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Validated Simulation Model for Evaluating Radial Force of New Stent Design

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Introduction

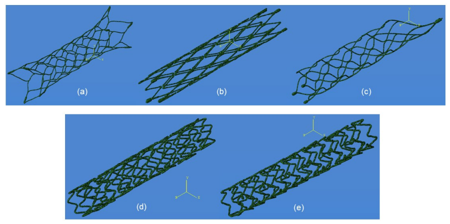
While radial force (RF) is an important mechanical property used in designing stents, high RF is associated with complications such as in-stent stenosis, an exuberant inflammatory response, or thrombosis [1]. In contrast, low RF leads to poor support of artery which may increase the risk of thrombosis and stent migration in the artery [2].

Since there are no standards which determine the maximum and minimum RF for designing the stent, the best references we have are commercially available stents. Thus, the aim of this study is to establish a validated simulation method for evaluating the RF of commercial stents.

Methods

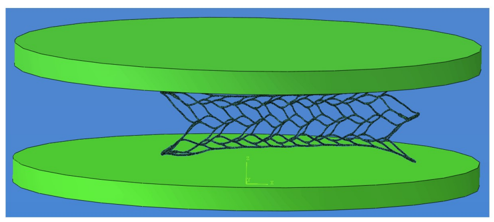
Three self-expandable intracranial (Neuroform (open-cell), Enterprise and Solitaire (both closed-cell)) stents and two balloon-expandable cardiac (Integrity and Multi-Link) stents were selected for RF testing. Stents were scanned using micro CT and DICOM images were obtained. Three-dimensional finite element models were then constructed using Simpleware software (Figure 1). The RF was simulated by compression of the stent between two plates using ABQUS software (Figure 2). Simulation results of self-expandable stents were verified by experimental testing using an ElectroForce® Load Frame Systems 3200 machine (Figure 3).

Figure 1



3D FEA model of commercial stents a) Enterprise, b) Neuroform, c) Solitaire, d) Integrity and e) Multi-Link.

Figure 2

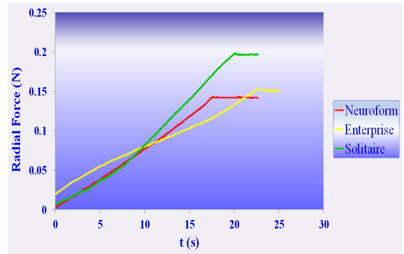


Simulation of the radial force by the plate-to-plate method.

Figure 3

BOSE ElectroForce® Load Frame Systems 3200 Product.

Figure 4



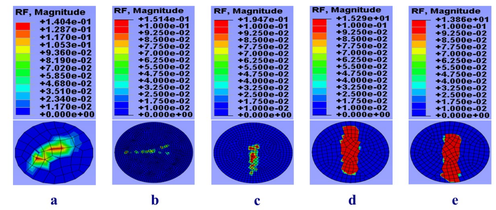
Experimental results of the radial force by the plate-to-plate method for Neuroform, Enterprise and Solitaire stents.

Results

The RF (in Newton, N) of the Neuroform, Enterprise, Solitaire stents was determined to be 0.142 N, 0.150 N, 0.196 N, respectively, by compression between two plates to 50% of the stent diameter experimentally (Figure 4). By comparison, the simulation results demonstrated the RF to be 0.140 N, 0.151 N, 0.195 N and for Integrity and Multi-Link1to be 15.3 N and 13.86 N, respectively (Figure 5).

When comparing balloon-expandable vs. self-expandable stents, the balloon expandable stents had a much higher RF. When comparing self-expandable open-cell and closed-cell stents, the closed-cell had a slightly higher RF.

Figure 5



Simulation results of the radial force by the plate-to-plate method, Radial force (in Newtons) was obtained from the maximum reaction force on the inner surface of the top plate. a) Neuroform, b) Enterprise , c) Solitaire, d) Integrity and e) Multi-Link.

Conclusions

These studies have shown that simulation results of radial force testing are in excellent agreement with experimental results for self-expandable stents.

Learning Objectives

This study can be employed in future studies in order to decrease cost of the stent designing process.

References

1. Julian Bedoya et al., Journal of Biomechanical Engineering, 2006, 128:757-765.

2. A. García, E. Peña and M.A. Martínez, Journal of the Mechanical Behavior of Biomedical Materials, 2012, 10:166-175.