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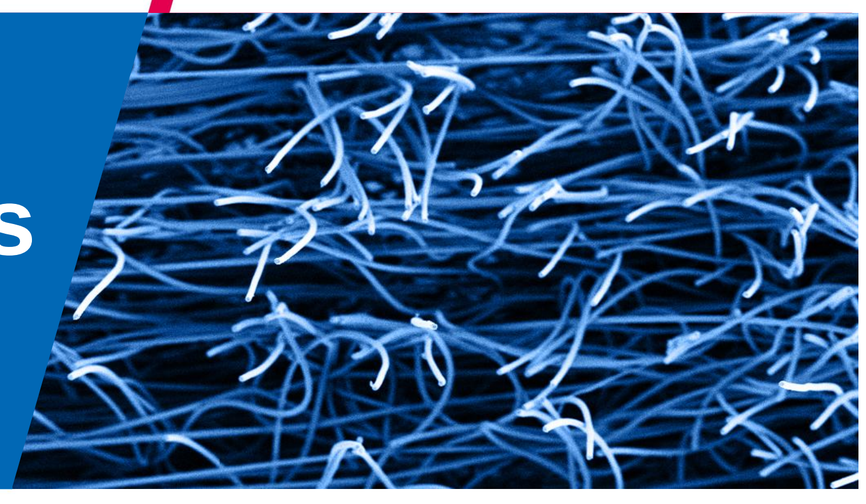
Hemodynamic testing of a 3D electrospun heart valve prosthesis

M. Simonet[1,2] , M. A. J. Cox[2] , C.W.J. Oomens[1], A. Driessen-Mol[1], F.P.T. Baaijens[1]
[1]Department of Biomedical Engineering, TU/e Eindhoven
[2]QTIS/e, Eindhoven



Introduction

The feasibility to use electrospun scaffolds as a valvular prosthesis has been tested previously by subjecting a thermoformed valve scaffold to pulmonary conditions in a valve exerciser. Electrospinning also offers possibilities to directly spin a three-dimensional heart valve scaffold. Here, we describe our first findings with a valve scaffold design, in which the valve consists of three separate electrospun leaflets.

Materials and Methods

The 3 leaflets were electrospun separately from a 20%(w/w) poly(ε-caprolactone) (PCL) solution and combined to a valve (d_i 27 mm) in a second step (see figure 1). The pores in the valve were sealed with a fibrin gel (thrombin 10 IU/ml + fibrinogen 10 mg/ml) prior to testing for 20 min at pulmonary conditions in a valve exerciser (n=1).

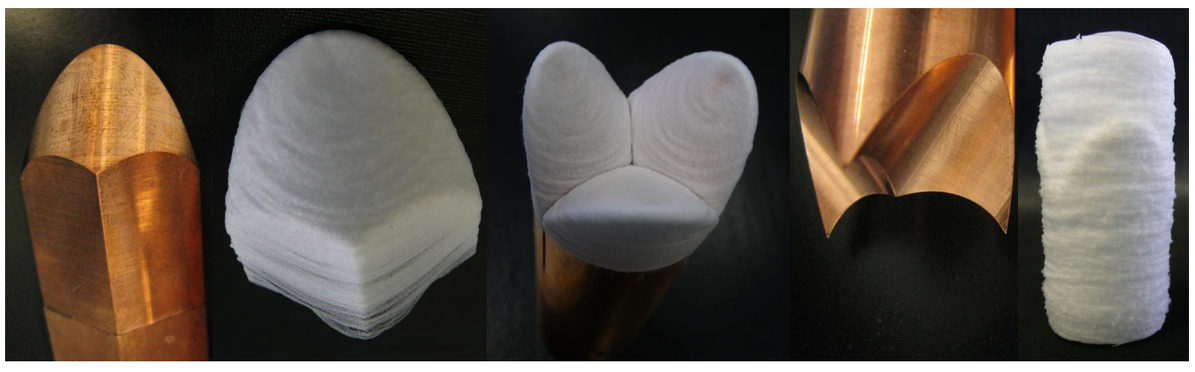
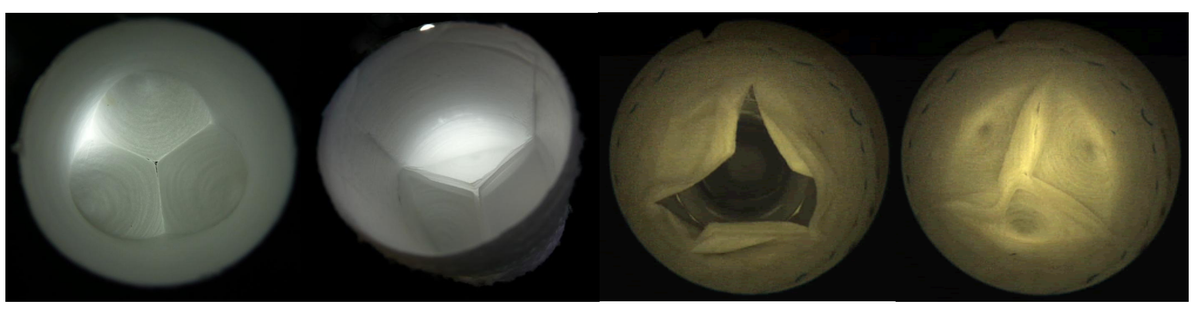


Figure 1 Process to electrospin a 3D valve starting with single leaflets

Results

The fibrin sealed PCL valve shown in figure 2 was tested in a valve exerciser (Hemolab B. V., Eindhoven). Successful hemodynamic characteristics were obtained, the leakage remained at 6%, whereas total regurgitation was at 10% and the valve showed an effective orifice area of 2.4 cm^2 (see table 1).



a b c d

Figure 2 Images of the used electrospun PCL valves; a) ventricular side, b) pulmonary side, c) open position in the valve tester, d) closed position in the valve tester

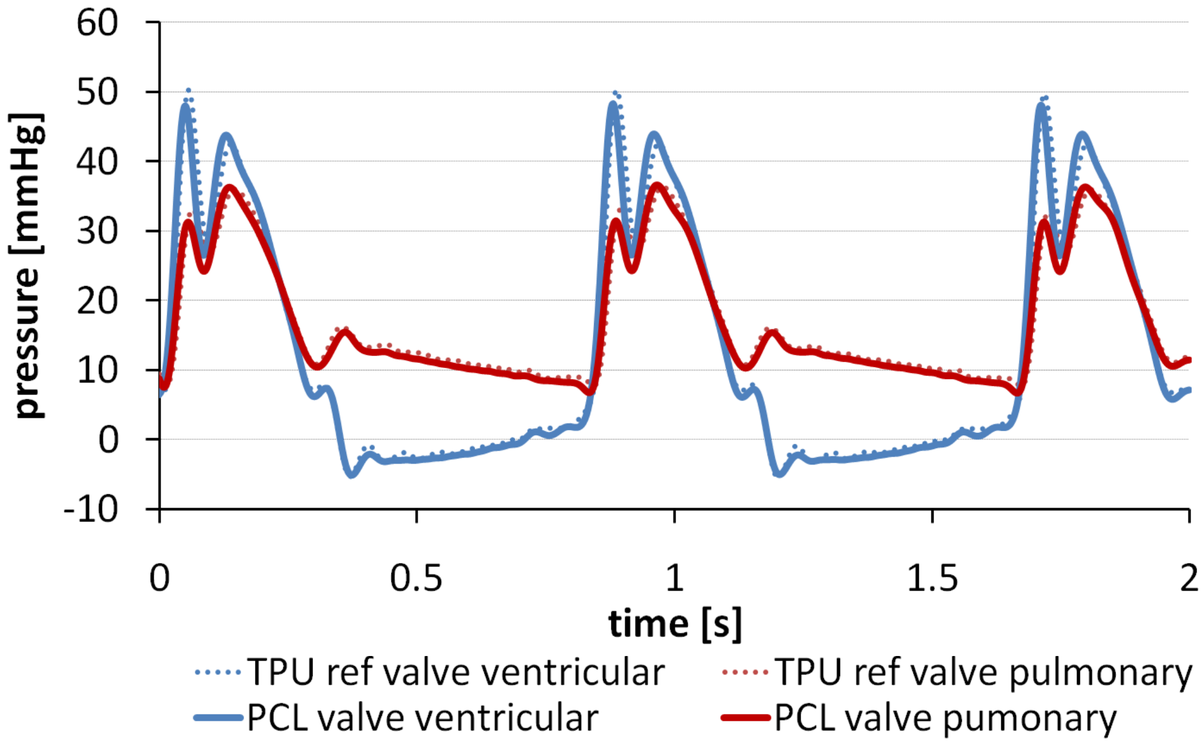


Figure 3 Pulmonary hemodynamic pressure curves of the electrospun PCL vs. the TPU reference valve

		ISO 5840	TPU film	PCL electrospun	
Time point	[min]	N.A.	0	0	20
General configuration					
Stroke volume	[mL]	N.A.	73	71	71
Cardiac output	[L/min]	5.0	5.2	5.0	5.0
Conditions					
Peak systolic pressure	[mmHg]	N.A.	36	36	36
End diastolic pressure	[mmHg]	N.A.	8	7	7
Open configuration					
Calculated A_{EO}	[cm^2]	≥1.7	1.6	2.1	2.3
Max. systolic p. gradient	[mmHg]	N.A.	8	10	8
Closed configuration					
Regurgitation	[%]	≤20	6	10	10
Leakage	[%]	N.A.	2	7	6
Closing volume	[%]	N.A.	4	3	4

Table1 Pulmonary performance values from Figure 3 of the electrospun PCL vs. the TPU reference valve with ISO values needed for an aortic valve implant

Conclusion

We demonstrated here an electrospun three-dimensional heart valve, capable to function under pulmonary conditions with some key performance factors above the minimum requirements stated in the “standard ISO 5840 for Cardiovascular implants - Cardiac valve prostheses” for the 20 minutes tested. Additional, specifically prolonged, testing is required to evaluate the potential of this valve types.

Acknowledgments

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