A Navigation Platform for Guidance of Beating Heart Transapical Mitral Valve Repair

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Abstract. Traditional approaches for repairing and replacing mitral valves have relied on placing the patient on cardiopulmonary bypass (on-pump) and accessing the arrested heart directly via a median sternotomy. However, because this approach has the potential for adverse neurological, vascular and immunological sequalae, there is a push towards performing such procedures in a minimally-invasive fashion. Nevertheless, preliminary experience on animals and humans has indicated that ultrasound guidance alone is often not sufficient. This paper describes the first porcine trial of the NeoChord DS1000 (Minnetonka, MN), employed to attach neochords to a mitral valve leaflet where the traditional ultrasound guided protocol has been augmented by dynamic virtual geometric models. In addition to demonstrating that the procedure can be performed with significantly increased precision and speed (up to 6 times), we also record and compare the trajectories used by each of five surgeons to navigate the NeoChord instrument.

Keywords: Image guided surgery, mitral valve repair.

1 Introduction

Degenerative mitral valve disease (DMVD) is a common heart valve disorder where a ruptured or prolapsing valve leaflet results in incomplete mitral valve closure, often resulting in shortness of breath, fluid retention, heart failure and premature death[1]. DMVD affects 2% of the general population [2]. Severe, symptomatic disease is treated by surgical repair or replacement. DMVD is characterized by abnormal connective tissue of the mitral valve, resulting in weakening and rupture of the chordae tendonae (chords), the support structures of the mitral valve, preventing its natural closure. Major advances in mitral repair surgery have improved short- and long-term outcomes of patients with this disease [3].

Conventional open heart cardiac surgery often requires a full sternotomy, cardiopulmonary bypass, temporary cardiac arrest and is associated with longer

P. Abolmaesumi et al. (Eds.): IPCAI 2012, LNAI 7330, pp. 84–93, 2012.

recovery periods, which may not be as well tolerated in elderly patients with multiple co-morbidities. Recent innovations in minimally invasive and robotic mitral repair techniques employ sternal sparing approaches to reduce the invasiveness of the procedure [4][5], but still require the use of cardiopulmonary bypass which has many associated complications. While the emerging field of transcatheter mitral valve repair avoids the risks of conventional surgery and potentially offers hopes of beating heart mitral valve reconstruction, concerns about residual mitral insufficiency, durability and inadequate mitral valve repair have been raised [6].

The NeoChord DS-1000 (NeoChord, Minnetonka, MN, USA) is a device capable of performing off-pump, mitral valve repair for certain forms of DMVD[7] [8]. The device uses trans-apical access to approach and capture the prolapsed portion of the mitral valve leaflet, attach a suture and anchor it at the apex, constraining the flail leaflet and reducing the prolapsed segment back into the left ventricle. Currently, this procedure relies exclusively on trans-oesophageal echocardiography (TEE) guidance in the form of 2D single plane, bi-plane, and 3D imaging. While TEE has thus far proven adequate for the final positioning of the tool and grasping the leaflet, there have been safety concerns relating to the navigation of the tool from the apex to the target MV leaflet. TEE guidance is problematic since it is not always possible to maintain appropriate spatial and temporal resolution in 3D, and it is not always possible using 2D and 2D bi-plane views to simultaneously maintain both the tool tip and target site in the field of view. Using 2D echo it also can be difficult to ensure that the tool tip is visualized, rather than a cross section of the tool shaft. Due to these navigation challenges, the tool can become caught in the 'subvalvar apparatus', risking chordal rupture or leaflet perforation.

Recently, a variety of augmented reality (AR) systems has been developed for intracardiac surgery [9], [10]. To improve the overall safety of the navigation process in the NeoChord procedure, we have evaluated the efficacy of employing an augmented reality technique capable of providing a robust three dimensional context for the TEE data. In this real-time environment, the surgeon can easily and intuitively identify the tool, surgical targets and high risk areas, and view tool trajectories and orientations. This paper provides a description of the overall navigation framework and proof of concept validation from an animal study. We begin with a summary of the current OR procedure workflow, followed by a discussion of our navigation system and its role in this workflow. We then describe and discuss our proof of concept experience from a porcine study.

1.1 Current OR Workflow

After extensive animal studies, the NeoChord device is currently undergoing preliminary in-human trials for the repair of flail mitral valves [11]. The procedure uses off-pump trans-apical left ventricle (LV) access. The tool is identified in 2D bi-plane echo (mitral valve commissural, mid-oesophageal long-axis view), and navigated into the commissure of the MV leaflets while the surgeon and echocardiographer attempt to maintain tool tip, tool profile, and final target site in the echo image planes at all times. Correct position and orientation of the tool gripper are then achieved using a 3D zoomed view. Returning to bi-plane echo for higher temporal resolution, the prolapsing leaflet is grasped by the jaws of the NeoChord device. Correct leaflet capture is verified using a fiber-optic based detection mechanism. After leaflet capture has been verified, an ePTFE (expanded polytetrafluoroethylene) suture is pulled through the leaflet and the tool is retracted with both ends of the suture. The suture is fixed at the leaflet with a girth hitch knot, adjusted under Doppler echo to ensure minimum mitral regurgitation (MR) and then secured at the apex using a pledget. Multiple neochordae are typically used to ensure optimal valvular function.

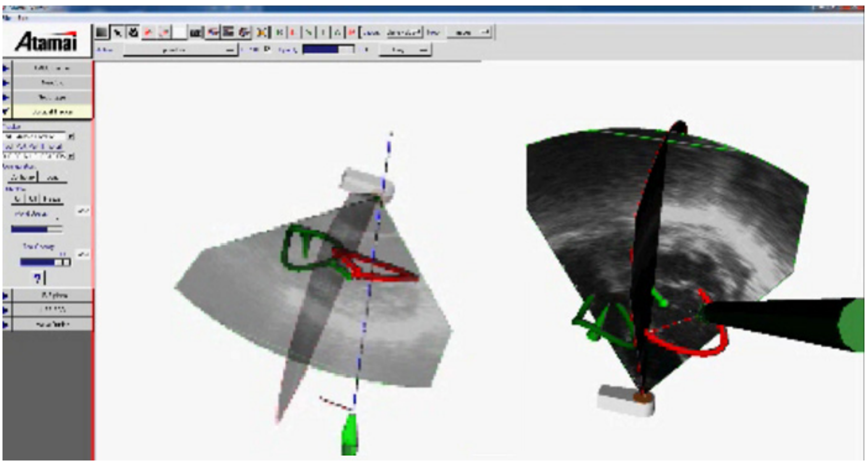
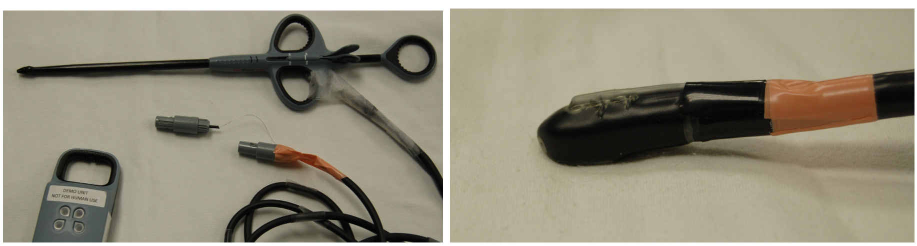


Fig. 1. Intraoperative guidance: Biplane ultrasound view augmented with targets denoting the Mitral (red) and Aortic (green) valve annuli, along with the representation of the delivery device with a blue axis indicating forward trajectory and red axis indicating direction of the jaw opening. "Bullseye" view (right) shows solid echo image, while "side" view (left) shows semi-transparent image data.

2 Methods

2.1 Augmented Echocardiography

The single largest problem in navigating the NeoChord device to the MV target region is that echo imaging must simultaneously keep the target region (MV line of coaptation) and the tool tip in view. To overcome this challenge, we have developed a visualization environment [9] that uses tracking technology to locate both the tool and the TEE probe in 3D space, making it possible to represent the real-time echo images with virtual geometric models of both devices and interactively defined anatomy within a common coordinate system (Fig.1). Sensors from the Aurora (Northern Digital, Waterloo, Canada) magnetic tracking system (MTS) were integrated inside the NeoChord tool (Fig.2a) and onto the TEE probe of the Philips iE33 ultrasound (Fig.2b). Virtual geometric models of each device were created in VTK (Visualization Toolkit) and the tools appropriately calibrated [12]. Axes with 10mm markings were projected from the virtual representation of the NeoChord DS1000, indicating the forward trajectory of the tool and the direction of the opening jaws. This greatly facilitated the surgeons ability to plan their tool trajectory towards the desired target site. In addition to representations of the tools, tracking the TEE image data makes it possible to define anatomy of interest (aortic valve annulus (AVA)), target location (MV line of coaptation, and regions to be avoided (mitral valve annulus (MVA)) for contextual purposes. These geometric features are defined by the echocardiographer intraoperatively, immediately prior to the introduction of the NeoChord tool into the heart. The MVA and AVA geometries are created by manually identifying a series of tie points along each feature, and fitting a B-spline through these points. All features are identified in mid-systole, since the MV annular ring is closest to the apex at this point in the cardiac cycle. This in effect provides an indicator of the first danger zone to be avoided as the tool is moved into the left ventricle from the apex.



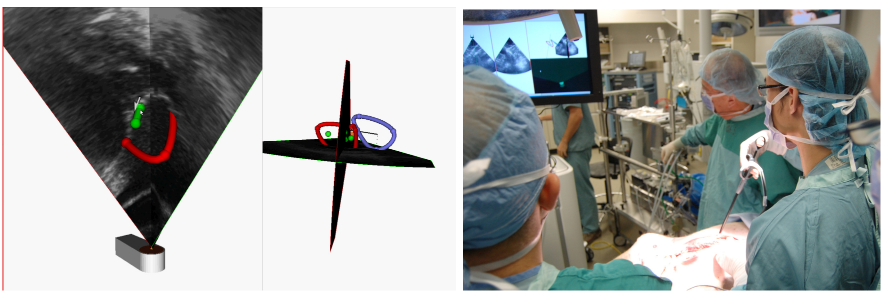
(a) NeoChord DS1000 (b) TEE

Fig. 2. Left: NeoChord DS1000 outfitted with tracking sensors. One 6-DOF sensor was installed near the tool tip, and a 5DOF sensor was built into the movable thumb grip in order to represent the tool as open or closed. Fiber-optic grasping monitor shown lower left. Right: Close-up of MTS sensor fixed to the back of the TEE transducer.

2.2 Integration into OR Workflow

Our AR guidance system is designed to assist the surgeon with three related navigation tasks; planning the left ventricular apical access point and trajectory; maintaining a safe and direct entry through the MV commisure into the left atrium, and establishing the correct tool orientation at the line of coaptation so the NeoChord DS1000 device can grasp the flail leaflet. To achieve this, prior to making the apical entry incision, the echocardiographer identifies a minimal number of tie points along the pertinent anatomy (AVA, MVA, line of coaptation). From these coordinates, a series of splines are generated to represent these features in virtual space (Fig.3a). Next, the surgeon uses the trajectory projection of the NeoChord DS1000 tool to plan the optimal entry point and orientation (Fig.3b). After apical access, the surgeon simply orients and points the tool trajectory towards the desired target site and advances the tool, monitoring the geometric model representations as seen on the real-time echo image data. By overlaying the geometric models on the real echo image data, the surgeon is able to assess the accuracy and reliability of these representations in real time. If the features have moved, for example due to the introduction of the NeoChord tool, the features can be re-defined before proceeding. Once at the desired target location, the procedure returns to the standard workflow, since additional guidance is no longer needed.

The technology associated with the AR navigation system has minimal impact in the operating room. The Aurora Tabletop magnetic field generator is specifically designed to work in the presence of various sources of metal. It has a large field of view, and easily fits on top of the OR table. Sensors attached to the TEE probe and surgical tools should not impede normal OR workflow. Furthermore, the cost associated with this technology is not prohibitive for most institutions.



(a) Feature definition (b) Planning access point

Fig. 3. Left: Side and 'top-down' views of intraoperatively defined anatomy (MVA in red, AVA in blue, line of coaptation in green). Right: Planning entry trajectory in the OR.

2.3 Proof of Concept: Animal Study

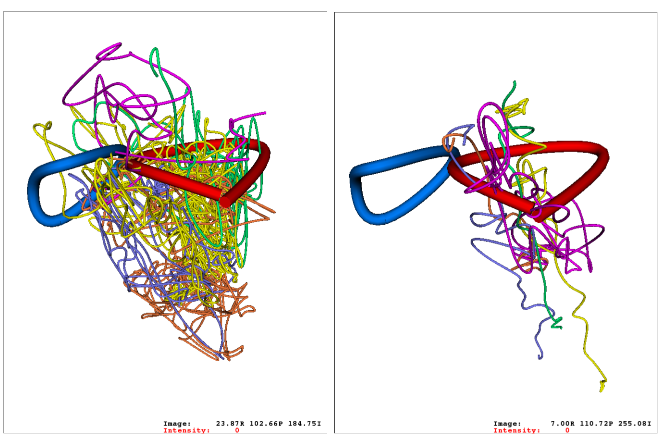
A porcine animal study was performed to provide a proof-of-concept validation for the AR navigation system. All procedures were performed in compliance with standards of the Ethical Review Board of Western University, London, Ontario, Canada.

A total of five cardiac surgeons participated in the study. The first goal was to evaluate different visualization options. A four-pane view showing the two biplane TEE images beside two AR views, which could be arbitrarily adjusted as determined by the surgeons (Fig.3b) was compared to a larger two-pane view of the AR scenes (Fig.1), with the surgeon relying on the bi-plane view on the iE33 monitor. A variety of viewing angles was evaluated anecdotally by the surgeons prior to finding a consensus. The second goal was to compare navigation of the tool from apex to target region with and without AR assistance. The surgeons were asked to navigate the NeoChord tool from a starting point near the apex, up through the mitral valve (MV) line of coaptation, situating the distal end of the tool in the left atrium. Meanwhile, the tool location was tracked and recorded at half second intervals and total navigation time was measured. The safety of the process was assessed using the tracking data, while task completion time acted as a measure of the cognitive demands placed on the surgeon.

3 Results

Prior to the study, the visualization configuration was optimized using input from the surgeons. The dual-pane AR view was consistently preferred over the four-pane version that included the bi-plane data also available on the iE33 unit. The consensus was that since the bi-plane information was readily available on an adjacent monitor, it was advantageous to have larger versions of the AR data available in the two-pane view. The surgeons quickly agreed on preferred viewing perspectives, one view representing a typical long-axis echo, the second view extending “up” from the apex towards the MVA (Fig.1). These views provided optimal intuitive presentation of navigation in all three dimensions.

Planning the point of entry at the apex and preparing the proper tool orientation was greatly facilitated by viewing the virtual tool axes relative to the MVA ring. While apical access is the standard procedure for trans-apical surgeries, there is some debate that a slightly more lateral entry point towards the papillary muscles may provide a better anchoring point for the neochordae. Our

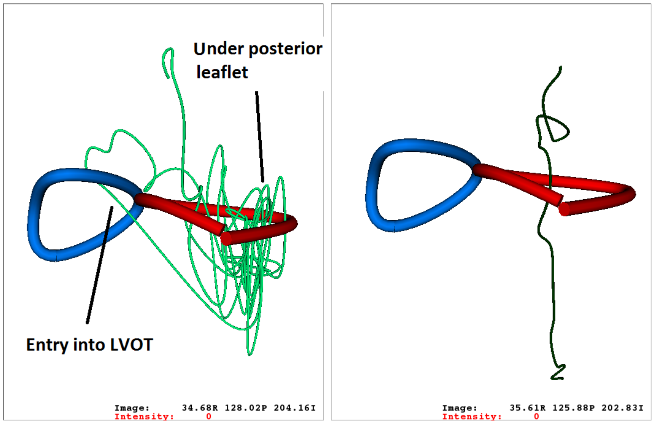


(a) Echo only (b) Augmented reality

Fig. 4. Colour-coded tool paths for all five surgeons: AVA shown in blue, MVA in red. Left: with biplane echo guidance. Right: AR guidance.

AR navigation platform makes it possible to evaluate such questions prior to making the incision.

Magnetically tracked tool paths are shown in Figures 4a and 4b with a unique colour coding for each surgeon. Figures 5a and 5b present path data for one of the surgeons in isolation. Navigation time data are presented in Table 1.



(a) Echo only (b) AR guidance

Fig. 5. Left: Navigation path for one of the surgeons. Note entry into left ventricular outflow tract (LVOT), and getting caught under the posterior MV leaflet. Right: Same surgeon using AR guidance.

4 Discussion

Minimal AR Overlay. AR displays often add considerable information to the real visual field. While the information added may be necessary for successful guidance of a given procedure, it also invariably obscures some of the native data when the two are overlaid, as well as increases the cognitive load on the surgeon. One solution to this problem is to present the new guidance information in a separate window without any overlay onto the native data. The disadvantage of this approach is that it is difficult to identify mis-registration of preoperative or tracking data, potentially reducing procedure safety. An alternative solution is to minimize the amount of information overlaid onto the native image data. The complexity of information to present depends primarily on the surgical task and where image guidance support fits into the surgical workflow. The problem we wished to solve was the difficulty of keeping the surgical target site (MV line of coaptation) and unsafe regions (MVA), and the tool tip in the echo image plane simultaneously. Hence, the minimal data needed are the MVA at systole, (since this is it's closest approach to the tools starting point at the apex), the line of coaptation and the tool tip itself. To this we added the AVA since it provides both a helpful anatomical reference point as well as a secondary "danger zone" to avoid. Finally, the tool axes were added as a means of planning a path trajectory with minimal footprint within the visualization scene.

Intuitive Navigation. Of the five surgeons involved in the navigation test only one had previous experience using the NeoChord device, while another performed the navigation task more quickly using echo alone. The mean task completion time fell by a factor of almost six when using AR, strongly indicating the AR system greatly reduces the cognitive demands of navigating a tool using echocardiography. Previous animal studies have indicated a significant difference between expert and beginner surgeons ability to use the NeoChord device[13]. In our results, the standard deviation dropped from 94 seconds in echo-alone guidance to 8 seconds for AR navigation, suggesting the AR platform provides a more universally intuitive method for tool navigation, and can greatly reduce the learning curve associated with this surgical procedure.

Table 1. Surgeon navigation: times from apex to target site (seconds)

Surgeon	AR-enhanced echo	TEE biplane alone
1	26	264
2	15	201
3	18	92
4	35	25
5	12	36
mean	21 ± 8.3	124 ± 93.9

Safety Considerations. The graphical representation of navigation paths (Figures 4a, 4b) clearly and consistently demonstrate that more direct paths were followed during the placement of the tool in position for grasping the MV leaflet using AR navigation. Figures 5a and 5b isolate the paths taken by one surgeon (the most experienced with the device), with and without AR navigation. Two interesting phenomena can be observed in the echo-only guidance path: at one point the tool entered the left ventricular outflow tract and passed through the the aortic valve, while later it appears to be caught under the posterior MV leaflet. Both these patterns can be seen in all five echo-only datasets, while they never appear in the AR navigation paths. The phenomena of getting caught under the MV leaflet is of particular concern for this procedure, since this is the circumstance where a thin leaflet could be perforated.

Areas for Improvement. For our animal studies, two NeoChord tools were retrofitted with MTS sensors to track the tool shaft and tip locations. Sensors in both tools suffered breakdowns during the procedures and needed on-site repairs. More robust sensor integration and strain relief is planned for future work.

While our semi-automatic feature definition software provides sufficient accuracy for the procedure, it took up to 20 minutes to define the AVA, MVA and line of coaptation in systole. The line of coaptation was particularly difficult to identify in healthy porcine hearts. We believe this feature to be much easier to define in humans, particularly when a prolapsed or flailing leaflet is present.

More careful selection of standard viewing angles must be performed to permit observation of both echo image data and geometric models representing tool and anatomy; in most cases, we needed to present the echo data in a semi-transparent fashion, otherwise the geometric model elements were occluded from view. While presenting echo data in this manner did not prove to be a large problem, it is important always to rely primarily on the real ultrasound data, rather than the geometric constructs. The advantage of integrating echo with geometric model elements is that it provides real-time validation of augmented reality accuracy; when the echo image data are made semi-transparent, the surgeon's ability to verify the accuracy of geometric model elements is hampered.

5 Conclusions

We show proof-of-concept validation for augmented reality enhanced echocardiograpy intracardiac navigation for the NeoChord off-pump mitral valve repair procedure. Using echo guidance alone compared to AR navigation, five cardiac surgeons used the NeoChord device to navigate the tool from entry at the apex of the heart to a point at the line of coaptation in the mitral valve. Tracked path results clearly show improved safety and time using AR navigation.

Future work will entail improving our feature definition software, more robust sensor integration into the NeoChord, a further analysis of psychophysical factors of AR navigation, and comprehensive surgical workflow analysis to integrate AR navigation into standard of care procedures. Further animal studies are planned to provide a significant sample size for thorough comparison of AR guidance versus echo alone. In addition the visualization environment will be enhanced to integrate planning functions based on pre-operative imaging.

Acknowledgments. The authors would like to thank John Zentgraf and Arun Saini (NeoChord) for assistance with tool development, and Dr. Richard Daly (Mayo Clinic, Rochester, Minnesota) for assistance with the animal study and data analysis. Funding for this work was provided by Canadian Foundation for Innovation (20994), the Ontario Research Fund (RE-02-038) and the Canadian Institutes of Health Research (179298).

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