Measurement of External Pressures Generated by Nerve Cuff Electrodes

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***Abstract*—When 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. Although many types of nerve electrodes have been designed to avoid or minimize this pressure during stimulation of the nerve or recording of its activity, the measurement of the pressure exerted by these cuffs has not been reported. Currently, only theoretical models are used to predict nerve cuff electrode pressures. We have developed a nerve cuff electrode pressure sensor to measure external pressures exerted by peripheral nerve cuff electrodes. The sensor has a high sensitivity, linear response with little hysteresis and reproducible output. Pressure measurements have been obtained for split-ring and spiral cuff electrodes. The measurements obtained are in agreement with theoretical predictions. Moreover, they indicate that the pressures exerted by cuffs currently used for stimulation generate only a small amount of pressure, which is below the pressure required to occlude blood flow in nerves. The results also suggest that this new sensor can provide reliable measurement of external pressures exerted by nerve electrodes and would be an important tool for comparing various nerve cuff electrode designs.**

I. Introduction

NERVE cuff electrodes (NCE's) are utilized for functional stimulation of muscle groups via electrical activation of peripheral nerves which innervate them [6], [9], [21], [22]. Advantages of using NCE's over surface or intramuscular electrodes include 1) lower threshold currents, decreasing power consumption and the probability of electrically induced tissue damage; 2) remote location of the electrode, reducing mechanical disturbance caused by muscle contraction; and 3) greater functional selectivity using fewer electrodes, minimizing the number of electrodes implanted and surgical procedures [6], [18]. These cuff electrodes have also been used with great success to record neural activity in peripheral nerves [4], [23]–[25].

One problem associated with the use of NCE's is mechanically induced neural damage [1]–[8], [10]–[12]. For safety reasons, early NCE models were designed with inner diameters much larger than the outer diameters of the corresponding nerves they were being used to stimulate. However, the looseness of these cuffs did not allow for selective stimulation of nerve fascicles. Newly designed cylindrically 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 [13]–[17], [19]. Nerve compression studies by Powell *et al.*[14] have shown that demyelination of axons can occur at external pressures as low as 10 mmHg (13.57 cm H_2O), while significant axonal damage including degeneration occurs at pressures greater than 80 mmHg (108.6 cm H_2O). Zochodne *et al.*[16] examined the effects of acute nerve crush injury and suggested that nerve damage, due to mechanical injury of nerve fibers, will occur after only 30 s of nerve crush. Rydevik *et al.*[13] examined the effects of compression on intraneural blood flow and found that venular flow was impaired at pressures as low as 20 to 30 mm·Hg (27–41 cm H_2O). Arteriolar and interfascicular capillary flow was retarded and completely stopped at pressures of 40 to 50 mm·Hg (54–68 cm H_2O) and 60 to 80 mm·Hg (81–109 cm H_2O), respectively. This decrease in blood flow may lead to ischemia and play a role in the degeneration of axons. Therefore, it is clear that NCE's should not exert more than 20 mm·Hg (27 cm H_2O) of pressure after implantation [13]. In order to design safe nerve cuff electrodes, it is important to determine the pressures than these cuffs can exert.

To date, only theoretical models [6] have been used to predict external pressures applied by NCE's, and no experimental measurements of these pressures have been made. The goal of this study is to design a method of measuring the pressures exerted by NCE's experimentally and to measure the pressures for various cuff designs. The relations between the diameter of the cuff and nerve diameter will be measured and compared to theoretical calculations. These results will be useful 1) to predict pressures and postimplant blood flow interference for NCE designs, 2) to quantitatively compare pressures exerted by different NCE's, 3) to compare results between theoretical and experimental models for NCE's, and 4) to aid in new NCE designs capable of minimizing pressures exerted on nerves. These results have been presented in abstract form [26].

II. Methods

A. Theoretical Pressure Analysis for Nerve Cuff Electrodes

Theoretical models to determine external pressures exerted by two commonly used NCE's, the split ring and spiral cuffs,

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were reported by Naples *et al.* [6]. The split ring cuff is a cylindrical tube cut open lengthwise and installed around a nerve without a suture for closure [Fig. 1(A))]. The theoretical pressure equation for this cuff is

$$\Delta P = \frac{EH^3 \Delta D}{2.25 D^4} \tag{1}$$

where $\Delta \mathbf{P}$ is the pressure exerted by the cuff, $\mathbf{E}$ is the Elastic Modulus of the cuff material, $\mathbf{H}$ is the cuff wall thickness, $\Delta \mathbf{D}$ is the difference between the nerve diameter and the cuff internal diameter, and $\mathbf{D}$ is the cuff mean ring diameter.

The spiral cuff is a self-coiling and self-sizing cuff with a cylindrical shape that wraps itself around the nerve [6]. The double-wrap spiral cuff is modeled as two overlapping split rings [Fig. 1(B)]. The theoretical pressure equation for a double wrap spiral cuff is

$$\Delta P = \frac{EH^3 \Delta D}{2.25 \left(D_i^4 + D_0^4\right)} \tag{2}$$

where $\mathbf{D}_i$ is the cuff mean inner ring diameter and $\mathbf{D}_o$ is the cuff mean outer ring diameter. These models' equations were derived assuming: 1) a constant Elastic modulus for silicone rubber, 2) small deflections of the cuff size, and 3) the nerve segment in the cuff can be treated as an incompressible fluid in a fixed volume.

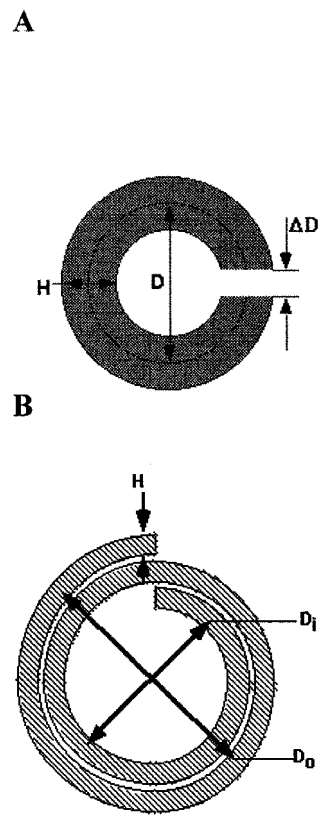

Fig. 1. Cross section of two types of nerve cuffs tested.: (A) split ring cuff and (B) double wrap spiral cuff. The pressure exerted by these electrodes was calculated using theoretical models [6] and measured experimentally.

B. Nerve Cuff Electrode (NCE) Pressure Sensor Design

The experimental apparatus designed to measure the external pressure exerted by NCE's is shown in Fig. 2(A). A rigid tube is sealed at one end and attached at the other to a 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. This section of tubing used in sensor manufacturing is prestretched and allowed to soak in water overnight before use in order to equilibrate changes in material properties due to water absorption, temperature, and stretching deformation. The sensor system is filled with distilled water (an incompressible fluid) at atmospheric pressure, and is sealed at all sections to prevent leakage.

Six NCE pressure sensors were built using silicone rubber tubing (Aero Rubber, Inc.) with resting diameters of 3.07, 3.28, 3.48, 3.68, 3.89, and 4.09 mm (with a tolerance of ± 0.05 mm). The tubing was installed around rigid plastic stopcocks (Baxter, Inc.) serving as the sealed rigid tubes. One stopcock was attached to an Ohmeda P23XL metal diaphragm pressure transducer. The entire sensor system was mounted in a rigid polypropylene tank (Qorpak) using epoxy putty. All junctions in the sensor were sealed using Dow Corning 734 silicone rubber sealant. Measurements were taken from the transducer output using a Gould RS3400 chart recorder/universal amplifier and Fluke 73 Series II Multimeter.

In order to measure applied external pressure, the NCE is installed around the section of silicone rubber tubing. Preliminary experiments were performed to analyze the effect of cuff length on NCE applied external pressure. Pressures were measured for split ring cuffs with lengths varying from 33%, 67%, and 100% of NCE sensor tubing length. Results of these experiments showed that maximum pressures were measured when cuff length was 100% of sensor silicone rubber tubing length. These maximum pressures also correlated closest to theoretical calculations for NCE applied pressure. Because we are concerned with the maximal pressures that can be potentially exerted by NCE's, equal cuff and sensor tubing lengths of 1.0 cm were used for the experiments in this study.

When a cuff electrode is installed on the silicone rubber tubing section of the NCE sensor [Fig. 2(A)], the internal pressure in the system increases and is measured by the pressure transducer, in volts. The change in internal pressure in the system is assumed to be equal to the pressure applied by the cuff. A cuff pressure versus sensor tubing diameter relationship can be generated for a NCE by measuring the cuff pressure for sensors with silicone rubber tubing of varying resting diameters. This ratio of diameters is defined to be the cuff-to-sensor diameter ratio (CSR), corresponding to the cuff-to-nerve diameter ratio (CNR) used in theoretical models [6].

The Ohmeda P23XL pressure transducer was calibrated as shown in Fig. 2(B). In order to relate the internal pressure change measured by sensor to the applied external pressure, the sensor must be calibrated using a known external pressure source. This calibration is necessary because the compliance of the silicone rubber sensor causes the internal pressure of the system to be lower than the actual external pressure exerted by the cuff. The NCE pressure sensor is calibrated in a tank using

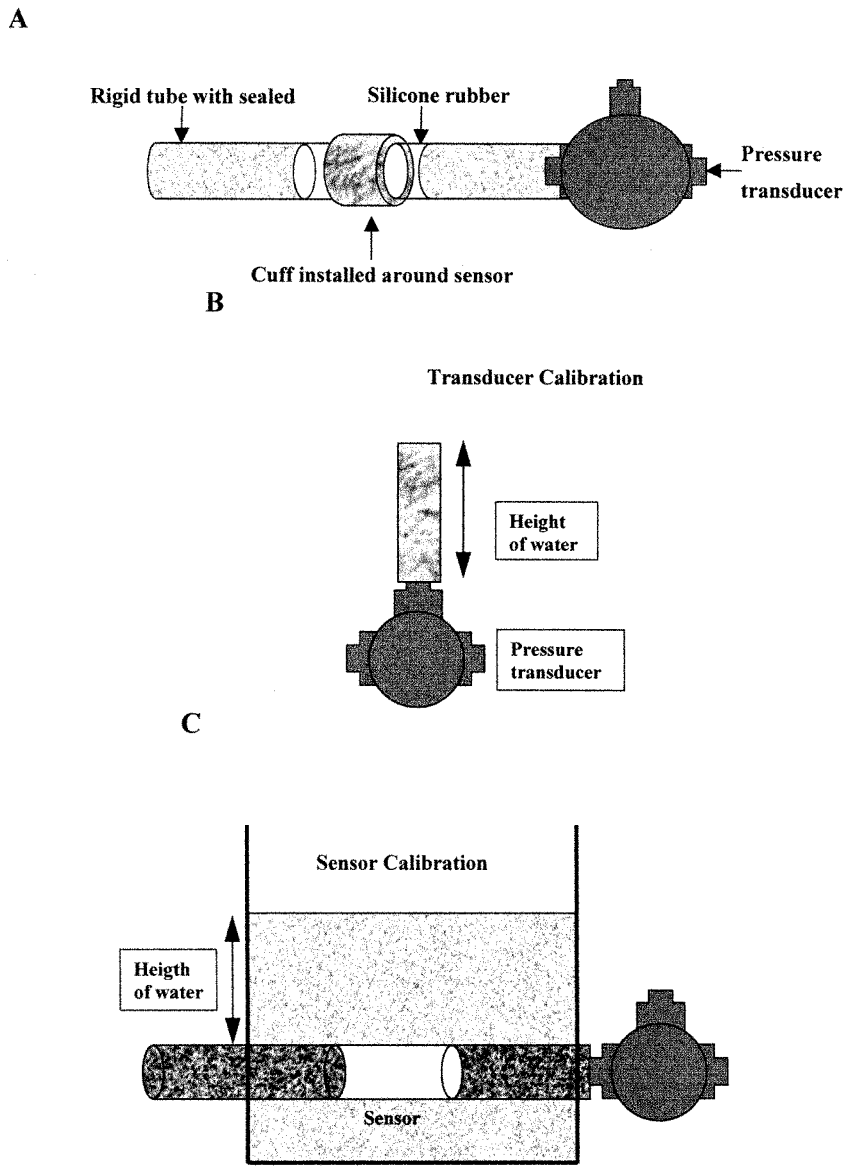

Fig. 2. NCE design and calibration methods. (A) NCE pressure sensor with a cuff installed. The sensor system is filled with water at atmospheric pressure and sealed to prevent leakage. A nerve cuff is installed around the silicone rubber sensor and the external pressure generated by the cuff is converted into an internal pressure measured by the P23XL pressure transducer. (B) P23XL Pressure Transducer calibration. (C) NCE pressure sensor calibration. The sensor is inserted into a water tank filled to a known height. Measuring the internal pressure generated at various known external pressures produces a calibration curve.

a column of water of known height as an external pressure source [Fig. 2(C)]. 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 divided by the known applied external pressure, and has the units of volts per centimeters H_2O. In order to determine the slopes and linearity of these calibration curves, linear regressions were performed.

External pressure measurements were made for the following cuffs, installed on the array of NCE sensors: 1) Vesta Class IV silicone rubber split ring ($E = 21000$ cm H_2O, $D = 3.1$ mm, $H = 508$ μm); 2) Silastic silicone rubber single wrap spiral ($E = 25375$ cm H_2O, $D = 3.125$ mm, $H = 350$ μm); 3) Silastic silicone rubber double wrap spiral ($E = 25375$ cm H_2O, $D_i = 3.125$ mm, $D_o = 3.9$ mm, $H = 400$ μm). Cuff diameter and thickness measurements were made under a microscope and repeated ten times to obtain mean values. A tolerance of ± 0.05 mm was obtained for diameter and wall thickness measurements.

III. Results

A. NCE Sensor Calibration

The P23XL transducer was calibrated first and its sensitivity was 50 mV/cm H_2O as shown in Fig. 3(A). Fig. 3(A) also shows the calibration curve of the NCE sensor. Using the NCE sensor calibration method from Fig. 2(C), internal pressure measurements were made and repeated ten times with applied external pressures of 0, 10, 20, 30, 40, and 50 cm H_2O. The standard deviation of the pressure measurements was less than 0.5% of

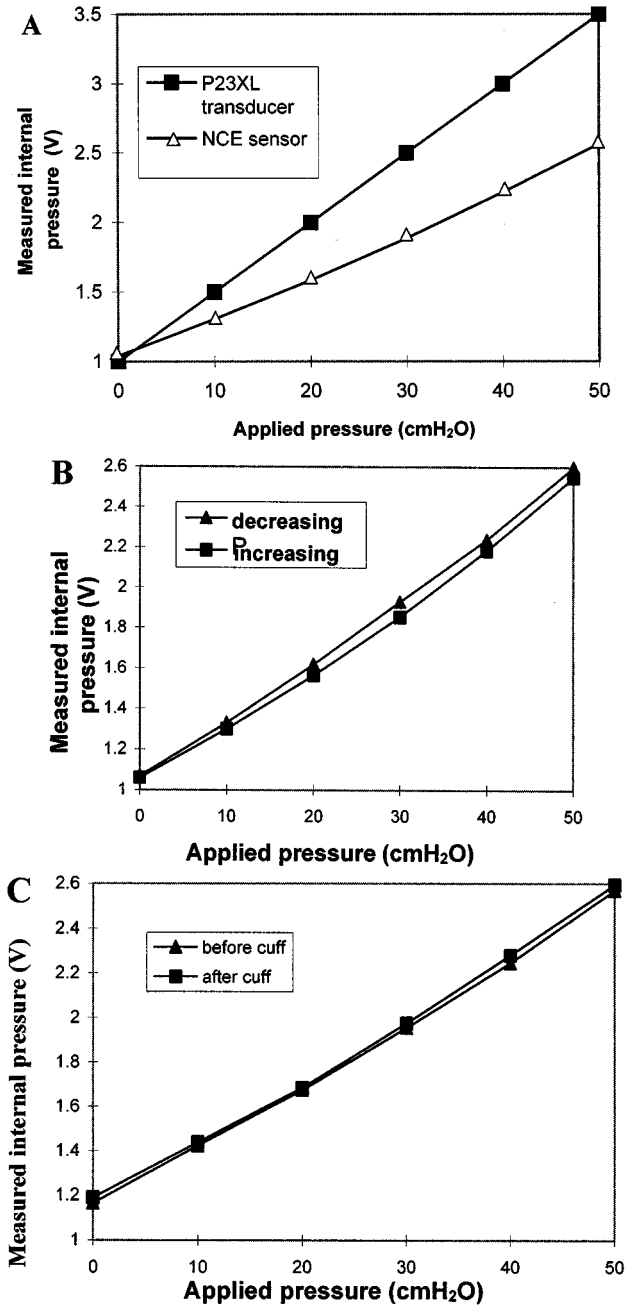

Fig. 3. Calibration results. (A) Internal pressure is plotted versus applied external pressure for the pressure transducer and a 3.89 mm diameter NCE pressure sensor. Sensitivity is defined as the slope of the calibration curves (volts per centimeter H_2O). Error bars are too small to be shown in the graph. (B) Hysteresis of the NCE pressure sensor. The maximum hysteresis is 4.9% of full-scale output and occurs at $P = 30$ cm H_2O. (C) The calibration of the NCE sensor is plotted before cuff installation and after cuff removal. The difference in sensitivity is less than 0.06% of full-scale output.

the sensor full scale output $(N = 10)$. Linear regression analysis for this calibration showed excellent fit to its linear response curve $(R^2 > 0.99)$. The deviation from linearity of the sensor output was less than 2.5% of the sensor full-scale output. The sensitivity for this sensor was found to be 30 mV/cm H_2O. Resolution of the sensor is less than 0.5 cm H_2O. Maximum hysteresis for the sensor calibration was less than 4.9% of full-scale output, as shown in Fig. 3(B). Sensor recalibration, illustrated in Fig. 3(C), showed less than 0.6% change in sensitivity between trials before and following cuff installation and removal. Similar results were obtained for other NCE sensors tested, indicating a stable sensitivity during the measurement.

B. Nerve Cuff Electrode Pressure

The cuff pressure is defined as the differential pressure between the steady state baseline pressure before cuff installation and the steady state peak pressure following cuff installation. Assuming that the cuff exerts its external pressure in a manner similar to a column of water, internal pressure measurements obtained for a given cuff are compared to the sensor calibration curve to yield a net external cuff pressure. These measurements are repeated ten times on the array of sensor sizes for each NCE design to obtain cuff pressure versus sensor diameter relationships. Results are presented in plots of external pressure applied by the cuff electrode versus the CSR.

The external pressure generated by the following three NCE designs was measured: a split ring, a single wrap spiral, and a double wrap spiral cuff. To determine the effect of CSR on NCE applied pressure, each cuff was tested on the array of NCE sensors. Fig. 4(A) shows the experimentally measured external pressure applied by the split ring cuff as a function of the CSR. The maximum standard deviation for ten trials was less than 4% of the full scale pressure range for the split ring cuff for all of the CSR's tested, except CSR's of 0.84 and 0.80, which have standard deviations of 6% and 8% of full scale, respectively. The theoretical pressures were also calculated for this cuff and are plotted along with experimental values. Excellent agreement between theoretical and experimental results is obtained at all points except for the CSR of 0.76, which shows an error of 12% of full scale. The mean error between theoretical and experimental values for the six CSR's tested is 4.3% of the full-scale pressure range. The maximum pressure generated by this NCE was 8 cm H_2O.

A plot of the experimentally measured external pressure applied by the single wrap spiral cuff versus the CSR is seen in Fig. 4(B). The standard deviation for the six CSR's tested ranges between 2.7% and 9.4% of the full-scale pressure range for the single wrap spiral cuff. The theoretical pressures calculated using the analytical model for a single wrap spiral cuff (which is identical to the split ring cuff model) are also shown. The mean error between theoretical and experimental values for the six CSR's tested is 8.2% of the full-scale pressure range. The maximum pressure generated by this cuff is 3.8 cm H_2O.

Finally, Fig. 4(C) shows the experimentally measured external pressure generated by the double wrap spiral cuff versus the CSR. The range of standard deviation for ten trials for the six CSR's tested is 1.9% to 11.1% of the full-scale pressure range for the double wrap spiral cuff. The theoretical pressures calculated using the model for a double wrap spiral cuff are not in as close agreement with experimental measurements as the previous model. There is a small offset, approximately 1 cm H_2O, between the theoretical and experimentally measured cuff pressures. The mean error between theoretical and experimental values for the six CSR's tested is 12.4% of the full-scale pressure range. The maximum pressure generated by the double wrap spiral cuff is 7.6 cm H_2O.

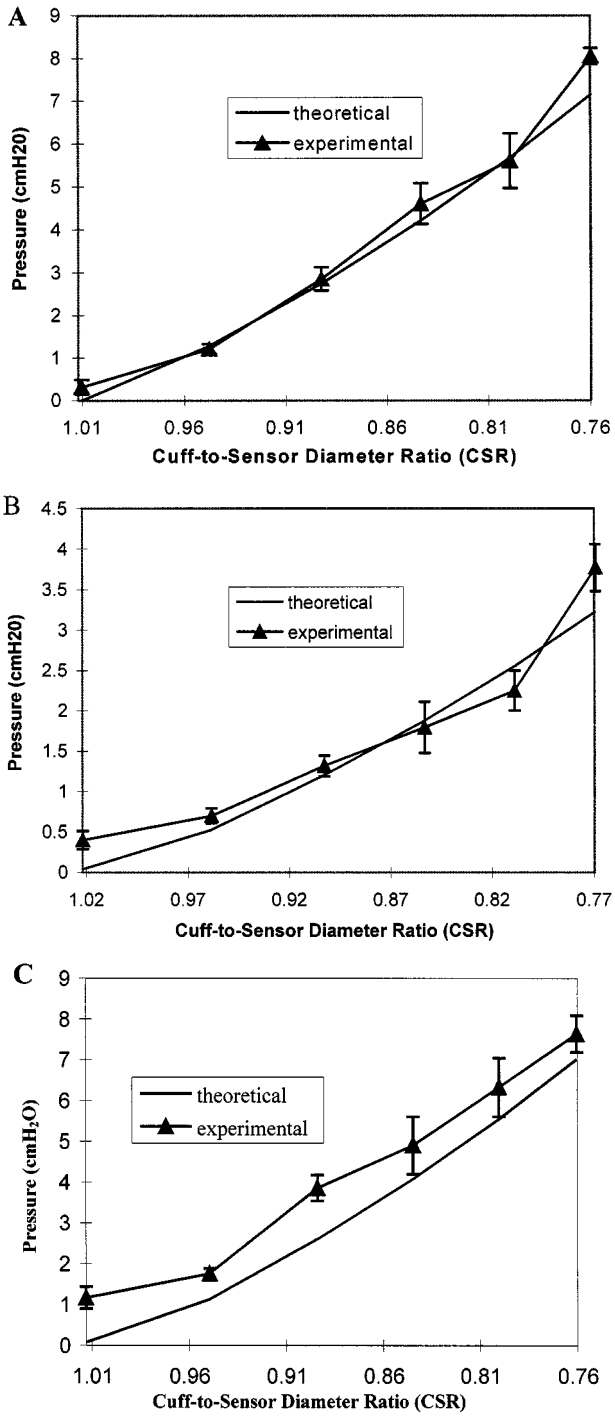

Fig. 4. Theoretical Pressure Calculations and Pressure Measurements for Three Types of NCE's as a Function of CSR $(N = 10)$. (A) Vesta silicone rubber split ring. The range of the standard deviation for the six CSR's is 1.5–8.2% of full-scale pressure. The mean error between theoretical and experimental values for the six CSR's tested is 4.3% of the full-scale pressure range. The maximum pressure measured for this cuff was 8 cm H_2O. (B) Silastic silicone rubber single wrap spiral cuff. The maximum pressure exerted by this cuff was 3.8 cm H_2O. Standard deviation for the six CSR's varied between 2.7% and 9.4% of full-scale pressure. The mean error between theoretical and experimental values for the six CSR's tested is 8.2% of the full-scale pressure range. The maximum pressure exerted by this cuff was 3.8 cm H_2O. (C) Silastic silicone rubber double wrap spiral cuff. Maximum and minimum standard deviation for the six CSR's are 1.9% and 11.1% of full scale pressure, respectively. The mean error between theoretical and experimental values for the six CSR's tested is 12.4% of the full-scale pressure range. The maximum pressure generated by this cuff was 7.6 cm H_2O.

IV. Discussion

The NCE pressure sensors designed in this study allow the first measurement of the pressure generated by nerve cuff electrodes. The sensor calibration results indicate that these sensors have linear and reproducible outputs. Hysteresis and differences between sensitivities before and after cuff application are minimal for the sensors and cuffs examined. Since the compliance of the silicone rubber sensor causes the internal pressure of the system to be lower than the actual external pressure exerted by the cuff, the sensors must be calibrated before and after use. This can be seen in Fig. 3(A), where there is a difference in sensitivity of 20 mV/cm H_2O between transducer and sensor calibration curves.

In order to relate the internal pressure change to the external pressure generated by the cuff, the sensor is calibrated using a known external pressure source (a column of water). This study makes the assumption that the known external pressure source and the cylindrical cuff will exert pressure by similar mechanisms. This assumption is made because cylindrical cuffs and the water both exert pressure uniformly around the cylindrical NCE sensor tubing. Although the pressure exerted by a NCE is theoretically independent of the length of the cuff, the experimentally measured pressure is maximum when the cuff length equals the sensor length, and decreased with shorter length (not shown). This can be explained by the fact that the walls of the sensor tubing which are not in contact with the cuff could be absorbing some of the pressure forces being exerted by the cuff. The assumption that a cylindrical nerve cuff and the water column will exert their external pressures on the NCE sensor in a similar manner seems to be valid if cuff length and sensor tubing length are equal.

The magnitude of the differences between the pressures measured at the CNRs tested and the theoretical models are small, less than 1 cm H_2O in most trials. The experimental pressures measured for the split ring cuff are close to those predicted by theory, with less than 5% error between values measured at the six CSR's considered. The single wrap spiral cuff model predicts accurately the experimental pressures measured, suggesting that the split ring model can approximate the first wrap of a spiral cuff. The double wrap spiral exerts pressures slightly greater than those predicted by theory. For all cuffs with a CSR greater than or equal to one, the external pressure measured is small, but not quite equal to zero as predicted by theory. A possible reason for this is the error made in sensor tubing and cuff diameter and thickness measurements. The tolerances given above correlate to a possible error of $\pm 6\%$, which corresponds to approximately 0.5 cm H_2O. This error could also explain the offset seen in the measurements for the double wrap spiral cuff. Although the double wrap spiral cuff was coated with detergent, the friction between the spiral cuff wraps and the walls of the sensor may have affected the cuff's diameter.

Additional sources of error between experimentally measured pressures and theoretical predictions are possibly false assumptions made in the theoretical models. For example, the models in Naples *et al.* [6] assume very small deflections in cuff diameter, but experimental measurements are made when the cuff is stretched to 133% of its resting size to simulate a snugly fitting cuff installed around a swollen nerve. As mentioned

above, the models do not take into account gravitational and contact forces, such as friction, between cuff and nerve/sensor surfaces and between wraps of the spiral cuff. Coating the NCE's with a soap solution (Liquinox and water) to reduce the coefficient of friction between surfaces minimized these frictional forces. Another possible source if error is that the silicone rubber does not have a constant elastic modulus through the cuffs' strain range, as the model requires. Finally, the models do not account for unavoidable sensor and cuff inhomogeneities including non-uniform wall thickness and varying hardness of silicone rubber used in manufacturing. These factors may explain some of the variance between experimental and theoretical data.

The results of this study imply that the models developed by Naples *et al*. [6] are good approximations for predicting pressures exerted by the NCE's examined. Moreover, the maximal pressure seen for the NCE's at the CSR's tested is 8 cm H_2O, a value significantly below the 27 cm H_2O of pressure required to impede intraneural blood flow. These results suggest that the nerve cuffs tested here would not generate enough pressure to occlude blood flow even if a nerve swells to 133% of its resting diameter, corresponding to a CSR of 0.75 (CSR's less than 0.75 were not measured in this study). This is an important finding because encapsulation and scar tissue that can grow between the nerve and NCE after implantation can cause increases in nerve diameter up to 133% of the nerves pre-implantation diameter [6]. This scar tissue may be less compliant than the cuff electrode and could exert larger pressures on the nerve that may occlude blood flow. Also, it has been suggested that the cause of nerve tissue damage may not be from the pressure exerted by the spiral cuff electrodes directly, but rather from the mechanical disturbance caused by lead wire movement [21].

This study found that the NCE pressure sensor is also sensitive to movements of the cuff around the sensor tubing, and using this technique, it should be possible to evaluate directly the pressure transmitted by lead movement to the cuff. Additionally, the sensor design could be modified to allow for the measurements of pressures generated by noncylindrical cuffs such as the helical spiral [9] and the interfascicular cuff [22].

V. Conclusion

An experimental apparatus was designed to measure the external pressure applied by NCE's. The sensors built have linear and reproducible outputs, in addition to high sensitivity. Measurements of external pressures generated by NCE's are in good agreement with theoretical calculations. These results suggest that the pressure models for the split ring and spiral cuff models are reliable for predicting pressures within the parameter range used in these experiments. Moreover, these measurements imply that the cuffs used in this study at the diameters tested (corresponding to CSR's of 0.75 and greater) would not exert enough pressure to occlude blood flow, which results in axonal degeneration. 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.

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