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Simulation study of inflation of a high compliant balloon inside idealized non-linear tissue geometry

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Abstract: High compliant balloon (actuators) containing strain sensing elements are currently under development. This special actuator-sensor system is intended for in-vivo application in vessels such as arteries and urethra. It could potentially reveal local tissue information regarding biomechanical properties and possible inner wall shape.

This simulation study in COMSOL (v5.6) focusses on inflation behavior of a balloon being equipped with several sensing elements, whose compliance is ideally magnitudes higher than the surrounding tissue in an idealized in-vivo 2D setup. We initialize the vessel's inner wall as 5 different structures. First as a perfect circle; second, a square; third, a closed convex-concave 4-fold structure similar to surface structures found in urethrae. The fourth and fifth tissue structure are like the third structure but with its folds having higher amplitudes. Three sensing elements were initialized on the actuator surface with the first sensing element closer to the tissue boundary while the third the farthest.

The inflation of the balloon inside tubular structures clearly suggests several important phenomena. The sensing elements on the balloon in the expansion within a perfect cylindrical shape undergo identical stretch throughout the input pressure range. In the other structures, the first sensing element on balloon shows a higher stretch at complete contact with the tissue wall, while the third element undergoes the least stretch within the three sensing elements.

It was observed and concluded from the inflation-study that balloon regions, which get into contact with tissue boundary earlier exhibit a faster rate of stretch change and a higher circumferential stretch than the balloon regions that are not getting into contact with the tissue early. The ratio of the difference between the sensing elements is positively correlated with the curvature amplitude of tissues.
This study reveals that simulation studies are powerful tools to understand and evaluate biomechanics in complex situations.

Keywords: shape, tissue, identification, biomechanics.

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1 Introduction

A high compliant inflatable actuator-sensor system is currently under development for intra-luminal application within urethra/artery [1]. The sensing elements (SE) embedded within the balloon could provide local stretch information of the tissue during the inflation procedure. Its inflation is influenced by the surrounding tissue properties.

Simulation studies have demonstrated that the local stretch of the tissue is influenced by the multifold/irregular shape of lumen inherent to vascular or urethral structures [2]. In arteries, irregular shapes in the inner lumen may be possible due to atherosclerosis and other pathologies [3].
It becomes of importance, therefore, to identify the initial vessel shape inside tubular structures to help identifying the local tissue properties.

2 Methods

This simulation study concentrates on expanding behavior of a high compliant balloon (containing circumferential strain-sensing elements) within a tubular vessel structure exhibiting geometrical non-linear characteristics. The explorative study may enable to effectively identify vessel shape of the inner wall of the vessel.

The balloon behavior is initialized by using Ogden model and parameter values as provided in [4] for material Sylgard® 184 and seen in Table1. Figure 1a shows the balloon with idealized embedded sensing elements that provide information about the circumferential strain. The circumference of the inner wall of the balloon is $1.1 \times \pi$ mm ($\emptyset = 1.1$ mm) while its thickness amounts 0.05 mm.

Table 1: Ogden 4 parameter model values.

Parameter	**Value**
α_1	2.17
α_2	9.06
α_3	34.3
α_4	-5.4
μ_1 [MPa]	2.91e-01
μ_2 [MPa]	3.40e-03
μ_3 [MPa]	2.01e-11
μ_4 [MPa]	1.15e-02
E [MPa]	1.09

The sensing elements are placed on the inner circumference of the balloon and have a 1/16th length of its inner circumference. Sensing element 1 (SE1) is placed on the -90° (-y-axis) on the balloon (blue in Fig. 1). The second (SE2 green) and third (SE3 red) sensing elements are placed adjacent to it in the anticlockwise direction, respectively. For evaluation and first insights into the problem, we chose a simple case where the structures are symmetric over the diagonals, the x- and the y-axis. If more SEs were added adjacent to the above three elements, each would have a matching stretch response to either one of the previously initialized elements. Therefore, more such elements are not considered for these current ideal geometries.

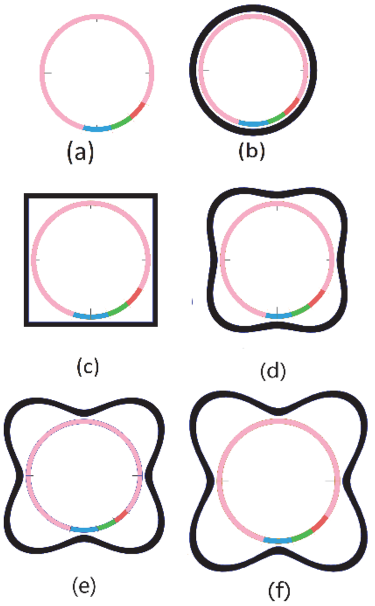

Figure1: (a) The inflatable balloon (pink) with embedded sensing elements SE1 (blue), SE2 (green), and SE3 (red). (b) balloon surrounded by circular tissue (Str1). (c) balloon surrounded by tissue of square geometry (Str2). (d) balloon surrounded by tissue with 4-fold (Str3). (e, f) balloon surrounded by structure tissue like (d) but with higher wave amplitude as well as greater cross section area

Figure 1b depicts the balloon within a circular tissue model (Str1) with the inner boundary $\emptyset = 13$ mm being 0.25 mm away from the balloon. Figure 1c shows the balloon within a square tissue model (Str2) with each side (inner wall) 12.5 mm in length. The center of each side is 0.25 mm away from the balloon.

Figure 1d, e and f show a tissue with pure sinusoidal pattern of 4-folds, which are drawn along a circle (Str3-Str5). These structures have sine wave amplitude of 2.6 mm, 3.4 mm and 4 mm, respectively. The balloon lies within these structures and the closest point of the structure is again 0.25 mm from the balloon.

Boundary Conditions:

All the tissue models (Str1-5) surround the balloon and have its external boundary as a fixed boundary condition. The tissue, therefore, may not deform during the balloon expansion and interaction with the tissues.

We applied standard boundary conditions like symmetry on the vertical and horizontal nodes of the structures that lie on the x- and y-axis for each simulation case. The inflation simulation is conducted as a time-dependent study with the pressure applied on the inner wall of the balloon. The applied pressure was increased from 0 kPa to 150 kPa in steps of 0.1 kPa. The used solver is allowed to choose a free time stepping over the range and interpolate. The contact between the balloon and the stiff tissue structure is solved by the penalty method.

The circumferential stretch is recorded by each SE and is plotted against the applied input pressure range for figuring out any stretch-structure relation and for general analysis and discussion. To understand shape information for these ideal shapes, we performed an analysis focused on the ratio of difference in stretch between SE1 and SE2 to the difference between SE2 and SE3 at pressure level where the stretch value may saturate.

3 Results and Discussion

The expansion of the balloon as a standalone study and balloon inside the 5 different structures was performed.

3.1 Stretch of the sensing elements

The standalone balloon expansion is shown in Figure 2a. All the three sensing elements on the balloon show uniform deformation as expected and, therefore, coincide in their circumferential stretch response to applied pressure. The balloon exhibits an approximately linear expansion till a stretch of 1.9 (corresponds to 60 kPa) and starts to behave progressively stiffer thereafter.

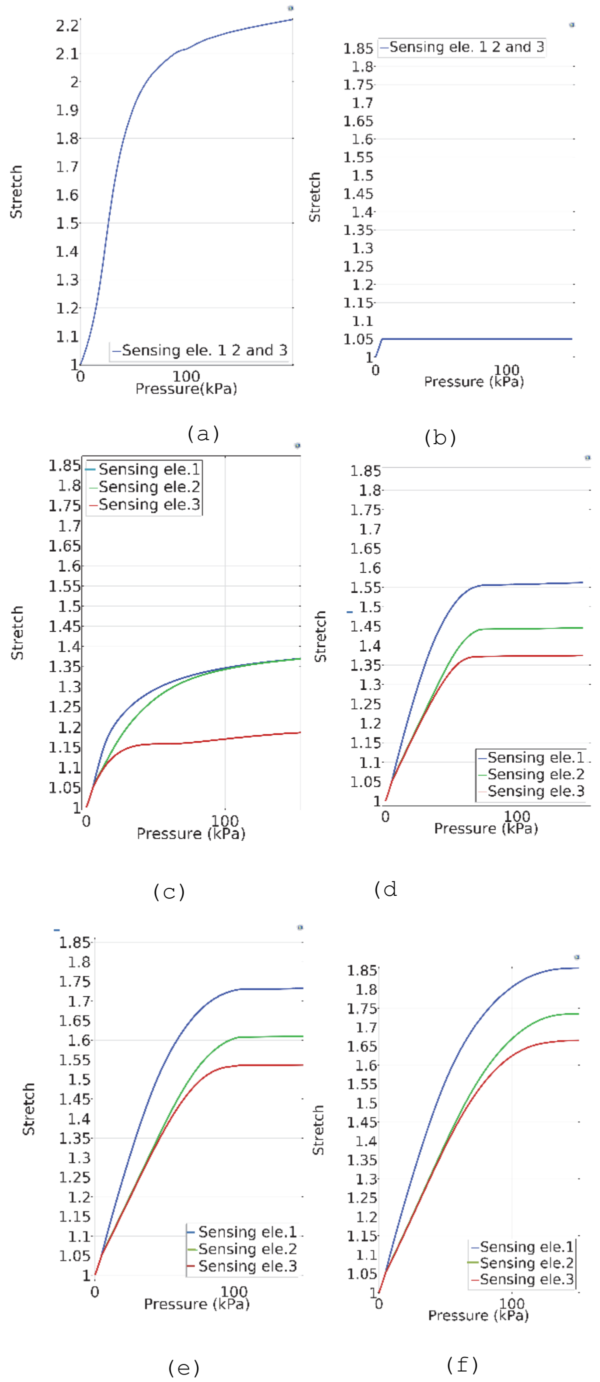

Figure 2: The circumferential stretch response of balloon sensing elements to pressure as standalone balloon expansion in (a), structure 1 in (b), structure 2 in (c), structure 3 in (d), structure 4 in (e) and structure 5 in (f). The general sensing element stretch w.r.t pressure inside tissues increases as the curvature and area inside enclosed the tissue boundary becomes higher.

The expansion of balloon inside Str1 (see Fig. 2b) also indicates an equal deformation of all the SE and the stretch saturates at a value close to 1.05 (corresponds to 5 kPa). From the performed FEM simulations and the observation that there is no change in the balloon SE stretch beyond 5 kPa, one may conclude that the balloon has completely conformed to the circular shape of the tissue.

For the Str2 (square), the stretch for sensing element 1 initially increases at a faster rate from 5 kPa to 10 kPa, when response is compared to the standalone balloon expansion. The stretch increases at a slower rate and behaves stiffer post 15 kPa, again when response compared to standalone balloon expansion. The SE2 undergoes a smaller stretch than SE1 till about 120 kPa but thereafter matches element 1 response. The SE3 shows a smaller rate of increase in stretches compared to SE1 and SE2 and this rate continues to reduce through the pressure range.

The expansion of balloon inside Str3 and Str4 and Str5 (see Fig. 2d, e and f) indicated an unequal deformation of all the sensing elements. The SE2 as well as SE3 feature overlapping responses till certain pressure but then SE2 stretch exceeds the SE3 at higher pressures. The expansion behavior of balloon inside all the tissue structures except the circular one (see Fig. 2c) indicated an unequal deformation response of the balloon sensing elements.

3.2 Saturation pressure and difference ratio

The available area enclosed by the tissue inner boundary gets larger from the first tissue structure (Str1) to the last structure (Str5). For the studied ideal geometries, the curvature of the slope is also higher from Str1 to Str5.

Table 2: Saturation pressure of stretch and the ratio of differences in stretch between the SEs.

Simulation study	Approx Saturation Pressure [kPa]	Sensing element 1 and 2 difference (A)	Sensing element 2 and 3 difference (B)	Ratio A:B
Balloon standalone	>200	0	0	-
Balloon in Str1	5	0	0	-
Balloon in Str2	150	0.001	0.1826	0.005
Balloon in Str3	80	0.1166	0.0708	1.647
Balloon in Str4	110	0.1228	0.0724	1.696
Balloon in Str5	140	0.1211	0.0702	1.725

The input pressure at which the sensing element stretch saturates is provided in Table 2. With the exception for the square structure (Str2.), all the other structures show that the further the region of tissue lie from the balloon boundary at undeformed condition, the higher is the pressure required to stretch the balloon sufficiently to conform it to the shape of the tissue. Moreover, the FEM simulations reveal that the balloon tries to conform to the sharp 90° corners of the square and the tissue stretch does not seem to saturate in the pressure range chosen.

The sensing stretch clearly shows a positive correlation with the area available within the tissue region to expand. From FEM outputs and the sensing element outputs, it could be clearly observed that the balloon region (SE1) will stretch more conforming earlier to the tissue surface, which is closer to it compared to the balloon region (SE3) that is away from tissue boundary. The balloon surface, which gets into contact with the tissue at higher pressure, exhibits eventual stretch that is lower compared to other balloon areas.

Table 2 also provides the difference in stretch in SE1 and SE2 (A), the difference of stretch in SE2 and SE3 (B), and the ratio of these differences. The SE differences 'A' and 'B' may not present themselves a clear trend. The difference ratio A:B, however, features a positive correlation with the curvature, namely 0.005, 1.647, 1.696 and 1.725 in structures 2, 3, 4 and 5, respectively. Consequently, the analysis suggests that such ratios between SEs and analysis may provide shape information characteristics.

4 Conclusion and Future Scope

General observation with shape information: The balloon regions that get into contact with tissue boundary earlier due to proximity of portion of tissue boundary to the balloon undergo a faster rate of stretch change and a higher greater circumferential stretch than the regions that are not getting into contact with the tissue earlier. This is confirmed by higher stretch value of SE 1 and smaller stretch value of sensing SE3. According to the presented study, the ratio of the difference between the sensing elements will increase when the curvature amplitude tends to increase. Shape information insights of the tissue may be comprehended from such ratio evaluations.

Future Scope: Further studies are simultaneously being attempted to generate a larger dataset that includes multiple geometries, different configurations of the balloon and 3D simulations.

The next step is to perform shape identification from circumferential stretch response of balloon sensing elements and develop algorithm(s) for the same. AI studies may provide some faster identification and solving techniques. Shape identification will be useful as an important step to identify local tissue properties. With complex modelling and identification techniques in future, we will explore balloon-tissue interaction in realistic in-vivo settings.

Author Statement

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