

# Endoclamp Balloon Visualization and Automatic Placement System

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## ABSTRACT

**Objectives:** Aortic occlusion is one of the most important open discussions in minimally invasive cardiac surgery. Different techniques can be employed, and all have benefits and drawbacks. The objective of our work is to improve the safety of internal aortic occlusion with the Port Access technique, which employs an endoclamp balloon catheter. We propose a combined information and positioning system based on augmented reality technology and robotics in which the position of the balloon can be seen at all times and can be automatically controlled by a robotic actuator.

**Methods:** The system was designed by a multidisciplinary team of engineers, medical doctors, and human factor specialists in a human-centered design approach. We measure the balloon position in real time with a magnetic tracking system. This position is superimposed on a 3-dimensional scan of the patient's thorax, with the balloon in the artery shown at all times. The position measurement is also used to control the robotic catheter inserter that places and maintains the balloon position at a specified target. The system was evaluated in 2 user studies that compared it with other visual aids.

**Results:** The user tests have shown that the system effectively supports the surgeon in the placement task, with an increase in placement accuracy and a reduction in time compared with the current visualization technique. The users also rated the system as supporting them well.

**Conclusions:** The clinical feasibility of the system was proved. The system provides better visualization and position control and can effectively increase the safety of the procedure. This system has the potential of making Port Access a more attractive technique.

## INTRODUCTION

Mitral valve repair or replacement is following the general trend of surgery and is increasingly performed with minimally

invasive techniques [Soltesz 2007; Modi 2008]. Studies show great benefits for the patient, especially reduced pain, less risk of infection, and a faster return to regular activities [Grossi 1999; Modi 2008]. This technique has also been used with success in reoperations [Seeburger 2009]. Compared with the classic procedure, the minimally invasive approach shows longer cardiopulmonary bypass and aortic cross-clamping times but reduced stays in the intensive care unit, earlier extubation, shorter hospital stays, and reduced total hospital costs [Geršak 2005]. After some initial less-encouraging results [Mohr 1998], this approach is now mature enough to be the standard choice for many surgical teams [Casselman 2003]. Outcomes can be similar to those of the sternotomy approach, as has been shown in some controlled trials [Dogán 2005].

There are many choices of specific techniques available to perform this intervention [Grossi 2002]. With regard to aortic occlusion for cardiopulmonary bypass, there are 3 choices: the transthoracic cross-clamp (TTCC) [Chitwood 1997], the PortaClamp (Cardio Life Research, Louvain la Neuve, Belgium) [de Cannière 2004], or internal aortic occlusion with an endoclamp balloon catheter, either the Port Access (PA) system (Edwards Lifesciences, Irvine, CA, USA) or remote-access perfusion (Esteche, San Ramon, CA, USA) [Grossi 2000; Schachner 2004]. Internal occlusion (PA or remote-access perfusion) is less invasive than the TTCC method because the latter requires an extra incision for insertion of the clamp. In addition, internal occlusion has an advantage over external clamping in reoperations in that it requires less aortic dissection to achieve aortic control [Burfeind 2002]. On the other hand, there have been some reports of endothelial damage at the site of aortic balloon occlusion [Farhat 2006], but no clinical correlation has been shown [Reichensperner 2005]. Thus, using an endoclamp is a good choice if we want to keep the number of incisions to a minimum [Reichensperner 2005; Casselman 2003].

Nevertheless, difficulties associated with the endoclamp technique still make it unclear whether it is the optimal choice compared with the TTCC. Initial balloon placement is typically done under visual guidance with transesophageal echocardiography (TEE), with good results [Gulielmos 1998]. Still, placement is a difficult task, leading to increased procedure times, mainly due to difficulties in maneuvering and visualizing the balloon [Aybek 2000]. Studies also have shown

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## Summary of System Requirements

Problem	Requirement
Difficult initial placement	Automatic fine-tune placement: balloon is placed manually in a region close enough (within 10 cm) within the aortic arch, and the system adjusts the position to the correct location (within 5 cm).
Difficulty in monitoring balloon migration and repositioning	System monitors balloon position at all times during surgery.
Difficult repositioning	Constant keep-in-place mechanism and automatic repositioning: balloon is deflated (to a certain "moving" pressure) for smother repositioning and reinflated in the correct location.
Aortic wall disruption	Automatic control of balloon pressure: pressure is maintained to a minimum, but balloon still seals the artery.

that the risks of aortic disruption [Mohr 1998], balloon disruption [Wimmer-Greinecker 1999], and balloon migration [Guliernos 1998; Aybek 2005] are small but not negligible. Most of these complications can be attributed to the beginning of the learning curve, which is quite long in the case of PA surgery [Greco 2002]. Nevertheless, they still present a real danger, and the risks have to be considered seriously. The quality of TEE visualization is much worse once the left atrium is opened; therefore, migrations are detected by monitoring the right radial artery pressure. A decrease in this pressure indicates brachiocephalic trunk occlusion [Guliernos 1998]. Monitoring of balloon migration is extremely important because damage can occur to the aortic valve in cases of distal migration or to the central nervous system due to hypoperfusion and ischemia produced by brachiocephalic trunk occlusion. In any case, a repositioning of the balloon has to be performed immediately. Compared with PA, use of the TTCC requires almost no training, is less costly, and carries no displacement risks [Aybek 2000]. Aortic cross-clamping also has its disadvantages, however. Besides the extra incision, there can be damage to the aortic wall [Geršak 1996], and the risk of aortic dissection cannot be excluded [Aybek 2000]. Better monitoring and control of the balloon position and better balloon pressure management are needed to fully exploit the benefits of PA. Such improvements could give PA a clear advantage over the other approaches.

The European research network Augmented Reality in Surgery (ARIS\*ER; <http://www.ariser.info>) has created technical building blocks in augmented reality and robotics to overcome common problems in minimally invasive surgery: lack of visual information and lack of haptic (tactile) information. In the context of this project, our report presents a combined information and positioning system based on augmented-reality technology and robotics to support minimally invasive mitral valve surgery (MVS) with the PA technique. The system provides constant, real-time monitoring of balloon position during the entire procedure, including automatic control of the balloon position to a specified target. This system is useful for initial placement and to correct migrations and automatic balloon pressure control. It keeps the pressure level to the minimum required for occlusion while protecting the aorta from disruption. Because such a system addresses the key safety issues in the current work procedures, we expect it to have the potential to make PA the technique of choice for minimally invasive MVS and therefore to profit from the most minimally invasive procedure possible.

In this study, we introduced the designed system and performed feasibility tests. We investigated the technical effectiveness of our system and gathered feedback from the potential users of the system, the surgeons.

The system is simple and effective. We measure the balloon position in real time with the help of a magnetic sensor. This position is superimposed on a 3-dimensional (3D) scan of the patient's thorax, which shows the balloon in the artery at all times. The position is also used to control a robotic catheter inserter that positions and maintains the desired balloon location at all times. If migration still occurs, the system automatically repositions the balloon to the correct location. Balloon pressure levels are also controlled automatically.

Our design follows a path similar to those of other systems implemented for the support of medical interventions, both cardiac [Linte 2007] and others [Hummel 2008]. In both situations, the authors use, as we do, a preacquired 3D data set and track surgical instruments, such as an ultrasound probe or an endoscope, by a combination of magnetic and optical tracking. Virtual surgical tools can then be superimposed on the real-time images to help guide the surgeon.

We extended the existing work in 2 ways. First, we designed a system specific for MVS and the problems associated with endoclamping. Second, our system not only provides information to the surgeon but also supports automatic robotic placement that relies on this information. To our knowledge, our system is the first to combine such techniques, providing a complete solution for monitoring and automatic placement specifically in support of MVS.

The rest of this article is dedicated to describing the system in detail and the results of its implementation. In the next section, we introduce the technologies that were used to implement the system and their beneficial combination that produces the desired results. Then, we describe the user interface and the catheter-placement procedure. Next, we describe the testing and evaluation procedure and present our test results. Finally, we discuss the strengths and weaknesses of our current system and review future development and research issues.

## MATERIALS AND METHODS

### Design

We followed a user-centered design approach, with engineers, clinicians, and human factor specialists involved in all

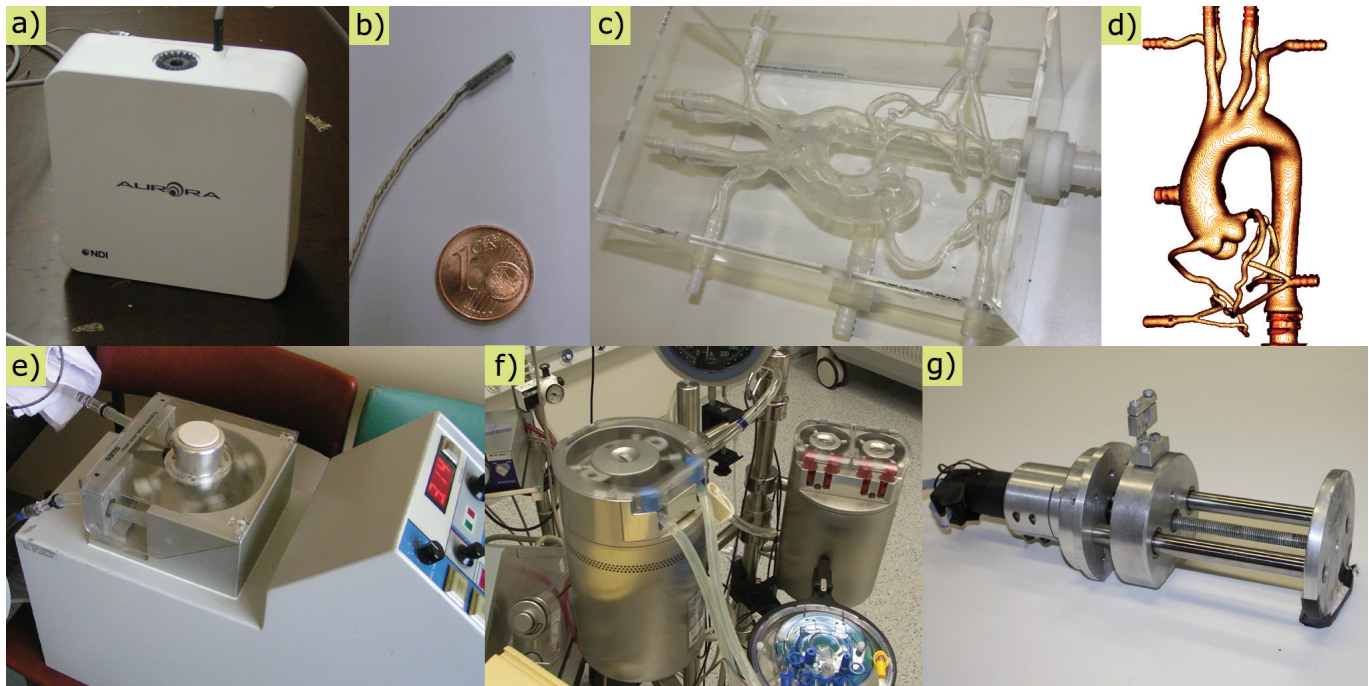


Figure 1. Materials used include magnetic field generator (a), minicoil (b), cardiac phantom (c), phantom data set (d), Sarns 7400 (e) and Stöckert (f) pumps, and robotic inserter (g).

of the development phases. Safety aspects were initially analyzed in a workshop [Stüdeli 2007] held at the project kickoff meeting. In this meeting, the key problems were identified, and high-level requirements were formulated. The Table summarizes these requirements, which are related to solving specific problems. These requirements were refined in an iterative process during the project in workshops, interviews, and surgery observations.

### Hardware

Our system fuses preoperative images with real-time information of the balloon's position shown by the images. The first step is the acquisition of a 3D data set of the patient's thorax. This data set can be any image modality—computed tomography, magnetic resonance imaging, or 3D ultrasound. In our experiments, we used a computed tomography scan with contrast agent to obtain 382 slices of  $512 \times 512$  pixels each.

The spatial position of the balloon catheter was measured with a magnetic tracking system (Aurora System; Northern Digital Incorporated, Waterloo, Ontario, Canada) (Figure 1A). The system can track minicoil sensors (Figure 1B) of  $8 \text{ mm} \times 0.55 \text{ mm}$  (length  $\times$  diameter) with an accuracy of 0.9 mm, which is appropriate for our application. We placed a sensor in the center of the balloon through 1 lumen of the catheter so that the spatial position could be measured in real time. The tracking system is fully approved for medical use.

We used a flexible, transparent silicon aortic phantom with real-size anatomy (model T-S-N-002+; Shelley Medical Imaging Technologies, London, Ontario, Canada) (Figure 1C).

Figure 1D shows the 3D data set obtained for this phantom. It is possible to perfuse the model with water or other fluids and to insert catheters in a conventional way.

Pulsatile pumps (Figure 1E, experiment in Sils-Maria, Switzerland, with Sarns 7400 pump by Terumo Medical, Somerset, NJ, USA; Figure 1F, experiment in Oslo, Norway, with pump by Stöckert, Munich, Germany) were used for perfusing the phantom with water. The flow rate was of 5 L/min.

We also custom-designed a mechanical actuator that can pull and push the catheter up to 10 cm to each side (Figure 1G).

### Software

The user interface shows a 3D model of the balloon superimposed on the 3D preoperative data set (Figure 2). This interface allows the medical team to have visual knowledge of where the balloon is located inside the aorta. There are 2 predefined 2-dimensional views (coronal and sagittal) and 1 customizable 3D view of the whole scene.

There is a tool to mark the target, ie, where the balloon should be placed (Figure 3, bright dotted lines). This target will be the reference for automatic corrections. Additionally, a tolerance region can be defined with buttons (T+, T-) and is indicated by additional lines parallel to the target axes (Figure 3, dark dotted lines). When the balloon is within this region, the indicator "Position" is switched from red to green, and no further automatic corrections will be made.

### Testing

The efficiency of the system was assessed in 2 user tests and in automatic-placement tests. We addressed 2 main questions,



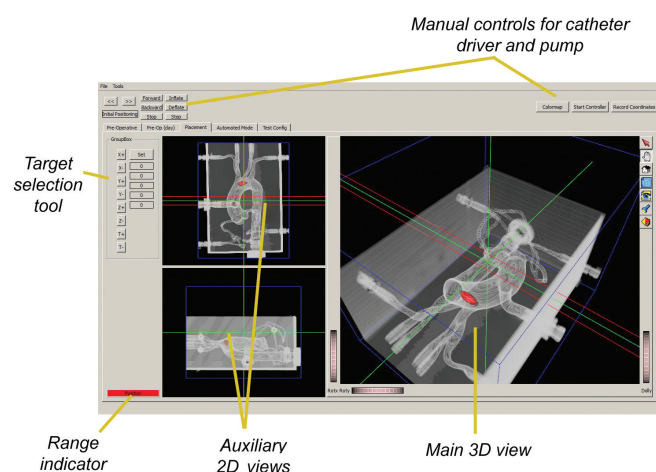


Figure 2. User interface with explanation of the different views and main components.

“Does the chosen visualization support the surgeon efficiently while placing the catheter by hand?” and “How can the actuator cope with the task of automatic placement?”

To answer the first question, we defined the following 3 test conditions of different ways of visual guidance:

- Total view. The phantom is transparent, so the users placed the catheter by looking directly through the vessel (Figure 4A).
- Restricted view (similar to the current ultrasound view). In the first test, we simulated the TEE image seen during actual surgery. The phantom box was filled with water, and an ultrasound probe was inserted so that a TEE image similar to that obtained in real surgery was obtained (Figure 4B). In the second test, an ultrasound probe was not available, so we used the system to simulate the TEE view (Figure 4D). This view provided medically relevant information equivalent to that of the ultrasound version in the first test, and of the real situation.
- 3D view (our system). The phantom was covered with black plastic, and the subjects used only the information available on the screen (Figure 4C).

The subjects had the task of using the different views to perform rounds of catheter placements on the aortic phantom to a target in the ascending aorta. Each placement started with the balloon in the descending aorta and finished with the balloon inflated on target.

Two sets of tests were performed. The first set consisted of  $3 \times 6$  placements (ie, 3 views, 6 trials) with 8 subjects (4 medical doctors and 4 engineers; age range, 28-46 years; mean age, 34 years). The second set consisted of  $3 \times 3$  placements (3 views, 3 trials) with 9 subjects (1 medical doctor and 8 engineers; age range, 28-46 years; mean age, 34 years).

In both sets of tests, we measured speed, placement accuracy, and subjective comfort in using the system. We briefed all of the subjects regarding the target position (the limits were roughly  $\pm 25$  mm, indicated qualitatively in the phantom) and the test objective (maximum accuracy

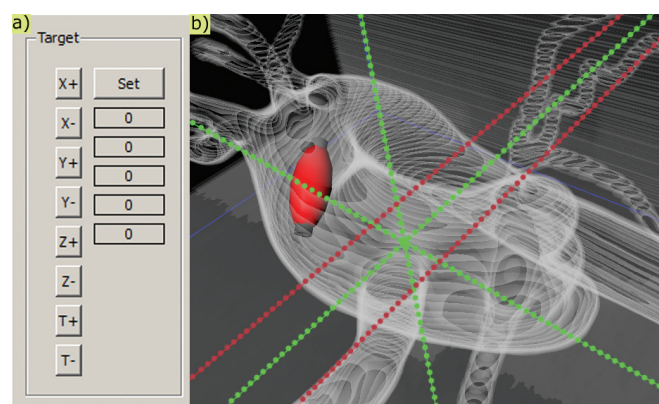


Figure 3. Target- and tolerance-control buttons (a); target and within-range lines (b).

in the minimum time). The subjects were asked to rate their actual psychological state before and after the test and to fill out a questionnaire on aspects of usability and visualization.

To answer the second question, we performed a series of fine-tuning placements with the robotic actuator. The series consisted of setting a target close to the aortic valve and a target close to the brachiocephalic trunk and moving between these 2 targets. This process was repeated 20 times and in 2 variations (with and without flow). We also carried out a series of 12 tests to measure the speed of fine placement, that is, the time taken by the driver to bring the balloon from a rough position to the target position.

## RESULTS

Figure 5 shows a user performing an insertion with the 3D view in one of the tests. We can see the phantom covered by black plastic and the user relying only on the screen to place the balloon.

### Placement Time

All of the subjects were able to perform the task in each of the 3 views. We defined a successful placement as being within  $\pm 25$  mm of the target (an acceptable range, considering the safety and effectiveness of placement, in concordance with the medical team). In the first test (Oslo, Norway, November-December 2007), 92.4% of the placements were made successfully within a reasonable time (all  $< 1$  minute). A better performance was expected with direct vision, and this expectation was confirmed. We obtained the following mean ( $\pm$ SD) placement times:  $26 \pm 11$  seconds in the total view,  $27 \pm 8$  seconds in the restricted view, and  $27 \pm 8$  seconds in the 3D view. In the second test (Sils-Maria, Switzerland, March 2008), we experienced even clearer trends. The mean placement times were  $34 \pm 20$  seconds in the total view,  $48 \pm 20$  seconds in the 3D view, and  $56 \pm 29$  seconds in the restricted view.

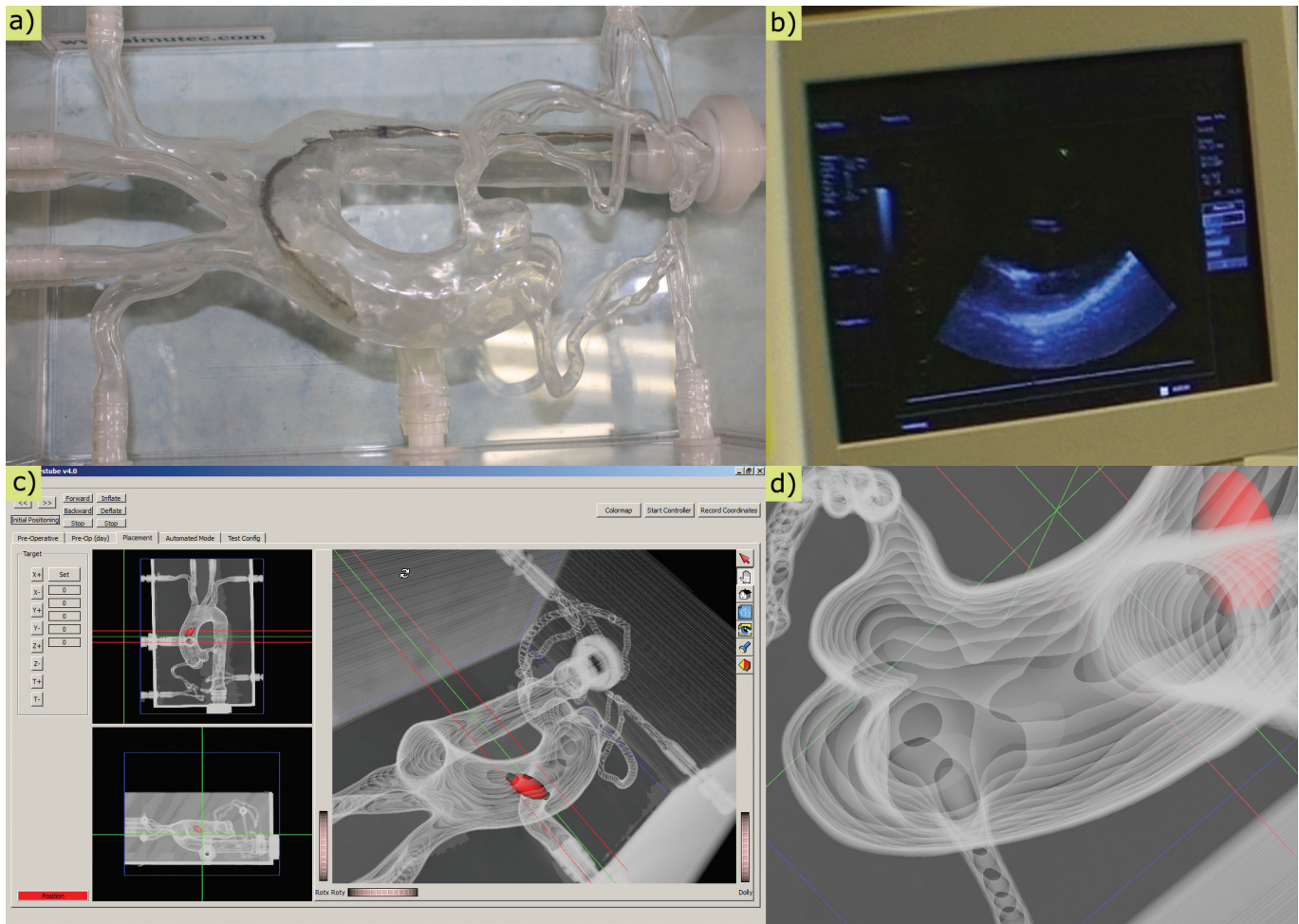


Figure 4. Test views: total view (a), ultrasound view (b), 3-dimensional view (c), simulated ultrasound view (d).

### Accuracy

**Human Accuracy (No Robot).** In terms of target accuracy, the mean placement distance in Oslo was  $1.3 \pm 10$  mm from the target (considering the target as position 0 mm) in the total view,  $0.5 \pm 12$  mm in the 3D view, and  $9.6 \pm 14$  mm in the restricted view. In Sils-Maria, the mean placement distance was  $12 \pm 3$  mm from the target in the total view,  $4 \pm 7$  mm in the 3D view, and  $7 \pm 9$  mm in the restricted view.

Regarding user-rated support, the users rated the total view as supporting them the best, a mean of  $9.25 \pm 0.75$  points on a scale of 1 to 10. The 3D view was rated at  $7.75 \pm 1.25$  points, and the restricted view was rated at  $4.5 \pm 2$  points.

**Robot Accuracy and Placement Times.** Automatic placement was performed with a mean error of 1.4 mm from the target when there was no flow and 1.9 mm with flow. Regarding placement times, the driver could push the catheter the requisite distance (the total displacement distance was always approximately 25 mm) in  $25 \pm 11$  seconds and pull it in  $15 \pm 2$  seconds in the no-flow situation. In the flow situation, the driver could push the catheter this distance in  $17 \pm 3$  seconds and pull it in  $11 \pm 1$  seconds.

### DISCUSSION

These results demonstrate the advantage of using the system. With respect to placement time and accuracy, the subjects always performed better with the total view and performed with the 3D view as good or slightly better than with the restricted view. The subjects were not instructed to place the balloon at 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 of the placements by the same subject as the accuracy measurement. The measurements of 1 subject in the first test were not included in the results because he had misunderstood the aim of the task, which was the maximum accuracy in the minimum time, and he had aimed only for accuracy.

These results were confirmed in the user questionnaires, which clearly stated that support was better in the 3D view (against the restricted view), and by our own observations. For instance, we observed that during some insertions the catheter became stuck in the brachiocephalic trunk. In this situation, the users needed to pull the catheter back a little



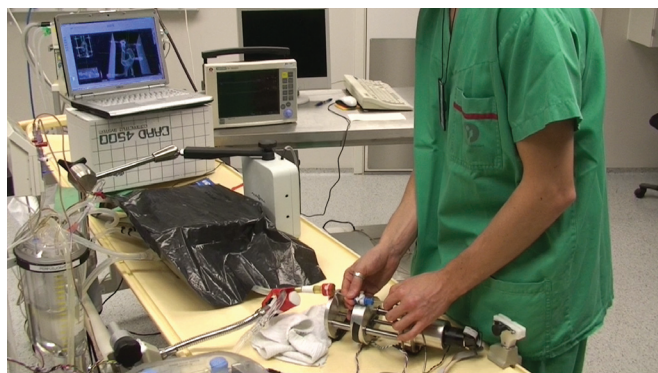


Figure 5. User testing the system with the 3-dimensional view.

and then to try to advance it again. This situation is common in real cases, in which catheters or guidewires can go into the wrong vessels. It was very clear from our observations and interviews that having visual support at all times provided the user with confidence regarding the cause of the problem (they could be sure the balloon was stuck there) and aided in the correction. In the restricted view, which had very limited visual feedback (only a very short part of the aorta), the users' difficulty in advancing the catheter was the only hint that this was happening.

All of the automatic fine placements with the actuator were done in <30 seconds and with <5 mm of error. These results fall well within our specifications. Combining this result with the good manual placements, we can say that the system's visual support enables a fast and safe manual rough placement, with accurate fine placement performed automatically.

It is important to note that we have not provided hard evidence on the system's behavior; that was not our intention. Instead, our aim was to test the clinical feasibility of such a system by technically proving the concept and by getting feedback from the potential users of the system, the surgeons. Thus far, we have been given clear positive feedback regarding the ability of the system to make the procedure safer and quicker. We have many challenges to face, but we now have a good indication on the feasibility of such a system and guidelines on the directions to follow.

One of the most important limitations of the system is that it works under the assumption that all of the structures are rigid. During the design phase, this assumption was considered a good first approach. Thus, for the time being, the results are valid only when the patient's anatomy does not change significantly between the time of image acquisition and surgery; however, if we want the system to cope with possible more-serious deformations (retracting the heart and the aorta for instance), we have to address this limitation in the future. These first proof-of-concept tests also showed us that the driver was insufficient for the task regarding stroke (ie, maximum distance of pushing and pulling). Because the initial idea was to use the driver only for fine adjustments, it is limited to 20-cm displacements, but because of the catheter slack, the driver is required to push or pull much more than that. This limitation led us to design a new driver, which

is currently under testing. Although the specified accuracy of the magnetic tracking system is suitable for this kind of application, we observed a sensitivity to mechanical vibrations, which are present when perfusion is administered. These vibrations introduce visible errors that we need to study in more detail. The system also aims to have minimal impact on the clinical work flow because it should be easy to integrate in the operation room. This aspect of the system also requires further development on the user interfaces of the different parts.

Our future work aims at addressing these limitations as well as increasing the system's robustness at the software level. The results achieved thus far represent a major step toward the final goal: to have a system that provides accurate real-time information about the balloon position and that controls the position in a robust way so that the task of occluding the aorta during endoscopic cardiac surgery becomes easier, safer, and thus accessible to more surgical teams and patients.

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