

Structural Design and Fabrication of Silk/Polyester-Based Bifurcated Stent-Graft [★]

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Abstract

The present paper describes the structural design and fabrication of silk fibroin (SF)/polyester (PET)-based bifurcated stent-graft (BSG) using orthogonal experimental design (OED) and range analysis (RA). An orthogonal design comprising of three factors was used, including basic weave, warp \times weft density and warp \times weft materials, each factor contains three different levels. As a result, nine kinds of BSGs with different weaves, densities and materials were prepared using a modified rigid rapier weaving loom. Water permeability and wall thickness were evaluated according to standard protocols (ISO 7198: 2016). Furthermore, weaving process was optimized and RA was used to detect how performance was affected by factors. The results showed that the thickness of almost all samples is near or less than 0.1 mm, which is required for BSG used in endovascular graft exclusion. Whereas, the water permeability is with a large variation compared to thickness, because BSGs made of pure SF possess significant lower water permeability than that made of pure PET or SF-PET mixed. The water permeability of sample g is only 5.19 ml/(cm² \times min), which can prevent blood leakage after transplantation according to the standard. In conclusion, the SF-based BSG has better performance in terms of water permeability, which is more suitable as BSG used in endovascular exclusion.

Keywords: Bifurcated Stent-graft; Silk; Woven; Wall Thickness; Water Permeability; Orthogonal Experimental Design

1 Introduction

Endovascular graft exclusion has appeared for arteriosclerosis, thromboembolism, intracranial aneurysm and other artery expansion diseases. It has the advantages of micro trauma, less

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bleeding, faster recovery and less complication compared with traditional remedy [1, 2]. Diagrams of endovascular graft exclusion and traditional remedy were shown in Fig. 1. It can be seen from Fig. 1(A) that lesions' vascular tissue would be segregated by bifurcated stent-graft (BSG) rather than being excised. In fact, a small mouth would be opened at the patients' arteries of the limbs, and then BSG would be guided into the lesion area with a catheter [3]. BSG expands through a balloon assisted technique to get back into shape, so as to isolate lesion blood vessel, ensuring the pathway. By contrast, lesions' vascular tissue would be replaced by artificial vascular prosthesis from surgical operation (Fig. 1(B)). As a consequence, traditional remedy is with lager injury, which is not suitable for the weak and the elder patients. Endovascular prosthesis is made up of metal stent and stent-graft. Metal stent is usually made of titanium, stainless steel and nickel alloy. The stent-graft in commercial field used to be prepared through sewing a flat woven fabric into a tube, which is not satisfactory because it may lead to exudation in the stitched line and branched part after transplanting. Structural design and preparation of BSG is different from ordinary artificial blood vessels, higher performance is required. It should not only meet the general performance of the artificial blood vessels such as biocompatibility and long-term stability, but also should have good permeability resistance under the condition of thinner tube wall. Based on previous studies [4, 5], the water permeability should be lower than $300 \text{ ml}/(\text{cm}^2 \times \text{min})$ and the wall thickness should be less than 0.1 mm , otherwise, exudation would happen after transplantation or guiding is hard during surgery procedures. However, there are internal conflicts between thinner thickness and higher anti-permeability. It is not easy to balance

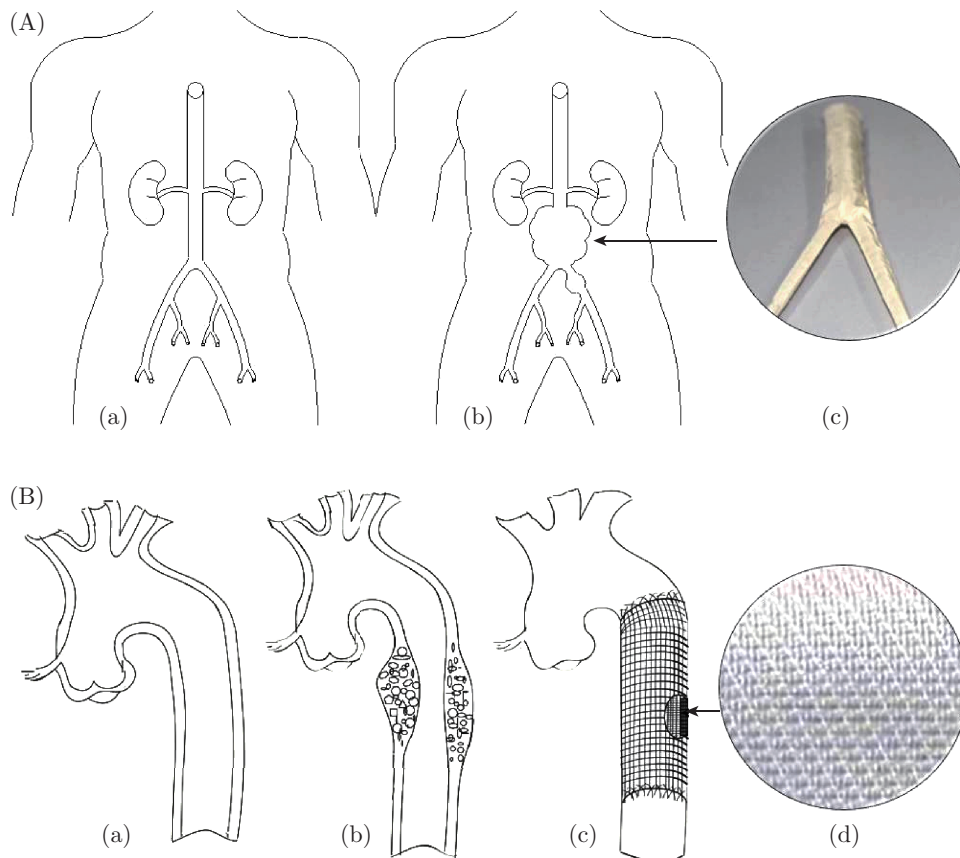


Fig. 1: Schematic diagram of endovascular stent (A) and replacement artificial vascular prosthesis (B): (a) normal blood vessel, (b) abnormal vessel, (c) and (d) artificial blood vessels prototyped in our team