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Planar stent segment expansion as multiaxial validation load case for stent development

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Abstract: The development of stent technologies faces new challenges with advent of polymeric materials, offering versatility in mechanical, physicochemical, and biological properties. Biodegradable polymers, such as poly-L-lactide (PLLA), are particularly promising. Numerical simulations, particularly finite element analysis (FEA), play a crucial role in optimizing stent designs. However, validating advanced material models for FEA is essential due to the lack of consensus on data collection and validation methods.
This study introduces a validation framework using planar stent segment expansion to assess the mechanical behavior of polymeric materials and designs efficiently without extensive stent production. PLLA specimens were manufactured via injection molding and tested at 37 °C. Two material models, a linear elastic-plastic (LEP) model and an advanced viscoplastic (AVP) model, were compared. In summary, AVP showed improved conformity with experimental data. Our results demonstrate the importance of advanced material models for accurate FEA simulations and bridges the gap between numerical simulations and experimental validation in polymeric stent applications.

Keywords: polymer stent, FEA, validation, PLLA,

1 Introduction

The field of stent technology is constantly facing new challenges as it expands into novel applications driven by advances in materials science and manufacturing technologies. Especially shifts to personalized medicine and unmet application fields require advanced materials and stent designs, which result in unknown complexities and necessitate robust testing.

Polymeric materials have emerged as a valuable alternative to established metal-based stent technologies, due to mechanical, physico-chemical, biological and consequently biomedical application specific versatility. Biodegradable polymers in particular are designed to gradually degrade after vascular healing, eliminating long-term implant risks, such as restenosis, endothelial dysfunction, mal-apposition and thrombosis, while enabling the possibility for controlled drug delivery through direct drug incorporation, eliminating the need for additional coating steps.

Innovations in stent technologies rely largely on numerical simulation methods such as finite element analysis (FEA). The representation of materials as mathematical substitutes for FEA as well as stent design development are challenges in this field. Numerical simulations enable insights into different application specific scenarios, e.g. crimping, expansion or recoil, without the need of extensive experimental characterization for every iterative state of the study. The experimental characterization of stents in particular is combined with a rather complex manufacturing process, including fabrication polymeric tubes and laser cutting the stent design afterwards. Nevertheless, the validation of advanced material models for FEA is imperative, as there is a lack of consensus in the community on data collection, material model calibration and validation methods.

In this context, we focused on the evaluation of a multiaxial validation load case that depicts a stress state during the described application scenarios, while minimizing the methodological effort for experimental validation. Herein, we introduce a planar stent segment expansion, which is based on a segment from a stent design previously published by our group [1,2]. The manufacturing of polymeric specimens is generally subdivided into solvent-based protocols, such as film-casting, dip-coating or spraying, and thermal processing, e.g. injection molding or melt extrusion. Thermal processing avoids using solvents and thus necessary solvent removal protocols. In addition, injection molding of test specimens offers a fairly high production rate while maintaining the

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reproducibility, which is essential for material screening and validation studies. Notably, to ensure equilibration of thermally processed polymers such as poly-L-lactide (PLLA), an annealing protocol is crucial to adjust crystallinity and equilibrate mechanical properties [3,4].

The technological gap is addressed by developing a validation framework for material screening and initial mechanical performance assessment for polymeric stent applications. The focus is on providing early insights into relevant mechanical properties without the need for extensive stent production. By leveraging planar stent segment expansion as a multiaxial validation load case, we seek to bridge the gap between numerical simulations and experimental validation, ultimately contributing to the transfer of numerical simulations to clinical therapies.

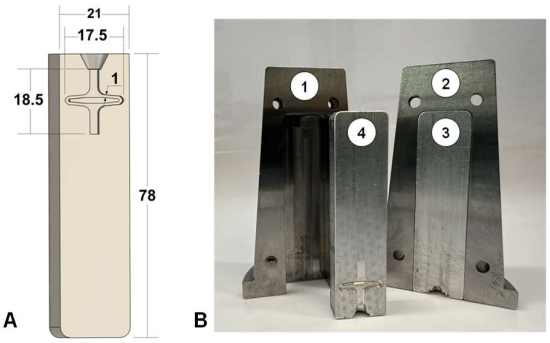

Figure 2: CAD construction of custom mold inlay (A) and assembly of manufactured inlay-system mold (B). 1) first outer mold half, 2) second outer mold half, 3) inlay half blank, 4) inlay half with stent segment cavity

2 Materials and Methods

2.1 CNC mold manufacture

To enable handling and experimental characterization by standard procedures using a universal testing machine, the stent design [1,2] was scaled up by a factor of seven (Figure 1). This also leads to a better machinability for CNC manufacturing of the mold, by ensuring a strut width of 1 mm.

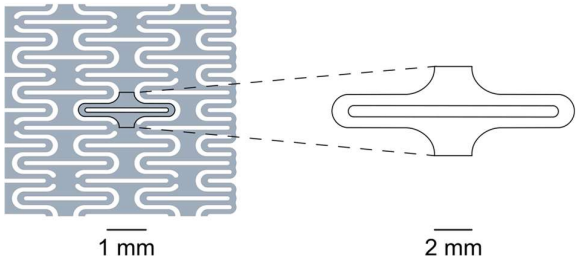

Figure 1: Planar unrolling of stent design [1,2] (left) and isolated stent segment for planar stent segment expansion experiments (right).

The implementation of custom molds into the injection molding machine was conducted through a custom inlay system with an original manufacturer mold (Figure 2). The stent segment geometry was complemented with a sprue channel for the polymer inlet. The inlay was machined out of AlZnMgCu1.5 with CNC machine Haas CM1 (Haas Automation Inc., Oxnard, USA).

2.2 Sample preparation

Poly-L-lactide (PLLA, M_w = 320 000 g/mol, Evonik, Essen, Germany) was used as received for injection molding with Haake MiniJet II (Thermo Fisher Scientific Inc., Waltham, USA). Processing parameters for injection molding process of PLLA were set to $T_{polymer}$ = 225 °C, T_{mold} = 67 °C, $p_{injection}$ = 750 bar (5 s holding time) and p_{hold} = 300 bar (10 s holding time). Specimens were annealed afterwards at 85 °C for 90 minutes based on an established annealing protocol [4].

2.3 Planar stent segment expansion

Planar stent segment expansion was performed using a universal testing machine Zwicki ZN 1.0 (ZwickRoell, Ulm, Germany). Specimens were tested at 37 °C in air in a temperature controlled chamber surrounding the whole test environment. The maximal displacement for the expansion was set to 6.3 mm to match the radial expansion factor of the original stent design. The gauge length was 10 mm, the crosshead speed was 5 mm/min. Videos were recorded with a microscope camera (Toolcraft DigiMicro 2.0 Scale, Conrad Electronics SE, Hirschau, Germany) using the testXpert III software (ZwickRoell, Ulm, Germany) for synchronization. The stiffness was determined by linear regression within the range of 0 - 1 mm planar expansion. A 0.2 mm expansion limit was used for the determination of the yield point.

2.4 Finite Element Analysis

Finite element analysis experiments were conducted using Abaqus 2023 (Dassault Systèmes SE, Vélizy-Villacoublay,

France). Material models were taken from literature for validation of planar stent segments. Linear elastic-plastic material model (LEP) was defined by ideal elasticity and plasticity with isotropic hardening, following Wang et al. [5], advanced viscoplastic material model for PLLA (AVP) was extracted from MCalibration and PolyUMod for Abaqus software package (ANSYS Inc., Canonsburg, USA). LEP is a model specified for 37 °C. AVP model consists of a Three-Network-Viscoplastic (TNV) material model with no given use temperature [6].

The geometry of the planar stent segment specimen was divided in quarters due to symmetry and computation efficiency (Figure 3). Relevant parameters for FEA are summarized in Table 1.

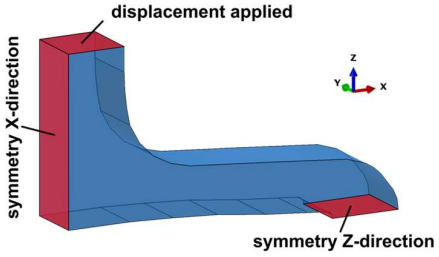

Figure 3: Overview of FEA geometry and applied boundary conditions. Shaded areas are used for the boundary conditions.

Table 1: Parameters for FEA

parameter	value
solver	Abaqus Standard, Dynamic Implicit
step	expansion step, 8.4 s (acc. 5 mm/min)
element type	C3D8I
mesh edge length	0.1 mm (curvature control 0.05)
applied displacement	3.15 mm (due to symmetry)
linear elastic material [5]	density = 1.25 g/cm³, E = 3.3 GPa, $\nu = 0.3$, σ_{Yield} = 51.5 MPa

To show strain rate dependency, material models were tested under uniaxial tensile and compressive loads through virtual experiments within MCalibration software using crosshead speeds of 0.5 mm/min and 5 mm/min.

3 Results and Discussion

The injection molding process was performed as described, and the manufactured mold exhibited satisfactory performance. However, a higher surface quality of the injection molding cavity would promote the demolding process of fragile and ductile molded parts.

Subsequent planar expansion testing of the specimens showed highly reproducible results with slight variability in beyond-yield characteristics. Initial failure mechanisms can be observed in the beyond-yield area prior to fully expansion range of 6.3 mm. Some curves (Figure 4) showed step formation, indicating (partial) strut fractures at around 4.5 mm expansion, which occured in predestined areas with high local strains (Figure 4D, E). These areas, characterized by increased opacity and therefore crystallinity, as evident in the image series (Figure 4), served as indicators of these early failure mechanisms. To enhance comparability with FEA results, the graphs were cropped to 4.0 mm maximal planar expansion, due to missing failure mechanics in the material models.

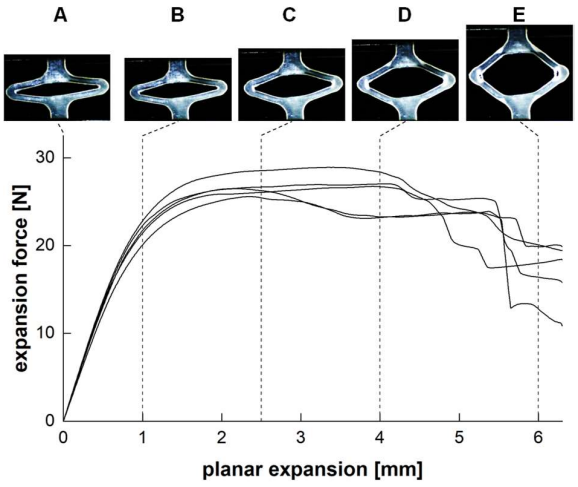

Figure 4: Experimental data of planar stent segment expansion experiments (n=5). Contour plots of a representative sample shows deformation of planar stent segment at indicated expansion states (A - D).

FEA with LEP and AVP material models showed different results when applied to the planar stent (Figure 5A). The structural stiffness of specimens was 22.22±0.97 N/mm in the experiments, yield force was determined as 24.06±0.97 N. In contrast, LEP showed a much higher stiffness (34.25 N/mm) and yield force (30.22 N). The AVP model displays a stiffness of 19.56 N/mm and a yield force of 22.58 N.

Considering that the ability to describe multiaxial loads, varying load directions and viscoelasticity is inherently limited by the LEP models constitution, the results were plausibly deviating from experiments, despite matching test temperatures between the material model data and our experiments. In contrast, AVP model showed higher convergence until yield, but failed afterwards. Overall, the characteristics of the AVP model were in better agreement

with the experimental data. To emphasize the difference between LEP and AVP, both models were additionally used to simulate uniaxial tension and compression tests via FEA (Figure 5B).

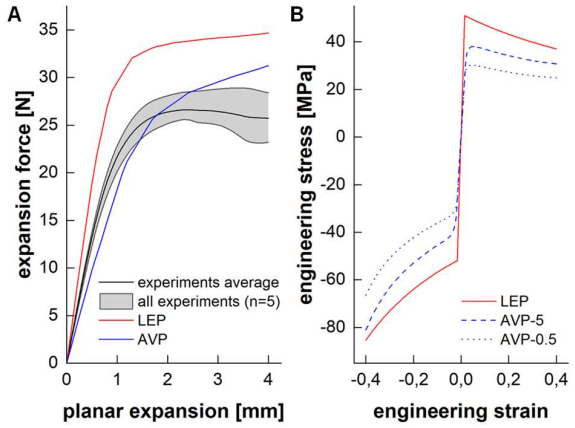

Figure 5: (A) Planar expansion experiments and FEA results of expansion simulation with LEP and AVP material models. (B) Mechanical characteristics of LEP and AVP material models in tension and compression. Crosshead speeds of 5 mm/min for LEP; 0.5 and 5 mm/min for AVP.

In summary, AVP showed considerably higher complexity and extended functionality, e.g. regarding strain rate dependency [6], but lacked accuracy in the plastic deformation state.

4 Conclusion

This study presents an approach for validating material simulations of polymeric stents using planar stent segment expansion. The method offers efficient mechanical behavior evaluation without extensive stent production.

Two material models were compared, while the LEP model provided acceptable results with overestimated stiffness and expansion force, the AVP model showed improved agreement with experimental data, especially until yield. These findings underscore the importance of advanced material models for accurate FEA simulations of polymeric applications. The planar stent segment expansion method offers a valuable tool for early-stage evaluation of stent materials and designs, potentially streamlining the development process for next-generation polymeric stents.

Future work should focus on improving mold surface quality, optimizing thermal protocols and stent designs to prevent strut fractures, expanding the experimental scope to include recoil analysis, and developing custom material models. Moreover, a detailed investigation of the applicability of the 2D results to 3D structures needs to be examined.

Author Statement

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