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Plenary Lecture

COMPUTATIONAL MODELLING TO ADVANCE UNDERSTANDING OF HOW MEDICAL DEVICE DESIGN INFLUENCES THE CELLULAR BIOPHYSICAL ENVIRONMENT

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Summary: Conventional design and development efforts for medical devices largely focus on establishing biological compatibility and mechanical stability of the devices. However, biological cells and tissues respond to these biophysical stimuli imposed by medical devices by activating mechanobiological processes that can dictate cell and tissue regeneration or cell death. These responses dictate post-surgical healing and long-term performance of implanted devices, but remain poorly understood. Although computational models are widely used to predict device performance for regulatory purposes, these have not yet adequately accounted the biomechanical environment presented in vivo and how the presence of the device alters this environment. Specifically, the native geometry, tissue properties and complex multi-physics environment are critical to the interaction between biological tissues and medical devices, but are often neglected. Our research seeks to develop advanced computational modelling platforms to analyse the biophysical stimuli imposed by medical device on cells and tissues, to enable preclinical assessment of the performance of medical devices. A particular focus of our research has been to study transcatheter aortic valve replacement (TAVR) devices used to treat aortic stenosis. Although TAVR devices are widely used, there are still procedural complications associated with conventional devices that must be overcome. In particular, paravalvular leakage, interferance with the normal conductance valve migration and plaque cavitation leading to stroke can arise. These have been proposed to be associated with variances in patient anatomies, device design, malpositioning or incorrect sizing. The mechanical disturbances presented by the device likely activate biological responses in the native environment. However, there is a lack of understanding regarding the optimal positioning and appropriate sizing of TAV devices for particular patient cases to account for and mitigate such responses. Patient-specific modelling approaches allow for the reconstruction of the individual patient anatomies to predict the tissue stress after device implantation *in-vivo*. In our research we have developed realistic aortic root models by segmenting Multi-Slice Computed Tomography (MSCT) images of TAVR patients, and used these to develop finite element models of the device implantation procedure. We have applied these patient-specific models to study tracking and deployment forces during TAVR implantation, and also to investigate the design and deployment conditions associated with conductance interference and paravalvular leakage. We also strive to provide an advanced understanding of surgical devices, which provide access to organs and joints of the body and enable surgical procedures on biological tissues. Surgical drills and electrosurgical tools can induce elevated temperatures (> 100°C) in the surrounding tissue and cells, which can lead to cell death by either necrosis or apoptosis and activate cellular responses in the remaining cells. Depending on the extent of the cellular thermal damage, cells in the damage vicinity will be either removed or recover, and this delays the healing process. Our research develops multiphysics computational models to investigate the relationship between surgical device design, operating conditions, and tissue properties and how these influence thermal elevations and the likelihood of cellular damage. This digital evidence can inform early device development and regulatory evaluation of medical devices.