

Cardiovascular Test Methods: Part III

Current Issues in Materials and Testing

PERU Workshop on Medical Device Regulation: Policy and Technical Aspects



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Standard Guide for Testing Absorbable Stents

F3036

Scope: Polymeric AND Metallic Materials

References:

ASTM F1635: Chemical Degradation

ASTM F2606: Stent System Bending

ASTM F2394: Stent Securement

ASTM F2079: Stent Recoil

ASTM F2606: Stent Radial Strength

ASTM F2477: Radial Pulsatile Testing

F3036 is a guide and primarily describes sample and testing conditions unique to bioabsorbable stents. It has appendices with special considerations for the referenced standard test methods (F2606, F2394 and F2079)

Standard Guide for Testing Absorbable Stents

F3036

Scope: Polymeric AND Metallic Materials

The scope for F3036 does not exclude metallic absorbable stents, HOWEVER, there are no current test methods available for these materials.

The issue: There was not consensus in the industry about the mechanisms of degradation, in vitro or in vivo when the standard was written. Specifically, There was not agreement on the best degradation media to use for testing metallic absorbable materials in vitro. Therefore, the best test methods and procedures could not be determined.

Standard Guide for Testing Absorbable Stents F3036

Ongoing Work:

Polymeric Bioabsorbable Materials

- Material Degradation Model developed by researchers at the FDA, to be published
- Include reference and modifications for Radial Force Testing of Stents (F3067)

Metallic Bioabsorbable Materials

- Three ASTM standards are being developed
 - in vitro degradation
 - material specification
 - biological evaluation

Test to Success versus Test to Fracture

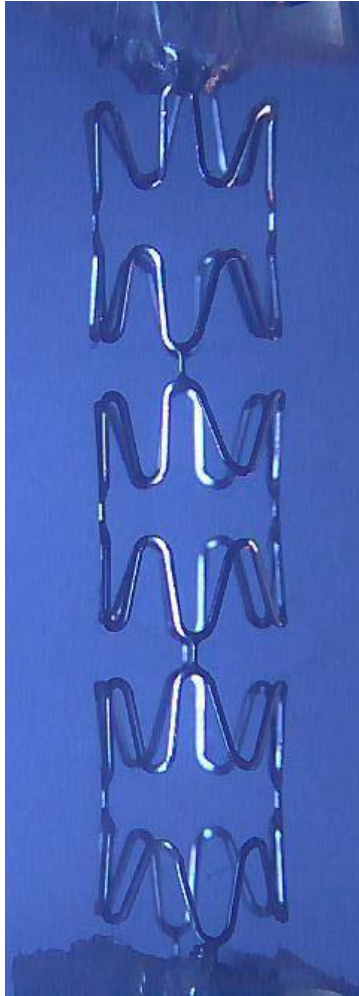
Do we learn more by testing a few devices to survive a limited set of loading conditions?

OR

Do we learn more by testing lots of samples to fracture and modeling the device under all anticipated loading conditions?

ASTM F04.30.06

Fatigue to Fracture Round Robin Study



Committee members participated in a round robin study of a generic balloon expandable stent.

300 stents were designed, manufactured and distributed to participating labs.

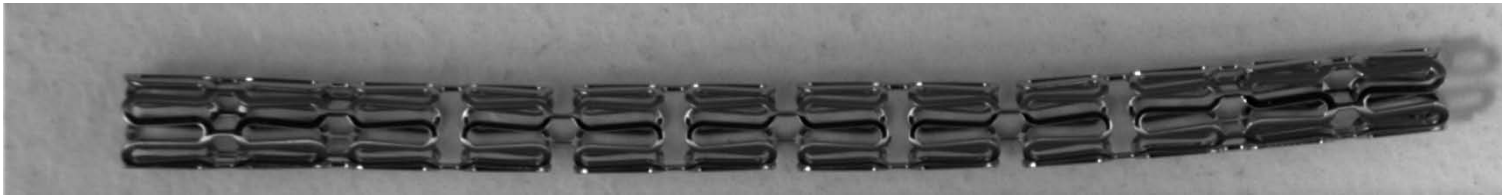
Objective of inter-laboratory testing study:
Perform Axial Fatigue testing of one design at multiple load levels. Compare results from independent labs.

Objective of computational modeling study:
FE and Fatigue analysis of 316 L SS stent in Axial Fatigue. Predict expected life for multiple load levels.

gStent[©] BE

Generic Balloon Expandable Stent

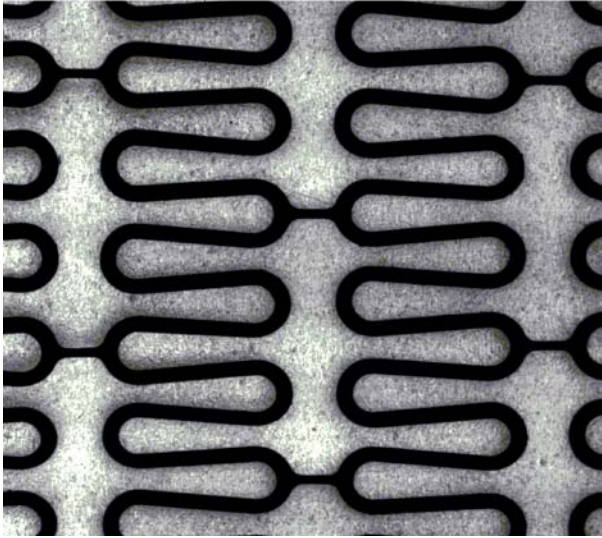
- Typical balloon expandable stent design
- Symmetric bridge structure (universal joint pattern)
- End sections have larger dimensions, fully bridged



- 0.070x0.058, SS tubing, typical
- Laser-cut and electropolished

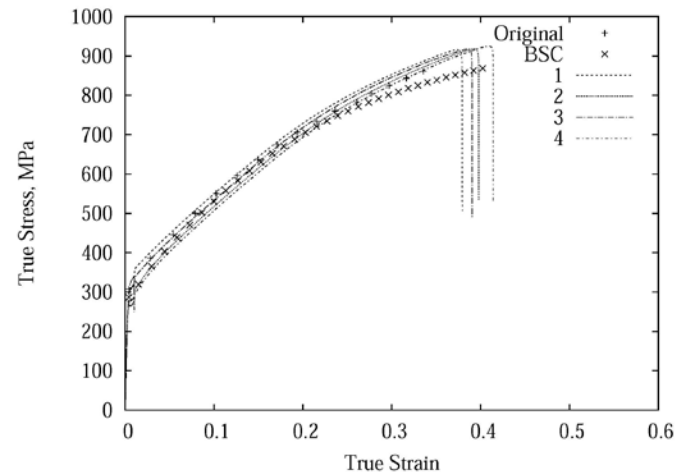
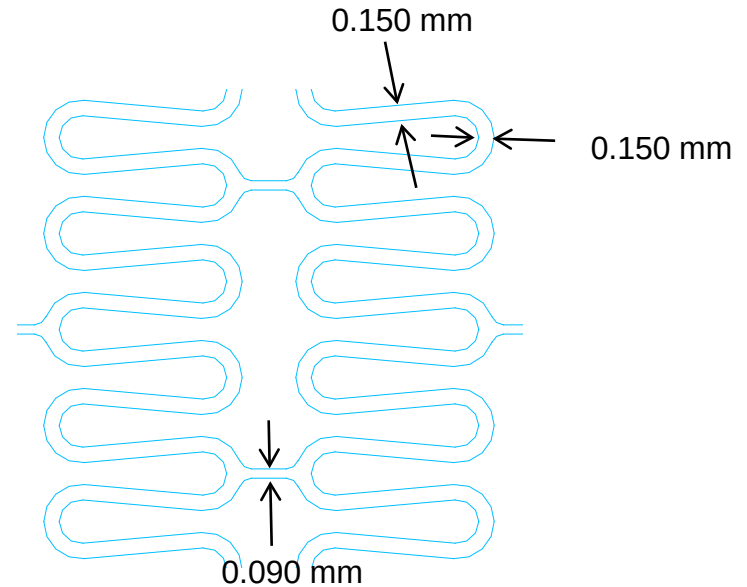
The gStent BE is a surrogate sample because it is created to mimic the final device, but with a simpler geometry that facilitates fatigue testing.

Verification of FEA Input Data



Optical scan of the finished device provided by BSC

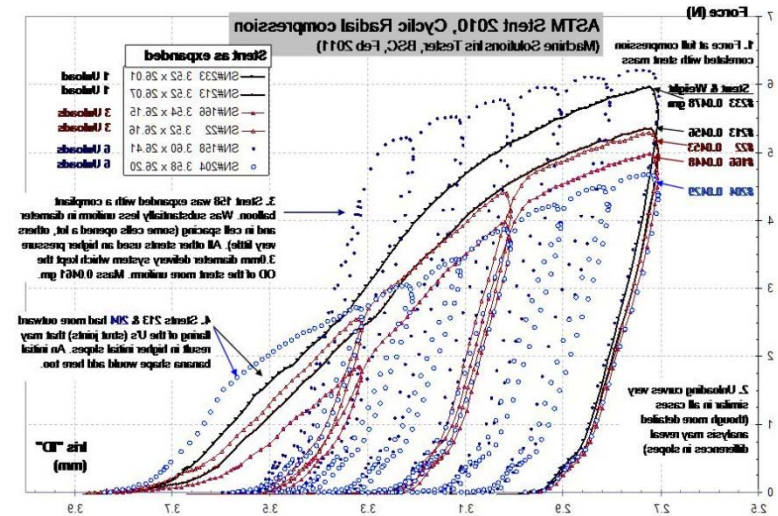
The geometric details and input material behavior were verified following the best practices for FEA for implantable medical devices



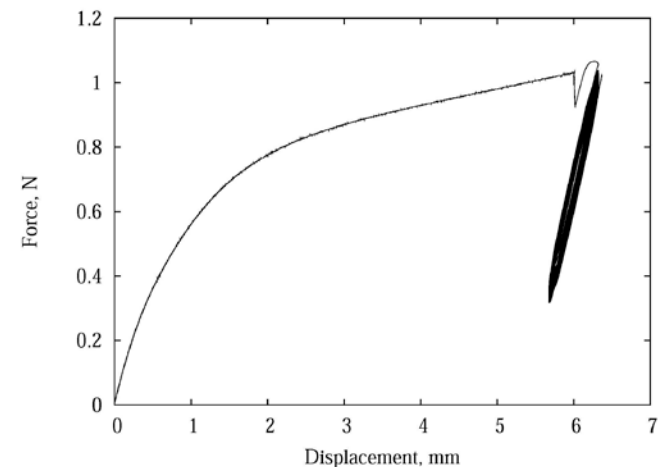
Validation Data from Bench Test Results

Participants provided measurements for radial force by several methods. The results of the radial force testing depended on the test method used. Test results for axial extension were also contributed.

These data were used in the computational modeling study that accompanied the fatigue testing.



Radial force versus diameter data provided by BSC



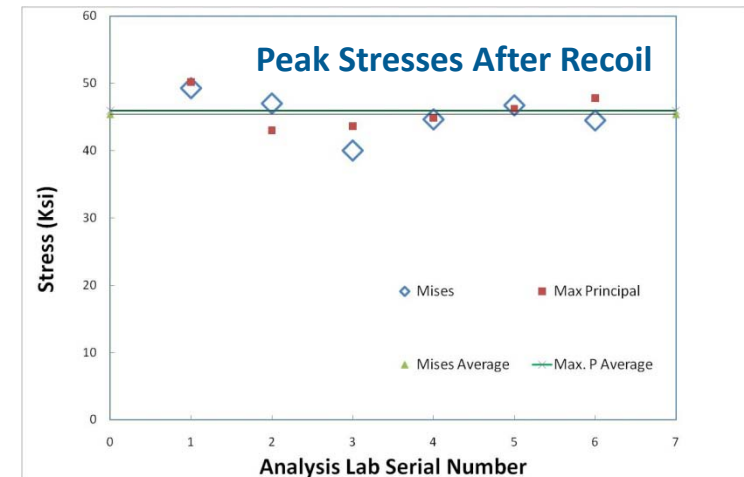
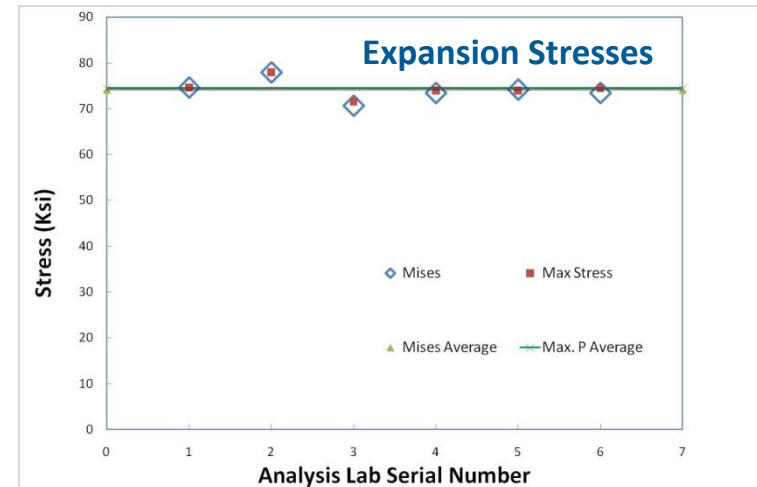
Axial force versus extension, data provided by ECHOBIO LLC

Inter-laboratory Computational Model Study

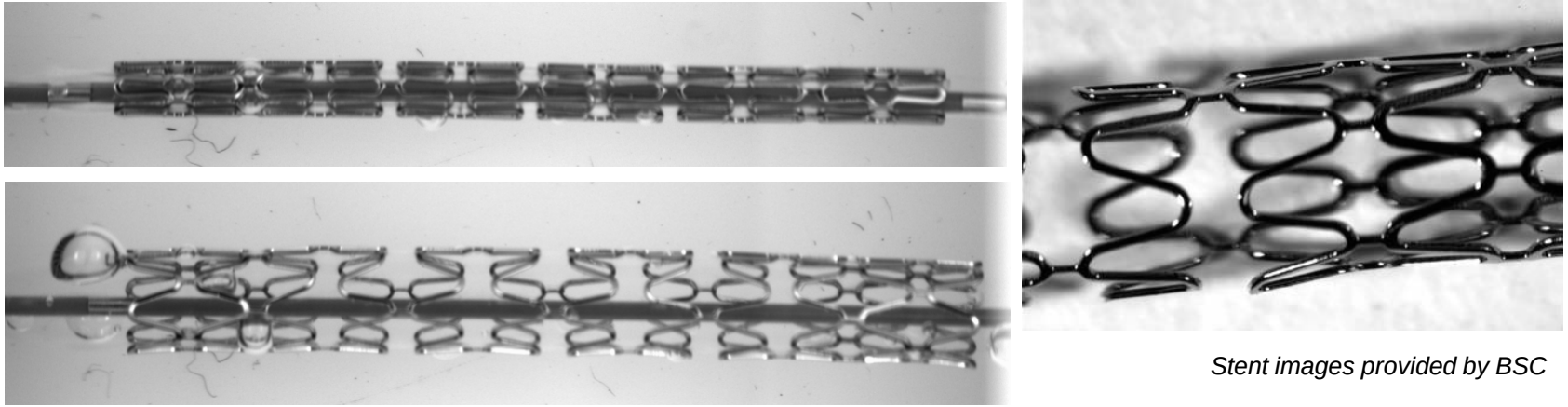
Computational modeling results were compared between the labs.

Differences between various FEA software, analysis parameters and methodologies were identified and understood.

Peak stress results according to the various labs are shown.



Consistent Loading History Observed



Stent images provided by BSC

Computational models suggested that material plasticity during balloon catheter expansion could affect the fatigue property.

Identical catheters were distributed to insure that all stents received equal expansion before fatigue testing.

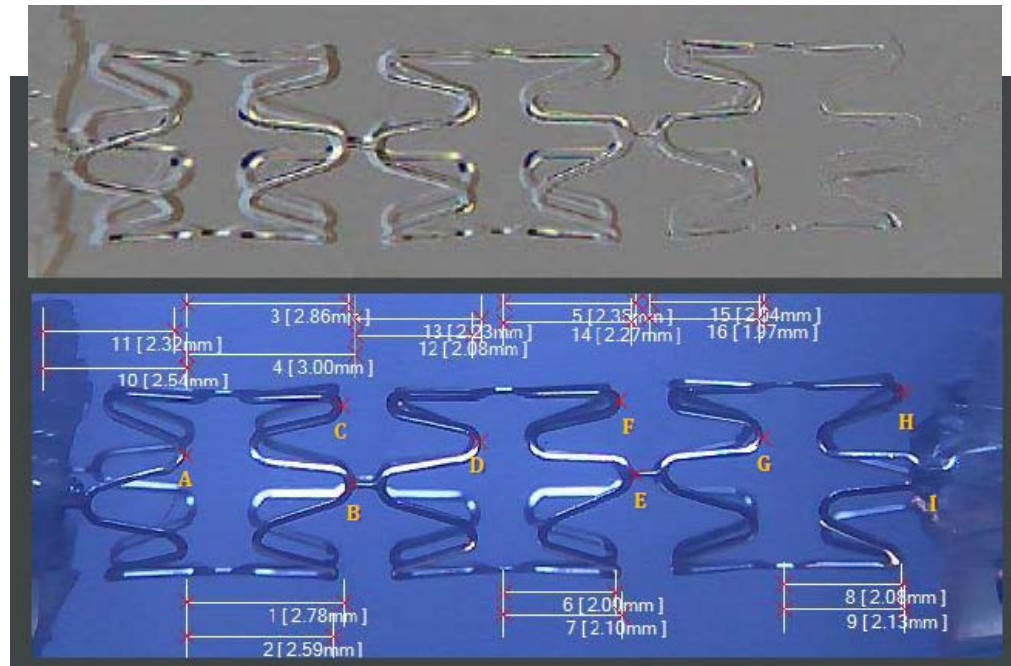
The most uniform expansion was achieved with non-compliant balloons.

Verification of Dynamic Motion During Axial Fatigue of the gStent BE using a High Speed Camera

The gStent was shown to significantly lower buckling than previous stents due to more symmetric design

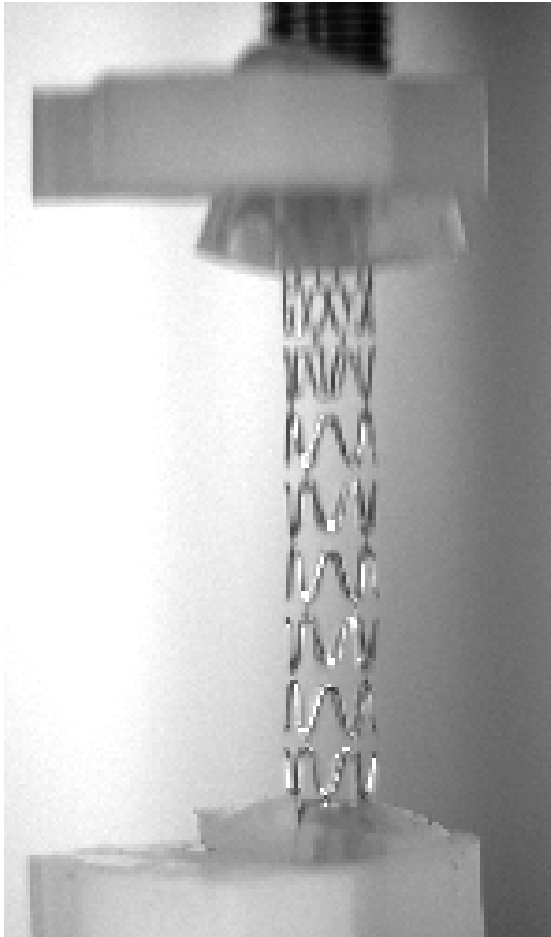
Possibly significant motion (0.05 mm) of stent was observed at non-moving silicone grip. The design of the gStent solved the problem of getting consistent results.

Accurate measurements of the loading conditions were obtained from the high speed images.



High speed imaging data provided by Cook's Med Institute

Round Robin Fatigue Test Protocol



Fatigue testing was performed by each lab according to a test protocol.

The stents were axially vibrated between fixed displacements to simulate the small movements of blood pressure

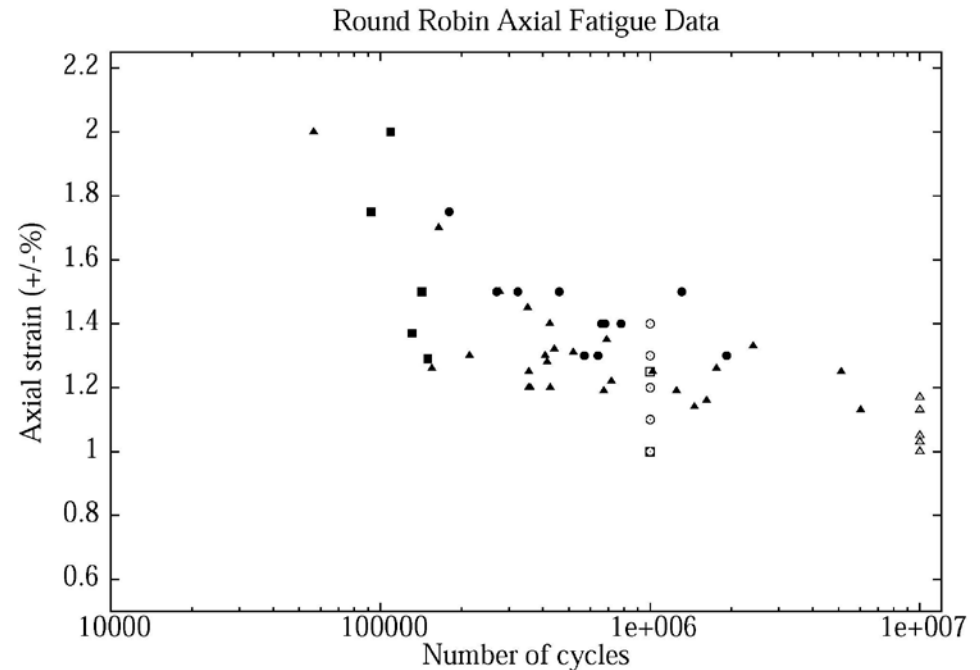
Testing was performed to 1 million cycles or until the sample broke

Round Robin Fatigue Results

Very good agreement
between the laboratories.

‘Soft’ grip conditions were
found to be most effective.

The data from all the labs
was combined and a better
analysis made of the
material limit property.

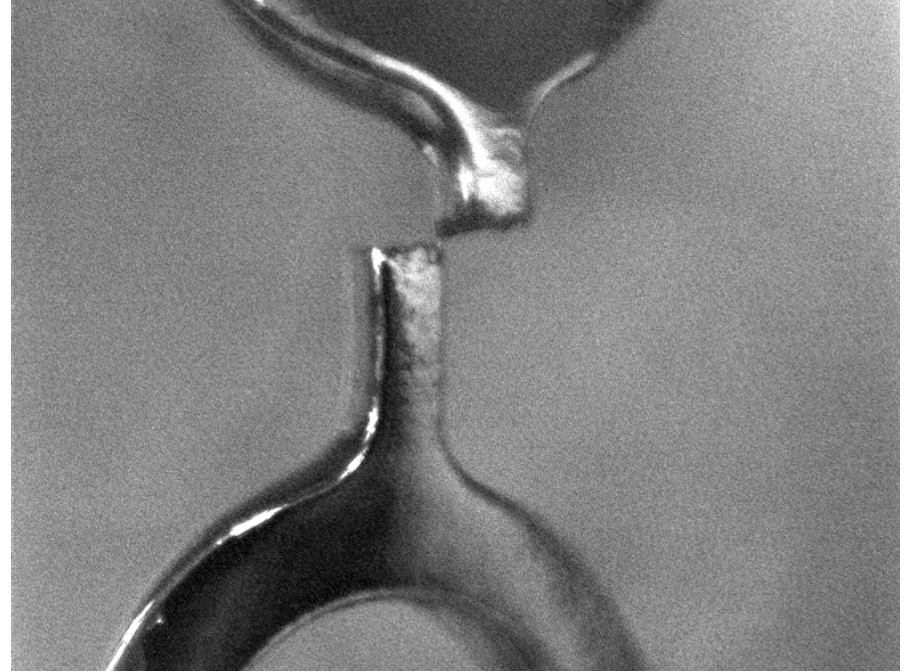


Fatigue Endurance Limit
1M cycles axial strain
50% survival rate
+/-1,23 % or 340MPa

Round Robin Fatigue Results

All of the fractures in the study occurred in the gage sections of the sample

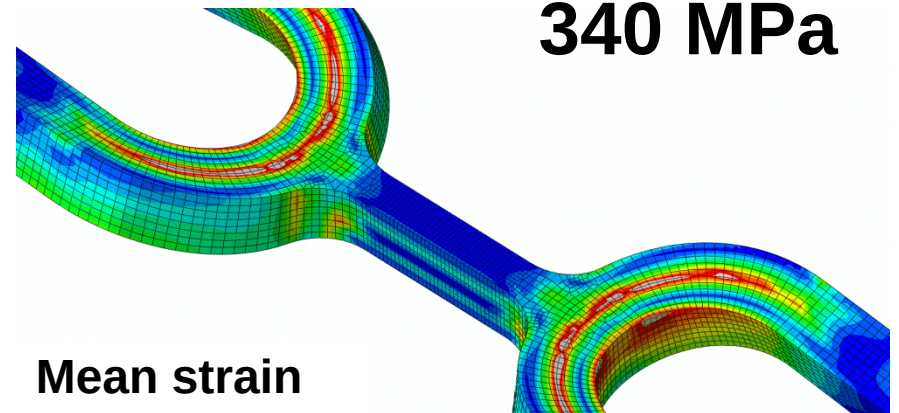
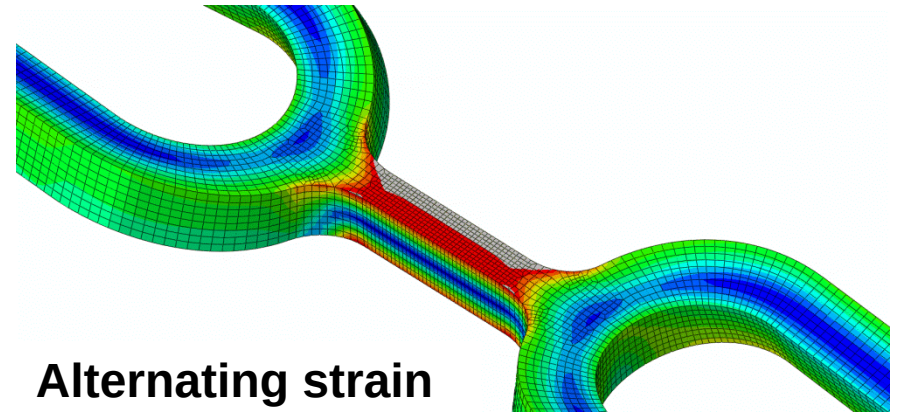
This is good news because it means the test article performed as it was intended.



Computational Model Results

The fractures occurred in regions of high alternating strain as predicted by FEA.

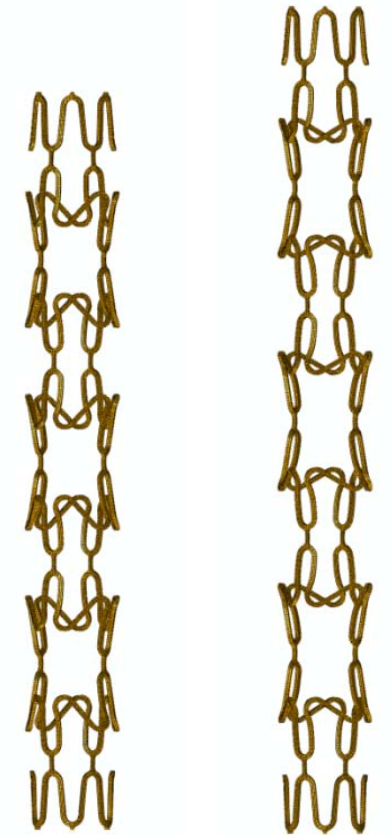
The mean strain at those locations were very low.



Fatigue Testing with Pre-Stretch

An additional study was performed to evaluate the effect of plasticity on the fatigue property.

Some samples were pre-stretched axially 6mm or 9mm before fatigue testing.



6mm

9mm

Fatigue Testing with Pre-Stretch Results

Fracture locations were different!

This is good news because it means the pre-stretch had the intended effect.

The results were statistically different for 6mm and 9mm!



Computational Model Results

Fracture locations occurred where computational models predicted high levels of mean strain

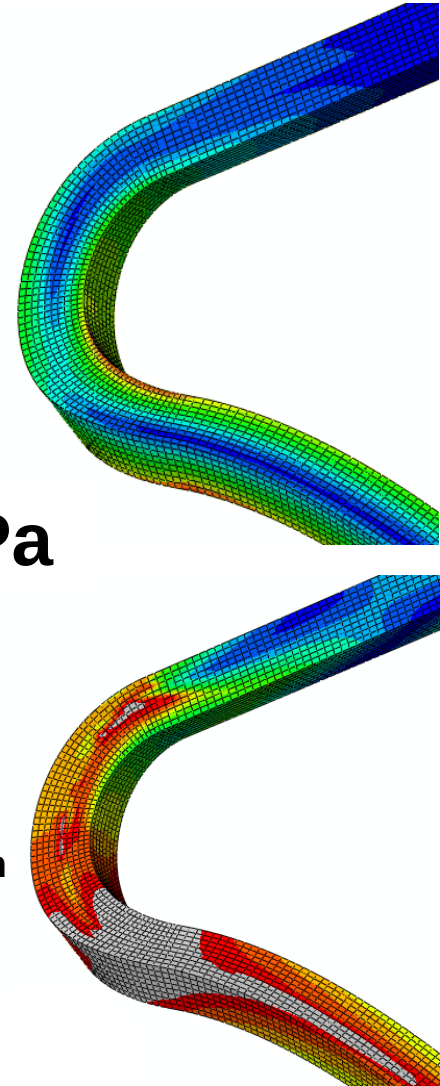
The pre-stretch creates localized plastic deformation which reduces the allowable alternating strain.

No stretch = 340 MPa
6mm stretch = 320 MPa
9mm stretch = 280 MPa

Alternate Strain

280 MPa

Mean Strain

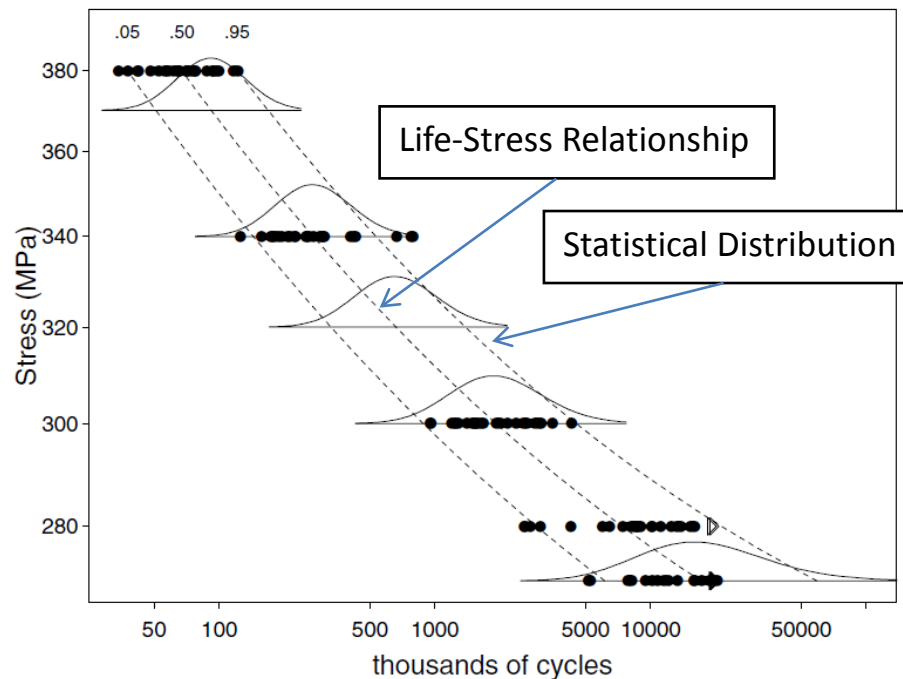


ASTM F04.30.06 Fatigue to Fracture

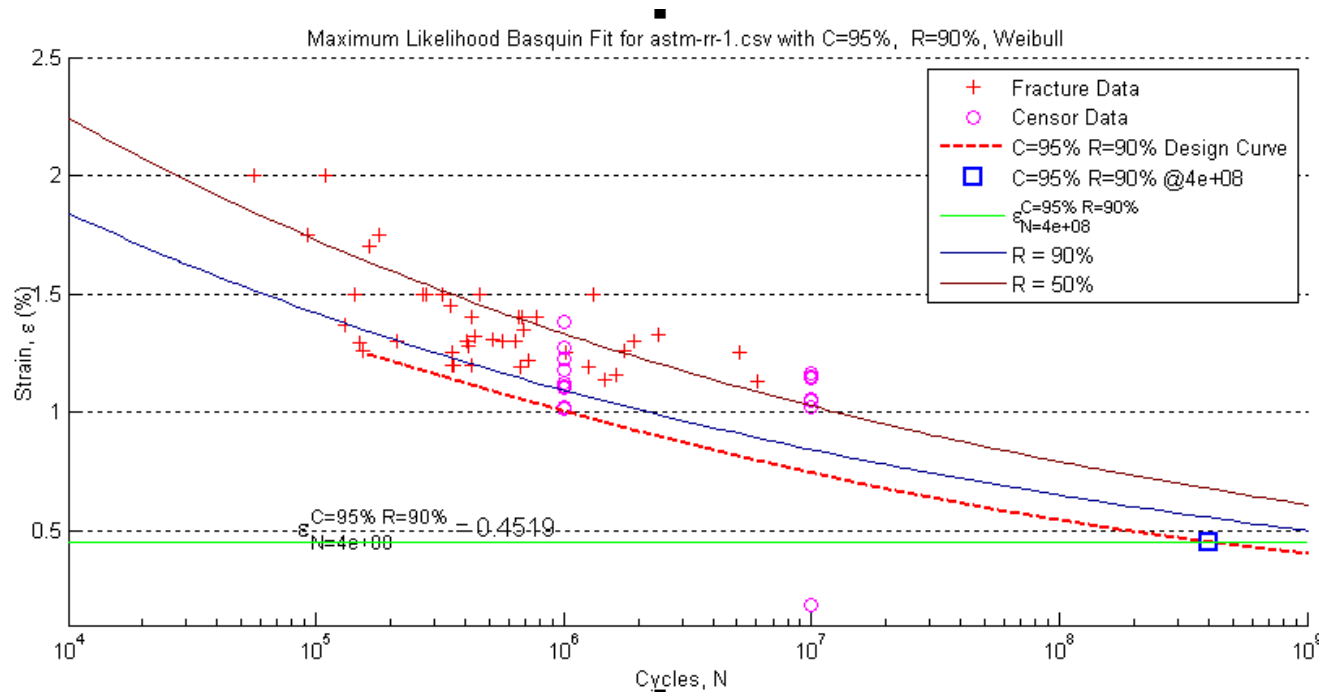
Guide to the Fatigue-to-Fracture(FtF) Methodology for Evaluating Durable Cardiovascular Medical Devices.

Scope

This guide is intended to provide methods to determine a lower bound on fatigue life at clinically relevant conditions by extrapolation of measured cycles to fatigue fracture(s) at hyper-physiological conditions.



Statistical Analysis and Extrapolation of Fatigue Data



Statistical analysis of the round robin data. The plotted results show the “95/90 design curve” i.e. the lower 95% confidence bound on the 90% reliability quantile.

Summary

**Computational models are most convincing
when material input data includes probability
statistics and confidence intervals**

Acknowledgements



ASTM F04.30.06

Medical and Surgical Materials and Devices:
Interventional Cardiology Task Group



Maureen Dreher



Andres Schulz
Rodney Dwyer
Kasondra Totura

