

## Clinical Validations of Simulated Neurovascular Braided Stent Deployments

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**Introduction:** Braided stents are increasingly being used for the treatment of cerebral aneurysms. Several studies have shown their effectiveness in treating a wide range of aneurysmal sizes. Nonetheless, proper device sizing remains a challenge. Braided stents can elongate by more than 50% of their labelled length, which complicates predictions of vessel coverage. Over- or under- sized devices can also lead to poor apposition and severe clinical complications [1]. In this study, we present a finite element (FE) modeling approach that can be used during pre-interventional planning to evaluate device size. The FE deployment approach was previously validated against in-vitro deployments in rigid urethane models. Here we present a follow-up study that compares FE and clinical deployments with the goal of determining the accuracy of simulated device diameters, lengths, and appositions.

**Methods:** Ten patient cases with pre- and post- treatment CT image data were acquired from two hospitals. The image data were segmented then reconstructed to form computational models of the devices and vessels. A library of FE braided device models was used to simulate deployment of the same sized devices into the pre-treatment vessels. The FE device library was previously validated against geometric and force-based measurements of physical devices. The device models were first navigated via virtual micro catheter to the landing zones observed in the post-treatment computational models. After navigation, device unsheathing from the micro catheter was simulated using a “push-pull” algorithm that mimics the clinical deployment procedure. Three post-deployment metrics were used for validations: device apposition to the vessel wall, device diameter, and device length after deployment. Apposition was defined as the percentage of vessel cross-sectional area covered by the device at each location along the stent centerline. Device diameter was calculated by determining the maximum inscribed spherical diameter (MISD) within the stent, at each location along the stent centerline. Errors between simulated and clinical post-deployment metrics were calculated then averaged over the 10 patient cases.

**Results:** Qualitative comparisons between simulated and clinical deployments showed good agreement, as shown in Fig. 1. Simulated deployments captured regions where the device stenosed or poorly apposed to the vessel wall and reproduced problematic scenarios where the device poorly covered the aneurysmal neck. Quantitative comparisons between simulated and clinical deployment metrics also showed good agreement, as shown in Fig. 2. Mean errors in the deployment metrics, as a percentage of clinical values, are provided in Table 1.

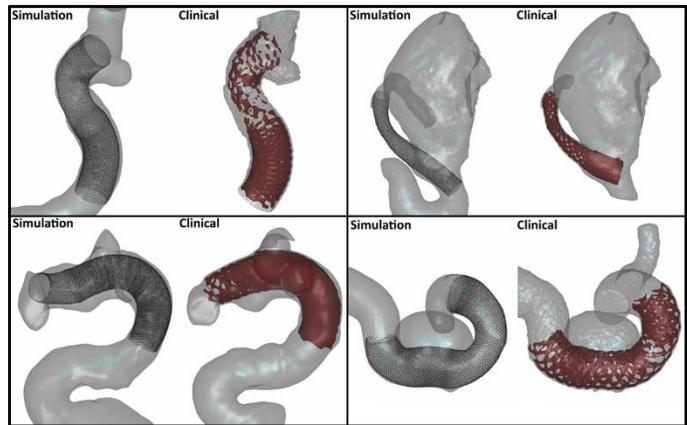


Figure 1: Simulated and clinical deployments for 4 cases

Table 1: Mean error between FE and clinical deployments

Post-Deployment Metric	Mean Error (%)
Device Diameter	8.7
Device Length	7.2
Apposition to Vessel Wall	7.9

**Conclusion:** FE simulations captured braided device shape and apposition after deployment. Less than a 9% mean error was found between simulated and clinical deployment metrics. These results provide additional support for the use of FE as a pre-interventional planning tool for device sizing or for virtual clinical trials.

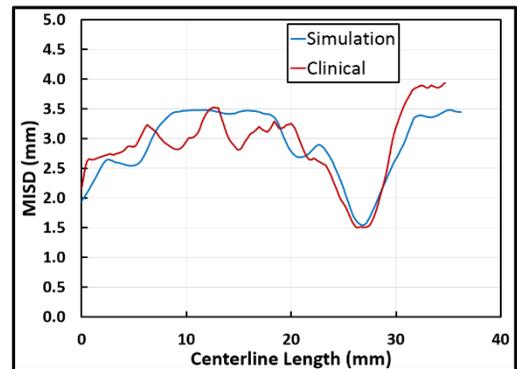


Figure 2: Example of simulated and clinical MISD profiles along the stent centerline

**References:** [1] N. Chalouhi, *Am. J. Neuroradiol.*, vol. 34, no. 12, pp. 2326–2330, Dec. 2013.