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SUTURE RETENTION STRENGTH OF BILAYER VASCULAR GRAFTS MADE OF PCL, PLA AND THEIR COPOLYMER

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ABSTRACT

The mechanical characteristics of small-diameter vascular grafts, including factors like modulus, elasticity, compliance, burst strength, and suture retention strength, need to be in line with those of native blood vessels. Even a slight mismatch in mechanical properties between the graft and the native vessel can lead to graft failure. Suture retention strength, a critical mechanical aspect, represents the force needed to remove a stitch from the graft or cause the graft wall to rupture. This property is vital for preventing leaks, maintaining proper blood flow, aiding tissue healing, ensuring long-term durability, and reducing complications in vascular grafts. In this study, bilayered vascular grafts are fabricated by electrospinning using polycaprolactone (PCL), poly (lactic acid) (PLA), and poly(l-lactide-co-caprolactone) (PLCL) polymers. The actual suturing conditions of vascular scaffolds are simulated and how the choice of polymer for the inner layer affects suture retention strength is assessed. At the post-mechanical stage, the morphologies of the scaffolds are investigated to gain a clearer understanding of how the material reacts to applied forces. The findings reveal that all the fabricated bilayer vascular scaffolds exhibit excellent suture performance, with strength values exceeding 10 N, and that polymer selection for the inner layer for the grafts significantly influences the results. Blending PCL and PLA in the inner layer is found to reduce suture retention strength, while using neat polymers results in better retention strength. This experiment offers a more precise assessment of suture retention strength for bilayer vascular grafts, facilitating further optimization of tissue-engineered grafts to meet specific mechanical requirements.

KEYWORDS

Suture retention strength; Vascular grafts; Blood vessels; Tissue engineering.

INTRODUCTION

Currently, due to global aging, cardiovascular disease (CVD) causes 17.3 million deaths each year, and this number is projected to rise to over 23.6 million by 2030 [1]. One of the most preferred treatments for cardiovascular diseases is graft bypass surgery using autologous blood vessels, allogenic blood vessels, or artificial blood vessels [2]. At present, various commercial artificial blood vessels made from synthetic materials like Dacron and e-PTFE are widely used for vascular replacement. However, these artificial grafts are nondegradable and often elicit long-term foreign-body responses [3]. In recent years, due to the collaborative efforts of researchers worldwide, tissue engineering vascular grafts (TEVGs) have made significant advancements. Large-diameter artificial blood vessels (greater than 6 mm) have shown considerable therapeutic success in clinical settings. However, it is unfortunate that small-diameter artificial vascular grafts (less than 6 mm), such as those used for inguinal and coronary artery transplants, have not yet achieved satisfactory outcomes [4]. Electrospinning is a well-established technique for creating customized vascular grafts. This process enables the fine-tuning of the mechanical properties of the final product. By using various materials, making micro- and macrostructural modifications, incorporating additives, and altering the electrospinning process, the mechanical properties can be adjusted and optimized [5]. Designing multi-layered electrospun vascular scaffolds is regarded as an effective method to replicate the structure and function of natural blood vessels [6].

Researchers have emphasized that the graft must be resilient and possess mechanical strength comparable to that of native vessels [7]. An ideal TEVG should have properties similar to those of the native artery and integrate seamlessly with it, as any disparity in mechanical properties between the TEVG and adjacent blood vessels can lead to graft rupture

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or blood leakage. TEVGs must withstand distortion and compression, possess adequate tensile and shear strength to endure the forces exerted during suturing and implantation, and maintain circumferential strength to resist hemodynamic pressure. This ensures the prosthesis avoids rupture, scattering, edge wear, seam tearing, and retains structural integrity [8]. The mechanical properties of electrospun fibers are heavily influenced by the raw materials used [1]. Recently, researchers have shown significant interest in synthetic biomaterials like PCL, PLA, and their copolymers to address the mechanical limitations observed in natural biopolymers [9]. Because of its exceptional biocompatibility, moderate degradation rate, and demonstrated tensile strength and elongation capabilities, PCL is highly recommended as a biodegradable polymer for developing vascular grafts. Additionally, PLA is favored in biomedical applications for its excellent mechanical strength and modulus, biocompatibility, rapid biodegradation, lack of toxicity, and composition derived from aliphatic bio-based sources [10].

In clinical applications, the suture retention strength typically determines the reliability of the anastomosis [11]. The suture retention strength assessment measures the force needed to tear a suture from a scaffold or cause rupture of the scaffold wall. It is noted that the human saphenous vein has a suture retention strength of 1.81 ± 0.02 N [12]. Thus, there have been many research attempts to examine the suture retention strength of vascular grafts along with other mechanical features. The study by Kim et al. (2013) focused on fabricating a tubular double-layered scaffold using the PLCL gel spinning method and salt leaching. Suture retention strength tests were conducted on PLCL scaffolds with different thicknesses (ranging from 1 mm to 1.5 mm) and compared to ePTFE grafts. The results showed no significant difference in suture retention strength between the PLCL scaffolds and ePTFE grafts. Suture retention strength values for PLCL scaffolds with varying thicknesses ranged from 5.89 N to 10.28 N [13]. In another study, Meng et al. (2019) investigated the suture retention strength of P(LLA-CL) tissue-engineered vascular grafts. The results demonstrated that P(LLA-CL) tissue-engineered vascular scaffolds exhibited excellent suture performance. The study also emphasized the influence of fiber direction and number of stitches on suture retention strength. Specifically, the highest suture retention strength, ranging between 2 and 2.5 N, was observed when the suture was perpendicular to the fibers (in the circumferential direction) [8].

This study aims to create bilayered vascular grafts through electrospinning with different polymers (PCL, PLA, PLCL), simulate suturing conditions, and evaluate how the choice of inner layer polymer affects suture retention strength. Post-mechanical testing examines scaffold morphologies under stress. Results indicate that all grafts exhibit strong suture performance (>10 N), with significant variation depending on inner layer polymer. Blending PCL and PLA lowers retention strength compared to using neat PCL.

EXPERIMENTAL

Materials

PCL (Mw 80,000), PLA (Mw 230,000), and PLCL are utilized as the polymers. The solvent system includes chloroform (CH), acetic acid (AA), and ethanol (ETH). All polymers and solvents are procured from Sigma Aldrich.

Methods

Bilayer scaffold fabrication

To create bilayer tubular scaffolds with fibers that are either randomly distributed or radially oriented, PCL, PLA, and PLCL polymers are dissolved in a CHL/ETH/AA mixture (with a weight ratio of 8/1/1). The samples codes and blending ratios are provided in Table 1. PCL and PLA solutions are prepared in both pure and blended forms, while PLCL is used in its pure form. The blending ratio is adjusted in 10% increments, ranging from 80% to 100%. The polymer concentration for pure PCL, as well as PCL-PLA blends, is maintained at 8%, whereas PLCL solutions are at 10%. PLCL is utilized for the outer layers of all scaffolds, while the inner layer employs both neat and blended fibrous surfaces to examine their impact on suture retention strength.

A custom-built electrospinning unit, equipped with a vertical feeding direction and a closed chamber from Inovenso, Turkey (Nanospinner, Ne100+), is used to fabricate the tubular scaffolds from PCL, PLA, and PLCL polymers. The neat and blended polymer solutions are delivered using a 10 ml plastic syringe pump at a controlled flow rate of 3 ± 1 ml/h. They are subjected to an electric potential of 11 ± 1 kV over a distance from the needle tip, with an inner diameter of 0.6 mm, to a collector positioned 20 cm away. Tubular vascular grafts are produced using rotating rod collectors with a 5 mm diameter. The rotation speeds applied are 200 rpm for randomly distributed fibers (inner layer) and 10,000 rpm for radially oriented fibers (outer layer). The production time is set at 20 minutes for the inner layer and 55 minutes for the outer layer.

Table 1. Sample codes and blending ratios.

Samples	PCL/PLA blending ratio
PCL_R+PLCL_O	100/0
PCLPLA90_R+PLCL_O	90/10
PCLPLA80_R+PLCL_O	80/20

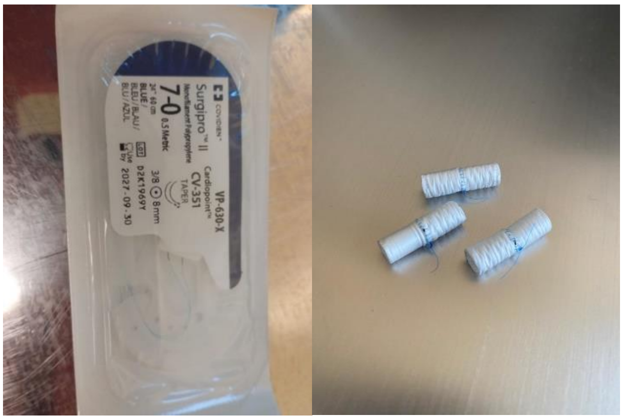

Figure 1. Images of the polypropylene thread used for stitching and the surfaces sewn with continuous stitching.

Table 2. Suture retention strength results of bilayer samples.

Samples	Suture retention strength (N)
PCL_R+PLCL_O	15.81 ± 4.06
PCLPLA90_R+PLCL_O	14.00 ± 3.47
PCLPLA80_R+PLCL_O	11.50 ± 0.63

<u>Scanning Electron Microscope (SEM) Analysis</u>

The morphology of the scaffolds is examined using FEI Quanta FEG 250 SEM after conducting suture retention tests. The samples are coated with a gold-palladium (Au-Pd) alloy in a sputter coating machine (Quorum SC7620) for observation.

<u>Suture retention strength</u>

To test the suture strength of the developed bilayer grafts, the grafts are cut into tubular pieces 1 cm in length, and two graft pieces are joined using continuous stitching, with 7/0 monofilament polypropylene thread applied to a standard vessel during surgery (Figure 1). The strength of the sutures in the scaffolds is evaluated by employing a Zwick-Roell Z005 universal testing machine fitted with a 200N load cell. The tubular segments, after being sewn, undergo testing in longitudinal direction. This examination is conducted at a cross-head speed of 10 mm/min and a gauge distance of 5 mm.

RESULTS AND DISCUSSION

SEM Analysis

SEM images of bilayer samples after suture retention strength can be seen in Fig. 2. When the suture areas are examined, it is seen that although the samples are damaged, they are not completely torn and are only opened from the seam areas.

Suture retention strength

Suture retention strength results are presented in Table 2. Upon examination, it is observed that the suture strength values of all samples fell within the range of approximately 11-16 N. This indicates superior results compared to the human saphenous vein, which typically exhibits suture retention strength between 2-3 N, known as the gold standard [14]. Furthermore, the highest suture retention strength is observed in the sample using neat PCL in the inner layer. In samples where PCL and PLA are blended, a decrease in results is noted with increasing PLA ratio. This decrease can be attributed to reduced mechanical integrity of the grafts, stemming from the immiscibility of PCL and PLA polymers, as well as increased incompatibility between the inner and outer layers due to blending polymers in the inner layer [10]. Phase separation results from the weak adhesion forces between the polymer chains in these scaffolds during the electrospinning process, which prevents the blending from being adequately achieved [15].

CONCLUSIONS

Based on the findings of this study, it is evident that the suture retention strength of bilayered vascular grafts is critically influenced by the choice of polymers used in the inner layer. The experiments demonstrated that grafts utilizing neat PCL in the inner layer exhibited superior suture retention strength compared to those incorporating PCL-PLA blends. The observed decrease in strength with increasing PLA content highlights the challenges posed by polymer immiscibility and phase separation during fabrication. SEM analysis further supported these findings, revealing structural integrity despite damage at suture sites. These insights underscore the importance of careful polymer selection and processing methods in optimizing the mechanical properties of vascular grafts for enhanced durability and clinical efficacy. Future research should focus on refining polymer blending and graft construction to better align with the demanding mechanical requirements of vascular applications.

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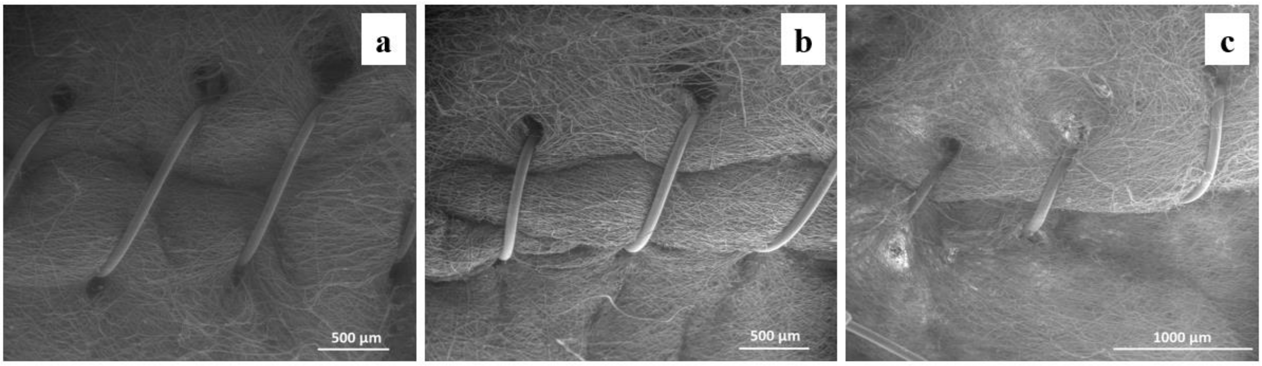

Figure 2. SEM images at 100x magnification of samples (a) PCL_R+PLCL_O, (b) PCLPLA90_R+PLCL_O, and (c) PCLPLA80_R+PLCL_O.

REFERENCES

1. Maleki S., Shamloo A., Kalantarnia F.: Tubular TPU/SF Nanofibers Covered with Chitosan-Based Hydrogels as Small-Diameter Vascular Grafts with Enhanced Mechanical Properties. Sci Rep, 2022, 12 (1). https://doi.org/10.1038/s41598-022-10264-2
2. Li M.X., Wei Q.Q., Mo H.L., et al.: Challenges and Advances in Materials and Fabrication Technologies of Small-Diameter Vascular Grafts. Biomaterials Research. BioMed Central Ltd., 2023. https://doi.org/10.1186/s40824-023-00399-2
3. Jia W., Li M., Weng H., et al.: Design and Comprehensive Assessment of a Biomimetic Tri-Layer Tubular Scaffold via Biodegradable Polymers for Vascular Tissue Engineering Applications. Materials Science and Engineering C, 110, 2020. https://doi.org/10.1016/j.msec.2020.110717
4. Yang L., Li X., Wu Y., et al.: Preparation of Pu/Fibrin Vascular Scaffold with Good Biomechanical Properties and Evaluation of Its Performance in Vitro and in Vivo. Int J Nanomedicine, 15, 2020, pp. 8697–8715. https://doi.org/10.2147/IJN.S274459
5. Stoiber M., Grasl C., Frieberger K., et al.: Impact of the Testing Protocol on the Mechanical Characterization of Small Diameter Electrospun Vascular Grafts: Dynamic Testing of Electrospun Small Diameter Vascular Grafts. J Mech Behav Biomed Mater, 104, 2020. https://doi.org/10.1016/j.jmbbm.2020.103652
6. Do T.M., Yang Y., Deng A.: Porous Bilayer Vascular Grafts Fabricated from Electrospinning of the Recombinant Human Collagen (Rhc) Peptide-Based Blend. Polymers (Basel), 13 (22), 2021. https://doi.org/10.3390/polym13224042
7. Liu D., Han J., Zhuang X., et al.: Evaluation of Mechanical Properties and Biocompatibility of Three-Layer PCL/PLLA Small-Diameter Vascular Graft with Pore Diameter Gradient. Eur Polym J, 186, 2023. https://doi.org/10.1016/j.eurpolymj.2023.111864
8. Meng X., Wang X., Jiang Y., et al.: Suture Retention Strength of P(LLA-CL) Tissue-Engineered Vascular Grafts. RSC Adv, 9 (37), 2019, pp. 21258–21264. https://doi.org/10.1039/c9ra04529e
9. Ozdemir S., Oztemur J., Sezgin H., et al.: Optimization of Electrospun Bilayer Vascular Grafts through Assessment of the Mechanical Properties of Monolayers. ACS Biomater Sci Eng, 2023. https://doi.org/10.1021/acsbiomaterials.3c01161
10. Ozdemir S., Oztemur J., Sezgin H., et al.: Structural Design and Mechanical Analysis of Small-Caliber Bilayer Vascular Prostheses. International Journal of Polymeric Materials and Polymeric Biomaterials, 2024. https://doi.org/10.1080/00914037.2024.2325968
11. Zhang F., Bambharoliya T., Xie Y., et al.: A Hybrid Vascular Graft Harnessing the Superior Mechanical Properties of Synthetic Fibers and the Biological Performance of Collagen Filaments. Materials Science and Engineering C, 118, 2021. https://doi.org/10.1016/j.msec.2020.111418
12. Montini-Ballarin F., Abraham G.A., Caracciolo P.C.: Mechanical Behavior of Polyurethane-Based Small-Diameter Vascular Grafts. In Advances in Polyurethane Biomaterials; Elsevier Inc., 2016, pp 451–477. https://doi.org/10.1016/B978-0-08-100614-6.00015-9
13. Kim S.H., Mun C.H., Jung Y., et al.: Mechanical Properties of Compliant Double Layered Poly(L-Lactide-Co-ε-Caprolactone) Vascular Graft. Macromol Res, 21 (8), 2013, pp. 886–891. https://doi.org/10.1007/s13233-013-1095-5
14. Rodriguez M., Kluge J.A., Smoot D., et al.: Fabricating Mechanically Improved Silk-Based Vascular Grafts by Solution Control of the Gel-Spinning Process. Biomaterials, 230, 2020. https://doi.org/10.1016/j.biomaterials.2019.119567
15. Carvalho J.R.G., Conde G., Antonioli M.L., et al.: Biocompatibility and Biodegradation of Poly(Lactic Acid) (PLA) and an Immiscible PLA/Poly(ε-Caprolactone) (PCL) Blend Compatibilized by Poly(ε-Caprolactone-b-Tetrahydrofuran) Implanted in Horses. Polym J, 52 (6), 2020, pp. 629–643. https://doi.org/10.1038/s41428-020-0308-y