Proceedings on Automation in Medical Engineering
Proc AUTOMED, Vol 2, No 1 (2023): Article Ref 764
www.journals.infinite-science.de/automed/article/view/764

Infinite Science Publishing

Evaluation of high compliant elastomer balloons for the identification of artery biomechanics

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Abstract: With a Finite Element Analysis (FEA) study the capability of elastomer balloons for the in-vivo identification of parameters for Strain Energy Function (SEF) based tissue models is investigated. Multiple Combinations were obtained by varying balloon thickness and radius. Each combination was simulated inside a carotid artery based on a hyperelastic model. As the chosen analytical formulation for parameter fitting suits well the simulated FEA model, all balloons can analyze the parameters with a relative error below 2 %. For real world correlates however, the analytical fit and the sensor sensitivity determine the accuracy of obtainable results.

I. Introduction

Current work at two research institutes of Furtwangen University focus on the development of inflatable balloon sensors to identify the biomechanical properties by tactile assessment of the vessel endothelium in-vivo. Strain sensing elements embedded into the balloon catheter wall provide localized strain data, which must be translated into biomechanical properties of vessels (with structural and/or material alterations) with suitable reverse models.

Phenomenological hyperelastic tissue models as well as hybrid physiologically motivated 'fibre' based models have accurately been able to characterize mechanical vessel responses [1, 2]. FEA studies highlight the influence of the tissue geometry on the circumferential stretches induced to the elastomer balloon during inflation [3]. A balloon-tissue interaction has been used to estimate the young's moduli of endothelium of ureters with volume-inflation metric and other approximations [4].

The current 2D FEA study focusses on how the balloon wall thickness and the starting diameter in respect to the vessel diameter have an influence on the reverse identification accuracy aiming to specify the parameters related to the mechanical response of the vessel.

II. Material and methods

The balloon and vessel components' mechanical behavior were initialized with experimentally validated models and the simulations were conducted within the commercial FEA software COMSOL® v6.0.

As idealized exemplary case for a vessel structure, a perfect cylindrical cross section of a healthy human carotid artery was initialized with inner and outer radial dimensions being 3.1 mm and 4 mm respectively [2, 5]. The tissue biomechanics were defined by the incompressible hyperelastic model by Demiray et al. [1], where the SEF W is given by (1).

$$W = \frac{A}{B}\left[\exp\left(\frac{B}{2} * (I_1 - 3)\right) - 1)\right], \quad (1)$$

'A' and 'B' are a stress like parameter and a dimensionless constant, respectively, and I_1 is the first strain invariant. The artery is initialized with validated 'A' and 'B' as 44.2 kPa and 16.7 respectively [1, 5].

The balloon mechanics were initialized by an experimentally validated incompressible hyperelastic 4-parameter Ogden model applicable to the elastomer material Polydimethylsiloxane (PDMS) which is currently used in our experimental work. The values of the Ogden model parameters μ_1, μ_2, μ_3 and μ_4 were 2.91e-01 MPa, 3.40e-03 MPa, 2.01e-11 MPa and -1.15e-02 MPa respectively; the parameters a_1, a_2, a_3 and a_4 were 2.17, 9.06, 34.3 and -5.4 respectively [6].

The balloon outer radius (BR) was parameterized as 2 mm, 2.5 mm and 3 mm while the thicknesses of the balloon (BT) were 500 µm, 50 µm and 5 µm, all leading to 9 simulations. The inflating balloon and tissue cylinders had coinciding center. Pressure was applied on the inner surface of the balloon leading at a certain contact point (CP) to a conform contact with the inner surface of the artery. Further inflation leads to an expansion of the artery with the balloon pushing it radially outward. The balloon pressure is varied from 0 to 50 kPa in fine steps of 1 Pa till CP and later thereon in steps of 10Pa. The contact was simulated using the 'Augmented Lagrangian' method for accurate simulations. The FEA pressure vs. balloon radial stretch outputs were exported to MATLAB® (v2022b) for the identification procedure. The stretches and stresses inside the balloon and tissue are computed with a two-layer analytical form of the FEA model [2]. Thereby, the geometry and given material parameters of the balloon were known while the tissue material parameters were taken to be unknown (to be identified). Common arithmetic algorithms were used to calculate the deformed dimensions of the balloon and the

tissue. The 2D cylindrical form for computing the analytical pressure P is given by

$$P(A,B,i) = \int_{BiR}^{BoR} \frac{\sigma_\theta - \sigma_r}{r} dr + \int_{TiR}^{ToR} \frac{\sigma_\theta - \sigma_r}{r}\, dr, \qquad (2)$$

where for the balloon (integral boundary from inner to outer surface BiR and BoR) and the tissue (integral boundary from inner to outer surface TiR and ToR) for each pressure level (i), the corresponding circumferential and radial stresses (σ_θ and σ_r) within the radially deforming balloon and tissue were utilized [3].
Minimization of the SEF function with the given input pressure and the modelled pressure was used to determine the unknown vessel parameters 'A' and 'B'.

III. Results and discussion

The values of 'A' can be interpreted as the tissue's isotropic matrix and following this, values of 'B' would correlate with the stiffening of the collagen fibres in the mid to large stretch range (compare also [2]).
The combination of BT 500 µm with BR 2.5 mm and 2 mm were unable to output any identified values for the artery model as the stiffening of the balloon during inflation is not inducing any radial expansion of the tissue. **Table 1** shows the identified tissue properties for each simulation case.

Table 1: Analytically identified tissue properties of each balloon-tissue interaction using dataset available through FEM .

BT in µm	BR in mm					
	3		2.5		2	
	A in kPa	B [-]	A in kPa	B [-]	A in kPa	B [-]
5	44.23	16.94	44.21	16.94	44.18	16.95
50	44.26	16.92	44.21	16.94	44.19	16.95
500	44.17	16.97	-NA-		-NA-	

For an interpretation of the results, it is important to recap, that the chosen fitting procedure is relating one dataset to two different material models. As the parameters for the balloon material model are fully defined, the deviation of the stresses or stretches between a standalone balloon expansion and an expansion in contact with tissue are the 'available' datasets for the identification of the model parameters. In **Figure 1** the difference of the radially averaged first principle balloon wall stress (in circumferential direction) and the corresponding difference of the balloon perimeter between a free balloon expansion and the expansion in contact with tissue is shown for two model configurations (highlighted in Table 1). Hereby, the stress and perimeter differences are plotted against the inflation pressure for a free balloon inflation after the contact (CP), up to the maximum balloon perimeter which is reached for an inflation in contact with tissue. Consequently, the displayed curve progressions of the stress differences reflect the part of the differential dataset to which the parameters 'A' and 'B' are estimated.
A max. relative error of ≈ 1,6 % overestimating the B parameter is obtained for the BT 500 BR 3 configuration while all A parameters are fitted with a relative accuracy of < 0.2 %. Dependent on the balloon stiffness and initial distance between the balloon and the tissue, the segment of the exponential curve resembling the tissue response shortens in the differential dataset (correlating with the reduced deformation of the tissue). Looking at Table 1 even the smaller induced tissue deformations are sufficient to fit the exponential function for the chosen combinations.

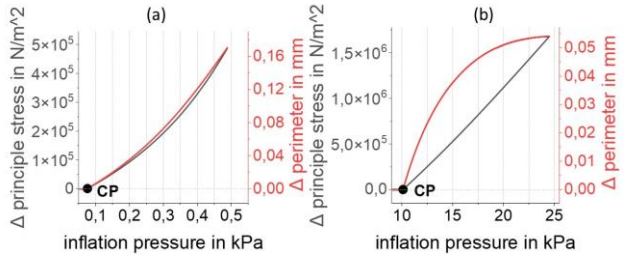

Figure 1 Difference of the averaged first principle stretch inside the balloon wall as well as the corresponding perimeter difference for (a) the free expansion of a BR 3 mm BT 5 µm balloon minus the expansion in contact with the tissue and (b) in respect to the similar method using BR 2 mm BT 50 µm balloon.

Consequently, for a parameter identification where the utilized analytical formulation fits well the 'real world correlate' (here represented by the FEA in-silico model), even a small dataset containing the characteristic tissue response is sufficient for the parameter estimation. However, looking at the decreasing magnitude of the differential perimeter data it can be further concluded, that with a higher balloon stiffness and or larger diameter difference the required strain sensor sensitivity increases to resolve the differential data sufficiently for the identification procedure.

IV. Conclusions

For the in-vivo determination of model parameters for SEF based material models with an inflation sequence of sensor equipped balloons, the characteristic tissue expansion must be detectable in the differential dataset available for fitting. The required sensitivity of strain sensing elements increases with increasing balloon stiffness and or diameter difference to the tissue. Future work will concentrate on a sensitivity analysis in respect to deviations between the in-silico models and the utilized analytical representation for fitting as well as possible refinements of the latter.

Author's statement

This work was partially supported by the German Federal Ministry of Research and Education (BMBF under grant CoHMed/Digitalization in the OR no. 13FH5I05IA). The authors declare that there are no conflicts of interest.

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