Fort Wayne Metals Research Products Corp

PHN 260.747.4154
FAX 260.747.0398

9609 Ardmore Avenue
Fort Wayne, IN 46809

fwmetals.com

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A CoNiCr-Nitinol Composite Wire for Guidewire Type Applications

D.L. Snider, E. Dietsch, A.J. Griebel, D. Plumley, M. Michael, J.E. Schaffer

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Introduction

The physical properties of multiple metals are combined in composite wires, such as Drawn Filled Tube (DFT® wire[1]) to solve specific performance needs in a variety of applications. The demand for these composite wire solutions in medical technology has risen steadily over the past two decades. One such example contemplated here is for guidewires that are simultaneously strong, stiff, and superelastic, giving proximal stiffness and distal flexibility. The properties published here, for example, may improve the crossing of chronic total occlusions (CTOs) by offering improved physician control and tip performance with a jointless core wire design [7-9].

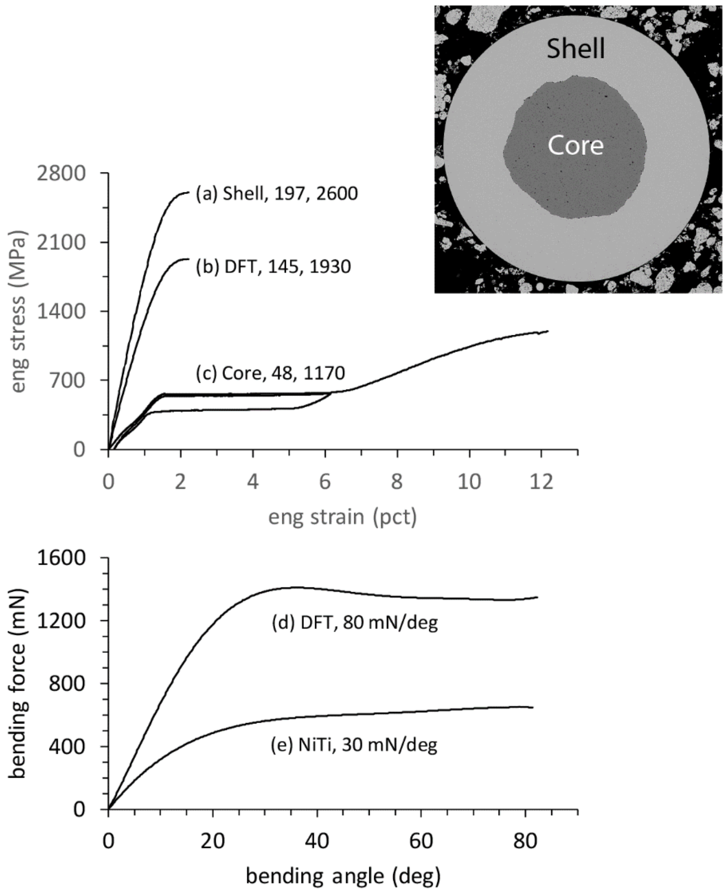

Figure 1 – Inset shows polished cross-section of 35N LT® (a CoNiCr alloy conforming to ASTM F562 Chemistry) where scale is indicated by 0.34 mm overall wire diameter (shell); (a) Stress strain extrapolation for shell CoNiCr element; (b) Measured stress strain response for overall 35N LT-DFT-30%NiTi wire; (c) Stress strain response for Core nitinol element after centerless grind removal to a diameter of 0.15 mm; (d) Higher stiffness bending response for overall DFT® wire construct; (e) Lower stiffness bending response for a 0.34 mm overall diameter superelastic nitinol wire at the same moment arm length as in (d).

[1] DFT wire is a registered trademark of Fort Wayne Metals, Fort Wayne, IN, USA

Materials

In the present example, a composite wire was constructed from a 35Co-35Ni-20Cr-10Mo (35N LT®[2] alloy) outer shell and a $Ni_{50.8}Ti_{49.2}$ nitinol core. The 0.34 mm [0.0135 in] wire was produced using the drawn filled tube (DFT® wire) production method similar to earlier publication [1], by filling seamless 35N LT® tubing with a nitinol rod core, and then co-processing through conventional wire drawing to achieve the target finish diameter with proportionate reduction of shell and core. Intermediate annealing temperatures were selected to soften both species for consistent draw reduction, grain size control, and property tuning. Final cold reduction ratios of 20 – 60% reduction of area and heat treatment were selected to optimize final wire straightness, 35N LT® strength levels, and core nitinol superelastic properties including plateau stresses and total recoverable strain potential. The terminology for the final DFT® wire configuration produced in this example is 35N LT-DFT-30%NiTi, indicating a Nitinol core within a 35N LT® sheath comprising about 30% of the wire's overall cross-sectional area.

Performance testing of the composite wire included tensile testing of the bulk wire, cyclic tensile testing of the nitinol core after centerless grinding, torque control testing comparing proximal to distal rotation response, and bend moment testing.

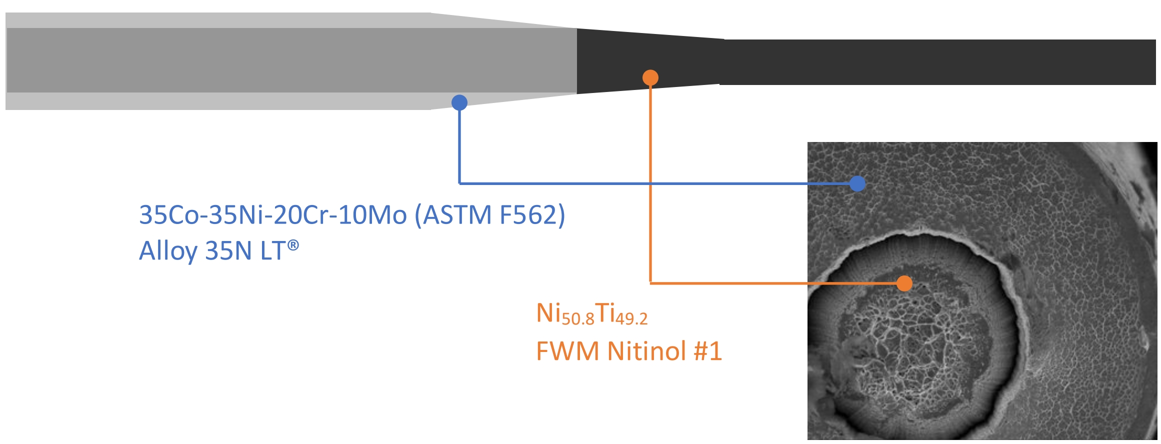

Figure 2 – An example DFT composite wire produced for use in a tapered guidewire component to provide relatively stiff and high strength proximal material (the handle, left side) with a relatively flexible and kink resistant superelastic tip without forming a joint during guidewire assembly. The superelastic nitinol tip is exposed simply by grinding or through e.g. laser machining or chemical removal.

Results

Figure 1 gives an overview of geometric and performance results with the present 35N LT-DFT-30%NiTi wire construction. Data include an as-polished cross-section of the wire geometry, monotonic uniaxial tensile testing (a-c) and bend load performance (d, e) over a constant moment-arm test for comparison against superelastic binary nitinol alone. There were no voids observed at the as-polished interface between the CoNiCr and nitinol species and centerless grinding to 0.15 mm (not shown here) revealed a

[2] 35N LT is a registered trademark of Fort Wayne Metals, Fort Wayne, IN, USA

clean and straight length of superelastic core material with good performance. Curve (c) for this 0.15 mm nitinol core illustrates the 48 GPa measured initial elastic modulus and ultimate tensile strength of 1170 MPa. Curve (a) provides the distinctive properties of the high strength CoNiCr shell element at 197 GPa, and 2600 MPa respectively for as-measured and calculated initial elastic modulus and ultimate tensile strength. Note that the shell properties were calculated from superposition as follows: The nitinol core properties were measured after centerless grinding and these stress-strain data were subtracted from stress-strain data of the composite wire, followed by use of the shell element area (70% of the total) for stress computation.

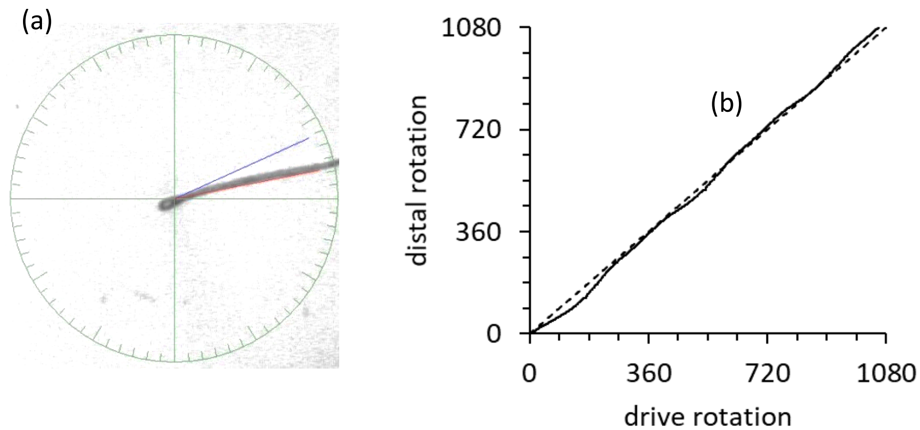

Figure 2 – (a) Image of distal rotation target shown by black "flag line" with light red overlay and drive rotation with slight "lag" indicated by blue line; (b) Drive versus distal rotation of one end of the present 0.34 mm 35N LT-DFT-30%NiTi wire over an approximately 1.8 meter length of wire wrapped through polyethylene guide tube through 2 x 200 mm loops showing good 1 to 1 input versus output response associated with well-balanced wire straightness.

Figure 2 provides data for an internally standardized whip test that is typically applied to superelastic straightened nitinol often used in guidewire core constructs. Here, the proximal end (drive end) of the 0.34 mm composite wire is rotated by a given drive rotation through three rotations (1080 deg), while the distal end is tracked by a "flag" affixed to the end using optical tracking (see Figure 2a). The drive rotation is compared to distal rotation as an indication of one-to-one controllability. Typically, wires that are not well-straightened and well-balanced in terms of residual stresses will show tens of degrees in lag-snap or whip response. The wire performance here falls within typical limits of Fort Wayne Metals SLT® (straight linear torque) processed wire of grades 2 to 4. In other words, the data suggest that the wire should provide satisfactory performance in a guide wire type control scenario.

Discussion

While many patents have discussed related ideas of combining high strength, high stiffness metals with high elasticity metals (such as nitinol), there are no known publications demonstrating the actual achievement of such properties in a composite wire [2-6]. For example, Abrams [2] discussed the use of a stiff handle element, superelastic tip, and a joint method to combine, e.g., stainless steel with nitinol. The possibility of integrated high strength and superelastic properties in a single wire can eliminate the need for device-level joint construction (e.g. the solder and glue of Palermo [4]), quality inspection overhead, and potentially less continuous property and handling transition.

To explain briefly, the taper shown in Figure 2 above has been applied to the example here with good results in "felt" property transition down the core wire length. The prototype composite wire given here is further distinct from Jalisi in [5,6] in that the core wire comprises only 2 elements with a superelastic core rather than a relatively stiff one.

Conclusion

The results shown here speak clearly to the successful integration of dissimilar metals to achieve a functionally-driven design. While the 35N LT® and Nitinol combination shown here performs well, other materials may be successfully combined as well. Table 1 gives a range of materials and purpose where performance can be realized across high strength species and relatively elastic species with integration into a single composite wire.

Table 1 – DFT material combination possibilities within the spirit of combining distinct high strength and elastic properties for various performance purposes.

Tube Material Possibilities	Purpose		Core Material Possibilities	Purpose
CoCr (e.g. L605)	High strength, high elastic stiffness, corrosion resistance, fatigue damage resistance		Nitinol	Superelasticity, torque response, kink resistance
CoNiCr (e.g. MP35N®[3], 35N LT®, FWM® 1058)	High strength, high elastic stiffness, corrosion resistance, fatigue damage resistance		Nitinol ternary alloy (e.g. NiTiHf, NiTiZr, NiTiNb, NiTiCo, NiTiCr)	Relative high stiffness/plateau superelasticity, torque response, kink resistance
Refractories including W-Re, Mo-Re, W or Rhodium	High strength, high elastic stiffness, stress fatigue damage resistance		Superelastic Ti-Beta alloy (e.g. TiNbZrSn, Ti-Ta, Ti-Mo)	Superelasticity, torque response, tissue compatibility, kink resistance
Titanium alloy (e.g. CP Ti, Ti 6/4, Ti Beta C, Ti Beta III)	Tissue compatibility, High strength, fatigue damage resistance		Multi-element array of superelastic alloys including Ni-Ti, NiTi-X-, NiTi-X-Y, or Ti-Beta	Configurability*, superelasticity, kind resistance, deployability
Platinum alloys including Pt-Ir	Tissue compatibility, electro-corrosion resistance at tissue interface, high elastic stiffness			

[3] MP35N is a registered trademark of SPS Technologies, Inc.

References

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