# A system for visualization and automatic placement of the endoclamp balloon catheter

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## ABSTRACT

The European research network "Augmented Reality in Surgery" (ARIS*ER) developed a system that supports minimally invasive cardiac surgery based on augmented reality (AR) technology. The system supports the surgical team during aortic endoclamping where a balloon catheter has to be positioned and kept in place within the aorta. The presented system addresses the two biggest difficulties of the task: lack of visualization and difficulty in maneuvering the catheter.

The system was developed using a user centered design methodology with medical doctors, engineers and human factor specialists equally involved in all the development steps. The system was implemented using the AR framework "Studierstube" developed at TU Graz and can be used to visualize in real-time the position of the balloon catheter inside the aorta. The spatial position of the catheter is measured by a magnetic tracking system and superimposed on a 3D model of the patient's thorax. The alignment is made with a rigid registration algorithm. Together with a user defined target, the spatial position data drives an actuator which adjusts the position of the catheter in the initial placement and corrects migrations during the surgery.

Two user studies with a silicon phantom show promising results regarding usefulness of the system: the users perform the placement tasks faster and more accurately than with the current restricted visual support. Animal studies also provided a first indication that the system brings additional value in the real clinical setting. This work represents a major step towards safer and simpler minimally invasive cardiac surgery.

**Keywords:** Minimally Invasive Surgery, Cardiac Surgery, Augmented Reality, Robotics

## 1. INTRODUCTION

In minimally invasive mitral valve surgery the heart has to be stopped and the aorta has to be sealed (clamped) to isolate the heart from the rest of the circulation. Unlike in the open chest procedure, the aorta cannot be clamped from the outside. This can be done with an endoclamp, a catheter with an inflatable balloon at its tip. Once inflated in the aortic arch, the balloon provides the required sealing[1]. This technique (Port-Access™ technique) is used nowadays as a standard procedure in several hospitals worldwide but it presents two main difficulties: initial placement, and monitoring of balloon migrations.

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Medical Imaging 2010: Visualization, Image-Guided Procedures, and Modeling, edited by Kenneth H. Wong, Michael I. Miga, Proc. of SPIE Vol. 7625, 76250C · © 2010 SPIE · CCC code: 1605-7422/10/$18 · doi: 10.1117/12.844100

Initial placement is normally done using Trans-Esophageal Echography (TEE) as visual guidance with good results, but it is a hard task with a long learning curve mainly due to difficulties in maneuvering (difficult to control the balloon while there is still blood flow) and visualizing the balloon (with TEE it is only possible to see the balloon on a very small section of the artery)[2,3]. Monitoring the balloon position during the surgery is even a harder challenge because TEE is unusable as there is air inside the heart. Monitoring is extremely important as there can be damage to the aortic valve, occlusion of the coronary arteries, or damage to the central nervous system (even resulting in death) as a result of occlusion of the brachiocephalic trunk. The latter case is monitored indirectly by comparing right and left arm arterial pressures (occlusion causes right arm pressure drop). But migrations are hard to detect and are difficult to correct without visual guidance. Better monitoring and control of balloon position is needed if we want to provide a safe and uncomplicated sealing of the aorta in this type of surgery.

The European research network "Augmented Reality in Surgery" (ARIS*ER)[4] developed applications using augmented reality (AR) and robotics to overcome common problems in minimally invasive surgery (MIS): lack of visual information and lack of dexterity. In the context of this project, we present a combined information and positioning system based on augmented reality technology and robotics to support minimally invasive mitral valve surgery using the port-access (PA) technique. The designed system provides constant, real-time monitoring of balloon position during the entire procedure, automatic position control to a specified target (useful for initial placement and to correct migrations) and automatic balloon pressure control. We believe that such a system helps overcome some of the most important difficulties in the PA technique and has the potential to make it the technique of choice for minimally invasive cardiac surgery.

# 2. METHODS

## 2.1 System design

We followed a user centred design approach with engineers, clinicians and human factor specialists involved in all the development phases. Safety aspects were initially analyzed in a workshop[5] held at the project kick-off meeting. In the meeting, the key problems were identified and high level requirements derived. Following, in a brainstorming session, conceptual technical solutions were defined. The requirements and technical solutions were refined in an iterative process during the project with workshops, interviews, surgery observations and brainstorming sessions.

Based on this, a concept for the system was designed. Figure 1 shows an overview diagram of the design. The balloon position is measured in real time using a magnetic tracking system with the help of a sensor coil placed inside the balloon catheter. This measurement is used to superimpose a visual model of the balloon on a 3D scan of the patient's thorax showing its actual position inside the vessel at all times. The dataset can be created from different image modalities such as computed-tomography (CT) or magnetic resonance imaging (MRI).

The deformation of the structures of interest is assumed to be negligible. This was defined together with the surgeons and considered to be a good first approach. Based on this assumption, a point-based rigid registration algorithm is used to align tracking data with the model. The position information, together with a user defined target, is also used to control a robotic catheter inserter which positions and maintains the balloon in the correct location at all times. If still there is a migration, the system automatically takes care of repositioning in the correct location. The robotic inserter was custom designed for the purpose and is able to push and pull the catheter inside the vessel. The pressure inside the balloon is also automatically controlled using a mechanical syringe pump based on pressure measurements and estimations taking into account the dynamics of the system catheter-balloon-aorta[6].

## 2.2 Software architecture

The system was implemented using the AR framework "Studierstube"[7]. Using this framework it is easy to combine tracking sources using the opentracker (OT) library[8] with 3D scene models and 3D dataset rendering using the coin3D and SimVoleon libraries (www.coin3d.org). Studierstube is a component based framework and thus easily extendable. A component exists for binding with the Qt graphical user interface (GUI) design framework (qt.nokia.com) which we used to develop our GUI shown in Figure 2b. The main visual feedback is given to the user through a 3D scene with the tracked balloon superimposed on the rendered aorta model. Figure 2a describes the main concepts in the scene. The scene is shown in three different views: 3D, coronal and sagittal (Figure 2b). The user can define a target position and a tolerance region using the controls. This will move the target and tolerance lines and activate the range indicator when

the balloon is within the tolerance. Finally it is possible to control the mechanical actuator and pump directly using the manual controls.

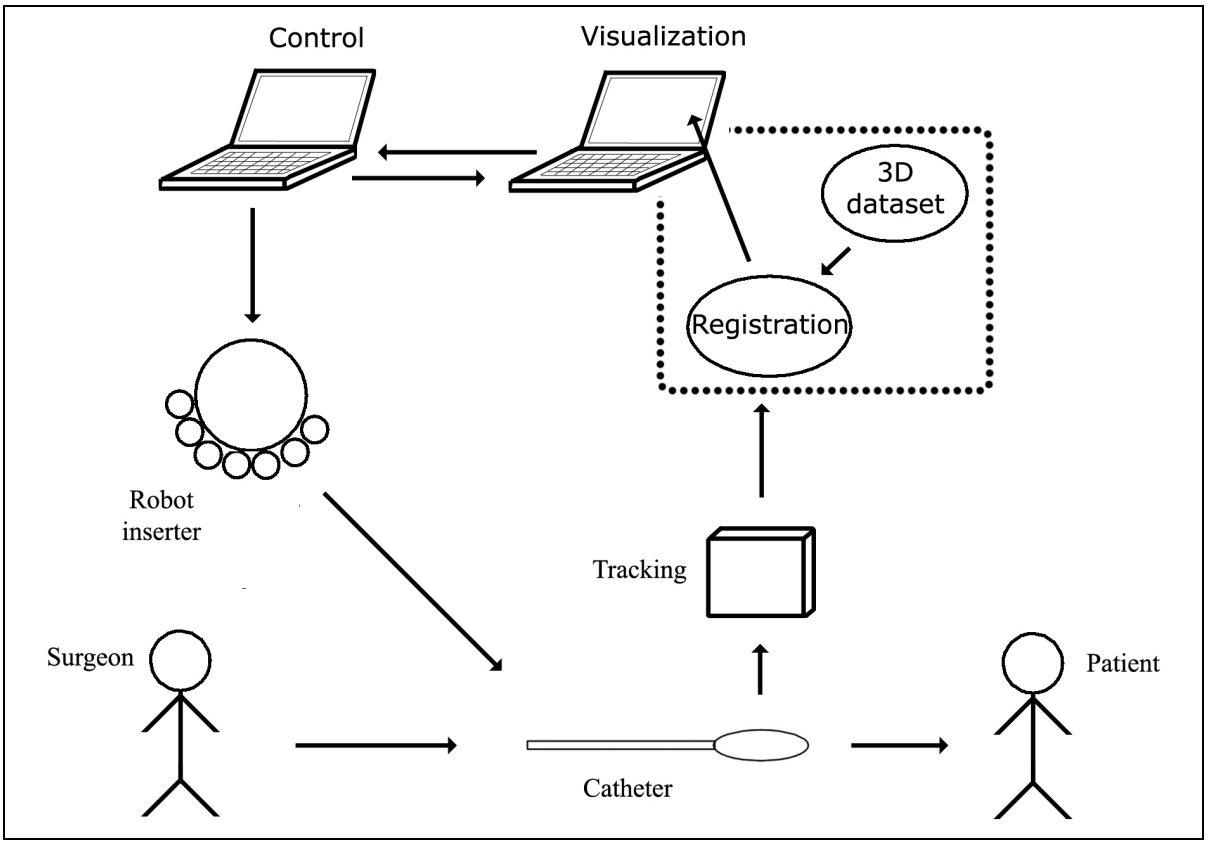


Figure 1. Overview of the system

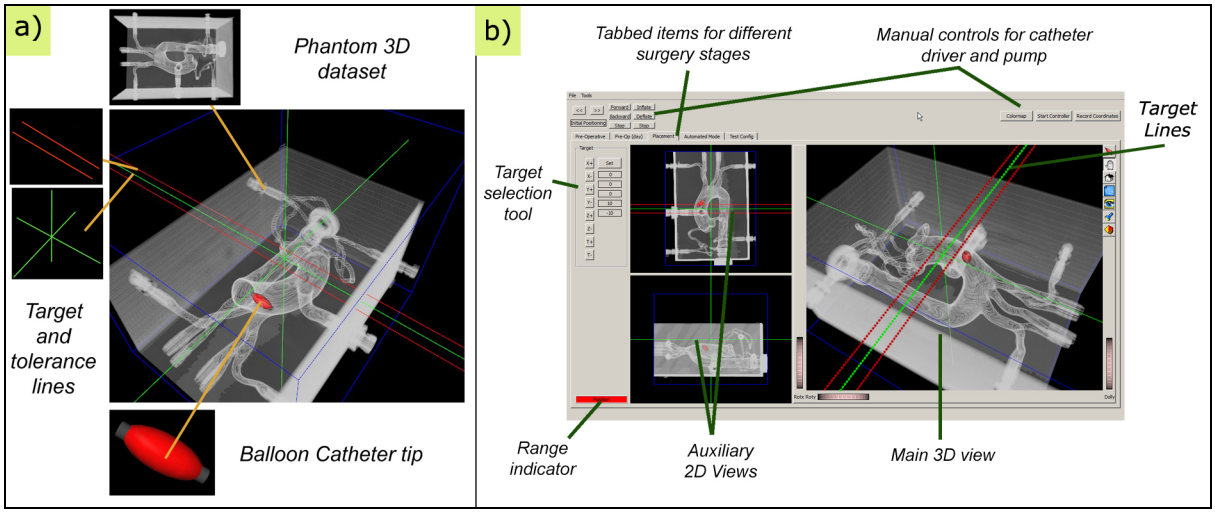


Figure 2. User interface of the system with explanation of the key concepts.

Figure 3 shows a simplified diagram of the scene graph (corresponding to what is seen in Figure 2a) with the indication of the Coin3D nodes used. Apart from the objects already mentioned (balloon, 3D dataset and target lines) the connection of the balloon object to the tracking data is highlighted. This connection is done using the SoMultimodalEngine, a Studierstube specific node that receives tracking data from Opentracker and by connecting the "trackingTransform" node to the engine. The transform parameters "translation" and "rotation" will follow the data coming from the SoMultimodalEngine. With this mechanism and after successful registration, the balloon model shows the position of the real balloon catheter tip within the aorta.

The 3D rendering in the scene is done using the SimVoleon library. This library renders a volume from a file in the "VOL" format[9] which consists of a single file with a header followed by the raw data slice by slice. In our case, we used axial CT slices in DICOM format which first had to be converted to raw 8 bit images and then compiled in a file in the proper VOL format by means of a MatLab script.

For the animal tests, an extra segmentation task was needed. This is because, with real anatomy, it is not easy to distinguish the aorta amongst the other structures. So instead of rendering the dataset on the screen, the aorta was segmented and only the obtained model was represented. For the segmentation, ITKSnap (www.itksnap.org) was used.

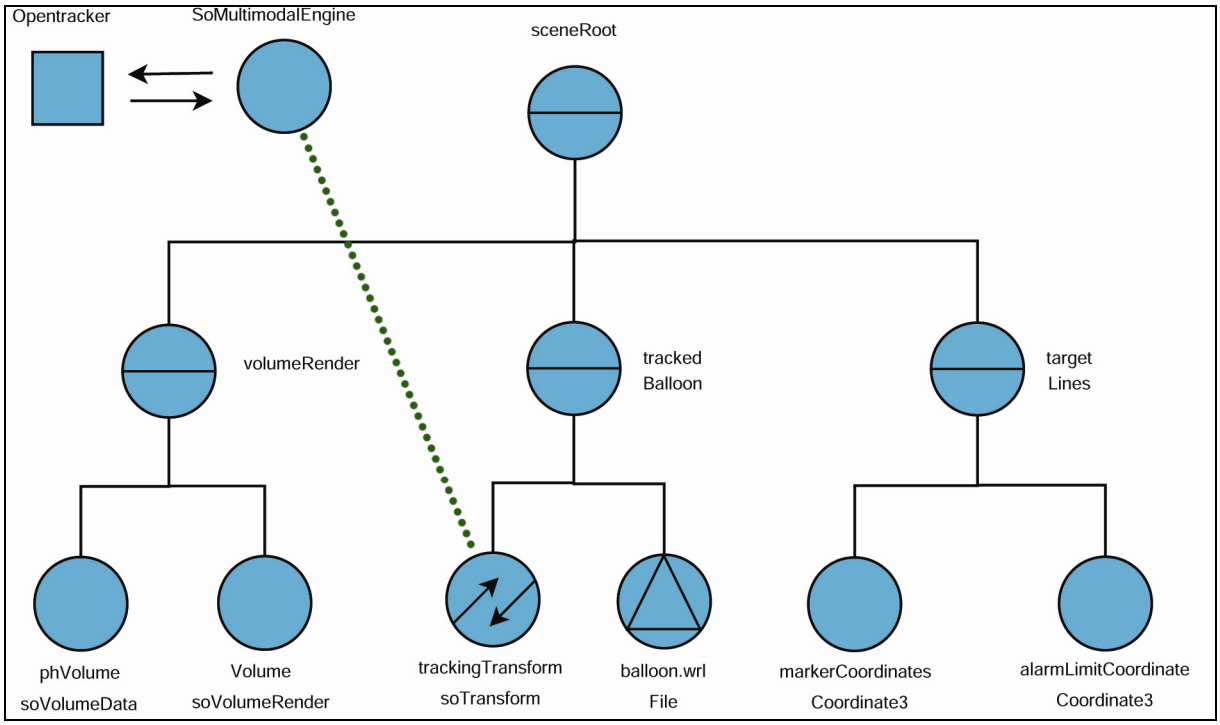


Figure 3. a) Simplified scene graph used in the application, b) opentracker config file showing the sink nodes

A rigid registration algorithm is used to align the tracking data with the 3D pre-operative dataset. A matrix transform is found by performing point based registration with the help of fiducial points which can be natural landmarks or implanted markers. Figure 4 shows the screen where registration is performed. On the right side, it is possible to mark a point in 3D space by selecting a slice and then selecting a point from the 2D image. The point will be represented by a sphere in the 3D view on the left side. After a collection of points has been selected, we acquire the same points in the patient using a tracking pointer and calculate the transform based on the matching pairs of points from the two collections.

The control algorithm was implemented in LabView. For the catheter position, a proportional-integral-derivative (PID) controller was used. For the pressure, a control scheme based on physiological parameters that estimates the aorta-balloon dynamic response to inflation was used. The software runs on a different computer and interfaces the mechanical inserter and the syringe pump using a National Instruments DAQ board. It needs the position error, that is, the distance between the current catheter position and the target. This error is made available to the control software by means of TCP/IP connection implemented in a client / server manner. The server resides on the main visualization part and the

client on the control part. The control part connects and requests the current error value which is provided by the server. As for the balloon pressure control, the control software reads the current value directly on pressure sensors and the same client/server mechanism is used for reading the target pressure which was defined by the surgeon on the visualization part.

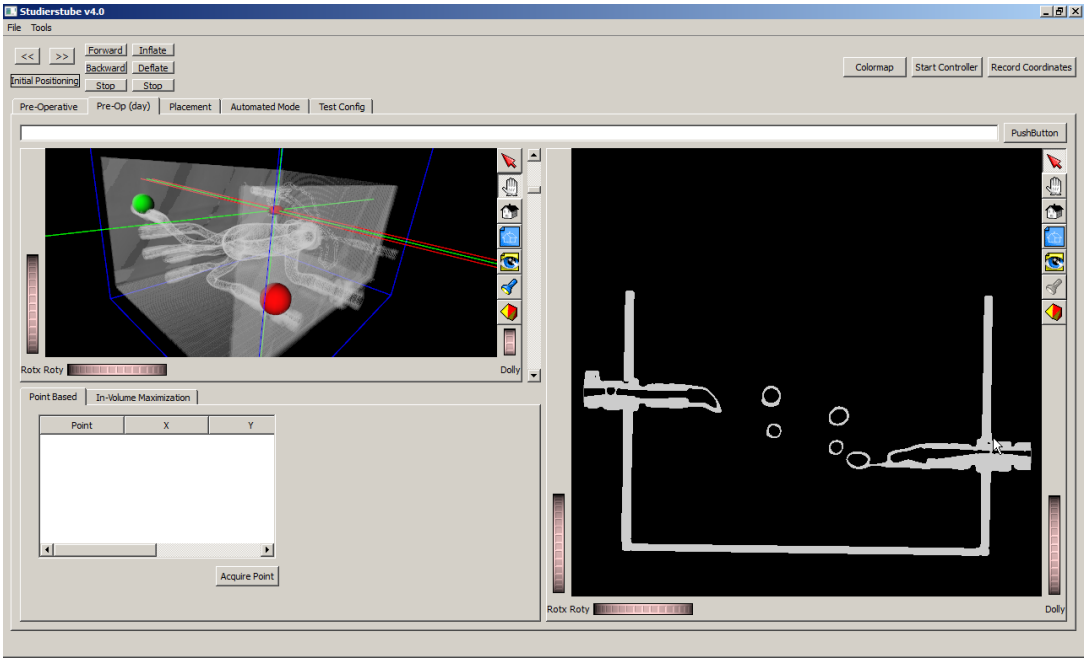


Figure 4. The registration interface

### 2.3 Hardware

The system was designed to use the Endoclamp™ balloon catheter manufactured by Edwards life sciences (Figure 5a). The tracking hardware used was the Aurora magnetic tracking system (Figure 5b). The system can track mini-coil sensors (Figure 5c) of 8 mm x 0.55 mm (length x diameter) with an accuracy of 0.9mm which is appropriate for our application. We placed a sensor in the centre of the balloon trough one lumens of the catheter so that the spatial position could be measured in real time. The tracking system is fully approved for medical use. We chose magnetic tracking because there is no line of sight to the inside of the patient during the surgery and by the fact that the mini coils are small enough to be inserted into one of the balloon's lumens, allowing the placement of the sensor exactly at the centre of the balloon.

To test the system, a flexible, transparent, silicon aortic phantom with real size anatomy was used (Shelley Medical Imaging Technologies, model T-S-N-002+ (Figure 5d). It is possible to perfuse it with water or other fluids and to insert catheters in a conventional way.

The robotic inserter was custom designed for the application and consists of a spinning wheel connected to stepper motor and free spinning wheels that guide the catheter through (Figure 5e).

### 2.4 Testing

The system was validated in several phases: initial proof-of-concept, two user studies and animal tests. The proof-of-concept and user studies were done with the silicon phantom model seen in Figure 5d. The phantom was perfused with water with a flow rate of 5 l/min. The users had the task of performing several full insertions starting with the catheter outside the model until it was placed in the correct location in the aortic arch. The aim was to be as fast and as accurate as possible. The insertions were performed to compare different forms of visual support: real view, where the users were looking inside of the transparent phantom, 3D view where they used only the system and restricted view where a simulation of the current TEE support was used. The time and accuracy of the insertion tasks was measured and the users filled out a questionnaire rating the visual support.

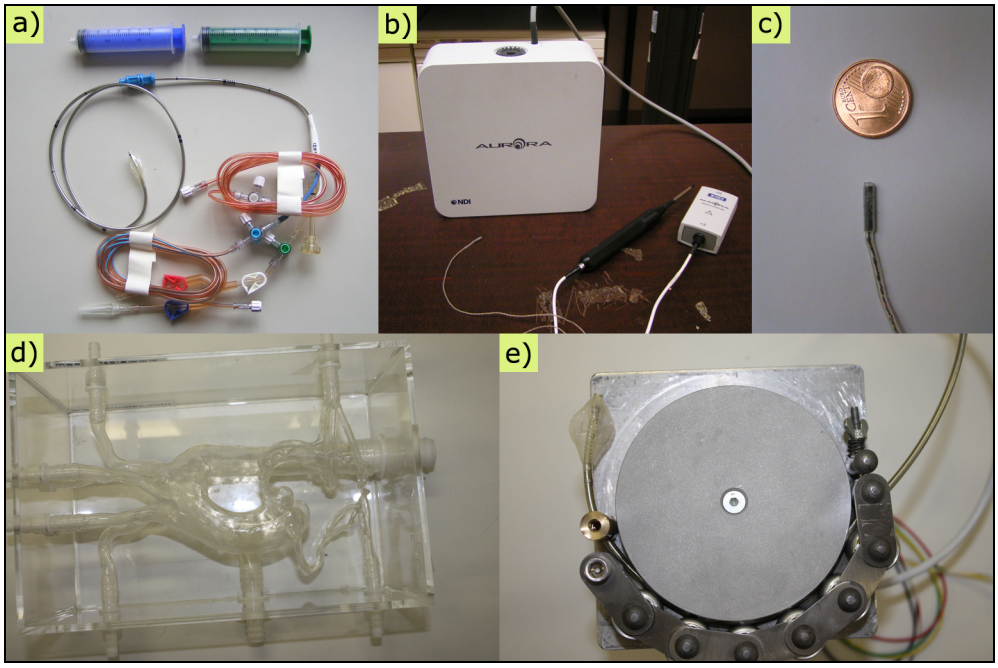


Figure 5. a) balloon catheter b) Aurora magnetic tracking. c) sensor coil, d) silicon phantom and e) robotic driver

Animal tests were performed with two pigs. These tests were done with the purpose of simulating a normal surgical workflow using the system in a harder environment. The aim was to understand and study the difficulties that would arise in a close-to-real clinical setting. Both animals were scanned in an MRI scanner and the obtained datasets were segmented to extract the aorta. For registration, multimodal markers were fixated in several locations in the animal's bodies. Figure 6 shows the multimodal markers on the pig and on the screen. In this case, the registration procedure was performed using the external software package "The SIGN"[10].

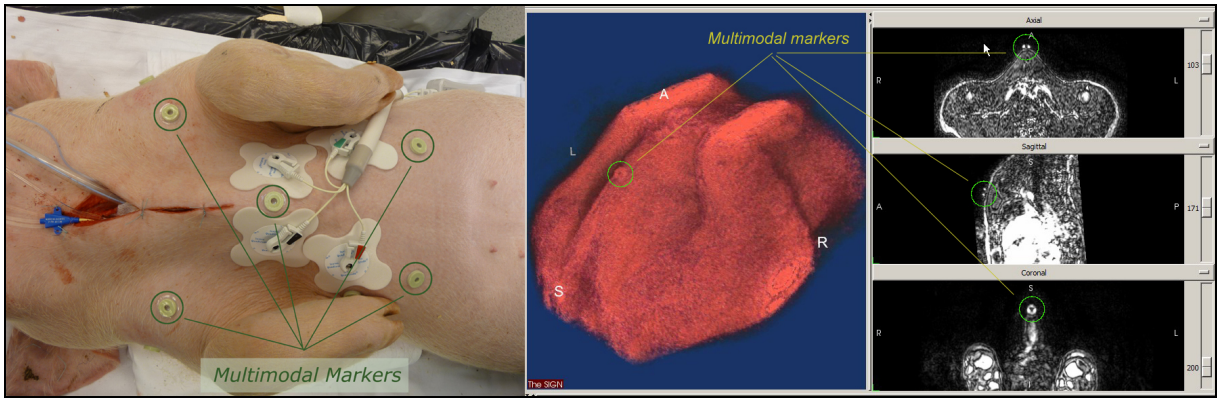


Figure 6. Illustration of multimodal markers in the body and how they are seen in the images.

## 3. RESULTS

In all the tests using the silicon phantom, the registration error was less than 5mm which is adequate for the purpose: with the surgeons it was defined that the balloon should be within ±25mm of the optimal target at all times. In the user tests, 92% of the users could perform the tasks successfully and the majority placed the catheter faster and more accurately when using the system than when using the simulated current visual support (simulated TEE). In the questionnaires, they also rated the system as supporting them much better than the simulated restricted view.

The actuator always positioned the balloon in the targets defined within a range of ±5mm and in average faster and more accurately than similar human placements. Actuator accuracy was tested with and without flow. Placement errors were higher when there was flow.

Regarding the animal tests, results are still preliminary. One first important finding is that rigid registration with fiducial markers (the error was also less than 5mm) is sufficient to provide good alignment for intuitive visualization of the balloon within the pig's aorta. Additional tests will have to be performed to prove reliability and the advantages of the system during real surgical practice.

## 4. DISCUSSION

So, far, and under the assumptions made, the effectiveness of the system could be demonstrated: comparing placing times and accuracy, the subjects perform as good or slightly better when using the 3D view compared with the restricted view. The performance using the total view is always better. This view represents the ideal situation where the aorta would be transparent. These results were backed up by the user questionnaires where there was a clear statement that support was better in the 3D view than in the restricted view. During the tests we could also observe that in some insertions, the catheter got stuck in the brachiocephalic trunk (just above the aortic arch). In this case, the users needed to pull it back a little and then try to advance again. It was very clear from our observations and interviews that having the visual support at all times provided the user with confidence regarding the cause of the problem (they could be sure the balloon was stuck in this location) and aided in the correction. In the restricted view, with very limited visual feedback (only a very short part of the aorta), the users only had a hint that this was happening because it was difficult to advance the catheter but had no indication of where the balloon was which made it harder to correct. The subjects were not instructed to place the balloon on a specific location but within a range so we considered accuracy as being the coherence between a subject's placements. Thus we considered the standard deviation between placements of the same subject as the accuracy measurement. The measurements of one subject in the first test were not included in the results because he misunderstood the aim of the task, maximum accuracy in minimum time and he aimed only for accuracy.

All this taken into account, it is important to note that tests with larger number of users are needed in order to provide harder evidence of the benefit introduced by the system. Also, all the measurements were made only with the magnetic tracking. We therefore had no golden standard with which to compare the measured position values.

One of the most important limitations of the presented system is that it works under the assumption that all the structures are rigid. During the design phase this was considered to be a good first approach. So, for the time being, the results are valid only when the anatomy of the patient doesn't change significantly between the time of image acquisition and surgery. This has been seen to be sufficient in all the tests we performed. But, if we want the system to cope with possible more serious deformations, like retracting the heart and aorta for instance, we have to address this limitation in the future.

The specified accuracy of the magnetic tracking system is suitable for this kind of application but we observed sensitivity to mechanical vibrations, present when perfusion is administered. These vibrations introduced visible errors that we need to study in more detail.

One of the drawbacks of the current registration procedure is that once the transform matrix is found, it has to be inserted in the Opentracker configuration file. Since this file is read at start time, the application has to be restarted after the matrix is written. This is inconvenient and in the future we plan to fix this with the help of a feedback connection from studierstube to OT, updating the configuration value automatically after the matrix is found.

The communication between the components executing in different computers is done using network connections. This is the case for communicating the position error and target pressure between the visualization and control and also to send the tracking data from OT to studierstube. This communication was seen to be effective. Nevertheless, especially the connection between the visualization and control is too simple, as there are no means to verify whether the connection is in good health or if the data is corrupt, and no means for client or server identification. This is a safety and security risk (possible loss of data without one of the parties realizing and patient data might be gathered by a third party) and it is already being addressed with a prototype design of a communication architecture which will include safety and security policies for network connections between medical applications[11].

## 5. CONCLUSIONS

The proposed system presents clear benefits regarding the current situation where balloon position management is done with poor visual support. It is simple and effective: it provides a clear and intuitive notion of the balloon's position and corrects positioning errors automatically. This eases up strenuous monitoring tasks and catheter handlings and reduces work rhythm brakes of the surgeon during actual surgery at the heart. The results are preliminary but we demonstrated that the system has the potential to make the technique safer and simpler reducing the learning curve for the surgical teams.

## ACKNOWLEDGEMENT

The authors are thankful to staff of Ljubljana Medical Centre and Interventional centre Oslo for their help and to all the participants of the project's workshops and braistormings. The authors would especialy like to thank Terumasa Morita, Primož Trunk, Adinda Freudenthal and Jakob Bergsland for their dedicated contribution to this work. This research was done within the ARIS*ER project, which is funded by the European Union as part of the 6th framework program for research under the Marie Curie Actions for Human Resources and Mobility, contract MRTN-CT-2004-512400. The authors also acknowledge the financial support from the state budget by the Slovenian Research Agency under grant P2-0095 and from the Austrian Science Fund FWF under contract No. P19931.

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