7th International Conference on Computational and Mathematical Biomedical Engineering – CMBE2021
28–30 June 2021, Italy
P. Nithiarasu, and C. Vergara (Eds.)

COMPUTATIONAL APPROACH TO DESIGN, ANALYSIS AND BIOFABRICATION OF IMPLANTS

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MINI-SYMPOSIUM PROPOSAL

Keywords: *Computational approach, Implants, Biofabrication, Mechanical design and simulation, Computational Fluid Dynamics, Microstructure design and analysis, 3d printing, bioprinting.*

1 BACKGROUND

Implants have revolutionized the treatment of human diseases and treatment such as bone fracture, repair of repair of bronchus, tracheomalacia, stenosis, aneurysm, dissection, deep vein thrombosis, tracheostenosis, valve replacement and inferior vena cava (IVC) filters, etc. Currently, several approaches for improving implant design, analysis and biofabrication technology have been conducted, such as computational simulation, biodegradable dynamics modeling & analysis, microstructure design optimization, 3D printing or bio-printing, micro-fluids chips and so on. However, improvement in clinical outcomes still requires detailed evaluation of the performance of implants biomechanics and the effectiveness as well as safety of biomaterials aiming at optimization of treatment. Computational modeling offers an efficient framework and indispensable information for analyzing and understanding the parameters that influence the success of implants and for investigating in silico multiple “What if?” scenarios using finite element analysis (FEA) and computational simulations. For many years, computational modeling and simulation (CM&S) studies have been used by sponsors to support device design/development and have been reported in medical device submissions. In 2016, FDA issued a report on reporting of computational modeling studies in medical devices submissions, which means computational modeling and simulation (CM&S) was identified as one of the most tools. The purpose of this guidance document is to provide recommendations to industry on the formatting, organization, and content of reports of CM&S studies that are used to support medical device submissions. Moreover, this guidance is also for FDA Staff, to improve the consistency and predictability of the review of CM&S studies and to better facilitate full interpretation and complete review of those studies. For the next stage of surgical planning, implants design, analysis and bio-fabrication issue should be included. This mini-symposium presents the current knowledge on implants design and analysis, biodegradable dynamical simulations as well as microstructure optimization, fatigue analysis, 3D printing focusing on the insights from computational modeling approaches.

2 MAIN FEATURES OF THE MINI-SYMPOSIUM

- Considering the state-of-the-art studies of implants via multi-disciplinary, multiscale and multi-timespan approaches.
- Focusing on the computational modeling of each approach.
- Aiming at the clinical issues of medical implant and intervention devices.

• Focusing on the design, analysis and bio-fabrications of implants, including but not limited to 3D printing and bioprinting.

3 SCOPE OF MINI-SYMPOSIUM

The general scopes of this mini-symposium are the investigation of the several factors associated with implants performance and clinical outcomes, such as the mechanical and microstructure optimization and bio-fabrication, the design and analysis, etc. For example, the scopes of mini-symposium are as follows but not limited to:

• Modeling the material properties and fabrication of implants, drug eluting stents (DES) and biodegradable implants

• Design and develop more comprehensive multi-physics and multi-disciplinary models.

• The optimization of the structure design and placement of implants considering the multimodal loading of combined bending, torsion, and compression under different implantation conditions.

• Modeling the compatibility of implants with regards biomechanical behavior, flexibility, high radial strength, durability, and corrosion resistance.

• The modeling of corrosion damage and degradation mechanism for bioresorbable polymer and bioresorbable metallic alloys, and the optimization of combination of materials and properties.

• The customization of dosage and elution kinetics for improving the therapeutic effect and eliminating the side effects, and the control of the corrosion rate of the implants coating influencing both biocompatibility and drug release.

• Optimization, 3d printing & bioprinting of bone scaffolds, vascular intervention devices etc.

• The fundamental interactions between the implants, the host tissue morphology and remodeling around the struts for prediction of devices safety and efficacy.

• The advanced and novel imaging modalities, such as intracoronary optical coherence tomography (OCT) and magnetic resonance imaging (MRI), for more realistic computational models of implantation & intervention.

• The CM&S for developing standards, and protocols to evaluate the safety and the efficacy of implantable biomedical products.

• Computational algorisms based on medical big-data and artificial intelligence.

4 THE SPEAKERS FOR CALL FOR PAPER

Organizers of the mini-symposium will consider the following recommendations when selecting speakers in the mini-symposium:

• Speakers should be selected for their current research contributions to the chosen topic area.

• Speakers from international research groups are encouraged to present their work.

• Speakers who can provide an overview of the topic area, and bring new ideas for continued research and application are also welcomed.

5 PROGRAM PROPOSAL

• At least 9 regular talks will be presented, and each talk may be for 15 min.

• One ‘session keynote’ will be organized, and the keynote will be for 25 min.

• At the end of symposium, 30 minutes of round-table discussion will be arranged which is opened for all participants.