"Assessing the Efficacy of Biodegradable PLA Dural Patches in Surgical Applications"

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Abstract

In this study, we demonstrated the manufacturing of a Dural Patch using a biodegradable polymer PLA Poly Lactic Acid (PLA), for use in neurosurgery. The focus of the study is on the manufacturing process, with particular attention to the compatibility and melting behavior of various components with PLA, as well as the techniques employed to achieve optimal integration. A series of experiments were carried out on the Patch to assess its biocompatibility, and its physical and mechanical qualities, which are crucial for its planned application in a clinical context. These assessments reveal that the PLA Patch has good mechanical qualities and biocompatibility and can be employed in surgery. Also, the present work discusses the Neurosurgical operation following implantation of the Patch in the topical tissues of the brain indicating its usefulness for postoperative problems, for instance, septic and CSF (Cerebro Spinal Fluid) leakage. The possible advantages include rapid patient recovery, and a lesser chance of issues connected to standard Patch biomaterials. Some benefits of adopting PLA-based materials in Dural healing are explored including their higher biodegradability and bio-absorbability compared to current plastic and biological alternatives. The results from the bench-scale study indicate promising performance of PLA Dural Patches. The findings highlight the PLA Dural Patch's robust mechanical properties and excellent biocompatibility, making it promising medical resolutions for neurosurgical applications. Its ability to reduce postoperative complications, coupled with the advantages of biodegradability and bio-absorbability, underscores its potential to improve patient outcomes in clinical solutions.

Introduction

Dural closure plays a crucial role in neurosurgery, as improper sealing of the Dura mater can lead to severe complications such as infections, CSF leaks, and meningitis. Neurosurgeons typically strive for primary closure of the Dura; however, this approach is not always feasible, necessitating alternative materials to address Dural defects [R, T. 2019.], [Wild, V. 1999.]. Historically, biological materials like bovine pericardium have been employed for their ease of suturing and effectiveness in preventing leaks [R, T. 2019], [B. 2024.]. Despite their utility, the advancement of material science has introduced synthetic options that offer distinct advantages [Wild, V. 1999].

Among these, biodegradable polymers PLAs such as Poly Lactic Acid (PLA) have garnered attention in the field of neurosurgery [Wild, V. 1999] [Londoño, O. 2024.]. PLA is a biocompatible polymer PLA derived from renewable resources, known for its ability to decompose into non-toxic by products such as water and carbon dioxide [B. 2024.], [Londoño, O. 2024.]. This characteristic makes it particularly appealing for delicate surgical applications, including Dural repairs. PLA has found its way into various surgical contexts, including cranial and peripheral nerve procedures, due to its favourable integration with biological tissues [K. 2022.], [Londoño, O. 2024.] [Z. 2020.].

This study aims to present a comprehensive methodology for fabricating a PLA-based Dural Patch specifically designed for neurosurgical applications. We will detail the manufacturing process, emphasizing the mechanical properties of the Patch and its compatibility with human tissues. By utilizing PLA, we anticipate a range of clinical benefits, including reduced risk of infection and expedited patient recovery times [H. 2016.], [R. 2015.] [A. 2023.].

In addition to its biodegradability, PLA offers enhanced mechanical properties that are critical for maintaining structural integrity during the healing process [Shukla Dhananjaya et al., 2023]. The use of PLA Patches in Dural repair may significantly mitigate the risks associated with traditional synthetic and biological materials, which can sometimes result in complications such as infection or inflammatory responses. This research will explore the unique properties of PLA, including its strength, flexibility, and conformability, which are vital for optimal performance in the complex environment of neurosurgical procedures [A. 2023.]- [Z. 2021.].

Furthermore, this study will address the implications of using PLA Patches in terms of postoperative outcomes, highlighting their potential to lower infection rates and improve recovery trajectories for patients. By integrating advanced biomaterial technology with surgical practices, we aim to contribute to the evolving landscape of neurosurgery, where patient safety and treatment efficacy are paramount.

In conclusion, the invention of a medical grade PLA-based Dural Patch constitutes a highly significant milestone in the field of cranial surgery and neurosurgery. By focusing on the manufacturing process, mechanical properties, and biocompatibility of this highly novel material, we intend to give insights that will great strengthen clinical procedures and enable safer, more successful surgical treatments. As the demand for improved Dural repair procedures smoothly continues to grow, our research underlines the importance of adopting new materials like PLA to overcome these difficulties [Wild, V. 1999]- [B. 2024.], [19-22]. Additionally, other biodegradable polymers, such as poly(L-lactide-co-D,L-lactide) (PLDA), polycaprolactone (PCL), and their composite formulations, can also be utilized for fabricating similar dural repair patches due to their comparable biodegradability and biocompatibility.

Materials and Method

PLA Biodegradable Material

Polylactic acid (PLA) is a biocompatible and biodegradable polymer widely known for its eco-friendly characteristics. Its ability to degrade naturally under standard room temperature conditions makes it an ideal choice for medical applications, including implants and tissue regeneration scaffolds, where controlled biodegradability and biocompatibility are important. The material is created from renewable resources including sugarcane and maize starch, making it environmentally sustainable. We utilized electro spinning, a standard process that allows for the proper synthesis of Nano Fiber structures from biocompatible polymer Poly Lactic Acid (PLA), enabling the production of super fine and intricate fiber networks ideal for biomedical applications. This method increases the material's utility in applications seeking biomedical, biocompatible and biodegradable qualities.

Poly Lactic Acid (PLA) is a frequently employed biomaterial due to its remarkable biocompatibility and safety within the human body. PLA is both recyclable and bioabsorbable, meaning it may break down naturally without negative consequences. When heated, it melts without producing toxic vapours or decomposing into unsafe chemicals. This feature permits for safe and cheap manufacturing of fine fibers, making PLA a perfect material for constructing medical devices such as sutures and Patches that require both strength and bio-absorbability in clinical settings.

In natural conditions, PLA biodegrades into water (H_2O) and carbon dioxide (CO_2), making it very biodegradable. But, In present work, we may use Chloroform N,N-Dimethylformamide (DMF) at a particular ratio. Here, PLA is used to fabricate Nano Fiber based Dural Patch aimed at stimulating pulp cell development and angiogenesis, necessary for tissue engineering, notably in dental applications. Electrospun PLA Nano Fibers displayed greatly better cell contact, assisting in the development of pulp cells into odontoblasts, essential for tooth regeneration. The electro spinning process developed a biocompatible porous matrix, giving it a suitable support refined structure for tissue engineering applications.

Designing the 3D Model:

The process of designing the 3D model commenced with the initiation of creating a comprehensive 3D model for the Nano-Fibrous Patch using solidworks software. The design considerations encompassed factors such as size, shape, structural integrity, and intricate details, all outlined in Table 1. The primary objective was to guarantee that the design adhered to the specified requirements of the Nano-Fibrous Patch, facilitating precise and accurate representation. The schematic view of 3D Model of nano fibrous Patch material is depicted in the figure. 1 (Nano-fibrous Patch-Tensile Specimen as per ASTM Standards)

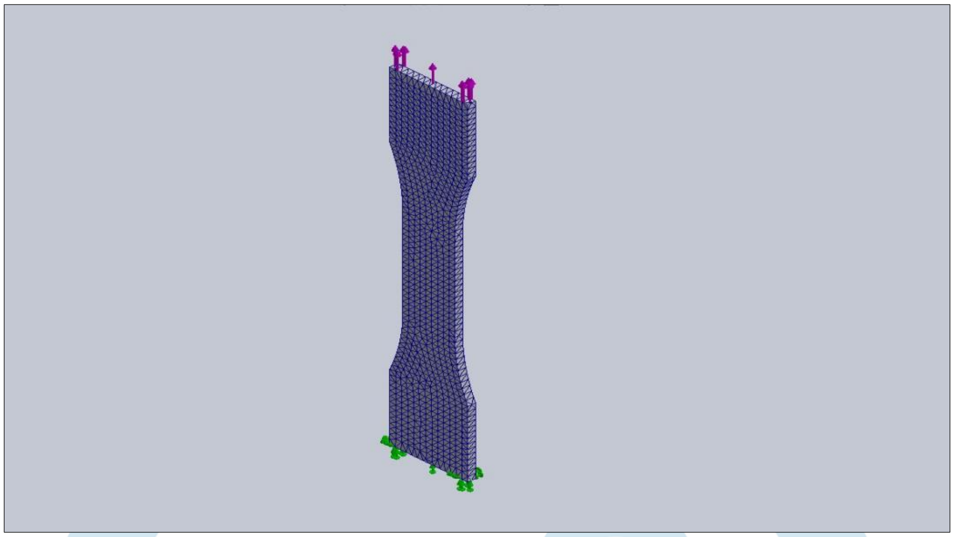


Fig.1. Nano-fibrous Patch with meshing-Tensile Specimen as per ASTM Standards

Table 1: Standard size for tensile testing specimen

Sr No.	Dimensions Type	Measurements (mm)
1.	**Length**	150
2.	**Width**	30
3.	**Thickness**	3
4.	**Edges Curve Angle**	25

PLA Biodegradable Patch

A biodegradable Nano Fibrous Patch was made using a technique called electrospinning. Here, In our work, we used biodegradable, synthetic polymer, PLA (GMP grade, Mw.ca. 1.500.000 g/mol, PURAC, Corbion, Netherland). First, PLA has been dissolved in a solution of chloroform & dimethylformamide (DMF). This provides a proper polymer PLA solution that had just the right viscosity.

The solution was loaded into a syringe and subjected to an electric charge. As the charged PLA solution was introduced with needle, it formed ultra-fine fibers. These fibers were collected on a rotating drum to create the Patch.

The developed Patch utilizes PLA Nano Fibers, exhibiting remarkable properties such as high porosity and significant flexibility. These Patches are specifically designed for Dural surgeries, facilitating tissue regeneration while undergoing safe biodegradation within the body, eliminating the need for additional surgical interventions. Furthermore, they enhance wound healing and support nerve regeneration. The commonly utilized PLA based Dural Patches displays degradation within 1-3 years, decreasing the potential for adverse tissue reactions. The controlled degradation of PLA fibers ensures optimal healing processes, contributes to effective recovery in neurosurgical applications.

Surgical Procedure for Dural Patch Application Using Poly-Lactic Acid (PLA)

The series of Procedures starts with the patient being administered general anesthesia to render them completely unconscious and pain-free during the procedure. The surgeon makes a small incision right next to the Dural tear, which is carefully lined over an optimal surface of this Dura mater. The next step is to expose the Dura mater, after which the surgeon meticulously assesses its size and performs careful debridement in order to properly clean the necrotic tissue or contaminants from it to prepare for application of the Patch.

The Dural Patch is then constructed (formed from Poly-Lactic Acid [PLA] —a biodegradable thermoplastic polymer PLA that has good mechanical properties and gradually degrades into harmless by-products in the human body). The PLA Patch has been designed to perfectly adapt the site of the injury. The PLA Patch is placed, and the remaining layers are secured back in place using techniques of sutures as well as tissue adhesives to seal effectively sealing the area and preventing leakages of CSF.

Once the Patch is positioned cranially, closure of the tissue layers is carried out carefully to re-establish anatomical integrity and minimize the CSF leaking risk. This includes suturing the tissues in layers, from the Dura mater to the subcutaneous layers, and finally closing the skin incision with proper suturing techniques.

In the recovery phase, the patient is monitored closely in the healing room. A lumbar drain may be inserted to control CSF pressure and detect any possible leaks. It is specifically advised that the patient take it easy and refrain from physically demanding all activities during the more easily healing process in order to promote healing and lower the chance of tough medical complications. The biocompatibility, bioactivity, biodegradability, and mechanical properties of PLA make it an especially useful material for the Dural Patch. These properties enable precise closure of the Dural tear and promote the healing process.

Description of Deployment Process through 3D Model Dummy & Prototype:

As mentioned above, the prototype of neurosurgical Patch has been deployed in the simulation model. That model has open brain structure as shown in figures 2(a), & 2(b) illustrate the various stages of how the Patch is used during surgery.

In figure 2(a), The 3D model has been shown which displays the open brain situation of a human. This deployment has been designed to provide an accurate representation of the placement of neurosurgical Patch on the surface of brain.

In figure 2(b), prototype of neurosurgical Patch has been kept with the help of surgical tool on 3D model of open brain, which show exact illustration of neurosurgical Patch on open brain where it may require.

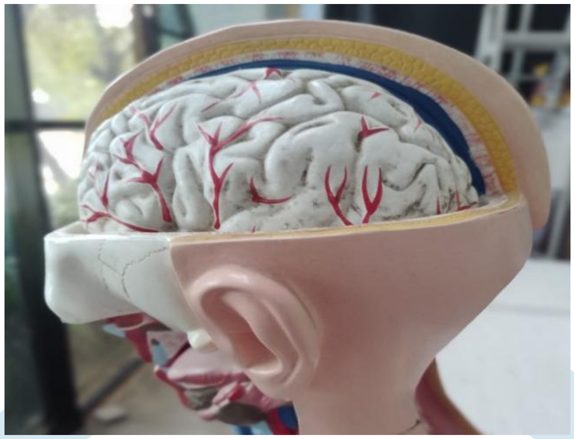


Figure. 2(a). Before Deployment of PLA Patch on 3D Model

Figure.2(b). After Deployment of PLA Patch On 3D Model

Results and Discussion

Mechanical Tensile Testing

The mechanical tensile analysis conducted through Finite Element Analysis (FEA) in Solid works aimed to evaluate the response of the nano fibrous Patch material under tensile forces. The following sections present the outcomes of the digital modeling, simulation, and the subsequent evaluation of the results.

Digital Model Creation:

The initial step involved the construction of a precise 3D digital model of the polymer PLA specimen using SolidWorks CAD tools. This step ensured that the model accurately reflected the geometry and dimensions of the nano fibrous Patch material.

Material Assignment:

The polymer PLA material as granules was selected for the nano fibrous Patch material, with its mechanical characteristics such as elasticity and strength defined the Solid Works material database. This selection was made based on the desired properties for the device's intended application.

Constraints and Loads:

To replicate real-world conditions, constraints and loading conditions were applied to the digital model. The designed prototype's bottom side was fixed, while a Tensile load of 1 N was applied to the top. These conditions were chosen to mimic expected operational scenarios and environmental factors.

Meshing:

The digital model was segmented into finite elements through meshing, using a solid mesh with curvature-based meshing. The mesh had a side length of 1 mm, and Table 2 provides detailed information about the mesh properties.

Table 2: PLA Polymer mechanical properties

S. No.	Mechanical Properties	Experimental Settings
1	Young modulas [MPa]	35.6
2	Poisson's Ratio[v]	0.29
3	Density (g/m^3)	1.24

Table 3: Mesh Properties

S. No.	Properties	Experimental Settings
1	Mesh type	Solid Mesh
2	Mesher Used:	Curvature-based mesh
3	Jacobian points for High quality mesh	16 Points
4	Standard element size	10 mm
5	Mesh Quality	High
6	Total Nodes	14994
7	Total Elements	8645
8	Maximum Aspect Ratio	666.89
9	% of elements with Aspect Ratio < 3	9.81
10	Percentage of elements with Aspect Ratio > 10	42.8%
11	Percentage of distorted elements	0
12	Time to complete mesh(hh;mm;ss):	00:00:37

Simulation Setup:

Solid works simulation tools were used to set up the tensile analysis. Parameters such as solver options, convergence criteria, and contact conditions were configured to ensure a precise and efficient simulation.

Analysis Run:

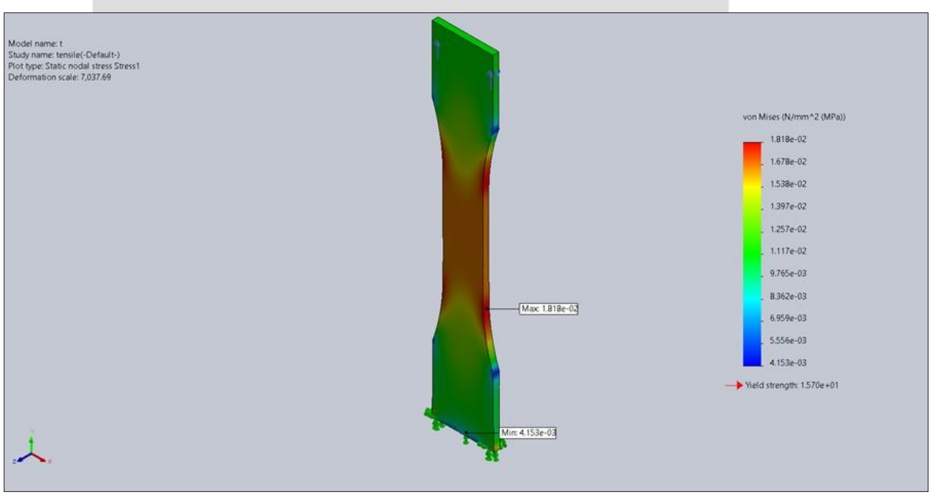
The tensile analysis was executed within SolidWorks, the stress distribution, deformation, and safety factors were calculated throughout the polymer PLA specimen under the applied tensile forces.

Results and Discussion:

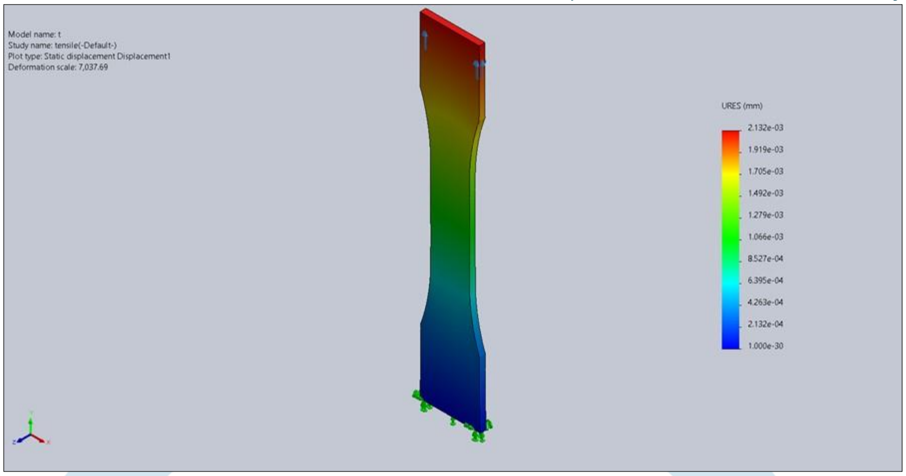
The results of the simulation were analyzed to identify regions of high stress, potential deformation, and safety margins. The computational stress analysis, as summarized in Table 3 and in figure 3(A), (B) & (C) accordingly, focused on the Von Mises stress for tensile.

Table 3 Computational Studies - Mechanical Tensile for Nano Fibrous Patch Composite

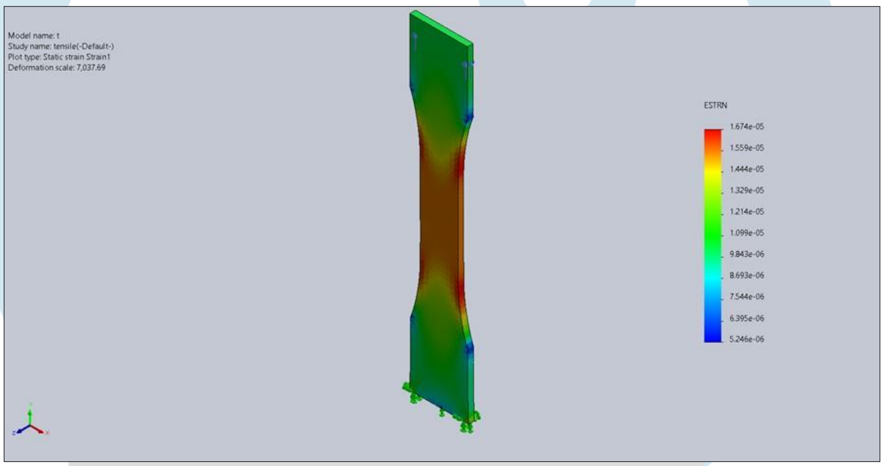
S. No.	**Name**	**Type**	**Min**	**Max**
1.	Tensile Stress	Von Mises Stress	$4.153*10^{-3}$ N/mm^2 (MPa)	$1.818*10^{-2}$ N/mm^2 (MPa)



(A)



(B)



(C)

Figure 3(a), 3(b) and 3(c) Tensile Stress Analysis for Nano Fibrous Patch Materials

Conclusion

In conclusion, the mechanical tensile analysis provided valuable insights into the behavior of the nano fibrous Patch material under realistic conditions. The results and subsequent optimization efforts contribute to the ongoing development and improvement of the device's structural integrity and overall performance. This work shows the great possibilities of Poly-Lactic Acid (PLA) as a material for neurosurgery, especially for Dural Patch fabrication. Poly-Lactic Acid (PLA) offers a hopeful substitute for conventional materials since it is a biocompatible and biodegradable polymer. Its tensile strength and Nano Fibrous construction give improved mechanical qualities, which qualifies for resisting the forces used on Dura repairs. Excellent mechanical stability of a PLA-based Nano Fibrous Patch shown in tensile testing guarantees efficient support during surgery and stimulates tissue integration. Strength of the Poly-Lactic Acid (PLA) Patch combined with tissue adhesives and sutures would produced a water tight seal that was vital in preventing CSF leaks and promoting smooth postoperative recovery. The special substance, which gradually breaks down in the body, eliminates the need for subsequent surgical and medical interventions, improving patient outcomes and reducing the risk of problems such as adverse tissue reactions and infections. Although the initial results are encouraging, more extensive clinical trials are needed to assess the long-term safety and efficacy of PLA in repairing Dural structures. These tests will reveal potential limitations and help to verify the material's suitability for general use in neurosurgical operations. Ultimately, polylactic acid (PLA) Dural Patches lead to faster recovery, fewer problems and a better overall outcome for patients with Dural defect repairs and thus represent a promising strategy in neurosurgery

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