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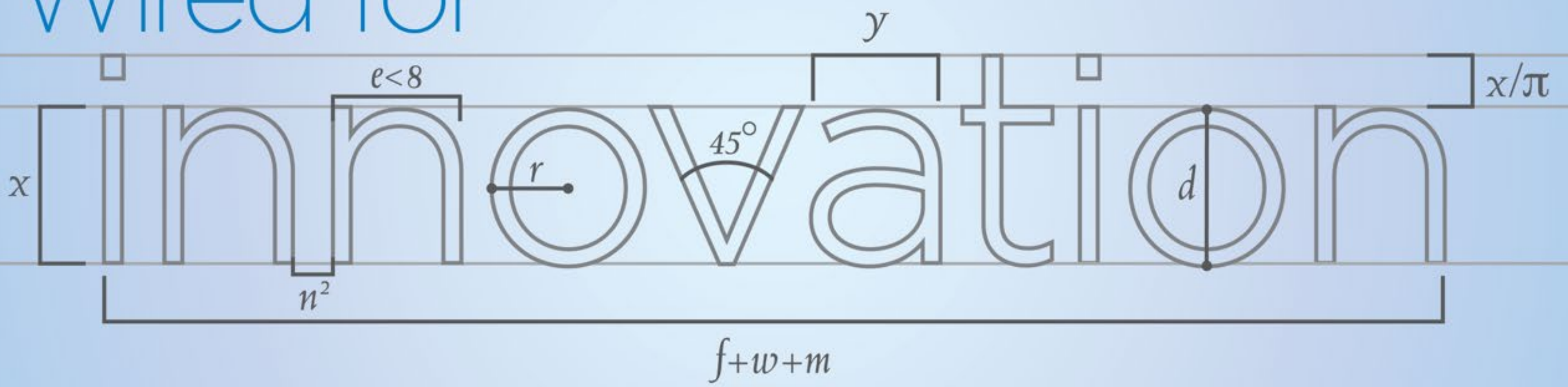

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The effect of platinum content on the performance of superelastic Nitinol DFT® composite wire for medical devices

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Presentation overview

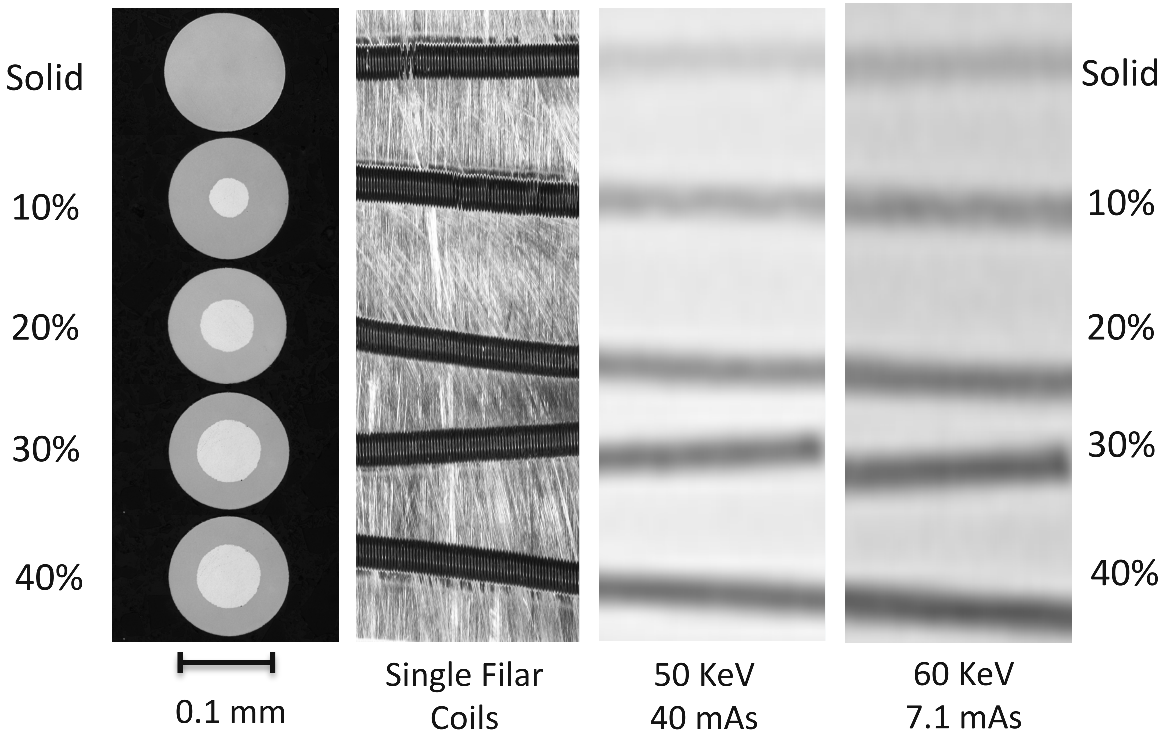
- Introduction/motivation
- Materials and methods used
- Results/discussion
  - Tensile
  - Bend and free recovery
  - Rotating bending fatigue
  - Fracture analysis
- Conclusions
- Acknowledgements

Introduction

- Decreasing size of medical devices
- Radiopacity concerns of fine Nitinol wire under X-Ray
  - Previous efforts melting Nitinol with radiopaque elements [1]
- Fort Wayne Metals' Nitinol DFT® composite wire
  - Superelastic Nitinol tube assembled to inelastic platinum core
  - Combines the beneficial properties of two materials (Nitinol and platinum) into one wire product

[1] Boylan, John F. "The development of radiopaque nitinol." *Guidant Corporation, Endovascular Solutions, Temecula, CA* (2004): 1-6.

Introduction



Motivation

- Finding the balance
  - Retention of superelastic/shape memory behavior
  - Superior radiopacity vs. effect on critical properties controlling medical device performance
    - i.e. transformation temperatures, tensile properties, and fatigue life

Materials

- Superelastic solid Nitinol wire and Nitinol DFT® composite wire with 10%, 20%, 30%, and 40% Pt fill percentages
- 0.10 mm nominal diameter
- 38% coldwork
- Light oxide surface

Materials

- All Nitinol heats VAR melted from same supplier meeting ASTM F2063 [2]

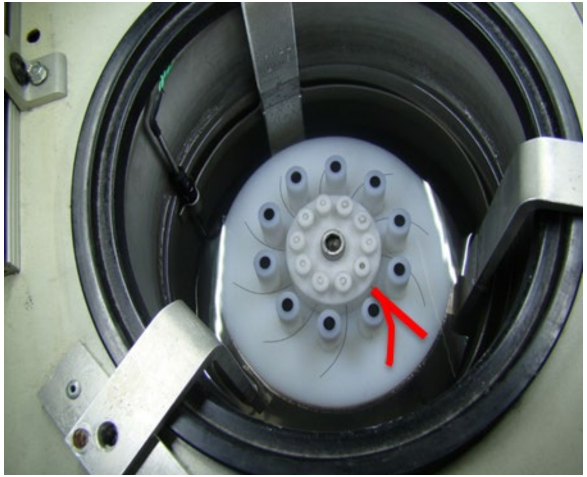
	Solid Nitinol	Nitinol DFT® composite wire
Ingot A_s	-30°C	-32°C
Inclusion Area Fraction	<1%	<1%
Max Inclusion Size	5.8 µm (T) 16.4 µm (L)	9.2 µm (T) 15.6 µm (L)

- 99.99% Pt per ASTM B561 [3]
- Heat treatment in fluidized alumina bed
  - 500°C for 5 minutes followed by an immediate water quench

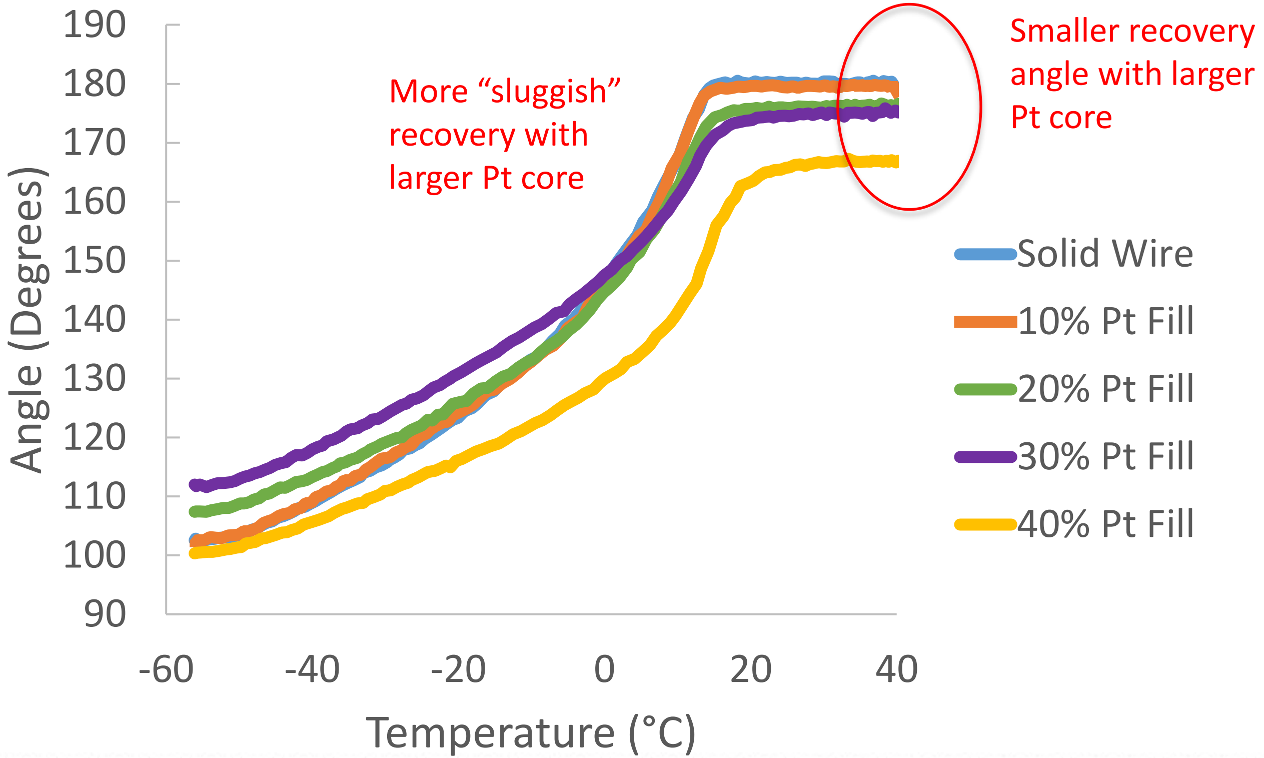
[2] "Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants" F2063-18, p. 1-6
[3] "Standard Specification for Refined Platinum" B561-12, p 1-2

Bend and free recovery - method

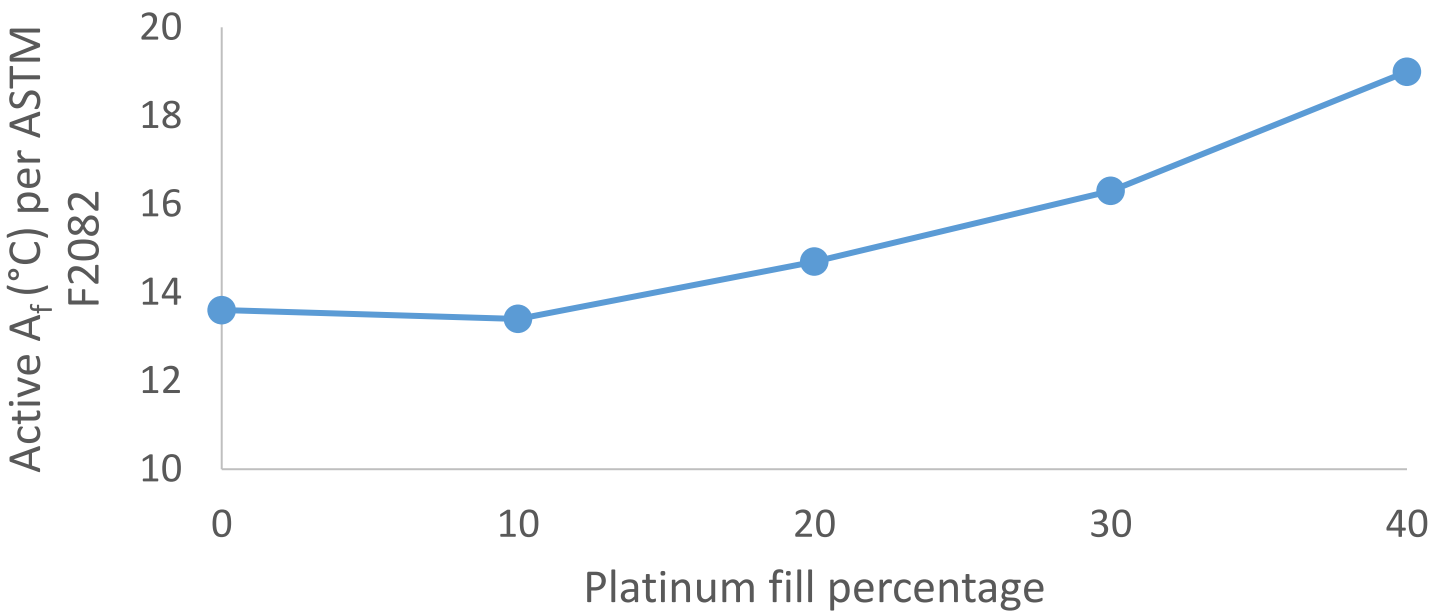
- ASTM F2082 using a BFR vision system [4]
- Cooled to -55°C in alcohol bath
- Deformed to 2-2.5% strain
- Heated at 0.5°C per minute
- Displacement measured using vision system



Bend and free recovery - results



Bend and free recovery - results



- Positive correlation between platinum fill percentage and Active A_f
- ~6°C difference in Active A_f between solid wire and 40% platinum fill

Bend and free recovery - results

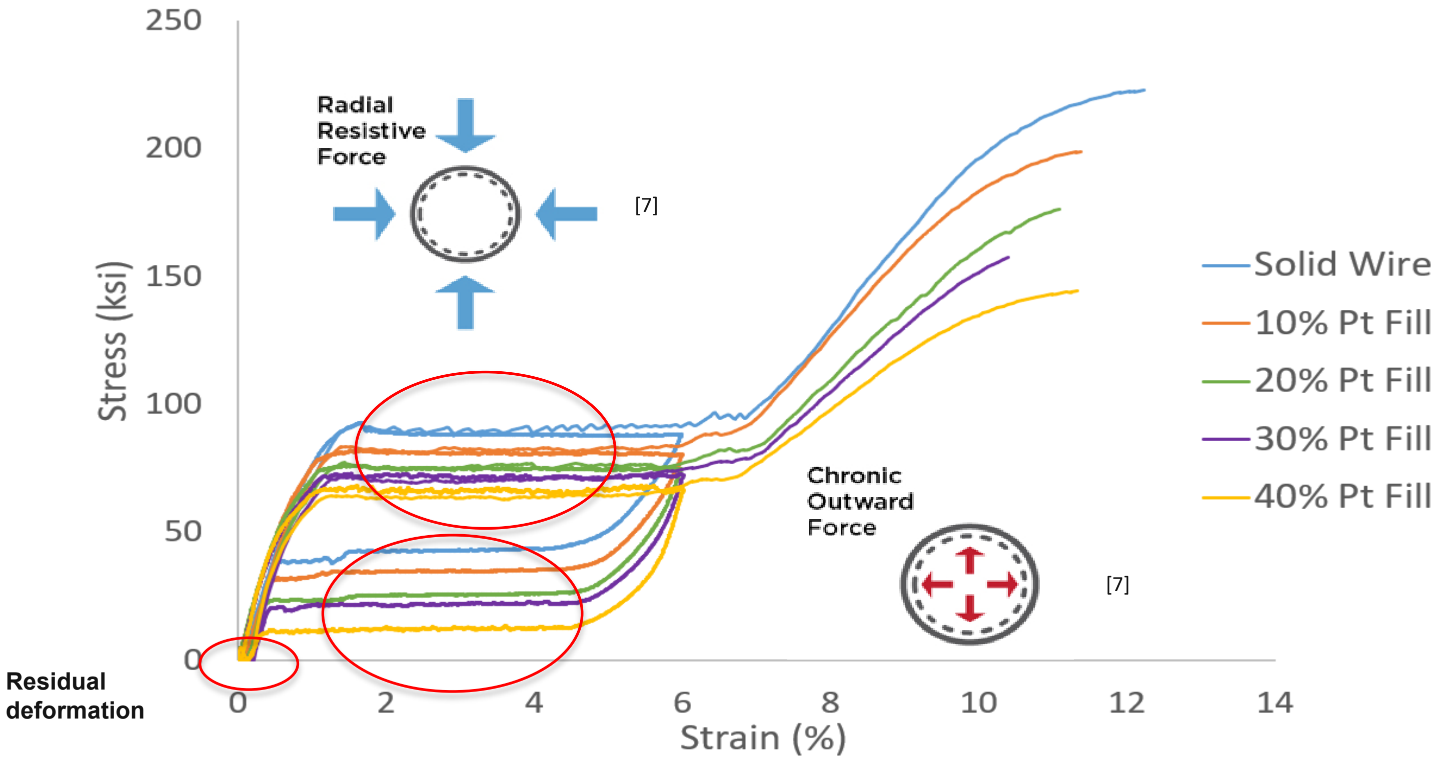
- Larger platinum core impedes the shape recovery of composite wire
- Evident by "sluggish" recovery and smaller recovery angle
- Higher temperature (more energy) needed to return the Nitinol DFT® composite wire back to original shape for higher fill percentages

Tensile testing - method

- ASTM F2516 [5]
- Two-cycle uniaxial test
- 150 mm gage length
- Strain determined using crosshead displacement
- 5 specimens tested per fill percentage
- All samples tested in environmental chamber at 37°C

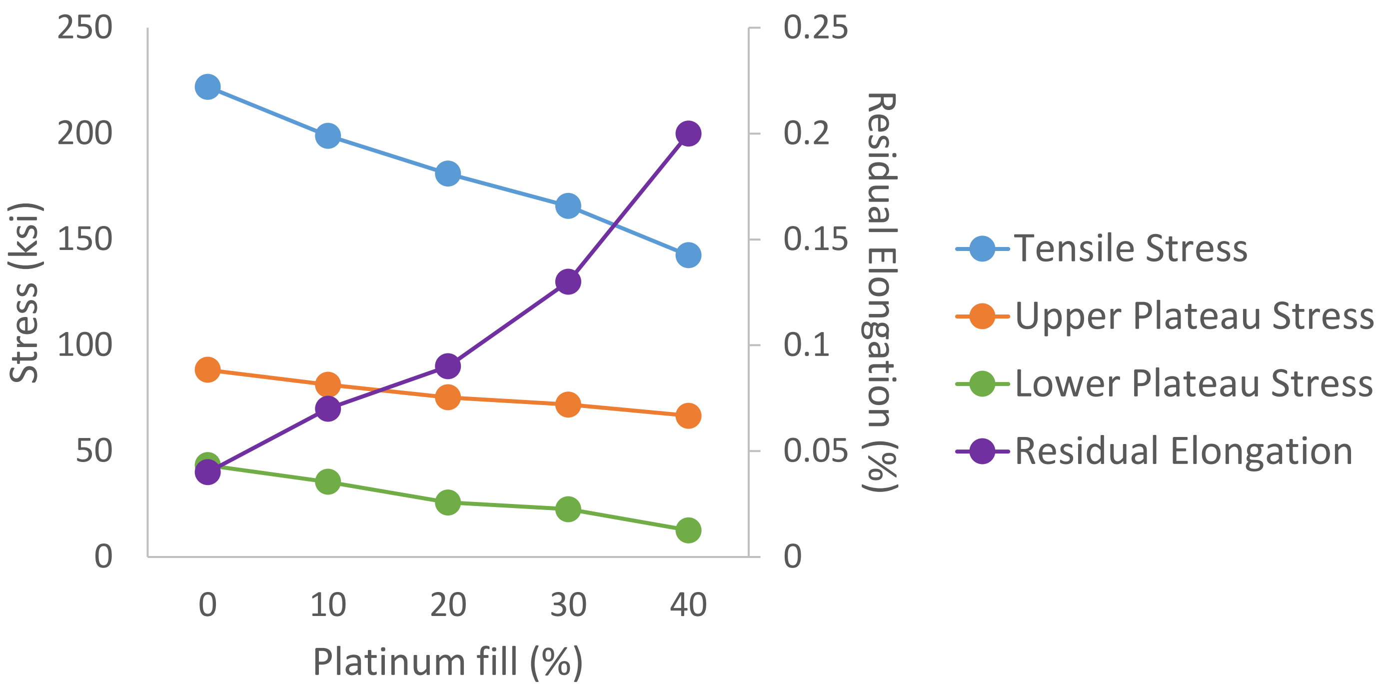
[5] "Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials" F2516-14, ASTM International, p. 1-6

Tensile testing - results



[7] Stoeckel, Dieter, Alan Pelton, and Tom Duerig. "Self-expanding nitinol stents: material and design considerations." European radiology 14.2 (2004): 292-301.

Tensile testing - results



Note: Results correlate with earlier work done by J. Schaffer and R. Gordon [6]

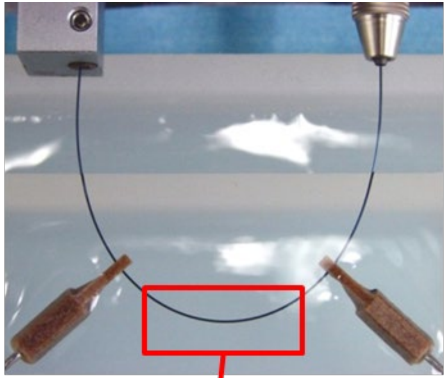
[6]Schaffer, Jeremy E., and Richard Gordon. "Engineering characteristics of drawn filled nitinol tube." *SMST-2003: Proceedings of the International Conference on Shape Memory and Superelastic Technologies (ASM International)*. 2004.

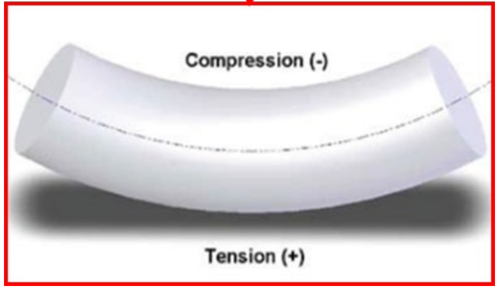
Tensile testing – results

- Tensile and plateau stresses all decreased linearly with increasing Pt core
- Expect decrease in crush/expansion forces of device with each increasing fill percentage
- Residual elongation increased with increasing Pt core
- Expect less shape recovery after deformation with increasing fill percentage

Rotating bending fatigue - method

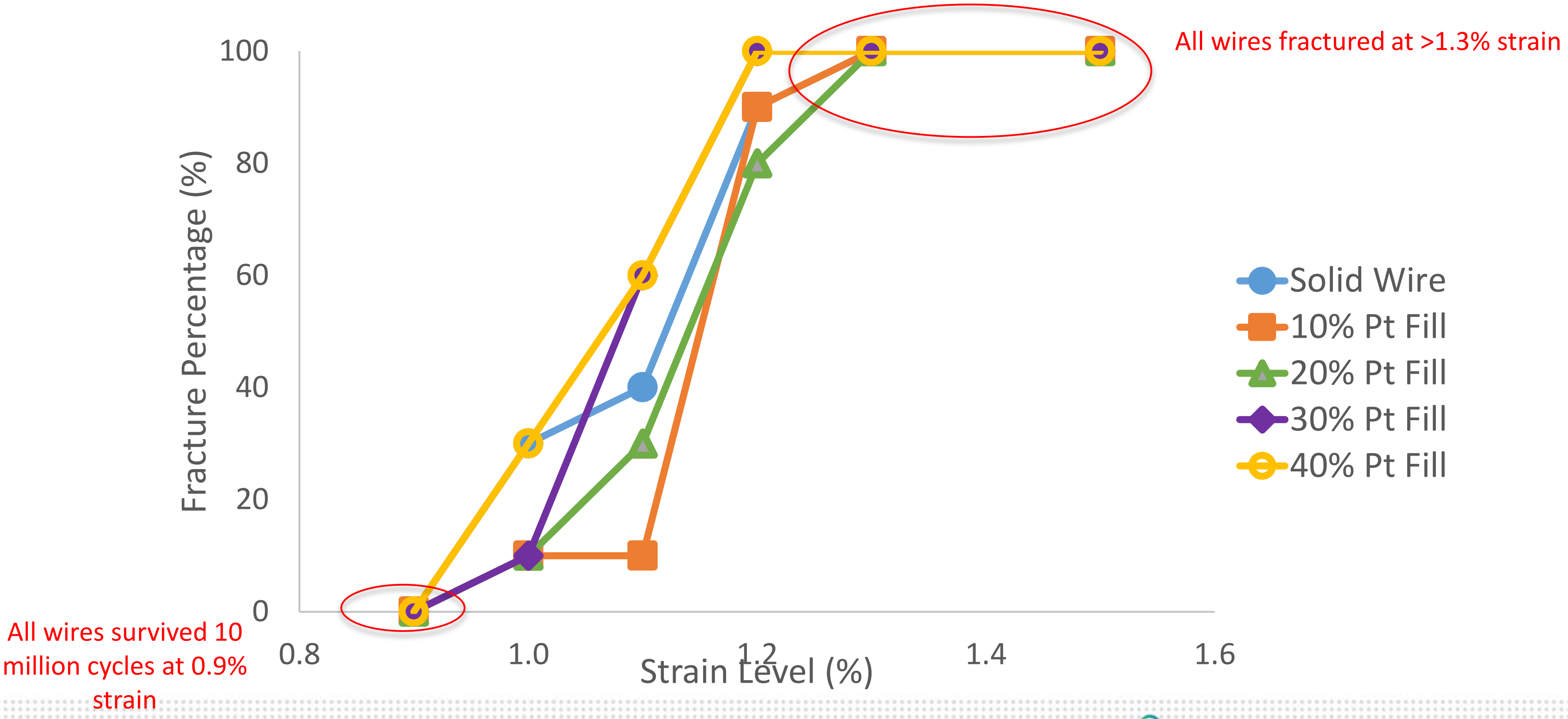
- ASTM E2948 [8]
- 0.9% to 1.5% strain
- Assuming central neutral axis at zero mean strain
- Wire subjected to various strain amplitudes and rotated at 3,600 RPM
- RO water bath at 37°C
- Ten specimens per fill percentage tested at each strain level
- Runout at 10 million cycles



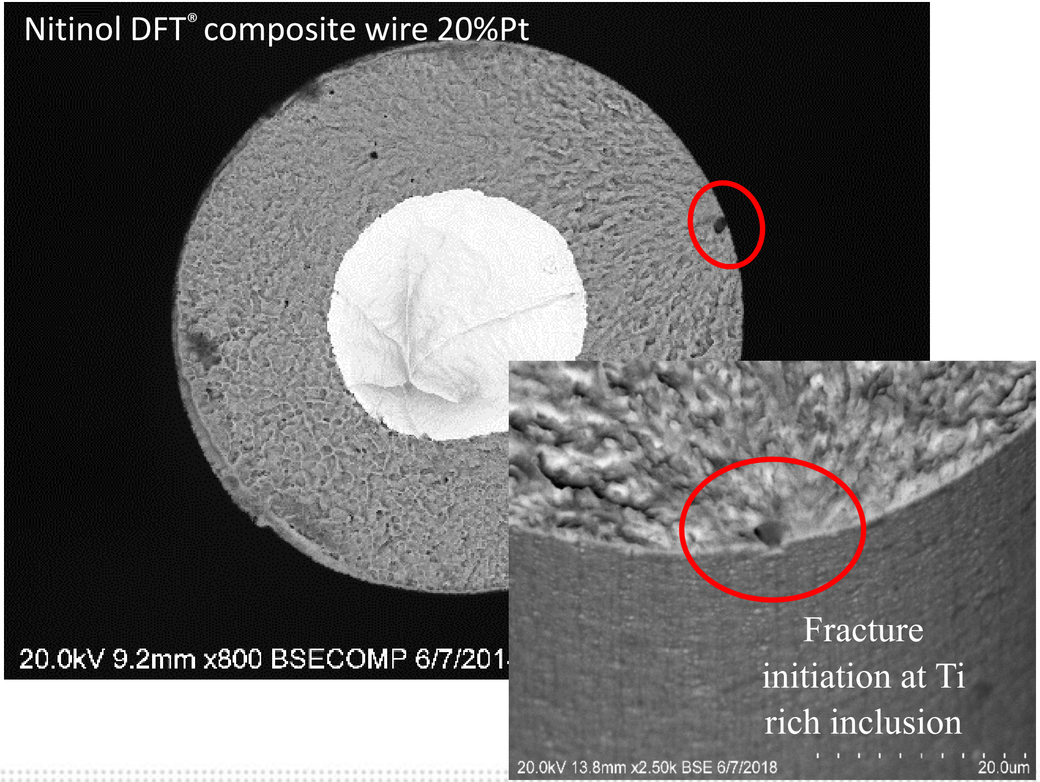


[8] "Standard Test Method for Conducting Rotating Bending Fatigue Tests of Solid Round Fine Wire" E2948-16a, ASTM International, p. 1-10
[9] Patel, Mitesh M. "Characterizing fatigue response of nickel-titanium alloys by rotary beam testing." *Journal of ASTM International* 4.6 (2007): 1-11.

Rotating bending fatigue - results



Rotating bending fatigue - results



Conclusions

- Platinum core impedes the strength, superelasticity, and shape recovery of DFT® composite wire compared to solid wire
  - Tensile stresses decrease with increasing Pt core
  - Residual elongation increases with increasing Pt core
  - The bend and free recovery curve displays more “sluggish” recovery and smaller recovery angle with increasing Pt core
  - More heat required to actuate composite wire against inelastic Pt core

Conclusions

- In this study, platinum core did not significantly alter rotating bending fatigue performance
  - All DFT® composite wire and solid Nitinol wires achieve high cycle (>10M) reunouts at 0.9% alternating, zero mean strain

Acknowledgements

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