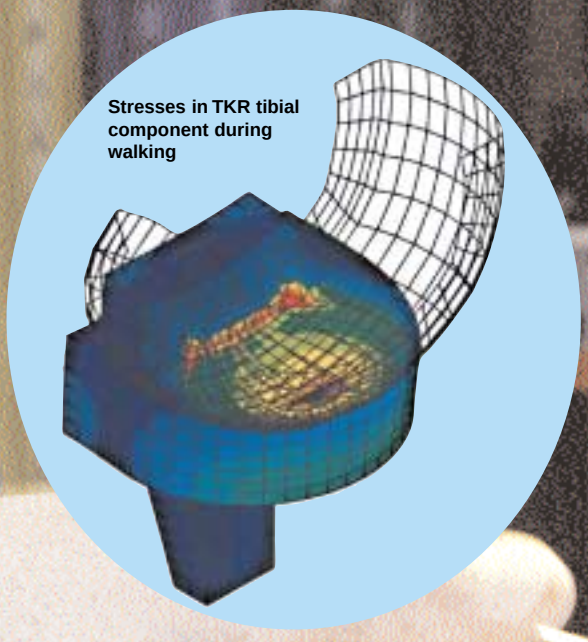
SES Medical Device Technologies

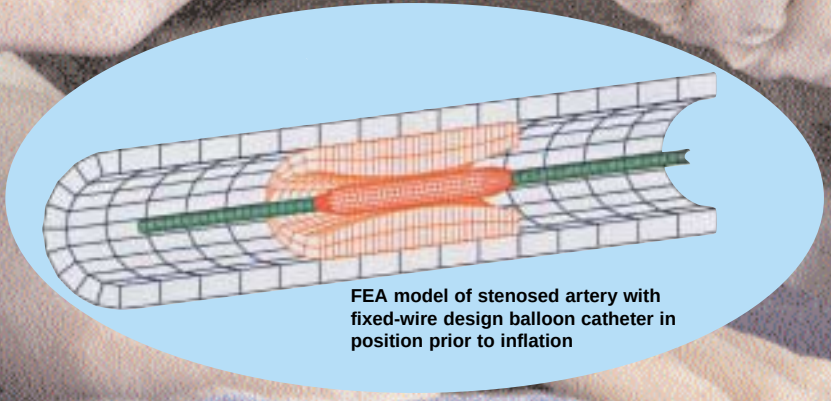
A Division of Stress Engineering Services, Inc.

Accelerate Medical Product Development



Stresses in TKR tibial component during walking

Total knee replacement (TKR) - Cruciate Retaining Design



FEA model of stenosed artery with fixed-wire design balloon catheter in position prior to inflation

Using advanced engineering simulation techniques, SES can help you predict the performance of medical devices, surgical tools, procedures, implants, and packaging.

Advanced Engineering is Becoming Essential

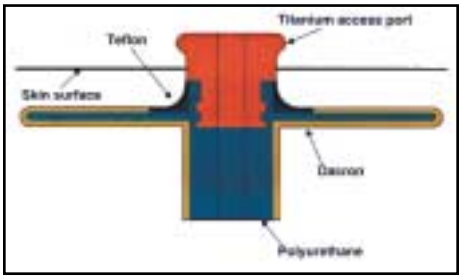
Medical devices are often fabricated from nonlinear polymeric materials which interact with living tissues… tissues that vary due to pathological state, age, type (collagen/elastin content), and microstructure. These variables, compounded by regulatory and competitive issues, make it clear that advanced engineering simulation is becoming a critical part of the product development process. Predictive engineering makes it possible to:

- Evaluate and improve performance before fabrication and in-vivo testing
- Generate data for Pre-Market Approval and 510(k) applications
- Perform "what if" studies on implant material options under critical conditions
- Analyze and understand implant failures

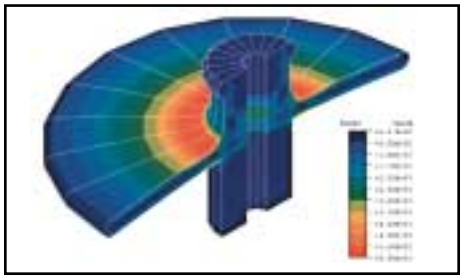
Continued success in this industry requires an engineering analysis partner with broad experience in the technology of biomedical device simulation and testing. SES can help. We offer the expertise, experience and facilities to get your company's medical products to market faster, with increased reliability and lower final costs.

Percutaneous Skin Implant Evaluation

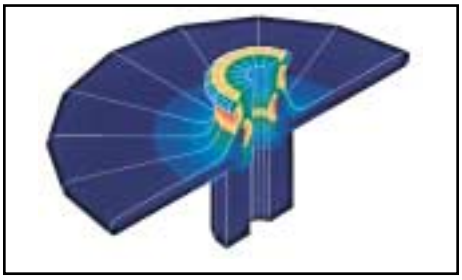
Percutaneous implants serve as conduits for general 'transfer of information', which often includes long term drug delivery, blood monitoring and dialysis as well as colon-rectal surgical procedures. Mechanical design issues for implant devices include material selection, minimizing tissue-device interface stresses, and optimizing implant geometry for motion.



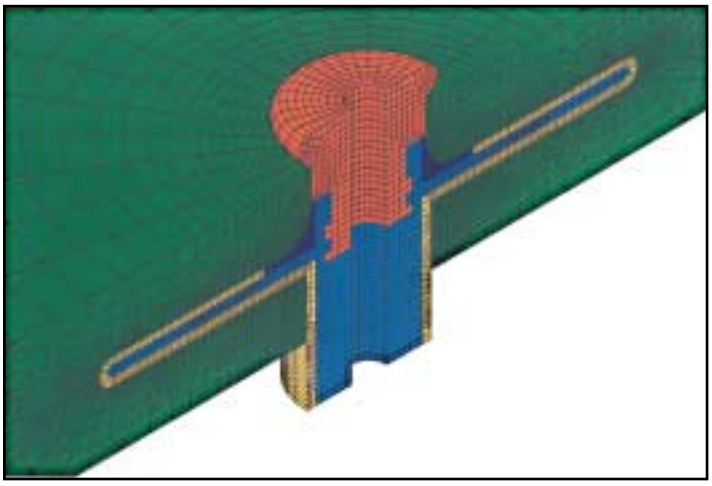
Percutaneous skin implant



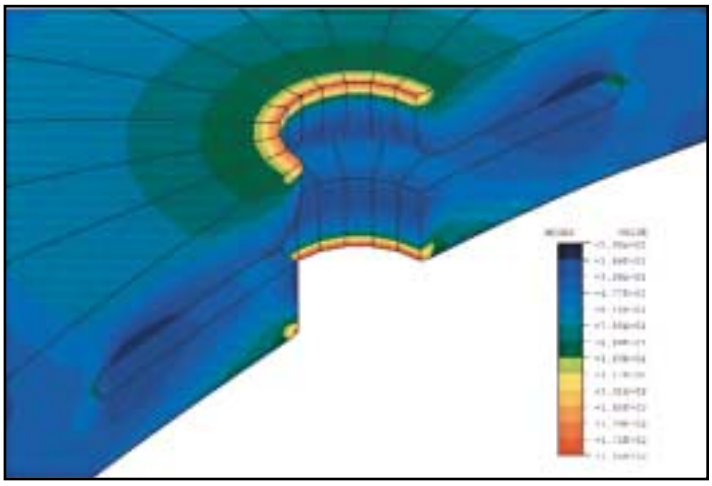
Implant stresses, pull-out loading



Implant stresses, torsional loading



FEA model of percutaneous device implanted in skin

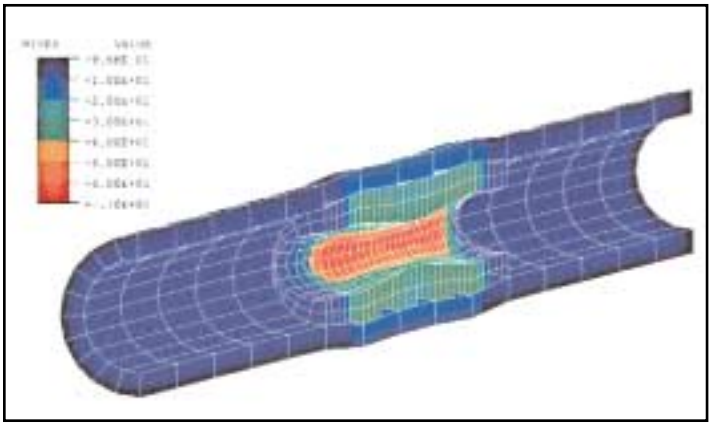


Skin stresses, pull-out loading

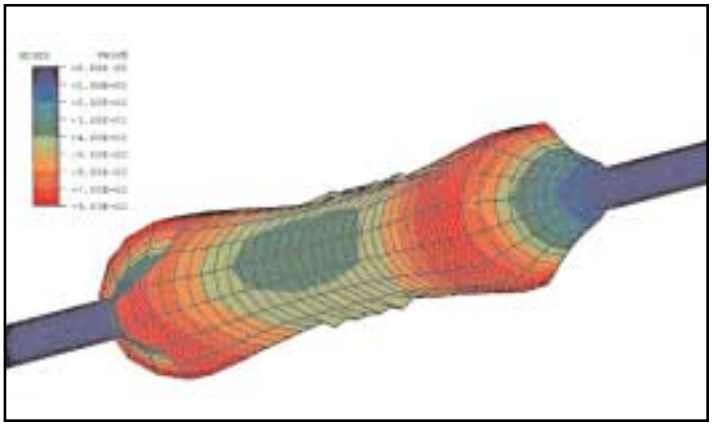
Fixed Wire Balloon Catheter Evaluation

Transluminal balloon angioplasty is a surgical procedure to enlarge the lumen of a stenosed vessel, maintain the lumen over time, and to provide an intimal surface that promotes neo-intimal hyperplasia.

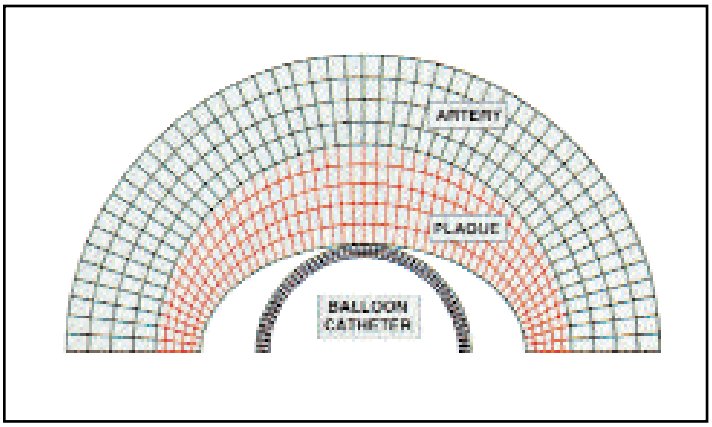
SES performed a series of free inflation simulations on several catheter materials, including PolyEthylene Terephthalate, Poly Olefin Copolymer, and Polyvinyl Chloride. An optimal balloon was then selected by performing simulations of the surgical procedure itself. This was accomplished by inflating the balloon designs against a virtual blocked vessel.



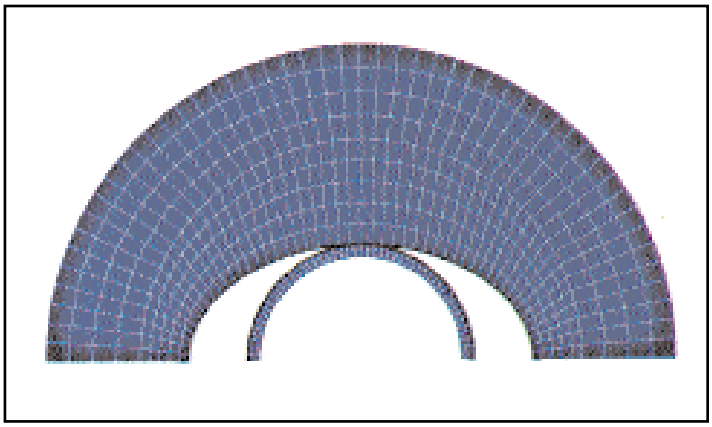
Plaque and artery deformations/stresses at the end of dilation



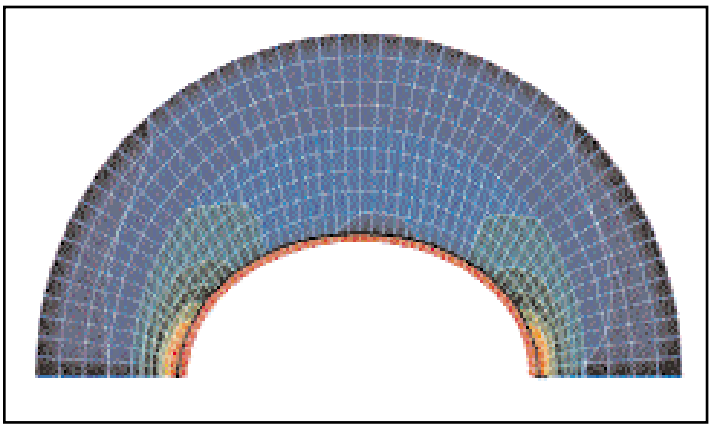
Balloon deformation and stresses at the end of dilation



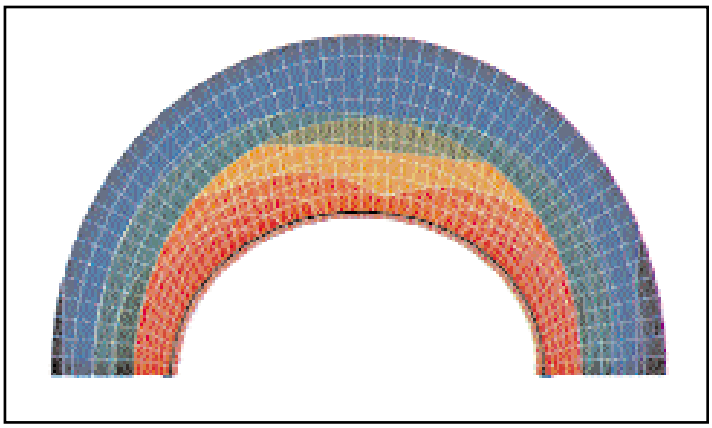
Non-circular calcified plaque/lesion



Inflation pressure: 0.0 mpa



Inflation pressure: 0.80 mpa



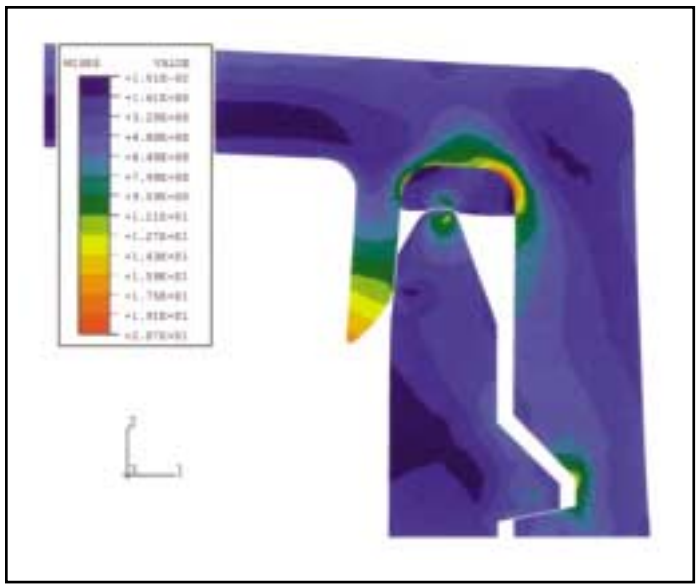
Inflation pressure: 1.00 mpa

Predictive Simulation of Medical Packaging

Predictive analysis of medical packaging completes the product development cycle, and SES has broad experience in applying advanced analytical and simulation tools to the concurrent design of plastic packaging for medical devices. Our expertise includes analysis of all aspects of product/package mechanical behavior, including finite element simulation of the manufacturing process, heat sealing analysis, and structural analysis of the resulting component under design loading. We routinely simulate various plastic manufacturing processes, including:

- Thermoforming (vacuum, pressure, plug-assisted, matched mold)
- Extrusion/blow and stretch/blow molding
- Injection molding

Biaxial inflation test rig for characterization of polymeric materials like PET, PS, PP, and PVC.



Stress relaxation, seal contact pressure and leakage analysis in a plastic closure during autoclave sterilization.

SES also performs structural and heat transfer finite element analysis (FEA) to evaluate medical packaging under in-service mechanical loading such as drop and impact, as well thermal loading that results from EtO and autoclave sterilization. Seamless integration of manufacturing process analysis, along with package performance and structural integrity simulations delivers several important benefits, including:

- Improved package life and resistance to drop or impact events
- Better resistance to material degradation during and after sterilization
- Improved microbial sealing systems
- Reduced total development costs
- Minimizing trial and rework of mold tooling

For more information about how we can help you move medical products to market faster, with increased reliability and at lower final costs, call the SES office nearest you today …Or visit our web site at www.medicaldeviceinnovation.com

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