3. UNCERTAINTY QUANTIFICATION IN THE VERIFICATION OF STENT COMPUTATIONAL MODELS

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SUMMARY

Computational analysis models, such as finite element analysis (FEA) and computational fluid dynamics (CFD), have been used widely in various industries to analyze critical product performance characteristics, such as fatigue life and safety factors. To apply these computational techniques, a set of input parameters are required, which may include geometry parameters, material properties, boundary, and loading conditions.

As all engineering and manufacturing processes are stochastic in nature, these input parameters all have built-in uncertainties. Manufacturing tolerances, as tight as they might be with modern precision manufacturing techniques, will affect the geometries of the computation models. Material properties may vary from one batch to another. This is especially the case for the new alloy and polymer materials, the properties of which are very sensitive to the fabrication conditions. Moreover, compared with geometry and material parameters, the boundary and loading conditions perhaps have many more variations depending on the in-work or testing conditions of the product. This is particularly acute in medical devices, in which quite often the in-work conditions reflect a relatively large range of physiological parameters. Therefore, having a single set of fixed input parameters neglects the uncertainties and will not be able to capture the distribution of performance characteristics as observed in physical testing or in-work condition. And thus poses challenge for validation and verification of computational models.

Monte Carlo simulation methods have long been considered the most accurate means of estimating the probabilistic properties of uncertain system responses resulting from known uncertain inputs. To implement a Monte Carlo simulation, a defined number of system simulations to be analyzed are generated by sampling values of random variables, following the probabilistic distributions and associated properties defined for each. Combining Monte Carlo simulation methods with computational modeling incorporates uncertainties in the input parameters and provides a more realistic stochastic view of computational modeling validation and verification.

In this study, using an analysis of an implantable stent as an example, uncertainties in boundary conditions, specifically dimensions and material properties of the blood vessel where the stent is deployed, and their effects on the computed fatigue life of the stent are simulated using Monte Carlo analysis. The example demonstrates how easy it is to incorporate probabilistic analysis in computational modeling verification and validation.