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Rapid Prototyping of Silicone-based Phantom Models for Stent Simulation Validation

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Abstract. Robust and reliable development of stent designs and materials is an important aspect for medical device manufacturing in relation to procedures such as Transcatheter Aortic-Valve Implantation. It is essential to perform a variety of experiments at an early stage of this process to define suitable material requirements and stent geometry. Mechanical simulation of realistic use case scenarios is a cost and time effective approach to optimize this task. In silico experiments can assist the device development phase and successively support patient-specific procedure planning. To establish confidence in the predictive power of in silico models and the corresponding simulation results, we therefore present a validation framework for stenting simulations. Our workflow allows the comparison of finite element analysis with actual mechanical response tests using optical tracking of stent deformation in artificial vessel phantom models. The results indicate that stent and vessel deformation can be analysed and validated across well-defined tissue properties within the presented framework.

Keywords: vessel, aorta, phantom, stent, simulation, validation, rapid prototype, finite element analysis

1 Introduction

1.1 Background and Previous Work

Stent placement is a minimal-invasive medical procedure to treat pathologies within the vascular system. It is commonly used to increase the diameter of blood vessels at narrow sections, treat artery enlargement and weakening due to aneurysms or replace dysfunctional heart valves, which show abnormal blood flow behaviour. Devices used in these procedures can be divided into two groups: self-expanding and balloon-expanding stents. Medical device manufacturers release a growing number of stent designs in variable sizes [1]. Creating an accurate simulation environment for their experimental validation can reduce development time and help to optimize design aspects. It can furthermore guide the choice of a specific stent type and size for an individual patient.

Mechanical validation of stents is commonly achieved through tensile loading experiments. Force measurement of crush tests between parallel plates as shown in [2] allows global material deformation modelling, but fails to provide testing scenarios similar to the stent's actual use cases. Finite element anaylsis (FEA) of stent deformation has been performed at a large variety of applications [3],[4],[5], but is commonly not validated against real world experiments. Image-based experiment tracking of vessel phantoms to analyse contact areas was shown in [6], however, local stent deformation measurements have not been performed. Other studies [7],[8] use phantom models for stent validation, but do not relate the results to simulated experiments.

1.2 Motivation

The central goal of this work is to outline a systematic approach to procedural validation of in silico experiments in relation to stent simulation within vascular structures. Initially, phantom modelling of common vascular structures in human anatomy allows experimenting with related medical procedures in a controlled environment. The ascending aorta and aortic root are of great interest for analysis of advanced stent design, where the focus is set on the replacement of heart valves. In this scenario the positioning and stent deformation after implantation are of critical importance to guarantee functional artificial valves and reduce potential leakage as well as conduction abnormalities. Predictive simulation based on numerical models of the mechanical behaviour could be an important aid in procedure planning. However, validation of these commonly simplified, abstract virtual models is required to establish confidence in the predicted results. Therefore, a flexible and robust validation framework for experimental validation of simulated stenting is required.

As mechanical vessel properties are patient-dependent, a rapid prototyping approach to generate artificial vessels can supply a variety of test cases for validation of simulated stenting procedures. A modular framework design allows to increase complexity of individual components iteratively. Simplified models support the controlled design of a predictable and robust experimental environment, which is required initially to validate proposed experiments before increasing material or model complexity.

2 Methods

2.1 Phantom Material Specification

For rapid prototyping of vessel-like phantom structures with mechanical properties in the range of soft tissue, a suitable material with adjustable elasticity parameters is required. The material needs to match mechanical properties of a common aortic vessel and enable the stable, homogeneous design of an arbitrary, hollow, cylindrical shape. The construction process has to offer repeatability and flexibility for versatile phantom model design to generate a suitable subset of vessel phantoms at different configurations. For further validation and experimental

analysis, the model is preferred to be transparent to expose the behaviour of an inserted object, such as a stent.

Silicone rubber compounds are used in medical phantom models to represent soft tissue due to comparable mechanical properties. Dependent on the type of silicone, it is commonly available as a translucent material, which can be modelled in an arbitrary form with variable mechanical properties. Figure 1 shows tensile strength of multiple silicone compounds available for rapid prototyping to generate phantom models of vascular structures, such as the aorta. Using a variety of material strengths with different elasticity and hardness values allows for adoption of the validation model to specific test cases (e.g. involving validation against pathologic tissue changes). Silicone-based phantoms commonly feature a high tear resistance and low shrinkage over time. They retain their shape after multiple iterations of applying high load and can be stored without significant material decomposition or hardening over a long period of time.

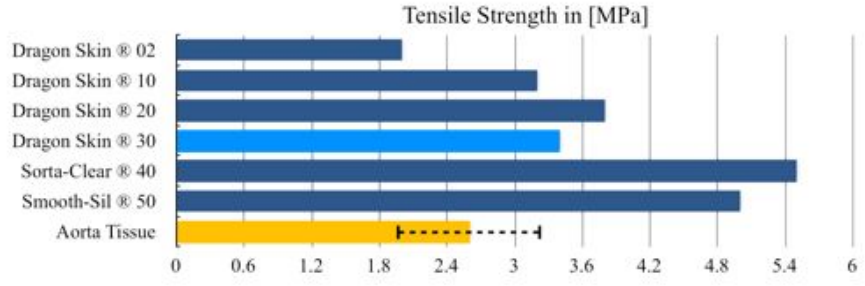

Fig. 1. Mechanical properties for silicone-based materials sold by Smooth-On, Inc. and their comparison to aortic vessel tissue.

2.2 Silicone Vessel Phantom Design Process

A vessel phantom is constructed by applying multiple layers of liquid silicone rubber onto a three dimensional structure representing the lumen of the vessel. Particular care is required to achieve an appropriate thickness of the material. By using a representation of the inner lumen, any artificial or patient-specific vessel structure can be reconstructed with this procedure in a chosen vessel thickness with variable mechanical properties. Figure 2 shows initial prototypes of vessel phantoms and corresponding material samples, which were used to determine mechanical properties of each silicone compound.

2.3 Image-based Stent Deformation Measurement

One solution to validate the deformation results of the described setup, is to use micro-CT imaging for accurate 3D reconstruction of the stent. However, the large density differences between metal and artificial vessel wall lead to metal

Fig. 2. Vessel phantom prototypes developed for experimental validation of stent deformation. Material samples for each silicone-compound have been tested repeatedly under uni-axial tensile loading.

streak artefacts in the images. As this framework aims for a rapid prototype development environment, we propose the use of a calibrated, high-resolution, dual-camera setup positioned with a 90 degree offset around the experiment to enable measurement of local stent and vessel deformation through optical tracking. We are using the "Caltech Camera Calibration Toolbox"[3] following a calibration approach presented in [9]. Using a camera-based setup, will allow the use of additional, larger mechanical equipment for load testing, which can not fit into a micro-CT. It does not require complex tracking equipment and simplifies the experimental design significantly.

By using translucent materials, the stent remains visible inside the vessel phantom. Marking the surface and stent points of interest allows their identification within corresponding images. If required, time dependent experimental analysis is possible in this setup, when using continuous image capturing. A strong limitation of this approach is the required accurate calibration, which constrains the resulting error. Figure 3 shows a standard calibration setup as used for deformation experiments and highlights two corresponding image points for reconstruction and tracking.

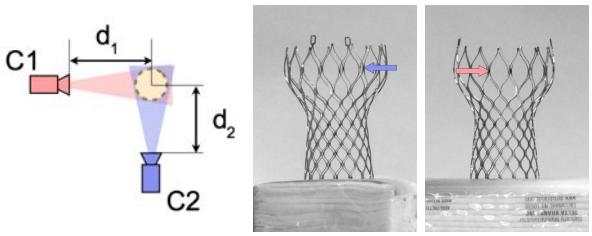

Fig. 3. Dual-camera setup for image-based local deformation measurement of stents. The arrows identify a matching image point seen from camera C1 and C2.

[3] `http://www.vision.caltech.edu/bouguetj/calib_doc/index.html`

3 Experiments

In this framework, preliminary experiments are required to ensure that the mechanical material model of the used silicone compounds has been characterized sufficiently as further deformation experiments will rely on these models.

3.1 Material Characterization

The silicone-based materials listed in Figure 1 have been analysed with robust uni-axial tensile loading tests to evaluate their elastic behaviour. Due to the homogeneous properties of silicone rubber, anisotropic effects are negligible. Within the maximal estimated strains, enforced in stent expansion experiments on the silicone phantom vessel structure, the mechanical response can furthermore be estimated with a linear elastic material model. However, as surface contact modelling will be essential, non-linearities have to be taken into account within the finite element simulation. The stent's material characterization is taken from literature [10] as well as using experimentally verified model parameters, acquired with a similar procedure as the load tests performed on silicone samples.

3.2 Stent Placement

For experimental validation, the stent is placed inside the vessel phantom as shown in Figure 4. At maximum level of expansion images are then being acquired to record the deformation. In the presented example, two different phantom vessels (V1 and V2) with different material thickness have been stented with a Medtronic CoreValve®. The self-expanding stent was inserted at the top end of the silicone tube, while the corresponding lower end of the phantom has been constrained in movement. In the final constellation the thinner vessel (V1) shows elastic deformation of 129.5% at its maximum diameter, while the thicker model (V2) deforms no more than 112.9 %, compared to the initial geometry configuration.

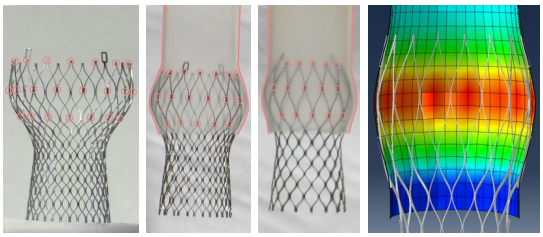

Fig. 4. 3D stent model reconstruction. Landmarks on the device are highlighted and used to generate a virtual stent representation. Point-based distance measurement between these markers define the amount of local deformation. FEA is used for stent simulation and allows the visualization of local deformation magnitudes for stent and vessel.

3.3 Simulated Stenting

Virtual experiments, assembled in correspondence to the validation setup, are performed using finite element solvers. An example FEA of the CoreValve® is presented in Figure 4. The outcome of these simulated experiments can then be compared with the previously measured deformation results to validate the material models and virtual simulation setup.

The simulation environment uses the Simulia® Abaqus Implicit and Explicit solvers. Finite element models of the vessel phantom as well as the virtual stent model are generated procedurally and by using common CAD applications.

4 Results

It is an essential aim of this validation framework to provide a controllable environment for experimental verification of simulated stent experiments. The vascular phantom is modelled using homogeneous silicone compounds to allow a high degree of control over the expected material behaviour and its experimental setup. A general validation method of virtual experiments has been described, which can later be used with more realistic and less predictable materials to provide a common platform for a variety of stenting experiments under predefined constraints.

4.1 Phantom Vessels

The generated silicone-based phantom vessels offer comparable mechanical properties in the same order of magnitude as common human vessels, such as the aorta. Strong non-linear and anisotropic characteristics as found in live tissue are not present. The homogeneous characteristics of silicone rubber can not imitate the complex muscular cell structure of vessels. It can, however, be constructed from multiple layers, which allow the combination of soft and hard silicone compounds to represent anatomical cell layers such as elastic membrane, muscle fibre and connective tissue as a step towards a more realistic soft-tissue model. Currently, the simplified material reduces uncertainties within the experiments and allows to focus the initial validation effort on stent behaviour. For advanced testing scenarios it remains to be determined if a more accurate material is required, which allows to model observed stress and strain values with higher realism.

The vessel phantom material used for Figure 4 is based on the DragonSkin® (Shore A: 30) compound. A corresponding finite element experiment with a linear elastic material model for both the CoreValve® stent and the silicone vessel, has found comparable deformation values with maximum vessel deformation of 125% (V1) and 110% (V2) compared to their original diameter.

4.2 Validation Framework

The complete, modular framework for validating stent simulation results is described in Figure 5. As seen within the presented diagram, real world experiments

and finite element simulation setup are aligned. The required virtual input model of a vessel lumen can be generated manually from generic CAD models or derived from segmentations of patient-specific imaging datasets. The actual vessel lumen can then be manufactured using a 3D printer. The volumetric model of the stent can be constructed in common CAD applications or acquired through imaging technologies. After performing the desired experiments in silico and within the vessel phantom, the deformation results can be compared directly.

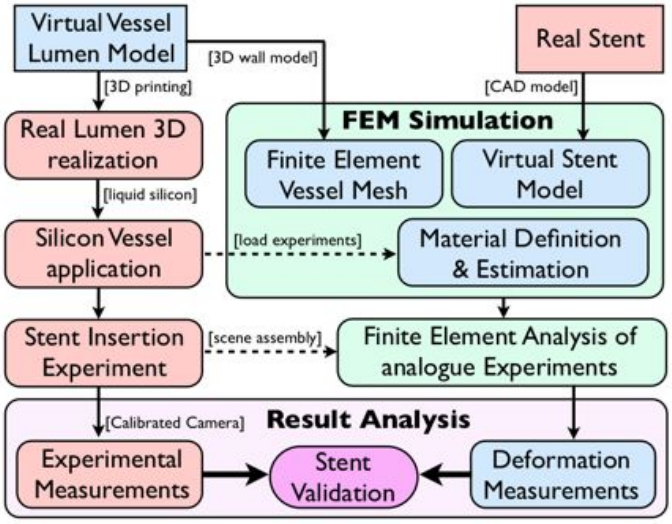

Fig. 5. Completed framework for experimental validation of stents within a rapid prototyping workflow for vessel phantom construction.

5 Conclusion

We have described a framework for rapid prototyping of silicone-based vessel phantoms and presented a workflow to validate a simulation environment for stenting procedures, which can be related to device design as well as patient-specific procedure planning. Our approach allows the consistent validation and initial testing of medical stenting simulations in a controlled and predictable environment. It is designed to offer flexibility towards geometric vessel structures and mechanical properties to support variability in the experimental setup and offer a potential for integrating pathologies into the phantom. Silicone models are suitable to establish a basic validation pipeline and allow the generation of an experimental test environment for a variety of simulation approaches. Due to their lack of material complexity, highly realistic results are not expected. For this purpose, mechanically more realistic materials for vessel simulation have been developed by companies, such as SynDaver™ Labs. However, silicone phantoms were used in this study with the target to establish an overall framework which can be used for the validation of more complex stenting models in the future.

Once the predictive performance of a specific model has been verified, it can be used as an in silico experimental environment for the systematic exploration of the effects of varying stent design parameters and therefore efficiently optimize new devices. At the same time it offers a rapid prototyping environment for fast-tracked testing and validation of stents. The presented workflow is furthermore suitable for the generation of patient-specific vascular geometries by extracting a model of the inner lumen from image based vessel segmentation as shown in [11]. This offers a powerful pre-operative surgical planning tool, when combined with the exploration of the dependency of the interventional outcome on inevitable uncertainties of relevant material parameters and boundary conditions.

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References

1. Webb, J. G., Binder, R. K.: Transcatheter aortic valve implantation: The evolution of prostheses, delivery systems and approaches. Archives of Cardiovascular Diseases. 105(3),153–159 (2012).
2. Labossiere, P., Perry, K.: Predicting Performance and Reliability of Nitinol Medical Implants. In: SEM Annual Conf. & Exp. on Expl. and Appl. Mech. (2007).
3. Kim, S. M., Park, S. Y. Finite Element Analysis of Stent Expansion Considering Stent, Artery and Plaque Interaction. In: Proc. of the 24th IASTED Intern. Conf. on Biomed. Eng. 143-146 (2006).
4. Egger, J., Großkopf, S., Freisleben. B.: Virtual Stenting for Carotid Stenosis with Elastic Artery Wall Modeling. In: 4th European Conf. of the Intern. Federation for Med. and Bio. Eng. (IFMBE). 22(22), 2499–2502 (2009).
5. Wu, W., Qi, M., Liu, X., Yang, D., Wang, W.: Delivery and release of nitinol stent in carotid artery and their interactions: a finite element analysis. J. Biomech. 40(13), 3034–40 (2007).
6. Takashima, K., Kitou, T., Mori, K., Ikeuchi, K.: Simulation and experimental observation of contact conditions between stents and artery models. Medical Engineering & Physics. 29(3),326–335 (2007).
7. Poerner, T. C., Ludwig, B., Duda, S. H., Diesing, P., Kalmár, G., Süselbeck, T., Kaden, J. J., Borggrefe, M., Haase, K. K.: Determinants of Stent Expansion in Curved Stenotic Lesions: An In Vitro Experimental Study. Journal of Vascular and Interventional Radiology. 15(7),727–735 (2004).
8. Kalejs, M., von Segesser, L. K.: Rapid prototyping of compliant human aortic roots for assessment of valved stents. In: Interactive Cardiovascular and Thoracic Surgery. 8(2),182–186 (2009).
9. Zhang, Z.: Flexible camera calibration by viewing a plane from unknown orientations. In: The Proceedings of the Seventh IEEE International Conference on Computer Vision. 666-673 (1999).
10. Petrini, L., Migliavacca, F.: Biomedical Applications of Shape Memory Alloys. Journal of Metallurgy. (2011).
11. De Santis, G., De Beule, M., Segers, P., Verdock, P., Verhegghe, B.: Patient-specic computational haemodynamics: generation of structured and conformal hexahedral meshes from triangulated surfaces of vascular bifurcations. Comput. Methods Biomech. Biomed. Eng. 14(9),797–802 (2011).