# Technical Training: Medical Device Manufacturer Perspective – ASTM Material Test Methods for Assessing the Performance of Cardiovascular Devices

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PERU Workshop on Medical Device Regulation and Standards: Policy and Technical Aspects
25 January, 2017

# Outline

## Relevant ASTM Committees & Some Specific Standards

## Mechanical Fatigue of Devices In-vivo

## Fatigue

# Lots of ASTM Committees provide Standards useful to Material Testing of Medical Devices

Committee D14 on Adhesives
Committee D20 on Plastics
Committee E04 on Metallography
**Committee E08 on Fatigue and Fracture**
Committee E28 on Mechanical Testing
Committee E11 on Quality and Statistics
**Committee F04 on Medical and Surgical Materials and Devices**
Committee G01 on Corrosion of Metals
Committee G02 on Wear and Erosion

**https://www.astm.org/COMMIT/alpha.html**

# Selection of ASTM F04 Material Test Methods

## Subcommittee F04.15 on Material Test Methods

F640-12 Standard Test Methods for Determining Radiopacity for Medical Use
F746-04(2014) Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials
F1801-97(2014) Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials
F2004-05(2010) Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis
F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
F2082/F2082M-16 Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery
F2119-07(2013) Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
F2129-15 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
F2182-11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
F2213-06(2011) Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
**F2516-14 Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials**
F3044-14 Test Method for Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants

## Subcommittee F04.12 on Metallurgical Materials

**F138-13a Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)**
F562-13 Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)
F2063-12 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants
F2633-13 Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants

**https://www.astm.org/COMMIT/SUBCOMMIT/F04.htm**

# Selection of ASTM F04 Device Test Methods

## Subcommittee F04.30 on Cardiovascular Standards

F2079 Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents
F2081 Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents
F2394 Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System
**F2477 Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents**
F2514 Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading
**F2606 Standard Guide for Three-Point Bending of Balloon Expandable Vascular Stents and Stent Systems**
F2743 Standard Guide for Coating Inspection and Acute Particulate Characterization of Coated Drug-Eluting Vascular Stent Systems
F2914 Standard Guide for Identification of Shelf-life Test Attributes for Endovascular Devices
**F2942 Standard Guide for in vitro Axial, Bending, and Torsional Durability Testing of Vascular Stents**
F3036 Standard Guide for Testing Absorbable Stents
F3067 Guide for Radial Loading of Balloon Expandable and Self Expanding Vascular Stents
F3172 Standard Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices

**Current Work Items**
WK52963 Development of Simulated Use Anatomical Models for Stent and Endovascular Graft Systems
WK8279 New Terminology for Standard Terminology Relating to Vascular Stents
**WK29690 New Guide for to the Fatigue-to-Fracture (FtF) Methodology for Evaluating Durable Cardiovascular Medical Devices**
WK46148 New Guide for Coating Characterization of Drug Coated Balloons
WK52295 Active Fixation Durability of Endovascular Prostheses
WK52296 Stent, Stent-Graft Kink Resistance
WK52980 Proximal Seal Leakage of Endovascular Grafts

# E08 – Fatigue and Fracture Standards

## Subcommittee E08.04 on Structural Applications

E739-10(2015) Standard Practice for Statistical Analysis of Linear or Linearized Stress-Life (S-N) and Strain-Life (ε-N) Fatigue Data
E1049-85(2011)e1 Standard Practices for Cycle Counting in Fatigue Analysis

## Subcommittee E08.05 on Cyclic Deformation and Fatigue Crack Formation

E466-15 Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
E468-11 Standard Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials
E606/E606M-12 Standard Test Method for Strain-Controlled Fatigue Testing
E2207-15 Standard Practice for Strain-Controlled Axial-Torsional Fatigue Testing with Thin-Walled Tubular Specimens
E2789-10(2015) Standard Guide for Fretting Fatigue Testing
**E2948-16a Standard Test Method for Conducting Rotating Bending Fatigue Tests of Solid Round Fine Wire**

## Subcommittee E08.06 on Crack Growth Behavior

E647-15e1 Standard Test Method for Measurement of Fatigue Crack Growth Rates
E1457-15 Standard Test Method for Measurement of Creep Crack Growth Times in Metals
E1681-03(2013) Standard Test Method for Determining Threshold Stress Intensity Factor for Environment-Assisted Cracking of Metallic Materials
E2760-16 Standard Test Method for Creep-Fatigue Crack Growth Testing

# Outline

✓ Relevant ASTM Committees & Some Specific Standards

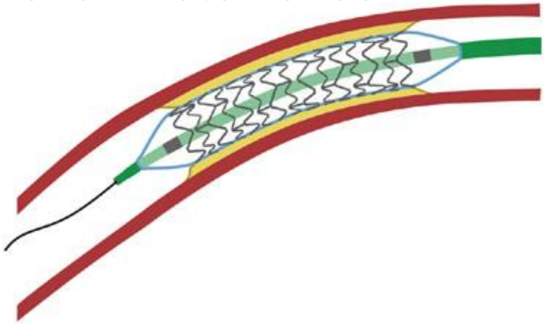
**Mechanical Fatigue of Devices In-vivo**

Fatigue

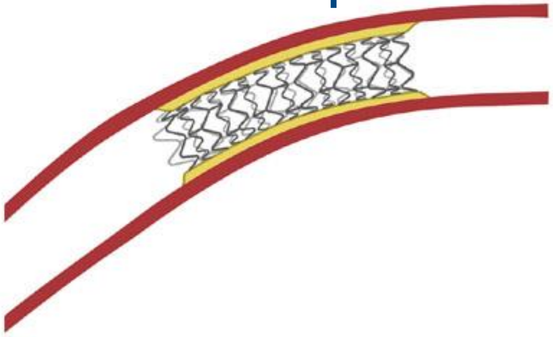
# Arterial Stenting and Deformation

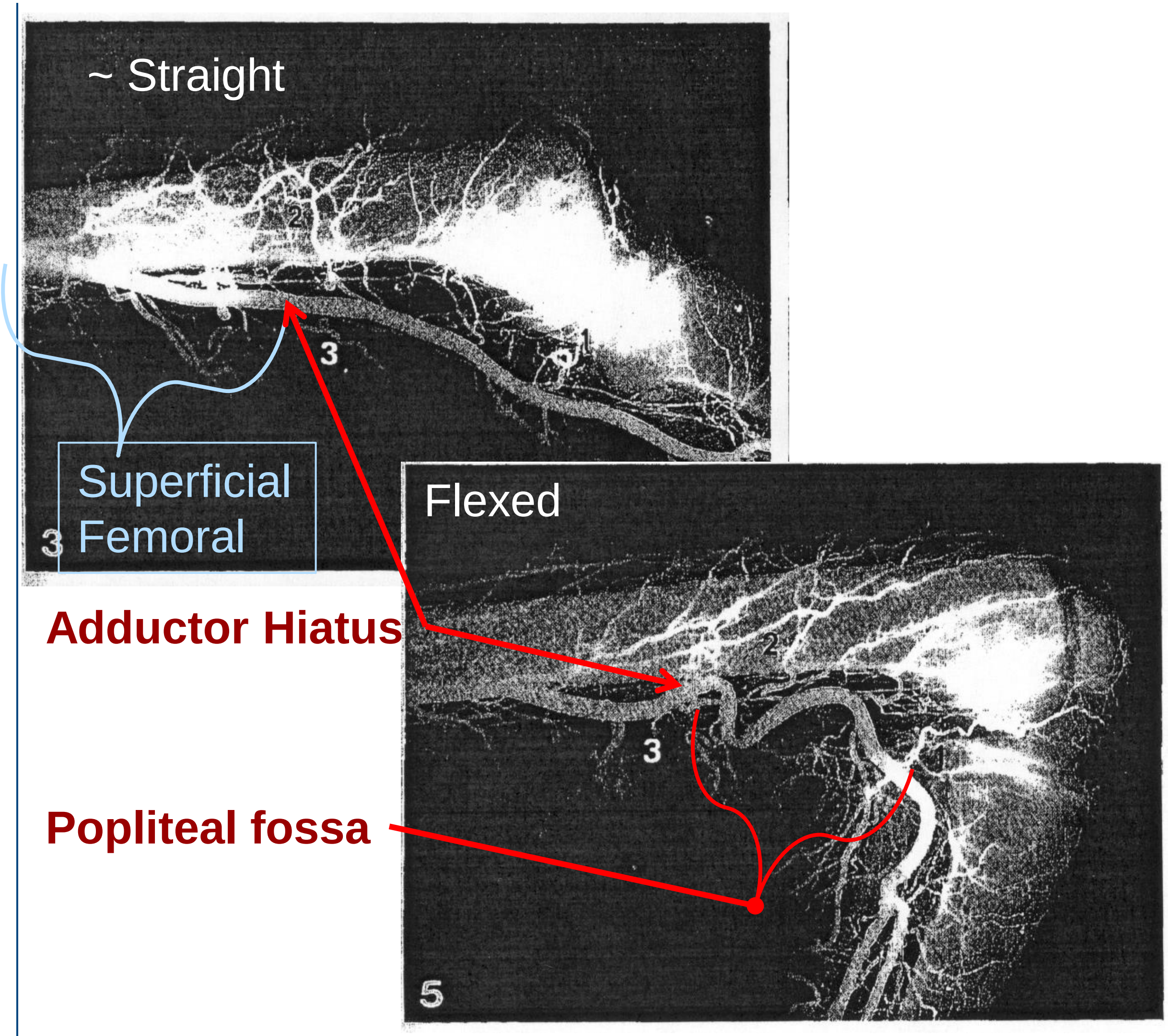
## Identify Occlusion

## Place Stent Delivery System and Inflate Balloon



## Final Result- Open Vessel





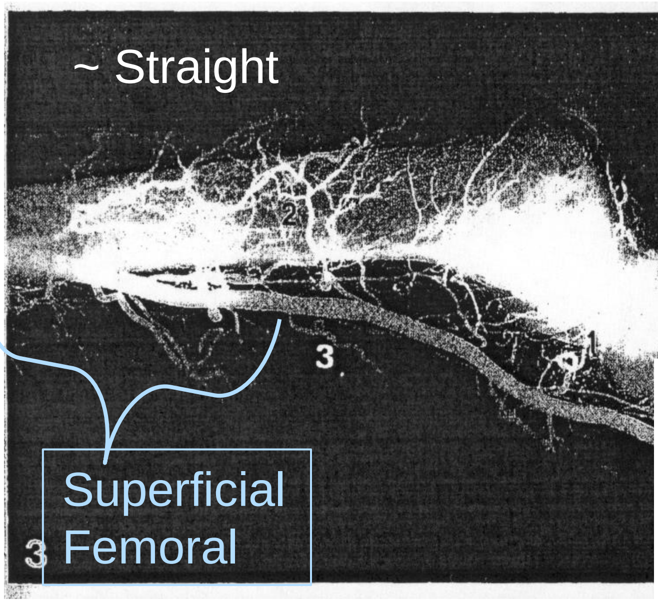
Superficial Femoral

**Adductor Hiatus**

**Popliteal fossa**

*P. Vernon P, Surg Radiol Anat. 1987;9(1):37-41.*

# Deformation in muscular tissue



## Muscles Contract and Vessels are tethered

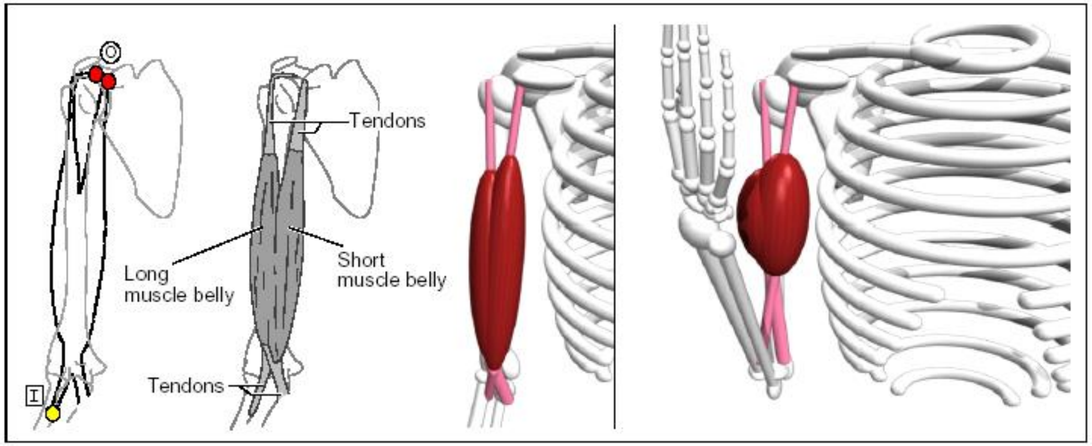


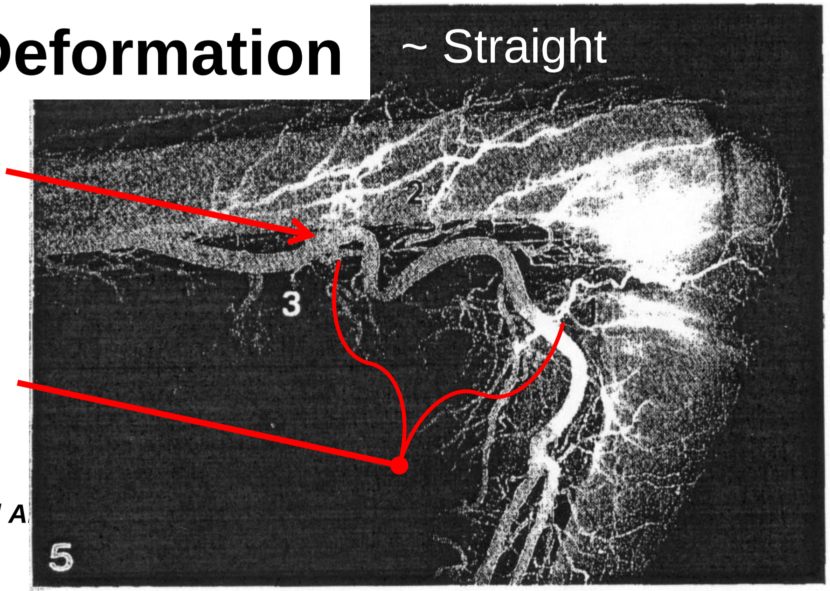
Figure 11: Front view of the biceps brachii and its behavior when the forearm is flexed at the elbow joint.

**Anatomy-Based Modeling of the Human Musculature**
**Ferdi Scheppers, et al, SIGGRAPH 1997**

***P. Vernon P, Surg Radiol Anat. 1987;9(1):37-41.***

# Deformation in non-muscular tissue

## Popliteal Deformation



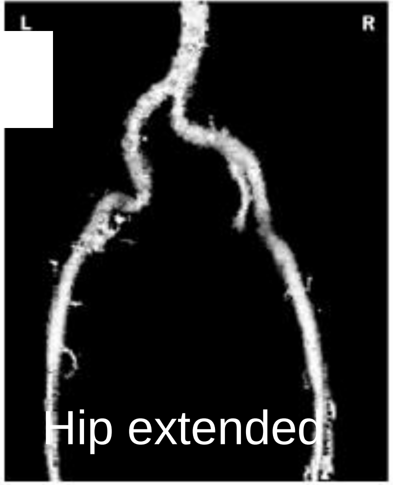
**Adductor Hiatus**

**Popliteal fossa**

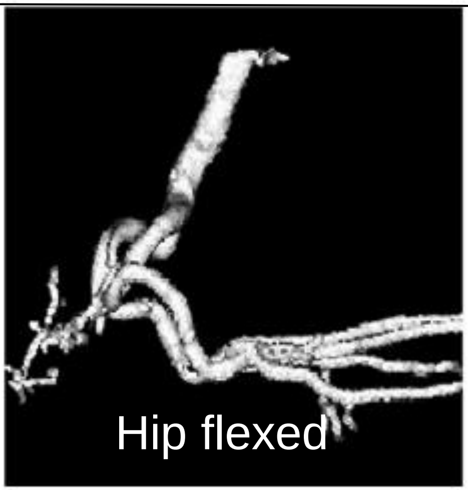
*P. Vernon P, Surg Radiol A*
*1987;9(1):37-41.*

**Elastic pre-tensioned vessels contract with flexure and lose elasticity with age.**

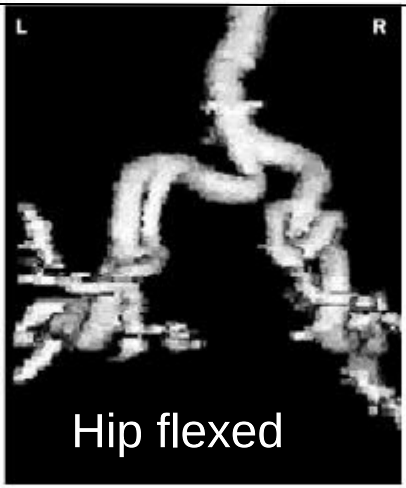
## Iliac Deformation



Hip extended



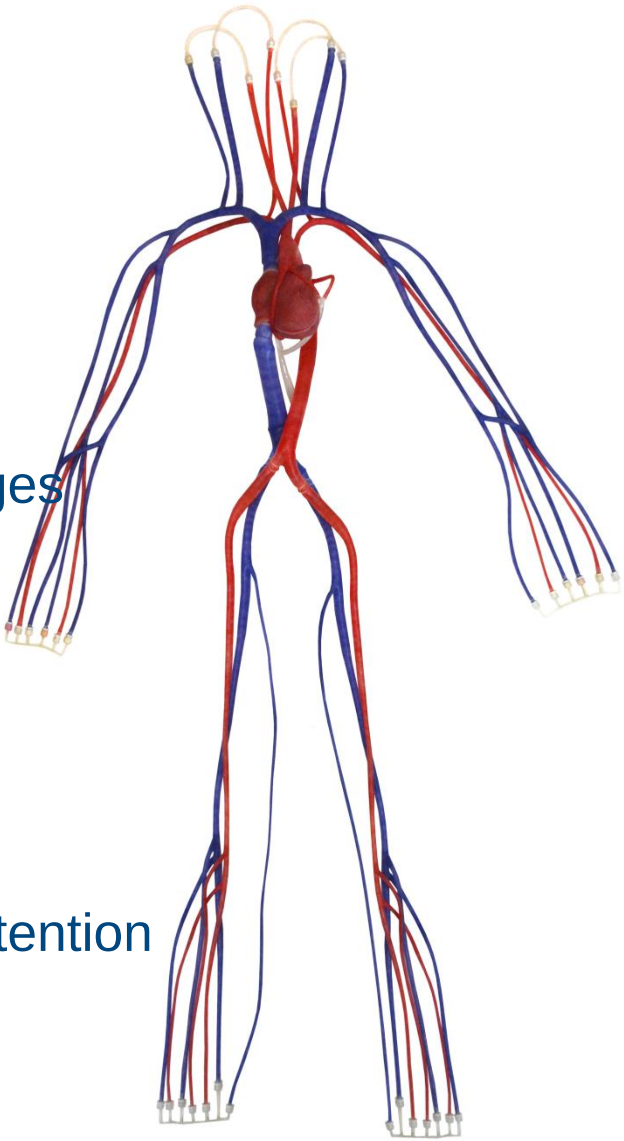
Hip flexed



Hip flexed

*G Schep, Saint Joseph Hospital, Veldhoven, Netherlands, Detection and treatment of claudication due to functional iliac obstruction in top endurance athletes: a prospective study, Lancet (359) 2002*

# What may deform vessels & devices in vessels:



**Cardiac Cycle**
- Pressure changes
- Fluid Mechanics

**Breathing**
- Diaphragm motion
- Internal pressure changes

**Flexure**
- Muscle contraction
- Tissue motion

**Disease?**
- Inflammation, Fluid Retention

**External Forces**

*Type of activity*

*Activity Intensity*

*Frequency of activity*

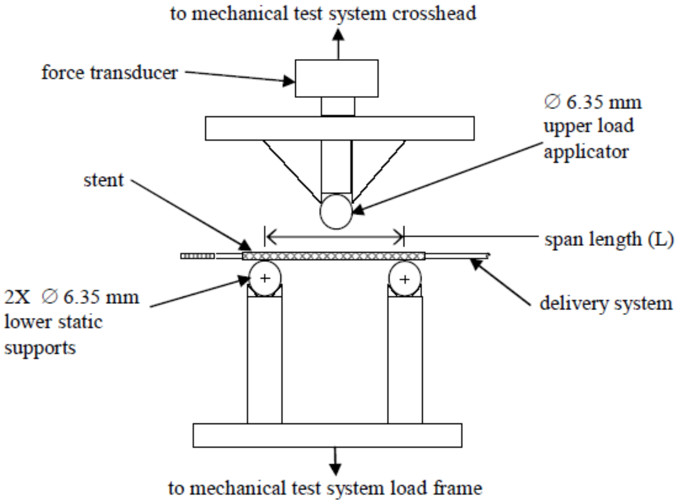
*Tissue mechanics*
- *Age*
- *Disease*
- *Fitness*

**http://syndaver.com/wp-content/uploads/2014/04/vasculature-complex-full-body-updated.jpg**

# Bending Deformation Mechanical and Fatigue Test *Guides* for Stents

**Designation: F2606 – 08 (Reapproved 2014)**

## Standard Guide for
## Three-Point Bending of Balloon Expandable Vascular Stents and Stent Systems[1]



**Designation: F2942 – 13**

## Standard Guide for
## *in vitro* Axial, Bending, and Torsional Durability Testing of Vascular Stents[1]

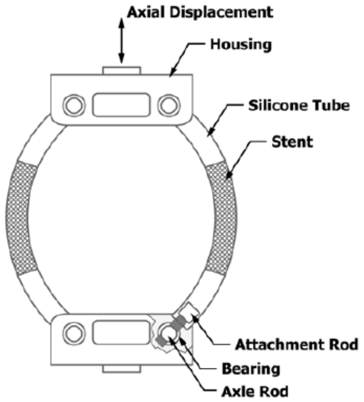


FIG. A2.3 Example of a Bending Fixture Assembly

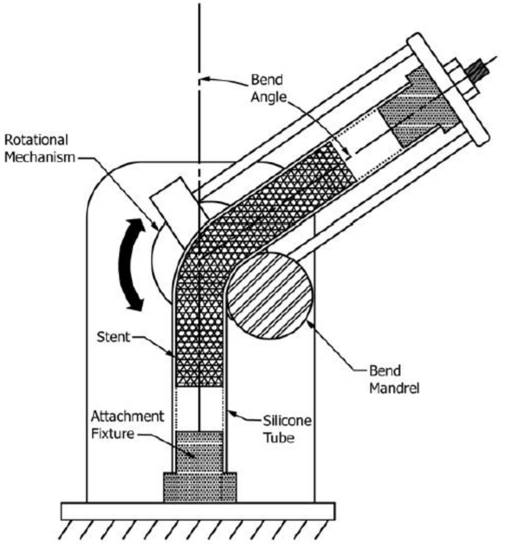


FIG. A3.1 Example Bending on a Mandrel Where the Mock Vessel is Moved in an Arc

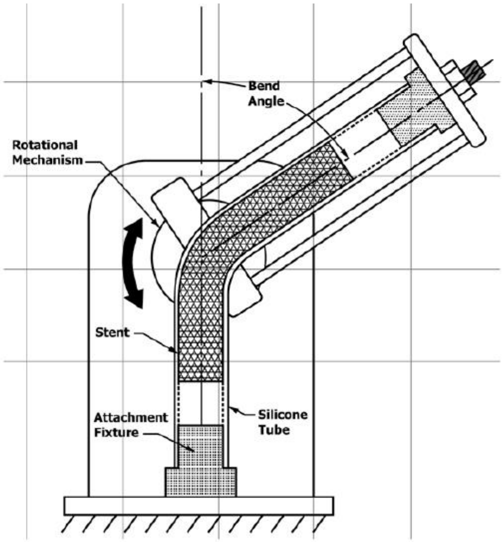
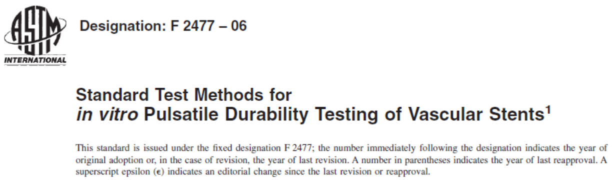


FIG. A4.1 Example Diagram of Bend in an Arc Without a Mandrel

# Additional device deformation modes to consider

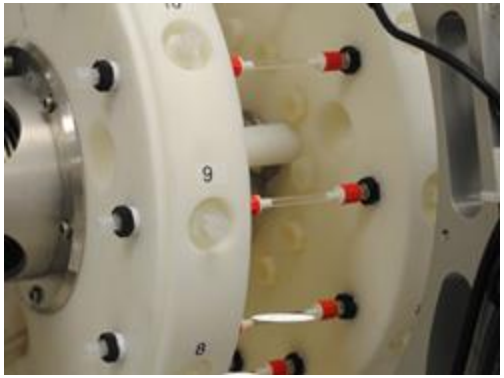
## Radial Pulsatile Motion



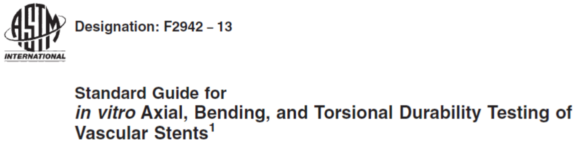
Designation: F 2477 – 06

**Standard Test Methods for**
***in vitro* Pulsatile Durability Testing of Vascular Stents**[1]

This standard is issued under the fixed designation F 2477; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.



## Axial Distension



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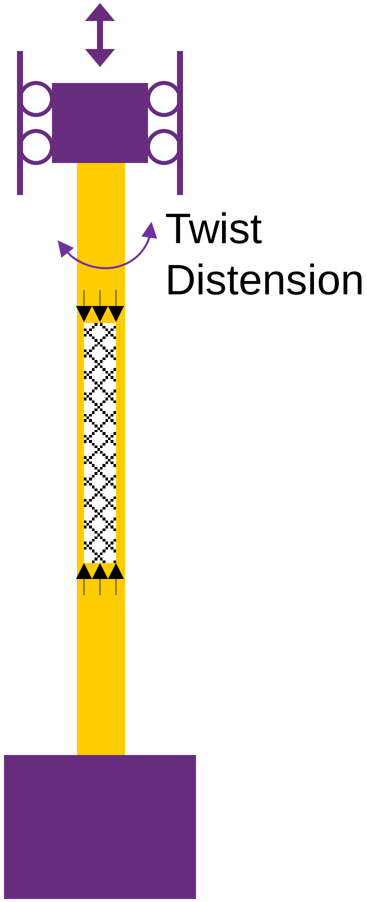
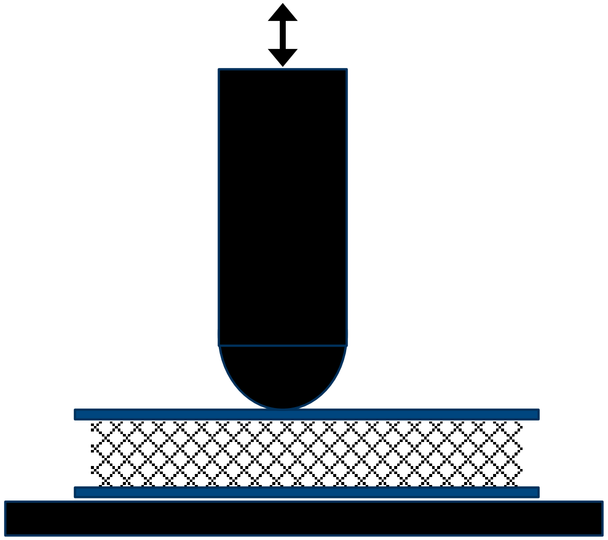


Twist
Distension

## Local Crush Distension



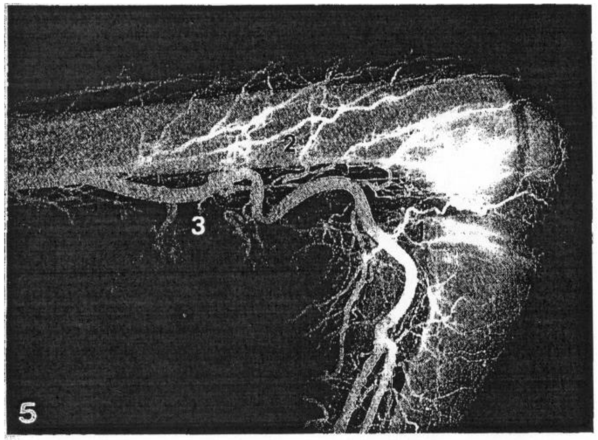
# Outline

✓ Relevant ASTM Committees & Some Specific Standards

✓ Mechanical Fatigue of Devices In-vivo

- Deformation due to cardiac & breathing cycles, muscles, & tissue motion
- Deformation modes & test apparatus for stent-like devices

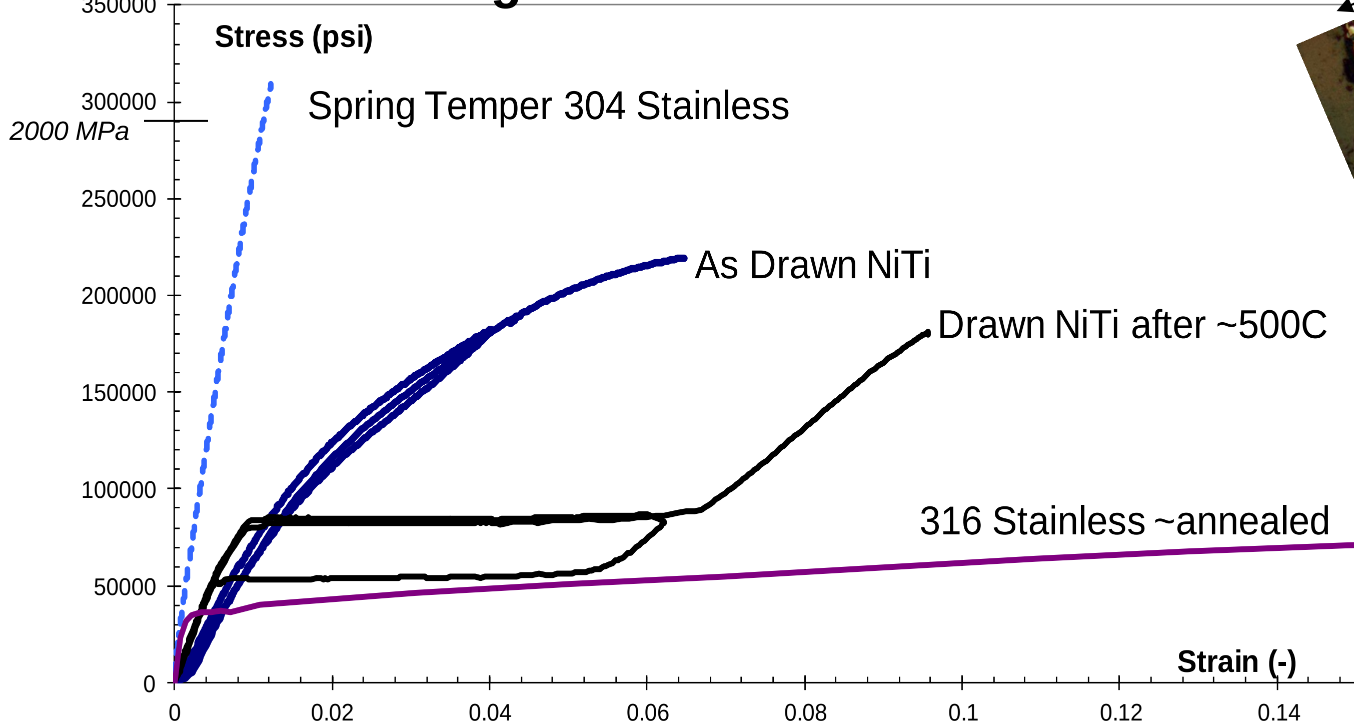
**Material and Device Mechanics and Fatigue**

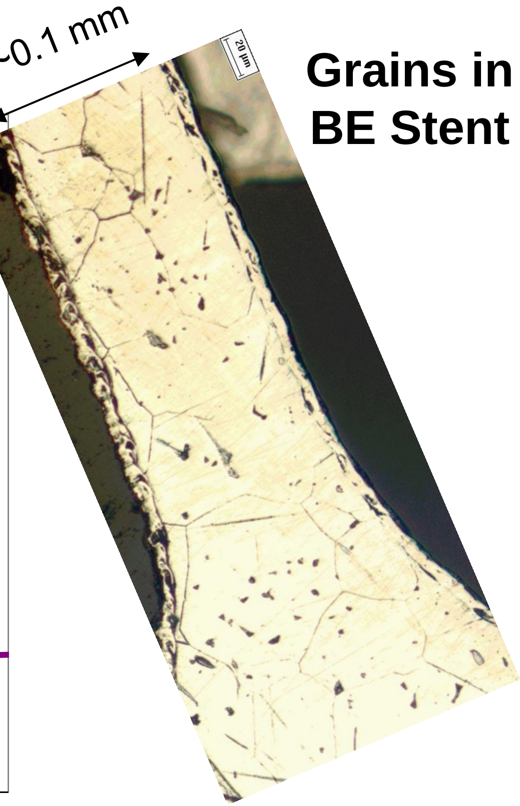


# Metal Mechanics and Fatigue depends on material and processing.

- **Material**
  - Alloy & Impurities - e.g. ASTM F138 not 316L.
  - Cold work & Heat treatment

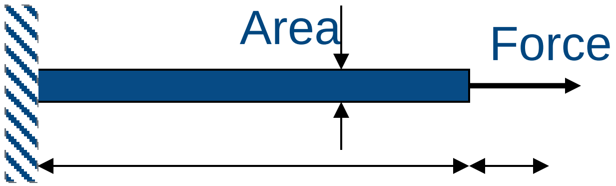
**Tensile Elongation - effect of heat treatment**

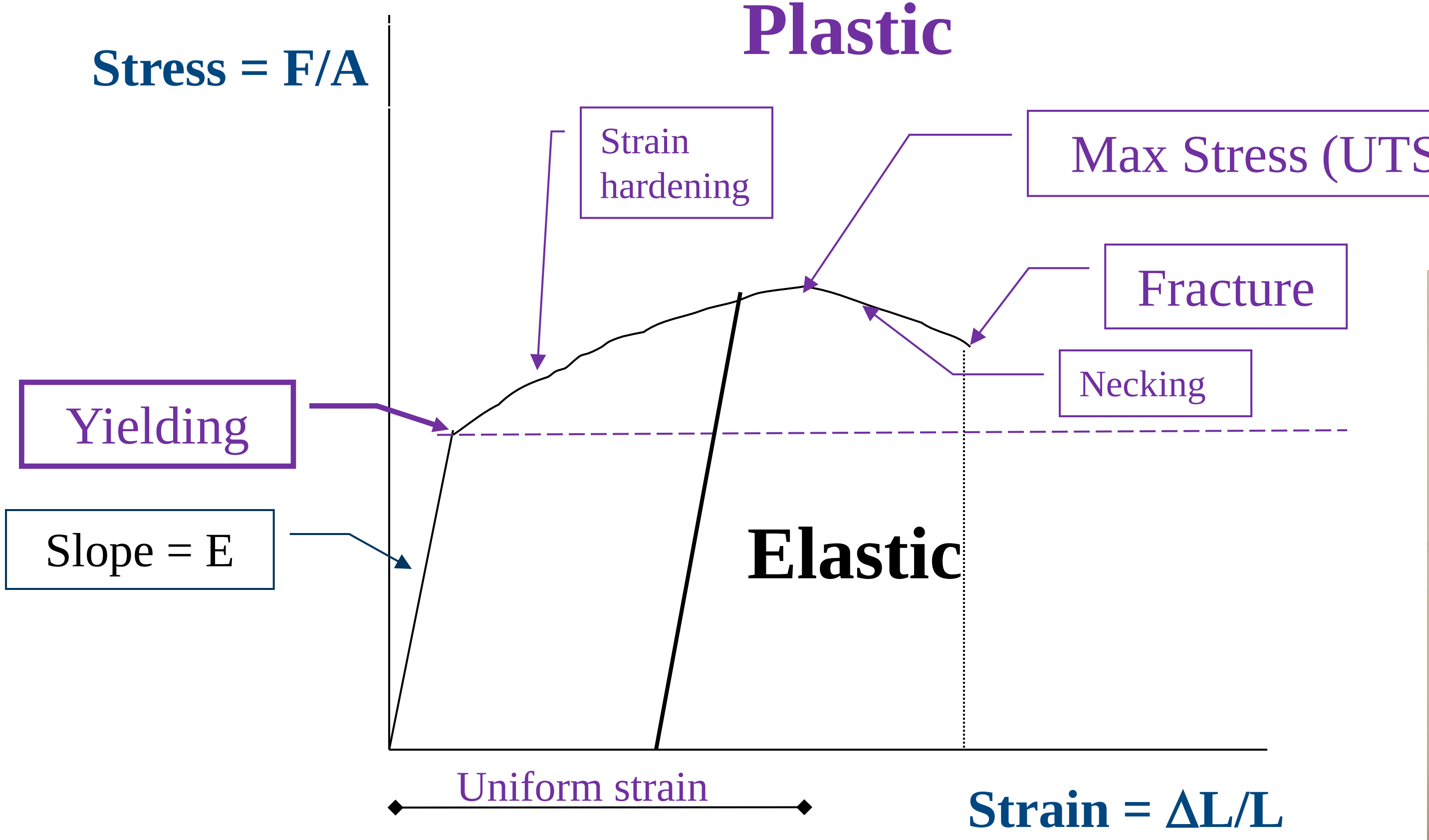




**Grains in BE Stent**

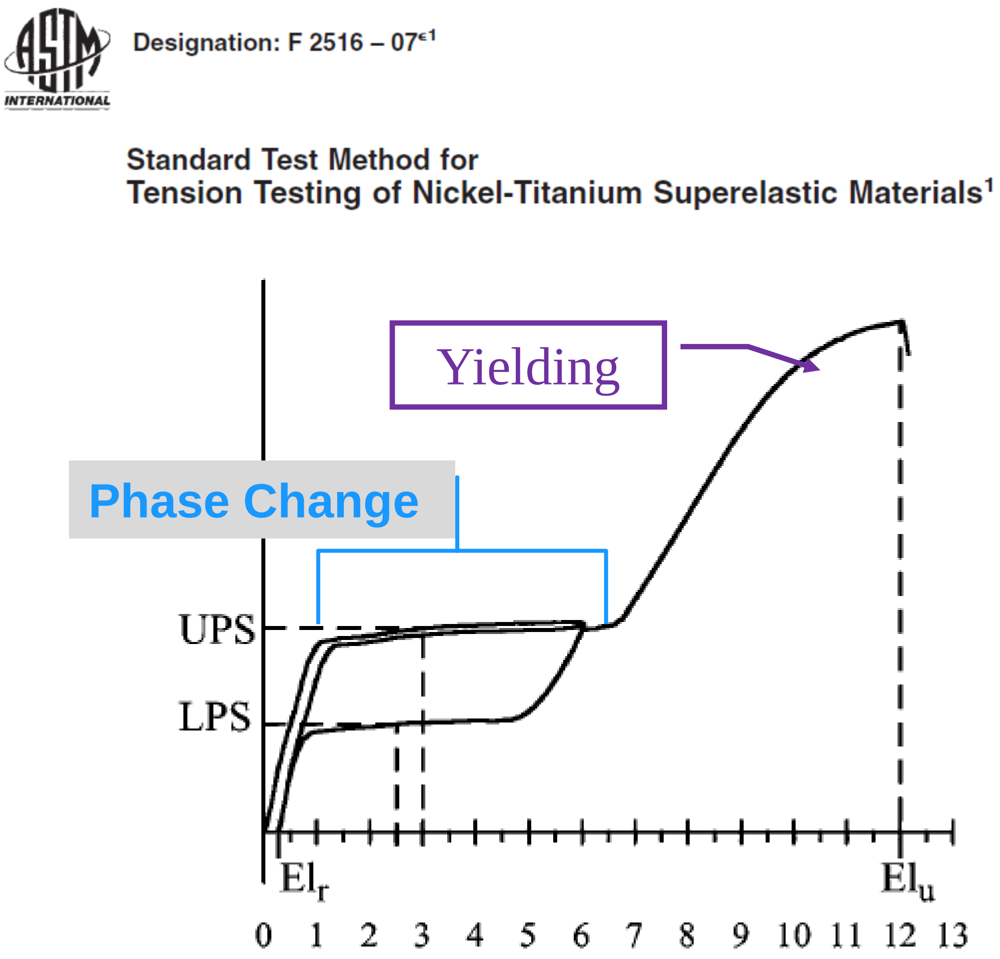
# Tensile test typically has an **elastic** domain and a **plastic** domain. Unloading distinguishes.





http://www.mtu.edu/materials/k12/experiments/tensile/

# Nitinol adds a reversible stress-induced phase transformation.



Designation: F 2516 – 07$^{\epsilon 1}$

Standard Test Method for
Tension Testing of Nickel-Titanium Superelastic Materials[1]

FIG. 1 Terms Illustrated on Typical Stress-Strain Diagram of Superelastic Nitinol

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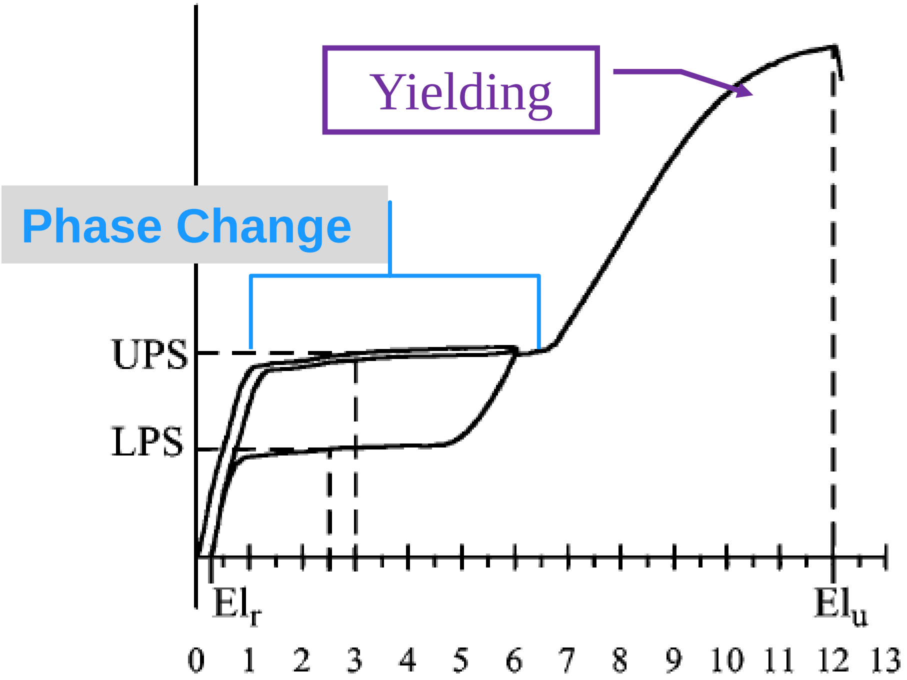
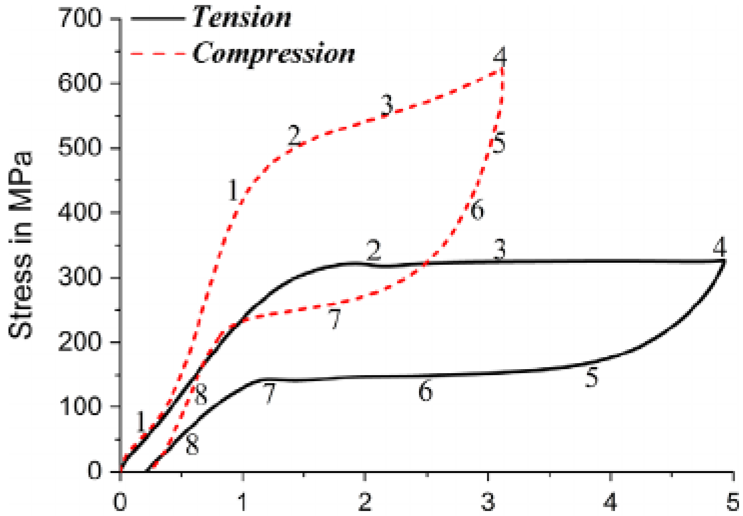
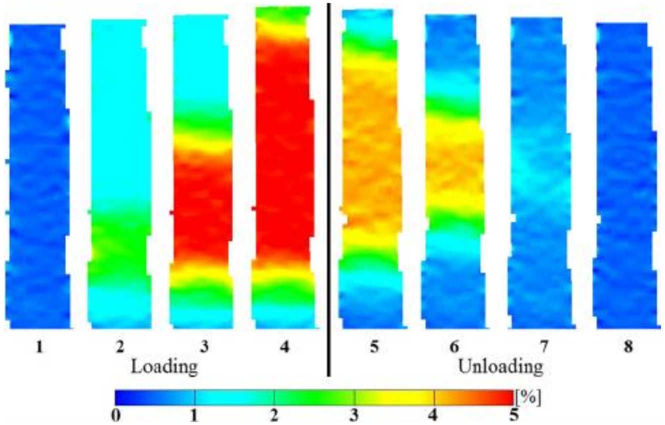


FIG. 1 Terms Illustrated on Typical Stress-Strain Diagram of Superelastic Nitinol

## Compression at HIGHER stresses than Tension.

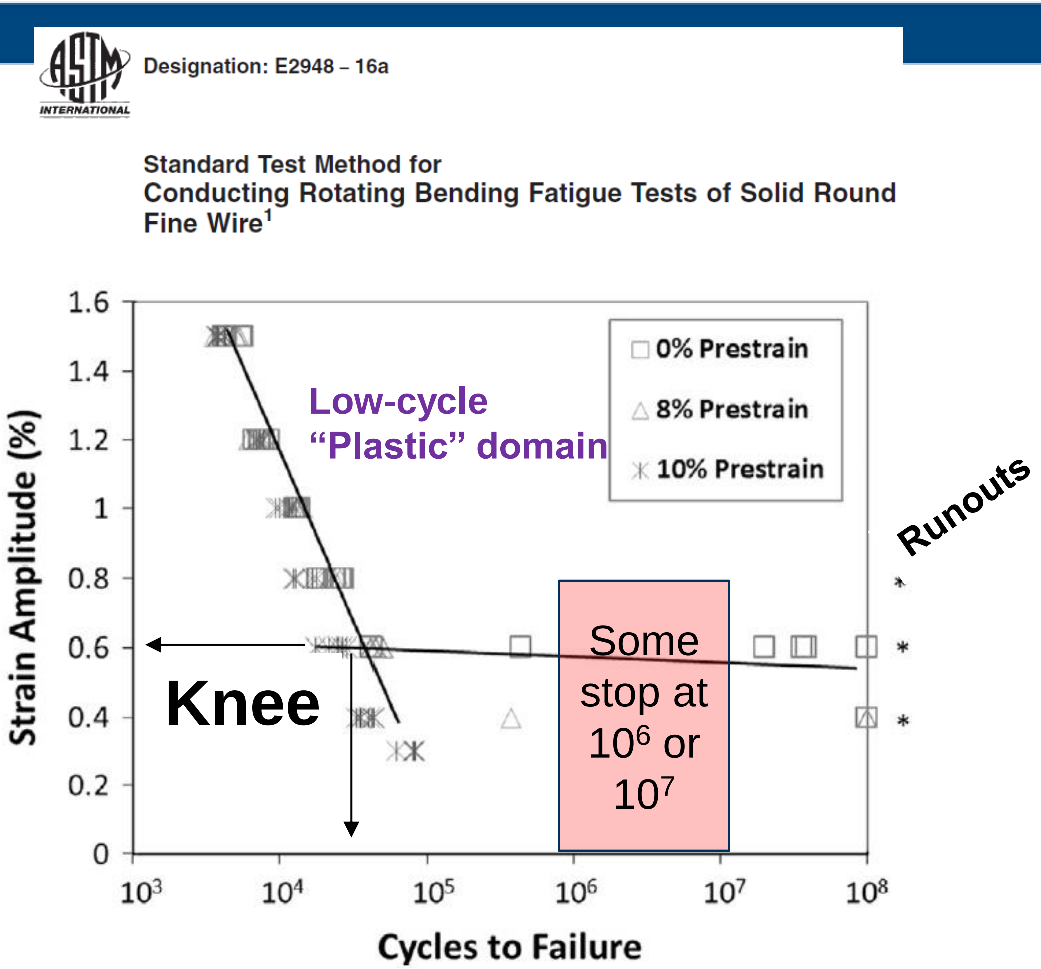


## Change phase is like ice in water.



*Investigation of the stress-induced martensitic transformation in pseudoelastic NiTi under uniaxial tension, compression and compression–shear,* Cagatay Elibol, Martin F.-X. Wagner, Materials Science and Engineering A 621 · January 2015

# **Metal Fatigue – Characterization begins with S-N fracture curves** (S = load, stress, strain,…; N = number cycles)



Designation: E2948 – 16a

Standard Test Method for
Conducting Rotating Bending Fatigue Tests of Solid Round Fine Wire[1]

Low-cycle
"Plastic" domain

Knee

Some stop at $10^6$ or $10^7$

Runouts

Fig. xxx – Wire rotary bend testing of Nitinol wire showing effects of damage induced by 10% pre-condition bending prior to testing. In the low-cycle region, fatigue life is comparable across pre-strain levels, but diverges significantly at strain amplitudes <= 0.8%. [Gupta S., Pelton, A. R., Weaver, J.D., Gong, X.Y., and Nagaraja, S., *High compressive pre-strains reduce the bending fatigue life of nitinol wire*, **Journal of the Mechanical Behavior of Biomedical Materials**, 2015 Apr; 44:96-108]

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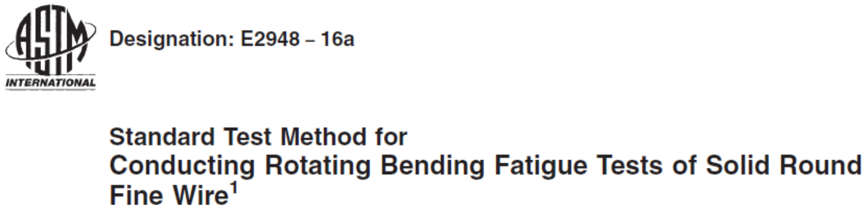

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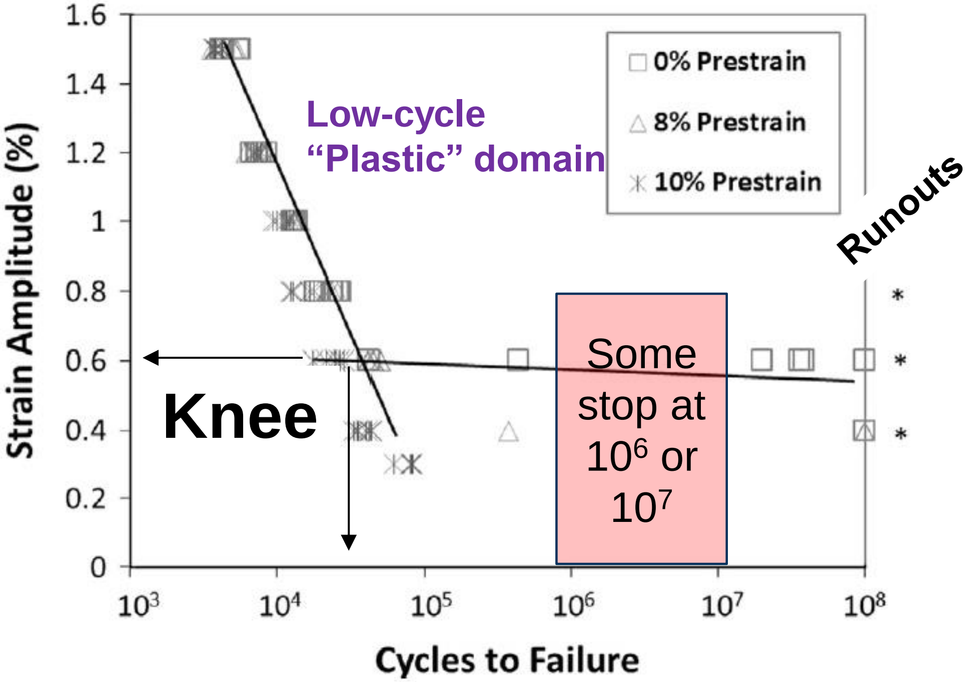

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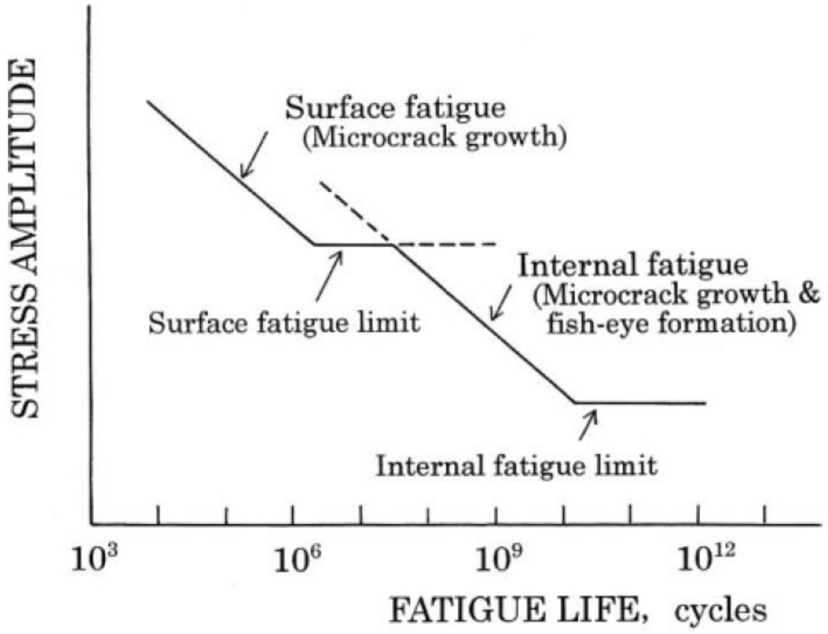
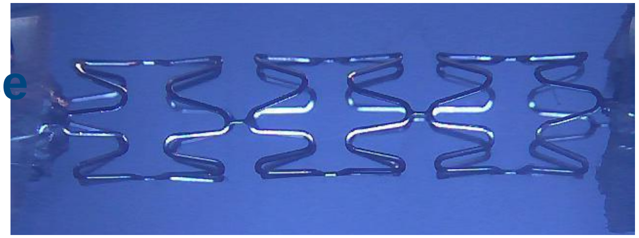
## Beyond knee, fatigue life depends on internal defects/impurities



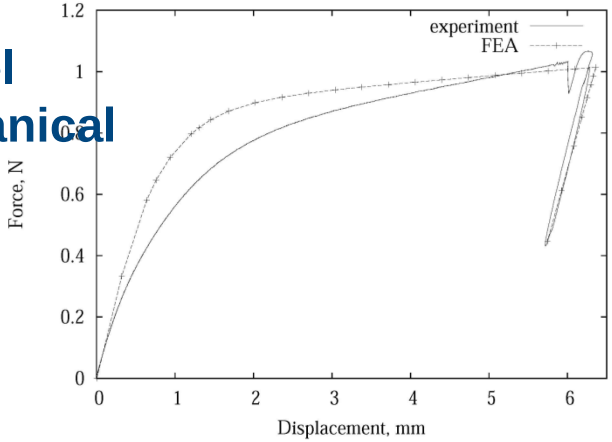
**Schematic illustrating fatigue failure modes on an S-N curve for high strength steels.** With increased surface roughness, larger grains, surface defects, and formation of slip bands the surface fatigue curve moves to the left. With fewer and especially smaller internal heterogeneities the internal fatigue curve moves to the right – longer fatigue life. [Li, S.X., *Effects of inclusions on very high cycle fatigue properties of high strength steels*, **Int. Mater. Rev.** 2012, p 92-114.]

# Classic – Test to Success

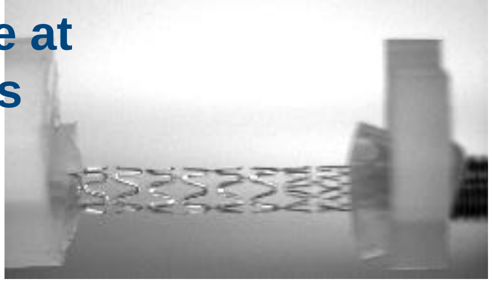
1 **Device**



2 **Model & Mechanical Test**

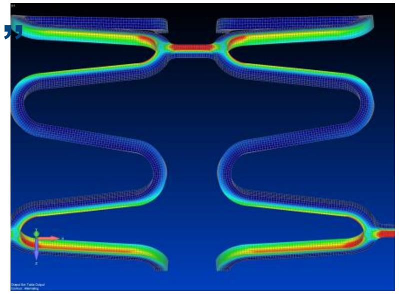


3 **Fatigue at conditions**

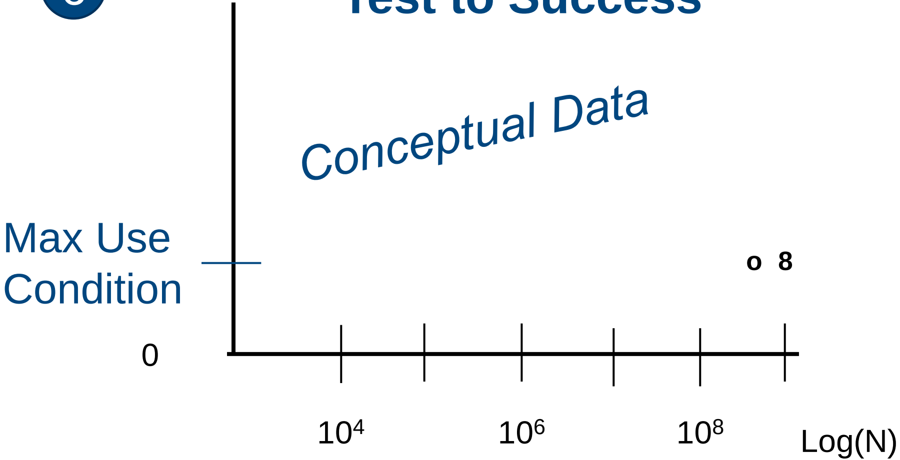


4 **No fractures**

5 **FEA "confirms" no fractures expected**



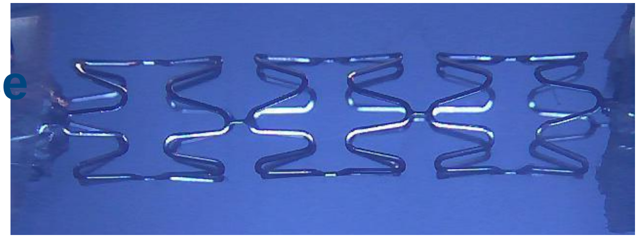
6 **Test to Success**



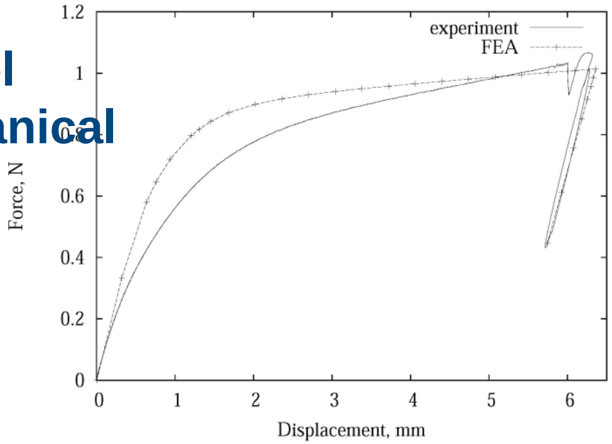
**Ken Perry, EchoBio, *Validation Testing and Computational Models for Fatigue Analysis of Medical Devices*, DMD Conference 2012**

# Fatigue to Fracture - basic process

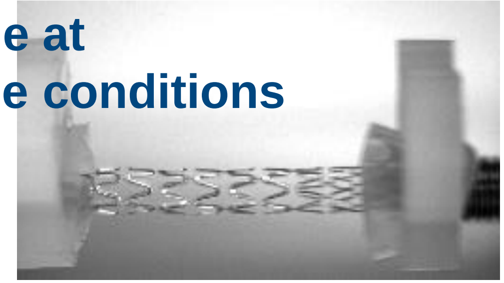
1 **Device**



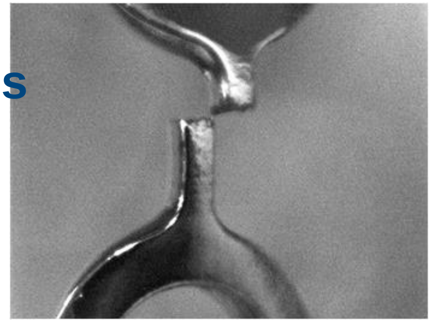
2 **Model & Mechanical Test**



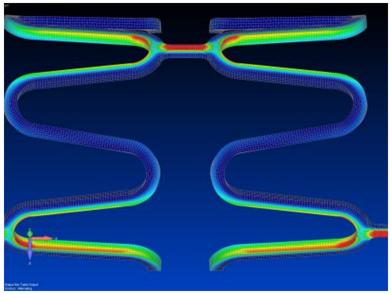
3 **Fatigue at above-use conditions**



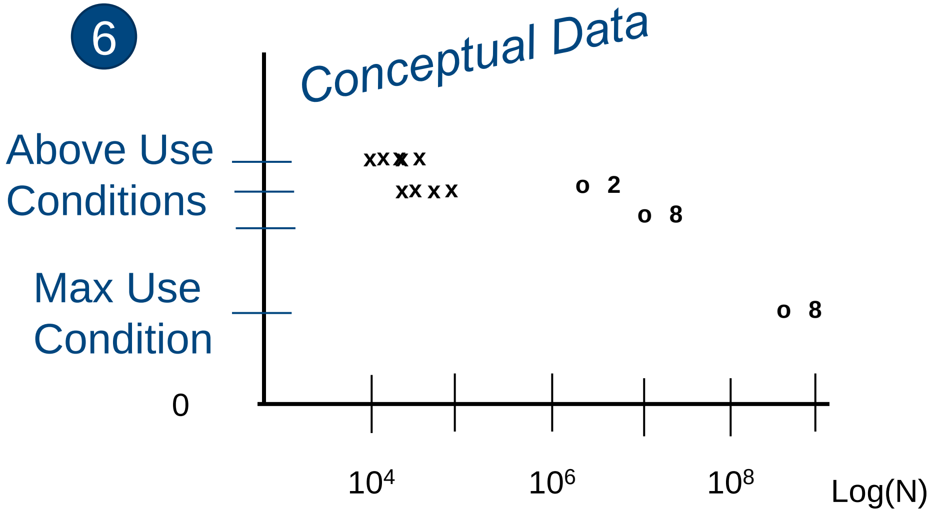
4 **Find fractures**



5 **Compare to FEA or to design iteration**



6



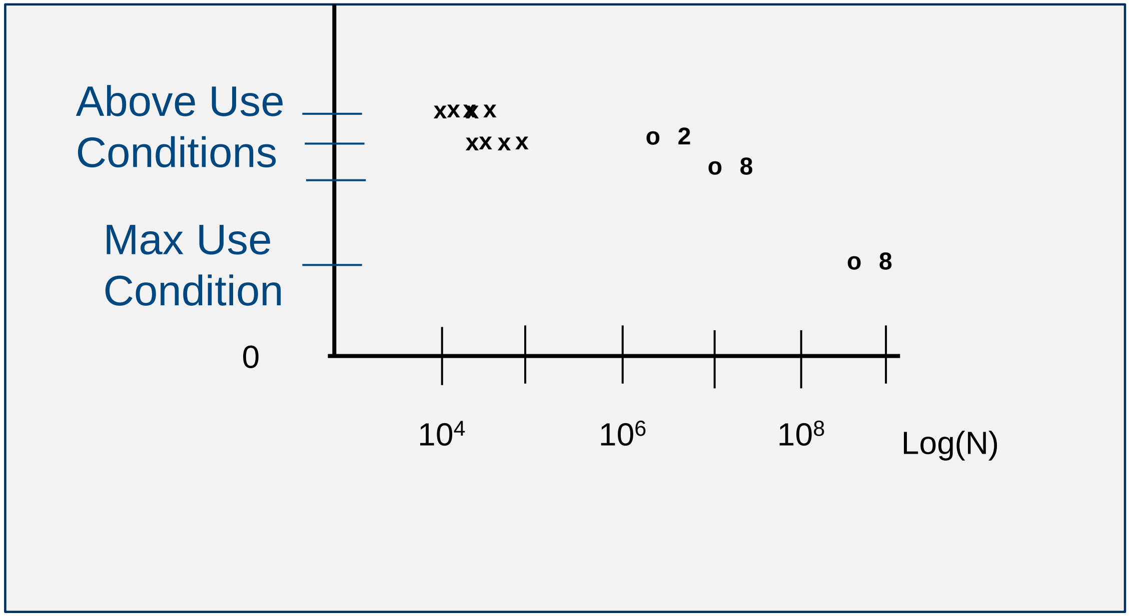
**Ken Perry, EchoBio, *Validation Testing and Computational Models for Fatigue Analysis of Medical Devices*, DMD Conference 2012**

# Theoretical advantages to a fatigue to fracture methods versus just test to success methods.

- <u>More reliable</u> by evaluating better and worse designs and by testing actual devices since processing and deployment affect results.

- <u>Faster</u> using supra-physiological conditions & extrapolation

- Could reduce severity of unanticipated fractures



Similar to automotive tests

# Conclusion

## Relevant ASTM Committees & Some Specific Material Standards

## Mechanical Fatigue of Devices In-vivo

- Deformation due to cardiac & breathing cycles, muscles, & tissue motion
- Deformation modes & test apparatus for stent-like devices

## Fatigue

- Measure mechanics of the material and the device
- Do fatigue tests, preferably take to fracture