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Combining material and structural elasticity – An approach to enhanced compliance of small-calibre vascular grafts

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Abstract. Up to date, commercially available vascular grafts for the replacement of diseased small calibre artery segments ($d \leq 6$ mm) show low patency rates. One of the commonly named causes in literature is a low radial elasticity of the vascular graft, compared to that of the native vessel. At the Institut für Textiltechnik of RWTH Aachen University, a new approach combining elastic and non-elastic yarns in the warp knitting process is used for the production of vascular grafts. This unique combination of material- and structural elasticity is used to better model the compliance of native vessels and thus increase the patency rates of synthetic vascular grafts. The first section in your paper

1. Introduction

Cardiovascular diseases are the most common cause of death in developed countries as Germany [1]. Today, several synthetic vascular grafts are commercially available for the treatment of diseased arteries. All available grafts with a diameter of less than or equal to 6 mm show low long term patency rates [2]. The compliance mismatch between the vascular graft and the native vessel is regarded to be a major cause of this issue (Fig. 1) [3].

The compliance describes the ability of a vessel to expand in radial direction when inner pressure is applied. A low compliance of the vascular graft may cause an exceeding tissue growth within the lumen of the prosthesis (neointimal hyperplasia). This can lead to narrowing or even full occlusion of the graft related then with repeated surgery [5]. Psychological stress for the patient as well as considerable health economic costs are the consequences. At the same time, the demand for vascular grafts steadily increases due to demographic change and unhealthy lifestyle especially within the western countries. Consequently, from 2005 till 2011 a constant growth of 3.8 % per year was registered in the European market for vascular grafts [6]. This shows the clear clinical need for an innovative small calibre vascular graft with a significantly higher functionality than today's clinical standard.



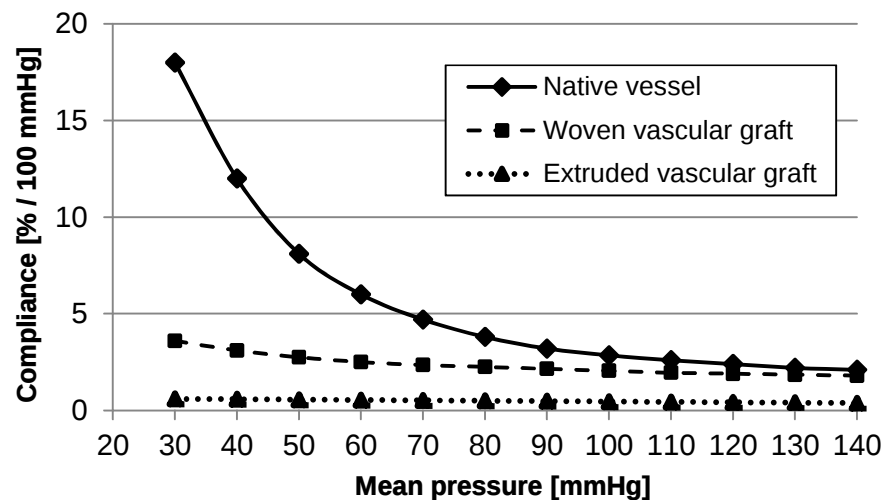


Figure 1. Comparison of the compliance of native vessels and synthetic vascular grafts [4]

2. Research objective and approach

The mechanical properties of native blood vessels are decisively determined by their structure of elastin and collagen fibres [7,8]. During the contraction phase of the heart, the so called systole, the pressure in the vascular system increases leading to strain in the arterial walls. The elastin fibres in the vascular wall bear the load within this pressure range. Due to its higher initial length and a winded structure the collagen fibres are not elongated yet and do not significantly contribute to the mechanical properties of the vascular wall in this phase. At higher pressures the substantially stiffer collagen fibres are fully stretched and protect the vascular wall from overloading. During the ventricular filling of the heart, the diastole, the stretched fibres contract to their initial state. In consequence of these differing functionalities of the vessel's components, arterial walls show a characteristic stress-strain curve (Fig. 2, left) [9].

Especially in the lower pressure range (20 – 80 mmHg) currently available vascular grafts have a significantly lower compliance and do not cope with the characteristic stress-strain behaviour of native vessels. This resulting compliance mismatch causes an exceeding tissue growth (neointimal hyperplasia) in the lumen of the synthetic vascular graft which leads to the reported constriction or even an obstruction of the lumen.

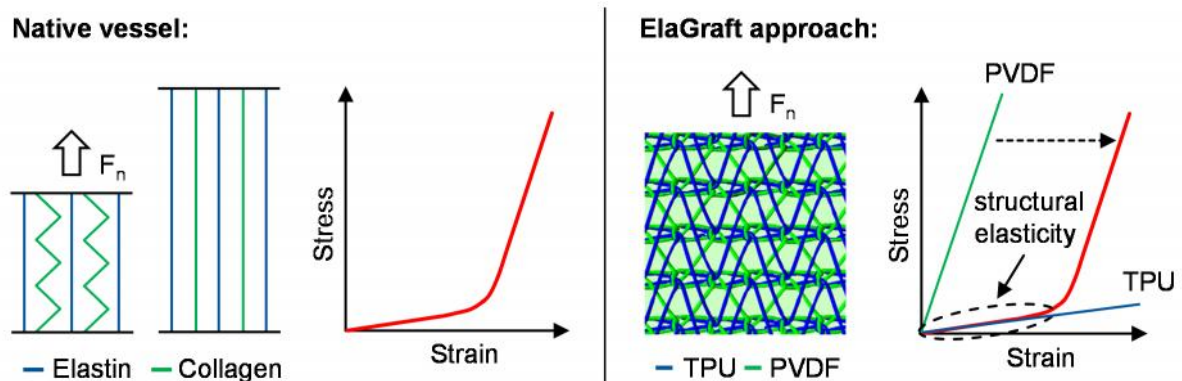


Figure 2. Simplified representation of the mechanical structure of native vessels (left) and transfer of these physiological characteristics into a vascular graft combining material (TPU) and structural (warp knit) elasticity (right)

At the Institut für Textiltechnik of RWTH Aachen University (ITA), a new approach incorporating both effects of material and structural elasticity in a vascular graft (ElaGraft) is proposed to model the stress-strain behaviour of native vessels. For this purpose, elastic and non-elastic yarns are combined in the tubular fabric by use of warp knitting technology (Fig. 2, right).

In a first step, melt spun thermoplastic polyurethane (TPU) multi-filament fibres are developed. Due to its elastic properties combined with high hydrolytic and oxidative stability, a medical grade polycarbonate urethane (PCU) is chosen for this purpose. The elastic TPU fibres are combined with non-elastic PVDF fibres in a warp knitted tubular fabric. The desired mechanical properties of the textile vascular graft are achieved by systematic variation and interaction of the melt spinning parameters and warp knitting parameters.

Tubular structures are manufactured on two double-face Raschel machines (DR 16 EEC/EAC and DJ 6/2 EL, Karl Mayer Textilmaschinenfabrik GmbH, Obertshausen, Germany) with gauges of 30 and 32 needles per inch. The processed materials are thermoplastic polyurethane (TPU) for the elastic yarn and polyvinylidene fluoride (PVDF) for the non-elastic yarn. The counter-lapping 1x1 lap - 2x1 lap (locknit) has proven in the past to be suitable for elastic fabrics. This lapping combination is further found in today's synthetic vascular grafts and is therefore selected for the present project. The density of the knitted fabric is tailorable by varying the stitch course density.

In order to ensure a stable process the elastic yarn has to be fed into the warp knitting machine at a constant thread tension. Therefore yarn feeders, enabling a tension-controlled feed in of every TPU-yarn, were installed at the warp knitting machine. The yarn is fed directly into the knitting area without further deflection to avoid variations in tension.

The compliance of the produced synthetic grafts is experimentally determined and compared to native vessels at physiological pressure. An enhancement of the compliance up to the characteristics of native vessels is aimed.

3. Results

In a first step, plain fabrics were produced to evaluate the process settings and their effect on the fabric's mechanical properties. The stress-strain behaviour of the fabrics was determined in a tensile test setup according to ISO 13934-1. By this means, the main influencing process parameters on the elastic properties of the fabric were determined. On the part of the melt spinning process, these parameters are the wheel speed or take-up velocity and the draw ratio. On the side of the warp knitting process the main effecting parameters are the stitch course density and the thread tension of the TPU yarn.

Based on these results, tubular fabrics were produced by systematic variation of the influencing parameters. For this purpose, fractional and full factorial experiments based on the design of experiments method were performed to evaluate the resulting effects on the elastic properties of the vascular grafts. The stress-strain behaviour was determined in a tensile test setup according to ISO 13934-1 and converted into the radial compliance at a pressure of 30 mmHg. The results show negative effects of the draw ratio and stitch course density (Fig. 3). These two effects are statistically significant with a 95 % confidence level. The effects of the wheel speed and thread tension of the TPU yarn are not statistically significant and greyed in Fig. 3.

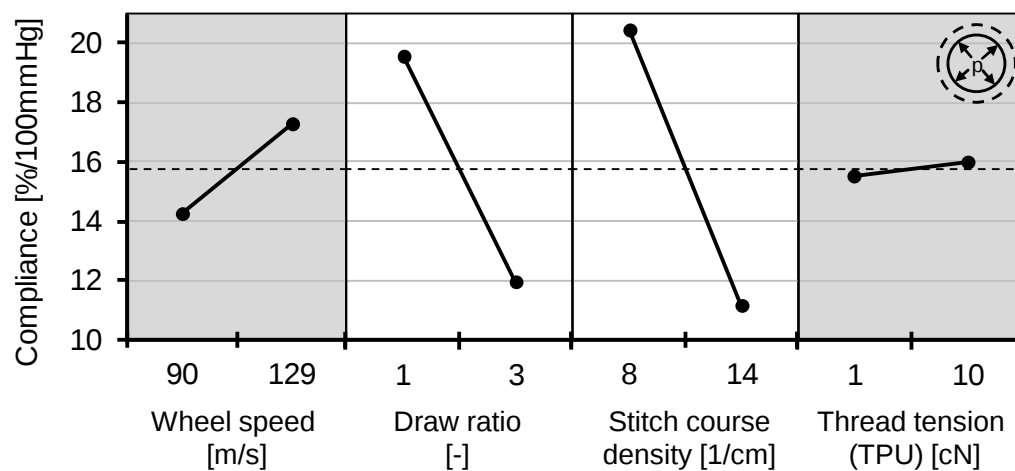


Figure 3. Main effect diagram for the target value "Compliance" at 30 mmHg

Due to the fact that a number of assumptions must be made to convert the stress-strain behaviour into the compliance, the calculated values do not fully match the actual compliance values. Thus the compliance of a vascular graft with low draw ratio yarn and low stitch course density was measured with a purpose-built setup according to ISO 7198. First results proved an enhancement of the actual radial compliance compared to current synthetic vascular grafts and native vessels (Fig. 4).

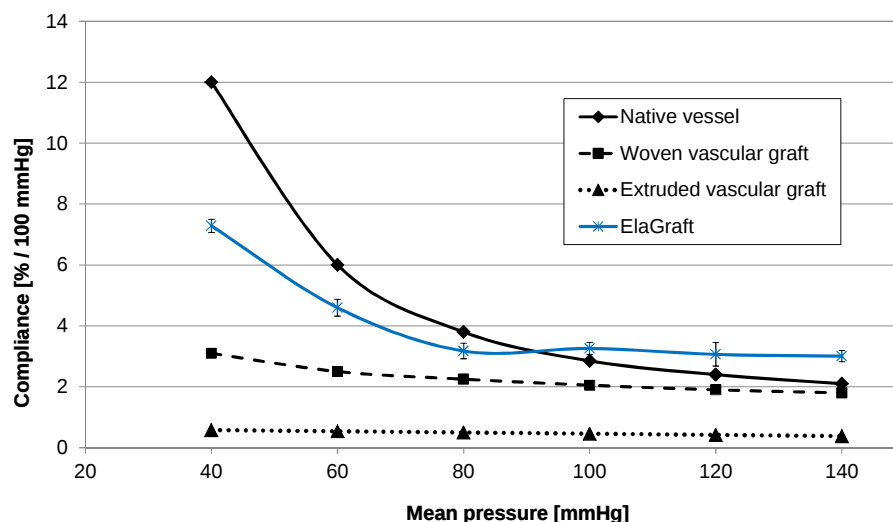


Figure 4. Comparison of the compliance of native vessels, synthetic vascular grafts and the ElaGraft approach [4]

4. Conclusion

By incorporating material- and structural elasticity into a textile vascular graft, its mechanical properties can be specifically adjusted. By using warp knitting technology, the functional principle of the native vessel using elastin and collagen fibres can be transferred to a synthetic vascular graft by processing elastic (TPU) and non-elastic yarns (PVDF) and selecting the influencing manufacturing parameters. By this means, a significant improvement of the graft's compliance compared to all synthetic small-calibre vascular grafts in use is intended, following the major objective of increasing

small calibre vascular grafts' long term patency rates. This will result in offering a suitable alternative to nowadays commercially available grafts.

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