Final Defense

PhD Course in Bioengineering – Final Thesis Defense

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Advisor: Prof. Giancarlo Pennati
Co-advisor: Prof. Lorenza Petrini

12.05.2021
h. 15:30
@ Microsoft Teams

Thesis: Computational methods for cardiovascular self-expandable stent-like devices

COMMITTEE MEMBERS

Prof. Sanjay Pant	Prof. Florent Budillon	Prof. Gianfranco Beniamino Fiore
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SCHEDULE OF THE DAY

15:30 - 15:40	Committee Meeting
15:45 - 16:45	Thesis presentation - Discussion
16:45 - 17:00	Committee meeting
17:00	Award Ceremony

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Final Defense

PhD in Bioengineering

POLITECNICO MILANO 1863

PhD student: ZACCARIA ALISSA – XXXIII Cycle

Thesis title: COMPUTATIONAL METHODS FOR CARDIOVASCULAR SELF-EXPANDABLE STENT-LIKE DEVICES

Advisor:	Prof. Giancarlo Pennati (CMIC) Prof. Lorenza Petrini (DICA)

Abstract:

The present work is focused on the computational modeling of cardiovascular self-expandable devices, deepening the implementation and validation processes, designed based on the intended context of use and the related accuracy requirements, computational cost and time constraints.
Chapter 1 illustrates the investigation subject, providing an overview of the cardiovascular system and the endoprosthesis used to treat the related pathologies, focusing specifically on self-expandable technologies involving both superelastic materials and particular designs such as braided structures. Following, concepts behind computational models, including standard finite element simulations and simplification strategies reported in the literature, are illustrated. The subsequent chapters present different modeling techniques based on three main investigation scenarios: design, testing and pre-operative planning. While the first two scenarios, design and testing, aim to support manufacturers during the definition of innovative stents or the assessment of prosthesis functionalities before commercialization, the models concerning pre-operative planning aim to provide clinicians support tools to identify the best device and implant condition based on patient specificities. Concerning scenarios related to manufacturers, if the design phase may benefit from a simplified but fast screening tool able to identify the suitable design parameters among several possibilities, the testing process requires a sophisticated model that can provide accurate information on the safety and efficacy of the investigated device. Chapters 2 and 3 refer to testing issues. The findings of these sections are then exploited in chapter 4 to validate the proposed design tools. II The second chapter deals with finite element modeling of braided stents, widely used endoprosthesis for which few numerical studies have been published so far. This section does not answer a specific need but illustrates and motivates the finite element approach adopted for braided stents in the subsequent chapters. The drawing method is outlined, and different contact strategies proposed in the literature are compared. The selected modeling approach is then applied and validated through the comparison with real polymeric braided stents. The content of this chapter was included in the manuscript "A. Zaccaria, F. Migliavacca, G. Pennati, and L. Petrini, Modeling of Braided Stents: Comparison of Geometry Reconstruction and Contact Strategies", published in the Journal of Biomechanics, in 2020. Chapters 3 and 4 took origin from the collaboration with ID NEST Medical (Strasbourg, France), provider of an innovative system currently in the trial process. The investigated device, ID Venous System, is a complex prosthesis, consisting in two interacting devices, a laser cut frame and a braided component, coupled through a compliant clip. The development and validation of the in silico model used for the testing purpose are illustrated in chapter 3. In this case, the feasibility of the system deployment needed to be assessed. Thus, an accurate model was required to corroborate experimental results providing insight on the stress to which the device is subjected during

the crimping and deployment procedure. Both the implementation and validation are illustrated. In particular, the validation account for several different tests of increasing complexity designed for the question at issue. The content of this chapter was included in the manuscript “A. Zaccaria, F. Migliavacca, D. Contassot, F. Heim, N. Chakfe, G. Pennati, and L. Petrini. Finite element simulations of the ID Venous System to treat venous compression disorders: from model validation to realistic implant prediction”, published in the Annals of Biomedical Engineering in 2021.

III The fourth chapter takes advantage of the model illustrated in the section above and aims to provide manufacturers with analytical tools to support the preliminary design phase. The method is focused on braided devices and can predict the diameter variation range and the radial rigidity, also when complex design features are involved (multiple twists or looped ends). In this case, the more sophisticated and previously validated finite element model was used for the validation. The content of this chapter was included in the manuscript “A. Zaccaria, G. Pennati, and L. Petrini. Analytical methods for braided stents design and comparison with FEA”, submitted to the Journal of the Mechanical Behavior of Biomedical Materials in 2021. Regarding clinicians, accurate but fast models are needed to compare the commercially available devices and different implant conditions without delaying the demanded therapy. Chapters 5 and 6 focus on this need. These sections took origin from the collaboration with the BioCardioLab (Massa, Italia) and aim to build and validate models suitable to support pre-operative planning of the left atrial appendage occlusion. Chapter 5 describes a laser-cut device, named Watchman, validating both the stand-alone stent behavior and its interaction with external surfaces during the crimping and deployment procedure. The final model can predict in a relatively short time the deployed configuration in patient-specific anatomies. The content of this chapter was included in the manuscript “A. Zaccaria, F. Danielli, E. Gasparotti, B. M. Fanni, S. Celi, G. Pennati, and L. Petrini, Left Atrial Appendage Occlusion Device: Development and Validation of a Finite Element Model”, published in Medical Engineering and Physics in 2020. Chapter 6 is focused on a braided device, Amplazter Amulet, for which a standard modeling approach would require prohibitive computational resources. Thus, in this chapter, a simplification strategy is illustrated. The simplified and realistic models are compared with experimental tests on the stand-alone device.