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3D Printed Nerve Conduit

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Introduction

When a nerve is cut, nerve axons regenerate from their base cell and propagate toward the distal site they formerly occupied. Upon encountering a gap, nerve cells are prone to dendritic growth, causing a painful and permanent neuroma. If axon growth is guided, the patient has an improved chance of recovery. Nerve conduits are manufactured devices that bridge gaps in epineural tissue to assist with effective nerve growth.

Problem Statement

The goal of this project is the creation of a customizable leak-proof nerve regeneration conduit that reliably stores and diffuses a volume of drug at a controlled rate, utilizing commonly available additive manufacturing methods. A manufactured device can aid in nerve regeneration following a nerve injury by guiding regrowth into extant nerve architecture.

Materials

PLA vs. PLA/PHA

Bioplastics are materials which are not petroleum based, made instead from renewable biomass sources. These materials are often biocompatible and bioresorbable in the body. PLA is one such material, commonly available as a 3D printing filament. Some surgical aids are currently produced from PLA, designed to be absorbed by the body rather than removed. Polyhydroxyalkanoate (PHA) is another nontoxic bioplastic and is absorbed by the body more quickly than PLA. A 3D printing filament composed of a mixture of PLA and PHA was selected as the subject of research for the design of this project.

Methods

Geometric Testing

Because of the small scale of these nerve conduits, we needed to verify that the prints matched the CAD model. The following geometries were measured:

- Outer Dimensions
- Inner Chamber Dimensions
- Channel Dimensions
- Diffusion Hole

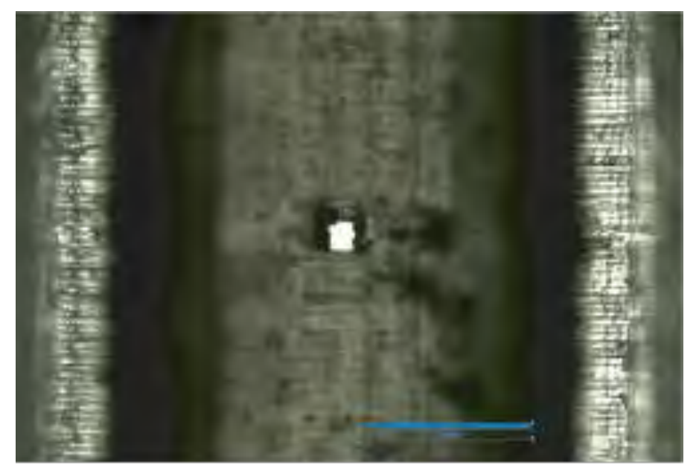

Figure 3 - A magnified picture of the diffusion hole. Microscope was used to measure the size of the diffusion hole. The blue bar represents 1000 micrometers.

Degradation Testing

An important aspect of the nerve conduit is to bio absorb into the body, eliminating the need for post-op procedure after healing. To compare two plastics that have been used in similar medical applications, we conducted a degradation test. The two tested plastics were PLA and PLA/PHA.

- Submersed in PBS to mimic the body
- Elevated temperature to shorten testing time
- 5 samples of each plastic were weighed over thirteen days

Diffusion Testing

Nerve regeneration can be greatly aided with the medication Tacrolimus (FK506). We designed a surrounding chamber that could slowly administer this drug over time through a diffusion hole. To test the diffusion rate, we used Dextran in place of FK506. Dextran has a similar viscosity to FK506 but can be detected by fluorescence.

- Drug chamber filled with Dextran
- Conduit submersed in PBS
- Concentration of Dextran in the PBS solution was tested every day for five days

Electro Spun Scaffold Testing

High voltage electrospinning was conducted using PLA/PHA polymer in solution. Electrospinning produces a porous polymer sheet composed of porous nanofibers, much thinner than is possible with a 3D print. The 6% solution was deposited at a rate of 5mL/min on a metal sheet, drawn by the voltage difference.

Figure 4- Completed conduit with electro spun scaffolding inserted into the channel where nerve growth would take place.

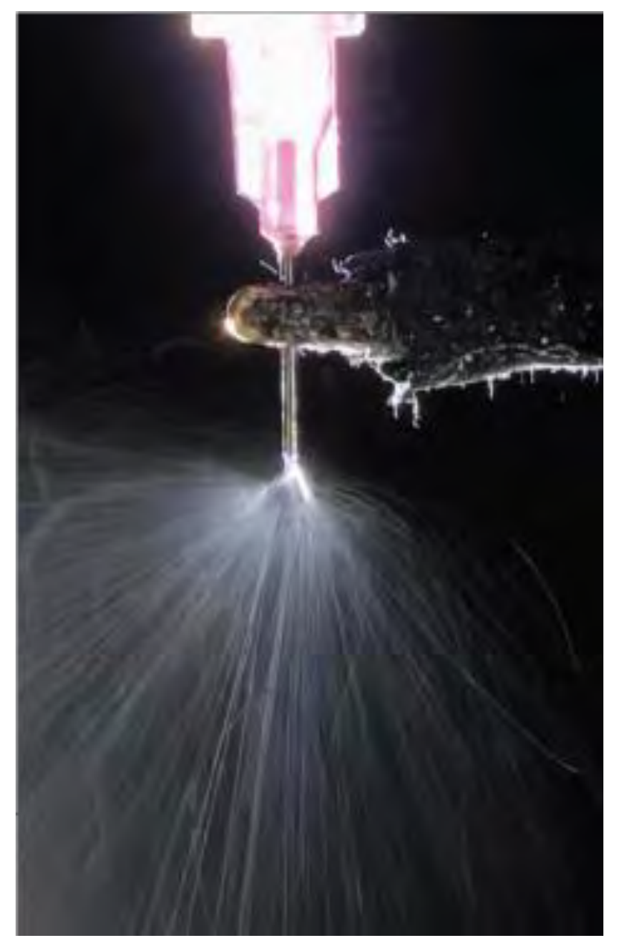

Figure 5 - Negatively charged PHA solution spraying from syringe during electrospinning process.

Figure 1 - Two 3D printed nerve conduits. Left conduit shows a cross-section of the design.

Specification	Target Value	Actual Value
Exterior Print Tolerance	±1 mm	🟩 ±0.8 mm
Diffusion Hole Area	0.038 mm^2 ± 0.019 mm^2	🟩 0.020 mm^2
Half-Life	30 weeks ±15 weeks	🟩 41.4 weeks
Diffusion Rate	12.45 ng/day ± 4.65 ng/day	🟨 19.1 ng/day

🟩 In Spec. 🟨 Out of Spec.

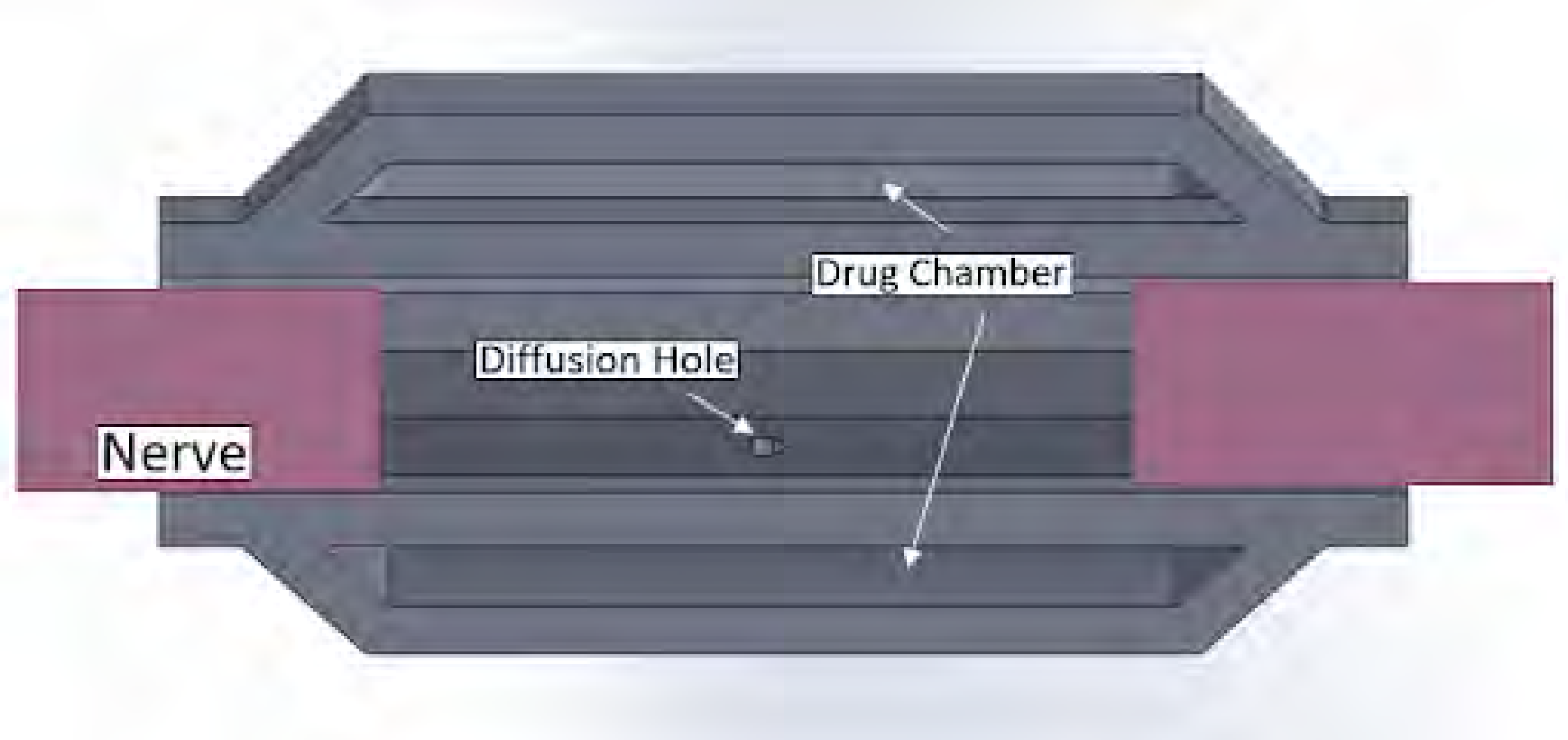

Figure 2 - Application of a conduit aiding nerve regeneration. Once a nerve is severed, surgeons can link the ends of the nerve using a conduit to guide this regeneration.

Results

Geometric Test Results

The average diffusion hole area measured was 0.020 mm^2 and the average exterior print tolerance measured was ±0.8 mm. Given the measured geometry and the expected geometry from the CAD model, the error between the two values was calculated.

- PLA average error of roughly 11%
- PLA/PHA average error of roughly 7%

Establishing that PLA/PHA provides more precisely printed conduits.

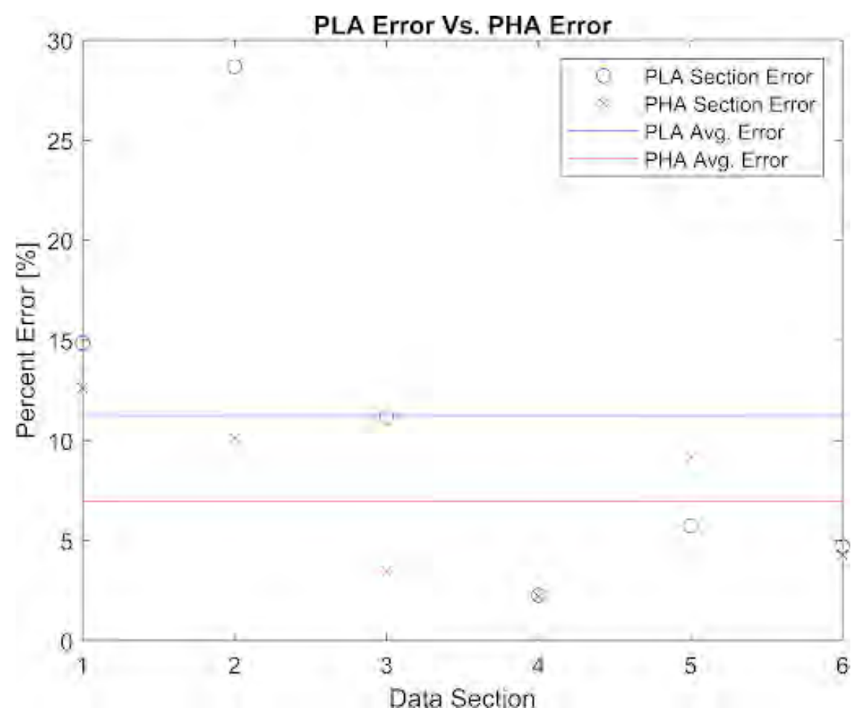

Figure 6 - Error in the area of the diffusion holes.

Degradation Test Results

After collecting the weight loss of each sample over the time period, the half-life was calculated for each PLA and PLA/PHA sample. A target half-life of 30 weeks ± 15 weeks was desired.

- PLA average half-life of 47.25 weeks
- PLA/PHA average half-life of 41.4 weeks

Establishing that PLA/PHA degrades at a slightly faster rate than the standard PLA, meaning it doesn't persist in the body longer than necessary.

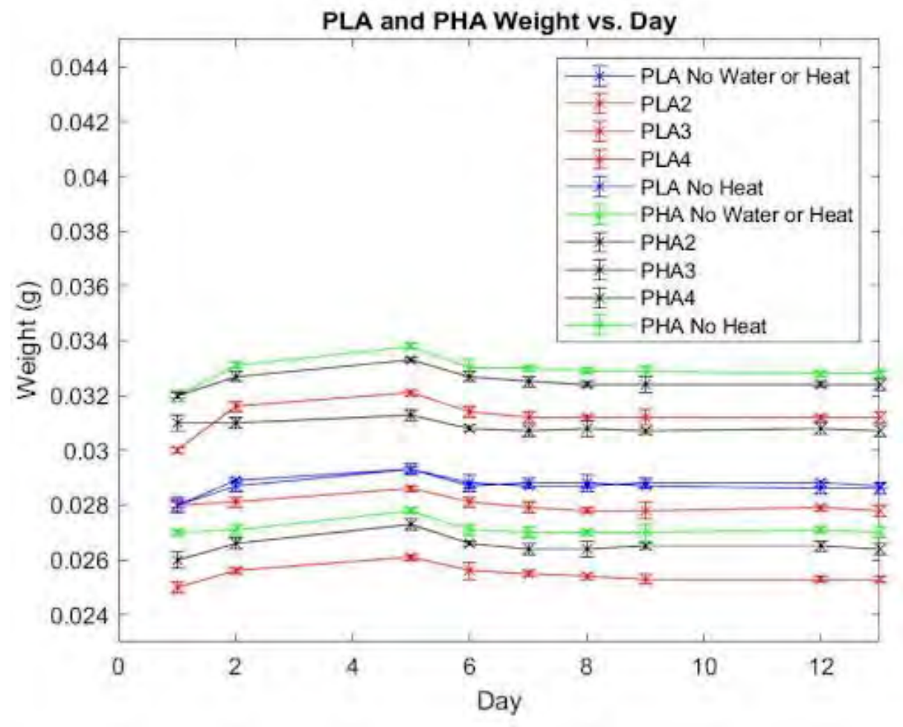

Figure 7 - Degradation rates of PLA and PLA/PHA samples under elevated temperature to validate that PLA/PHA degrades faster than PLA.

Diffusion Test Results

Collected data from the diffusion of Dextran over each day can be visualized in the adjacent plot. The average diffusion rate for each material was then calculated. The target diffusion rate for the conduits was 12.45 ng/day ± 4.65 ng/day.

- PLA average diffusion rate of 16.1 ng/day
  - Average standard deviation of 14.9 ng/day
- PLA/PHA average diffusion rate of 19.1 ng/day
  - Average standard deviation of 12.5 ng/day

Although both materials exceeded the target value, the PLA/PHA prints had better precision due to lower standard deviations within the data. However, from previous research on this subject, it is more desirable to error over the target diffusion rate than under.

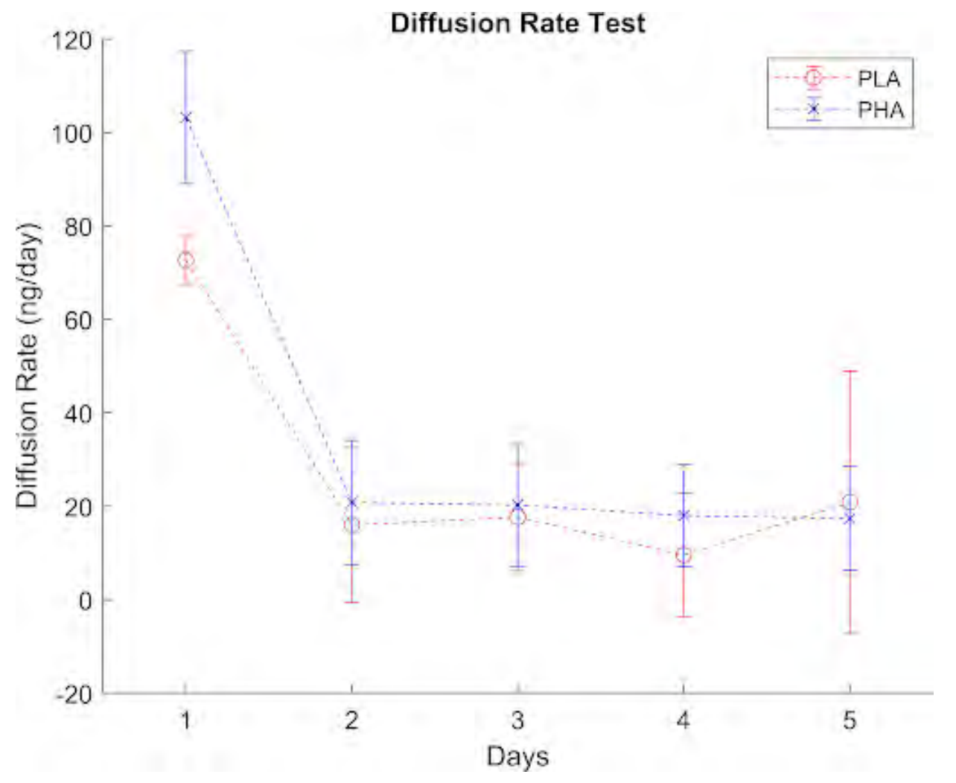

Figure 8 - Average diffusion rates of 10 conduits, 5 of each material. Diffusion test carried out over 5 days.

Electro Spun Scaffolding Results

Electro spun scaffolding proved to be a viable addition to the project, providing a permeable scaffolding that allows medication to reach the regenerative nerve site while providing a structure to guide the nerve. The scaffolding will degrade at a faster rate than the other features of the conduit, ensuring that it will not inhibit the growth of the nerve.

Conclusion

1. Created a functioning 3D printed nerve regenerative conduit with a PLA/PHA filament that included interior features to help nerve growth. Metrics analyzed for the conduit included exterior print features, diffusion hole area, half-life, and diffusion rate.
2. PLA/PHA filament offered advantages against the previously used PLA filament through more precise geometric dimensions, better controlled diffusion rates, faster degradation rates, and creation of electro spun interior structures.
3. The new material provides an improved method of the creation of 3D printed conduits to diffuse a more controlled amount of drug to help the nerve grow, along with providing the nerve with interior features to help promote quicker growth. It also showed trending results of the ability to adjust the material properties to decrease the time for the conduit to linger in the body.

Future work could include more analysis on the impacts of changing the amount of PHA included in the PLA/PHA filament. Along with this, the method of creating the diffusion hole, rather than having it be included in the 3D printing process, should be altered to create a more consistent and desired diffusion rate.