P72. Patient-Based Finite Element Medical Device Evaluation Tools

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Introduction: Finite element (FE) modeling is commonly used to evaluate medical device designs during various stages of the product development cycle. Real world bench top experiments are virtually modeled using FE to provide device designers with valuable data regarding design specifications and tolerances. While these bench-top FE simulations help guide the design process, they offer limited insight into the deployment behavior of the device in the intended patient population. Only through several iterations of prototype testing, clinical studies, and physician use does the device deployment behavior become more known. Extending the capabilities of early-stage FE modeling to virtual patient testing has great potential for improving the efficiency of product development and enhancing patient safety. Further, it provides new capabilities for tailoring a device to a specific patient population. In this study, we examine the accuracy of patient-based finite element modeling using commercially available stents and explore its potential benefits in understanding the influence of device design on deployment.

Methods: Two neurovascular devices were examined in this study: a neurovascular flow diverter and laser-cut stent. Device geometry was first reconstructed from 3D micro CT scans of the physical device and high magnification images. Tensile test data was then used to calibrate the computational material models of the devices. Bench-top FE simulations (e.g., device crimping and axial stretching) were compared to experimental measurements and, in some cases, theoretical calculations. The clinical deployment procedure was then modeled in EVIS (EndoVantage LLC, Scottsdale, AZ) and the devices were virtually deployed in rigid patient anatomies. Device apposition, porosity, and the unsheathing and deployment forces were calculated for each deployment simulation. The diameters of the virtually deployed devices were then quantitatively validated against physical deployments in urethane models of the same patient anatomies. Additional quantitative validations of the simulated deployments were also performed against post-treatment clinical data.

Results: Figures 1 and 2 show good agreement in device diameter between the simulated and physical deployments. Good agreement was also observed between the simulated and clinical deployments. Device apposition, and deployment forces were also found to be dependent on the curvature of the patient anatomy.

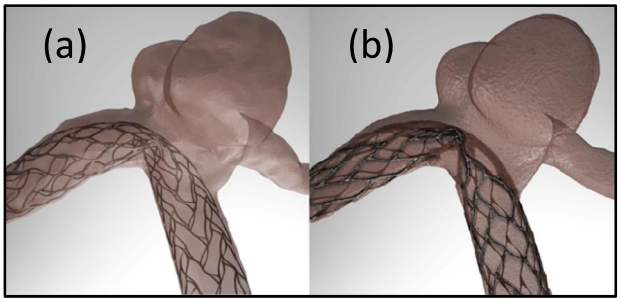

Figure 1: Simulated (a) and physical (b) deployment of a laser-cut stent in a patient model. The physical deployment (b) was scanned using micro CT.

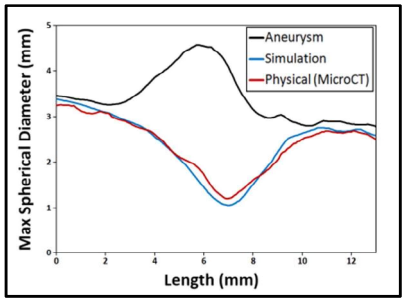

Figure 2: The maximum spherical diameter of the simulated and physically deployed stent along the length of the vessel centerline.

Conclusion: Patient-based FE modeling has great potential for understanding device deployment behavior earlier in the product development cycle. Simulated deployments showed good agreement with both experimental and clinical data. Deployment metrics such as apposition and unsheathing forces provided valuable data on the influence of patient anatomy on device deployment. The FE approaches utilized in this study also provide new capabilities for evaluating the suitability of a medical device in a specific patient before treatment.