Mechanical characterization of implantable composite leadwires for next generation Neuroprostheses system

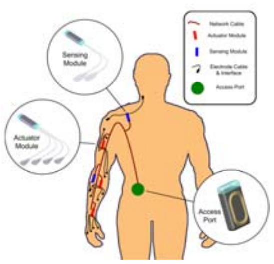
Ravikumar Varadarajan, Brian Smith*, John J. Lewandowski

Department of Materials Science and Engineering, *Department of Biomedical Engineering
Case Western Reserve University, Cleveland, Ohio

ABSTRACT

A team of materials scientists is supporting the development of Networked Implantable Neuroprostheses (NNPS) Systems on an NIH-Bioengineering Research Partnership. The Materials Group is leading the material and structural evaluation, analysis, and testing of implantable leadwires and interconnects that form part of the NNPS. The leadwire comprise of 2 to 6 helically coiled individual insulated conductors. Currently the potential use of silver cored Drawn Filled Tube (DFT) cables as conductors is being investigated. The response of various DFT cables to static and cyclic mechanical loading imposed during long-term implantation has been studied. Silver cored MP35N wires with 25%, 28% and 41% silver with various cable configurations (1x7, 1x19, 7x7, 7x19) have been tested. Monotonic tensile tests were performed and the fracture surfaces of the cables were observed under scanning electron microscope to reveal the fracture mechanisms involved. Fully reversed cyclic tests of the cables were conducted in a flex tester under various strain loading conditions in order to determine the fatigue behavior of the cables both in the low cycle and high cycle regime. The fatigue behavior of the cables was modeled using the Coffin-Manson-Basquin relationship. The effect of changes in mean stress on the fatigue behavior of the cables was also investigated. Curently, work is on progress to evaluate the flexibility and endurance of the multi-conductor leadwires under different physiologically relevant loading conditions.

SCHEMATIC OF NNPS CONCEPT



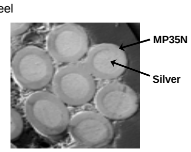
MATERIALS

316 LVM wire

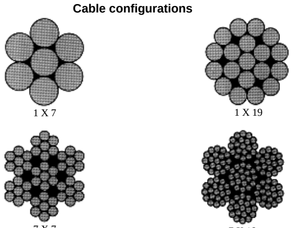
- Low carbon (0.023%) stainless steel
- Vacuum Arc Remelted

Drawn Filled Tube (DFT™) wire

- Metal-to-Metal composite
- Silver core(25%, 28%, 41% Ag)
- MP35N(Co-Ni-Cr-Mo alloy) tube



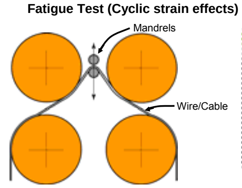
Cable configurations



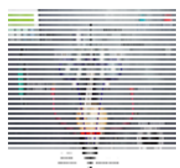
METHODS

1. **Tensile test**
   - Instron 1130 screw driven machine
   - Specimen gage length : 25 mm
   - Loading rate : 0.5 mm/min
   - High speed data acquisition system
   - True fracture stress and strain obtained from fracture surface

2. **Fatigue Test (Cyclic strain effects)**



- Cables are tested in cyclic fatigue via bending over a mandrel (R = -1).
- Mandrel radius controls stress and strain experienced by wires.



Flex tester used for cyclic fatigue tests

- Cyclic frequency: up to 5Hz.
- Break detector automatically detects failure and stops cycle counter.

3. **Fatigue Test (Mean stress effects)**

- Bose Electroforce work bench machine
- 140º flex at 4Hz
- 6 mm diameter mandrel
- Loads: 0.25 to 5N axial

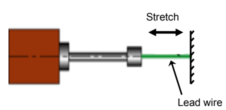
4. **Leadwire endurance Tests**

Multi-conductor leadwires

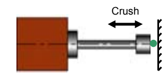
1. DFT - 2 conductor
2. DFT - 4 conductor
3. 316LVM - 2 conductor
4. 316LVM - 4 conductor

Endurance Tests

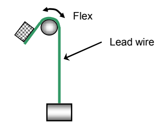
- Stretch Test
  - 20% stretch
  - 1,200,000 cycles
  - 4 Hz



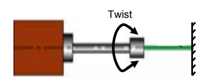
- Crush Test
  - 1 Kg/cm² pressure
  - 120,000 cycles
  - 4 Hz



- Flex Test
  - 140º Flex
  - 1,200,000 cycles
  - 4 Hz



- Twist Test
  - 140º Twist
  - 600,000 cycles
  - 4 Hz



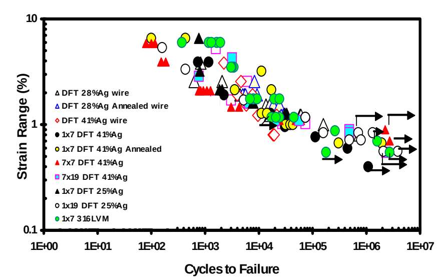
RESULTS

1. **Tensile Tests**

	ID	Wire dia (mm)	Cable dia (mm)	Yield stress (MPa)	UTS (MPa)	Reduction in area (%)	True fracture stress (MPa)	True fracture strain
1	DFT 28%Ag wire	0.076	0.076	1336	1424	14.11	1658	0.15
2	DFT 28%Ag wire Annealed	0.076	0.076	732	936	46.58	1753	0.63
3	DFT 41%Ag wire	0.076	0.076	1239	1395	34.39	2126	0.42
4	1x7 DFT 41%Ag	0.038	0.114	1109	1148	30.82	1660	0.37
5	1x7 DFT 41%Ag Annealed	0.064	0.191	702	863	47.76	1652	0.65
6	7x7 DFT 41%Ag	0.046	0.411	1051	1068	33.08	1596	0.40
7	7x19 DFT 41%Ag	0.036	0.533	808	1111	12.38	1268	0.13
8	1x7 DFT 25%Ag	0.064	0.191	1593	1643	38.63	2678	0.49
9	1x19 DFT 25%Ag	0.036	0.178	1627	1655	43.20	2913	0.57
10	1x7 316LVM	0.034	0.103	1135	1239	89.90	5407	2.29

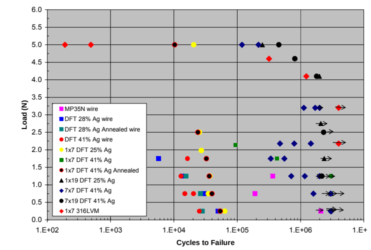
- **DFT® cables exhibit strengths comparable to 316LVM**

2. **Fatigue Test (Cyclic strain effects)**

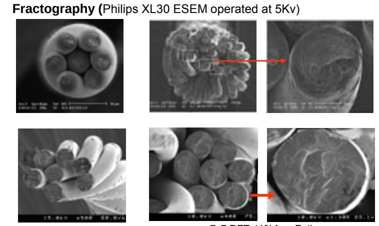


- **DFT® cables exhibit fatigue performance comparable to 316LVM**

3. **Fatigue Test (Cyclic strain effects)**



4. **Fractography** (Philips XL30 ESEM operated at 5Kv)



1x7 316LVM - Fatigue   7x7 DFT 41%Ag - Fatigue

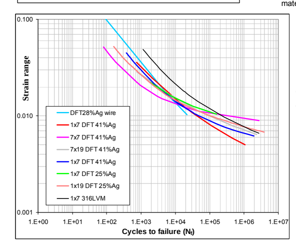
- **Images reveal high tensile ductility and strength producing good fatigue resistance for both 316LVM and DFT® cables**

5. **Modeling of Fatigue data**
   Coffin-Manson-Basquin relationship*

$$\frac{\Delta\varepsilon}{2} = \left(\frac{\sigma_f'}{E}\right)\left(2N_f\right)^b + \varepsilon_f'\left(2N_f\right)^c$$

$\Delta\varepsilon$ - Strain range
σ'_f ~ True fracture stress
ε'_f ~ True fracture strain
b - Fatigue strength exponent
c - Fatigue ductility exponent
E - Elastic modulus

* Manson SS, Halford GR. Fatigue and durability of materials, ASM International, 2005



Coffin-Manson-Basquin analysis can be used to model the fatigue performance of different cable materials and configurations

SUMMARY

- **Test techniques have been developed to mechanically evaluate candidate implantable cable materials and configurations.**
- **Tension and strain-controlled fatigue data have been generated on a variety of DFT® cables with different configurations.**
- **Preliminary analysis/modeling of the fatigue performance is being used to downselect amongst the candidate materials.**

ACKNOWLEDGEMENTS

This research is supported by NIH-NINDS Grant No. NS-041809 and NIH-NIBIB Grant No.EB-001740. Principal Investigator P. Hunter Peckham