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Original Research

Development of an Educational Application of Multimodal Imaging of Clinically Implanted and Bifurcation Stenting Procedures

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ABSTRACT

Background: Today, the implantation of stents is the most common procedure to treat coronary artery disease and reopen occluded vessels. It is difficult to fully comprehend the procedures and outcomes of complex techniques such as bifurcation stenting. Here, we describe the development of an educational application that includes anatomic tutorials, multimodal imaging of hundreds of performed complex procedures, outcomes of clinically implanted procedures, and step-by-step imaging of bifurcation procedures.

Methods: Bifurcation procedures were performed within reanimated large mammalian hearts and formalin-fixed human hearts. The procedures performed in reanimated hearts and clinically implanted stents from cadaveric hearts were imaged using an endoscope, fluoroscopy, and optical coherence tomography, and the final implant was micro computed tomography scanned. The mobile app was developed to visualize the resulting 3D models in augmented reality, and additional imaging was also added.

Results: The application successfully allows the user to view the outcomes of both clinically implanted stents and bifurcation procedures and associate these outcomes with clinical imaging. Additionally, clinical imaging including fluoroscopy and optical coherence tomography were available in conjunction with endoscope videos to integrate the 3D views with the images that would be acquired during a typical clinical case.

Conclusions: As this mobile app is open-access, the educational opportunities for direct visualizations of stent implantations can be expanded to those who cannot personally utilize the Visible Heart Laboratories. The provided observations and studies of these procedures should aid everyone, from students to experts, with important insights into the implantation of stents that can improve their understanding and clinical practice.

Introduction

Percutaneous coronary intervention (PCI), including stent implantations, is the most common treatment to reopen coronary occlusions and restore needed blood flow to the myocardium. Today, there are approximately 6600 physicians, predominantly interventional cardiologists, performing over 965,000 PCI procedures annually in the United States alone.[1,2] There is a need to train more interventional cardiologists on the complexities of these therapies, as the number of cases continues to increase. These procedures are commonly performed using fluoroscopy guidance and, in some cases, intravascular ultrasound or optical coherence tomography (OCT). Clinically, OCT is the only imaging modality that permits a physician to visualize the resulting stent structure in 3D; however, OCT is only used in approximately 1.5% of PCI cases.[3]

The Visible Heart Laboratories maintains a unique human heart library, containing human heart donations that were not viable for transplant. Some of these specimens are procured with clinically implanted devices including coronary stents. These stents can then be visualized to study the device-tissue interface, often years subsequent to the clinical procedure.

Additionally, the use of Visible Heart methodologies allows for the multimodal imaging of the implantation of stents in an in vitro model with direct visualizations, fluoroscopy, and/or OCT.[4,5] Subsequently, the outcomes of the stenting procedures can then be scanned, using micro -computed tomography (CT) to develop high-resolution 3D models to better visualize the given procedure. These heart reanimation procedures have been utilized extensively to study the various bifurcation stenting techniques.[5–11] Because there are no clinically available single stents designed for bifurcation procedures, various complex approaches are used to treat these lesions, including 1-stent and 2-stent

Abbreviations: AR, augmented reality; CT, computed tomography; OCT, optical coherence tomography; PCI, percutaneous coronary intervention.

Keywords: augmented reality; calcification; education; mobile application; percutaneous coronary intervention; stent.

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techniques. There are currently many very useful instructional tools available to determine what bifurcation technique and specific steps should be used in a given clinical case including an instructional mobile application and the annual European Bifurcation Club's expert bifurcation consensus.[12–14] These tools as well as other publications often utilize 2D drawings and diagrams to describe the optimal steps of the various bifurcation techniques.[13–15] Additionally, there are many bifurcation stenting case studies and live cases; however, these studies often only provide clinical imaging such as fluoroscopy, intravascular ultrasound, and OCT.[16,17]

The open-access mobile application presented here is a novel educational tool that employs both the capabilities of the Visible Heart Apparatus and our human heart library to allow one to visualize and study clinically implanted stents and complex bifurcation procedures. The Visible Heart methodology is an invaluable tool for the assessment of a cardiac device implantation; these reanimated hearts are functional and can beat in native sinus rhythm outside the body. The hearts are perfused with a clear buffer, and the absence of blood allows for direct endoscopic visualizations within the coronary arteries while various stents are being implanted. This preclinical model allows for comprehensive imaging of various device-tissue and device-device interfaces throughout a performed procedure that cannot be obtained through typical clinical imaging. These images provide a novel understanding of how the stent structures change from one step to the next or when complications occur. These endoscopic images as well as imaging from clinical modalities (fluoroscopy and OCT) are included in our developed mobile learning application. Additionally, micro CT–generated 3D models of the obtained outcome of each procedure are included in augmented reality (AR), allowing the user to holistically view the structural outcome that resulted from a given set of steps and/or associated procedural difficulties. The available AR models can be moved, rotated, and sliced through to obtain infinite perspectives and angles that cannot be seen in diagrams and clinical case studies alone. This mobile application will also be continually updated as new procedural data are collected within our laboratories.

Methods

Organ procurement

Large mammalian hearts were and continually are reanimated on the Visible Heart Apparatus using previously described methodologies.[4] Routinely, reanimated swine hearts are used as the primary coronary stenting model, and occasionally the bifurcation procedures are performed on reanimated human hearts. The Visible Heart Laboratories collaborates with a local organ procurement agency, LifeSource (Minneapolis), to receive hearts that are deemed nonviable for transplant. These hearts may have varying degrees of coronary artery disease prior to donation. For the swine studies, male Yorkshire swine (75-80 kg) were used; the animal was anesthetized and monitored. All animal handling and treatment were in compliance with approved Institutional Animal Care and Use Committee protocols at the University of Minnesota. A medial sternotomy was performed, and refrigerated cardioplegia was directed into the coronaries through an aortic cannula. The heart was then explanted following arrest.

Heart reanimation

Next, either the swine or human heart specimens were prepped for reanimation on the apparatus. The pulmonary veins, pulmonary artery, aorta, and inferior and superior vena cava were cannulated. The heart was then connected to the Visible Heart Apparatus and perfused with a modified Krebs-Henseleit buffer solution and supplemented with pharmacological agents that promoted vasodilation and improved contractility.[4] Each heart was then defibrillated into sinus rhythm using 30 J of energy.

The bifurcation procedures could then be performed on the beating heart utilizing multimodal imaging, including fluoroscopy, OCT, and 2.4 mm and 4 mm endoscopes (Evident) (Figure 1).

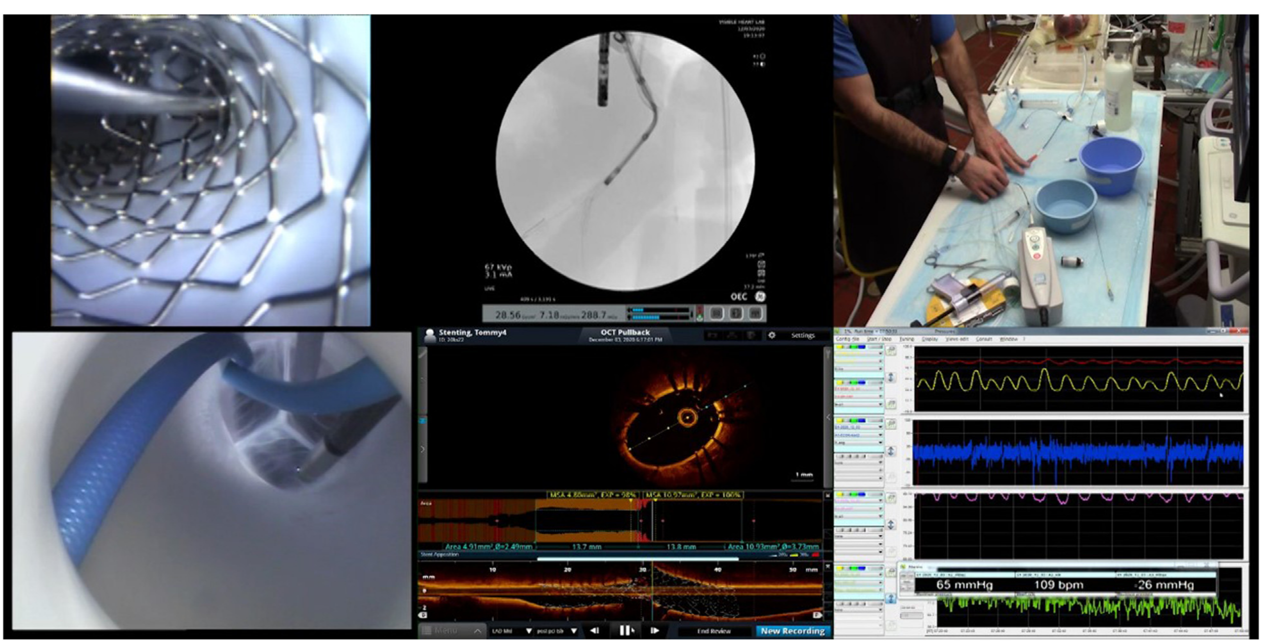


Figure 1.
Multimodal imaging utilized during stenting procedures on the Visible Heart Apparatus. Endoscope view in the coronary (top left), fluoroscopy (top middle), overhead cameras (top right), endoscopic view in the descending aorta (bottom left), optical coherence tomography (OCT) (bottom middle), and cardiac pressure readings (bottom right).

Heart preservation and micro-CT scanning

The human heart donations that could not be reanimated, including 40 specimens that were procured with a total of 48 previously implanted stent procedures, were preserved and fixed in a dilated state with patent coronaries in a 10% formaldehyde solution, allowing for future studies and analyses. Select hearts were perfused with water via the cannulated aorta. A pressure head was then used to ensure the aortic valve was closed so that the coronaries were well-perfused. Stent procedures were performed, using the previously described multimodal imaging, in these hearts with real human anatomies and/or disease.

The clinically implanted stents and bifurcation procedures performed in fixed and reanimated hearts were micro CT–scanned with approximately 45-μm resolution. The stents and calcifications, in the clinically implanted procedures, were segmented, and 3D models were developed.

Application development

An AR mobile app was developed to include the stent models in AR and corresponding imaging, including endoscope video, fluoroscopy, and OCT for each procedure. This app was made with the Unity Engine and coded in the programming language C#. Stent models, videos, and text were pulled from the Visible Heart Laboratories' server at runtime to reduce the required storage space on the user's mobile device. The stent models can be placed in the user's environment and manipulated using Unity's AR Foundation packages. The video player in the app was designed to accommodate side-by-side combinations of OCT, fluoroscopy, and endoscope videos. Additionally, the search functionality allowed users to search the descriptions of each procedure for any combination of keywords. This app was engineered to allow for any stent model, video, and description to be added to the server and automatically become available, which ensured this application could continue to efficiently grow its library of stent procedures and improve its usability. To date, 40 clinical and 135 bifurcation stent models have been added to the app. Additionally, information on the stenting procedures and appropriate references for continued learning are also included.

Results

The currently available mobile app provides the option to study the following: (1) clinically implanted stents, (2) bifurcation procedures implanted in reanimated large mammalian hearts, or (3) bifurcation stents implanted in fixed human hearts (Figure 2). Once the desired procedure type is selected, a drop-down menu, indicated in blue in Central Illustration, allows the user to choose between the 40 clinical procedures and 135 bifurcations in reanimated and fixed hearts. If desired, the user can use the search feature (orange button in Central Illustration) to identify procedures with particular characteristics, such as a bifurcation strategy, a specific stent location, whether or not a vessel dissection was present, as well as many other options.

AR functionality

Once a given procedure is selected, the user can "place" the stent in AR and visualize the model overlayed over the user's surroundings, using the mobile device camera (Figure 3). The user can then zoom in and out, slice into the model by moving the device closer, and turn the model using the buttons indicated in red in Central Illustration. The model can be visualized with a solid background, and it can be locked in position, using the buttons indicated in green and purple, respectively (shown in Central Illustration). These controls allow both the external and internal structures of the stents and calcification to be visualized at any angle or magnification, as shown in Figure 4. The menu (yellow button in Central Illustration) is used to access the procedure description and additional multimodal imaging, including OCT, fluoroscopy, and endoscope videos.

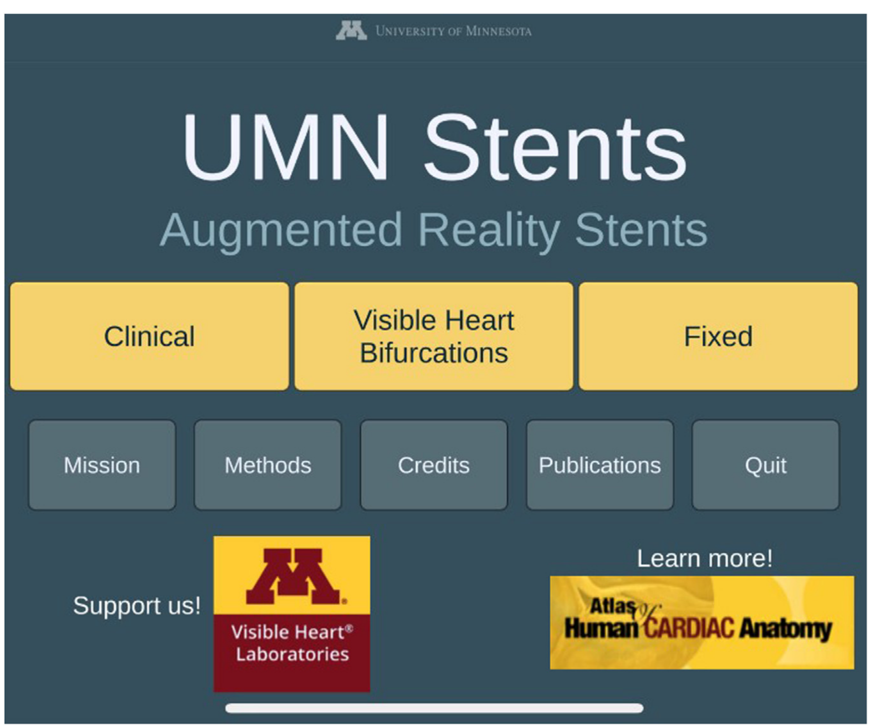
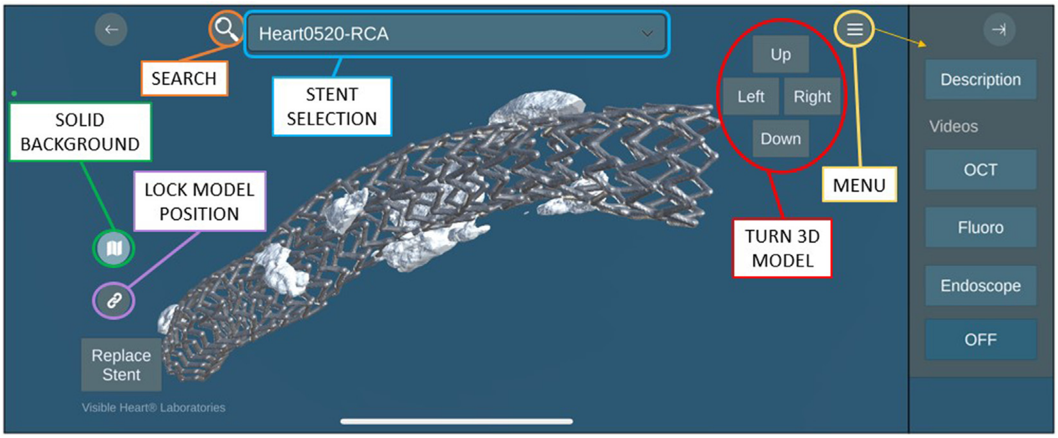


Figure 2.
Augmented Reality Stents app home screen. This allows the user to select between clinically implanted procedures, bifurcation procedures implanted on the Visible Heart Apparatus, and bifurcation procedures implanted in the formalin-fixed human hearts.



Central Illustration.

User interface after selecting a stent from the drop-down menu (blue). The buttons are labeled including the search button (orange), the button that changes the background to a solid blue color (green), the button that locks the model in position (purple), the buttons that can turn the model (red), and the menu button (yellow). The menu that appears is shown on the right (indicated by the yellow arrow), which includes a description, optical coherence tomography (OCT) images, procedural fluoroscopy, and procedural endoscope videos.

Multimodal imaging of clinically implanted procedures

The description for the clinically implanted stents (Figure 5A) includes the donor's deidentified medical history, including any other stent procedures in addition to the selected one. Additionally, the procedure itself is briefly described including the given stent location and whether or not calcification or restenosis was present. In some cases, the OCT images (Figure 5B), angiography (Figure 5C), and direct visualizations via endoscope cameras (Figure 5D) were obtained for the procedures allowing for the comparison between the clinical imaging modalities and the more comprehensive micro-CT models and direct visualizations.

Multimodal imaging of bifurcation stenting procedures

Both the Visible Heart reanimation and fixed human heart bifurcation procedures had the same application capabilities (Figure 6A), which were similar to those of the clinically implanted stents. For these procedures, the descriptions (Figure 6B) included the operators who implanted the stents, who in many cases were expert interventional cardiologists. Additionally, the exact steps, such as proximal optimization techniques and kissing balloon inflations, and the order in which they were performed throughout the procedure were listed. Anything unique about the procedure was also described, such as stent migration, the presence of dissection, wire wrap, stent deformation, and others. Lastly, the relative quality of the result was described, based on the opinions of expert interventional cardiologists. As previously mentioned, the search feature allowed the user to isolate stent procedures of interest that had keywords within their descriptions.

Like the clinically implanted stents, the included bifurcation procedures had corresponding fluoroscopy, endoscope, and OCT videos. However, for these in vitro cases, the videos and imaging contained the entirety of the implantation procedures; as opposed to visualizing the final result alone. The fluoroscopy and endoscope videos were also time-synced to allow the user to view both imaging modalities simultaneously (Figure 6C). Watching both modalities concurrently allowed for a better understanding of how the steps that were being observed via direct visualizations would be seen during a clinical case employing fluoroscopy. Additionally, in many of these cases, several OCT scans were taken at various points throughout the given procedure. The user can choose to view any of these scans (Figure 6D). To date, the app includes provisional, T, T and small protrusion, inverted T/T and small protrusion, Szabo, crush, double kissing crush, mini crush, nano crush, culotte, reverse culotte, simultaneous kissing stents, failed bifurcations, and various bailout procedures.

3D printing

In addition to the multimodal visualizations of the numerous stent procedures available on the application, the models can also

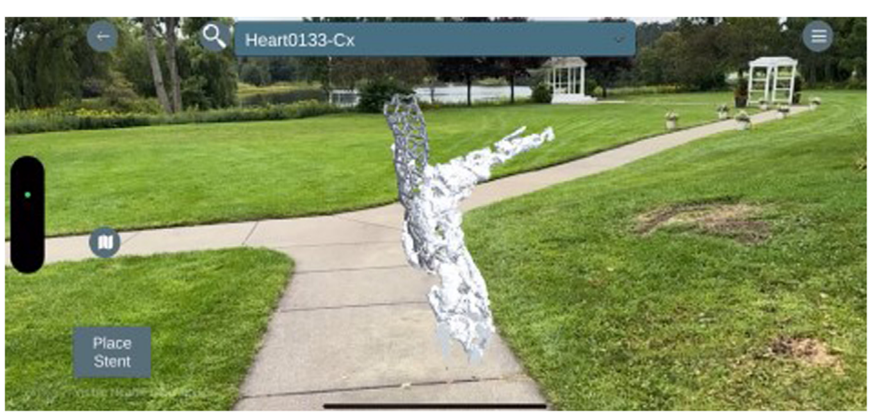


Figure 3.

An example of how the user can view the 3D models of the stents in augmented reality, with the stent overlayed over the real world via the user's camera.

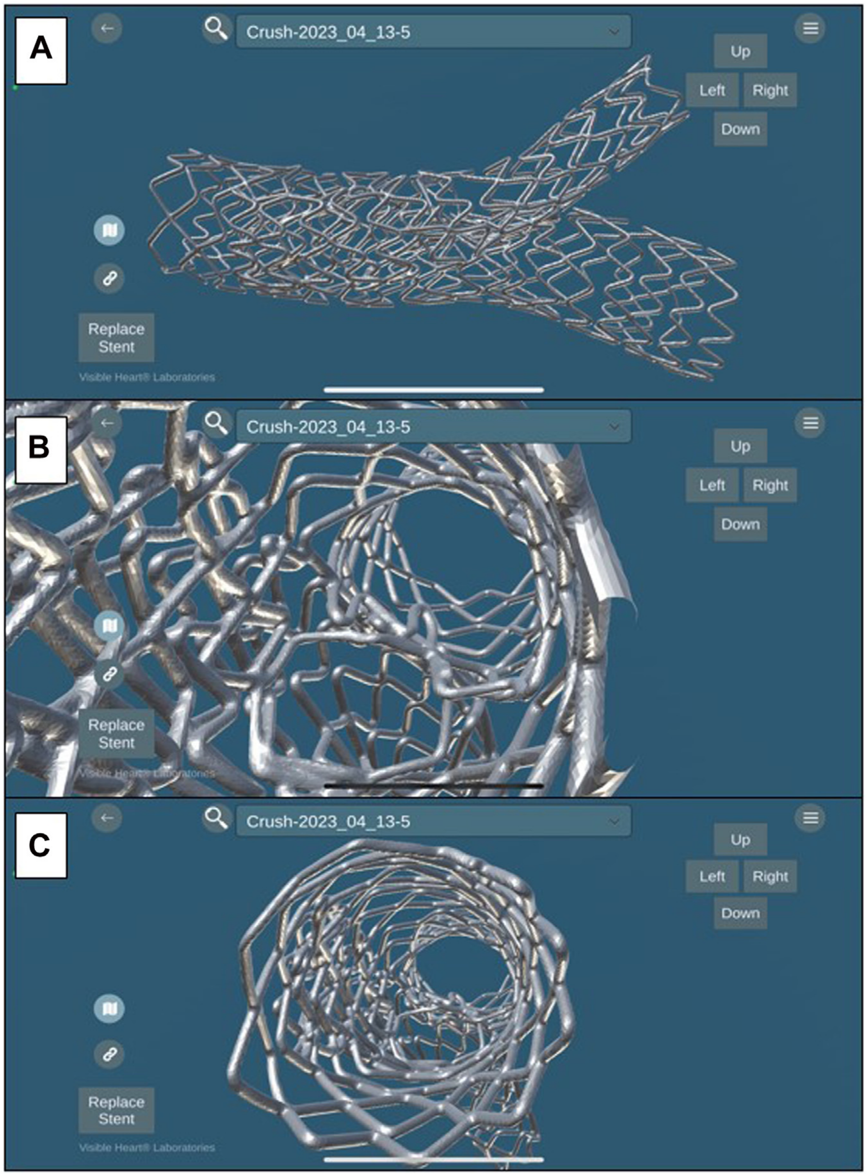


Figure 4.
This figure shows a few angles from which the 3D models of the stents can be viewed including the external view (A), the internal view of the bifurcation (B), and the external view of the proximal region of the stent (C). The stent can be looked at from any angle using the augmented reality movement of the device along with the model rotation controls.

be 3D printed at any scale for additional understanding of the device-device and device-tissue interactions (Figure 7). All the models are available to download, on the Atlas of Human Cardiac Anatomy Website (http://www.vhlab.umn.edu/atlas/), so that any user can print their own 3D model for educational purposes.

Application outreach

To date, this stenting mobile app has been available for a year and has been downloaded by approximately 180 users (Figure 8) in 35 countries.

Discussion

Here, we describe the development and use of a novel educational mobile phone application containing the multimodal imaging of hundreds of stent procedures, including bifurcation techniques and previously performed clinical procedures. Studying the clinically implanted stents provides information regarding what happens to the device-tissue interface several years postimplant. Calcification, endothelization, and restenosis can be observed in the incorporated endoscope videos and 3D models. The procedural observations can also be studied in obtained fluoroscopy and OCT imaging to learn to better interpret the imaging used in such clinical cases. The current advantages and limitations of the application are summarized in Table 1.

As has been well described, the Visible Heart heart reanimation approach provides unique opportunities to not only perform complex stent procedures in large, mammalian, reanimated, beating hearts, without any risk to any patient, but also allows for direct visualizations of the implantations using an endoscopic camera.[5–11] Reanimated swine hearts are accepted as a valuable model for coronary stent implantation; yet it should also be noted that these vessels are healthy and somewhat distensible and thus do not mimic diseased or calcified coronaries. Procedures implanted in the formalin-fixed human hearts

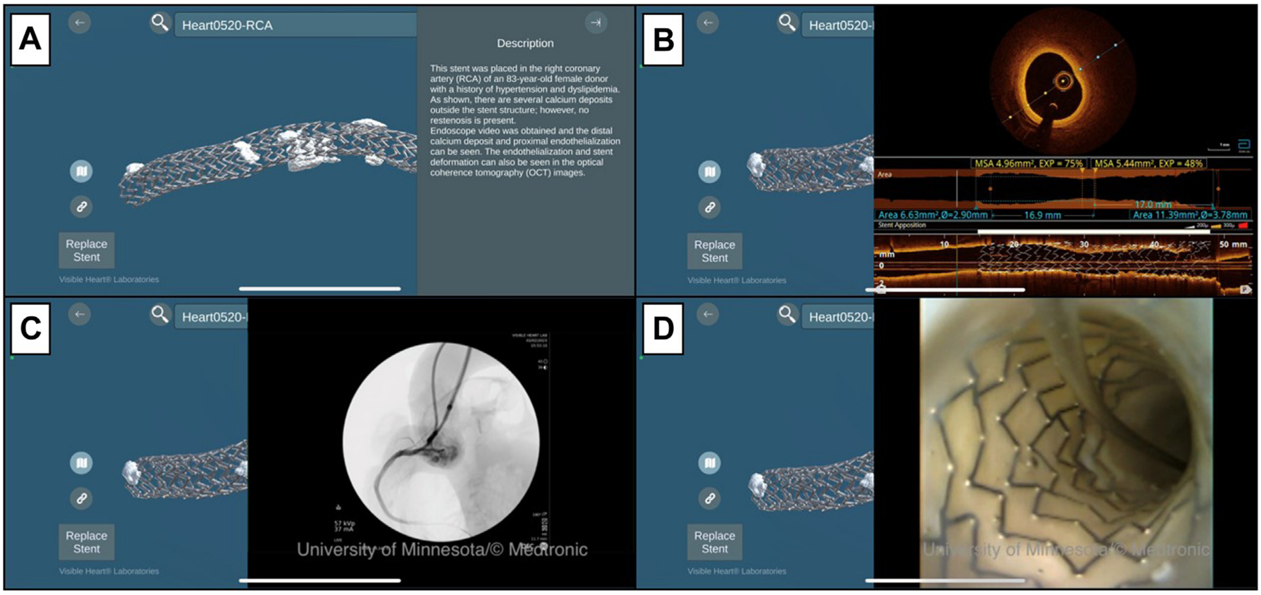


Figure 5.

This figure shows what the options in the menu (Central Illustration) look like for the user. For the clinical cases, description (**A**) includes the patient history, whether there were additional stent procedures and the procedure location, the optical coherence tomography (OCT) (**B**) of the procedure, the angiograph (**C**) of the vessel of interest, and the endoscope video (**D**) of the clinically implanted stent.

are additionally valuable because they are in real human anatomy and often have disease states present, although they are not beating. On occasion, within our laboratories, we have the unique privilege and ability to reanimate human hearts, and within such, stents can be implanted in the coronaries of beating hearts. In all 3 employed preclinical research models described here, a multitude of insights regarding stent implantations and bifurcation techniques can be observed when watching the device-tissue and device-device (for 2-stent procedures) interfaces in real time during the various procedures. Clinically, PCI procedures are guided by fluoroscopy, which does not provide a 3D visualization of the case. Today, in a smaller number of cases, OCT is utilized, which does provide 3D visualizations, but cannot be performed in real time during stenting. These clinical imaging modalities currently limit the interventionalists' understanding of what happens to the stent structure in real time and step-by-step, such as what challenges may be preventing them from more readily performing their procedures, and most importantly what the final structural outcome is. The combination of direct visualizations and postprocedural 3D models with the employed clinical imaging modalities (fluoroscopy and OCT) is particularly educational, as the learner or physician can better interpret the clinical images by comparing them to the more comprehensive imaging. The mobile application was

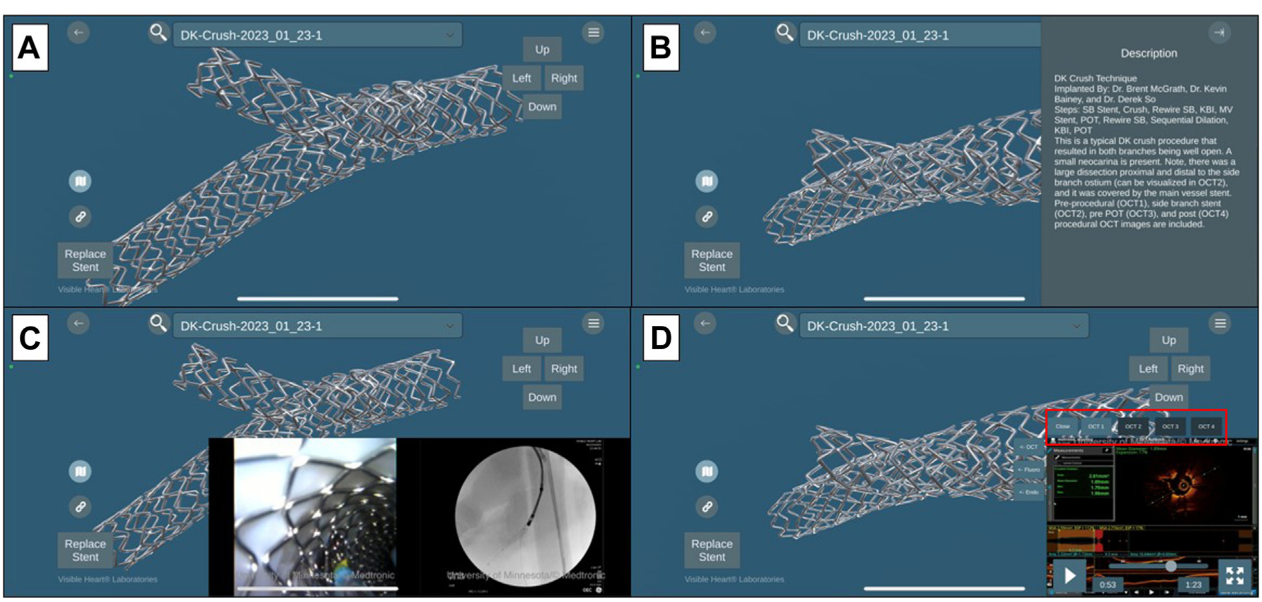


Figure 6.

This figure displays the user interface for the bifurcation stenting techniques in the reanimated and fixed hearts (A). The description (**B**) for these procedures includes the operator(s) who implanted the stents and the procedural steps used. For these procedures, the fluoroscopy and endoscope videos are time-synced and can be watched simultaneously to observe the clinical imaging and direct visualization at the same time (**C**). Additionally, in some of these cases, multiple optical coherence tomography (OCT) scans were taken throughout the procedure, and all of these can be observed using the buttons in the red box (**D**).

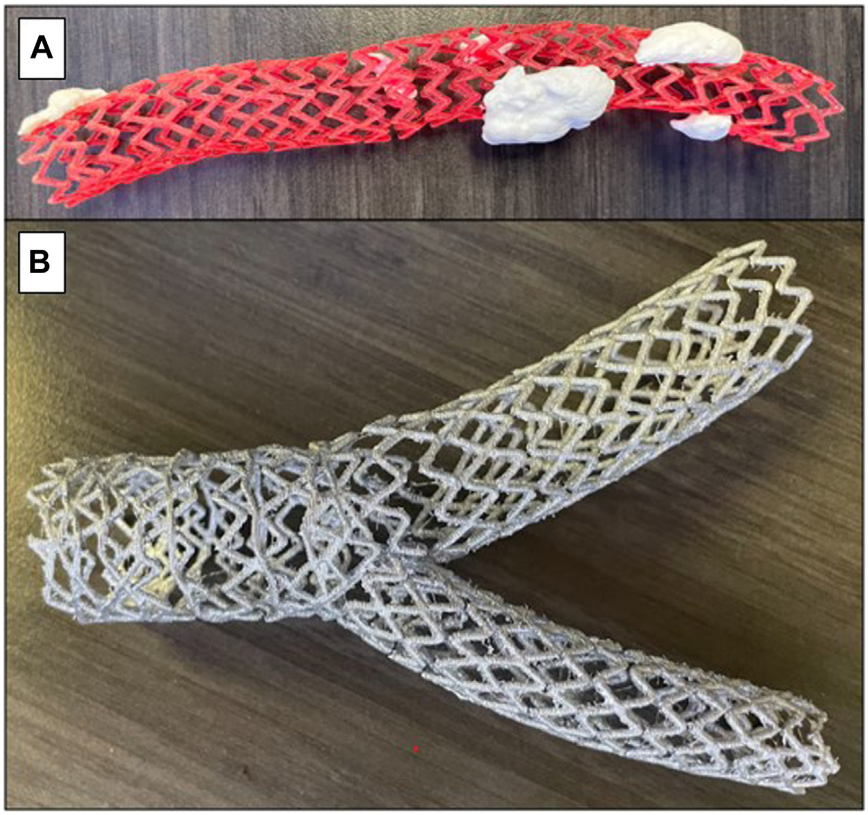


Figure 7.
Enlarged 3D prints of a clinically implanted stent (A), and a culotte bifurcation procedure (B). The stent models in the app can be downloaded from the Atlas of Human Cardiac Anatomy Website (http://www.vhlab.umn.edu/atlas/) (Figure 2) so that any user can print them for educational purposes.

designed to allow for the simultaneous viewing of the endoscope video and fluoroscopy, which has been time-synced, for direct comparison throughout all the steps of various coronary artery stenting procedures.

Although the benefit of performing and observing stent procedures in the Visible Heart Laboratories has not been quantified from an educational trial, many expert interventional cardiologists expressed they have gained critical understandings while being in the laboratories. The feedback indicates that their experience with this preclinical approach has and will directly impact their practices. Live cases performed on the Visible Heart Apparatus are also commonly used for ongoing international bifurcation stenting webinars. However, only a limited amount of the thousands of practicing interventional cardiologists can or have visited the lab in person or joined a webinar. Additionally, these physicians only see a few procedures within a given session. Therefore, the development of this free mobile application allows any patient, student, physician, and device developer to observe

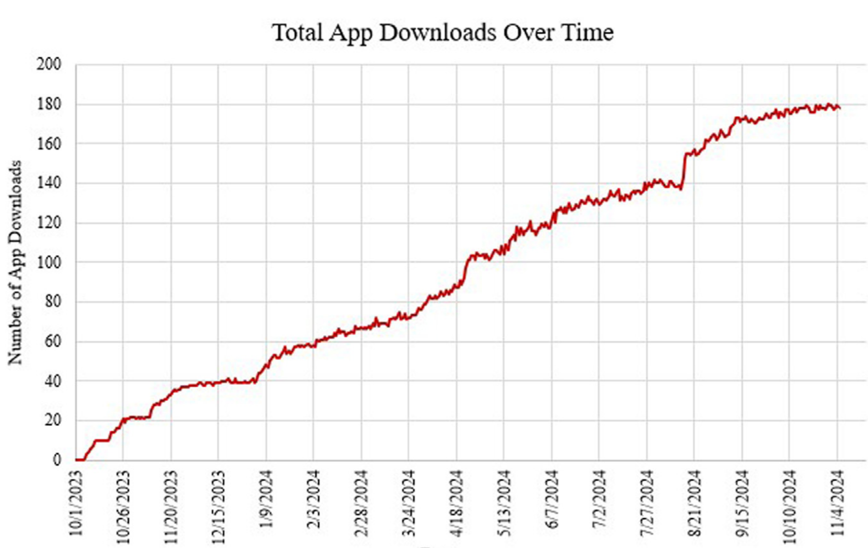


Figure 8.
The number of mobile app downloads from the Apple App Store and the Google Play Store since the launch of the app.

Table 1. Advantages and limitations of the educational mobile app.

Advantages
Provides multimodal imaging of hundreds of bifurcation procedures (case studies)
Visualization of the stents in 3D and in augmented reality
Searchability for desired techniques, steps, and complications
Content includes a wide variety of procedures and steps with varying outcomes
Visualization of calcification interaction with clinically implanted stents in various imaging modalities
Allows comparison between comprehensive endoscope and 3D models and clinical imaging (OCT and fluoroscopy)
Fluoroscopy and angioscope videos are time-synced for simultaneous visualization
Videos and imaging can be used by users to develop additional educational materials
Free and accessible to anyone with an OS or Google Play–accessible mobile device
Limitations
Does not provide hands-on training or user interaction with the procedural steps
3D models are not included for every step but are available for the final outcome
The procedures are often performed in healthy coronary vessels, which may affect the structural outcome
Educational benefit has yet to be quantified

OCT, optical coherence tomography.

and study hundreds of coronary interventional cases that have been performed in the Visible Heart Laboratories over the last several years; all done so to improve one's understanding of stenting procedures. As shown in Figure 8, to date, approximately 180 users have downloaded the app, many of whom have performed or seen 3 to 5 procedures in the lab. These physicians utilize this learning application to study many additional case outcomes, techniques, and bailout strategies that they were not able to visualize during their given visit, highlighting the educational value of these images. As the number of users continues to grow, these visualizations that hopefully will positively influence clinical practice can be seen by a much larger percentage of practicing interventional cardiologists, residents, fellows, and other trainees interested in this field. Additionally, these publicly available images, models, and 3D print files can be utilized in lectures and conference proceedings to further educate and describe different interventional techniques and outcomes.

Conclusions

The open-access mobile application we present and describe here is a new and unique educational tool to learn about coronary artery stenting. It provides a multitude of case studies and multimodal imaging of clinically implanted stents, as well as complex bifurcation procedures implanted both employing the preclinical Visible Heart methodologies and within donated human hearts. As this mobile app is open-access, the educational opportunities for direct visualizations of stent implantations can be expanded to those who cannot personally utilize the Visible Heart Laboratories. The provided observations and studies of these procedures should aid everyone, from students to experts, with important insights into the implantation of coronary stents that can improve their understanding and/or clinical practice.

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Declaration of competing interest

Paul A. Iaizzo has a research contract and educational consulting role with Medtronic. Amanda N. DeVos and David Buyck reported no financial interests.

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Ethics statement and patient consent

LifeSource secured consent from donors or their families to use organs for research. The Institutional Review Board at the University of Minnesota granted exemption from ethics approval, being the heart specimen was considered waste tissue donated for medical research. All animal handling and treatment were in compliance with approved Institutional Animal Care and Use Committee protocols at the University of Minnesota.

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