such medical device is a Ventricular Assist Device (VAD), a mechanical pump used to increase blood flow to offset a malfunctioning ventricle in the heart and take over the function of the failing heart. While developing a VAD, computational modeling is an efficient tool in finding the best design of the blood pump, the key component, even before building a prototype. Blood pumps in VADs need to deliver the required blood flow while minimizing blood damage like hemolysis and thrombosis from the equipment. The use of CFD allows analysis and optimization of the blood flow and the pump, while offering quantitative prediction of hemolysis, recirculation and blood damage.

To talk about the recent developments in blood pump design using CFD and optimization techniques, we visited Terumo Corporation's (hereinafter, "Terumo") Shonan Center in Japan. The Shonan Center houses the R&D Center, where a variety of next-generation technology is developed, from the application of core technology to the development of new areas, such as diagnostic and therapeutic devices, along with myocardial regenerative therapy and device development for emerging markets.

Terumo - "Contributing to society through health care"

Terumo was established in 1921 as a small-town factory near Tokyo to manufacture thermometers. The company was born from the desire of physicians to produce high-quality thermometers in Japan following a drastic reduction in the volume of thermometers imported from Germany due to World War I. One of the founders of the company was Dr. Shibasaburo Kitasato, who is known as the father of modern Japanese medicine and is famous for his discovery of the plague bacillus and his invention of

Figure 1: Takehisa Mori, Principal Research Manager, R&D Department, Terumo Corporation

tetanus serum therapy. The company name originates from the German word for "thermometer."

Based on the corporate mission of "contributing to society through healthcare," Terumo is expanding its products and services to medical fields around the world through three business domains: cardiac and vascular, general hospitals, and blood management. Terumo is truly a global company with a high overseas sales ratio, with sales by region (as of March 31, 2015) at 63 percent abroad and 37 percent in Japan.

Numerical simulation at Terumo

On this occasion, we talked with Takehisa Mori of the R&D department's exploration team. Mori is responsible for basic research on medical devices, along with investigation, design and development of next-generation products in the field of cardiovascular surgery. In particular, he evaluates the feasibility and challenges of new devices at the conception stage, utilizing computational fluid dynamics (CFD) analysis methods. The Exploration Team is not a specialized CAE department, but applies CFD and optimization techniques to design exploration. Within the field of cardiovascular surgical devices, CFD is used particularly in the development of blood pumps at Terumo. The purpose of introducing a CFD-based design exploration tool is to increase the efficiency of blood pump development and bring a better design to market, faster.

Terumo introduced CFD about ten years ago, and Mori was the first to apply it to development. He assumed a leadership role in promoting CFD within the company and also served in a support role for other departments that were introducing it. In addition to blood pumps, there are still many areas at Terumo where CFD can be applied, such as artificial lungs, devices using drug solutions, pharmaceuticals, stents and various manufacturing processes.

"When I started with CFD, I realized how much I was able to understand designs better. I have been trying to share with researchers in other departments that the (information) range can be too narrow when using only experimentation, and that the range expands if you perform numerical analysis. One cautionary point is that some people think too lightly of simulation, assuming that anything can be simulated or imagined. In reality, it is important to consider what the problem means and what the physical implications are. If there are no such approaches or suppositions, the answers that come out of it are simply images that do not lead to the next step. It is possible that an incorrect solution will be used," says Mori. "Especially in relation to medical devices, for which standards are strict, you can't simply accept results - you must conduct substantial verification. Therefore, it can't all be done with CFD. The prototype is also important. By utilizing CFD, we can build a base for prototype manufacturing to some extent."

Application of CFD and optimization in blood pump development

Next, we asked about design optimization using STAR-CCM+® software and Optimate+, the add-on for design exploration, in

Figure 2: Types of VAD: Extracorporeal-type CAPIOX® (left) and Sarns® (right)

Figure 3: Blood circulation during surgery (left); Implantable type: left ventricular assist device (right)

centrifugal blood pump design. Conventionally, the design method for blood pumps has involved using CFD to analyze dozens of initial-stage models in order to estimate the performance of each under the same conditions, and this method produced several candidate models. Then, pump performance evaluation and blood-related experiments were conducted, with problems in design being rectified. This process was repeated until a final prototype was determined. Consequently, the development period for one product took years.

With STAR-CCM+ and Optimate+, Terumo was able to significantly reduce the development time for blood pumps while achieving a better design, faster. Venturing into this optimization process required simulating a base design in STAR-CCM+ validated with experimental data, which could then be optimized using Optimate+. The simulations led to a prototype which underwent testing for validation of performance. The fluid used in the experiments was blood, and because there are variations in the blood itself and variations in the experimental results, verification was difficult if a relatively long period of data was not available. Furthermore, the viscosity of blood varies from person to person. The blood used for the actual experiments came from animals such as cows, and viscosity differed depending on the type and age of the animal. Therefore, developers also experienced difficulties in accounting for the different viscosity parameters in the experiments.

Two examples of blood pumps used in medical settings are shown in figure 3. When designing a blood pump, it is necessary to meet the following requirements:
> Low hemolysis: low blood trauma (hemolysis)
> Antithrombogenicity: reduced risk of blood clots
> Good pump efficiency: low power consumption, miniaturization of the drive system

Design variable	Casing	3 cases
	Impeller	3 cases
Objective function	Pump efficiency average value	Maximization
	Force applied to impeller	Minimization
Constraint condition	2 L/min	Efficiency of 20% or higher
	8 L/min	Efficiency of 35% or higher

Table 1: Summary of analysis

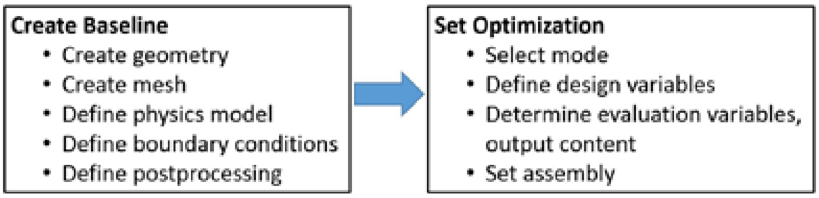


Figure 4: Workflow of the optimization calculations

> Small and simple structure: portability, a size that is easy to implant, reduction in failure probability
> Wide operating range: flow rate of 2-10 L/min; Lifting height of 50-800 mmHg

A streamlined optimization procedure is used because if a researcher is inexperienced, it is difficult to create an optimum form design without design optimization, and parameters that should be explored may be missed. Also, the goal is to see how efficient one can make the design process through optimization calculations.

Terumo researchers aimed at making an extracorporeal centrifugal pump with a general structure and improved pumping efficiency. The pump after optimization was as follows:
> Number of impeller vanes: 12
> Impeller diameter: 60 mm
> Casing having a volute structure

The optimization settings used during the analysis are shown in table 1.

The pump efficiency (η) average value is characterized as:
$\eta \quad (L \times H) / (Rot \times T)$
where L is the pump flow rate, Rot is the rotational speed (2,800 rpm), H is the pump head (pressure loss) and T is the torque applied to the impeller.

As it was necessary to account for the respiratory rate range of an individual, the flow rate was changed in stages from 2 L/min to 8 L/min through a Java macro in STAR-CCM+. The pump efficiency and force applied to the impeller was output using the report function. The optimization calculation flow using Optimate+ is shown in figure 4.

The geometry of the pump was created using the 3D-CAD modeler in STAR-CCM+, as shown in figure 5. As 3D-CAD can parameterize the design variables and as additional licenses are unnecessary, optimization calculations can be implemented in a more seamless manner, saving time and additional license costs.

In addition, Optimate+ is a STAR-CCM+ add-on for the HEEDS™ multidisciplinary design exploration tool. Better designs can be found in a much smaller number of computations with SHERPA, the powerful exploration algorithm of HEEDS.

For the STAR-CCM+ analysis, blood was used as the working fluid, realizable k-ω model was used for the turbulence computations, and the rotational speed of the pump was set to 2,800 rpm. A polyhedral mesh was used, and a prism layer mesh was created for the wall, with approximately 3.4 million cells in total, as shown in figure 6.

The total number of analysis cases from the optimization process was 102, and the time required for the calculations was about six days. Based on the constraints and the base case, Optimate+ automatically refined the design variables (impeller diameter and casing) and iterated the simulations for all cases. Of these, 38 cases met the constraint conditions. Solutions that met all the optimization constraints are shown in figure 7, with the force on the impeller shown on the horizontal axis and the average pumping efficiency shown on the vertical axis.

The best design was defined, not as the one with the best global average pump efficiency, but as the one with the highest average efficiency and the least variations across the range of flow rates. Furthermore, the optimization results showed that a design with good pump efficiency that satisfies the constraint conditions tends to

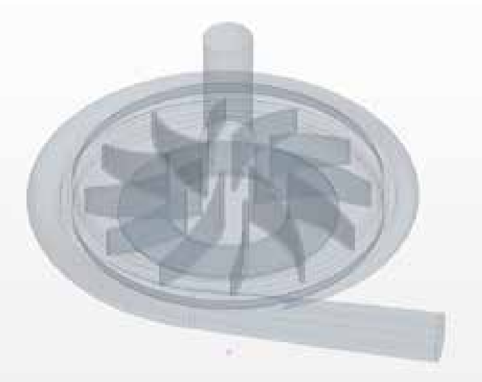
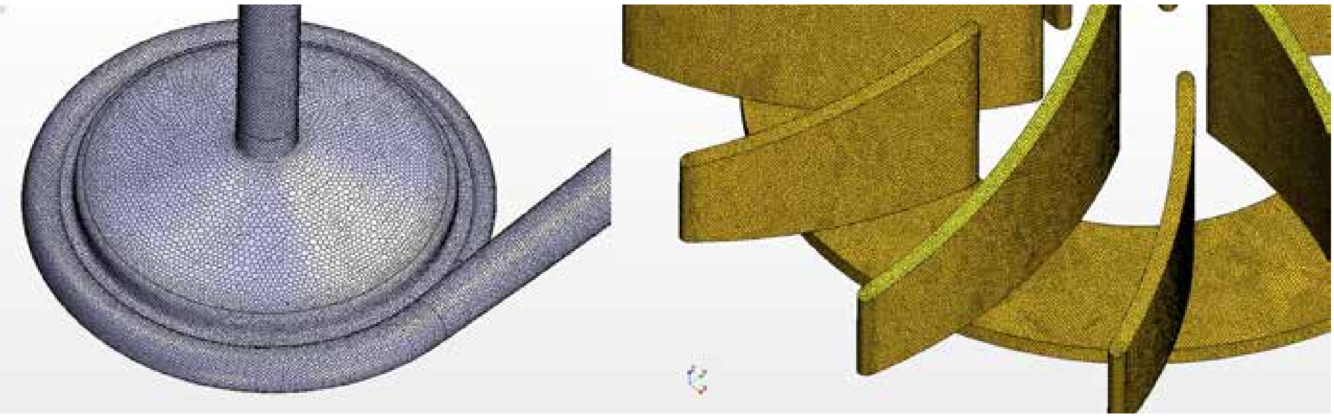


Figure 5: Geometry creation using 3D-CAD (left)

Figure 6: Illustration of mesh (below)



be a design with small values for the height of the opening of the casing side and a small starting diameter. It was found that the shorter the interval between the impeller and casing is, the more efficient the pump becomes. The best design was identified within a week with the simulation-led optimization process.

Difficulties in pump design

One problem when designing a pump is that, although researchers want the pump to be efficient if efficiency takes too high a priority problems with hemolysis occur. Previously, the only way to assess the occurrence of thrombosis was through experimentation, but now a technique using CFD is being established at Terumo. The assessment method indicates that thrombi do not occur as easily if the shear rate in the retention area is lower than a certain threshold. Correlation with experiments is good. Therefore, it has gradually become possible to elucidate various phenomena using CFD instead of experiments. If a problem occurs with products designed before CFD application, it is possible to conduct a root cause analysis and change the design quickly by performing a re-analysis using CFD. Design and troubleshooting have become extremely efficient with the application of STAR-CCM+ to pump design. Previously, the structure of medical devices was simple, thus it was possible to design such instruments without CFD, but due to the increase in design parameters associated with increased functionality, CFD and optimization calculations have become indispensable for design efficiency.

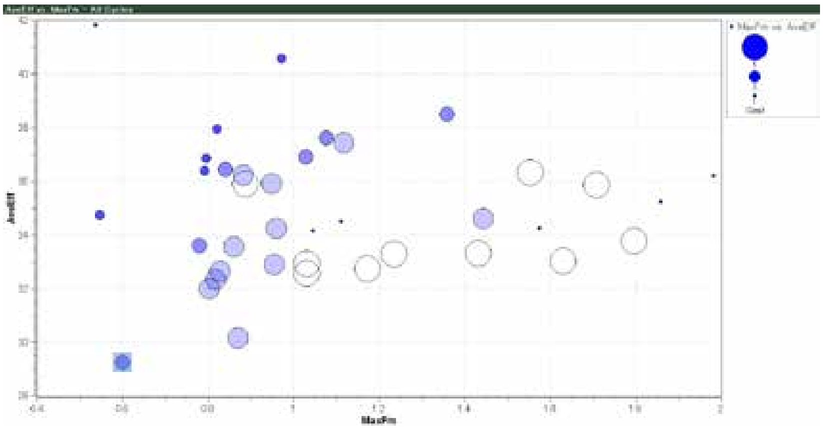


Figure 7: Analysis results showing designs that satisfy the constraint conditions

Lastly, Mori talked about important considerations in the implementation of optimization calculations: "A variety of solutions emerge when implementing optimization calculations. For pumps, values for efficiency etc., are output. However, at that time, if you use only these values, without confirming what is happening to the actual flow, it is possible that you will obtain a meaningless result a week later.

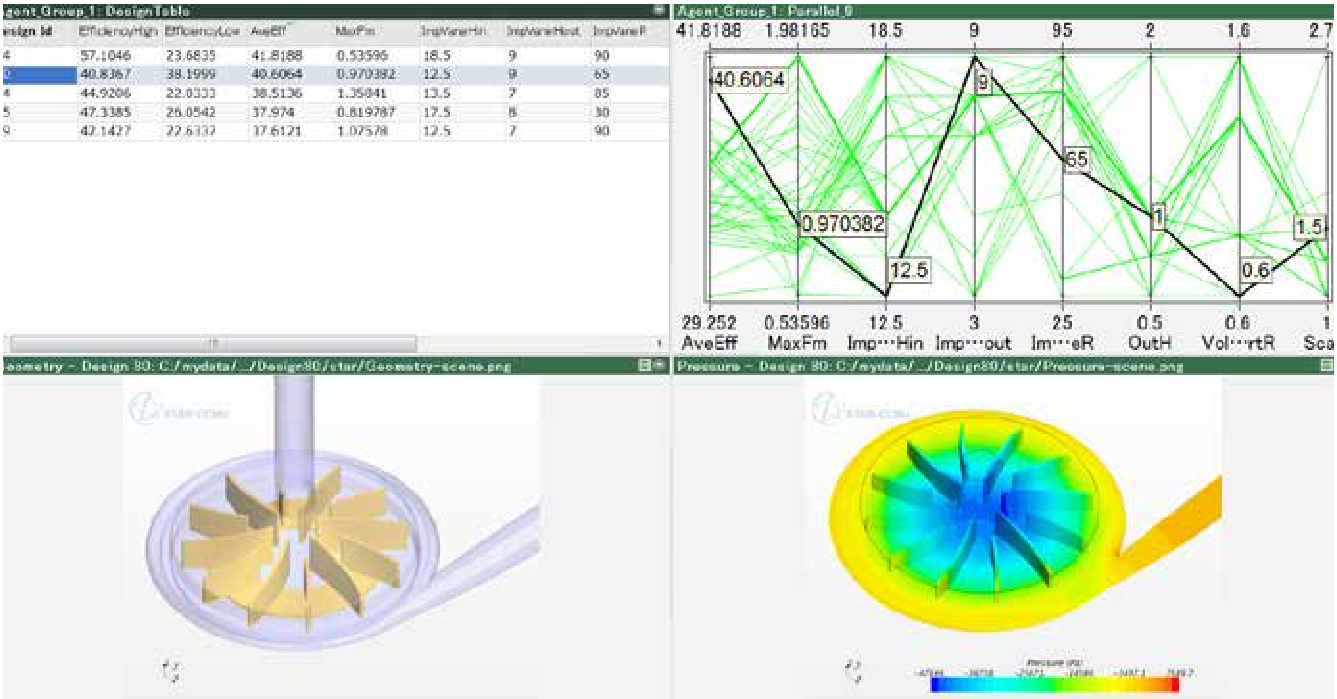


Figure 8: Analysis results showing the pressure profile of the best design

Therefore, a few models should be made in advance, calculations performed, the flow checked properly, and then optimization calculations should be applied. This is more efficient. It is extremely important to check the flow field and understand it precisely."

Reason for choosing STAR-CCM+

STAR-CCM+ is equipped with 3D-CAD modeler, which enables the entire process, from geometry creation to postprocessing, to be implemented in a streamlined fashion from a single integrated user interface. It is especially attractive in that it does not require other software when implementing optimization calculations. In addition, meshing, including STAR-CCM+ surface wrapping for cleaning problematic geometry, is easy, says Mori. "These advantages are the reasons why the team chose STAR-CCM+. Previously, when we used different CFD software, we took the various components of the pump apart, meshing each part, and assembled it using the interface to create one analysis model. Then, we performed analysis, changed the model again, created the mesh, and repeated the process many times. Therefore, analysis was very time-consuming, and the meshing was extremely hard work. We also had to rely on another software to conduct the design optimization. With STAR-CCM+, the meshing is very simple, and the time required has been reduced significantly due to the in-built optimization capability. We basically wanted our workforce to focus more on product design, thus spending a lot of workforce resources for computational modeling is like putting the cart before the horse. This has been improved tremendously."

The next challenge in further fine-tuning this process is to create guidelines for best practices for meshing and analysis. The product groups developed at Terumo are nearly one-of-a-kind, such as their blood pumps and infusion devices, and there is a real need to create standardized best practices for simulation.

Conclusion

Mori is very satisfied with the technical support from Siemens PLM Software, which has helped the group achieve success in deploying simulation-led design. The "My Case" feature and knowledge base articles (FAQ) of the Steve Portal, and Support News, an e-mail magazine, are helpful in directly connecting with the support team at Siemens PLM Software to resolve issues. Technical workshops are also utilized for CFD expansion at Terumo and are contributing to the increase in actual users within the company.

Furthermore, because the overseas ratio of Terumo sales is very high, medical devices are not only being established for use in the Japanese market exclusively, but products are also designed with the global market in mind, from the start of planning and design. Through their use of STAR-CCM+ and Optimate+, Terumo can now discover better designs, faster and play a part in "contributing to society through health care."