Sylvia Pfensig*, Daniela Arbeiter, Stefanie Kohse, Sebastian Kaule, Michael Stiehm, Niels Grabow, Klaus-Peter Schmitz and Stefan Siewert

Development of a constitutive law for numerical simulation of artificial leaflet-structures for transcatheter heart valve prostheses

Abstract: While the current generation of devices for minimally invasive treatment of severe symptomatic aortic valve stenosis is based on xenogenic leaflet-material, artificial polymeric leaflet-structures represent a promising approach for future improvement of heart valve performance. For enhanced long-term success of polymeric leaflet-structures, limitations regarding calcification and durability have to be addressed. The objective of the presented study was the development of a constitutive law representing the material properties of artificial polymeric leaflet-structures of transcatheter heart valve prostheses in numerical simulation to assess the *in silico* leaflet-performance. Mechanical characterization of cast films and nonwoven specimens of a polycarbonate based silicone elastomer were conducted by means of uniaxial tension and planar shear testing, respectively. For validation purposes, experimental data were compared with the results of finite-element analysis (FEA) using different hyperelastic models. Strain energy function for third-order ogden hyperelastic model achieved the best fit of the non-linear stress-strain behavior of the isotropic polymeric material with the experimental data. It was chosen for further FEA of valve leaflet-performance under physiological pressurization to analyze the suitability of various manufacturing processes for polymeric leaflet-structures. Therefore a specific leaflet-design with a wall thickness of 400 μm was used. As a result of FEA, time dependent leaflet-deformation, leaflet coaptation surface area (CSA) and leaflet opening area (LOA) of cast and nonwoven leaflet-structures were calculated. While LOA was comparable for cast and nonwoven leaflet-structures,

obtained leaflet-dynamics in a cardiac cycle under physiological pressurization demonstrated crucial influence of the manufacturing process. For nonwoven leaflet-structures, an enhanced CSA could be demonstrated in comparison to cast structures. FEA using a validated hyperelastic constitutive law represents a useful tool for *in silico* performance evaluation of polymeric leaflet-structures under physiological loading and proves the suitability of the polymeric artificial leaflet-material for percutaneous heart valve prostheses.

Keywords: Finite-element analysis, transcatheter heart valve prosthesis, polymeric leaflet-structures, constitutive law.

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1 Introduction

The future generation of devices for minimally invasive treatment of aortic valve stenosis will benefit from leaflet-structures based on artificial polymeric materials. Therefore, crucial improvements concerning heart valve performance, durability, calcification and shelf life properties represent key aspects of the current research in the field of polymeric leaflet-structures [1,2].

Finite-element analysis (FEA) represents an essential tool for the design development of heart valve leaflet-structures. The mechanical behavior and *in silico* deformation of aortic heart valve leaflets under physiological loading and the influence of various design parameters on its performance has been investigated in structural mechanical FEA, previously [3-5]. Within the current work, we developed and validated a hyperelastic constitutive law for polymeric leaflet-structures for FEA. The influence of the constitutive law on time-dependent leaflet-deformation within a physiological cardiac cycle was analyzed with regard to leaflet coaptation surface area and leaflet opening area. Furthermore, the suitability of various manufacturing processes for polymeric artificial leaflet-material for percutaneous heart valve prostheses was assessed.

*Corresponding author: **Sylvia Pfensig:** Institute for Implant-Technology and Biomaterials e.V., Friedrich-Barnewitz-Str. 4, 18119 Rostock-Warnemünde, Germany, e-mail: sylvia.pfensig@uni-rostock.de

Daniela Arbeiter, Stefanie Kohse, Niels Grabow, Klaus-Peter Schmitz: Institute for Biomedical Engineering, Rostock University Medical Center, 18119 Rostock-Warnemünde, Germany

Sebastian Kaule, Michael Stiehm, Klaus-Peter Schmitz, Stefan Siewert: Institute for ImplantTechnology and Biomaterials e.V., 18119 Rostock-Warnemünde, Germany

2 Materials and methods

2.1 Design of artificial leaflet-structure

The leaflet-structure was designed as axially-symmetric trileaflet heart valve geometry in an unpressurized and closed configuration as a stress-free state. For modelling, the computer-aided design (CAD) software Creo Parametric 5.0 (Parametric Technology Corp., Needham, MA, USA) was used, taken previously published literature on leaflet-geometry into account for design development [5].

A single leaflet was designed using the parameters summarized in **Table 1** and patterned three times, rotated by 120° around the centre of the valve. The model is basically built by the valve height and base diameter. A leaflet wall thickness of $400\ \mu\text{m}$ was used. For the lunula angle, a value of 34° was chosen in accordance with further design studies [5]. The belly line is formed by the three parameters commissure angle, coaptation angle and curvature of the belly. **Figure 1** illustrates the described design parameters of the trileaflet heart valve model.

Table 1: Design parameters and corresponding values describing the leaflet-design in unpressurized and closed configuration.

Symbol	Design parameter	Value
H_V	Valve height	18.5 mm
D_b	Base diameter	26.0 mm
s	Leaflet-thickness	$400\ \mu\text{m}$
Ω	Lunula angle	34°
φ	Symmetry angle	120°
R_A	Arc radius	2.0 mm
α	Commissure angle	20°
β	Coaptation angle	80°
C	Curvature of the belly	0.5

Figure 1: Side (A) and Top view (B) of the heart valve model: H_V valve height, Ω lunula angle, α commissure angle, β coaptation angle, C curvature of the belly, s leaflet-thickness, D_b base diameter, φ symmetry angle and R_A arc radius.

2.2 Development of a constitutive law

As artificial leaflet-material for polymeric leaflet-structures a polycarbonate based silicone elastomer was chosen. For the development of a hyperelastic constitutive law for the artificial leaflet-structures, cast films and nonwoven specimens were manufactured by means of dip coating and electrospinning, respectively.

Mechanical characterization was conducted by means of uniaxial tension and planar shear testing. Cast films ($n = 10$) were analyzed at room temperature, because no influence of a saline solution was observed. Nonwoven specimens ($n = 10$) were analyzed in 0.9% saline solution at 37°C , using a universal testing machine Zwick/Roell Z2.5/TN (Zwick GmbH & Co. KG, Ulm, Germany).

Figure 2 presents the dimensions of rectangular specimens and illustrates the stress-strain behavior of cast films and nonwoven specimens during uniaxial tension and planar shear testing.

Figure 2: Dimensions of specimens for uniaxial tension (A) and planar shear testing (B) and averaged curves of the stress-strain behavior of mechanically characterized cast films and nonwoven specimens by means of uniaxial tension and planar shear testing (C).

2.3 Finite-element analysis

For validation purposes, experimentally determined data of uniaxial tension and planar shear testing were compared with numerical results of FEA using ABAQUS/Standard 2017 (Dassault Systèmes, Vélizy-Villacoublay, France). Numerical stress-strain behavior for different hyperelastic models of order N was evaluated with regard to stability and accuracy compared to the test data for cast films and nonwoven specimens, respectively. The strain-energy models of Ogden, Mooney-Rivlin and Neo-Hookean were used for validation.

Furthermore FEA (ABAQUS/Explicit 2017, Dassault Systèmes, Vélizy-Villacoublay, France) was used for numerical simulation of the leaflet-dynamics during two complete cardiac cycles with a duration of 0.854 s, respectively. *In vitro* hydrodynamic testing of a commercially available heart valve prosthesis was used in order to define physiological ventricular and aortal pressure conditions for numerical simulations [5].

For fixation, the displacement of the commissure was constrained. Surface-to-surface contact was applied between neighbored leaflets using a friction coefficient of 0.3.

A generalized isotropic hyperelastic constitutive law with a density of 10^{-9} kg/mm³ and a Poisson's ratio of 0.475 was defined to describe the polymeric material properties. Meshing was conducted, using a total of 9,474 C3D8 continuum elements with a global edge length of 0.40 mm.

3 Results and discussion

3.1 Material model for polymeric leaflets

Strain energy function for third-order Ogden ($N=3$) hyperelastic model achieved the best fit of the experimental data and full stability of the non-linear stress-strain behavior of the isotropic polymeric material (see **Figure 3**). It was chosen for further FEA of valve leaflet-performance under physiological pressurization to analyze the *in silico* deformation and assess the suitability of cast and nonwoven leaflet-structures for future heart valves (see **Table 2**).

Table 2: Material parameters of stable third-order Ogden hyper-elastic model for cast films (1st line) and nonwovens (2nd line).

I	μ_i	α_i	D_i
1	0.2101	2.8384	4.5010E-02
	0.2892	2.5195	0.3498
2	1.1649E-07	13.9474	0
	2.0215E-04	6.6970	
3	2.0449	-2.8359	0
	1.3335E-03	-6.3761

Figure 3: Comparison of stress-strain behavior of an averaged curve based on experimental investigations and numerical results of FEA using different hyperelastic models: uniaxial tension (A,C) and planar shear (B, D) of cast films and nonwoven specimens.

3.2 Leaflet-dynamics in a cardiac cycle

As a result of FEA, time dependent leaflet-deformation, leaflet coaptation surface area (CSA) and leaflet opening area (LOA) of cast and nonwoven leaflet-structures was calculated (see **Figure 4**). While the maximum LOA within a cardiac cycle was comparable for cast (3.78 cm²) and nonwoven (3.93 cm²) leaflets, obtained leaflet-dynamics under

physiological pressurization demonstrated crucial influence of the manufacturing process of the polymeric leaflet-structures. The duration of systole for cast leaflets was less than half the time for nonwovens. Furthermore, an enhanced CSA could be demonstrated for nonwoven (37 mm²) in comparison to cast leaflet-structures (79 mm²). The current findings indicate better suitability of the polymeric nonwoven leaflet-material compared to the cast leaflet-material.

Figure 4: Results of FEA: performance of cast and nonwoven leaflet-structures according to aortic and ventricular pressure curves (A), average coaptation surface area (B) and leaflet opening area (C) during opening and closing for a cardiac cycle of 0.854 s.

4 Conclusion

Within the current study, we developed a hyperelastic constitutive law for a polycarbonate based silicone elastomer describing the non-linear stress-strain behaviour of the isotropic artificial leaflet-material. FEA represents a useful tool for *in silico* performance evaluation of polymeric cast and nonwoven leaflet-structures under physiological loading and demonstrated the better suitability of the nonwoven leaflet-material for future percutaneous heart valve prostheses.

Author Statement

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