A NERVE CUFF ELECTRODE FOR CONTROLLED RESHAPING OF NERVE GEOMETRY: MODEL and EXPERIMENTAL RESULTS

Anthony V. Caparso and Dominique M. Durand
Department of Biomedical Engineering, Neural Engineering Center,
Case Western Reserve University, OH, USA
dominiquedurand@case.edu

Abstract

The Flat Interface Nerve Electrode (FINE) can reshape the nerve into an elongated oval and provide selective stimulation. The rate of closure of this electrode is difficult to control. The Slowly Closing – FINE (SC-FINE) has been designed to provide an opening height larger than the size of the nerve to accommodate initial swelling an to close at a controllable rate. The design is created by combining the reshaping properties of the FINE and the controllable degradation of Poly (DL lactic-co-glycolic) acid (PLGA). Bonding 50/50 or 65/35 PLGA to a stretched FINE increased the opening heights (OH) on average from 0.1 mm to 1.66 ± 0.45 and 2.05 ± 0.55 mm respectively. A computer model was generated to guide the design of this electrode. The addition of the PLGA films controls the time course of closure over a period of 16 ± 1 days and 14 to 16 hours for the 50/50 and 65/35 SC-FINEs respectively *in vitro*.

Key Terms: FES, neural, prosthesis, compression, electrode, biodegradable, polymer

1. INTRODUCTION

To improve the selectivity of extraneural nerve electrodes, the Flat Interface Nerve Electrode (FINE) [3] was designed, built and tested. The FINE is designed to reorganize the transverse cross-section of the nerve and its fascicles into ovals by applying a small, non-circumferential force to the nerve. By realigning the fascicles within the electrode, the FINE provides both fascicular [1,2,3] and subfascicular [4] selectivity. The oval shape of the FINE improves the selectivity for stimulation and recording but the FINE's ability to quickly reshape nerve geometry may cause acute compression type injury.

This paper describes this modified FINE called the Slowly Closing Flat Interface Nerve Electrode or SC-FINE, and addresses the following three hypotheses: 1) the original opening height of the FINE can be increased by 1500% of the initial height to accommodate nerve swelling, 2) the time course of closure can be controlled over a longer time period to minimize trauma and 3) a mechanical model can predict the opening height and facilitate the design of the electrode for various applications.

2. METHODS

2.1 DESIGN and MANUFACTURE

The SC-FINE is built by bonding a co-polymer film onto a stretched FINE (fig. 1). The FINE is stretched using a micromanipulator by 25% of its length (~ 2 mm). The PLGA co-polymer is cut to dimension (0.5 cm by 1 cm) and is coated with a very thin layer of silicon primer (CF6-135, Nusil Silicone Technology, Carpinteria, CA). The primer is allowed to hydrolyze in room air for thirty minutes, while a very thin layer of silicone adhesive (MED1-4260, Nusil Silicone Technology, Carpinteria, CA) is applied to the top and bottom of the stretched FINE. The application of the siliconec adhesive is done after the primer is hydrolyzed due to the quick curing time of the adhesives (5 minutes). The PLGA film is then placed onto the FINE while in the stretched position, and a heat gun

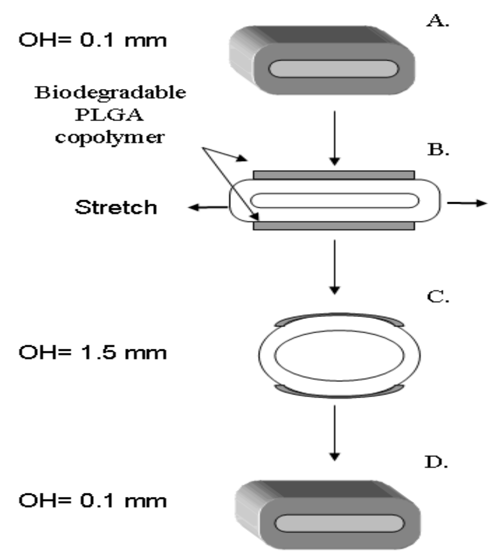


Figure 1: Slowly closing FINE design

is used to seal the polymer to the electrode. Each side is heated for approximately ten seconds, while the air is pushed out from in between the materials. The system is cured for 24 hours before releasing the stretch.

This process is done in a clean hood with all tools and materials first passing through a cleaning procedure. Once the film is made in the press, it is cut to the desired dimensions. The films are ultrasonicated for five minutes to remove any dust or particles.

Each SC-FINE is stored in a moisture free desicater until ready for experimental use. The opening height is measured using a digital microscope camera (Olympus DP-10 Digital Camera, Melville, NY). Three digital images are taken of each electrode, and the new opening heights are determined using Scion Image (Scion Corportation, Frederick, Md), and the values averaged. A statistical power analysis is done to determine the amount of images needed to produce less than five percent error (α = 0.05) in measurements of the opening heights. It was determined that three images are sufficient to reduce the error in the estimate to less than five percent.

2.2 COMPOSITE BEAM MODEL

A composite beam model was developed to determine the relationship between the amount of stretch and the opening height of the composite electrode. The electrode model consists of two identical composite beams, each corresponding to a wall of the FINE and the co-polymer film (fig. 2).

The SC-FINE is modelled to determine the deflection at its center.

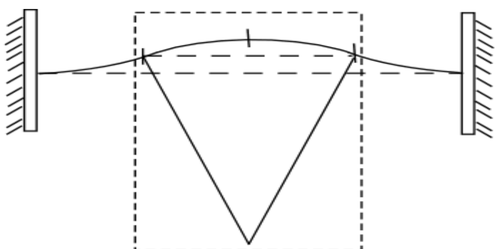


Figure 2. Model of the electrode deflection

since the electrode is symmetrical about the horizontal plane, the opening height can be calculated by determining the deflection of one composite beam and doubling the amount to account for entire electrode. The beam is analyzed using standard composite beam theory to determine the position of the neutral axis. The neutral axis is defined as the plane through the composite beam with zero stress or strain. The length of the neutral axis is equal to the original length of the electrode plus the applied stretch.

The deflection of the electrode is based upon the curvature of the composite beam. The curvature in the beam depends upon the end conditions of the beam. The end conditions are determined to be moment resisting because once each end of the FINE is cut the curvature increases. Given the end conditions, it is determined that the beam takes the shape that is shown in figure 2. The two identical fixed end beams have the same deflection with an inflexion point directly in the center of each beam. The deflection at the inflexion point is exactly half of the overall deflection in each beam. Thus, the overall deflection of the electrode can be determined by analyzing the center portion of the beam.

To determine the deflection in the center portion of the beam, it is assumed that the inner surface of the SC-FINE returns to the original length of the FINE since the Young's modulus of the silicone elastomer is much less than that of the co-polymer. The deflection can be calculated using:

$$Y = \left(R_i \left(1 - \cos\left(\frac{\theta}{2} \right) \right) \right)$$

The overall Opening Height (OH) is given by:

$$OH = 2 \times 2Y + 0.102 \text{ (mm)}$$

The above equation describes the opening height of the electrode given the amount of stretch. The deflection in the center portion, Y, is doubled once to account for the symmetry of the beam, and twice to account for the symmetry of the electrode.

2.3 IN VITRO EXPERIMENTS

Two PLGA co-polymers are investigated to study the effect of film composition on the duration of the reshaping or closure period *in vitro*. The ratio of lactic to glycolic acid in the co-polymer determines the mechanical, chemical and degradation properties of the film. 50/50 and 65/35 lactic to glycolic PLGA co-polymers are used in the *in vitro* experiments.

Both types of SC-FINEs are immersed in a Dulbecco's Phosphate Buffered Saline (DPBS) (Gilbo Inc., Cleveland, OH) bath maintained at 37°C for a period of no less than 20 days and no more than 30 days. The DPBS bath is changed every eight hours for the first two days, every day for the first week, and every week thereafter. Each day the electrodes are removed from the bath and three digital images are taken to study the rate of closure or the rate of reshaping over time. The experiments are terminated once the electrodes reach their final relaxed geometry, or when the hydrolyzed co-polymer starts to delaminate.

3. RESULTS

3.1 SC-FINE OPENING HEIGHTS

The composite beam model provides one analytical relationship between the amount of stretch applied to the electrode and the new opening height. The model predicts an opening height of 1.63 mm when a stretch of two millimeters is applied to the FINE with a thickness of 1.27 mm. This opening height is similar to that obtained from experimental data (average OH = 1.66 ± 0.48 mm, n = 28) (two-sample t-test).

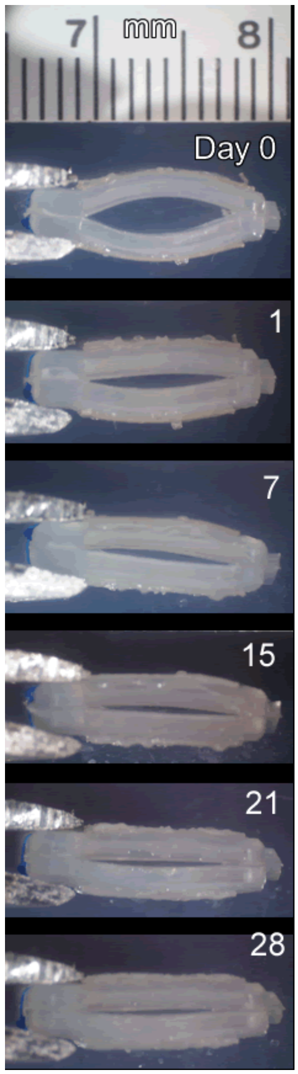
The validity of the model is further tested by predicting the value of the opening height with one millimeter of stretch applied to the FINE. The SC-FINEs produced are made with 50/50 PLGA co-polymer with dimension of 0.5 cm by 0.9 cm by 0.2 mm. The average of 20 SC-FINEs opening heights is 0.81 ± 0.23 mm. The model predicts a value of 0.87 mm, which is not significant from the mean value of the experimental work (two-sample t-test).

Table 1. Comparison of opening heights between the model predictions and the experimental data (mean±SD).

Opening Height	Amount of Stretch	
	1 mm	2 mm
Predicted	0.87	1.63
Measured	0.81 ± 0.23	1.66 ± 0.48

3.2 IN_VITRO EXPERIMENTS

SC-FINEs produced with either 50/50 or 65/35 PLGA films were built to investigate the effect of the biodegradable co-polymer layer on the electrode's new opening height and time course of closure. Forty-four 50/50 and ten 65/35 PLGA SC-FINEs were measured to determine the opening height of the new oval geometry. Figure 6(a) and (b) show histograms of the opening heights of these electrodes. The mean new opening heights of the 50/50 and 65/35 SC-FINEs increased from 0.102 mm to 1.66 ± 0.48 mm and 2.05 ± 0.55 mm respectively. There are statistical differences between these electrodes (Linear Anova, p = 0.015).



Following opening height measurements, the SC-FINE's are immersed in a bath of DPBS at 37°C to investigate their time course of closure. Figure 7 shows a typical example of a 50/50 PLGA electrode with an increased opening height and a controlled closure period over 28 days. Sixteen 50/50 PLGA SC-FINEs were investigated until the closure period was complete. Figure 8(a) is a graph of opening height versus immersion time and shows the average time course of these electrodes over a period of twenty-eight days. These electrodes reached 90% closure in 16 ± 1 days post immersion with a final value of 173 ± 90 µm.

Ten 65/35 SC-FINEs were studied and the time course of closure, shown in figure 8(b), was much quicker than those of the 50/50 PLGA electrodes. These electrodes reached 90% closure in fourteen to sixteen hours post immersion and a final opening height of 150 ± 33 µm. The magnified view of the first day of immersion shows the very fast reshaping period for these electrodes.

4. DISCUSSION AND CONCLUSIONS

A new composite nerve cuff electrode has been designed and tested to increase the opening height and slowly reshape peripheral nerve geometry. The original opening height of the electrode is increased by a minimum of 1600% compared to the final resting opening height by the addition of PLGA co-polymer film to the FINE. The time course of closure is determined by the properties of the biodegradable co-polymer and can be prolonged from 12 hours to a minimum of 16 days using 50/50 SC-FINEs. The degradation rates are similar *in vitro* and *in vivo*.

References

[1] Yoo P. and Durand DM, Selective stimulation of the hypoglossal nerve using a multi-contact cuff electrode, **Annals of Biomedical Engineering**, 32:511-519, 2004

[2] Leventhal D. and Durand DM, Chronic Measurement of the Stimulation Selectivity of the Flat Interface Nerve Electrode, **IEEE Transactions on Biomedical Engineering**, 51(9):1649-58, 2004

[3] Tyler DJ and Durand DM. Functionally Selective Peripheral Nerve electrode: Stimulation with a flat interface nerve electrode **IEEE Transactions on Neural Systems and Rehabilitation**;10(4):294-303, 2002

[4] Leventhal D. and Durand DM, Subfascicular stimulation selectivity with the flat nerve electrode, **Annals of Biomedical Engineering**, 6: 643-652, 2003

Acknowledgements

The authors thank K. Leder for assistance with the animal procedures. This work was supported by NIH-NINDS grant number 2R01 NS32845.