Journal of Medical Devices

Guest Editorial

Special Issue: Cardiovascular Device Development and Safety Assessment Using Computational Modeling and Experimental Approaches

Cardiovascular devices interact with a complex physiologic environment that can severely challenge device performance and longevity. These challenges include biocompatibility issues such as hemolysis and thrombosis, changing contact conditions during each heartbeat, high-cycle fatigue-to-fracture, the need to accommodate the highly variable geometric, material, and hemodynamic environment encountered in the target population, and many other design and performance concerns. Simultaneously, cardiovascular devices are expected to deliver improved therapeutic benefits with each new product release. Thus, the cardiovascular device industry increasingly relies on computer modeling as a controlled and repeatable methodology for assessing device design-related factors. This allows reduction in number of in vitro, ex vivo, and in vivo experiments, leading to decreased expense. Clinicians are also adopting computer modeling as a pre-interventional planning tool that can confirm (or reject) a diagnosis, assist with surgical planning, and optimize treatment outcomes. And regulatory bodies are looking to computational modeling and improved in vitro testing to help ensure the safety and efficacy of approved devices.

It is therefore a great pleasure to introduce this special issue of the *Journal of Medical Devices*, which presents some of the latest advancements in the use of computational and experimental methods to support the in vitro and in vivo evaluation of cardiovascular device performance. The contributions naturally reflect a heavy concentration on implanted devices, which present the greatest challenges to industry today. The tools used in these studies range from computational (e.g., fluid dynamics and finite element) to clinical (e.g., medical imaging, segmentation, and statistical shape analysis) to experimental. An overview of the use of computational modeling tools throughout the lifecycle of a peripheral vascular device, including the regulatory review process, is also provided.

As Guest Editor, I would like to thank all the authors and co-authors for entrusting us with the publication of their original research. Over 30 full-length research papers and technical notes were submitted to the special issue, 16 of which were accepted for publication at the end of the peer-review process. And my sincere thanks to all the reviewers, without whose significant time and effort we would not have such a high-quality collection of papers. And a very special thanks to Editor and Professor Rupak Banerjee, who provided significant guidance (and patience) over the past several months. I would also like to thank the ASME editorial staff for their invaluable assistance in bringing this issue to fruition. I hope everyone involved in this process is as pleased as I am with the resulting issue.

Finally, I would like to recognize the six co-authors: Arthur Erdman, Barney Klamecki, Steve Deline, Benedetta Biffi, Taoming Liu, and Leonardo Angelone, who presented a summary of their manuscript during a session devoted to this special issue at the 2017 Design of Medical Devices Conference in Minneapolis, MN. It was a great honor to provide the opportunity to share your research with the medical device community. This session was a highlight of the computational modeling track at DMD.

And so, without further ado, enjoy reading this special issue.

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