Evolving Protocol for Qualification Testing of Implantable Cables

CASE WESTERN RESERVE UNIVERSITY EST. 1826

John J. Lewandowski and Joe H. Payer

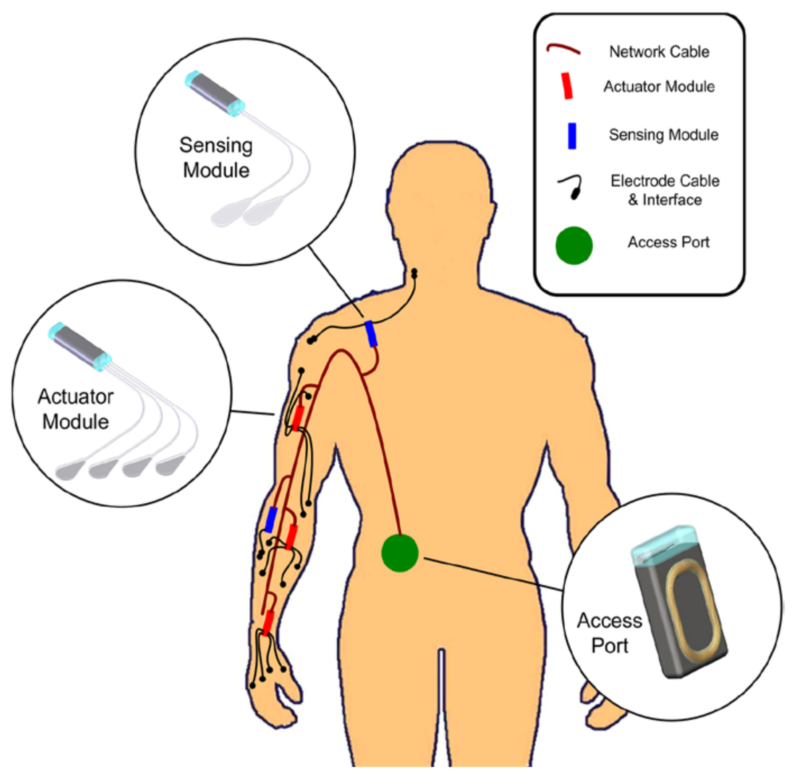
Department of Materials Science and Engineering

Case Western Reserve University, Cleveland, Ohio

ABSTRACT

A team of materials scientists is supporting the development of a Networked Implantable Neuroprostheses (NNPS) System on an NIH-Bioengineering Research Partnership. The technical basis and protocol for evaluating future cable designs is presented in this poster. The evolving protocol describes a series of accelerated tests designed to evaluate the mechanical and corrosion durability of implantable cables. The mechanical evaluations utilize the unique facilities housed in the Center for Mechanical Characterization of Materials at CWRU, directed by John Lewandowski. Accelerated cable mechanical testing under conditions of stretch, crush, flex, and twist/torsion are described, in addition to procedures for electrical resistance measurements in order to detect any damage in the cables and/or electrical insulation.

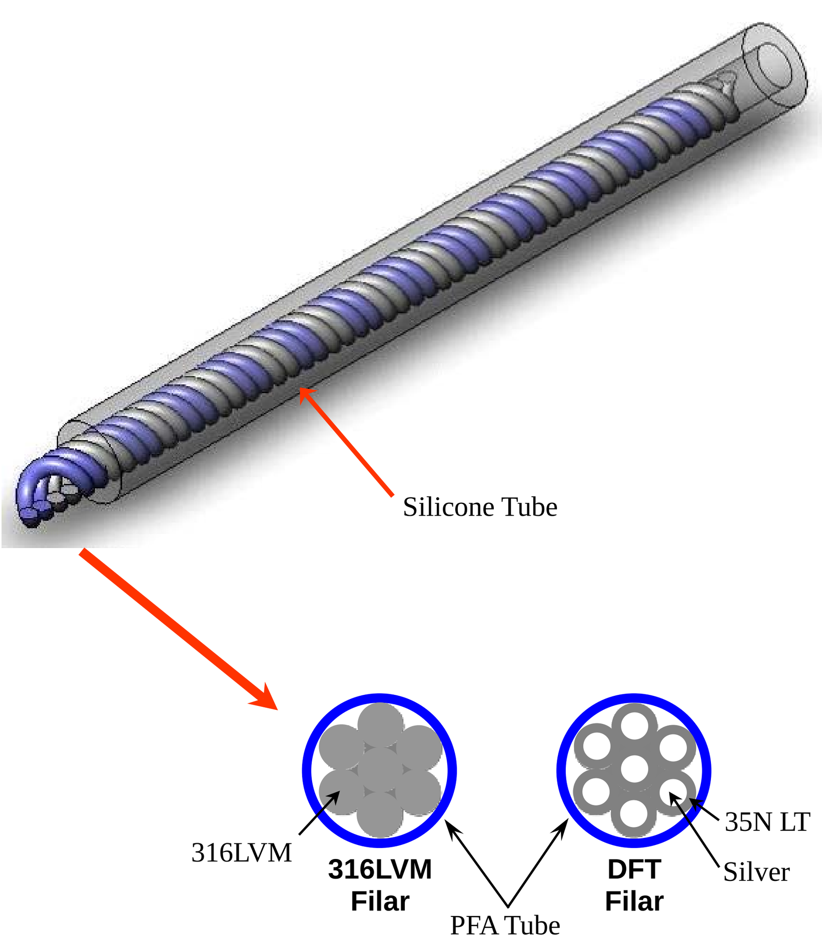
SCHEMATIC OF NETWORKED SYSTEM



THE NEED: Electrodes, cables and connectors are essential to the performance of implantable systems. An advanced cable with lower electrical resistance than conventional 316LVM cables is required for the NNPS. Silver-cored, 35N LT® provides lower resistance (Ag-core) along with mechanical strength and corrosion resistance (CoCrNiMo alloy-outer tube). However, there was little information on the cable's mechanical durability or fate of silver for damaged wires.

OBJECTIVE: To evaluate the mechanical durability of implantable cables by performing a series of accelerated tests and evaluate the corrosion release of Ag. An evolving protocol is described here for a series of accelerated tests.

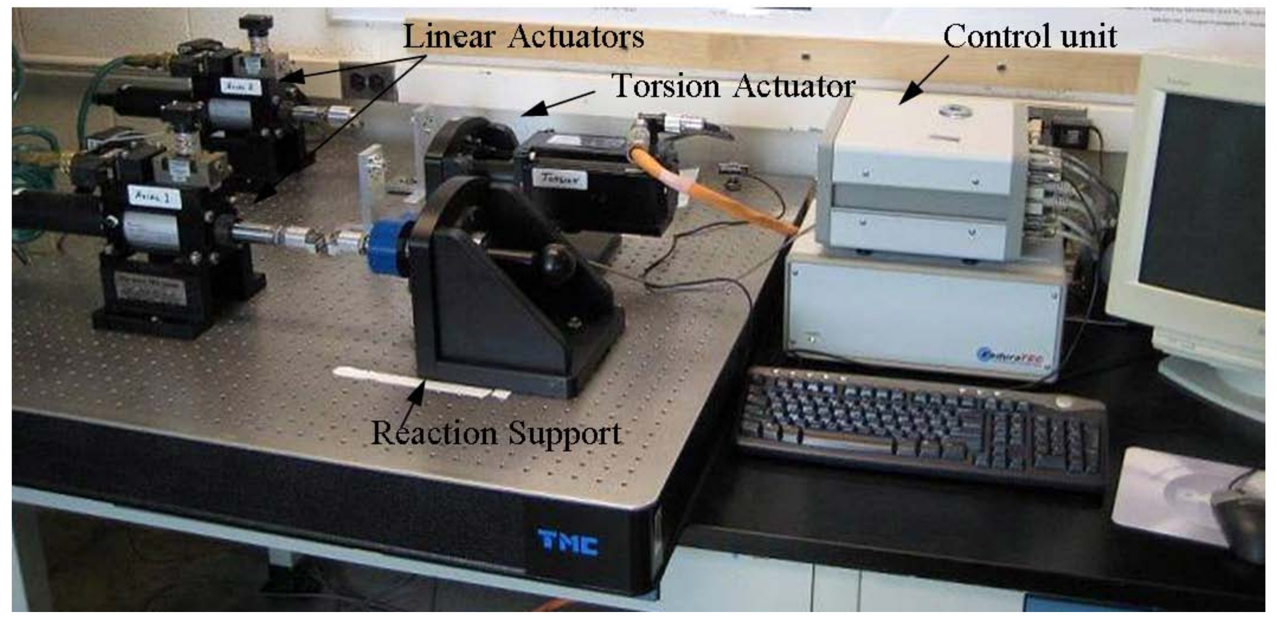
IMPLANTABLE CABLES



- DFT™* 2 Filar
- DFT™ 4 Filar
- 316LVM 2 Filar
- 316LVM 4 Filar

* Drawn Filled Tube (35N LT - 41%Ag) Fort Wayne Metals, Fort Wayne, IN

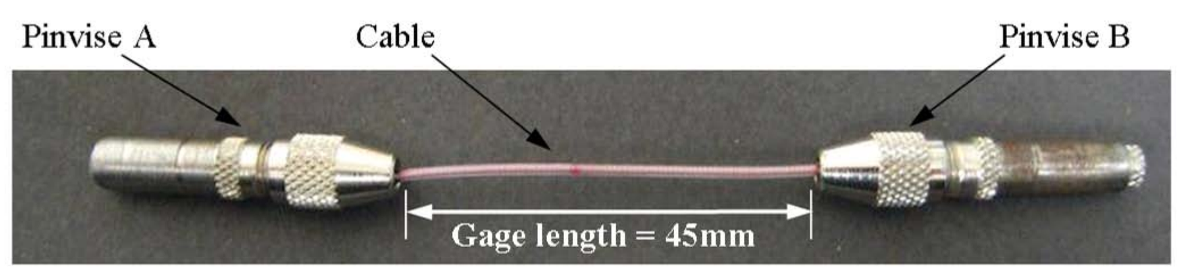
TEST EQUIPMENT



EnduraTEC TestBench (Bose Corporation, Minnetonka, MN) equipped with two pneumatic linear actuators and one electromagnetic torsion actuator

MECHANICAL TEST PROCEDURES

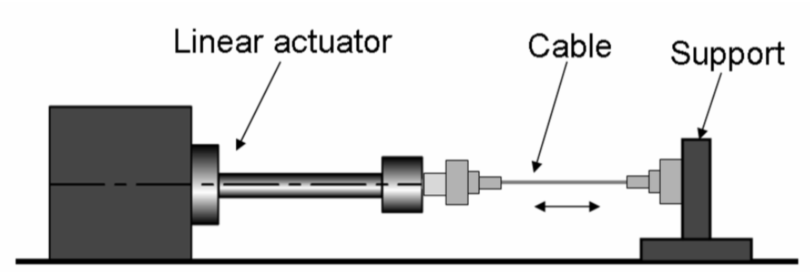
- Measure electrical resistance and impedence of the cables.
- Grip each end of the cable (finger tight) using a pinvise on each end so that the gage length between the pinvises is 45 mm.



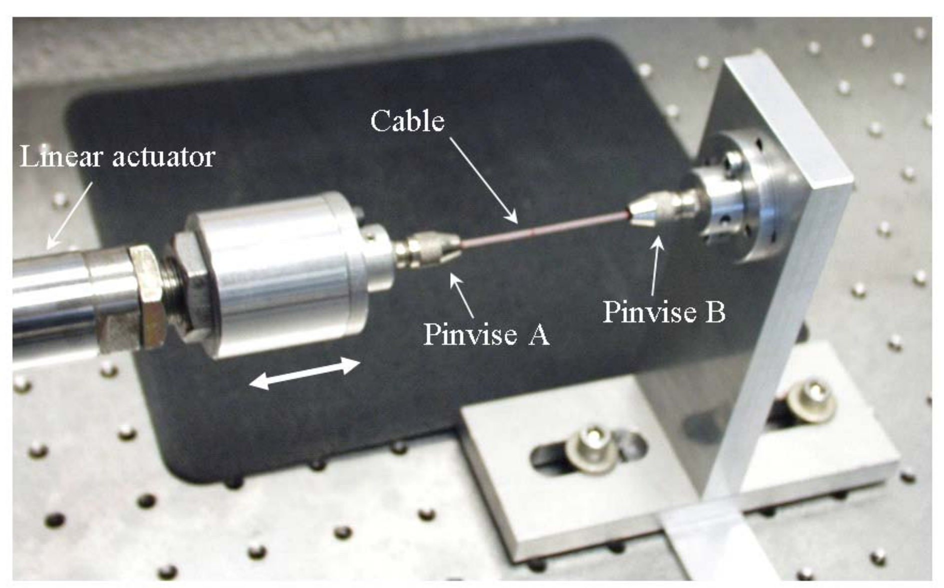
Cable with pinvises

Stretch test

- Apply a static pre-stretch of 2% (ie. 0.9mm) on the cable using the linear actuator to keep it taut prior to any cyclic stretch testing
- Apply 20% cyclic sinusoidal stretch @ 4Hz for 1.2 million cycles
- Monitor the actuator displacement and record actuator displacement vs time



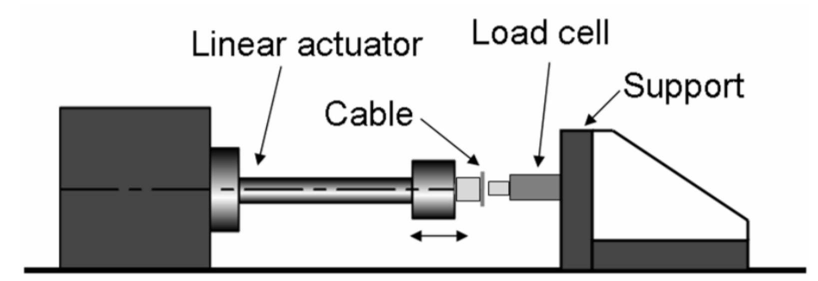
Stretch Test: Schematic



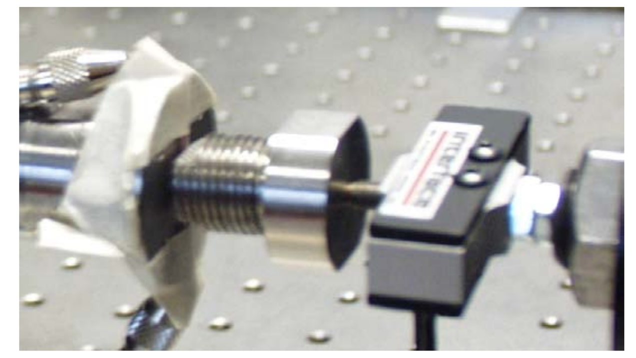
Stretch Test: Setup

Crush test

- Let the linear actuator reciprocate sinusoidally for 500 cycles with 5mm peak-to-peak amplitude at 4 Hz with no load on the cable
- Apply 1.2N load crushing force to the cable using the crusher by incrementally pushing the crusher-load cell assembly toward the cable
- Monitor the actuator displacement and load. After 500 cycles, continue to sinusoidally reciprocate the linear actuator for 0.12 million cycles with 5 mm amplitude at 4 Hz.
- Record the actuator displacement and load data



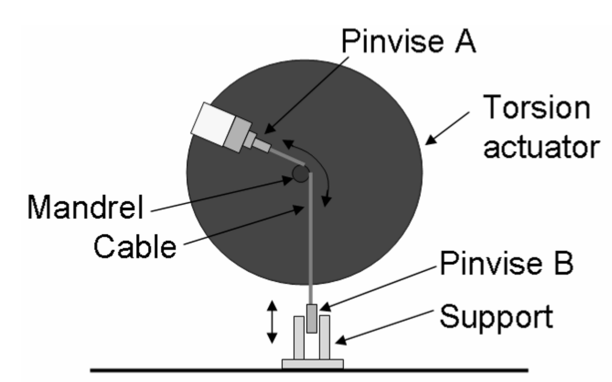
Crush Test: Schematic



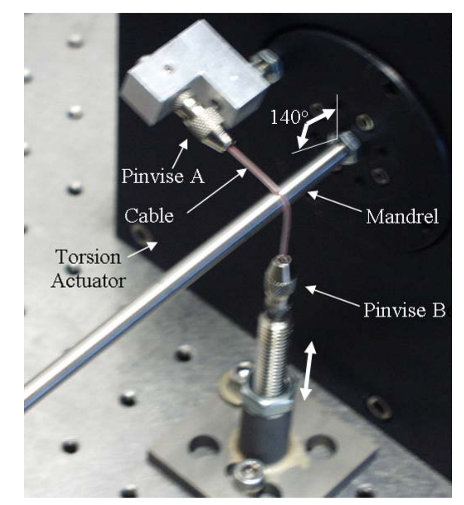
Crush Test: Setup

Flex test

- Pinvise A is fixed and pinvise B slides inside a hollow support.
- Subject the cable to 140° flexion over 6mm diameter mandrel for 1.2 million cycles at 4 Hz.
- Monitor the actuator rotation and record actuator rotation vs time data



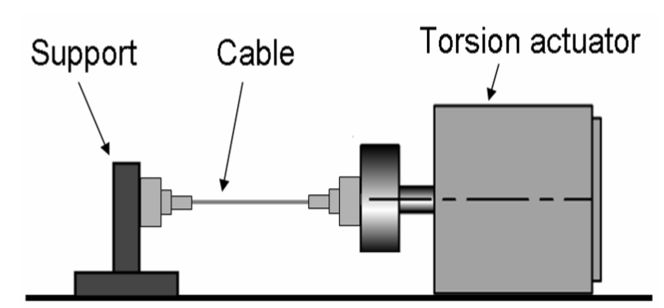
Flex Test: Schematic



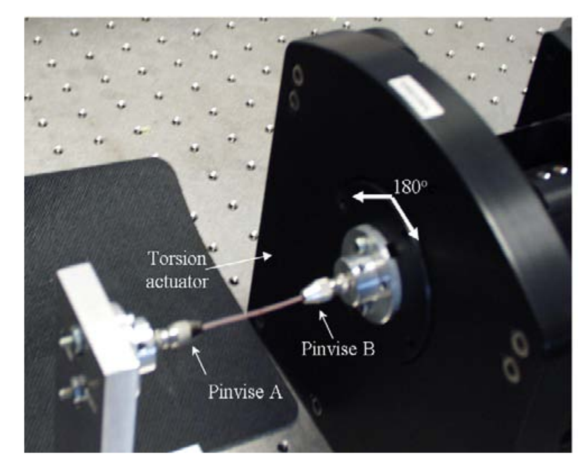
Flex Test: Setup

Torsion test

- Apply a static pre-stretch of 2% on the cable
- Subject the cable to 180° cyclic rotation for 0.6 million cycles at 4 Hz in such a way that the torsional load tends to tighten the helically twisted filars
- Monitor the actuator displacement and record actuator displacement vs time



Torsion Test: Schematic



Torsion Test: Setup

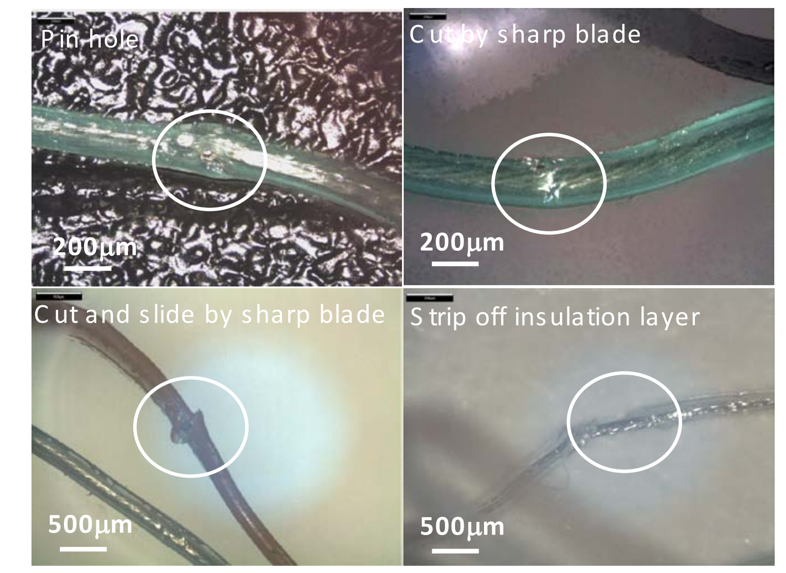
Post-Test Evaluation

- Visual and physical examination
- Wire electrical continuity examination
- Detection of damage and leakage current

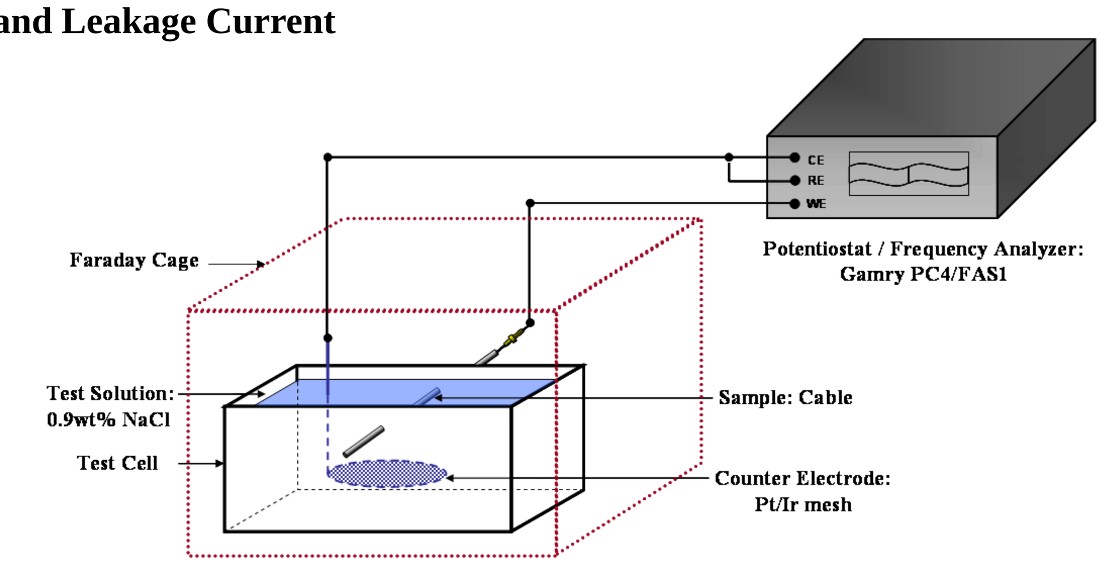
Scenarios of Damage on Cable

Type	Description of damage	Schematic
1	Pin hole through insulation layers to a single filar; pin contact confirmed by ohm meter	
2	Cut through the insulation layers on longitudinal direction without cutting wire	
3	Strip off insulation layer (~0.5mm)	
4	Cut through insulation layers and several individual wires (1/7, 3/7, 6/7, 7/7)	
5	Broken wires spike through the insulation layer-simulation	
6	Broken cable	

Infinite Focus Optical Microscope for Visual Examination



Electrochemical Impedance Spectroscopy for Detection of Damage and Leakage Current



Impedance measurement: Schematic

- Electrochemical Impedance Spectroscopy (EIS) technique detects damage.
- Intact cable showed nearly pure capacitor behavior (impedance ~$10^9 \Omega$ at 10mHz)
- Different levels of damage on insulation layer cause deviation from the nearly pure capacitor behavior of the cable.

ACKNOWLEDGEMENTS

This research is supported by NIH-NINDS Grant No. NS-041809 and NIH-NIBIB Grant No. EB-001740, Development of Networked Implantable Neuroprotheses (NNPS), Principal Investigator P. Hunter Peckham. We are grateful to Brian Smith for his technical support and discussions along with others in Cleveland Functional Electrical Stimulation (FES) Center at CWRU who provided technical support and assistance during this work.