CONSIDERING MIXED EPISTEMIC AND ALEATORIC UNCERTAINTY IN THE STRUCTURAL VALIDATION OF A SAPIEN-3 TAVI FEM-MODEL

Nils Götzen (1), Omar Zahalka (1), Tahir Turgut (1), Salvatore Pasta (2), Vincent Bouwman (1)

1. 4RealSim Services BV, The Netherlands; 2. University of Palermo, Italy

Introduction

SimInSitu (EU-funded Project 101017523) is aiming to develop a patient-specific FSI-computer model, capable to predict the short- and long-term behavior of in-situ tissue engineered heart valve devices. Model credibility will be established based on a hierarchical development- and VVUQ-concept. The backbone of this platform is a Sapien-3 TAVI model, which is undergoing a tiered validation approach. Due to the limited availability of reliable Sapien-3 device specifications and in-vitro performance data, epistemic and aleatoric uncertainty play a crucial role during the model development and validation. Hence, a mixed UQ approach was implemented. We report here on the validation of the Sapien-3 FEM model considering structural in-vitro data.

Methods

A fully parametric FEM-model of the Sapien-3 TAVI device (Edwards Lifesciences) was developed in Abaqus Explicit for the sizes 23 & 26. All components, (stent-frame, leaflets, skirt, sutures, and balloon system) were considered. The VVUQ program was established in compliance with V&V-40. An exhaustive model verification was conducted, while the parametric approach allowed us to identify and select all relevant parameters for the uncertainty quantification.
The structural model validation was conducted independently for the leaflet- and the stent-component, considering their principal mechanical functions. For the stent frame load-case, the expansion behavior (recoil diameter) using the balloon catheter was considered as the comparator [1], while for the leaflet load-case (Figure 1), the deformation in the closed state under quasistatic loading was chosen [2].

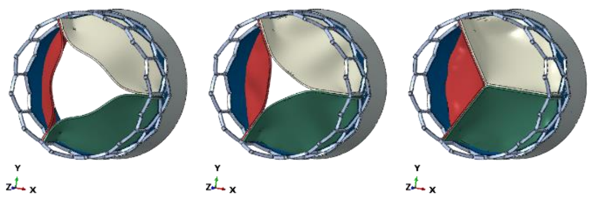

Figure 1: parametric Sapien-3 FEM model

Uncertainty propagation was conducted by means of a second order probability approach [3] and was implemented as a double-layer Monte-Carlo-Simulation (Figure 2). Individual metamodels were generated for both validation load-case models and both device sizes (Response-Surface-Models).

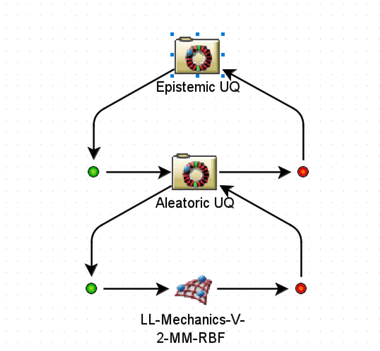

Figure 2: Nested Monte Carlo Simulation

Results

A small underestimation of the stent-frame expansion diameters was identified, while the leaflet-displacement was overestimated in general. The computed CDFs indicate for many output parameters a symmetric normal-like behavior while some stent-diameters show a very unsymmetric behavior, which could not be explained so far. The lower and upped bounds of the CDFs help to indicate the influence of the epistemic uncertainty.

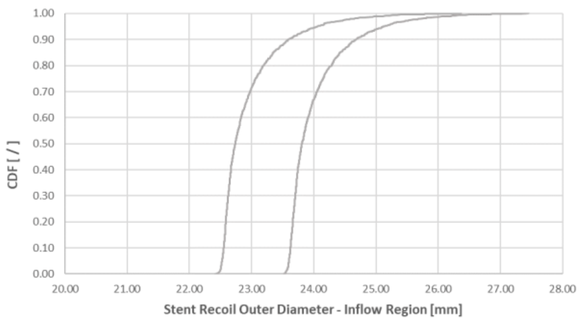

Figure 3: p-box for a stent diameter (lower and upper bounds for the CFD cohorts)

Discussion

The implemented mixed UQ approach is very helpful assessing the individual impact of the epistemic and aleatoric uncertainty.

References

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3. Eldred, M. S. & Swiler, L. P. Efficient algorithms for mixed aleatory-epistemic uncertainty quantification with application to radiation-hardened electronics. Part I, 2009.