Part I
FEA of Metallic Stents (F2514)

PERU Workshop on Medical Device Regulation: Policy and Technical Aspects

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ASTM F2514

Standard Guide for
Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading[1]

1.1 *Purpose*—This guide establishes general requirements and considerations for the development of finite element models used in the evaluation of the performance of a metallic vascular stent design under uniform radial loading. Suggested criteria are provided for evaluating the typical cases of metallic tents under uniform radially oriented and pulsatile loading.

Recommended procedures for checking and validating the finite element model(s) are provided as a means to assess the model and analysis results.

Finally, the recommended content of an engineering report covering the mechanical simulations is presented.

Types of ASTM Standards

ASTM publishes six different types of standards:

Test method
A definitive procedure that produces test result.

Specification
An explicit set of requirements to be satisfied by a material, product, system or service.

Guide
A compendium of information or series of options that does not recommend a specific course of action.

Terminology
A document comprising definitions of terms; explanations of symbols, abbreviations, or acronyms.
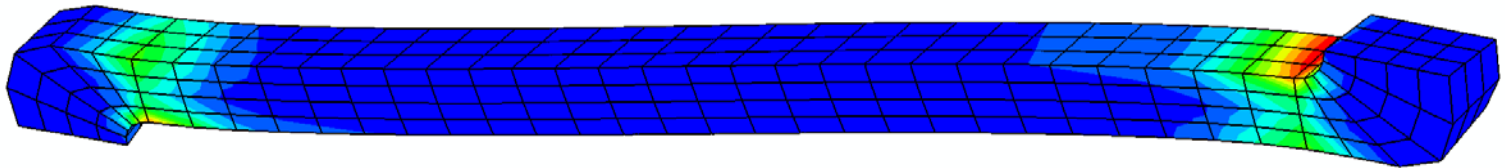
Practice
A definitive set of instructions for performing one or more specific operation that does not include a test result.

Finite Element Analysis
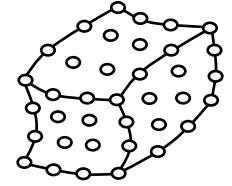
1) Device geometry is subdivided into small elements
2) Material properties are assigned to each element
3) Boundary and loading conditions are applied
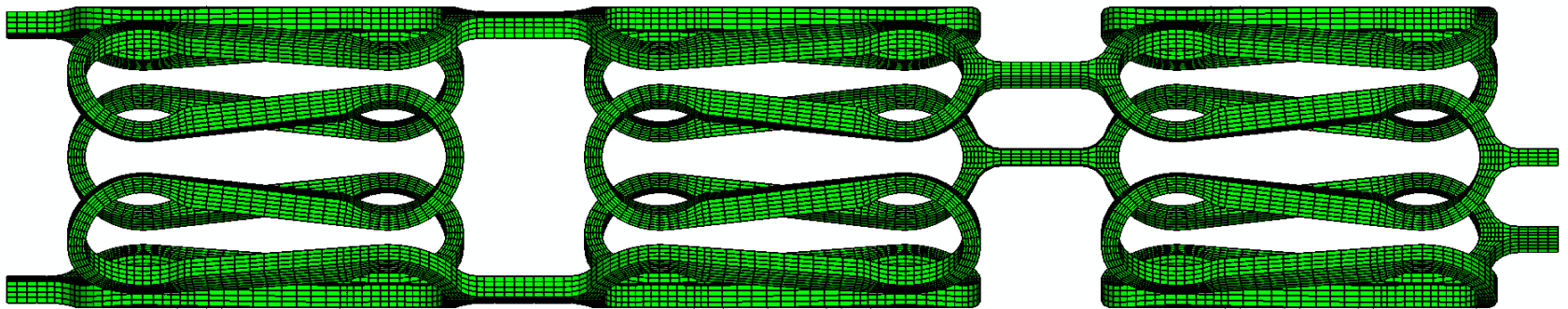4) System of equations are solved

• Results include detailed stress/strain for entire model
• Peak values are compared to material limit properties
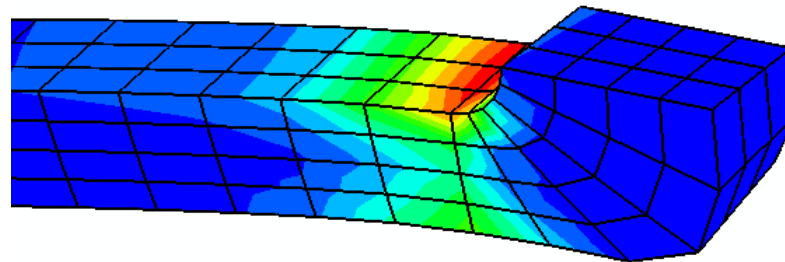
Role of FEA in the Engineering of cardiovascular devices

- Proof of concept: materials and design
- Evaluate new designs, gain insight
- Identify and evaluate worst-case conditions
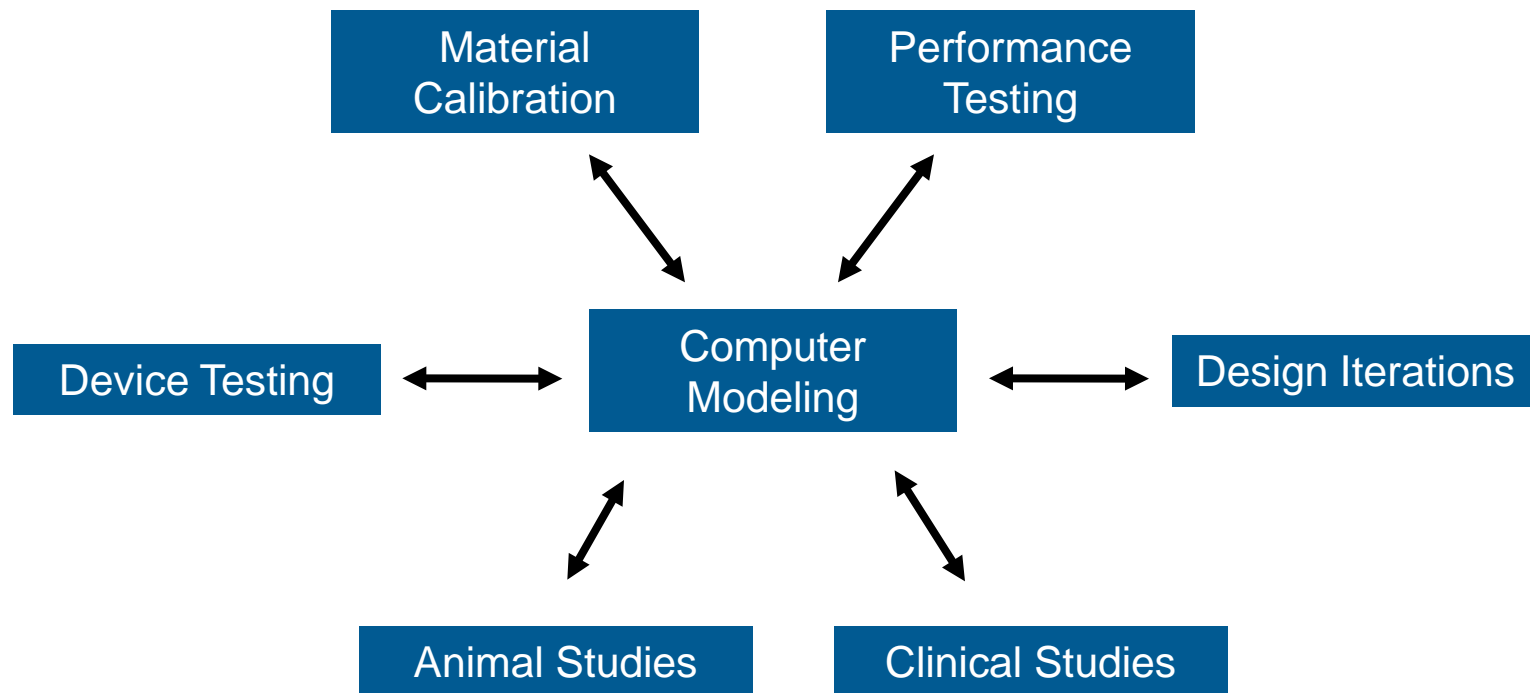- Demonstrate safety and efficacy

"*The purpose of computing is <u>insight</u>, not <u>numbers</u>*"
R. W. Hamming

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Product Development and Regulatory Approval

FEA is central in the product development of an implantable medical device
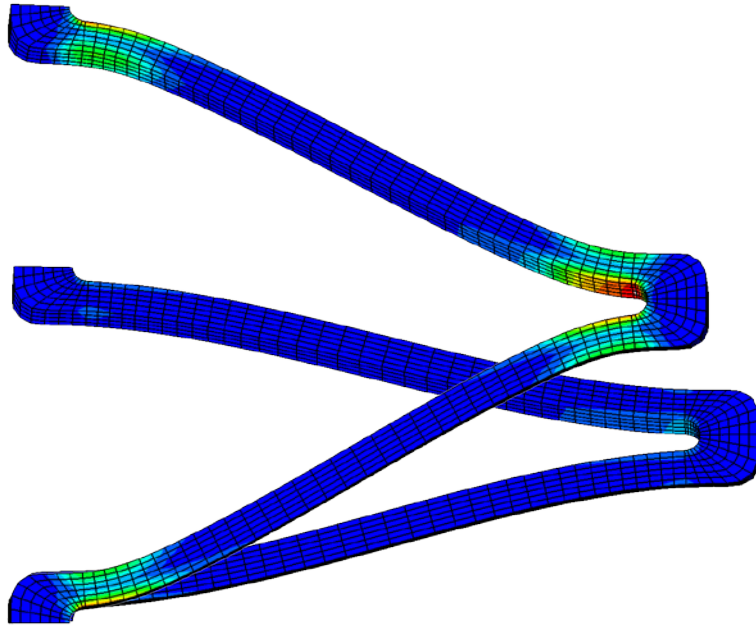

FEA Is Fundamental To Gaining Regulatory Approval

Optimize Prototype Fabrication

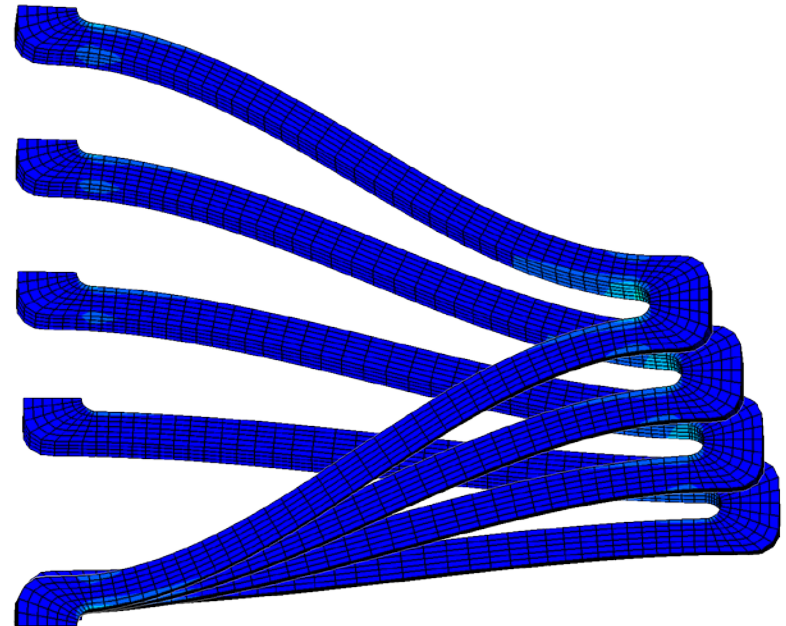2 expansion steps:
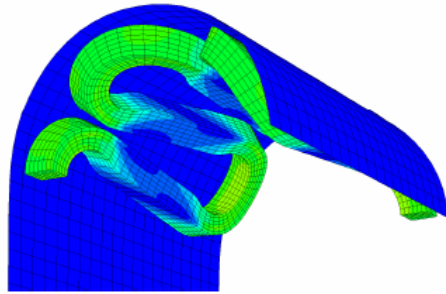Strain > 12%
Stent prototype BREAKS

4 expansion steps:
Strain < 6%
Stent prototype SUCCESS
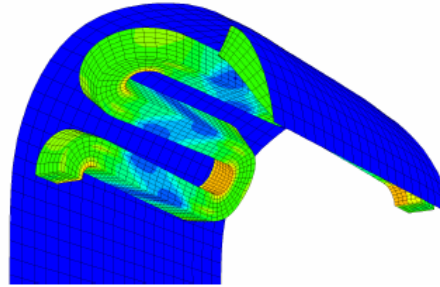

Start-up loses time and money
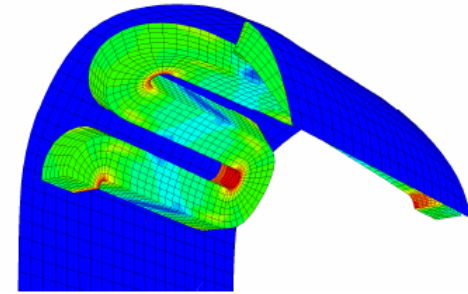
Start-up has more confidence, design improves more quickly

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Evaluate Design Changes

Part 1

Part 2

Part 3

Carga

Stent Diameter
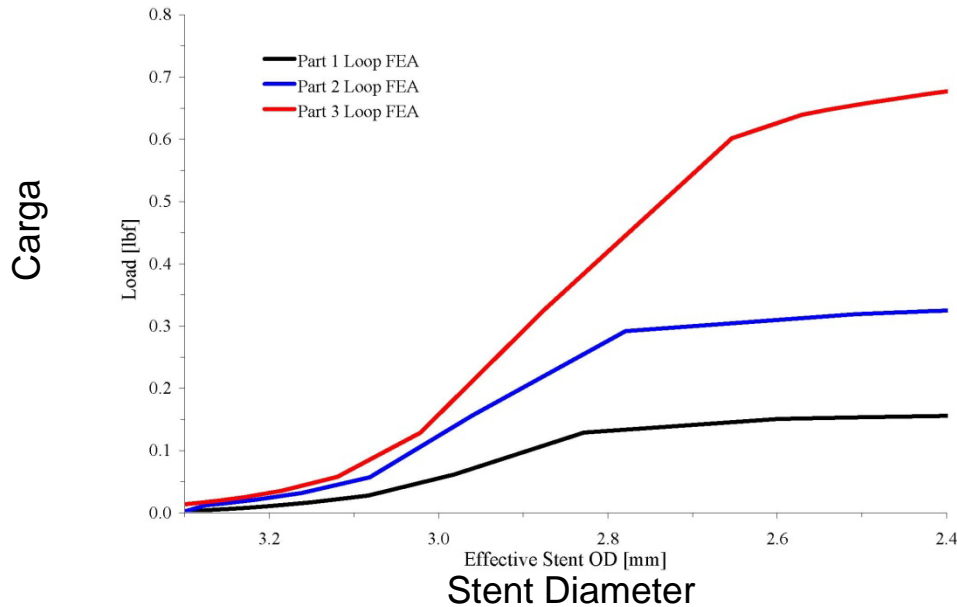
Design changes are subtle
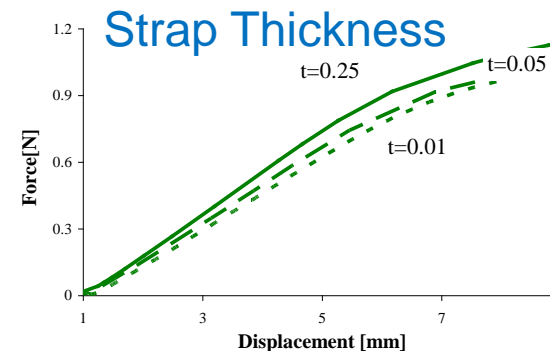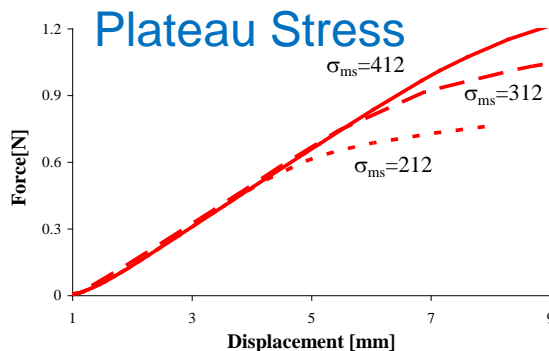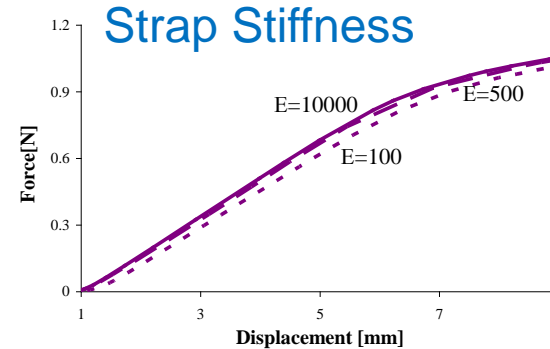
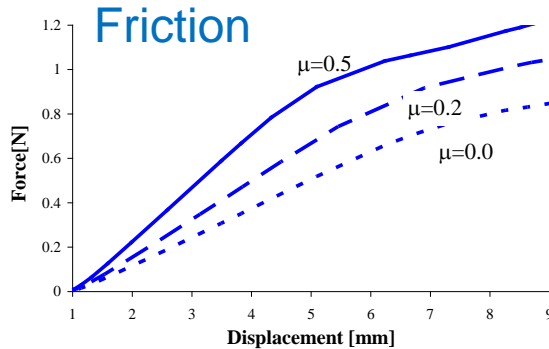New design concepts can be evaluated and ranked

Performance properties can be compared to design requirements

Sensitivity and Calibration Studies

Sensitivity studies can consider ideal behavior and hypothetical conditions and lead to insight and understanding. FEA can be used to relate loading conditions between animal and bench models directly in terms of the material's strain capacity.

Identify Worst Case Size/Loading
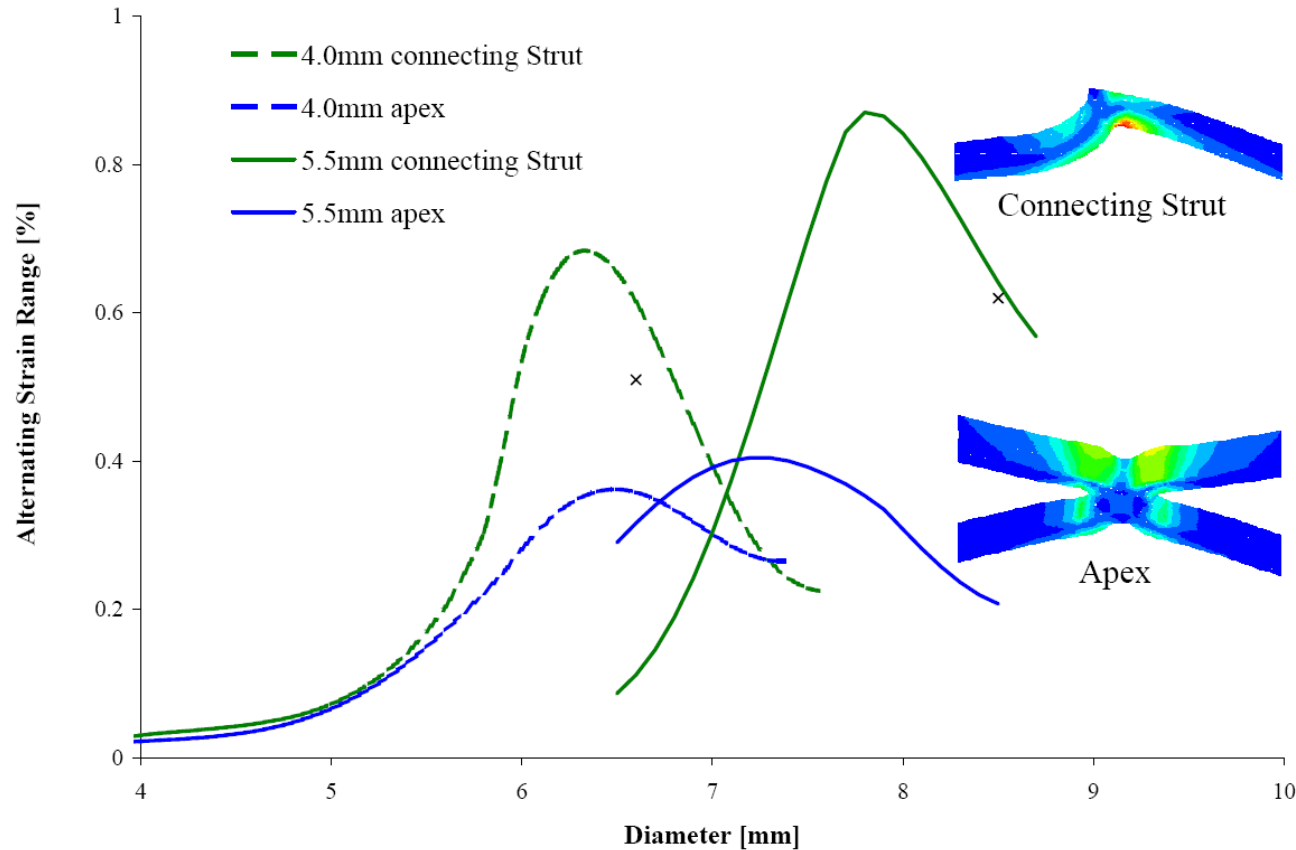
Company identifies worst case size/loading conditions, confirms fractures consistent with bench/animal model data and gains regulatory approval.

Confirm Input Geometry
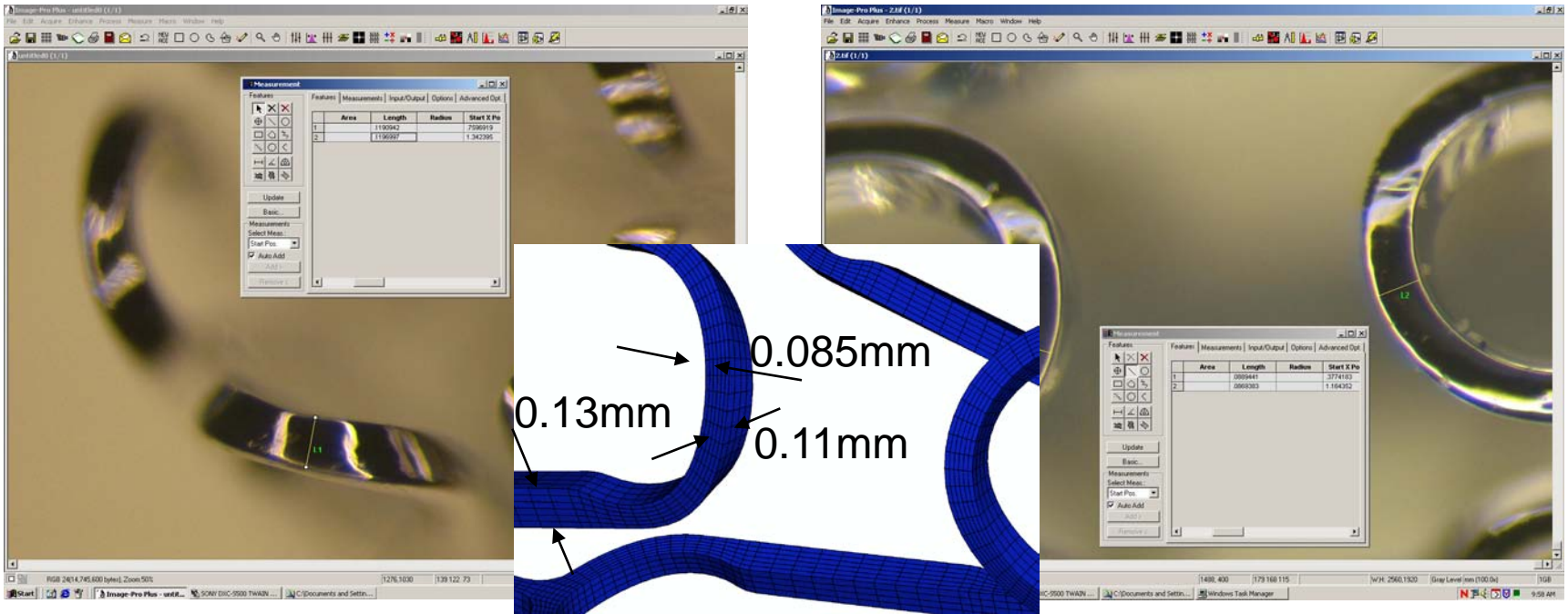
Specifications and dimensions may change during the product development process and differ from those on preliminary CAD drawings.

Consider Variance of Geometry Data

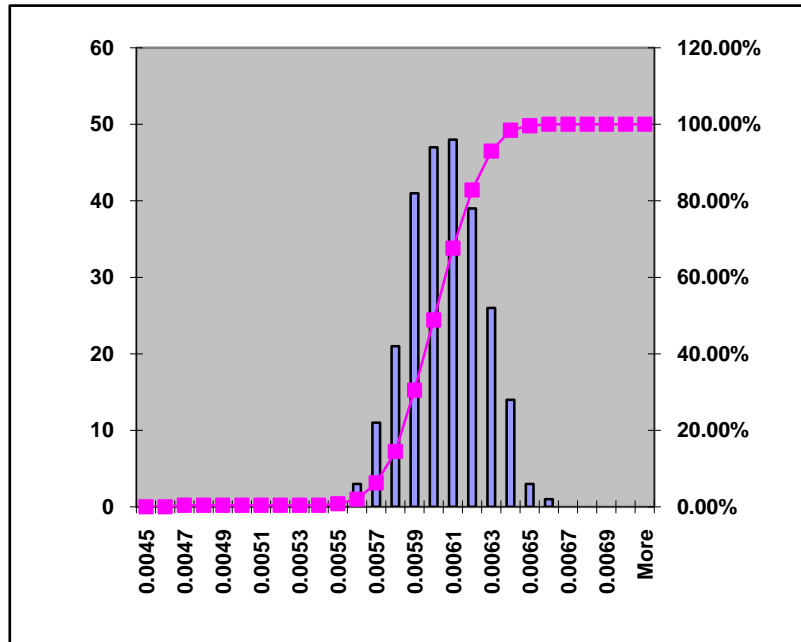Random inspection of the strut
dimension for 32+ stents

Nominal strut dimension = 0.061
Maximum strut dimension = 0.064
Minimum strut dimension = 0.058

Use nominal dimensions
for the base model
analysis.

A sensitivity study can be
performed on the worst-
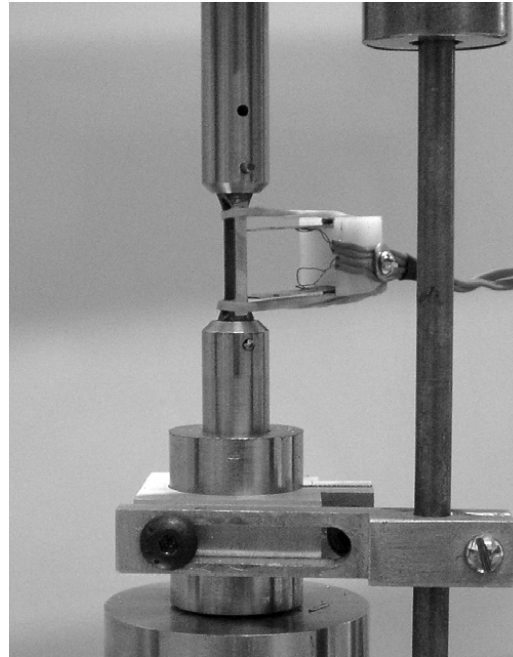case combination of
dimensional variances.

Characterize Material Behavior

Test samples

- Made from the same source as the device: tubing, wire, etc
- Must experience the same manufacturing steps as the device
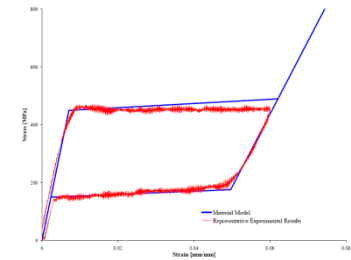
Measurements

- Load
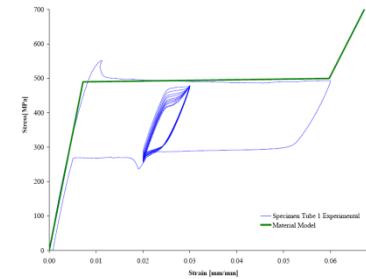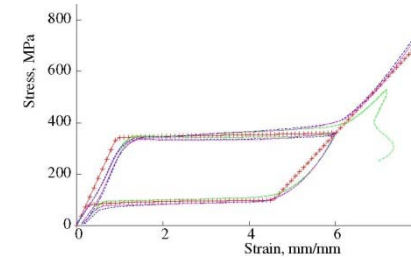- Displacement
- Extensometer strain!

Tensile testing of nitinol tubing

Tensile testing of stainless steel wire

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Confirm Material Behavior

The response of the model should be compared with experimental data
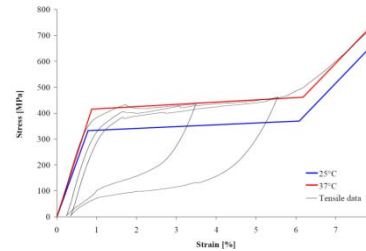
A single element model is generally used
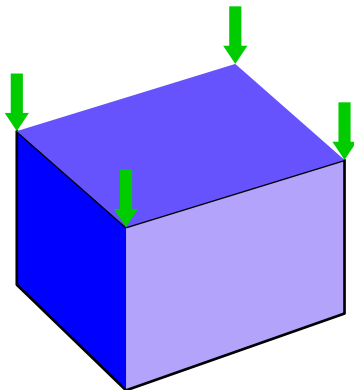
The output from the model should match the experimental data over the range of anticipated loading

Material Behavior may change over time

For example, repeated loading of a device can cause incremental changes in a material each cycle

Material properties may depend on temperature and/or environment (especially for bioabsorbale materials)

These scenarios require more sophisticated material models and generally more difficult to obtain calibration parameters.

The sophistication of the model should match the physics of the problem and the purpose of the analysis

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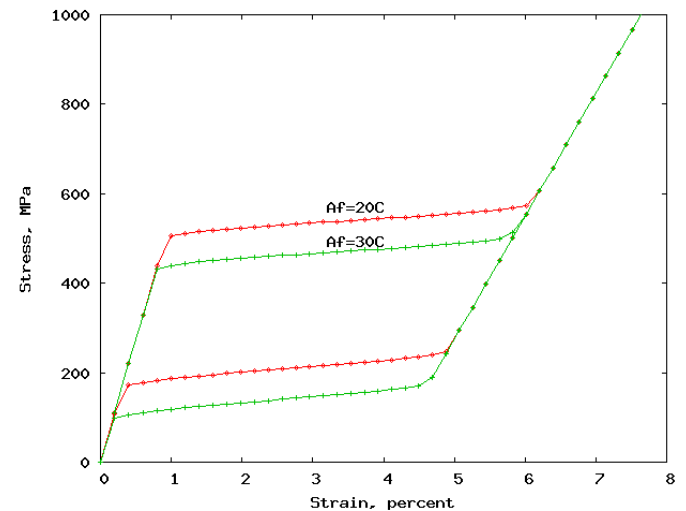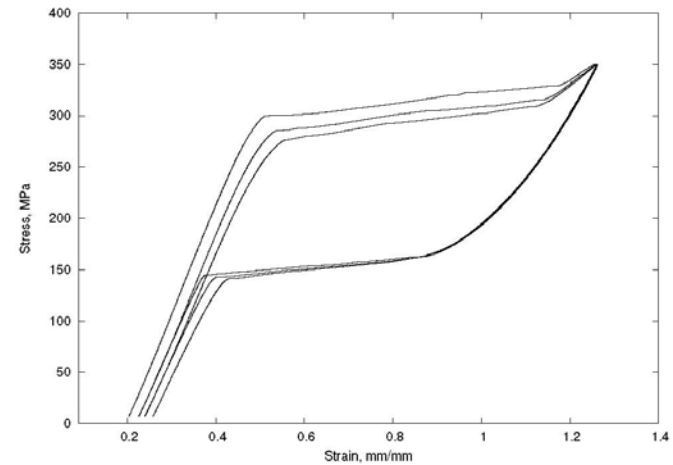
Material Limit Properties

- <u>Material Behavior </u>Properties describes the mechanical response of the material, the relationship between stress and strain.

- <u>Material Limit </u> Properties specify limitations of the material, critical values that if exceeded, result in damage or fracture of the structure.

- Material limit properties can sometimes be determined from handbooks or material specifications

- Other times, it is necessary to determine them experimentally

Material Limit Properties from Testing Equivalently Processed Samples
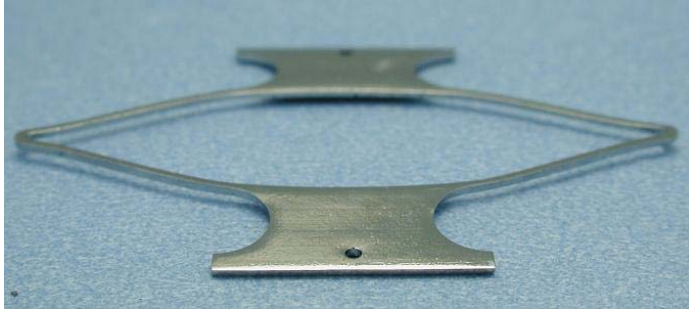
Fatigue and fracture of materials are inherently stochastic processes.
There is random behavior associated with a fracture occurring, or not, for a given set of loading conditions.

A sufficient number of samples must be tested to achieve an estimate with confidence.

Material Limit Properties from Testing Equivalently Processed Samples

`Coupon' samples are clipped from the final device (like a `coupon' from the newspaper).

`Surrogate' samples are created to mimic the final device, but with a simpler geometry that facilitates fatigue testing.

In all cases, the samples should be subjected to the same manufacturing processes used on the device.

Mesh Density Study and Solution

| Mesh	DOF	CPU	Strain	Stress
2x2	405	1.5	1.0	480
3x2	972	4	2.0	620
4x3	2220	10	3.0	950
5x4	4410	22	3.2	962
6x5	7686	42	3.21	965
8x6	16065	112	3.22	970
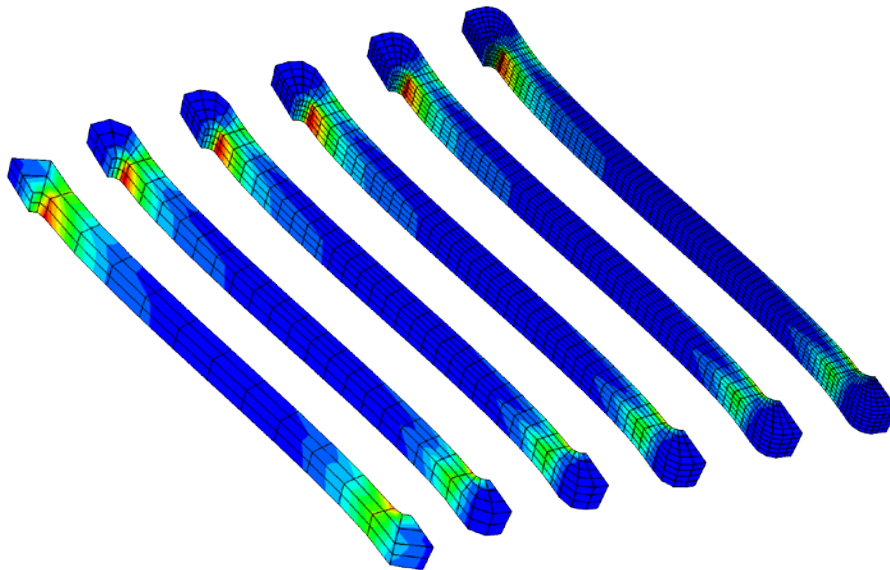
A mesh density study is used to show that any further refinement of the element size yields a negligible effect on the output from the model.

Most computational models for cardiac devices involve solving non-linear equations which requires and numerical iteration.

The analyst must also demonstrate sufficient numerical stability and convergence criteria for the model.

Simple Model Validation

	Expansion	Recoil
Ideal ID Expansion [mm]	2.926	-
Maximum OD [mm]	3.34	3.19
Minimum ID [mm]	2.9	2.75
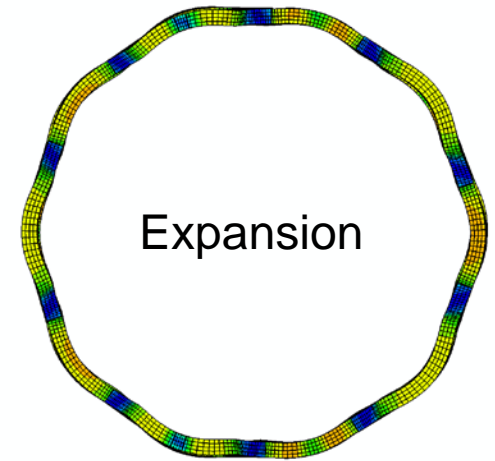
A simple way to validate a computational model for a stent is to compare measurements of the expanded or recoiled shape to that predicted by the model.

Expansion

Minimum ID

Maximum OD

Recoil

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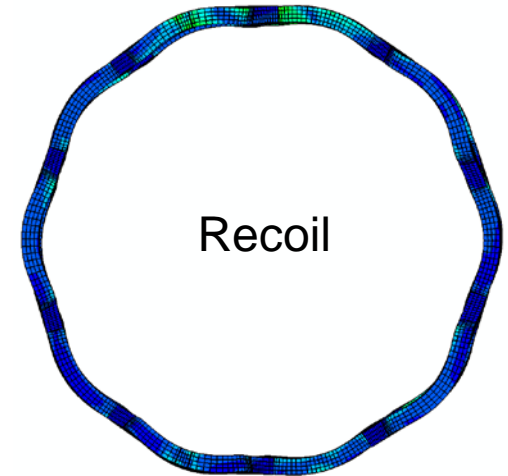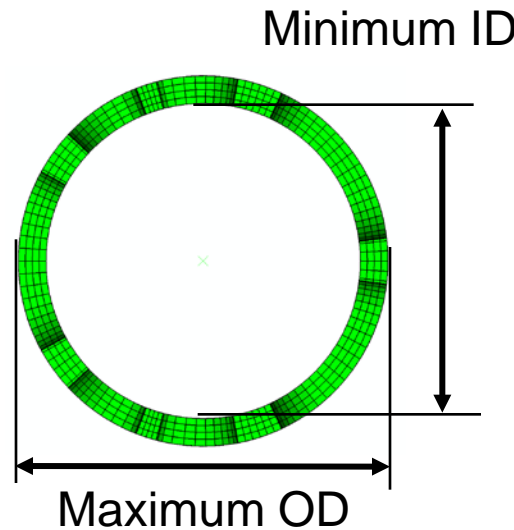
Validation of Model with Bench-Top Testing

Radial force measurements from an iris-diaphram test compared to FEA results
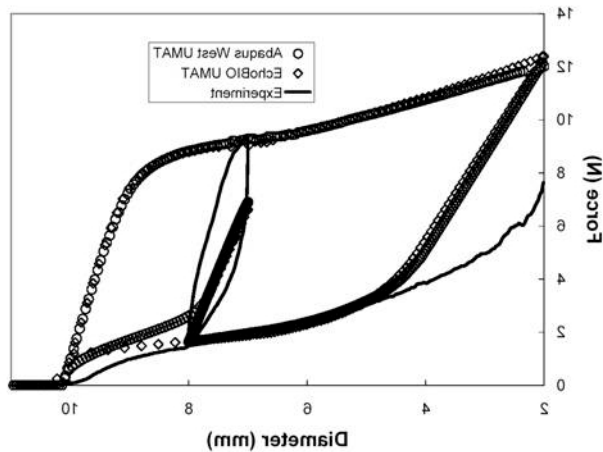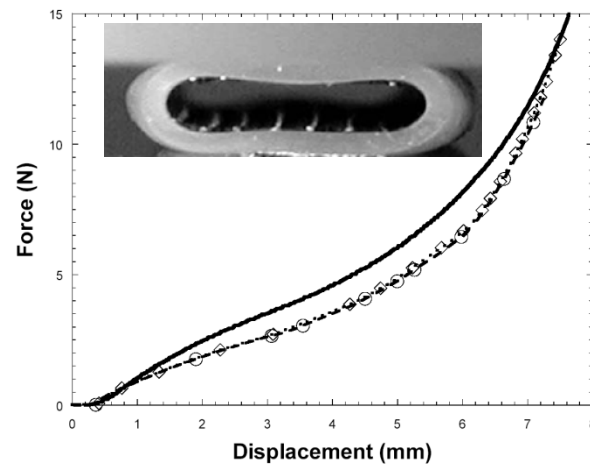
Radial force measurements from a flat-plate test compared to FEA results

Validation is most effective when performed over the full range of physiologically relevant conditions and include multiple sizes for a scaling reference.

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Complete Loading History of Device Must Be Considered!

Can include manufacturing processes of raw materials
- Wire, sheet and seamless drawn tubing

Can include device fabrication processes
- Stent expansion and forming

Can include device handling, loading and packaging
- Compression to catheter dimensions, sheathing

Can include clinical procedures
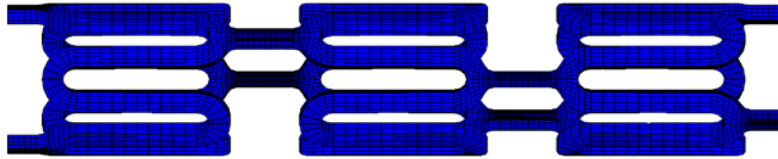- Deployment, balloon expansion, positioning or removal

Can include long term loading and environment conditions
- Pulsatile loading from heart beat, tidal breathing

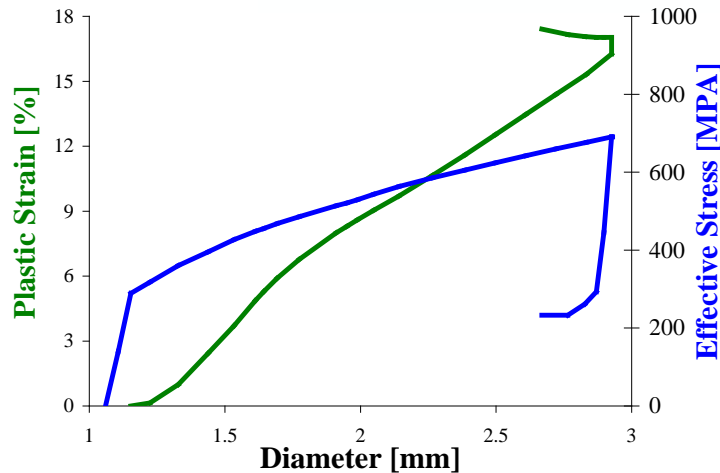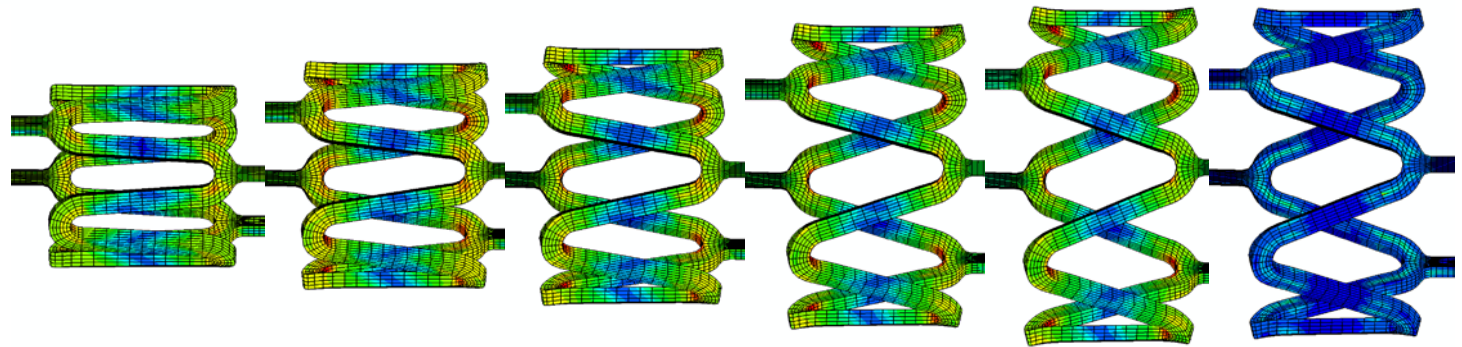Can include other relevant anatomical loading
- E.g. bending or focal compression

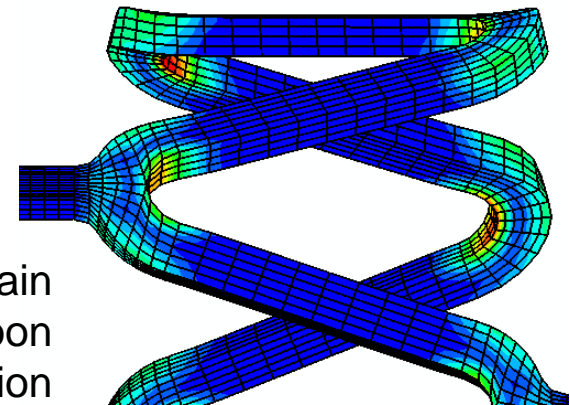# Loading History for a Balloon Expandable Stent (Before Fatigue)

For laser-cut stents: No residual stress
For wire stents: Maybe residual stress

Stresses during Expansion and Recoil

Plastic Strain during balloon expansion

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Fatigue Analysis Using Material Limit Data from Handbook

The endurance limit is assumed to be one half of the ultimate tensile strength of the material:

$$S_e \sim 0.5\ S_{ult}$$

The ultimate strength is a function of the plastic strain, which is increased during balloon expansion

% Cold Work	Tensile Strength	Endurance Limit 1M+ cycles
0	520 MPa	260 MPa
17	810 MPa	405 MPa

Endurance limit is increased by the effect of plasticity
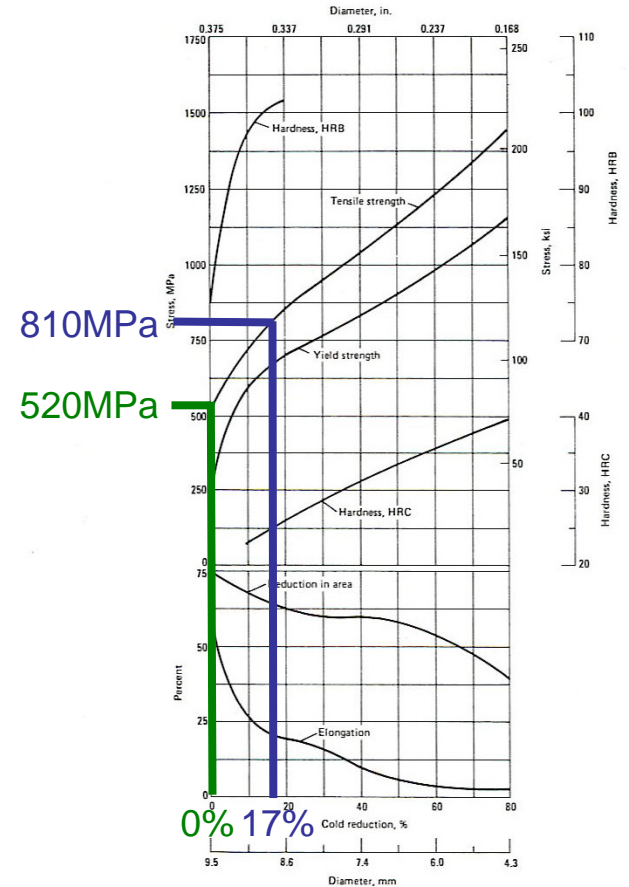
Fig. 6 Effect of cold reduction on the tensile properties of annealed type 316L stainless steel rods (9.53 m Elongation was measured in 50 mm (2 in.); yield strength at 0.2% offset. Source: Ref 6

Handbook of Materials for Medical Devices, Editor J.R. Davis, 2004.

More Fatigue Analysis
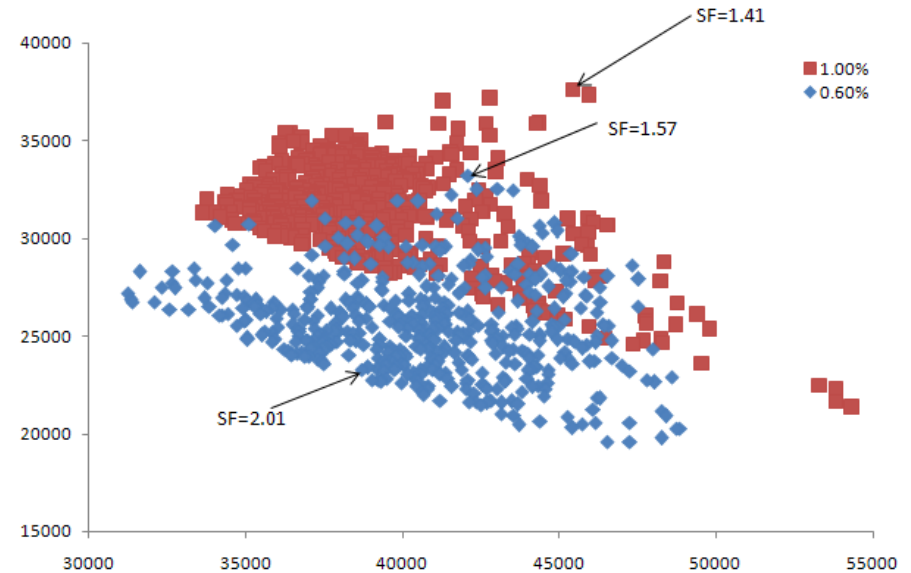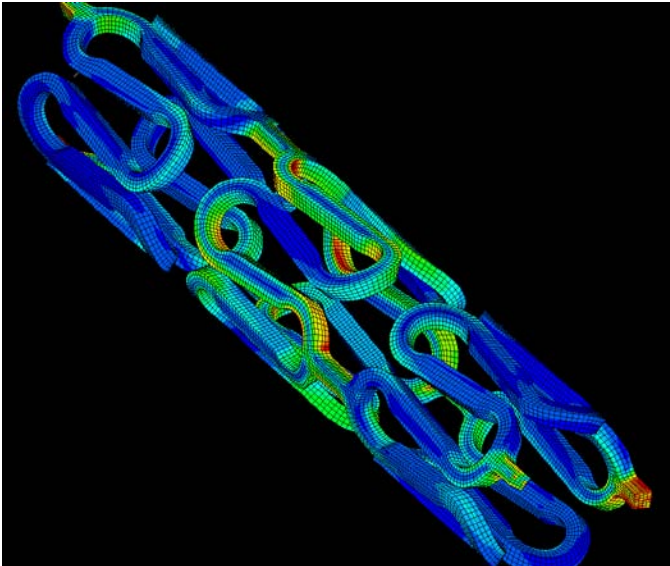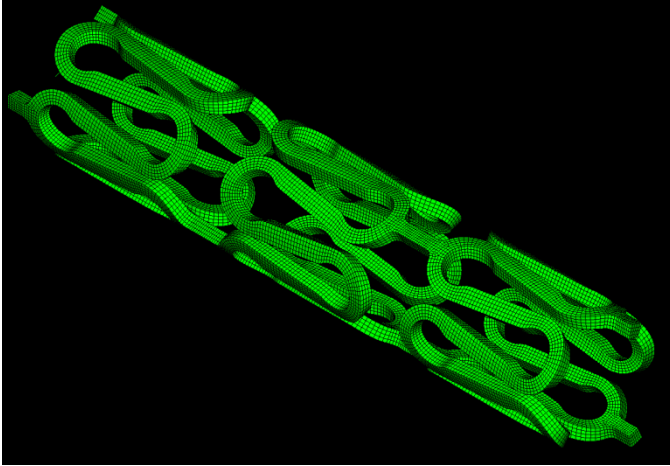
Fatigue Analyses relate the stress and strain output from FEA to the material failure criteria.
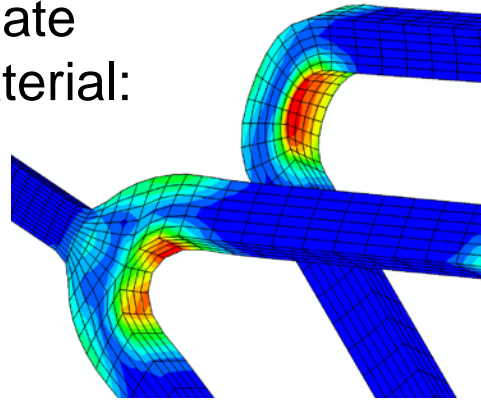
These criteria account for residual and mean stress conditions to determine a Safety Factor for the design.

Loading History Affects Fatigue
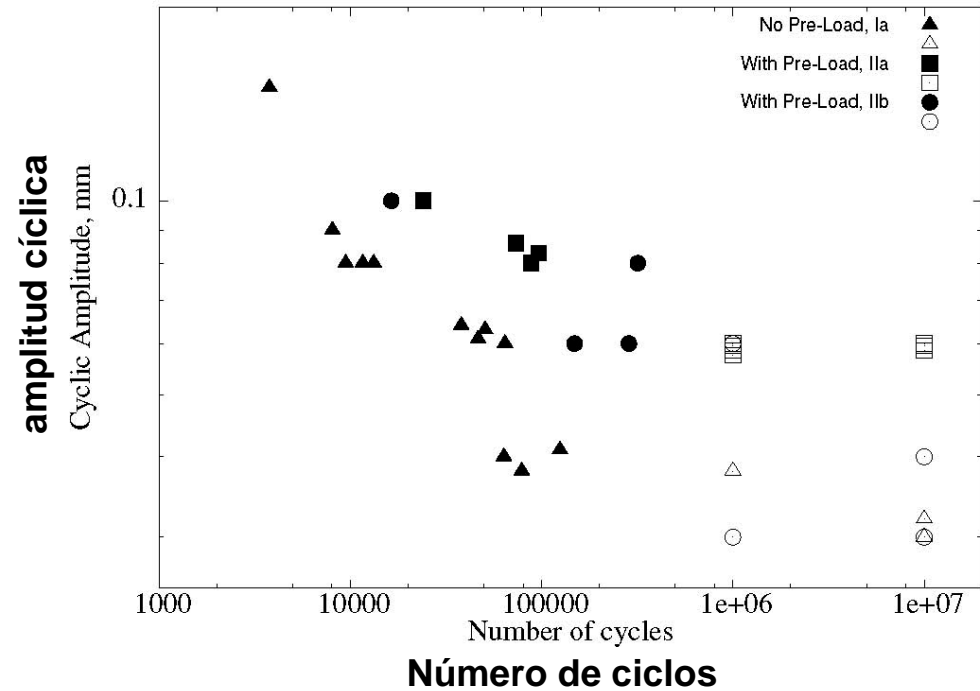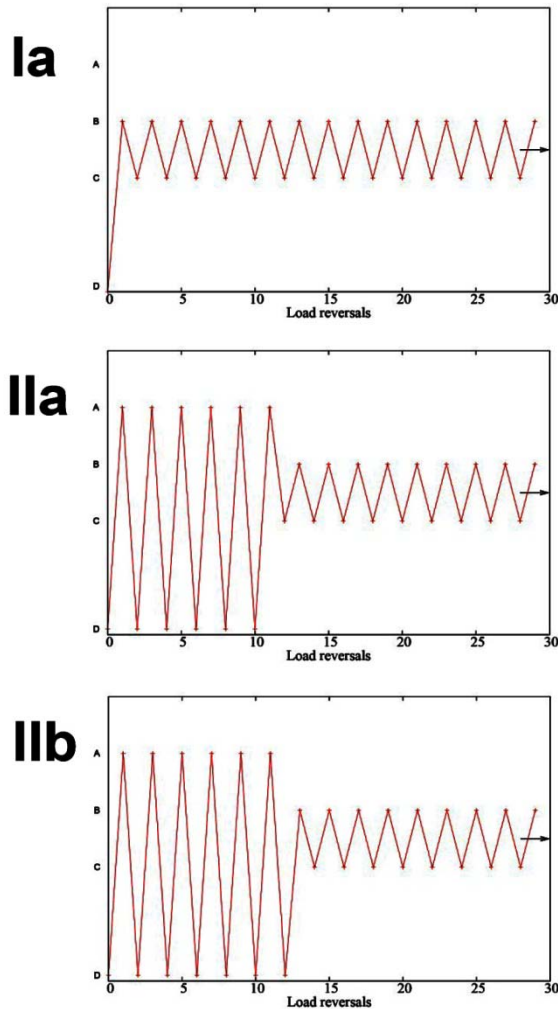
Large amplitude pre-loads can influence the durability of implantable medical devices

Residual Stress Affects Fatigue
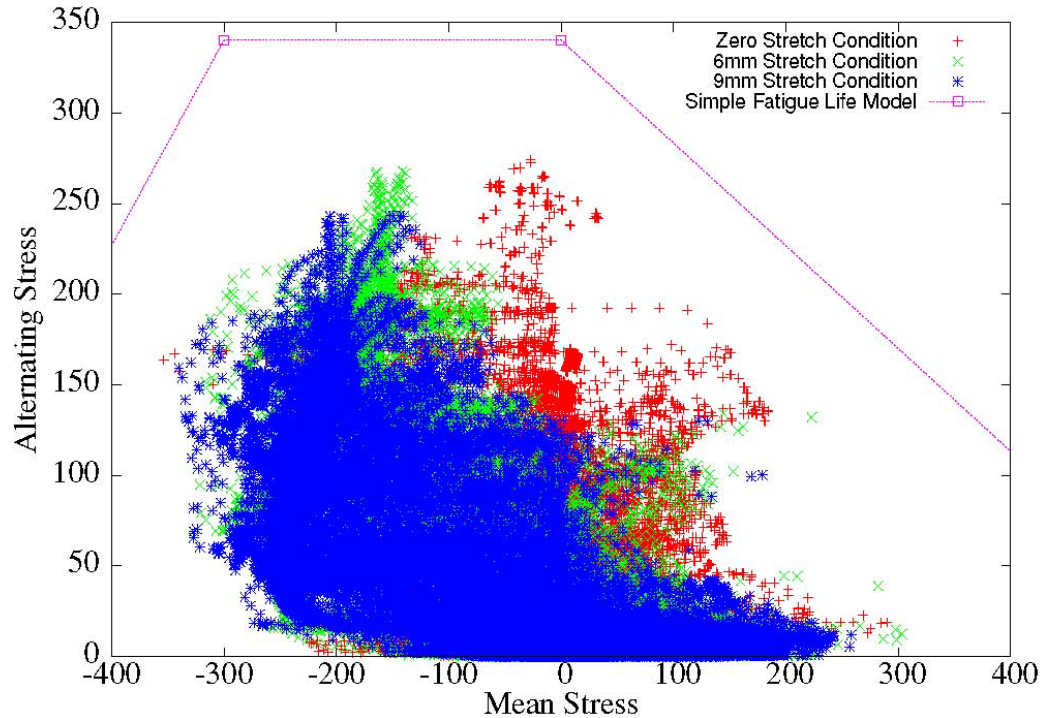
Residual stress caused by balloon expansion of stents changes the material limit properties and may need to be considered when performing a fatigue analysis

Mean Strain Affects Fatigue
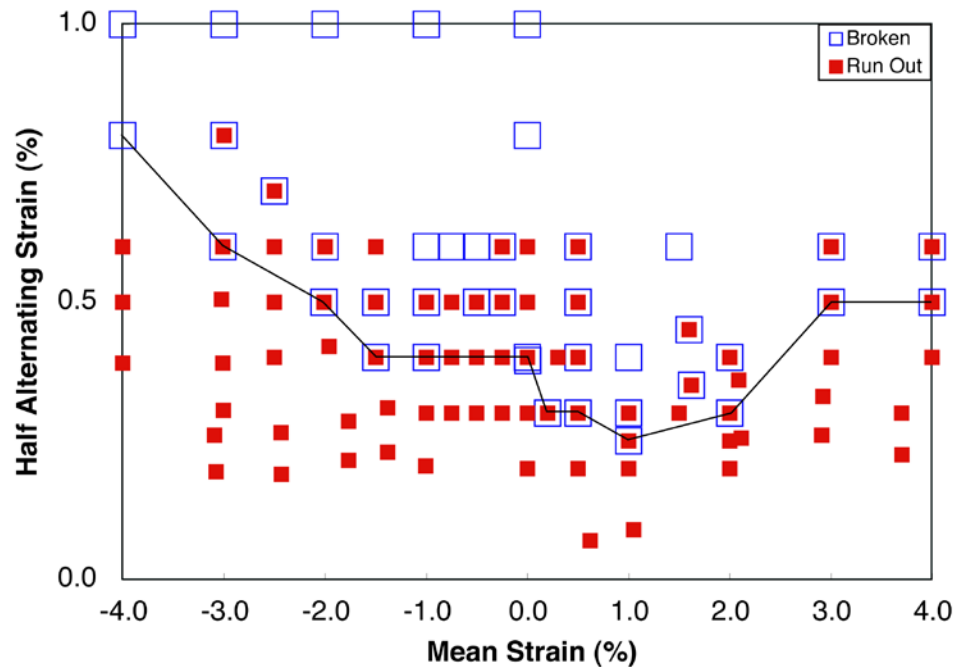
X-Y Gong, T. Duerig, A. Mehta, V. Imbeni, B. Berg, Presented at Society for Experimental Mechanics 2004 Annual Meeting

Mean strain levels affect the durability of medical devices made from nitinol

Device Engineering Best Practice

- A combination of Testing and Modeling is essential for successful device development

- Testing provides:
  - Material behavior information
  - Device performance validation data
  - Material limit information

- Modeling provides:
  - Self-consistent approach utilizing all experimental data
  - Bounds on the impact of uncertain information
  - Safety factors for complex loading scenarios

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High Priorities at the FDA

FDA has identified an important role for Computer Modeling and Simulation in its strategic priorities.

Science Priority Areas

#1 Modernize Toxicology

#2 Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes

#4 Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

#5 Harness Diverse Data through Information Sciences to Improve Health Outcomes

- (Q)SAR models to predict human risk
- Computer models of cells, organs, and systems to better predict product safety and efficacy
- Virtual physiologic patients for testing medical products
- Clinical trial simulations that reveal interactions between therapeutic effects, patient characteristics, and disease variables
- Knowledge building tools
- Methods to verify, store, share

http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/Regulatory Science/UCM268225.pdf

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M&S at the FDA

- Guidance on documentation and reporting M&S results in pre-market submissions;
  - **FDA DRAFT Guidance on *Reporting of Computational Modeling Studies in Medical Device Submissions* – published Jan 2014[1]**

- Systematic assessment and understanding of device-use conditions;
  - **Critical Path Innitiative[2]**
  - **FDA Library of Models and Simulation[3]**
  - **Medical Device Innovation Consortium[4]**

1, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm371016.htm
2, http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm
3, http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm346375.htm
4, http://mdic.org/projects/computer-modeling/

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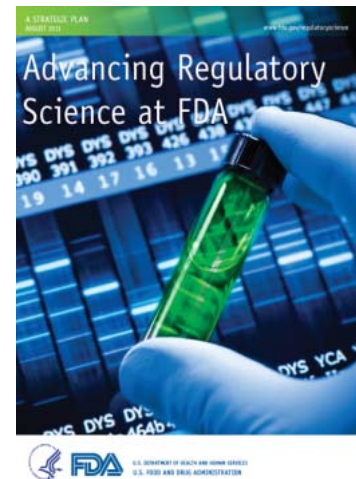
M&S at the FDA

- Methodologies to experimentally validate M&S;

- Test methods and guidance document development

  - **CDRH at FDA is actively engaged with ASTM**

- Sensitivity analyses and uncertainty quantification

  - **ASME verification & validation standards committee V&V 40**

- Better elicitation of the consequence of the M&S being incorrect.

  - **CDRH is getting ready to launch a pilot program to expand the current uses of M&S in regulatory submissions, and to implement the credibility strategy**

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Acknowledgements

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design engineering analysis