Predicting Flow Diverter Deployments and Clinical Validation

Brian Chong[1,4], Haithem Babiker[1], Yashar Kalani[2], Carlos Baccin[3], Matthew Mortensen[1], Michael Levitt[2], Cameron McDougall[2], David Frakes[1,5], and Felipe Albuquerque[2]

[1] EndoVantage, AZ | [2] Barrow Neurological Institute, AZ | [3] Hospital Israelita, Brazil | [4] Mayo Clinic, AZ | [5] Arizona State University, AZ

Introduction: Flow diverters (FDs) are sized to the recipient vessel during pre-treatment planning. However, sizing can be challenging because of large changes in vessel curvature and diameter. Further, FDs can elongate by more than 50% of their labeled length after deployment, which complicates sizing. Significant complications can result from over- or under- sized devices. Here we present a finite element (FE) modelling approach for evaluating FD size and compare that approach to clinical deployments to determine its accuracy in predicting device length, diameter, and apposition.

Methods: Ten patient cases treated with the pipeline embolization device were acquired from two hospitals. Pre- and post- treatment CT image data were segmented then reconstructed to form computational models of the devices and vessels. A library of pipeline FE models, which was previously validated against physical devices, was used to simulate deployment of the same devices into the pre-treatment vessels. The pipeline models were first navigated via a virtual microcatheter to the landing zones observed in the post-treatment vessels. A "push-pull" algorithm was then used to simulate device unsheathing. Three post-deployment metrics were compared: device apposition to the vessel wall along the vessel centerline, device diameter along the stent centerline, and device length.

Results: Simulated and clinical deployments showed good agreement both qualitatively and quantitatively (Figure 1). Simulations captured regions where the device poorly apposed to the vessel wall and poorly covered the aneurysm neck. Mean errors between simulated and clinical deployments (as a percentage of the clinical value) were less than 5% for device length and 9% for device apposition and diameter.

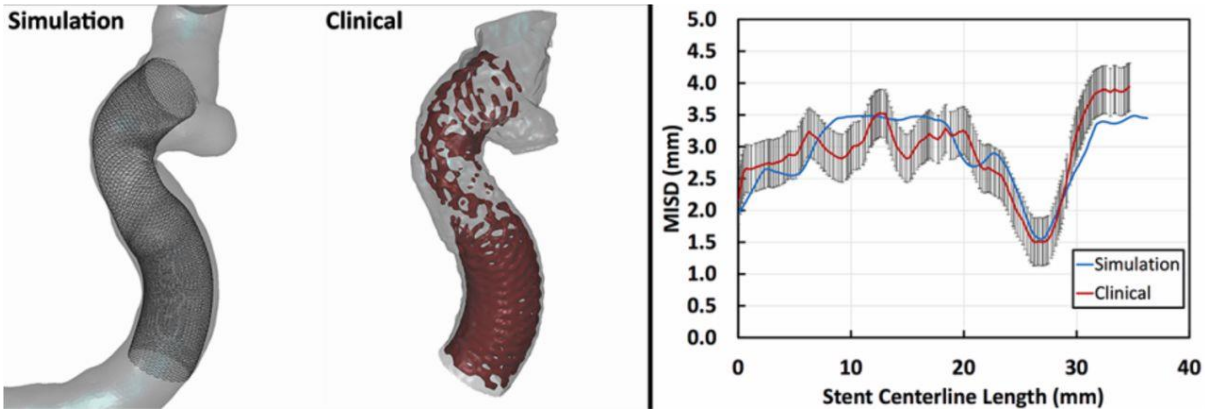

Figure 1: Simulated and clinical pipeline deployment

Conclusion: FE simulations captured post-deployment FD shape and apposition. Less than a 9% mean error was found between simulated and clinical deployment metrics. These results provide additional support for the use of FE for evaluating device size during pre-treatment planning.

References: [1] Babiker M. H., B. W. Chong, Y. Kalani, F. Albuquerque, and D. H. Frakes, "Patient-Based Finite Element Medical Device Evaluation Tools," presented at the BMES/FDA Frontiers in Medical Devices Conference: Innovations in Modeling and Simulation, Washington, D.C, 2015.