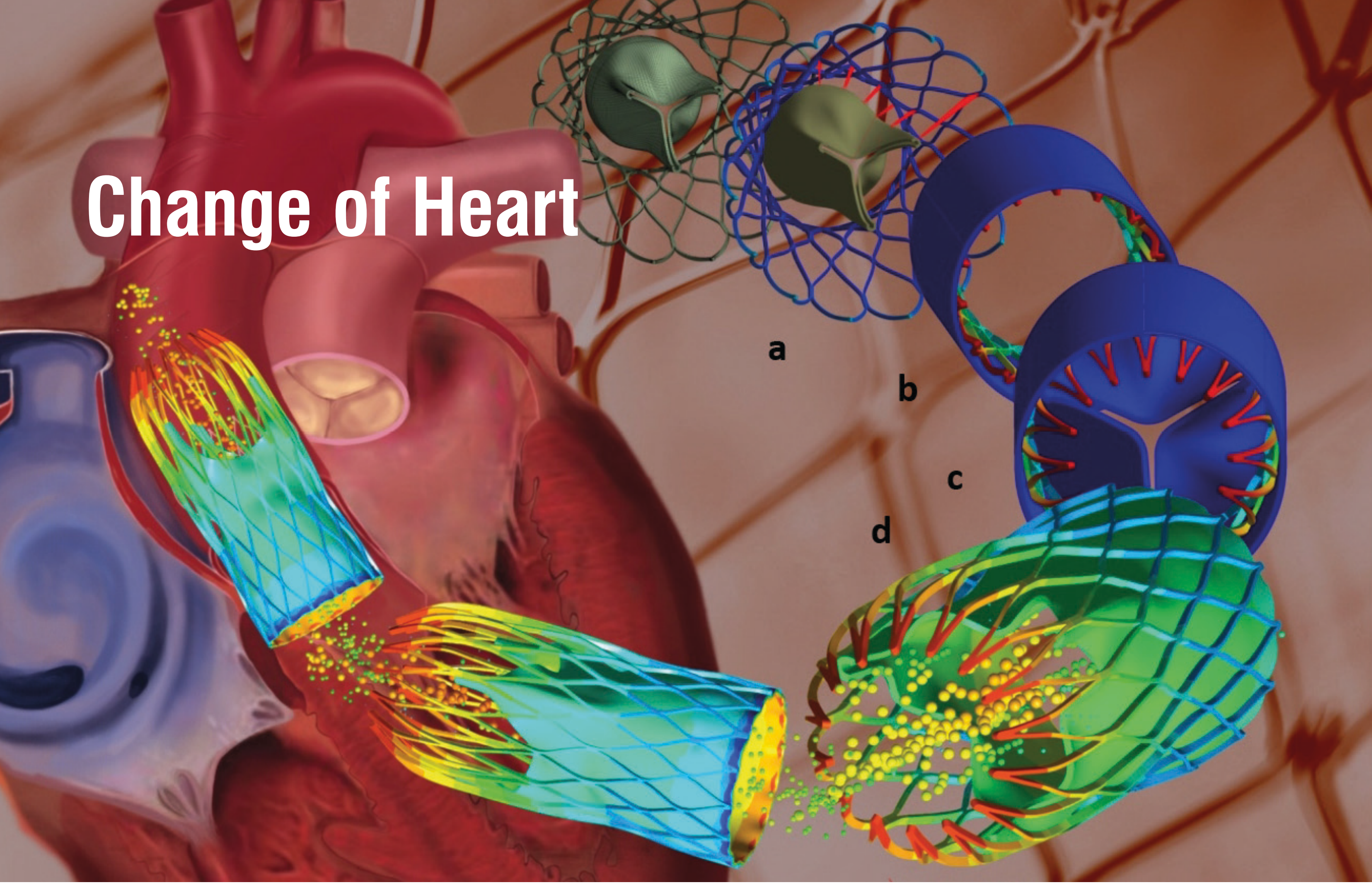
Change of Heart



A new heart valve replacement procedure modeled with multiphysics simulation could eliminate the need for open-heart surgery

SCHUESSLER ADMEDES

Aortic valve stenosis, a narrowing of the aortic valve, is the most common type of heart valve disease. It affects about 2 percent of adults aged 65 or older. Symptoms of this chronic progressive disease include chest pain, difficulty breathing, and fainting; in some cases, congestive heart failure can occur if the valve is not replaced.

Surgical aortic valve replacement, which involves open-heart surgery with a heart–lung machine, has been the definitive treatment for aortic valve stenosis for over 40 years. The surgical team replaces the aortic valve with either a mechanical valve or a tissue valve taken from a human donor or animal. The operative mortality of aortic valve replacement in low-risk patients younger than 70 years is around 2 percent.

Long-term survival following aortic valve replacement is similar to that of patients of a similar age who do not have the condition.

The number of elderly patients with aortic valve stenosis is increasing. These patients are often high-risk candidates for traditional aortic valve replacement. A recent study reported an operative mortality rate of 24 percent for patients who are 90 years and older after open-heart surgery — so there is a need for a less-invasive aortic valve replacement technique.

Transcatheter aortic valve replacement (TAVR) (also called transcatheter aortic valve implantation or TAVI) is a relatively new approach to traditional treatment. For this procedure, a tissue valve attached to an expandable stent is inserted into an artery near the groin and delivered via a catheter into position in the aorta. The stent is then expanded against the aortic wall to hold the existing valve open and secure the replacement valve in the proper position. This method eliminates the need for open-heart surgery.

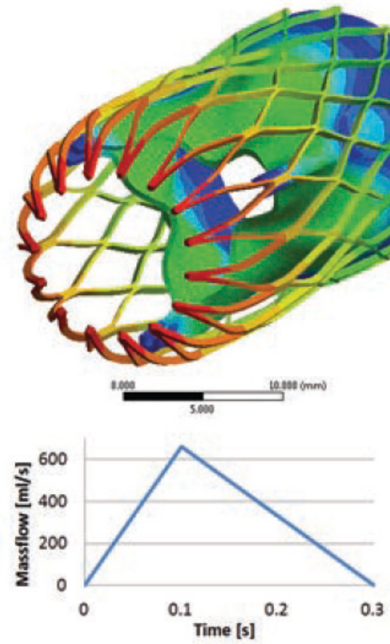


Fig. 1 – Deformation of stent due to blood flow as predicted by multiphysics simulation

Answers needed to improve new surgical method

TAVR has been performed only a relatively small number of times, so there are many unanswered questions. What are the forces exerted by the blood and aortic wall on the stent, and how long will the stent last under these loads? Is the friction between the stent and aortic wall sufficient to hold the stent and valve in the proper position over a long period of time? Answers to these and other questions could lead to the design of improved stents and help surgeons make more informed decisions on which type of surgery to use for specific patients.

There is no way to accurately measure forces on an implanted stent, so manufacturers of TAVR stents are simulating the process of implanting a stent and valve to better understand the method and estimate the forces on the implanted stent. This is a very complex analysis problem. The first challenge is modeling the highly nonlinear material properties of the shape-memory alloy (SMA) Nitinol™, which is commonly used for TAVR stents. Nitinol is an alloy of approximately 50 percent nickel and 50 percent titanium with a high biocompatibility and corrosion resistance.

The most important characteristic of this shape-memory alloy is its super-elasticity, which allows self-expansion of the stent after release from a catheter. Simulation needs to include folding the stent prior to surgery (crimping) as well as releasing the stent against the aortic wall when it reaches its resting position in the aorta. An even greater challenge is the need for two-way coupled fluid–structure interaction, which shows forces on the stent that result from the relationship between flowing blood and the aortic wall.

Mesh morphing and remeshing in the fluid domain is required because of large displacements of the replacement valve.

First successful TAVR multiphysics simulation

CADFEM engineers overcame these challenges and produced what they believe to be the first successful simulation of a TAVR procedure that accounts for the impact of flowing blood on the stent after expansion. They used ANSYS Fluent computational fluid dynamics (CFD) software to simulate blood flow because its remeshing capabilities make it possible to accurately model the large displacement of the heart valve during simulation.

The engineers employed ANSYS Mechanical to model the stent and heart valve because the software can accurately model the memory alloy and orthotropic properties of the tissue valve. The orthotropic model accounts for the fact that the valve is stiff when pulled but bends easily. Both simulation tools run in the ANSYS Workbench environment, in which it is relatively simple to unite fluid and structural models in a two-way coupled transient simulation using system coupling. The transient fluid–structure interaction simulation was run from 0 to 0.3 seconds. CADFEM engineers used a constant-temperature super-elastic model for the material properties of the shape-memory alloy because they didn't have enough data to model the effects of temperature changes. The model undergoes a phase change as it is crimped to its compressed state. Solid shell elements, which can model thin geometry more efficiently, made up the structural model.

A rigid model of the aortic wall was used in this initial analysis to save modeling and computation time. Engineers employed a bonded contact to connect the replacement valve to the stent; they used frictional contacts at the interface between the stent and the aortic wall. They applied the non-Newtonian Carreau model to predict variation of blood viscosity as a function of its shear rate. The boundary condition for the fluid model is utilized as a function for the mass flow rate of blood that models the heart's pumping action. Blood flow causes the valve to open and close.

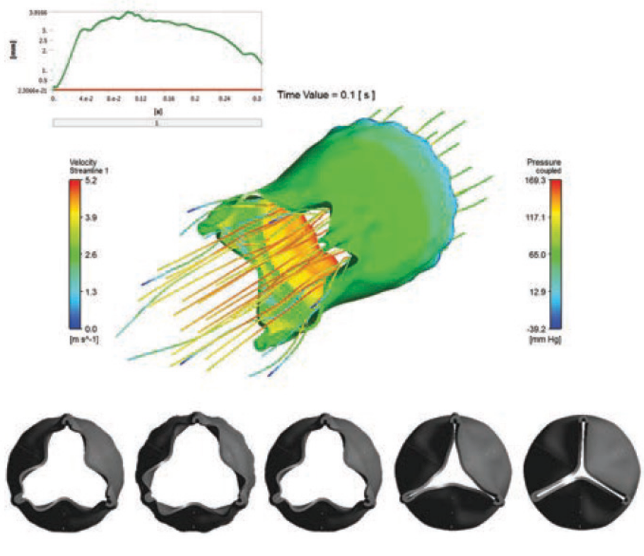


Fig. 2 - Fluid–structure interaction tracks displacement of the heart valve

Simulation useful for surgeons and stent manufacturers

Simulation results showed the contact status and pressure at the stent–aortic wall interface. The results will be useful in evaluating the ability of proposed stent designs to lock the valve firmly in place. Simulation makes it possible to design the stent to avoid exerting too much stress on any part of the aortic wall. Von Mises stress–strain curves were generated for specific points on the stent model, and these curves could be used to predict fatigue life of the stent using a fatigue analysis model. The simulation also generated the time evolution of forces at joints between the valve and the stent. The model predicts a patient's blood pressure following surgery, which is another critical factor in stent design. The systolic blood pressure in this case was about 175 mm Hg.

CADFEM produced the simulation for Admedes Schuessler GmbH, the leading global provider of finished Nitinol self-expandable components to the medical device industry and a manufacturer of TAVR stents. This pilot study proved the feasibility of accurately modeling TAVR surgery. It provided results that can be used to optimize stent design for patients under different conditions, such as various amounts of hardening of the aortic wall. The next step is to incorporate a flexible aorta using either the ANSYS Mechanical anisotropic hyperelasticity model, which models fiber reinforcements in an elastomer-like matrix typical of living tissue, a userdefined model or simply a visco-elastic model.

Finally, these results demonstrate the potential of multiphysics simulation to drive improvements in stent design and surgical procedures by providing insights that otherwise could be gleaned only through the experience of operating on human patients.

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This work was made by CADFEM (Suisse) AG. Founded in 1985, CADFEM provides everything that is required for the success of the simulation from a single source: First-Class software and complete, ready-to-use systems; comprehensive services; the latest knowledge. CADFEM is the ANSYS Competence Center FEM in Central Europe.
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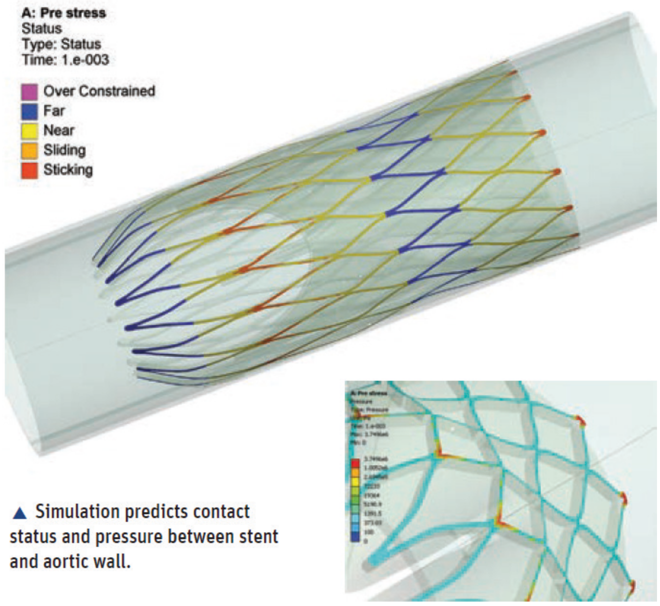

Fig.3 - Simulation predicts contact status and pressure between stent and aortic wall

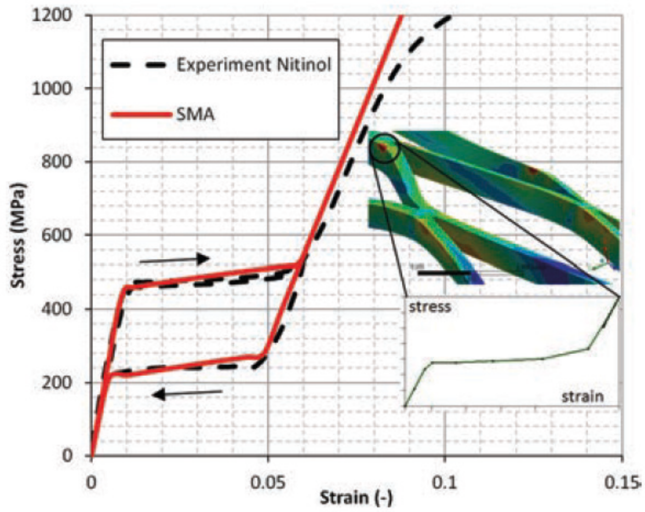

Fig.4 - Stress prediction for selected point on the stent helps determine fatigue life of stent

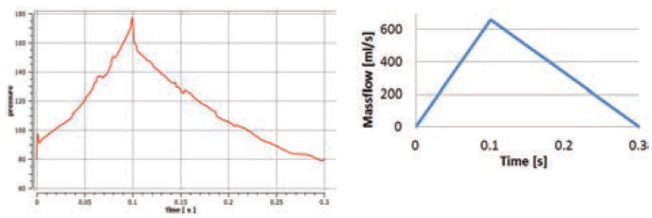

Fig.5 -Simulation predicted the patient's blood pressure after valve replacement. The blood pressure reading was high because the aortic wall was modeled without flexibility

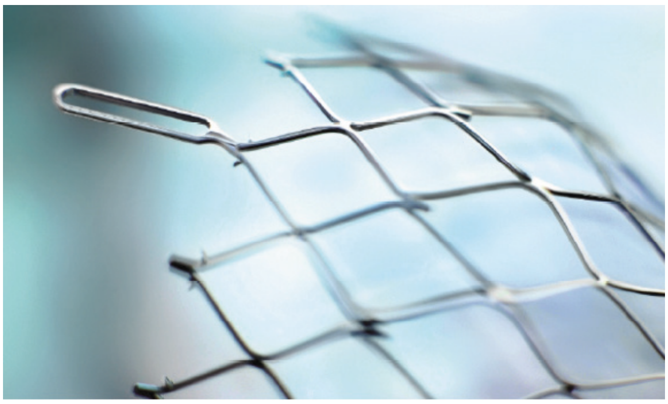

Fig.6 - A real expanded stent on which pericardium leaflets will be mounted

For more information in Biomedical CAE applications:
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