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2.2.3: Peripheral Electrodes

External Pressure Measurements for Nerve Cuff Electrodes

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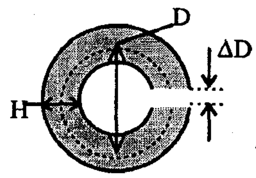
When large external pressures are applied to a peripheral nerve, tissue damage can occur via compression and blood flow occlusion, resulting in degeneration and demyelination of axons. This tissue damage must be avoided when implementing nerve cuff electrodes for electrical stimulation of axons. However, post-implant nerve swelling can result in these cuffs exerting large pressures. Currently, only theoretical models are used to predict nerve cuff electrode pressures. The goals of this investigation are 1) to develop a technique to measure external pressures applied by cuff electrodes, 2) to compare experimentally determined cuff pressures with those predicted by theoretical models, and 3) to quantitatively compare different cuff electrodes using a cuff pressure versus nerve diameter relationship. This report describes a pressure measurement technique designed for cuff electrodes and presents some preliminary measurements for various cuff designs.



Equation 1

$$\Delta P = (E*H^3*\Delta D) / (2.25*D^4)$$

Figure 1. Cross-section of a split ring cuff with its corresponding theoretical pressure equation, where **P** is the pressure exerted by the cuff, **E** is the Elastic modulus of the cuff material, **H** is the cuff wall thickness, **ΔD** is the difference between the nerve diameter and the cuff internal diameter, and **D** is the cuff mean ring diameter.

Introduction:

Nerve cuff electrodes (NCEs) are utilized for functional restoration of muscle groups in the upper and lower extremities, bladder, and diaphragm via electrical activation of peripheral nerves which innervate them. One problem associated with the use of NCEs is mechanically-induced neural damage[1]. These cylindrical shaped cuffs are placed snugly around the peripheral nerve to ensure good electrical contact for stimulation. They are fixed in place using suture or another closing mechanism. During surgical implantation, mechanical disturbance of the nerve can cause tissue swelling, increasing the nerve diameter by up to one-third of its original size. If nerve swelling exceeds the dimensions allowed by the cuff, the cuff will begin to exert external compressive forces on the nerve.

Large external pressures have been shown to cause neural damage leading to demyelination and degeneration of axons [2], [3]. Nerve compression studies by Powell *et al* [3] have shown that demyelination of axons can occur at external pressures as low as 10 mmHg, while significant axonal damage including degeneration occurs at pressures greater than 80 mmHg. Rydevik *et al* [2] examined the effects of compression on intraneural blood flow and found that venular flow was impaired at pressures as low as 20 to 30 mmHg, and arteriolar and intrafasicular capillary flow was retarded and completely stopped at pressures of 40 to 50 mmHg and 60 to 80 mmHg, respectively.

In order to reduce external pressures, many different variations of NCE designs have been reported. Naples *et al* [1] developed theoretical models to analyze pressures for two NCEs: a split ring and a spiral cuff electrode [1]. Both NCEs are manufactured using silicone rubber, because it is lightweight, flexible, and biocompatable. Figure 1 illustrates a diagram of the split ring cuff and also shows its theoretical external pressure equation. The spiral cuff has a cylindrical shape with an overlapping spiral cross-section which wraps around the nerve, allowing for intimate contact with the nerve and free expansion if nerve swelling occurs. The spiral cuff is modeled as two overlapping split rings, described by equation 2:

$$\Delta P = (E*H^3*\Delta D) / (2.25*\{D_i^4+D_o^4\}) \quad \textit{(equation 2)},$$

where D_i is the mean inner ring diameter and D_o is the mean outer ring diameter.

To date, only theoretical models have been used to predict external pressures applied by NCEs. The focus of this study is to design a method of measuring the pressures exerted by NCEs experimentally. Pressure measurements will be made for cuffs on varying size nerve models, giving a cuff pressure versus nerve diameter relationship for any given diameter NCE. These results may be used 1) to predict pressures and post-implant blood flow interference for NCEs, 2) to quantitatively compare different NCEs, 3) to compare results between theoretical and experimental models for NCEs, and 4) to aid in new NCE designs to minimize pressures.

NCE Pressure Sensor Design:

An experimental apparatus was designed to measure the external pressure exerted by NCEs. Figure 2 illustrates a diagram of the sensor used to measure cuff pressure. A rigid tube is sealed at one end and attached at the other to a Gould P23XL metal diaphragm pressure transducer. A small section in the middle of the rigid tube is replaced by a thin-walled section of silicone rubber tubing. The sensor system is filled with distilled water (an incompressible fluid) at atmospheric pressure, and is sealed at all sections to prevent leakage. When a cuff electrode is placed around the section of silicone rubber tubing, the internal pressure in the system increases and is measured by the pressure transducer, in volts. The internal pressure increase measured by the transducer is defined to be the cuff pressure. A cuff pressure versus tubing diameter relationship can be generated for a NCE by measuring the cuff pressure for sensors with silicone rubber tubing of various resting diameters.

In order to realize the internal pressure change measured by sensor into an external pressure, the sensor must be calibrated using a known external pressure source. Figure 3 illustrates

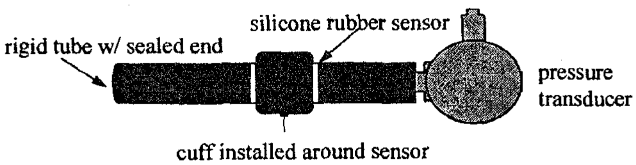


Figure 2. A diagram of the NCE pressure sensor with a cuff installed. The sensor system is filled with H_2O at atmospheric pressure and sealed to prevent leakage. As the cuff is installed around the silicone rubber tubing, the pressure transducer measures the increase in internal pressure.

the apparatus used to calibrate the sensor. The identical NCE pressure sensor described above is placed in a tank, using a column of water of known height as an external pressure source. A calibration curve is generated for the sensor by taking internal pressure measurements from the sensor at varying heights of the column of water. The sensor sensitivity is defined as the slope of this calibration curve, the measured internal pressure by the known applied external pressure, and has the units of volts/cmH_2O.

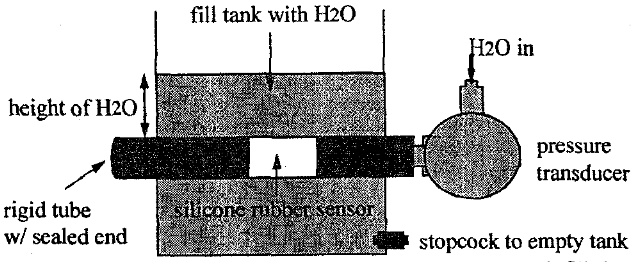


Figure 3. A diagram of sensor calibration. The sensor system is filled with H_2O at atmospheric pressure and sealed to prevent leakage. When the tank is filled with H_2O, the internal pressure in the sensor increases and is measured by the transducer. The calibration plot will realize a change in internal pressure to a known external pressure in cm H_2O.

The protocol for NCE external pressure measurements is as follows: 1) calibrate of the P23XL pressure transducer; 2) establish a steady baseline internal pressure (atmospheric) for the NCE pressure sensor; 3) calibrate sensor using the column of water as an external pressure source; 4) install cuff around silicone rubber sensor and measure internal pressure; 5) repeat sensor calibration to ensure sensitivity remains constant after cuff installation and removal. Assuming that the cuff exerts external pressure by similar mechanisms as the column of water, internal pressure measurements made for the cuff are compared to the sensor calibration curve to yield a net external cuff pressure. These measurements are repeated for varying sensor sizes and NCE designs to obtain cuff pressure versus nerve diameter relationships.

Results:

Seven NCE sensors were built with silicone rubber tubing resting diameters of 2.8, 3.0, 3.2, 3.4, 3.6, 3.8, 4.0 mm to measure pressures for 3.0 mm cuffs. Figure 4 depicts a sensor calibration curve for the 3.8mm sensor. Internal pressure measurements were made and repeated ten times for external pressures of 0, 10, 20, 30 , 40, and 50 cmH_2O. The mean standard deviation of the pressure measurements was less than 0.39% of the sensor full scale output. The linearity of the sensor output deviated less than 2.5% of the sensor full scale output. The sensitivity for this sensor was measured to be 30mV/cmH_2O. Resolution of the sensor is less than 0.5cmH_2O. Maximum hysteresis for the sensor calibration was less than 4.9% of full scale output. Sensor recalibration showed less than 0.6% change in sensitivity between trials before and after cuff application. Similar results were found for other NCE sensors tested.

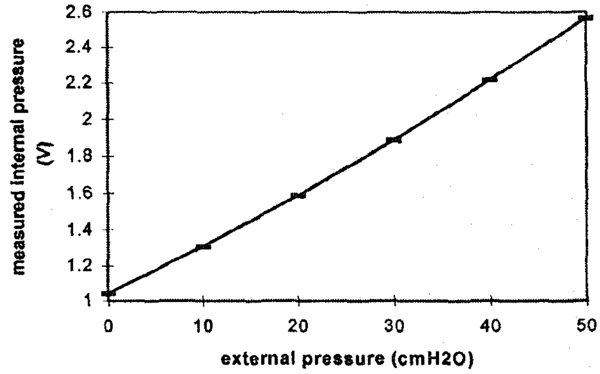


Figure 4. Sensor calibration plot of measured internal pressure versus applied external pressure. Slope is 0.03V/ cmH_2O. Error bars represent standard deviation for measured internal pressure +/- 0.006V.

Preliminary measurements have been made for split ring and spiral silicone rubber NCEs. Table 1 compares the experimental pressure measurements with those predicted by the Naples models for two different cuffs installed on the 3.8mm NCE sensor.

cuff design	cuff ID (mm)	cuff H (mm)	Exp. P (cmH_2O)	Theory P. (cmH_2O)
split ring	3.35	1.3	**5.38**	**5.47**
spiral	3.05	0.35	**9.25**	**8.0**

Table 1. Experimental and Theoretical NCE pressures for split ring and spiral cuff designs of shown internal diameter (ID) and wall thickness (H) installed on a 3.8mm NCE sensor.

Discussion and Conclusions:

An experimental apparatus was designed to measure the external pressure applied by NCEs. The sensors built have linear and repeatable outputs, in addition to high sensitivity. Moreover, preliminary measurements of external pressures generated by NCEs are in agreement with theoretical calculations. These measurements suggest that both cuffs, at the diameters tested, would not exert enough pressure to occlude blood flow or cause degeneration. Future work includes testing different NCEs on varying diameter sensors to generate cuff pressure versus sensor diameter plots for each cuff. This new sensor allows for measurements of the pressures applied by various cuffs prior to implantation and should help to improve cuff design and reduce nerve damage.

Acknowledgments:
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References:

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