Characterization of Nitinol Material Behavior for the Design and Validation of Medical Implants

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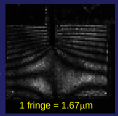
Material Characterization

Nitinol Material Testing

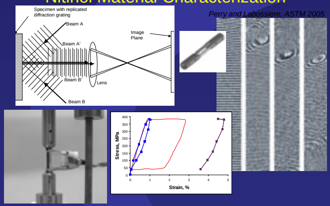
- Purpose
  - Characterize the deformation behavior of nitinol
    - Coupon and component scale measurements
    - Monitor and control temperature
    - Real-time and full-field strain measurement
- Experiment
  - Materials and processing
  - Load fixtures and test sample design
  - Temperature measurement, control
  - Phase shifted moiré interferometry
- Key results presented
  - Superelastic loading and unloading
  - Two-way shape memory free recovery
  - Four-point bending
  - Component measurements

Phase Shifted Moiré Interferometry

- Four-beam fiber optic phase shifting portable moiré interferometer
  - 1280x960 10bit resolution
  - Preserves fine spatial detail (10µm)
  - Carrier fringes (0 to 5+% resolvable strain)
- Diffraction gratings
  - Holographic exposed photographic plate
  - Thin epoxy replication method (5-20µm)
  - Specular reflection, high diffraction efficiency
- Fringe pattern analysis
  - Manual fringe counting, +/-0.02% strain precision
  - Video frame rate processing

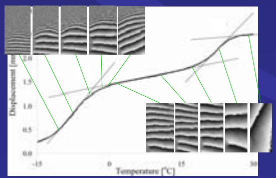


Moiré Interferometry and Nitinol Material Characterization



Perry and Labossiere, ASTM 2005

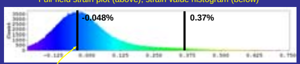
Thermal free recovery – Treatment A



Unconstrained cooling – Treatment B

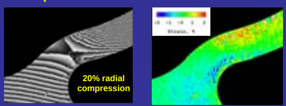
Wrapped fringe pattern at T = -18 C

Full-field strain plot (above), strain value histogram (below)



Coefficient of thermal expansion

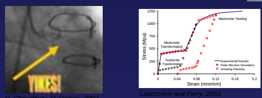
Component Scale Measurements



Fracture and Fatigue – Testing to Feedback

Motivation

- Characterize the material behavior of Nitinol for better design and engineering of medical implants
  - Force-deformation response
    - input for and validation of material models
  - Fatigue and fracture material limits
    - data and methodology to validate design life



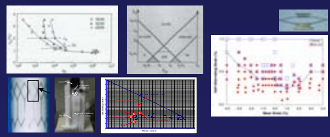
P. Chowdhury, G. Ramos, 2002; commentary by B. Berg

Labossiere and Perry, 2003

Fatigue and Fracture of Nitinol

Fatigue/Strength of Materials

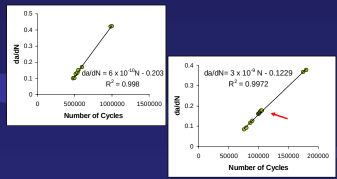
- Kim and Miyazaki; SMST-1997
- Tabanli, Simha and Berg; Mat. Sci. and Eng. A 1999
- Kugler and Perry; SMST-2000, Harrison and Lin; SMST-2000
- Pelton, Gong and Duerig; SMST-2003



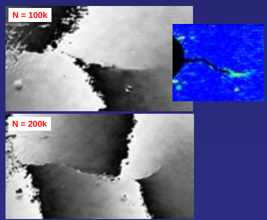
Methodology

- Initiate and grow short cracks in Nitinol C(T) samples
- Characterize range of materials and processing
- Consider three primary loading conditions
  - A: elastic loading and unloading of austenite phase only
  - AM: both phases present, forward/reverse transformations
  - M: small amplitude loading of heavily transformed material
- Test Protocol – Load Control
  - Visual/interferometric crack length measurements
  - Full-field displacements at K_{max}, K_{min} and K = 0
- Goals
  - Comparison of initiating conditions and evolution
  - Data for FEA material model development suitable for fatigue

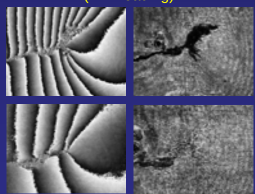
Crack length/number of cycles



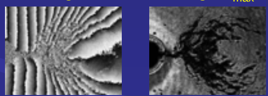
Incremental Crack Growth



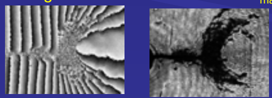
Loading and Unloading with Transformation (AM Loading)



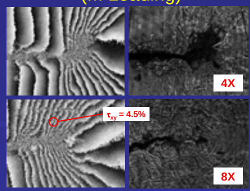
Initiating the crack at a high K_{max}



Growing the crack at a decreased K_{max}



At the Tip of a Long Crack (M Loading)



Conclusions

- A Loading in linear region,
  - No transformation/wake effects
  - Initiation and propagation occur in a consistent and uniform fashion
- AM and M loadings with transformation influence
  - Wake effects
  - Non consistent transformation zones (Sideshow Bob hairdo)
  - Pinning and bifurcations from interruptions in testing
    - Due to transformation/temperature coupling
    - Due to microstructural obstacles
- Size effects can be resolved in the different test protocols
  - Transformation zone size relative to notch and crack sizes
    - Short cracks – Notch-tip fields control transformation zone size
    - Long cracks – Crack tip fields control transformation zone size
- Crack initiation and growth in Nitinol is complex
  - Heterogeneous phase transformation and localization
  - Crack path tortuosity, deflection, pinning of the crack
  - Characterize material and processing influence
  - Loading rate and history effects
  - Thermal sensitivity and transformation temperature coupling
  - Notch geometry effects

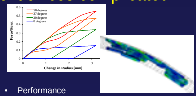
Ongoing Efforts

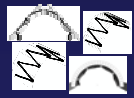
- Identification of useable material limit data and methodology
  - Traditional threshold crack growth rates not applicable to medical devices
  - Singular stress fields affected by transformation (LEFM does not work!)
- Refine existing in-house material models and numerical algorithms based on new data and observations
- Perform additional experimentation based on what we've learned so far
- Refine specimen geometry and processing to study in more detail crack initiation from defects, inclusions, etc

Design Application

Why are Nitinol devices complicated?

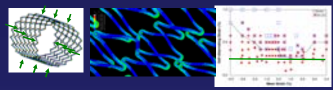
- Material
  - Multiple material phases
  - Localization, instability
  - Moving phase boundaries
  - Processing history
  - Thermoelastic behavior
- Boundary Conditions
- Geometry
  - Stress concentrations
  - Large deformations
  - Contact and interactions

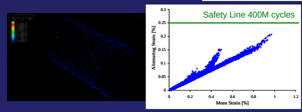




- Performance
  - Radial force, bend stiffness, twisting
- Reliability
  - Crimp, deployment, fatigue
- Difficulties with modeling
  - Material Behavior, Boundary Conditions, Contact
  - Fatigue and in-use integrity and stability
- Typical In-Vitro Radial Test Methods
  - Flat Plate, Loop Strap, Shell, Pressured tube, Iris
- Verification of Performance Results
- Reliability

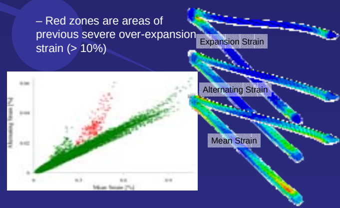
Uniform Radial Fatigue



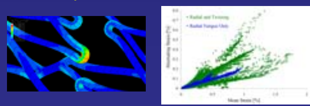


Possible OverStrain Damage

– Red zones are areas of previous severe over-expansion strain (> 10%)



Coupled Deformation Modes



Load case	Anticipated Cycles	Alternating Strain Limit	Alternating Strain Predicted	Safety Factor
Radial Fatigue	400M	0.40	0.20	2.00
Twisting Fatigue	10M	1.00	0.70	1.40
Radial and Twist	10M	1.00	0.80	1.25
Crushing	10k	1.50	1.30	1.15

Device Performance and Reliability

- Testing to 400M cycles with over-idealized loading scenarios does not adequately address stent fractures seen clinically
- Take a Linear Damage Model Approach and assess contribution of each combined loading mode:

$$\sum \frac{\text{IntendedN}_i}{\text{PredictedN}_i \text{ for each given load}} = {}^{1}/_{\text{SafetyFactor}}$$

- Testing to failure provides relevant feedback and realistic safety factors
  - Better measurements and analysis of clinically relevant deformations
  - Rigorous testing to provide feedback for material limit data and components
  - Comprehensive engineering methodologies based on analysis, testing and rational safety factors
  - Assessment of impact of fractures: design tolerance

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