Efficacy study of CT-FFR software using 3D printed patient-specific coronary phantoms

By Dr LM Shepard, Dr. KN Sommer, Dr. E. Angel & Prof CN Ionita

In the last decade 3D printing has made significant technological advances which have catalyzed acceptance and the development for a various health related applications, including development of comprehensive patient-specific coronary phantoms that mimic some of the tissue mechanical properties while being capable of sustaining physiological flow and pressure conditions. In this article, we present a summary of a more extensive study where patient-specific phantoms were used for CT cardiac imaging, flow measurements and validation of a research level CT-FFR software currently being devloped by Canon Medical Systems.

In recent years, 3D printing has become an invaluable tool in many medical applications. These include surgical planning, structural disease simulations, and device testing [1]. This technology provides the capability to replicate complex patient anatomy and diseases. These phantoms can be used in both benchtop flow systems and can be imaged according to patient protocols, making this tool particulalrly useful for validation of image-based diagnostic software. Thus for technical efficacy studies, 3D printing can save significant time in the validation process by reducing the wait time needed for medium or large patient cohorts. In addition, highly controllable physiological measurements can be obtained using 3D printed patient-specific phantoms in benchtop flow systems.

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This work expands upon recent applications of 3D printed patient-specific coronary phantoms within a physiological benchtop flow system for accurate CT imaging of coronary blood flow [2, 3].

In our paper titled "I*nitial evaluation of three-dimensionally printed patient-specific coronary phantoms for CT-FFR software validation*" [4], we investigated the technical efficacy of using 3D printed patient-specific coronary phantoms to assess a CT-FFR research software (Canon Medical Systems, Otawara Japan). Using CT imaging, the 3D printed phantoms were successfully imaged using the patient coronary CT angiography (CCTA) protocol and were implemented in the CT-FFR software to assess the accuracy of replicating the patient results. The accuracy of the phantoms was verified using measurements from the CCTA images and benchtop assessment of Fractional Flow Reserve (FFR) for comparison with the reference invasive FFR measurement. This research thus verifies the use of 3D printed patient-specific phantoms as an invaluable tool for highly controllable benchtop experimentation and imaging for validation of image-based diagnostic software.

MATERIALS AND METHODS

Patients included in this study gave written and informed consent following IRB approval. All patients underwent clinically indicated 320-detector row CCTA followed by coronary catheterization that included invasive FFR measurement. The CCTA patient data was automatically segmented using a Vitrea workstation (Vital Images, Minnetonka, MN) to include the aorta, left anterior descending (LAD), left circumflex (LCX), and right coronary artery (RCA); contours were reviewed and edited as needed. The coronary vasculature was manipulated into a previously reported three branch approach [5] to create a phantom capable of

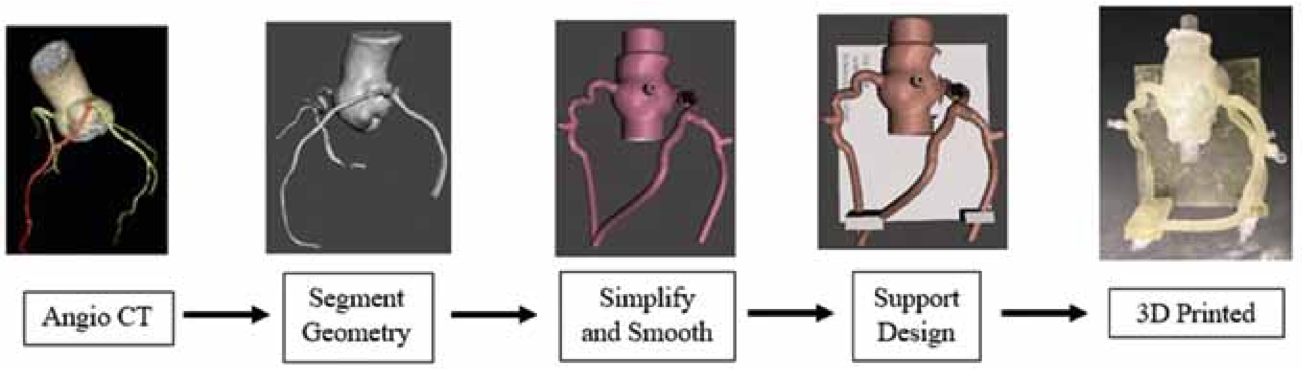

Figure 1. The five key steps in phantom design process, starting with CT angiography images from the patient, segmentation of the desired geometry, simplifying and smoothing of vasculature, designing a support for the vasculature and appending it, then finally 3D printing the phantom

undergoing physiologically accurate simulated flow and pressure conditions. The phantom creations steps are outlined in Figure 1.

Each phantom was established in a flow loop that simulates pulsatile flow rates mimicking those seen in the coronary arteries using a CompuFlow 1000 programmable physiological flow pump (Shelley Medical Imaging Technologies, London, Ontario, Canada). Each phantom had pressure sensors appended to the aorta and three coronary arteries using access ports that were created in the mesh manipulation to ensure each phantom was undergoing physiologically accurate pressure conditions. Once physiological flow conditions were achieved, the patient-specific phantoms underwent 320-detector row CCTA (Aquilion ONE, Canon Medical Systems), triggered during the 70-99% R-R cycle by the CompuFlow 1000 flow pump. Figure 2 demonstrates one of the phantoms in the CT gantry and CCTA images.
Both the patient and phantom CCTA images were then utilized in a CT-FFR algorithm that is currently an on-site research tool (Canon Medical Systems). CT data between the 70-99% R-R cycle is imported into the software to calculate CT-FFR. Details regarding this software have previously been published [6]. An example of patient data in the CT-FFR software is shown in Figure 3.

RESULTS

Pressure measurements were collected during flow experimentation to determine the benchtop FFR, defined as the ratio of distal to proximal pressure. The benchtop FFR results were compared to invasive FFR as well as the CT-FFR measured for both patient and phantom images. All FFR values were measured at approximately the same location as the invasive FFR, about two lesion lengths below the distal end of the stenosis. Results showed agreement for treatment outcome in all cases except for one case measured in the phantom CT-FFR. Pearson correlation values for invasive FFR to patient CT-FFR and to phantom CT-FFR were both 0.92. In addition, the patient CT-FFR and phantom CT-FFR had a Pearson correlation value of 0.95.
In addition, CT-FFR was recorded at 10 mm increments from the ostium of each coronary artery, with a range from 10 mm to 100 mm in patient and phantom CT data. The Pearson correlation for all patient's CT-FFR and phantom CT-FFR values was 0.81 and the absolute mean percent difference was 4.34%. Figure 4 displays the comparison of all CT-FFR results for the three main coronary arteries as well as a line of unity.

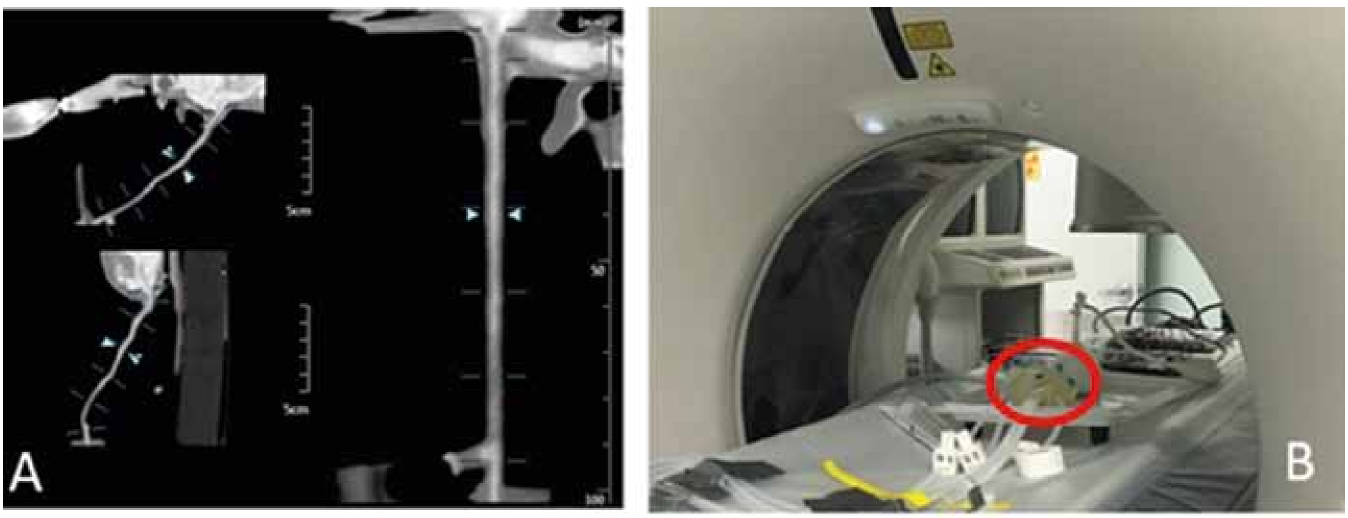

Figure 2. Phantom CCTA images of LCX (A) and phantom, outlined in red, in Aquilion ONE scanner for CCTA image acquisition.

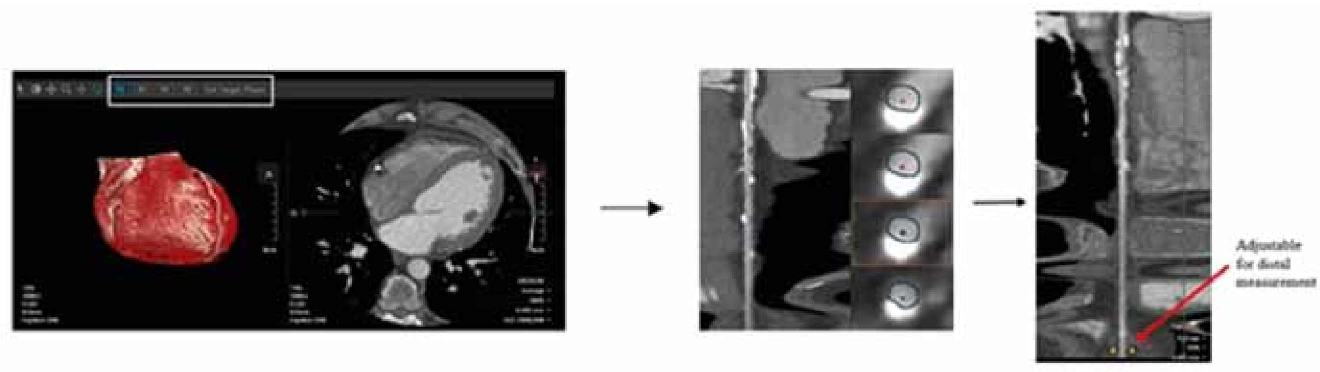

Figure 3. CT-FFR research software utilized for this research, patient data. Viewing imported images from 70-99% R-R and selecting the phase with the least amount of motion as the target phase (left image). Generation of centerline and contours (middle image). CT-FFR measurement with user control for distal measurement location indicated (right image).

CONCLUSION

We have expanded upon previous research using 3D printed patient-specific phantoms to develop a system that utilizes these phantoms with physiological flow and pressure conditions for successful imaging to simulate coronary CT angiography. We have presented the accuracy of 3D printed patient-specific phantoms produced using the current state of the art. As the temporal and spatial resolution of CT scanners and the print resolution of 3D printers continue to advance, we anticipate this accuracy will continue to improve.

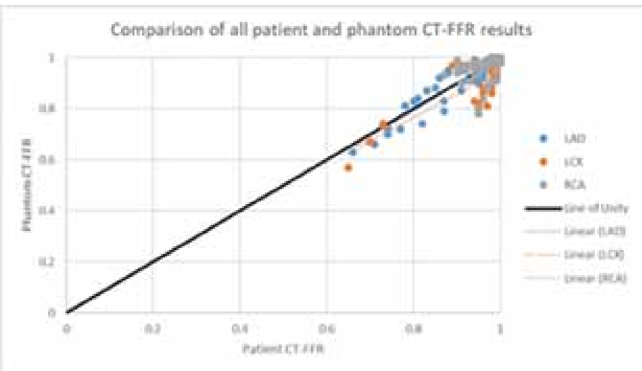

Figure 4. Comparison of all CT-FFR results for both the phantom and the patient.

3D printing offers a unique benchtop solution as patient-specific phantoms can be created that replicate the mechanical and elastic properties of vasculature. We have demonstrated the capability of our patient-specific phantoms to undergo clinical CT protocols and be utilized within a CT-FFR software. While the phantom accuracy and mechanical behavior of the phantoms can continue to improve, this is an important first step towards using 3D printed patient-specific phantoms for software validation. As medical 3D printing continues to improve, we believe these patient-specific phantoms within benchtop flow systems can become a standard tool for validation of not only a CT-FFR software, but any image-based diagnostic software.

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Book Review

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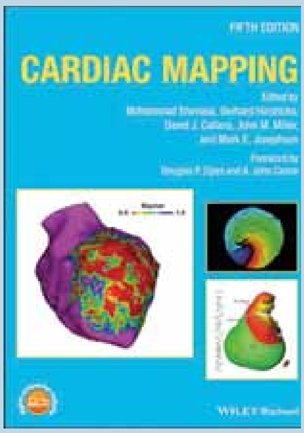

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