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Design of Textile Stents-A Review of Some Significant Developments

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Abstract

The article surveys some recent advances in the development of textile stents. Owing to their merits related to biocompatibility, biodegradability and dispensing with surgical removal, biodegradable polymer stents have gained more focus. poly-L-lactic monofilaments with three different diameters were adopted to produce multi-ply strands and then fabricated into Z-structure stents. The effects of strand parameters on stent radial force were studied. +ecomplication of stent graft-induced new entry (SINE) after thoracic endovascular aortic repair (TEVAR) may be caused by the spring-back force of both ends of the stent grafts. Spring-back force, which is exerted by the curvature and ends of stent grafts on the greater wall of the aorta, suggests poor flexibility. Research on stent graft flexibility via design optimization has been widely disregarded. A large number of patients suffer from vascular diseases, resulting in the need for bypass surgery. Since there are still limitations in the replacement of small diameter vascular grafts, the need and demand for developing more desirable grafts is increasing day by day. In this study, polycaprolactone small-diameter (6 mm) vascular grafts were produced successfully using custom-designed electrospinning apparatus. Radial fiber orientation was achieved by increasing the rotational speed of the collector. The morphological, structural, mechanical, and biological properties were examined. A large number of patients suffer from vascular diseases, resulting in the need for bypass surgery. Since there are still limitations in the replacement of small diameter vascular grafts, the need and demand for developing more desirable grafts is increasing day by day. In this study, polycaprolactone small-diameter (6 mm) vascular grafts were produced successfully using custom-designed electrospinning apparatus. Radial fiber orientation was achieved by increasing the rotational speed of the collector. The morphological, structural, mechanical, and biological properties were examined.

Keywords: Biodegradable, Flexibility; Stents, polymers, Finite element method, Radial force; Structural parameters; Z structure

Introduction

Thoracic endovascular aortic repair (TEVAR) technology for thoracic dissection and aneurysm treatment has developed rapidly since the first successful thoracic stent graft device application [1]. And subsequent short- and midterm clinical results were promising compared with those of open surgery [2]. However, not all long-term outcomes were fully satisfied [3, 4]. thus, further research is needed to reduce incidences of long-term complications. Stent intervention is the most effective method for the treatment of human luminal stenosis by playing a supportive role permanently or temporarily. Metal stentshave been widely used clinically due to their rigidity[5];however, the long-term existence of metal stents in thehuman body may bring complications of inflammation,thrombus and even restenosis. Furthermore, the surgicalremoval of the metal stents is required after thestenosis has healed, since they are non-degradable,causing additional trauma to patients [6]. Recently,increasing attention has been directed toward endoluminalstents using biocompatible and biodegradablepolymer materials in the fields of cardiovascular, esophagouses,bile ductsand so on[7-9]. As a temporary stentfor the treatment of luminal stenosis, these stents couldbe degraded into micro-molecules and be absorbed orexcreted out of the body by the metabolism after supportinglumens over a certain period of time to avoidfurther stimulation to the tissue and prevent restenosis[10]. Biodegradable polymers offer a number of advantagesfor developing stents, including their moderate rigidity,similar chemical composition with human tissue, easyworkability and controllable biodegradation time tomatch the healing period[11]. However, the lower radialforce of biodegradable polymer stents is their mainshortcoming in comparison to the metal stents[12].

Cardiovascular diseases (CVDs) are the number one cause of death globally: more people die annually from CVDs than from any other cause [13]. Conventional therapeutic strategies include angioplasty, endoarterectomy, or bypass grafting [14]. Currently available synthetic grafts work well in the replacement of large diameter (>6 mm), high-flow vessels. However, they fail for small diameters due to acute thrombogenicity of the graft, anastomotic intimal hyperplasia, aneurysm formation, infection, and progression of artherosclerotic disease [15]. Autologous arterial and venous grafts seem to be the best choices for small-diameter bypass grafts, butin many patients their usage is limited for reasons such as vasospasm, limited length, poor quality, and prior use. Considering these requirements with the large number of patients in need of replacement grafts, the demand for an alternative small-diameter graft is enormous and has driven scientists to search for new materials.

Influence of structural parameters on the flexibility of stent grafts

Rigid thoracic stent grafts cannot fully conform with the anatomy of the aortic arch, although they work well for descending thoracic aorta[16]. The complex aorta arch morphology can lead to a mismatch between thoracic aorta and stent grafts, and thus, potential risks of bird beak resulting in endoleak and stent graft collapse may occur [17]. Moreover, the short angulated necks of abdominalaorticaneurysmsdemandhigh-levelstentgraftflexibility, stent graft displacement, and kinking can cause limb occlusions [18-20]. Therefore, stent grafts should be flexible and conformable with the host artery [21-25]. Stent graft-induced new entry (SINE) is a new tear caused by the rigid stent graft itself when ends spring back to the initial form after they are passively bent along the aorta arch [26, 27]. SINE may be proximal or distal. Dong et al. posited that spring-back force could potentially cause SINE, especially in the proximal end[26]. Proximal SINE was observed when the oversizing rate was only 3%, and this could decrease radial force to the maximum extent. Thus, radial force was disassociated with proximal SINE and instead was considered as the main factor of distal SINE. In general, spring-back force is the force exerted by stent grafts acting on the greater curve when placed in a tortuous arterial anatomy, such as aorta arch and popliteal artery. No unified evaluation index estimates the flexibility of stent graft at present. Different evaluation indexes, such as percentage change in diameter, bending force, and spring-back force, were presented in literature[28,29]. Bendingforce is the force to bend a stent graft, whereas spring-back force is the force to recover a straight stent graft after bending. Flexibility evaluation can be done by finite element analysis (FEA) or in vitro experimental studies[30]. Demanget et al. modeled seven commercial aortic stentgrafts by FEA to assess their flexibility and calculate luminal reduction rate. Only a few FEA studies were conducted on the mechanics of stent grafts, although several other FEA studies have focused on stents alone. +e gaps may be attributed to the complexity of the stent graft, which isa combination of a rigid stent and a soft textile tubular graft [31]. Several assumptions were offered to simplify numerical work. However, this could decrease the result accuracy. Qualitative and quantitative in vitro experimental studies were also conducted. Singh and Wang estimated the bending behaviour of segmented and plain knit stents by bent configuration observation immediately and bending moment with the free-bending end of the stents at 90° from the stent axis estimated the percentage change in the diameter at 90°, which represents the flexibility of weft-knitted and braided stents[32]. Hirdes et al. suggestedthat measuring the force exerted by the stent from bending to straightening (i.e., spring-back force in this study) is much more meaningful than the force to bend it (i.e., bending force). Spring-back force was measured by recording the force required to keep the stent at the bending angle of 20° at 20mm from the bending point; however, load cell foot was not placed vertical to the sample[33]. Thus, the force tested was not the real spring-back force [34,35] used a similar method in the vertical orientation to test the spring-back force of stents and stent grafts. However, only the forces under limited curving angles were tested. The structure of stent design determines the behavior of stent graft. Although a number of research have reported the importance of flexibility, majority of these studies only compared the different stent strut types and disregarded the optimal stent design studied the relationship between stent graft design and flexibility by comparing the flexibility of Z- and spiral-stented grafts via FEA[36]. However, the effects of Z- and spiral-stented graft structures on flexibility were unreported. Clinical and animal trails also confirmed the relationship of flexible devices and low incidence of complications after surgery [37, 38]. However, evaluating flexibility as a design parameter of stent grafts was not discussed in detail. Moreover, the structures of stent grafts and their effects on flexibility have not yet been tested via animal trails. Several difficulties are encountered in designing flexible stent grafts. Therefore, a feasibility study on the relationship between the structural parameters and flexibility of stent grafts is necessitated. Results may particularly benefit Z-stented devices, which is currently a common design of several commercial products'. The present study tested bending force and spring-backforce by employing a newly designed device under a continuous curving angle. The force tester foot was placed vertical to the surface of the sample. The two forces (bending and spring-back) served as indicators of stent graft flexibility. Both forces were estimated and compared using stent grafts with different structural characteristics. Consequently, the optimal design factor that may affect the flexibility of stent grafts is established.

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Proximal SINE as a form of TEVAR complication has attracted wide attention. SINE formation can be attributed to stent graft inflexibility. In this study, bending force and spring-back force were estimated to evaluate the flexibility of endovascular stent grafts [39]. The relationship between structural design factors and flexibility was also determined, the results of which may be used for designing new generation stent grafts. Findings showed that long stent spacing, large apex angle, and Z-stented strut configuration are potential structural designs of stent grafts. Results can help engineers design and improve stent graft structures and guide clinicians on the best types of stent grafts. The best stent grafts are those with excellent comprehensive performance, particularly, high levels of flexibility.

Mechanical behaviour of Z structure stents made of PLLA multiply strands

The conventional methods of fabricating metal stents are typically to carve the metal tube by laser engraving or chemical erosion[40]. However, the mechanical property of polymer tubes without drafting cannot be guaranteed and the polymer tubes are easily splintered during the carving process. Therefore, to fabricate polymer stents by a textile process with wire materials isan optimal method to solve these limitations. By braiding monofilaments of biodegradable polymer into a tubular structure, a zig-zag structure stent simulating the metal ones could be easily fabricated[41]. In our previous study, we designed a perforated mold to fabricate Z-structure stents with polymer monofilaments[42]. Poly-L-lactic acid (PLLA) is a relatively inexpensive, biocompatible aliphatic polymer with advantageous mechanical properties, including biodegradability and nontoxicity[43]. It is authorized by the US Food and Drug Administration for clinical application and is widely used in stent fabrication. The high rigidity and long degradation time of PLLA are mainly attributed to its high crystallinity, ensuring sufficient structurally stability and high mechanical properties until the completion of the therapeutic purposes[44,45]. PLLA monofilaments are widely used in the fabrication of vascular stents,esophageal stents and other biodegradable stents[46-48]. However, the brittleness of PLLA, attributed to its high crystallinity, has limited its application for fabricating stents. Stents have poor elastic recovery ability under large deformation, and tend to collapse due to interior fractures of the material[49]. In our previous study, we found that the PLLA monofilament showed brittle failure at the bending point during the stent fabrication process. This crispy problem could be solvedby adopting a multi-ply strand braided by thinner filaments as the stent strand, and stents would have a better recovery rate[50,51]. Meanwhile, the radial force of stents could be enhanced by optimizing the parameters of the PLLA strand.

This study aimed to optimize the processing technique of biodegradable stents with a textile structure to enhance their radial force. PLLA monofilaments with small diameter were firstly braided into multi-ply strands and then fabricated into Z-structure stents. Then the mechanical properties of the filaments, strands and stents were examined to reveal the effect of strand parameters on stent radial force. Samples were subsequently degraded in vitro to examine the change of morphology, thermal characterization and mechanical properties in certain time intervals to evaluate the long-term application effects of these stents.

In this present study, multi-ply strands were adopted to prepare Z-structure stents. The influence of strand parameters on stent radial force were studied, and the degradation behaviour of the filament, strand and stent were observed[52]. The tensile strength of the strand was weakened compared with that of the monofilament, and increased with less twist and more plies. Tensile properties have less influence on the stent radial force. The radial force of the stent was primarily determined by the bending rigidity of its strut. With a thicker monofilament, less twist and more plies, the strand could be produced into a stent with higher radial force. The crystallinity of PLLA had sustained growth during the degradation process, making the materials hard but brittle. So, the radial force of stent tends to increase up to the 40th week and retained 93.21% of its original force at the end of the 48thweek. Overall, by optimizing the strand parameters, the stent radial force could be improved to widen its application in many fields. Meanwhile, these stents had good shape stability and favourable strength resistance during long-term experiments. The present research provides a theoretical foundation for further study of optimizing the radial force and degradation time of stents with a textile structure.

Design of Polycaprolactone Vascular Grafts

The ideal vascular graft has to possess mechanical strength, compliance,biocompatibility, nonthrombogenicity, nontoxicity, nonimmunogenicity, and offthe-shelf availability [53,54]. The issue of small-diameter blood vessel graft remains amajor challenge yet to be overcome in the production of appropriate substitutes.To develop a suitable scaffold for small diameter blood vessel replacement, thenative structure and properties has to be considered. The native artery is an extremelycomplex multilayered tissue composed of a number of different extracellularmatrix (ECM) proteins and cell types. In order to withstand the high flow rate, highpressure, andpulsating nature of blood flow, an artery is comprised of three distinctlayers called the tunica intima, tunica media, and tunica adventitia. Each ofthese layers has a different composition and plays a different physiological role [55].The composition varies in cell types as well as in the morphology of ECM. Theintimal layer of the blood vessels consists of a single layer of endothelial cells (ECs)lining the vessels internal surface [56]. This layer is in contact with the bloodstreamtherefore it provides a critical barrier to platelet activation. The endothelium hasmany functions. It provides the vessel with a dynamic layer of cells which, moreover,displays antithrombotic properties in their resting state. This is achieved byphysically preventing elements in the blood to come into contact with prothromboticelements in the subendothelium and by active synthesis of various mediators[57]. ECs are comprised of a laminin-rich basement membrane which lines underthe endothelial interior surface of the blood vessel. The ECM in the tunica intimaprovides critical support for vascular

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endothelium and it influences ECs migration,invasion, survival, and organization. ECs are attached to ECM by cell-surfaceintegrins. Cell adhesion can be supported by interstitial fibrin and collagen I [58].The tunica media begins in the internal elastic lamina that separates the tunicaintima and the tunica media. The middle layer is composed of smooth musclecells (SMCs) with many functions, including vasoconstriction and dilatation; synthesisof various types of collagen, elastin, and proteoglycans; and elaboration ofgrowth factors and cytokines. The tunica media is organized into concentriclamellar units composed of elastic fibers and SMCs, separated by an interlamellarmatrix containing collagens, proteoglycans, and glycoproteins [59]. Collagen fibersprovide tensile stiffness whereas elastin gives the tube the required elastic properties.

Compressibility of the vessel and the irreversible deformation against pulsatingblood flow are provided by proteoglycans and glycoproteins. The composition ofECM in the tunica media regulates the activity and phenotype of SMCs [60]. In vitro studies confirm the involvement of ECM–SMC signaling in establishingand maintaining the mature tubular structure [12]. Finally, the adventitia extendsbeyond the external elastic lamina and is composed mainly of randomly arrangedcollagen fibers and Ebroblasts[61,62]. This outermost layer is nourished by vasavasorum, thin capillaries providing an important source of nutrition [63]. Whendesigning a multilayer structure for vascular grafts, it is important to mimic thetopographical,morphological, and mechanical properties of each layer as much aspossible [64]. For this purpose, an electrospinning technique was utilized as themain technology. An electrospunnanofibrous structure provides a biomimetic cellularenvironment which resembles the ECM of native blood vessels. Moreover, thehigh surface-to-volume ratio of these structures provides potential anchoringpoints for cell attachment [64]. To achieve the different structures of the abovementionedlayers, various modifications to the electrospinning process wereemployed. The AVfloTM Vascular Access Graft is the first commercial vascularaccess graft to exploit the unique properties of electrospunnanofabrics. Since it ismade of polycarbonate urethane which is a biocompatible synthetic polymer, it hasimproved patency levels. On the other hand, the use of multilayered nanofibrousstructure provides many advantages one of which is easy suturing that offers asolution for hemodialysis patients [65].

The choice of material is another crucial task that has to be considered.Biodegradable materials provide a key advantage. As the material degrades hydrolyticallyover time, cells continuously infiltrate the matrix, producing collagen,elastin, and proteoglycans to replace the degrading material. Eventually, a fullyfunctional artery is created composed of autologous smooth muscle and ECs. Therefore, long degradation time is one of the most important properties for thebiopolymer that provides prolonged mechanical backbone for cells to infiltrate andlow inflammatory response [66].Polycaprolactone (PCL) is a promising candidate for vascular grafts due toits bioactivity for both ECs and SMCs, nontoxicity, and comparatively high elasticbehavior. In addition to that, hydrophobic nature and the high level of crystallinityof PCL scaffolds result in a long degradation time (more than 18 monthsin vivo [67]) which provides a prolonged mechanical support for cell infiltration[68].

There are many studies which call for the usage of electrospun PCL for vasculargrafts. Lee et al. produced scaffolds from the blends of biodegradable polymers(PCL, Poly-L-lactic acid (PLLA), poly (lactic-co-glycolic acid) (PLGA), poly (Llactide-co-caprolactone) (PLCL)) with structural proteins (elastin and collagen).Based on the results it can be said that long-term patencies of the scaffolds consistingof PCL are better in comparison with other scaffolds produced frombiodegradable polymers (PLLA, PLGA, PLCL) [69]. On the other hand, Wise et al.indicates that the mixture of PCL with structural proteins improves the mechanicalstrength [70]. In a study of Gaudio et al., the use of chloroform as a solvent forPCL results in micro-scaled fibers (3.6-0.8 mm) which leads to better SMCs viability,improved interfacial surface between cells and fibers, and promoted cellcolonization in comparison with Nano fibrous web produced by PCL inDMF: tetrahydrofurane (1:1) solvent system [71].Beside in vitro studies, the in vivo implantation of PCL vascular grafts in ratswas successfully realized by [72], with the results of adequate long-term patency levels againstto thrombosis risk[73,74].This study aims to design the best copy of native vessel ECM. We presume thatthe internal morphology of such a graft, mimicking the native ECM, will facilitatecell ingrowth and maintain all its essential functions. In this respect, pore size andfiber orientation become crucial design parameters for vascular grafts. Ju et al.produced two layered scaffolds with differing pore sizes from PCL/collagen solution.Both SMCs and ECs were seeded on the scaffold and results indicate thatdifferent pore sizes can be produced by varying fiber diameters. Moreover, it isstated that the increase in fiber diameter enables improved SMCs diffusion whereasless than 1 mm pore size was found insufficient for SMCs infiltration. On theother hand, Lee et al. defined suitable pore sizes for SMCs infiltration in the rangeof 100-400 mm [29]. Radial fiber orientation is essential for SMCs infiltration whilemimicking tunica media. Hu et al. produced tubular scaffolds from PCLin Dichloromethane (DCM)/Dimethylformamide (DMF) solution by using differingrotational speeds (250, 1000, and 1500 r/min) for 10 cm diameter cylindricalcollector. For radial fiber orientation, minimum 200 m/min peripheral speed wasfound to be required [75]. Edwards et al. similarly studied on radial fiber orientationsfor PCL/diclorethane solution. For 3.2 cm collector diameter, peripheralspeed of collector was varied from 0 to 480 m/min. Results show that fibers arenot exposed to a notable extension force when less than 120 m/min speed was used.150 m/min was defined as an optimum speed for fiber orientation achievementwhereas mechanical fiber deformation was observed at 300 m/min.

In this study, tubular scaffolds were produced using custom-designed electrospinningapparatus with a needle spinning electrode and modified rotating mandreltype collector. PCL in chloroform:

ethanol solvent system with 18% weight ratiowas chosen and predetermined electrospinning production parameters were used inthe light of our previous works [77,78]. Radial fiber orientation was achieved byvarying the rotational speed of the mandrel in order to improve the mechanicalperformance and cell organization. Fiber diameter distribution as well as pore sizearea and porosity analysis was examined to evaluate its suitability for cell proliferationand diffusion through the tunica media. The relationship between the orientationof fibers and cells was confirmed in vitro by seeding 3T3 mouse fibroblasts.

This study aims to constitute a considerable step forward in designing multilayeredvascular graft.This study provides a new perspective for designing small-diameter vascular grafts. Based on the hypothesis of tissue engineering, mimicking cellular environment ofnatural tissue is beneficial for cell infiltration[79]. Therefore, an understanding of thestructure and properties of the target tissue has to be attained. With this in mind,histological and morphological analyses of the native blood vessel were carried out,the results of which provided an insight into designing vascular grafts. Cell organizationsas well as structural proteins were observed to enlighten our design parametersfor vascular grafts. Tubular scaffolds used as vascular grafts wereproduced under optimized conditions by a custom-designed electrospinning apparatus.

Fiber orientation was obtained by increasing the rotational speed of the collectorand besides mechanical performance structural properties mainly, fiberorientation, pore sizes, and porosity were investigated in order to test its adequaciesfor cell attachment and cell diffusion ability[80]. Biocompatibility of PCL was foundsufficient by MTT test using 3T3 fibroblasts, while morphological analysis ofseeded samples under fluorescence microscope and SEM confirms that cells arealigned along the fibers. Although many design parameters were successfully examinedin this study, future attempts should mainly be directed at: (i) design of a multilayer scaffold to mimic native vessel, (ii) improving the radial elasticity, and (iii) seeding the graft with specialized cell types using dynamic cultivation.

Conclusion

Research on stent graft flexibility via design optimization has been widely disregarded. +us, this study investigates the relationship between stent graft structure and flexibility by measuring bending and spring-back forces. Stent spacing (5, 10, and 15 mm), apex angle (30° and 45°), and strut configuration (Z- and M-stented) were considered for the structural parameters. +e overall tendency of spring-back and bending forces was similar. The stent graft with15mm spacing attained the lowest force level. The force difference between samples with 30° and 45° apex angles becameprominent as the curving angle increased. +e sample with 45° stent apex attained low force value. The Z-stented graft obtaineda lower force than the M-stented graft with the same number of struts per hoop. Consequently, optimal flexibility was obtainedwhen the structural design was characterized by long stent spacing, big stent apex angle, and Z-type strut configuration. Radial fiber orientation was achieved by increasing the rotational speed of the collector. The morphological, structural, mechanical, and biological properties were examined. The results show that oriented scaffolds with 2 mm average fiber diameter provide 1 MPa ultimate tensile strength in the radial direction. The pore size area was found to be adequate in the oriented samples required for cell proliferation and diffusion through the tunica media. In vitro biocompatibility of the grafts was proven with 3T3 mouse fibroblasts. After cell seeding, the oriented fibers serve as a cue for radial cell alignment. An understanding of electrospun material parameters together with knowledge of native blood vessel structures and properties is a considerable part in designing small-diameter vascular grafts. The effects of strand parameters on stent radial force were studied. The monofilament, strand and stents were subsequently degraded in vitro for 48 weeks. The thermal properties, morphology change, mass retention and strength retention of samples were recorded to forecast the long-term application effects of the stents. The results of this research provided theory to optimize the processing technique of stents with a textile structure to acquire higher radial force.

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