

Where Cardiac Surgery Meets Virtual Reality: Pains and Gains of Clinical Translation

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Abstract. Off pump intracardiac surgery is an area of research with many unique challenges. Surgical targets are in constant rapid motion in a blood filled environment that prevents direct line of sight guidance. The highly restrictive workspace requires compact yet robust tools for proper delivering therapy. In this paper we describe a comprehensive system currently under development for the treatment of conditions including mitral valve replacement, atrial septal defect repair and ablation therapies for atrial fibrillation. We describe the basic features of our system and our preliminary experiences towards its clinical implementation.

1 Introduction

In the context of cardiac interventions, minimizing invasiveness has inevitably led to more limited visual access to the target tissues. Minimally invasive approaches have emerged in response to the need to reduce morbidity associated with traditional techniques. Two key components of image-guided surgery (IGS) consist of first, the ability to register multi-modal pre- and intra-operative images to each other and to the patient, and secondly, to track instruments in real time during the procedure, while displaying them as part of a realistic model of the surgical volume. For the most part, IGS relies on the assumption that pre-operatively acquired images provide a sufficiently accurate representation of the intra-operative anatomy. This assumption is typically valid in areas such as orthopedic interventions, where the anatomy primarily undergoes rigid transformations. However, it may not necessarily be valid for other soft tissue interventions, and it definitely poses a significant issue in the case of cardiac interventions. Considering the large myocardial deformations, intra-operative imaging using X-ray fluoroscopy, interventional MRI, US or video that provide accurate, real-time information on the anatomical changes are often employed in the modern operating rooms (OR) to ameliorate this situation. Moreover, stereoscopic, virtual and augmented reality techniques have been implemented to enhance visualization and surgical guidance.

We developed a novel surgical guidance package to facilitate therapy delivery on the beating heart. Our platform relies on trans-esophageal echocardiography

(TEE) for real-time intra-operative guidance, pre-operative cardiac models for anatomical enhancement, and magnetic tracking technology for real-time tracking of surgical instruments [1]. We envision that virtual reality (VR)-enhanced ultrasound (US) guidance will eliminate the need for intra-operative fluoroscopic imaging and allow the fusion of surgical planning and guidance [2, 3].

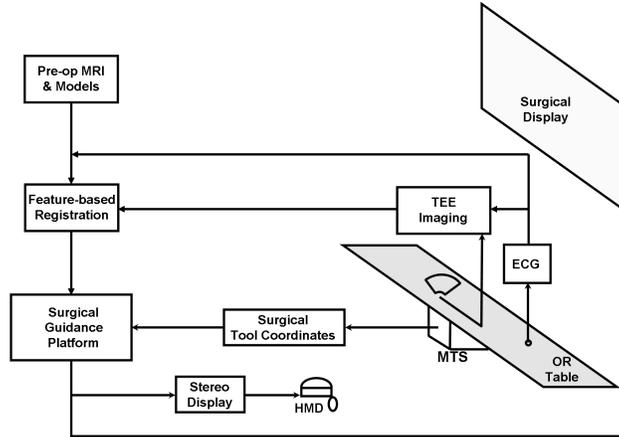


Fig. 1. Schematic representation of the OR setup during a VR-enhanced US guided procedure. Information is delivered to the surgeon either via overhead monitors or stereoscopically via head mounted displays (HMD).

To illustrate our long-term research endeavours, we follow a subject through the prospective clinical routine associated with this proposed technique. Pre-operatively, a dynamic cardiac MR dataset is acquired and used to generate a subject-specific heart model [4]. Peri-operatively, ECG-gated, dynamic real-time cardiac images are acquired via a tracked TEE probe, which are then post-processed into 3D volumes depicting the heart at different cardiac phases [5]. A feature-based registration technique is used to map the pre-operative model onto the the intra-operative anatomy revealed in US [6, 5]. Ultimately, the virtual surgical environment is augmented with models of the surgical instruments (i.e., the ablation tool) tracked in real-time using a magnetic tracking system (MTS) (**Fig. 1**). As a result, clinicians can explore the intracardiac environment in real-time via US, using the registered pre-operative models as guides, and navigate tracked surgical tools intuitively relative to the 3D cardiac anatomy.

This paper provides an overview of our augmented reality-based surgical guidance platform and focuses on the translation of the research from the IGS laboratory into the operating room. We discuss the clinical translation from the perspective of common intracardiac procedures, while outlining the necessary infrastructure and challenges that must be overcome to ensure smooth integration within the clinical environment in a modern OR.

2 Surgical Platform Architecture

Our surgical guidance platform integrates a wide variety components for IGS applications, including multi-modality image visualization, anatomical modeling, surgical tracking, and haptic control. Moreover, given the lack of visualization during off-pump surgery, we used this platform to build an AR environment to provide surgeons with a virtual display of the surgical field that resembles the real intracardiac environment to which they do not have direct visual access.

2.1 Augmented Reality Environment

Intra-operative Echocardiography: Ultrasound is widely employed as a standard interventional imaging modality. Specifically, 2D TEE provides good-quality images and eliminates the interference between probe manipulation and surgical work-flow, but the main drawback arises due to its inadequacy of depicting sufficiently crisp representations of the anatomical targets and surgical tools. While such inadequacies may be tolerable in *in vitro* studies performed in a laboratory environment under ideal conditions, they are highly amplified in a clinical setting by the complexity and variability of the anatomy, image quality, and orientation of the US beam with respect to the anatomy (**Fig. 2**). To address these limitations, we augment the 2D intra-procedure images with anatomical context supplied by the pre-operative models generated from CT or MR images acquired prior to the intervention.

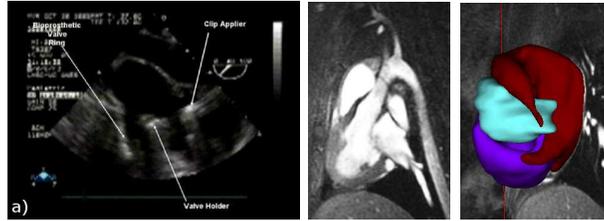


Fig. 2. a) 2D TEE image of the valve tool and clip applicator inside a beating porcine heart; b) Pre-operative MR image and c) model of porcine heart at mid-diastole.

Pre-operative Anatomical Modeling: For *in vitro* studies involving cardiac phantoms, we rely primarily on pre-operative CT images for model building, given their good contrast and temporal resolution, and make use of automatic techniques for image segmentation, such as the Vascular Modeling Toolkit⁴. On the other hand, once translating to clinical porcine studies, the insufficient contrast between cardiac structures provided by CT without contrast enhancement

⁴ VMTK: <http://villacamozi.marionegri.it/~luca/vmtk/doku.php>

forced us to resort to the use of MR images. Their excellent soft tissue characterization capabilities facilitated the of anatomical feature identification, leading to better quality subject-specific models. We first model each cardiac component, then assemble them together according to the complexity of the procedure. Typically, the main features of interest include the left ventricle myocardium (LV), the left atrium (LA), and the right atrium and ventricle (RA/RV).

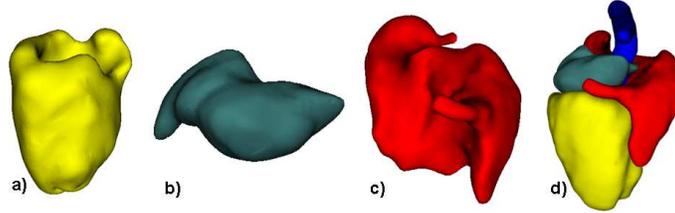


Fig. 3. Anatomical models of porcine heart chambers extracted from pre-operative MR images: a) LV; b) RA/RV; c) LA; d) Complete heart model: LV, LA, RA/RV.

However, MR imaging is still not the answer to all our doubts, as a next common obstacle is extracting fine anatomical structures (i.e. mitral or aortic valve) from low-resolution, thick-slice, clinical MR data. To ameliorate this inconvenience, we have developed and tested a technique on human data that relies on fitting a high-resolution, average heart model to clinical-quality MR datasets of new subjects via non-rigid registration, leading to reasonably accurate subject-specific models. Nevertheless, for the time being, porcine cardiac models are generated via manual segmentation, as we are in the process of building a porcine heart atlas similar to the human one.

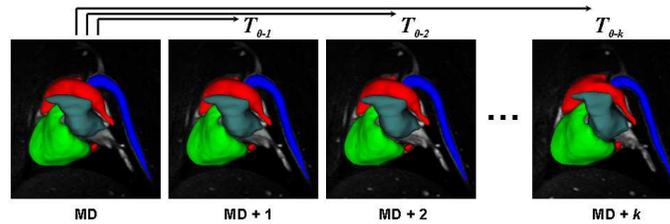


Fig. 4. Dynamic model of a porcine heart depicted at different cardiac phases.

Ultimately, a dynamic cardiac model depicting the heart at different time points in the cardiac cycle, is obtained by sequentially propagating the static model throughout the cardiac cycle with the motion estimated via non-rigid image registration [7] and rendered to portray the dynamics of the heart **Fig. 4**.

Pre-to Intra-op Registration: We employ a peri-operative feature-based registration technique to augment the intra-operative US images (**Fig. 5a**) with the pre-operative cardiac models (**Fig. 5b**). Easily identifiable targets in both datasets, the mitral (MVA) and aortic (AVA) valve annuli, are chosen to drive the registration. The pre-operative annuli are segmented manually from the cardiac MR image using a custom-developed spline-based segmentation tool (**Fig. 5b**) ; the intra-operative annuli are extracted from “pseudo” 3D US volumes generated by assembling 2D TEE images acquired at finite angular increments, according to their spatial and temporal time-stamps encoded by the MTS and ECG-gating. The algorithm first aligns the centroids (translational component) and normal unit vectors (rotational component) corresponding to the homologous annuli, and ultimately refines the alignment via an iterative closest point approach, minimizing the distance between homologous features.

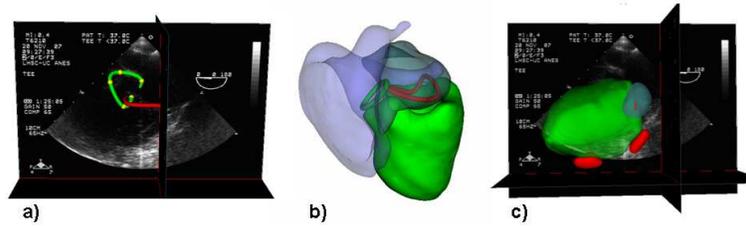


Fig. 5. a) Intra-operative US image, and b) pre-operative model, showing the MVA and AVA; c) Pre- and intra-operative datasets fused via feature-based registration.

This mapping technique is suitable for cardiac interventions, as the selected valvular structures are easily identifiable in both datasets, and they also ensure a good alignment of the pre- and intra-operative surgical targets. Furthermore, given the location of the features used to drive the registration, we expect good anatomical alignment in the surrounding regions, enabling us to employ this technique for a variety of image-guided interventions inside the heart.

Surgical Tracking: For all off-pump interventions, it is crucial for the surgeon to know the position and orientation of the instruments with respect to the intrinsic surrounding anatomy at all times during the procedure. In our platform, this feature is integrated via the NDI Aurora (Northern Digital Inc., Waterloo, Canada) MTS, which of course, imposes a series of limitations with respect to what equipment may or may not be present in the surgical field. Virtual representations of the instruments, registered to their physical counterparts, are tracked in real time relative to the pre- and intra-operative anatomy within the AR environment. In addition, a reference sensor is attached to a stationary region of the subject to avoid the need to recalibrate the “world” coordinate system in case of accidental motion of the subject or field generator. As an example, for a MV implantation, we need virtual representations for the TEE transducer,

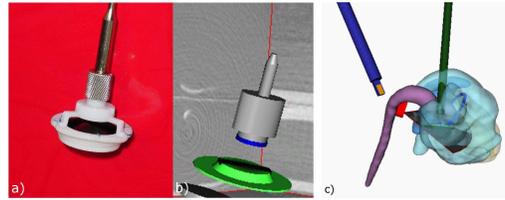


Fig. 6. a) Physical and b) virtual representation of a prosthetic mitral valve attached to the valve-guiding tool; c) AR environment specific to an *in vivo* porcine study.

valve-guiding tool and valve-fastening tool **Fig. 6**. A more sophisticated model is required for the US probe, as it incorporates the video feed from the scanner and the image plane must be automatically adjusted to changes in rotation angle and depth as manipulated by the sonographer.

3 Image-Guided Therapy Applications

Mitral Valve Implantation: Direct access was achieved using the Universal Cardiac Introducer (UCI) [8]. The AR environment consisted of the pre-operative model registered to the intra-procedure US, and virtual representations of the valve-guiding tool and valve-fastening tool — a laparoscopic clip applier. The procedure involves the positioning and fastening of the valve onto the native mitral annulus. Both steps entail the navigation of the tools to the target under guidance provided by the virtual models, followed by the correct positioning and attachment of the valve via surgical clips, guided via US (**Fig. 7**). Intra-operative assessment using Doppler imaging confirmed a successful valve placement, also observed in the post-procedure analysis. Nevertheless, one of the applied surgical clips failed to properly secure the valve due to poor penetration into the tissue.

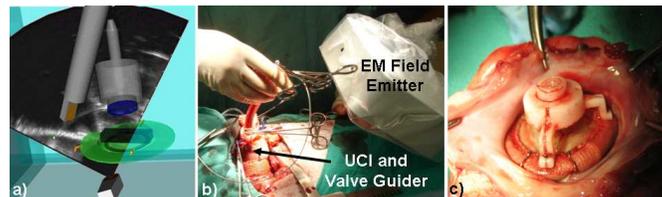


Fig. 7. a) AR environment showing virtual models of the US probe and surgical tools; b) OR setup during AR-guided interventions; c) Post-procedure assessment image.

Atrial Septal Defect Repair: The ASD repair procedure entails similar tasks as the MV implantation, however the surgical target is not readily defined. The

septal defect was created by removing a circular disc of tissue from the fossa ovale under US guidance, using a “hole-punching” tool. The blood flow through the ASD was identifiable on Doppler US. The repair patch was guided to the target under virtual reality guidance. Once on target, US imaging was used to correctly position the patch onto the created ASD and anchor it to the underlying tissue. Correct ASD repair was confirmed in the post-procedure assessment (**Fig. 8b**). While the VR-enhanced US guidance provided significant assistance in both navigation and positioning, this study also raised the need to improve tool design to better suit the limited intracardiac space.

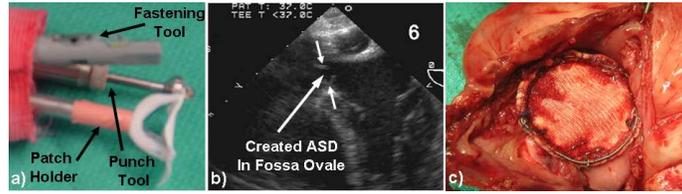


Fig. 8. a) Tools employed during the ASD creation and repair; b) 2D US image showing the septal defect; c) Post-operative image showing the successful ASD repair.

4 Roadblocks in Clinical Translation

In spite of our recent successes, the translation from the lab to the clinic has helped us identify caveats specific to the OR environment that had not posed major concerns within the *in vitro* laboratory conditions. Here we summarize some of these the lessons, hoping that some of you will learn from our experience.

How Accurate is Accurate Enough? One of the most frequent questions in IGS is “How accurate is your surgical platform”? One must keep in mind that, unlike orthopedic or neurological applications, cardiac IGS will always be prone to higher inaccuracies, mainly due to the high degree of rapid movement of cardiac tissue and the limitations of working in a blood filled environment, and amplified by the difficulties in building perfect anatomical models of the heart and the limited accuracy when mapping the pre-operative models to the intra-operative patient anatomy. We previously generated sufficiently accurate subject-specific models of the human heart capable to predict the MVA location throughout the cardiac cycle [4], and registered the models to their corresponding US images. Moreover, we quantified *in vitro* the alignment of the virtual models with their US images [9, 10], and assessed the accuracy in targeting static and dynamic “surgical targets” located on the epicardial surface of a beating heart phantom [11]. Given these applications, our system proves clinically feasible, considering the accuracy of the MTS on the order of 1-2 mm and the scope of the pre-operative models to enhance intra-operative anatomical context.

Zoom in where Needed: Surgical Target Identification. We currently employ the pre- and intra-operatively defined AVA and MVA to drive the model-to-subject registration peri-operatively in the OR. While the pre-operative features are better defined given the improved image quality, the intra-operative feature identification poses many challenges. We are currently exploring ways to acquire and reconstruct 3D US images from tracked 2D US images in nearly real-time, and employ automatic or semi-automatic algorithms to extract features. This approach would allow us to quickly and accurately identify the intra-operative surgical targets, and provide the flexibility to update the pre- to intra-operative registration as often as needed during the procedure. In spite of the recent launch of 3D TEE, this modality has a restrictive field of view which very often makes it impossible to visualize both the surgical targets and tools in the same volume; reconstructed 2D US, with its much larger field of view, is more robust if it can be achieved in near real time.

Cutting-edge Hardware: Surgical Tool Design. Surgical tool design and manufacture is a project of its own in IGS, especially when subject to multiple constraints imposed by the cardiac anatomy, interventional application, and surgical environment. We have always faced the challenge to design and build our own tools or adapt other available tools for the application at hand. For example, we had to build various prototypes for the valve- or ASD patch-guiding tools, embed the MTS sensors inside the tools, and test their compatibility with the surgical environment. Moreover, we adapted a laparoscopic stapler for abdominal interventions as a fastening device for both the valve and ASD patch, in spite of its slightly over sized dimensions for intracardiac applications. Most off-the-shelf tools do not comply with our requirements, and we do believe that the most efficient approach would be to involve a medical device manufacturer into the project and have them build tools that fit the applications. After all, sub-millimeter accuracy is meaningless unless appropriate surgical instruments are available for safe therapy delivery.

Minimizing our “Footprint” in the Operating Room. A “busy” environment is not uncommon in an OR, raising the concern of using magnetic tracking technology for surgical tool tracking as opposed to an optical system, which in turn implies the avoidance of any ferro-magnetic objects in close proximity to the magnetic field emitter [12]. Moreover, given that tracking accuracy decreases away from the magnetic field emitter, it is imperative that the field generator be placed within a range of 20-30 cm from the most probable tool location . Initially we had the field generator overhanging just above the surgical field, but space is also “expensive” in the OR, especially when surgeons complain of not having sufficient room in doing what they are best at. As this setup was obstructing the regular “task flow”, we adopted the approach of embedding the magnetic field generator within the mattress of the operating table, underneath the heart. This location has the additional benefit of placing tracked sensors closer to the field generator than large bodies of metal such as rib spreaders, making the MTS

substantially more robust. Cables from the sensors are placed under or along the OR table to be as unobtrusive as possible. Similarly, the overhead monitors must be placed such that the surgical team can access them with minimal effort.

Making the New Look like the Old: Teaching AR to Surgeons. The AR guidance platform is a novel surgical technique and in spite of our efforts to make it a common part of the current operating rooms, we are well aware that it may not make its way into conventional surgery for a few years. Over the years, surgeons have become familiar with “standard views” of human anatomy. Although we are now able to provide an unlimited range of oblique views of tools and surgical targets, it is often best to stick to the displays surgeons are most familiar with to maintain intuitive guidance. The best approach is to make the new look as much like the old, and instead of overwhelming them with a lot of new technology at once, rather give them the time to get accustomed to the new environments, and let them tell you how impressed they are. After all, very few surgeons will give your new guidance platform the time of the day while still in development, but they will all want to be the first ones to perform the clinical trials, especially if highly ranked by their colleagues and widely advertised by a large medical device manufacturer!

Maximizing Returns: Optimally Display the AR Environment. Minimal invasiveness restricts both visual and surgical access. For off-pump intracardiac interventions, surgeons can’t “see” what they do, and therefore the AR guidance platform **is** their eyes. We have considered several approaches regarding the most appropriate display of the AR environment to the surgeons, including a simple computer monitor, a flat screen overlaid onto the patient and located above the operating field, a stereoscopic screen enabling 3D visualization, or head-mount display (HMD) units, which allow the surgeons to directly “navigate” within a virtual volume [13, 14]. These different alternatives will be explored in our future work; for the time being, our surgical team has reported great comfort using both overhead monitors and HMD units for visualization.

5 Conclusions

We briefly described several IGS components developed and validated in our laboratory and outlined the path to transpose traditional cardiac surgery into an AR environment in a clinical setting. Some of the lessons learned while paving the road to the clinic have proved to be rather harsh and we still expect several other surprises down the road, given the increased complexity of the procedures attempted. But nevertheless, new image guidance tools are being developed almost every month, new generations of clinicians complete their medical training every year, so it really is not unrealistic at all to expect that operating rooms of the future will be readily equipped with image-guidance systems.

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