

International Conference on Clinical Trials

July 27-29, 2015 Orlando-FL, USA

Pre-surgical hemodynamic planning of reconstructive congenital heart surgery- Design of clinical trials to asses image-guided pre-surgical planning

Kerem Pekkan¹ and Tijen Alkan Bozkaya² ¹Koc University, Turkey ²Koc University Hospital, Turkey

pproximately 1 in 100 children are born with a clinically significant and complex congenital cardiac defect representing 47,000 $oldsymbol{\Lambda}$ children each year in the EU and 1,500,000 children worldwide. In order to survive, these patients usually require at least 2 or more consecutive open-heart surgery stages. During these surgical stages, the abnormal great vessel anatomy is reconstructed in three-dimensions using native tissue and artificial materials. Achieving optimal blood flow distribution (hemodynamics) through the reconstructed surgical pathway is essential for healthy multi-organ physiology (cerebral, pulmonary, renal and gastrointestinal systems) which in turn will result improved post-operative quality-of-life and neurodevelopment. Unfortunately it is not possible for the surgeon to guarantee the best flow-split unless a sophisticated bioengineering analysis is performed for each patient. This analysis leads to a patient-specific hemodynamic performance report where numerical values for several hemodynamic parameters are computed and include the systemic to pulmonary flow split, pulsatile flow quality indices and flow-based vascular reactivity maps and systolic to diastolic pressure ratios. Through this approach a large number of surgical configurations can be analyzed for each patient in the computer before in vivo execution. In the present talk, we will discuss this procedure through case studies, validation tests and recent developments featuring its applicability. We will highlight the challenges of designing a clinical trial to prove the benefit of this simulation-based approach which includes scaling problems due to patient-size and cardiac output, complex sensitivity analysis of a large number of parameters. Finally we will propose a clinical research study design that can prove the efficacy of the proposed hemodynamic analysis technique for complex congenital heart cases. Thus better quality and longer life expectancy might be presented to many complex congenital heart patients with these efforts.

Biography

Kerem Pekkan is an Associate Professor at Koc University Biomedical and Mechanical Engineering Departments. He is trained at Middle East Technical University, Purdue University and Georgia Institute of Technology. He studies congenital heart defects, embryonic fluid mechanics, cardiovascular biology and developing bioengineering tools for pre-surgical planning of complex cardiovascular reconstructions. Computational arm of his research involves the development of multiscale computational tools to optimize vascular systems, neonatal devices and novel micro-imaging protocols. He has authored over 70 peer-reviewed manuscripts and holds three US patents. He is the Associate Editor of *Artificial Organs and BMES Cardiovascular Engineering and Technology journals*. He is supported through NSF CAREER, AHA, NIH and ERC awards.

dr.tijenalkan@gmail.com

Notes: