Augmented Reality for Closed Intracardiac Interventions

Gerard Guiraudon CSTAR, Robarts Research Institute, University of Western Ontario, London, Ontario, Canada gerard.guiraudon@cstar.ca

John Moore Robarts Research Institute, London, Ontario, Canada jmoore@imaging.robarts.ca

Doug Jones University of Western Ontario, London, Ontario, Canada doug.jones@schulich.uwo.ca

Nick Hill Robarts Research Institute, London, Ontario, Canada nhill@imaging.robarts.ca

ABSTRACT

Many intracardiac procedures can currently be performed on the heart only after it has been arrested, and the patient has been placed on cardio-pulmonary bypass. We have developed a new method for operating on multiple targets inside the beating heart, and describe a procedure for accessing them under virtual-reality (VR)-assisted image guidance that combines real-time ultrasound with a virtual model of tools, and the surgical environment acquired from pre-operative images. This paper presents preliminary results aimed at assessing the operator's ability to accurately position and staple an artificial valve to a "valve orifice" within a cardiac phantom, when guidance is performed via ultrasound alone, and with US augmented by the VR environment.

Keywords: image-guided surgery, virtual reality, cardiac surgery

1 INTRODUCTION

"Surgery is a side-effect of therapy". This rather provocative statement underlines the fact that most complications that are associated with "surgical" procedures, relate not to the therapy itself, but to the process of approaching the target to be treated. In order to reduce patient trauma, many conventional surgical procedures are being replaced by minimally-invasive approaches. If most therapies could be achieved without the need for significant surgery to access the site of disease, procedure time would be shortened, patient trauma and side-effects eliminated, and health costs correspondingly reduced.

While cardiac surgery has relied for 50 years on cardiopulmonary bypass technology, new technologies are now available to transform the "old" open heart approaches into target-specific interventions with fewer invasive side effects. Here we describe an evolving technology that draws upon intra-operative imaging Andrew Wiles Robarts Research Institute, London, Ontario, Canada awiles@imaging.robarts.ca

Dan Bainbridge University of Western Ontario, London, Ontario, Canada dan.bainbridge@lhsc.on.ca

Chris Wedlake Robarts Research Institute, London, Ontario, Canada cwedlake@imaging.robarts.ca

Terry Peters Robarts Research Institute, CSTAR, University of Western Ontario, London, Ontario, Canada tpeters@imaging.robarts.ca

and virtual reality, aimed at performing targeted interventions inside the beating heart, without direct vision. The objective of our work is to develop and demonstrate a virtual environment that realistically represents the heart, and augments the standard ultrasound view to provide the means to plan and guide minimally-invasive intra-cardiac interventions.

It is useful to consider the delivery of therapy using a "shooting" analogy. The degree of invasiveness relates to the magnitude of side effects of a procedure, or undesirable outcomes that are unrelated to the therapy delivered to the target, (i.e. the condition causing the symptom or disease under consideration). We refer to a "bullet" as the physical agent that neutralizes the target, (i.e. delivers energy to ablate cells, physically excises tissue, etc), while the "gun" is the delivery system that guides the bullet to the target.

Conventional open heart surgery provides unobstructed direct vision and access to the target. However, direct access and vision comes with the high price of side effects including general anaesthesia, cardiopulmonary bypass, aortic cross-clamping, cardiotomy, cardiac arrest and myocardial preservation. The surgical delivery of the treatment is a side effect responsible for most of the morbidity and mortality associated with the intervention. Catheter-based interventions separate access (via the vascular system) from visualisation (using X-ray or ultrasound imaging, and when feasible, electrophysiological recording/ablation). Their use is associated with fewer side-effects and positive outcomes. Unfortunately the open heart approach is still routinely employed for most intracardiac targets like valves, septal defects, and aneurysms,.

In the case of cardiac therapy, surgical trauma is associated with this delivery system rather than the actual therapy, and while some side-effects are temporary with minimal risk and the patient fully recovers (e.g. general anesthesia), others are associated with immediate risk of severe morbidity and mortality, including permanent neurological damage (an occasional side-effect of cardiopulmonary bypass surgery). While minimally-invasive surgical techniques have application in many parts of the body, this paper describes the efforts of our laboratory to develop targetspecific interventions in the heart that have minimal intraoperative side effects.

Recently, we embarked on a project to modernize procedures inside the beating heart using new surgical technologies and support of image-guidance via pre-operative imaging and intraoperative 2D Ultrasound (echo-cardiography) to substitute for direct vision. Our goal was to provide a system with a safe cardiac port access that augmented the traditional ultrasound approach with virtual reality to substitute for the absence of direct vision, while at the same time, delivering quality therapy to the target. Specific targets include the repair and replacement of heart valves and the repair of septal defects (i.e. hole in the heart). The objective is to duplicate the success rate of conventional openheart surgery, but to do so via a small opening in the patient's chest, and to evaluate the efficacy of the procedure as it is performed.

As an example of our goals, we describe our methodology with respect to the implantation of a mitral valve.

2 MATERIALS AND METHODS

2.1. The Universal Cardiac Introducer.

The first task was to design a device that could provide safe heart port access, which could accommodate up to four tools, instruments or devices, access all cardiac cavities and intracardiac targets, and which could be removed at the end of the intervention. This device, the Universal Cardiac Introducer® (UCI) [1] (Fig. 1) has been tested in animal studies to demonstrate feasibility for endocardial atrial fibrillation surgery, and mitral valve replacement. The UCI is designed as an "air lock" between the cardiac cavity containing blood, and the atmosphere of the chest. It is comprised of an insertion cuff,



Figure 1. Universal Cardiac Introducer (UCI) showing its components, including the three arms to accommodate instruments. along with an artificial mitral valve and holder.

which is attached to the heart port access, and which in turn, is connected to the introductory chamber. This chamber can be affixed to the heart via a mini-thoracotomy, can accommodate bulky devices and has 3 or 4 sleeves that allow the introduction of the tools or holders. The introductory chamber is "loaded" with the device and tools before being connected to the cuff. For mitral valve implantation, the sleeves of the introductory chamber accommodate the valve holder, a pressure line and a "clip applier". The introducer is safe and versatile and does not compromise the manipulation of tools.

2.2. Ultrasound

Echocardiographic guidance uses technology that is readily available in the cardiac operating room. While cardiac ultrasound systems are available in several forms, namely trans thoracic echography - TTE (image is acquired through intercostals spaces), trans esophogeal echography - TEE, (images are obtained from a transducer placed in the esophagus behind the heart) and intra cardiac echography – ICE (a miniature US transducer is introduced into the heart through a vessel). A limited number of 3D systems are also available, but the transducers are large and image acquisition is restricted to trans-thoracic views. Important considerations relating to US images are that they are extraordinarily difficult to interpret unless they are viewed in the context of the surrounding anatomy. In addition, it is very difficult to accurately visualize the targets and instruments being manipulated within the heart using US.

2.3. Image-guidance using Ultrasound

In order to both demonstrate the feasibility of the intracadiac procedure using the UCI, and to highlight the limitations of using US alone as a navigation tool, we employed a TEE system to navigate a bioprosthetic mitral valve into the left ventricular inflow tract of a pig. In this study, a full sternotomy was employed to provide ready access to the site with epicardial ultrasound employed as an adjunt visualization modality. The valve was guided into the left ventricular in-flow tract, ensuring that the struts in the valve holder valve (Fig. 1) were aligned to lie parallel to the long axis of the left ventricle. When we felt that the valve was appropriately positioned, a 3D transthoracic US probe was used to acquire an image of the left ventricular base from the epicardial surface. Using this imaging modality, the bioprosthetic valve could be manipulated to ensure proper positioning. In addition, to further assist in visualization, an intracardiac echocardiography (ICE) catheter was introduced into the right atrium via the left internal jugular vein. Suematsu et al [2;3] have also presented the use of 3D echocardiography as an alternative to 2D US for guiding instruments within the beating heart. They report their experience using only 3D US, without the benefit of a virtual environment, as the guidance platform in a laboratory environment. In addition they had the advantage of access to the real-time digital 3D US data imported to a custom image processing system.

Once the valve is successfully placed, it may be fastened to the valve annulus using a laparoscopic clip applier introduced via the UCI.

2.4. Limitations of ultrasound image guidance

Our initial experience in valve placement through the left atrium into the mitral valve orifice relied on ultrasound image guidance alone, and emphasized the significant limitations imposed by the low quality 2D images. The US images were often difficult to interpret due to lack of anatomical context, and required cautious trial-and-error manipulation of the valve based upon the imperfect US images. In these tests, the final positioning of the valve was performed using a large dynamic 3D ultrasound transducer placed on the epicardium. Such devices are very bulky and have a small field of view, and access to the target may be compromised. In addition, real-time visualization is confined to the ultrasound imaging system itself, i.e. it is not possible to extract the 3D data for further manipulation in an independent system. Tools and targets are poorly perceived in both 2D and 3D images. From our initial experience, we conclude that the use of 2D TEE guidance has significant limitations when used as the sole imaging modality. Estimation of orientation of tools and their motion is virtually impossible to assess since the 2D cross section image does not provide the necessary context of the 3D cardiac anatomy. As demonstrated below, this limitation can be addressed by augmenting the 2D dynamic cardiac US with virtual models of the surgical instruments and target. This approach offers the advantage of real time 3D imaging while employing only standard 2D US modalities.

In spite of the limitations discussed above, the Doppler capability of ultrasound imaging is ideal for assessing the quality of the intervention based on blood-flow measurements. Residual flow around the valve seat, inappropriate flow through the valve, or incomplete Atrial Septal Defect repair, can be readily identified through aberrant flow patterns.

This initial experience allowed us to identify the limitations of ultrasound in this context, and the need to supplement the US image with other modalities. The incorporation of pre-operative CT or MR ivolumes would permit the analysis if the 2D or 3D ultrasound images, along with virtual representations of the tools or instruments, within the context of the 3D cardiac anatomy. We also point out that the introduction of models, based upon preoperative imaging, opens the way for the incorporation of additional electrophysiological information from systems such as the BioSense-Webster CARTO® Electrophysiological mapping system.

2.5. Visualization Environment

Image guided surgery has been a major part of the research at our Institution, and over the past years we have developed many tools and techniques that impact the current project, including cardiac image registration [4]; cardiac modelling [5]; dynamic MRI-US



Figure 2. Virtual environment showing orthogonal plane view of the model cardiac wall, the ultrasound fan, and the virtual valve and tool.

image registration [6] and procedure planning [7]. The development of our image-guidance platform takes place within the laboratory for Virtual Augmentation for Surgery and Therapy (VASST) at the Robarts Research Institute. The primary visualization tool for this project is a custom-developed software package, the 'AtamaiViewer' (http://www.atamai.com), designed to integrate all components necessary for image guided intervention applications (Fig.2).

This software platform integrates the visualization of preoperative MR, CT and other modalities with intra-operative US, endoscopic data, tracked surgical tools, haptic devices and virtual models. It provides the ability to selectively combine the different imaging components, set transparency levels for overlays, view volumetric data from orthogonal or oblique planes, as well as cine sequences. It is also possible to combine optical and magnetic tracking systems in a common virtual workspace for a single application. The viewer is designed to support stereoscopic visualization, and is based on software initially developed for neurosurgical applications [8], and the tracking component has a similar base to that being developed for the Image Guided Surgery Toolkit (http://www.igstk.org/). The modular design of the platform facilitates the ready addition of new components and features. An example of a physical tool (in this case the mitral valve introducer attached to the valve itself) and its virtual counterpart is shown below (Fig. 3).



Figure 3. Valve attached to its insertion tool (L) and its virtual representation (R).

2.6. Cardiac Intervention Phantom

We constructed a heart phantom (Fig. 5), similar in concept to that described by Rettmann et al [9], made entirely from non-magnetic materials to minimize interference with magnetic tracking devices. A long tube descends into the bottom of the phantom to simulate the esophagus, and facilitate the use of both intra-cardiac or trans-esophageal US probes. The phantoms are divided into two sections, the larger being used to evaluate different US calibration techniques, the smaller being used to simulate the chambers and tissues of the heart. Three plates (two horizontal, one vertical, approximately 7cm x 12cm) hold PVA cryogel membranes [10]that can represent various cardiac walls and chambers. By varying the parameters used in the formation of the PVA-C, it is possible to mimic a variety of tissue properties. It is also designed to make it relatively easy to introduce water flow patterns into this chamber to simulate cardiac motion.



Figure 4. Left: US image of tool shaft; Center: US image with virtual tool added. Right: US and tool augmented by 3D CT of phantom and target (dark disk on PVA-C is the "valve orifice").





Figue 5. a) Plexiglass heart phantom, showing "esophagous" and membranes representing heart wall tissue. b) Equivalent schematic representation of anatomy. Note that the valve holder enters the chest from the chest wall (out of the page).

These phantoms provide a significant advantage in developing and assessing new surgical techniques under image-guidance, while progress can be monitored and assessed with direct video (endoscopic) inspection of the target. This also reduces the reliance on time consuming and expensive animal studies. The phantom allows testing of tools, devices, and surgical techniques and skills in a laboratory setting that closely mimics the "real clinical setting" for a range of procedures. It also permits testing of surgical rationales, imaging and navigation, insertions techniques and tools, devices, holders, clips, needles etc. in a controlled environment.

2.7. Tracking

In order to ascertain the position of an ultrasound image in space relative to the patient the transducer must be tracked relative to some coordinate system. In many cases when the US transducer is hand-held, optical tracking may be employed. However, the US modalities generally used in cardiac surgery create images via a transducer placed in the esophagus, (TEE), or in the heart chamber itself (ICE). Since line-of-sight is not available in these cases, magnetic tracking must be used instead. To this end, we track both the ultrasound and instruments using the NDI Aurora® system, which identifies the position and orientation of miniature 6 Degree-of-freedom (DOF) sensors fixed to the transducer and tools respectively through measurement of magnetic field pulses emitted by a closely-placed magnetic field generator.

tracked objects are needed for the mitral valve Three implantation procedure, one for tracking the US transducer, and another for tracking the valve insertion tool, and a third for determining the position and orientation of the stapler or "clip fixation device". The AtamaiViewer software platform has many tools for calibration of both tracked surgical tools and US transducers. In the present study, the tracked US probe was calibrated using a z-bar device. The valve insertion tool was calibrated by first defining a transform for the tool tip and orientation without the valve being attached. After the valve was attached to the tool, it was possible to refine the calibration transform by defining a series of landmarks on the virtual tool, scanning the real tool with the calibrated US, and performing a least-squares fit with the corresponding landmarks identified in the US fan. A similar procedure was used to calibrate the clip applier. Registration of the tracker coordinate system to the heartbox phantom CT was achieved using glass beads embedded in the phantom as landmarks, and all measurements were made relative to a 5 DOF magnetic sensor rigidly fastened to the phantom box.

3 EXPERIMENTAL METHODOLOGY:

3.1. Targeting accuracy

The first test attempts to measure the target localization accuracy of localizing a target (locating a 1mm diameter hemisphere fixed to a rigid wall of the phantom) based upon US guidance alone; VR alone (employing the VR system to guide the pointer), and VR plus US guidance (where the operator was able to see both the image on the US fan and the pointer, represented within the VR environment). The Atamai Viewer was interfaced to an Aurora magnetic tracking system (Northern Digital Inc., Waterloo, ON, Canada) and a transesophageal echo probe (Philips T6207). An Optotrak 3020 optical tracking system (Northern Digital Inc) acted as an independent "gold measurement standard". This independent system provides the reference measurements against which the image-guided surgery software and tools may be compared. The heart phantom described above was modified to enable the targeting accuracy test to be performed. To ensure stability, the pointer was mounted on a 3D positioning stage that was controlled by the operator during the placement experiment. Three operators positioned the probe three times each for each condition. The results (expressed as RMS positioning error and standard deviation across all subjects) for each trial are listed in Table 1.

3.2. Placement of valve "on target".

The next set of studies examined the accuracy with which an experienced cardiac surgeon could place the valve within the valve annulus under 2D US guidance alone, and with US complemented by the virtual representation of the valve and its insertion tool. The target in this case was a hole in a pliable PVA-C membrane that could move freely under pressure from the valve and tool as the valve was being positioned. The virtual environment included a CT scan of the cardiac phantom with the membrane. However, since in practice the virtual (pre-op) model may not be precisely registered with the target (because of registration errors, motion etc) we deliberately misaligned the target aperture by several mm from its virtual representation. This emphasises the fact that the pre-operative virtual model is there to give context to the US image rather that for accurate guidance to the target. The virtual environment nevertheless contained an accurate representation of the tracked manipulation tool and valve, robustly registered with respect to the ultrasound transducer.

Tracking of both US probe and insertion tool was performed using the NDI Aurora system with tracking and registration accuracy better than 1.0 mm.

3.3. Placement and stapling the valve.

Our initial experience using a combination of intra-operative US and Virtual Reality for valve implantation and fixation was performed using the phantom described above. As before, a 2cm diameter hole in a PVA-C membrane acted as the valve-seat aperture. The task was to guide the valve prosthesis mounted on a three-pronged manipulator, place it accurately over the aperture, and to staple it in place using a laparoscopic clip-applier. A 4-7.5MHz 2D TEE ultrasound probe was used to visualize the instruments and target. Both instruments and the US probe were tracked using 6DOF Aurora sensors, and were calibrated for position relative to fixed fiducials on the phantom casing. Virtual representations of the valve/tool combination, the ultrasound probe, and a previously acquired CT volume of the phantom were created within the visualization environment and registered to the physical phantom. A virtual target (a 2cm disk) was also placed within the volume by interactively aligning it with the edges of the actual aperture as seen in the 2D US images. Again we emphasize that even though the target is represented in the preoperative images, because of the pliability of the artificial membrane material, the target as seen in the pre-operative scans is unlikely to be precisely registered with the actual target. This is also a realistic representation of what will happen in practice in a real heart. Virtual representations of both instruments, along with live images acquired from the video stream of the US system were mapped into the virtual visualization environment (Fig. 6).



Figure 6. Virtual environment showing valve, valve holder, stapler, ultrasound transducer and US image.

When manipulating the valve with the rod, the US image depicts the sonic reflections from the intersection plane of the rod or the valve (Fig. 4a), and while certain characteristics of the tool may be appreciated, it is extremely difficult to determine exactly where the tool is and what its relationship is to the target. The position of the target may be determined by interpreting the US image as it is swept across the valve aperture and this information is used to position the target disk. However, when the US image is complemented by a virtual representation of the tool (Fig. 4b) and shown in the context of the 3D pre-operative model (Fig. 4c), navigation of the valve towards the target becomes trivial. Once the valve is in place superimposing the target, it is a relatively simple matter to introduce the clip fastener, place the staple head at several points around the valve flange, and staple it to the underlying membrane as demonstrated by Fig. 6.

4 **RESULTS:**

4.1. Targeting Accuracy

In Table 1, the summary statistics of the distance errors between the target point and the achieved position are provided for both the magnetic tracking system used for guidance and the independent optical tracking system used for the accuracy assessment. All errors are computed in the phantom frame of reference relative to a digitized model of the target point that was created prior to the experiment.

A good agreement is found between the magnetic tracking system and the independent optical tracking system showing that the magnetic tracking system has sufficient accuracy for the application. However, the VR+US results are higher than the VR alone. This small discrepancy is attributed to the ability to recognize the tip of the tool in the 2D ultrasound image. Future experiments will use targeting tools that are viewed better in the ultrasound images. Although this discrepancy exists, the usefulness of the combined VR with US is best exhibited in the valve insertion test.

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Method	Magnetic Tracking			Independent Tracking		
	Measurements			Measurements		
	Mean	Std. Dev.	RMS	Mean	Std. Dev.	RMS
US only	4.96	2.31	5.42	4.90	2.24	5.34
VR only	0.99	0.29	1.02	0.94	0.33	0.99
US + VR	1.22	0.71	1.39	1.13	0.53	1.23

Table 1: Summary statistics of the distance errors between the target location and the achieved location for the single target point. All values in millimeters

4.2. Valve Placement:

Three attempts were made to place the valve in a free-hand manner in the aperture under both 2D US guidance alone, and US/VR. The results were visualized using an endoscope directed at the target.



Figure 7. a) Poorly placed and stapled valve placed under US only navigation (left), while b) the image on the right shows the correct positioning and stapling achieved under US/VR guidance. Arrows indicate the staples in both cases.

The results of using the 2D ultrasound alone to position the valve were consistent with those from our previous experience, i.e. that parts of the valve circumference could be identified but that the image was contaminated with artifacts. Positioning that seemed appropriate using US alone, was often several mm off target, both in translation and angulation (Fig 7a). When the valve placement was complemented by the VR environment, the operator found that it was much easier to place the valve close to the final target initially, and that the refinement of the positioning could then be carried out using the 2D US. Typically the valve seating was much closer to the ideal under these conditions. Perhaps the most important helpful characteristic of the virtual environment was its ability to visualize the entire 3D valve and insertion tool and to appreciate its orientation with respect to the plane of the target information that is not immediately evident in the US-only approach (Fig. 4a).

At the time of writing, the placement and fixation task had been performed several times with US guidance alone, and with VR assistance. In all cases the US-guidance attempt was unsuccessful in properly placing the valve on the aperture, or achieving a patent fastening of the valve to the membrane(Fig 7a). However, with VR/US guidance, the success rate has been 100% (Fig 7b).

5 DISCUSSION

This project is still in its infancy, and a great deal of additional work remains to be done, including instrumenting the phantom to simulate cardiac motion and blood-flow. However this early series of experiments has convinced us that the use of virtual reality in this environment can significantly enhance the surgeon's ability to navigate within body cavities without direct vision. It also suggests that the VR environment is much more important to establish the initial positioning and orientation of the interventional tools, than it is to perform the final targeting, which is refined under the control of the US image in spite of its limitations. The general conclusion however, based upon both the quantitative target localization studies, and the qualitative valve positioning experiments, was that the virtual environment significantly assisted the operator in completing the task. When using US guidance alone to position the stapler and fix the valve to the underlying membrane, the procedure preoved to be complex and largely unsuccessful. However, when the same task was attempted using VR and US, the same task became trivial.

6 CONCLUSIONS AND FUTURE WORK

The use of the VR environment can be a key element to enhance the performance of off-pump, beating, intracardiac surgery. Enhanced with US imaging for final positioning, the combination provides both the elements of visualization of the target, planning optimal routes to the target, and the guidance for directing therapeutic interventions. The phantom allows evaluation of the surgical approach as well as training of the team. Future developments will need to incorporate dynamic motion and flow to the phantom and then to refine the imaging to be useful for intracardiac surgery. This initial work has demonstrated the tremendous potential of multiple-modality imaging, combined with tracking of tools and real-time US, for providing the capability to both visualize and assess the surgical intervention, in a manner that will ultimately be superior to direct vision, with its inherent limitations. Initial experiments have been aimed simply at comparing the targeting and valve placement/fixation procedures with and without the assistance of the virtual environment, and to identify the limitations of the system. While we used a laparoscopic "stapler" to fastenthe valve in place, there are othere fixation technologis that need to be explored as well. We also note that it would be ideal to employ dynamic 3D US within this environment, however this facility is not generally available and so we must achieve a similar effect by complementing the 2D US images with the 3D virtual environment.

One aspect that we have yet to consider is the optimum way of displaying the information to the surgeon in the operating room. A number of questions on this topic have yet to be addressed: Is a stereoscopic display of the information necessary? Should the images be presented to the operator via a head-mounted display? Should the images be projected into the operating volume in an Augmented reality framework of the kind advocated by Sauer et al [11;12] or Birkfellner [13].

Last but not least, we must design tools and devices that deliver the required treatment to the target, while being compatible with standard imaging and tracking systems.

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