QME
Qualified Medical Engineer

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Design of a CFD workflow to predict & assess XABG device performance

Xeltis bv

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Coronary Artery Disease (CAD) is a cardiovascular disorder which is characterised by atherosclerotic lesions or occlusions of the coronary arteries. The formation of these plaque depositions - which often happen in more than one of the coronary arteries of affected patients - causes a mismatch between the oxygen demand of the myocardium and the capability of the body to supply it, introducing the risk of a heart attack. Every year in the US, approximately 805,000 people suffer a heart attack. Treatment options for CAD depend on the clinical setting, number and location of coronary lesions, and stenosis severity. One of the treatment options is a Coronary Artery Bypass Graft (CABG), in which a blocked or narrowed coronary artery is bypassed with another vessel. The golden standard is to use the LIMA artery; however, patients require 3 bypasses on average. Since a patient only has 1 LIMA artery, the other bypasses are performed by harvesting the Saphenous Vein from the leg, however this comes with a few disadvantages. The massive wound and scar-tissue decrease quality of life, as well as the harvesting site has a 1-4% infection rate.

Therefore, there is a clinical need - as well as a massive market opportunity - for an off-the-shelf CABG. Xeltis (Eindhoven, The Netherlands) has developed a restorative, small (4 mm) diameter, off-the-shelf CABG, branded the XABG (Xeltis CABG) and is currently partaking a First in Human trial. Preliminary results of this FIH study have been inconsistent, however. Some of the patients have had occluded XABG devices within the first 30 days of implant, whereas other patients have had excellent patency at 30 days follow-up. One hypothesis is that the current clinical protocol of Xeltis for patient trials lacks information on both the pre- and post-operative condition of the patient. To increase efficacy of the trials and improve patient safety, a new workflow including predictive and evaluative computational models will be designed. More specifically, it is the aim of this design project to design a workflow which will result in a flow prediction through the graft pre-operation, as well as create a more detailed (3D) CFD model which will supply essential information about the performance of the device after implant.

To meet these objectives two models were created. One to predict the flow through the XABG before it was actually implanted, for which a physiological model was used which has been developed at the TU/e. This model required the 3D locations of the coronary arteries and since these patients only receive angiograms at that stage of the clinical workflow, a reconstruction algorithm had to be written, which reconstructs the coronary arteries in 3D space based off 2 2D angiograms.
Secondly, a 3D CFD model was created which computes critical hemodynamical parameters related to the device performance.

A first prototype of this tool has successfully been made. With this first prototype, a proof-of-concept of the methodology was demonstrated on a cardiac phantom. Firstly, angiograms of this phantom were made. Then, with this new tool the coronary tree was reconstructed, a stenosis and a CABG were added and flows and pressures were calculated through the system. This first iteration showed great potential in offering extra, crucial information prior to implant which would aid Xeltis in patient selection. The reconstruction of the coronary tree from cardiac angiograms became a central element of this project and due to the clinical workflow of CABG patients it is a great foundation to build on for future projects.
An idealised - yet applicable - geometry of a coronary anastomosis was used to show and apply the capabilities of CFD to asses the performance of the XABG device. The model calculates and visualises carefully selected hemodynamical output metrics which relate to the performance of the device, offering a platform to analyse the device's performance.