# VIAS Life Science - Capabilities

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# Who We Are

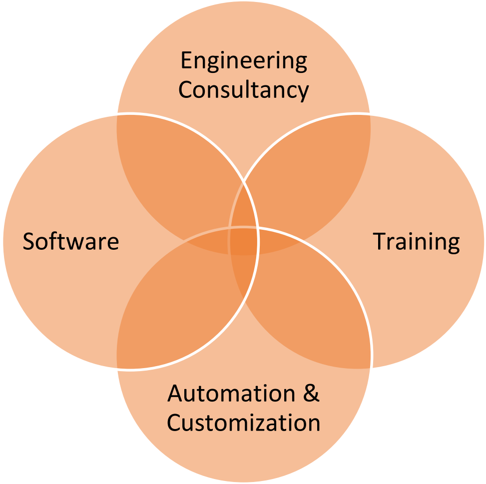
- Multiple Industry Experience – Life Science, Medical Equipment, Oil & Gas, Petrochemical & Process, Machinery & Equipment, Nuclear, Aerospace, CPG, Hi-tech, Manufacturing and Automotive

- Global Presence with Head Quarters in Houston, TX, USA

- Team consists of +50 employees with 7 PhD's and 7 MSc/MTech's in Design, Manufacturing, Structural Mechanics, Fluid Mechanics, Electromagnetics, Optimization & Reliability, Data Analytics, System and Hardware Architecture

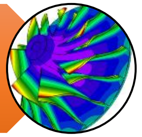
- Dassault Systèmes Platinum Partner

- Provide Engineering and PLM Consultancy, Training, Software Sales and Support, Automation and Customization

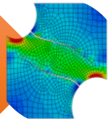



# VIAS Technical Capabilities for LS

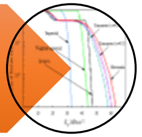
FEA based Design and Validation using Simulation



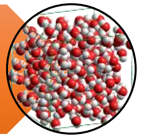
FEA based Fracture / Damage Mechanics



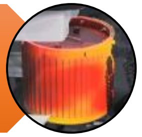
Design Optimization and Reliability



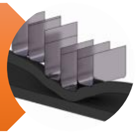
Molecular / Chemistry Simulation



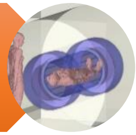
Flow & Themal

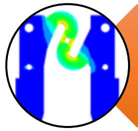


Fluid Structure Interaction

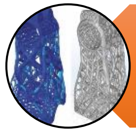


MRI & Thermal Treatment





Multi-physics Simulations (Thermal-Electrical -Structural)

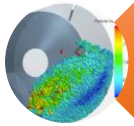


3D Printing – Process Simulation

Non-linear FEA – Tissue Modeling, Material Souroutine, etc.

Simulation Automation

Smart Health and Communication Devices



Discrete Element Method (DEM)

Data Analytics & Mechanical Testing

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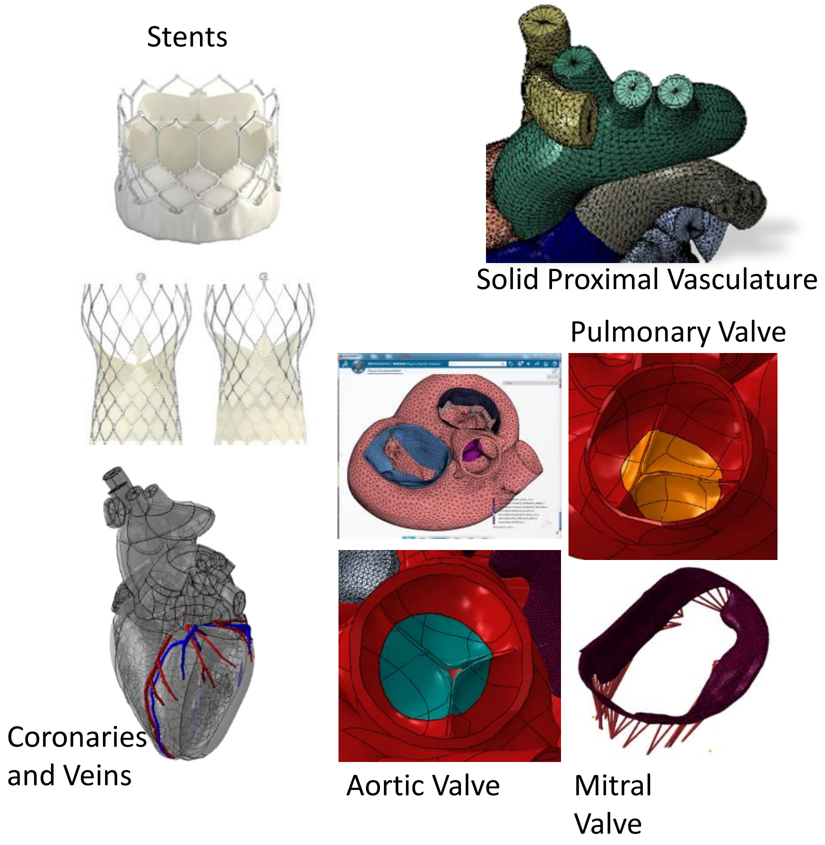
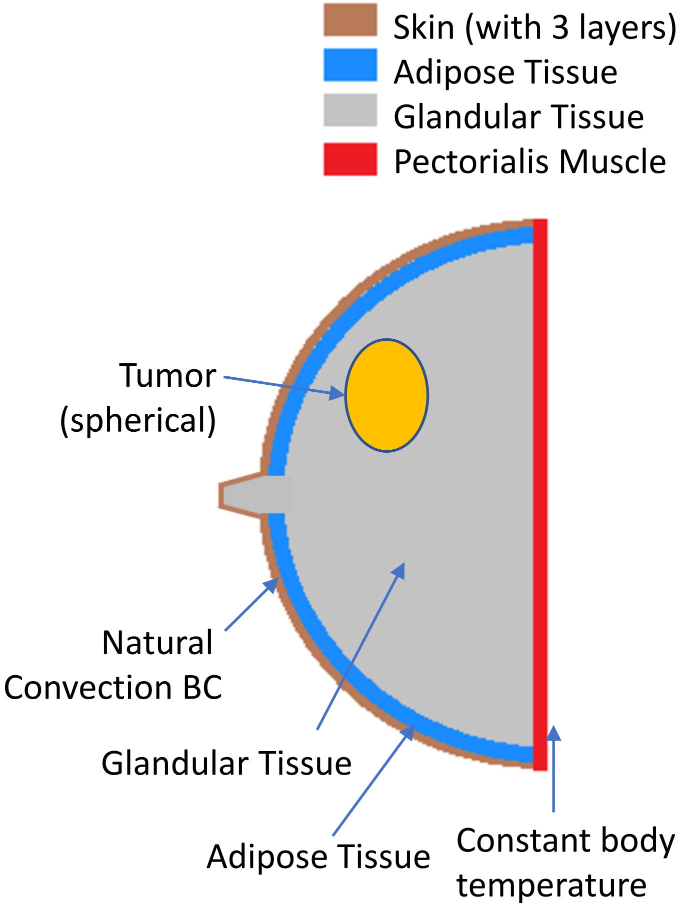
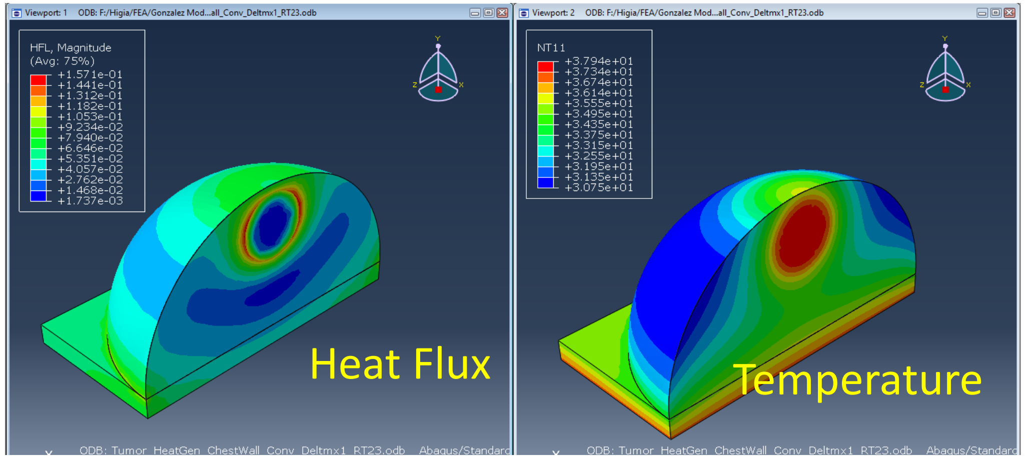
# Life Science Simulation Applications

- Design and Optimization of stents, heart valve, LVAD (Left Ventricular Assist Devices), Pacemakers, etc.
- Simulating Surgical Procedures
- Pharma: Drug-Induced Arrhythmia
- Medical Image Diagnostics
- Heart Performance Evaluations
- Patient Specific Design and Evaluation
- Generating Realizations of Cardiac Parameters
- Etc.



# Thermal Simulation of Tumor



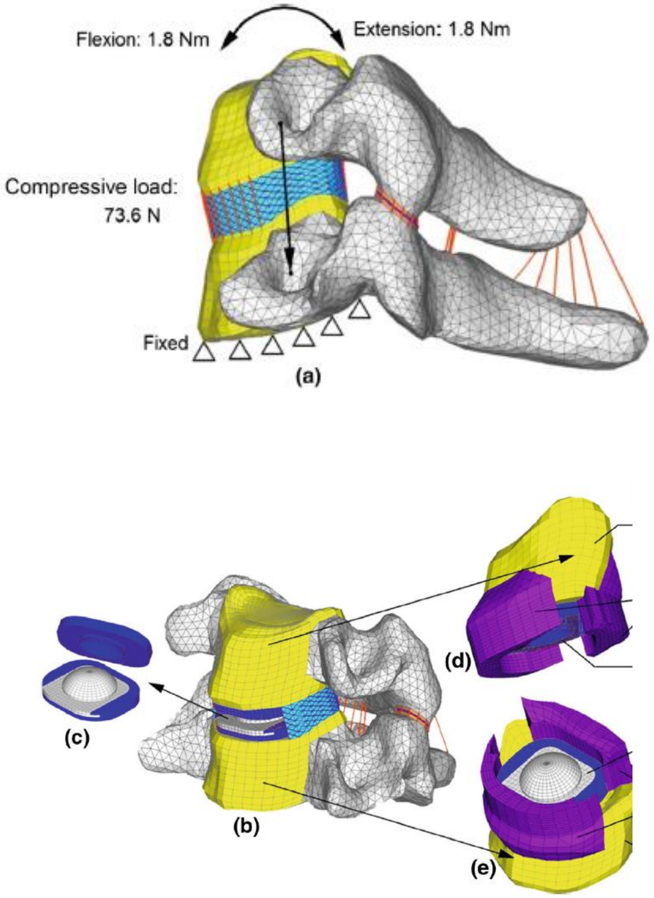




Variable Parameters
- Tumor (#, shape, loc)
- Breast Shape
- Tissue Properties
- Bio-Heat Generation

Output of Interest
- Temp. on skin

# Interbody Implant Cages

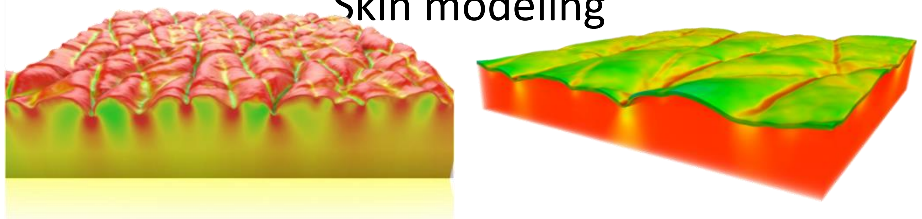
- Study the spine behavior with the complete osseointegration of the interbody implant cage.
- Compare different shapes and materials of interbody implant cages.
- Bone fusion can be simulated using various load transfer mechanisms (e.g. for incomplete fusion – no extension load will be transferred).
- Subsidence can be calculated based on von Mises stress on the bone surface.
- Using strain energy density (SED) from FEA, ossification can be considered.



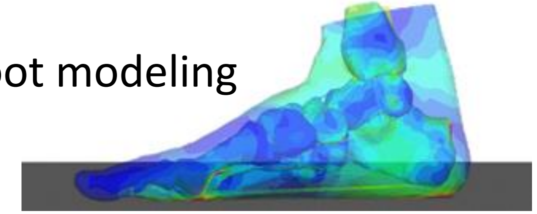
# Tissue Modeling

- Complex material model
- Extreme range of environment: skin, blood vessels, tendons, ligaments, muscles, bones, organs, skin, cartilage, etc.

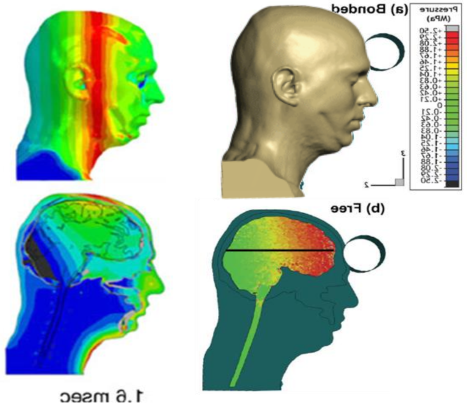
Skin modeling

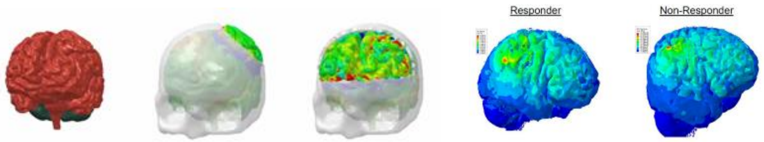


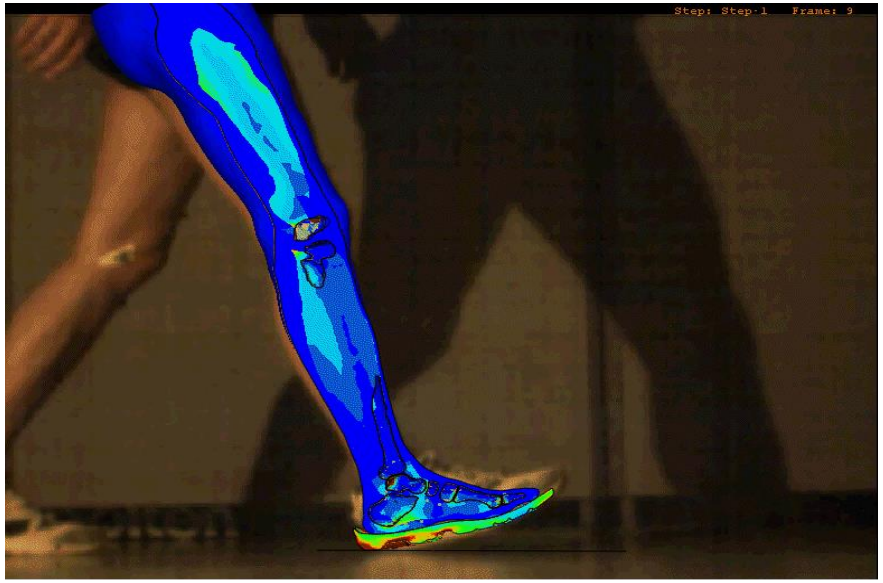
Foot modeling



Head impact modeling

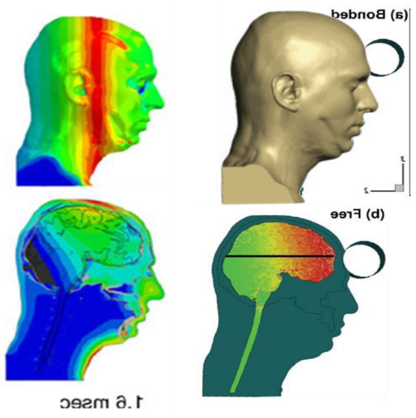




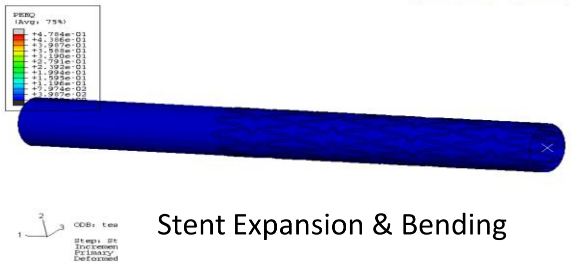




Gait analysis including bony structures, soft tissue, cartilage, ligaments and fascia

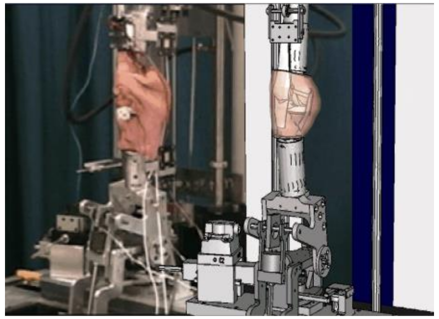
# Other FEA Applications in Life Science



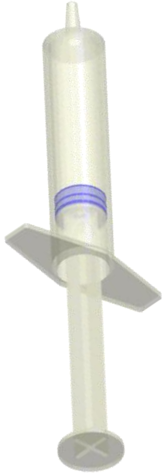
Head impact simulation



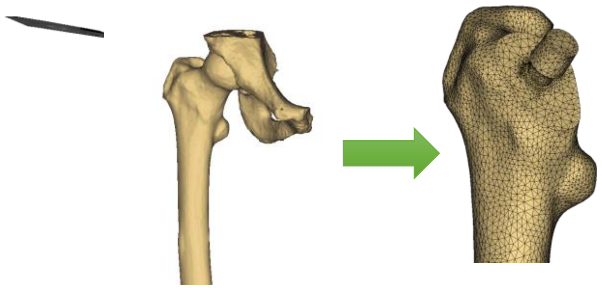
Stent Expansion & Bending



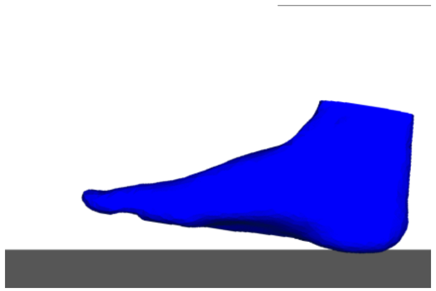
Knee Joint Wear



Syringe leakage analysis



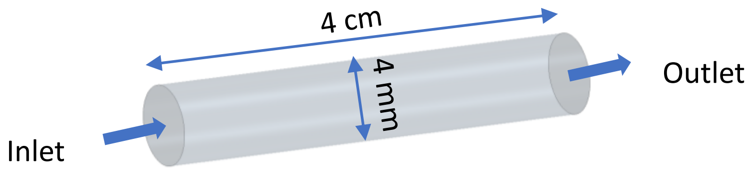
Implant Solutions



Foot modeling

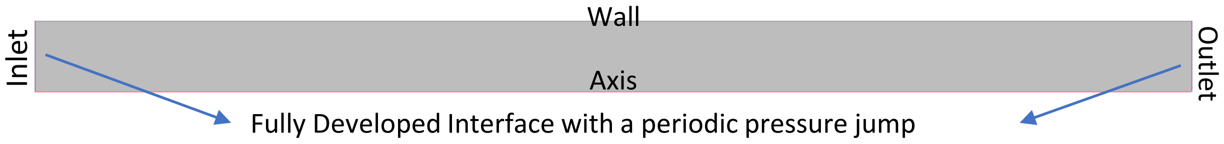
# ASME V&V 40 CFD Subgroup–Womersley Flow Code Verification

Problem Description: The Problem of interest is Womersley flow which is unsteady, fully-developed laminar flow in a rigid tube exposed to an oscillating pressure field.

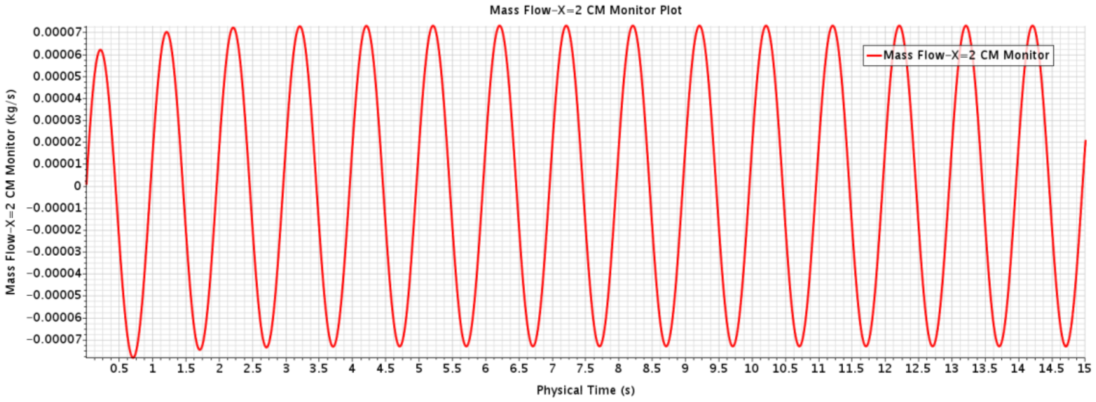



Boundary Conditions:

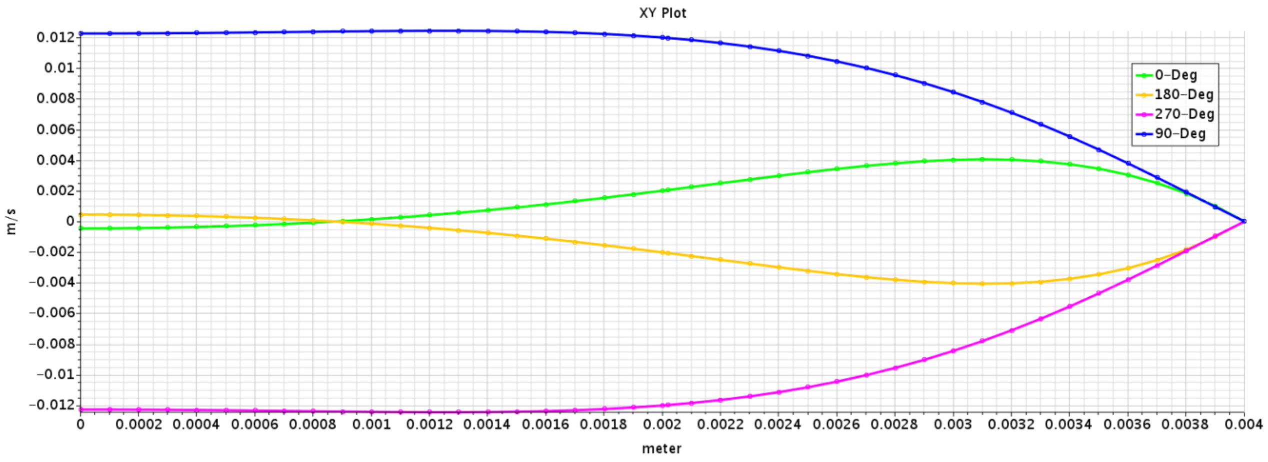
- Inlet Pressure: (dP/L)*cos(ωt)
  - dP: 3 Pa (Max. Pressure drop)
  - ω: 1 sec
- Outlet Pressure: 0 Pa




**Mass Flow Rate at X=2 cm**




**Axial Component of Velocity across Pipe Radius (Phase Angles)**

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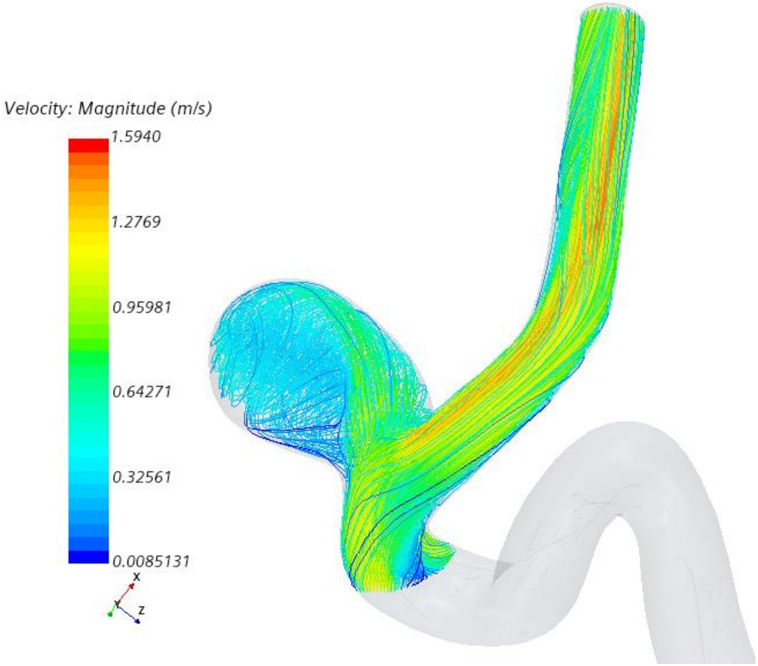
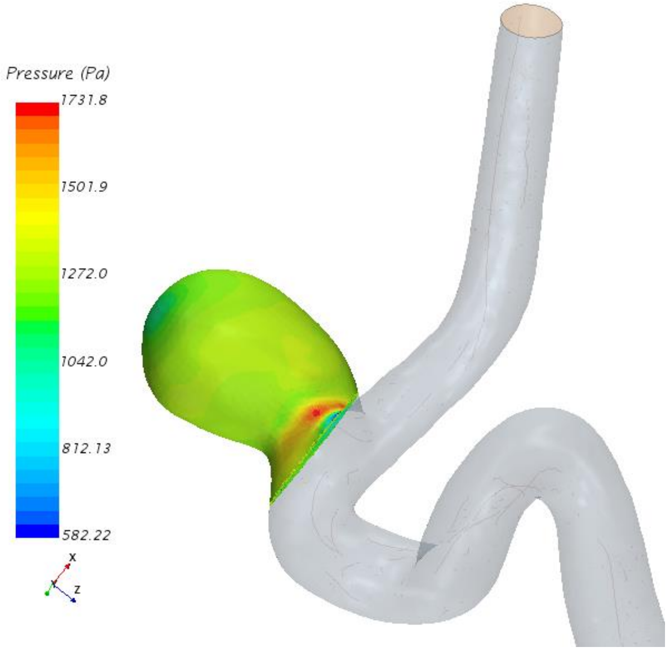
# Aneurysm

<u>Problem Description:</u> Numerical modelling of Flow through Aneurysm

Pressure
Outlet

Mass flow

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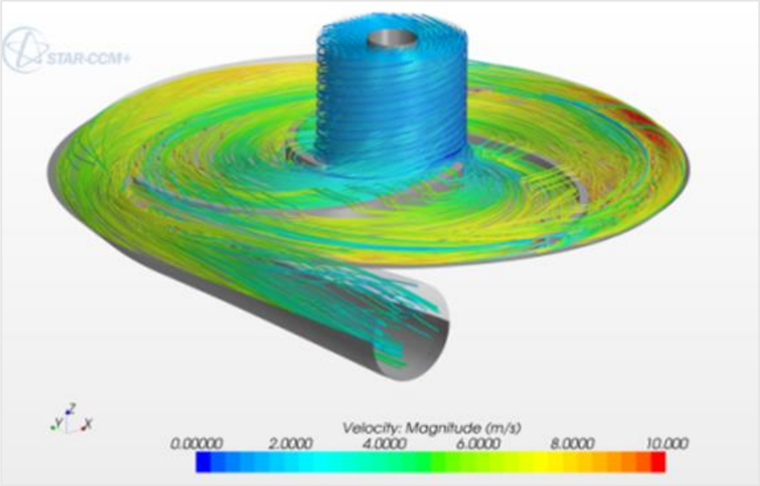
# Flow Modeling – Blood Pumps

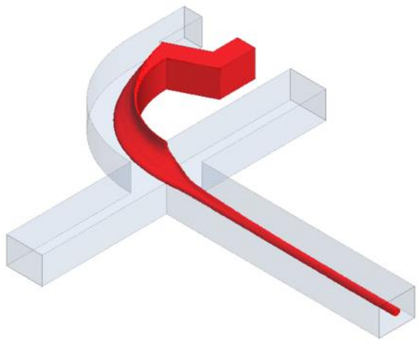
- Gain insight into cavitation threshold and maximum allowable shear rates with CFD

- Simulate clots with DEM in pulsatile non-Newtonian blood flow

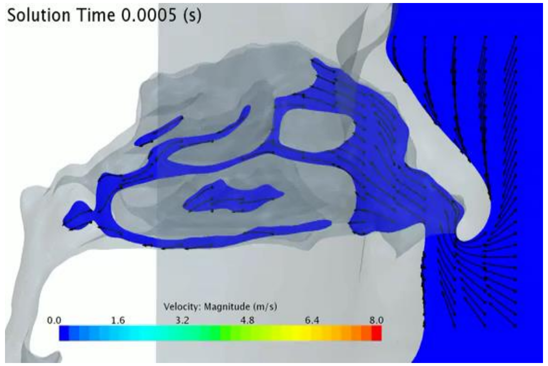
- Avoid excessive cavitation, damaging both blood an pump



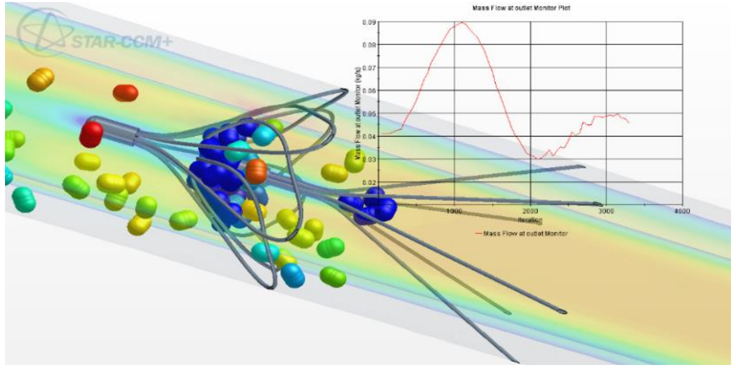

# Other Life Science Applications using CFD …



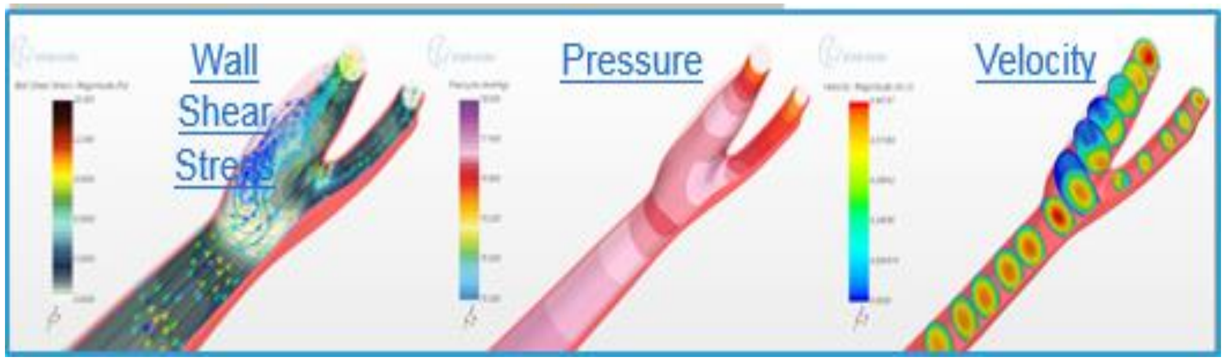
Microfluids



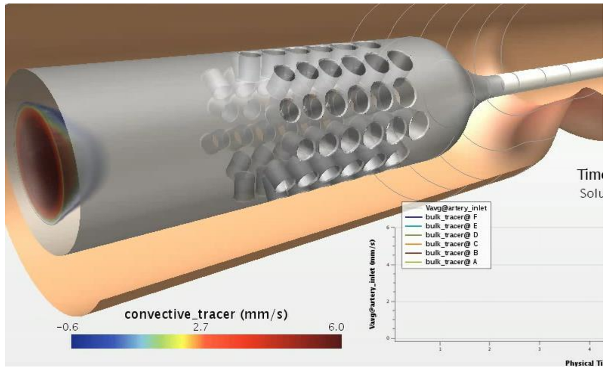

Velocity profile during a  Sniff




Aortic Coarctation - Windkessel model




Hemodynamic Model




Catheter – Drug Delivery

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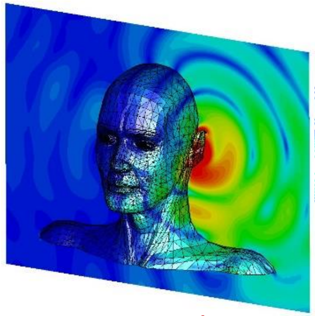
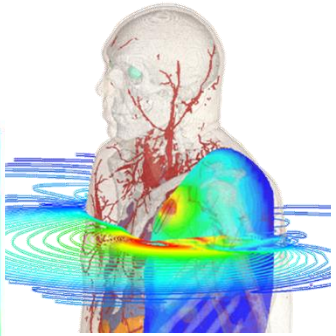
# Electromagnetics in Life Science

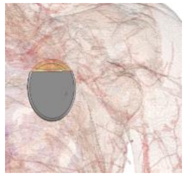
- Wearable and implantable devices
- Treatment of cancer or tumor using electromagnetic energy
- The use of electromagnetic waves to image the internal parts of the body
- Magnetic Resonance Imaging

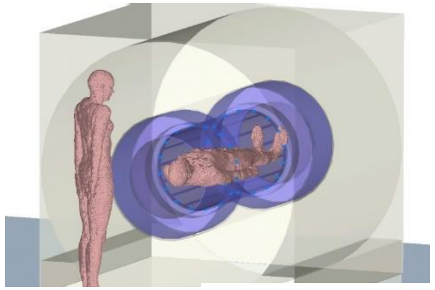


Hearing Aids

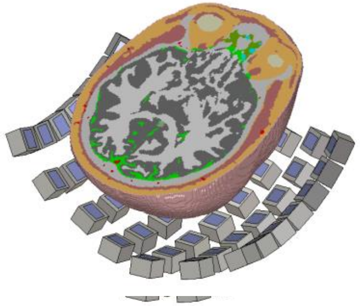


Pace-Makers

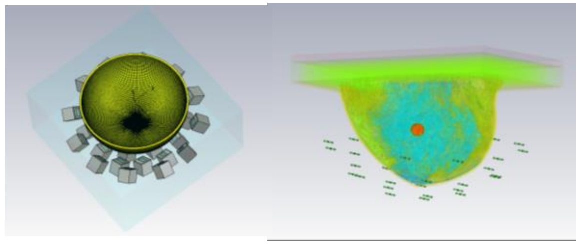




MRI

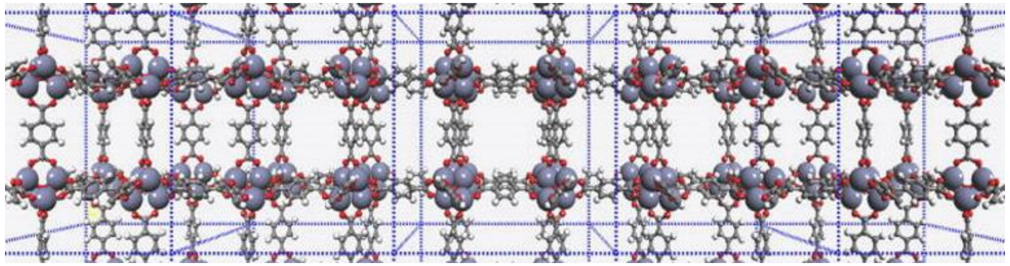


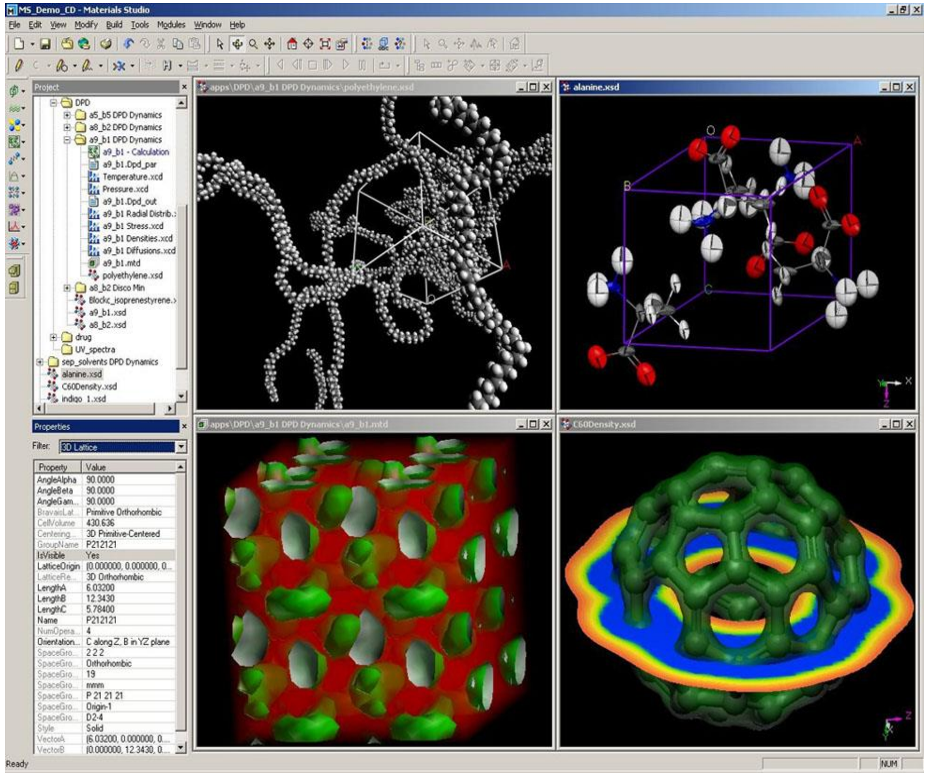
Microwave Imaging



# Drug Research and Development

- Modeling and simulation environment to enable researchers in materials/drug science and chemistry to develop new materials
- Predicting the relationships of a material's atomic and molecular structure with its properties and behavior



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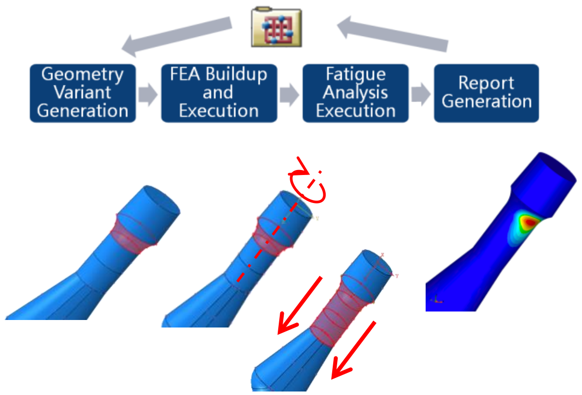
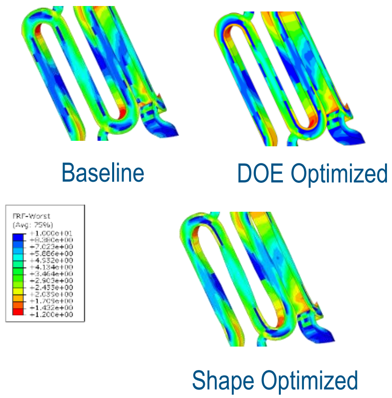
# Performance, Efficiency & Reliability

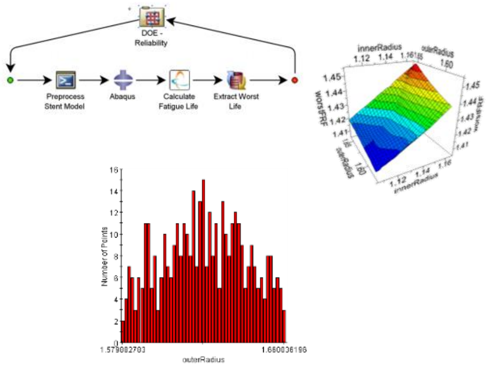
Study wider range of designs, tolerances, and operating conditions




Process Capture and Automation




Optimization

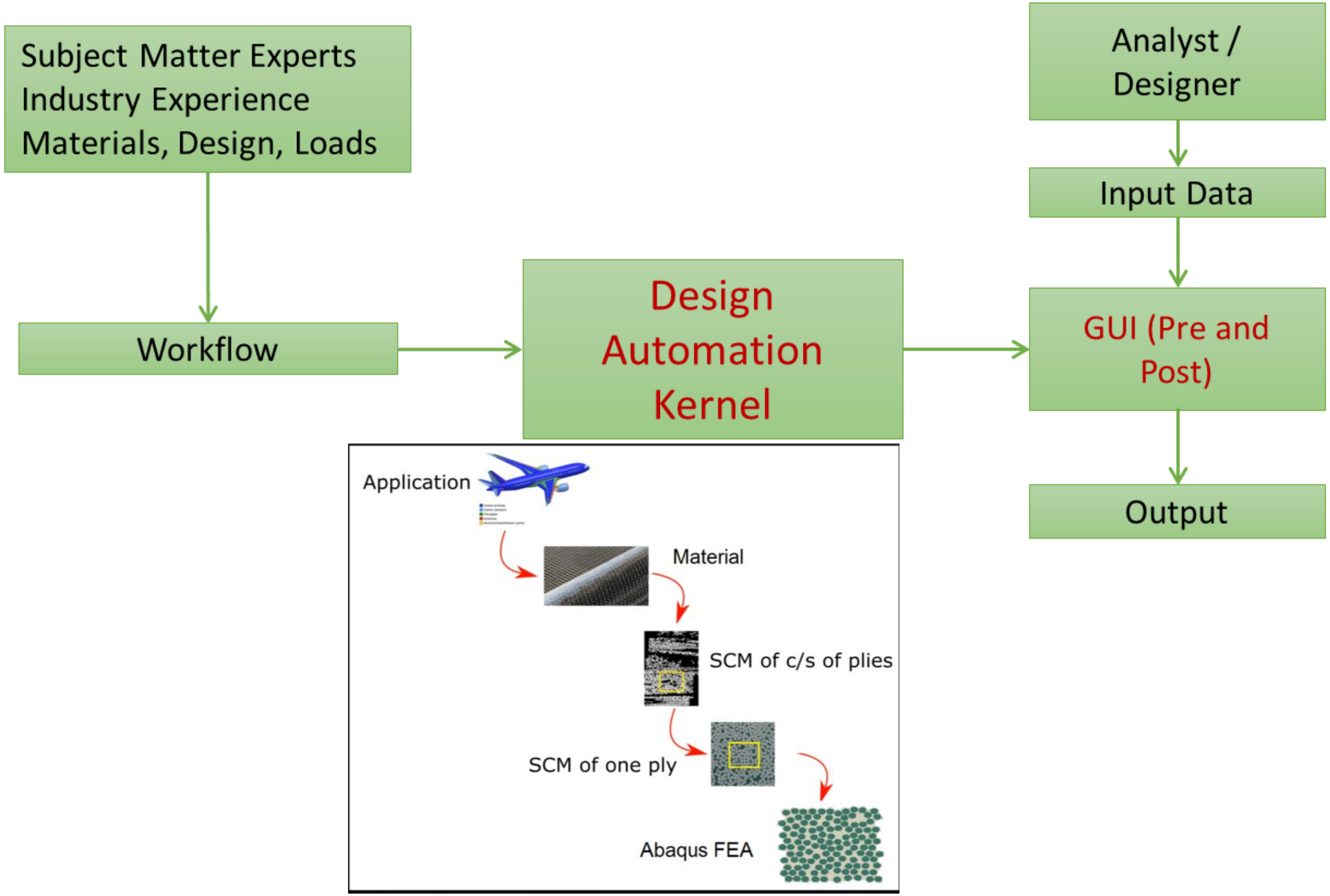



Uncertainty Assessments

Reduce device development time and costs

Improve confidence in device reliability

# Simulation based Design Automation Solutions / Plug-Ins

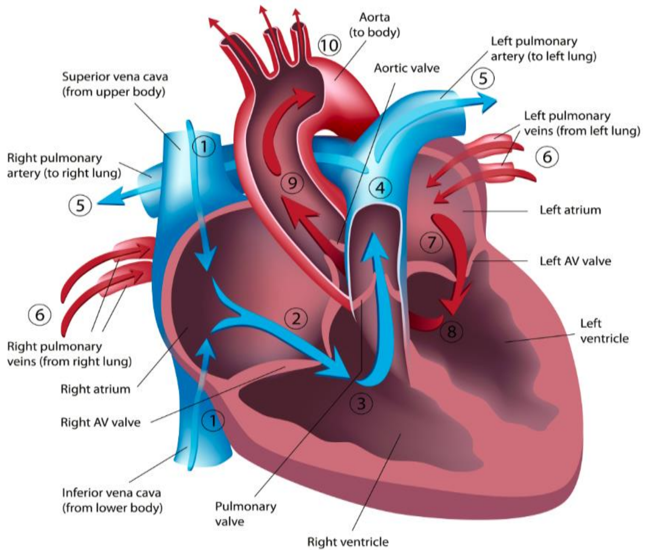


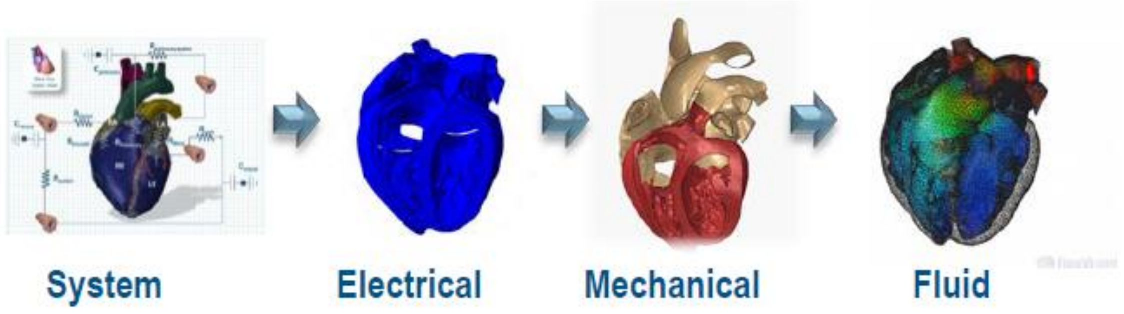
# Heart Modeling

# Cardiac Physics

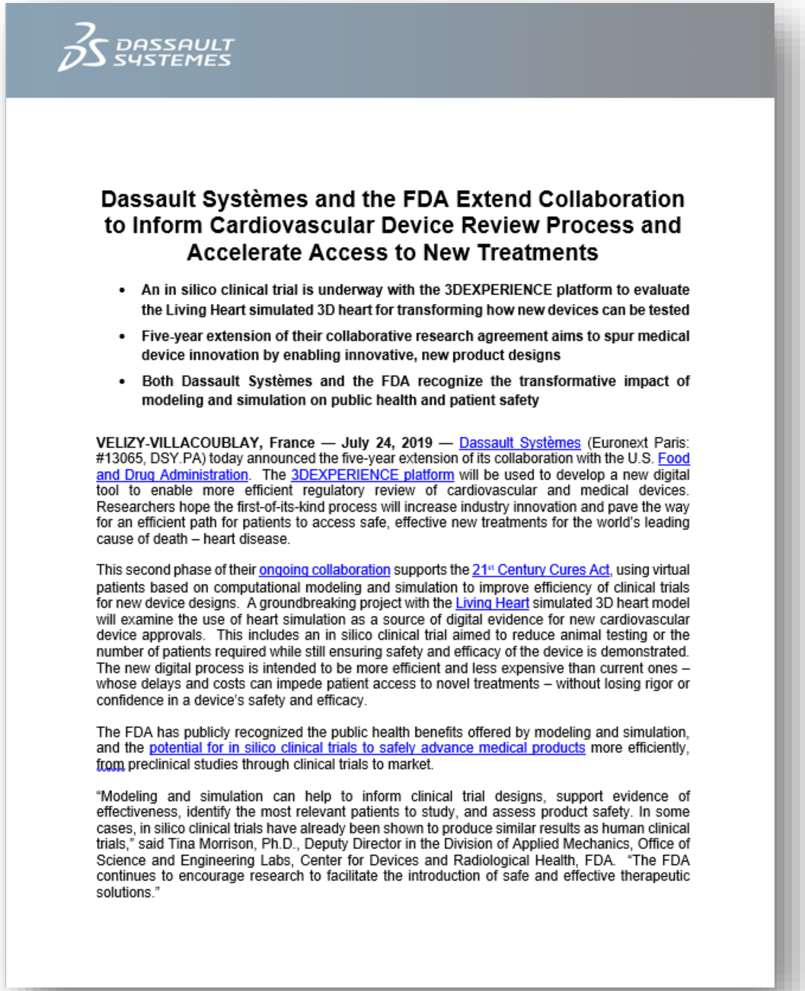
***Complete Cardiac function involves multiple physics & multiple scales***

- Fluid: Pressure changes in heart chambers force blood through the heart and around the body
- Mechanical: Muscular contractions in heart muscle affect chamber volumes and pressures
- Electrical: Electrical stimuli cause muscle contractions



# Simulation in the Context of FDA



DASSAULT SYSTEMES

**Dassault Systèmes and the FDA Extend Collaboration to Inform Cardiovascular Device Review Process and Accelerate Access to New Treatments**

- **An in silico clinical trial is underway with the 3DEXPERIENCE platform to evaluate the Living Heart simulated 3D heart for transforming how new devices can be tested**
- **Five-year extension of their collaborative research agreement aims to spur medical device innovation by enabling innovative, new product designs**
- **Both Dassault Systèmes and the FDA recognize the transformative impact of modeling and simulation on public health and patient safety**

**VELIZY-VILLACOUBLAY, France — July 24, 2019 —** Dassault Systèmes (Euronext Paris: #13065, DSY.PA) today announced the five-year extension of its collaboration with the U.S. Food and Drug Administration. The 3DEXPERIENCE platform will be used to develop a new digital tool to enable more efficient regulatory review of cardiovascular and medical devices. Researchers hope the first-of-its-kind process will increase industry innovation and pave the way for an efficient path for patients to access safe, effective new treatments for the world's leading cause of death – heart disease.

This second phase of their ongoing collaboration supports the 21st Century Cures Act, using virtual patients based on computational modeling and simulation to improve efficiency of clinical trials for new device designs. A groundbreaking project with the Living Heart simulated 3D heart model will examine the use of heart simulation as a source of digital evidence for new cardiovascular device approvals. This includes an in silico clinical trial aimed to reduce animal testing or the number of patients required while still ensuring safety and efficacy of the device is demonstrated. The new digital process is intended to be more efficient and less expensive than current ones – whose delays and costs can impede patient access to novel treatments – without losing rigor or confidence in a device's safety and efficacy.

The FDA has publicly recognized the public health benefits offered by modeling and simulation, and the potential for in silico clinical trials to safely advance medical products more efficiently, from preclinical studies through clinical trials to market.

"Modeling and simulation can help to inform clinical trial designs, support evidence of effectiveness, identify the most relevant patients to study, and assess product safety. In some cases, in silico clinical trials have already been shown to produce similar results as human clinical trials," said Tina Morrison, Ph.D., Deputy Director in the Division of Applied Mechanics, Office of Science and Engineering Labs, Center for Devices and Radiological Health, FDA. "The FDA continues to encourage research to facilitate the introduction of safe and effective therapeutic solutions."

Demonstrate how digital evidence in the form of *virtual patients* can be used to significantly reduce the time, cost, and risk associated with human clinical trial data development and collection


Demonstrate that a collaborative PLM platform can improve the robustness, response time, and transparency of the medical device review process.

FDA

Enable regulators with full digital access to all relevant information and people required to make rapid, science-based, informed regulatory decisions.

Ref. Also the Avicenna Alliance (Association for Preventive Medicine, Avicenna-alliance.com) "The Avicenna Alliance itself has its origins in the Avicenna Roadmap, a 2-year EU funded project, led by DG Connect whose goal was to create a research and technological development Roadmap outlining a strategy for *in silico* Clinical Trials (ISCT).

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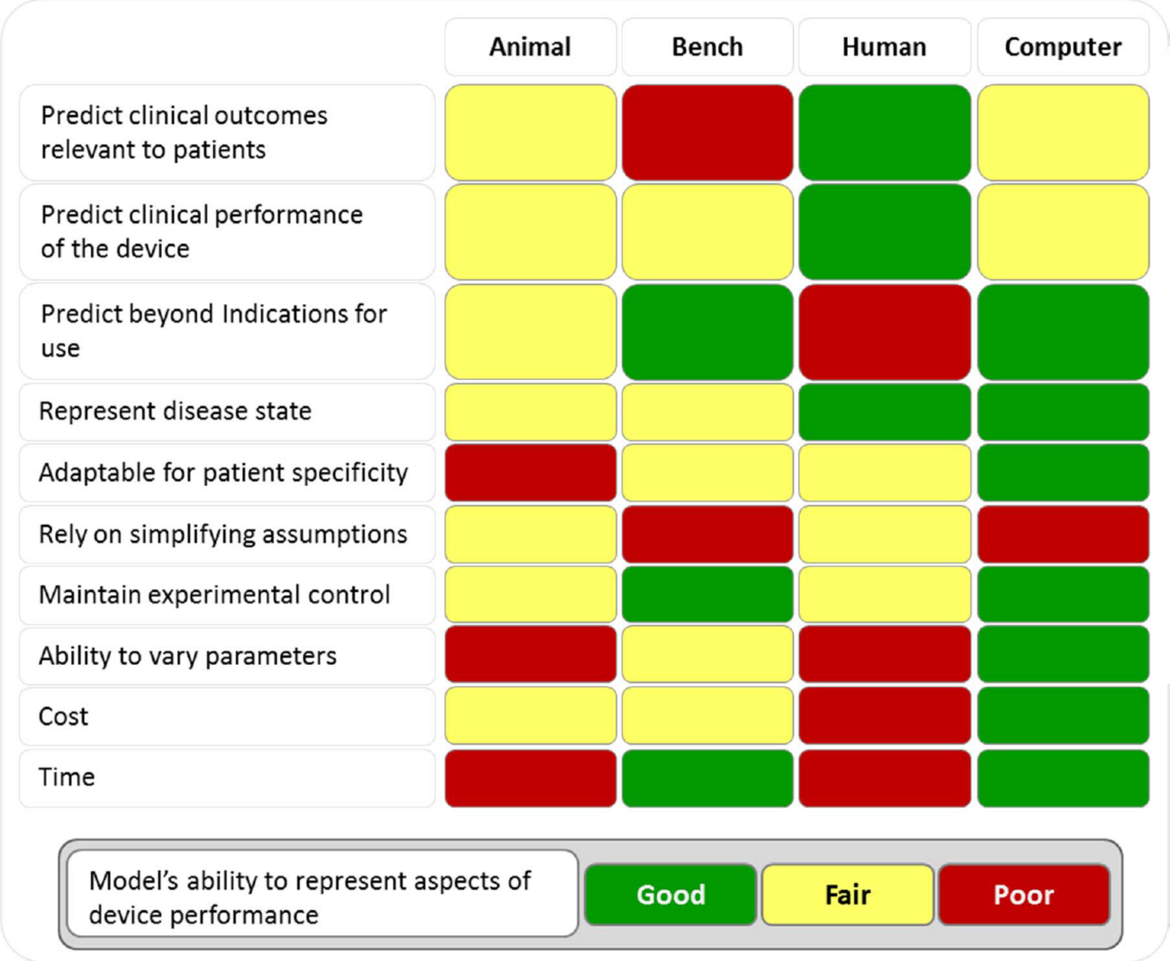
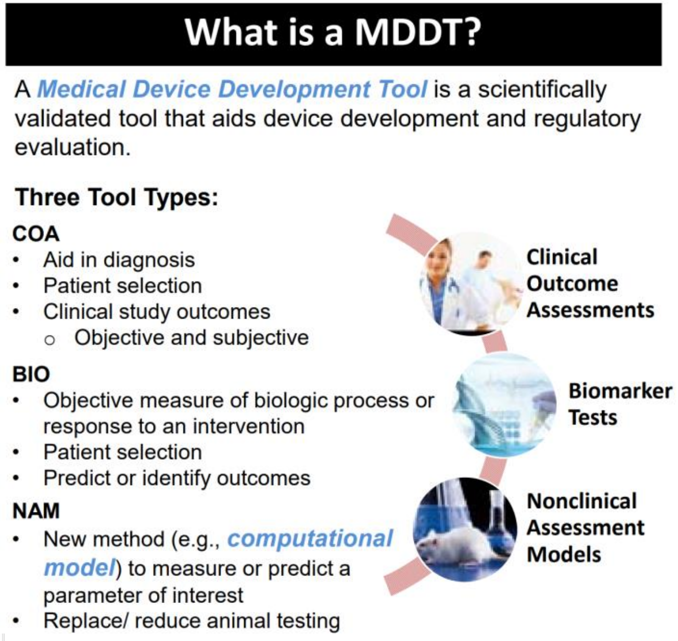
# FDA – Computational Modeling & Simulation




Morrison T.M., *et al., The Role of Computational Modeling and Simulation in the Total Product Life Cycle of Peripheral Vascular Devices,* accepted J Med Dev, in press in 2017

https://dx.doi.org/10.6084/m9.figshare.3409288.v1

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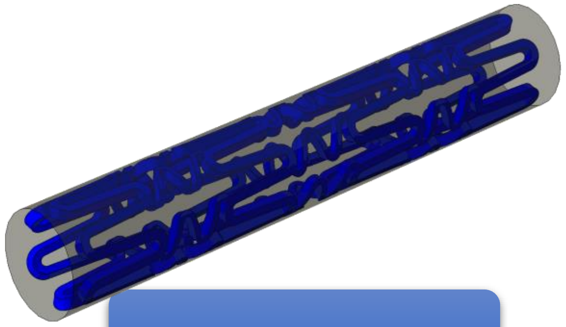
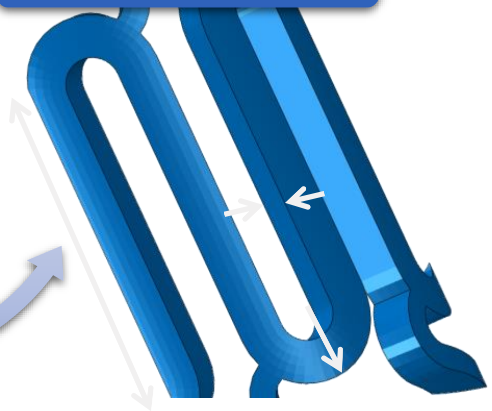
# Patient Specific Coronary Stent Design



Stress Analysis

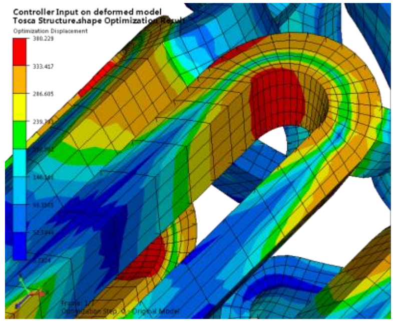
Crimping and Insertion of the stent. Evaluation of peak stresses and strains

Parametric Design Optimization



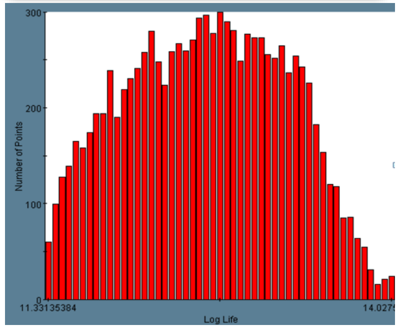
Vary design parameters and evaluate target behavior to optimize the stent design

Fatigue Life




Stent life estimation using the fatigue analysis

Reliability Analysis




Evaluating sources of uncertainties in the model

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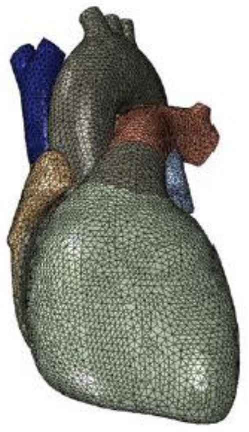
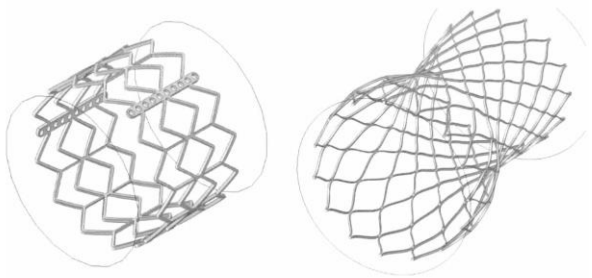
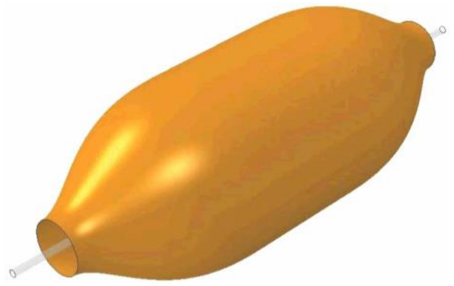
# Heart Modeling: Materials

- Heart
  - The material parameters of the heart can be carefully calibrated to match clinically relevant metrics of a normal adult heart
- Stent
  - Self-expanding Medtronic CoreValve
    - Superelastic NiTi alloy
    - Crimped by surface cylinder
    - Deployed by pulling cylinder and allowing gradual expansion
  - Balloon-expandable
    - Stainless steel (nonlinear, plastic)
    - Crimped and placed on deflated balloon (linear elastic)
    - Deployment by uniform internal pressure on balloon

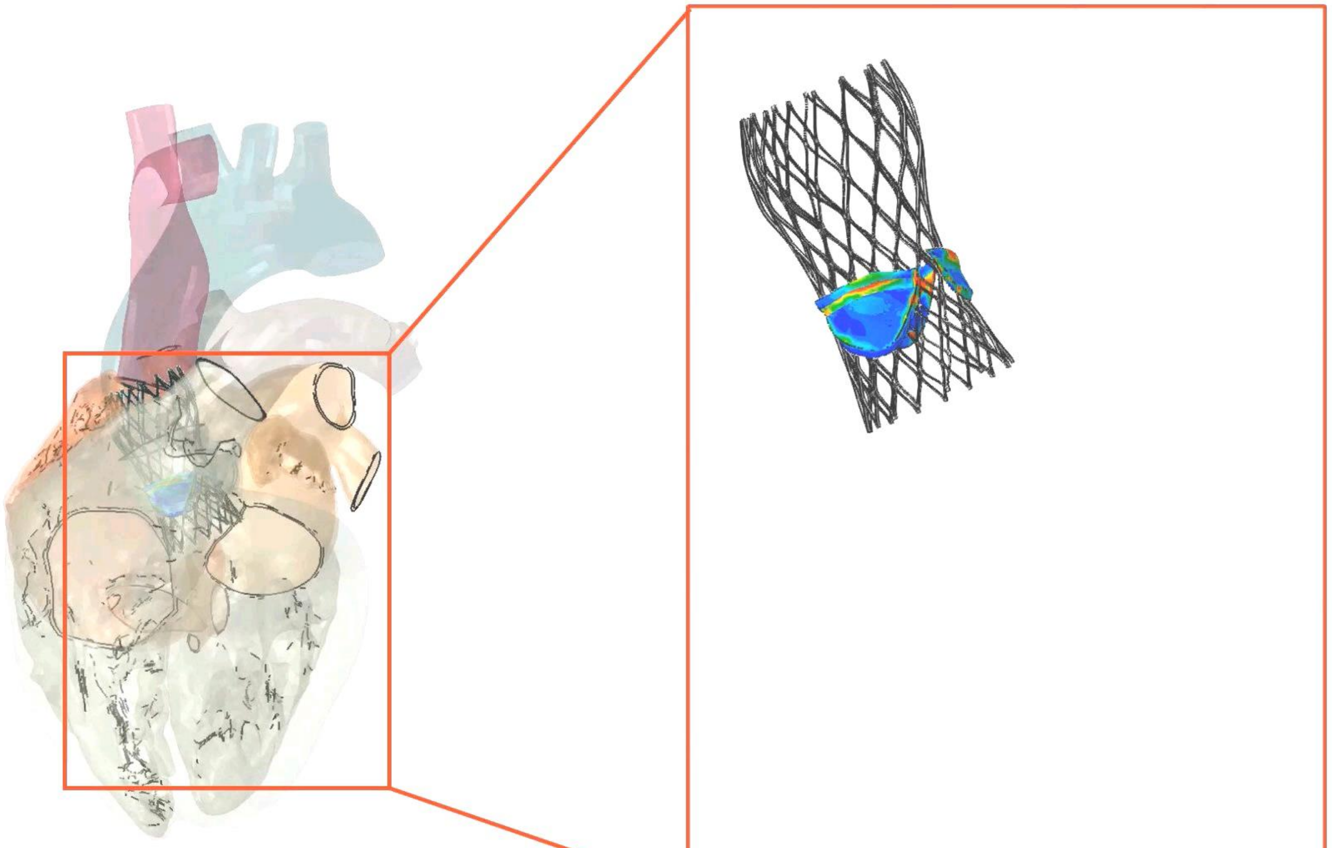






# Valve Stent Deployment

- Mechanical behavior
  - Anisotropic hyperelastic modeling
  - Time-varying elastance model for active response
- Mechanical analysis (Abaqus/Explicit) can determine cardiac structural response
- Influence on stent deployment and motion can be modeled



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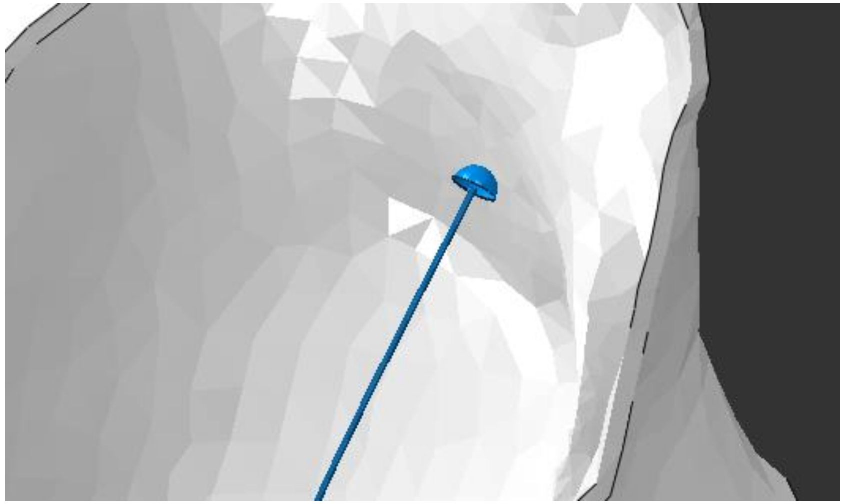
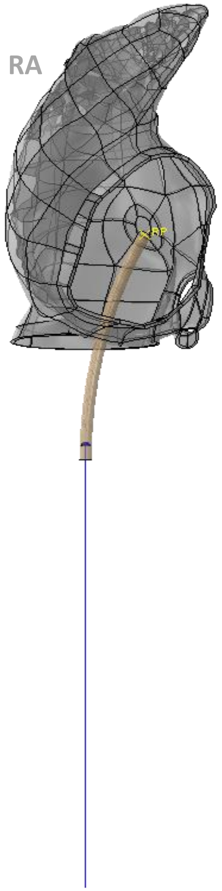
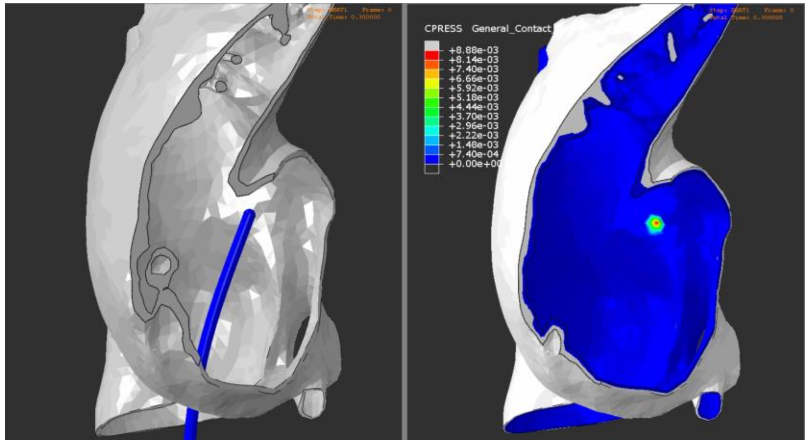
# Transseptal Modeling

- Catheter inserted in the heart and guided to the septum until contact
  - Catheter modeled with beam elements & rigid half dome tip
  - Displacement of the catheter modeled with connector (catheter tip pulled to the contact location)
  - Catheter moves inside a guide (curved rigid cylinder )



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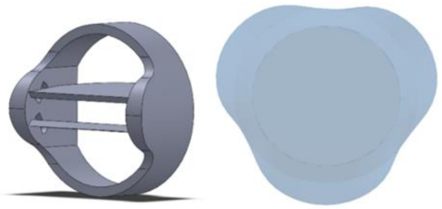
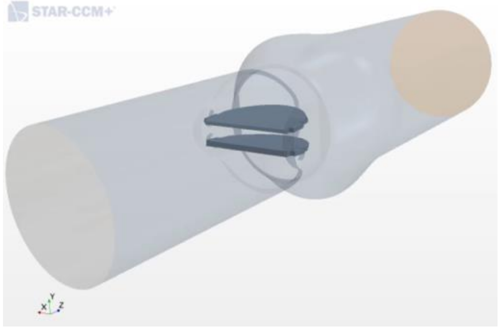
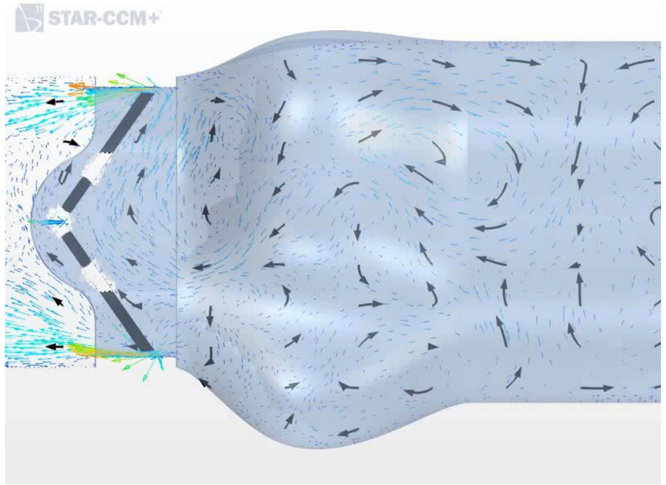
# Bileaflet Mechanical Heart Valve

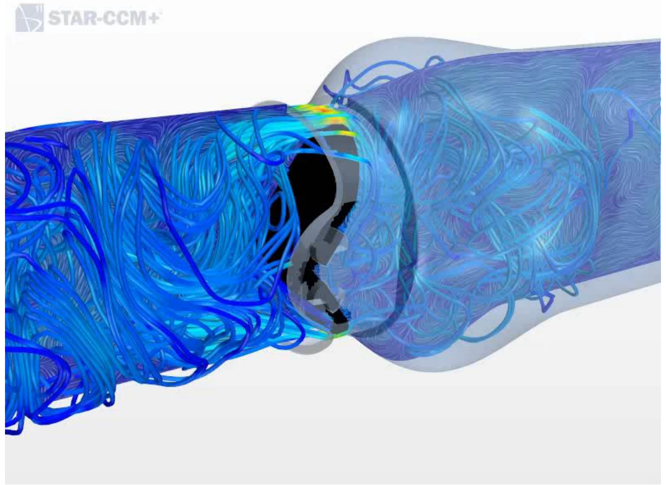
- Bileaflet Mechanical Heart Valve to replace the aortic value (a naturally tri-cuspid valve)
  - **Open** during Systole and **closed** during diastole
- Simulation identified:
  - the necessity of the split-second backflow of blood close to the leaflets
  - Unwanted regurgitation with the current valve design, present at the top and bottom of the leaflets when closed. Regurgitation may lead to hemolysis, thrombus and pannus
- Sudden closing may also suggest the necessity to study the effect of water hammer on this valve



(a) (b)

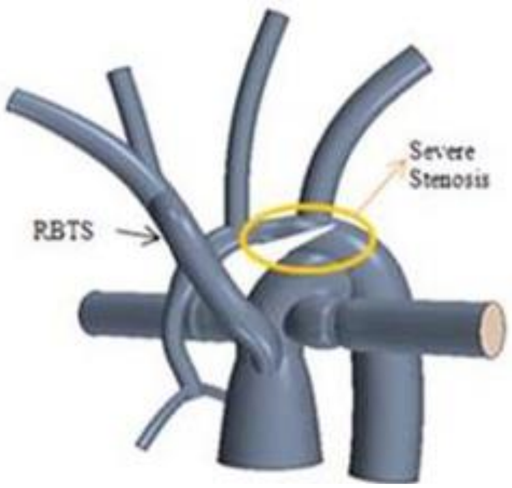


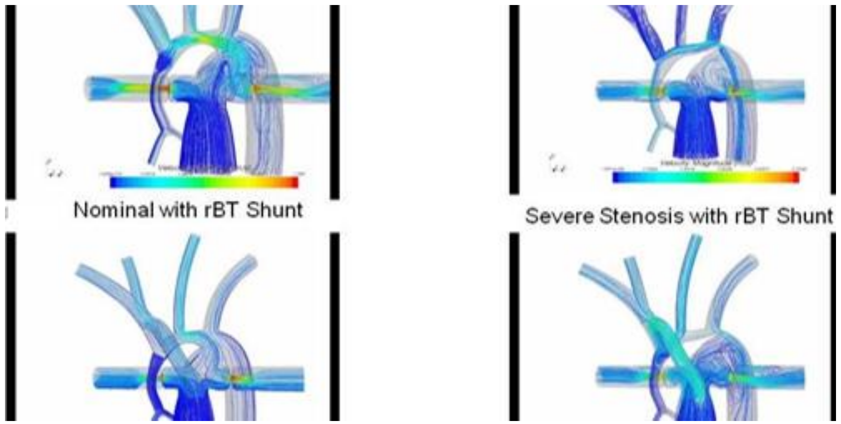



# Hemodynamics Effect

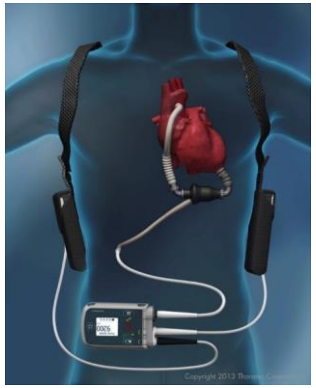
- Flow patterns causing thrombi formation/vessel wall remodeling.
- Clear understanding of risks involved with different RBTS placements to identify the correct procedure.
- Blood flow obstruction

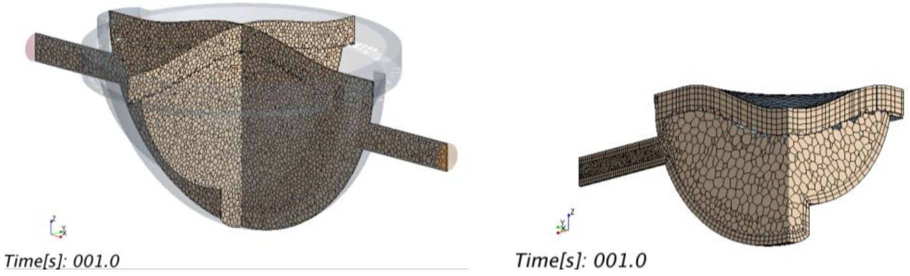


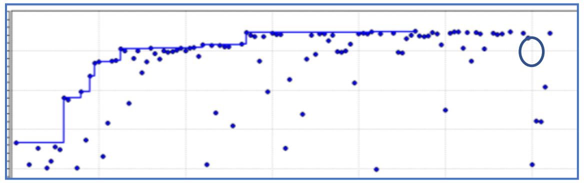
# Heart Pump Design

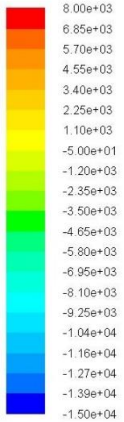
- Improve heart pump efficiency
- Obtain greater understanding and insight into blood pump behavior
- Designing blood, perfusion or dialysis pumps, LVADs
- Avoid excessive cavitation, damaging both blood and pump

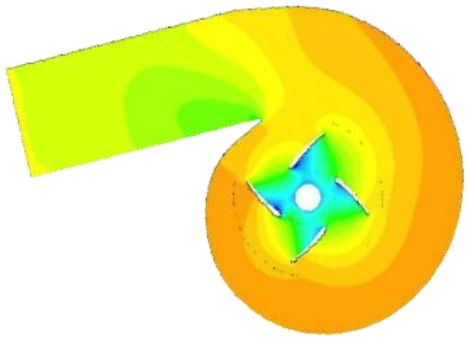





Perfusion Pump using FSI (Fluid Structure Interaction)





# Why VIAS?

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# Thank You

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