A PRELIMINARY STUDY EXAMINING THE BURST STRENGTH OF VASCULAR TUBULAR SCAFFOLDS

OZTEMUR JANSET*, ÖZDEMIR SUZAN, SEZGIN HANDE AND YALCIN-ENIS IPEK

Istanbul Technical University, Textile Engineering Department, Istanbul, Turkey

ABSTRACT

In this study, neat PCL, neat PLA and PLA/PCL (50/50) based tubular surfaces are produced by electrospinning to simulate the native blood vessel structure and to investigate the effects of both graft material and fiber orientation on burst strength. The burst pressure values of these vascular graft structures that designed with both randomly oriented fibers and oriented fibers, measured by a custom-burst pressure tester, and the results are compared. The results show that fiber orientation have a great influence on burst pressure, regardless of the type of biomaterial. It is determined that grafts with oriented fibers have at least twice the burst strength than those with random fibers. The findings indicate that changing the graft material has also an effect on burst strength. When the results are analyzed by polymer type, although the PLA100_O sample has the highest burst strength among all oriented fiber sample groups, it is better to determine the vascular graft candidate by taking into account radial elasticity.

KEYWORDS

Vascular graft; Fiber orientation; Burst pressure; Mechanical properties; Electrospinning.

* **Corresponding author:** Oztemur J., e-mail: oztemurj@itu.edu.tr

INTRODUCTION

According to data from the World Health Organization, among various chronic and non-chronic diseases, cardiovascular diseases have a mortality rate of 31%, making them the most common cause of death [1]. Although blood vessel replacement is the most popular and recommended treatment for cardiovascular diseases, its usage is constrained due to a shortage of accessible vessel resources, donor site morbidity, vasoplasma problems, dimensional incompatibility, and poor quality [2]. Vascular grafts now assist the development of the native artery by enabling surviving cells to adhere, develop, and proliferate. While materials like polyethylene terephthalate (PET), polytetrafluoroethylene (PTFE), and polyurethane (PU) have been effectively employed in large-diameter grafts in the past, an adequate success rate for small-caliber grafts has not been attained [3]. The use of these materials in small-diameter vascular grafts results in large-scale thrombosis (tendency to produce clots), restenosis (stenosis of the vessel and consequent blood flow limitation), and various infections. They also have properties like insufficient structural porosity, insufficient cell adhesion and proliferation, and low level radial elasticity [4]. For this reason, researchers are looking for novel vascular graft materials that can imitate the injured artery in all of its characteristics.

Due to its exceptional mechanical qualities, including high elongation, slow biodegradation time, biocompatibility, and cell survival, polycaprolactone (PCL) is a particularly desirable material for vascular graft applications [5]. Moreover, another aliphatic polyester, polylactic acid (PLA), is also in demand because of its high strength, biocompatibility, and biodegradability [6].

On the other hand, vascular grafts are successful to the extent that they can mimic native vessels and approximate the artificial tissue to native tissues in all their properties. The designed vascular grafts should match the native vascular structure, which is a very complex structure, in terms of physical, histological, topographic and biological properties as well as mechanical properties [7]. The vascular structure, which is subjected to many loads such as blood pressure and stress cycling, must have burst strength to prevent aneurysmal expansion [8]. The burst pressure values of the saphenous artery and the internal mammary artery can be seen in Table 1 (Table 1).

Table 1. Burst strength values of native human blood vessels.

Type of Blood Vessel	Burst Pressure (mmHg)	Reference
Saphenous vein	1599±877	[9,10]
Internal mammary artery	3196±1264	[9]

Studies on vascular graft designs that include burst strength are regularly reported in the literature. The burst strength values in the study by Gao et al. (2019), in which they developed PCL and poly(lactide-co-glycolide) (PLGA) blend-based vascular grafts, were found to be extremely similar to the human blood vessel strength properties, and the burst resistance was over 1500 mmHg [11]. Yalcin-Enis et al. (2017) designed surfaces with randomly oriented fibers and oriented fibers using PCL and poly(L-lactide) caprolactone (PLC) with various molecular weights, and then they examined the mechanical strength of those surfaces. The study's findings showed that the molecular weight and surface orientation both affected the burst strength of the graft formations [12].

The graft structures developed within the scope of the study aim to examine the effects of the raw materials and the fiber orientation on burst strength, as well as an imitation of the native vessel structure with synthetic materials. In this context, tubular scaffolds are produced from both neat PLA and PCL and blend forms of these materials in 50/50 ratios, and the effects of material and fiber orientation on the burst strength of scaffolds are examined.

EXPERIMENTAL

Materials

PCL (Mn 80,000), PLA (Mn 230,000; Ingeo 2003 D with 4.3 mol% D-lactide content), and the components of solvent systems (chloroform (CHL), ethanol (ETH), and acetic acid (AA)) are supplied from Sigma Aldrich.

Methods

Neat PCL, neat PLA, and PLA/PCL (50/50) are dissolved in CHL/ETH/AA (8/1/1 wt.) at 8% polymer concentrations. Each polymer solution system is stirred for 2 hours at room temperature. Tubular vascular graft structures with 6 mm diameter are fabricated using electrospinning set-up with rotating feeding unit that supplied from Inovenso, Turkey (Nanospinner, Ne100+).

Moreover, graft surfaces are produced at two different rotational speeds; 200 rpm for randomly oriented fibers and 10000 rpm for oriented fibers. Sample codes and descriptions are given in Table 2. For textile fabrics, the burst strength analysis is often applied in a planar form. Due to their constrained size, tubular samples cannot be tested using this implementation. For that reason, the burst pressure properties of the tubular graft structures are measured by custom design burst tester (Inovenso, Turkey, Figure 1) developed within the scope of the study. The following succinctly describes the measuring methodology for the burst pressure in the aforementioned device; the sample is secured to the ends, and pressure from the air inlets is applied to it.The pressure value is then read from the screen and recorded when the sample bursts.

Table 2. Sample codes and descriptions.

Sample Code	PCL ratio (%)	PLA ratio (%)	Production Rotational Speed (rpm)	Fiber Orientation
PCL100_O	100	0	10000	Oriented
PCL100_R	100	0	200	Random
PCLPLA50_O	50	50	10000	Oriented
PCLPLA50_R	50	50	200	Random
PLA100_O	0	100	10000	Oriented
PLA100_R	0	100	200	Random

RESULTS AND DISCUSSION

Burst strength test results are given in the Table 3. As can be clearly seen from the table, the burst resistance of vascular graft samples with fiber orientation is considerably higher than those of samples with randomly distributed fibers. Examining the burst pressure readings of each sample group reveals that the fiber orientation increases the burst pressure value of each sample by two to three times. This situation is also encountered in vascular graft studies in the literature. Tubular grafts were created by McClure et al. (2009) using a variety of biomaterials, including neat PCL, PCL:silk, neat polydioxanone (PDO), and PDO:silk-based, at two distinct rotational speeds, 500 and 8000 rpm. According to the study, grafts produced at high rotational speeds (8000 rpm), independent of the kind of material used, had greater burst pressure value (3095, 2009, 3336, and 1256 mmHg for PCL, PCL:silk, PDO, and PDO:silk, respectively) with better-aligned fibers than grafts with randomly aligned fibers (2202, 1237, 1152 and 834 mmHg for PCL, PCL:silk, PDO, and PDO:silk, respectively) [13]. Grasl et al. (2021), on the other hand, produced thermoplastic polyurethane (PUR) and polylactid acid (PLLA) based vascular graft structures with both circumferential and axial fiber orientation as well as random fibers. In both PUR and PLLA graft samples, it was observed that the burst resistance was better on the surfaces with oriented fibers (894 mmHg for PUR, and 7641 mmHg for PLLA as circumferentially oriented, and 606 mmHg for PUR and 1587 mmHg for PLLA as axially oriented) compared to the surfaces with random fibers (200 mmHg for PUR, and 570 mmHg for PLLA) [14].

The ideal vascular graft should be similar to native arteries to minimize issues related to mismatch, have enough mechanical strength to resist arterial pressures, and pulse-rate blood flow to prevent aneurysms [15]. Moreover, human saphenous vein burst strength is frequently used as a benchmark for the burst strength of other manufactured grafts since it is considered the "gold standard" of vascular grafts [13]. The PCL100_O, PCLPLA50_O, and PLA100_O samples are found to be highly successful in terms of burst resistance and their burst pressure values are found greater than the burst resistance of the human saphenous vein which is 1599 mmHg [9,10].

Table 3. Burst pressure results of vascular graft samples with standard deviations (SD).

Sample	Burst Pressure ± SD (mmHg)
PCL100_O	1449,0±10,6
PCL100_R	730,3±94,45
PCLPLA50_O	2001,0±44,6
PCLPLA50_R	702,5±39,7
PLA100_O	2362,5±109,6
PLA100_R	936,5±10,6

On the other hand, the data also demonstrate how the type of biomaterial affects burst resistance. The PLA100_O and the PLA100_R are found to have the highest burst strengths among the all sample groups with orientated fibers and random fibers, respectively. This is a result of PLA's improved mechanical properties [16]. Although PLA has a great mechanical strength, its stiff structure prevents it from possessing the flexibility that vascular grafts should have [6]. PCL, on the other hand, has a relatively lower burst resistance than PLA. The beneficial effect of the PCL/PLA combination becomes apparent at this point. As can be seen in Table 3, PCLPLA50_O has a sufficient burst resistance at about 2001 mmHg. In addition, it was noticed during testing that this sample (PCLPLA50_O) has a much more flexible structure than PLA100_O.

CONCLUSIONS

The purpose of the study is to produce PCL, PLA, and PCL/PLA-based vascular graft constructions in two different rotational speeds (at 200 and 10000 rpm) to test the burst strength of tubular structures with both orientated fibers and randomly distributed fibers. In order to develop a structure that closely mimics the behavior of the native vessel, it is first determined how fiber orientation and material selection influence burst pressure. When the results are examined, it is seen that oriented fibers are effective in burst resistance and PLA100_O has the highest value with 2362 mmHg. However, in native artery replacement, the elastic structure of the material is of great importance as well as the burst resistance of the material. Since the rigid structure of PLA does not match the characteristic elastic structure of the native artery, PCLPLA50_O sample is thought to be a more suitable substitute among the samples produced considering both properties. Nevertheless, examining the radial elasticity of the material to be used in vascular grafts is important in terms of material selection.

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