Augmented Reality and wireless sensor networks applications to support minimally invasive cardiac surgery

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Doctoral Dissertation
Jožef Stefan International Postgraduate School
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JOŽEF STEFAN INTERNATIONAL POSTGRADUATE SCHOOL

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Doctoral Dissertation

Uporaba dopolnjene resničnosti in brezžičnih senzorskih omrežij za podporo minimalno invazivni kirurgiji

Doktorska disertacija

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Abstract

Minimally invasive surgery is one of the most promising trends in medicine. Despite of its obvious advantages - the use of small incisions reducing trauma and risk of infection - it still represents a great challenge for the surgeon, as visual guidance and dexterity are severely impaired. In the case of minimally invasive mitral valve surgery, a special technique for blocking the blood flow in the aorta (aortic occlusion) is required, resulting in the need of a specific and long training.

Our work focuses on aortic occlusion by means of the Port-Access technique which uses the EndoClamp^{TM}, a catheter with an inflatable balloon at its tip. We aimed at solving the difficulties associated with poor monitoring and difficult manual placement of this catheter.

In this thesis we present a fully functional prototype which is a combined information and positioning system based on augmented reality technology and robotics where the position of the EndoClamp^{TM} can be seen at all times and can be automatically controlled by a robotic actuator. The results of our evaluation demonstrate the usefulness of the system: the users place the catheter faster and more accurately than with the current visual support. This work represents a major step towards safer and simpler minimally invasive cardiac surgery.

Systems such as the one we propose can greatly benefit from wireless sensor technology. Wireless body area networks are a promising technology which can increase sensing ability in the patient while being almost unobtrusive. Nevertheless, integration of wireless sensors in existing computer assisted surgery applications in far from seamless. We addressed this problem by developing a component to manage connectivity and interaction between wireless sensors and applications. The component also manages quality-of-service (QoS) of data connections in the operating room. Such a component eases up the integration of sensor nodes in the system and increases reliability of the communication network, one of the most important issues in medical applications.

Keywords: Minimally Invasive Surgery, Cardiac Surgery, Augmented Reality, Robotics, middleware, wireless sensor networks

Povzetek

Minimalno invazivna kirurgija (MIK) postaja ena izmed najobetavnejših disciplin v medicini. Zaradi njenih prednosti - uporaba majhnih vstopnih kirurških vrezov, ki zmanjšajo poškodbe in tveganje okužbe - je tovrstna kirurgija še vedno velik izziv za kirurga, ker sta vizualno vodenje in uporaba kirurških tehnik močno omejena. Pri minimalno invazivni operacije srčne mitralne zaklopke je treba uporabiti posebno tehniko zapiranja dotoka krvi v aorto (aortna okluzija), ki zahteva specifične spretnosti in znanja, katera lahko kirurg pridobi le z dolgotrajnim usposabljanjem.

Naše delo se osredotoča na aortno okluzijo s tehniko Port-Access, ki se izvaja z EndoClamp™ katetrom z napihljivim balončkom na njegovem koncu. Namen našega dela je reševanje težav, povezanih z zmanjšanim nadzorom in otežkočenim ročnim vodenjem ter pozicioniranjem katetra.

V doktorskem delu predstavljamo delujoč prototip za pozicioniranje katetra s pomočjo tehnologije dopolnjene resničnosti in robotike, ki omogočata določanje položaja EndoClamp™ katetra v realnem času in avtomatsko z robotskim aktuatorjem. Rezultati, pridobljeni med preverjanjem prototipa, dokazujejo uporabnost sistema v dveh pogledih; kirurg lahko s predlaganim postopkom in opremo hitreje in bolj natančno pozicionira kateter kot z dosedanjo standardno vizualno podporo. Naše delo je pomemben korak k varnejši in enostavnejši uporabi minimalno invazivne kirurgije.

Potrdili smo, da je predlagani sistem moč znatno nadgraditi z uporabo tehnologije brezžičnih senzorskih omrežij. Brezžična telesna senzorska omrežja so obetavna tehnologija, ki povečuje zmožnosti zaznavanja procesov v pacientu, ob tem, da je zanj skoraj nemoteča. Kljub temu je povezovanje brezžičnih senzorjev z obstoječimi računalniško podprtimi sistemi za kirurgijo še daleč od popolnosti. V našem delu smo se odpravljanja težav lotili z razvojem komponent za upravljanje povezljivosti in interakcij med brezžičnimi senzorji in aplikacijo. Te komponente upravljajo tudi s kakovostjo storitev (QoS), povezanih s podatkovnimi komunikacijami v operacijski dvorani. Komponente olajšujejo integracijo senzorskih vozlišč v sistem in s tem povečujejo zanesljivost celotne komunikacijske mreže, ki je ena najpomembnejših zahtev vsake medicinske aplikacije.

Ključne besede: Minimalno invazivna kirurgija, kirurgija srca, dopolnjena resničnost, robotika, medslojna programska oprema, brezžična senzorska omrežja

Abbreviations

Abbreviation	Description
3DUS	Three-Dimensional Ultrasound
API	Application Programmer Interface
AR	Augmented Reality
ARIS*ER	Augmented Reality in Surgery
BSN	Body Sensor Networks
CAS	Computer Assisted Surgery
CPB	Cardio-Pulmonary Bypass
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DOF	Degree-of-Freedom
DSA	Digital Subtraction Angiography
DWARF	Distributed Wearable Augmented Reality Framework
ECG	Electro-Cardiogram
EM	Electromagnetic
HF	Human Factors
ICP	Iterative Closest Point
IGS	Image guided surgery
IGSTK	Image Guided Surgery Toolkit
IR	Infra-red
ITK	Insight Toolkit
LAN	Local Area Network
MD	Medical Doctors
MICS	Minimally Invasive Cardiac Surgery
MIMVRR	Minimally Invasive Mitral Valve Repair or Replacement
MIS	Minimally invasive surgery
MITK	The Medical Imaging Interaction Toolkit
MRA	Magnetic Resonance Angiography
MRI	Magnetic Resonance Imaging
MVS	Mitral Valve Surgery
NIDAQ	National Instruments Digital Acquisition
OIV	Open Inventor
OR	Operating Room
OS	Operating System
OT	Opentracker
PA	Port-Access
PC	Portaclamp
PDA	Personal Digital Assistant
PET	Positron Emission Tomography
PID	Proportional-Integral-Derivative
QoS	Quality-of-Service
RAP	Remote Access Perfusion
RFID	Radio-Frequency Identification
SIGN	Slicer Image Guided Navigation
TEE	Trans-Esophageal Echocardiography

Abbreviation	Description
TTCC	Trans-Thoracic Cross-Clamp
UCD	User Centered Design
US	Ultra sound
VTK	Visualization Toolkit
WBAN	Wireless Body Area Sensor Networks
WSN	Wireless Sensor Networks
XIP	Extensible Imaging Platform
XML	Extensible Markup Language

1 Introduction

This Thesis describes the study design and implementation of a computer aided surgery system to support minimally invasive surgery. In this chapter, we provide a general introduction to the main topics concerned by this work and state the objectives and methodologies used to achieve our final results.

1.1 Minimally Invasive Surgery

Since the nineteen-eighties surgery underwent an important shift towards minimally invasive techniques. Minimally invasive surgery (MIS) became one of the most important and promising trends in modern medicine. The aim of this shift is to reduce the iatrogenic damage, the damage induced to the patient by the medical procedure itself rather than by the disease. To achieve this, surgeons developed alternative methods to effectively operate the patient using the smallest possible incisions. By reducing the size of incisions and the damage to adjacent organs, trauma is minimized. As an example, Figure 1 shows a comparison of a cholecystectomy, the removal of the gallbladder, done in the invasive (open) way and in the minimally invasive way. In the open way, the inside of the abdomen is exposed and easily accessible with the hands and surgical tools. In the minimally invasive approach, the surgery is performed through small incisions, called ports and the surgeon uses specially designed instruments, which are inserted through the ports. An endoscope, with a video camera and a source of light, is inserted in one of the ports to visualize the inside of the abdomen (Figure 1c).

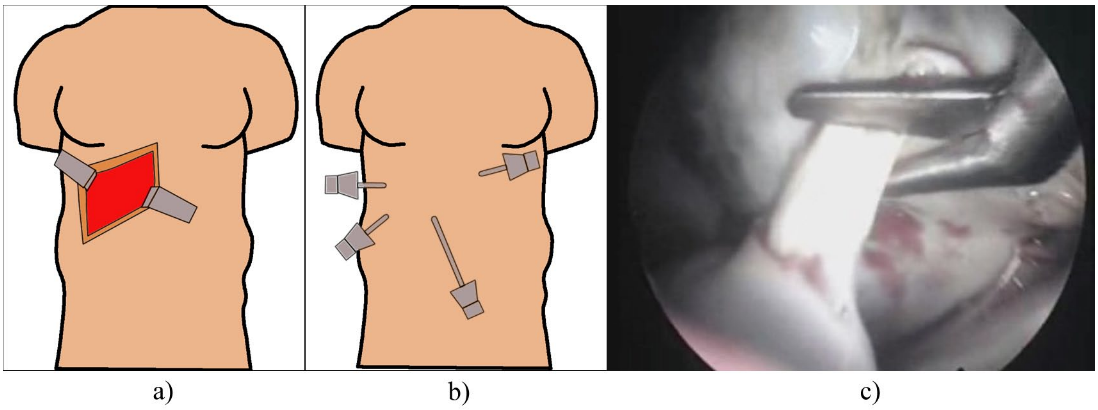

Figure 1 - Differences between open surgery and minimally invasive surgery. a) location for the large incision in open cholecystectomy, b) placement of ports, trocars and endoscope in minimally invasive cholecystectomy and c) typical image seen from an endoscope

One of the first references to MIS comes from Wickham in the British Medical Journal [1]. In fact, back in 1987, surgeons were not so keen on operating through small incisions. As Wickham writes, “Surgeons applaud large incisions and denigrate ‘keyhole surgery’”. If on the one hand this is understandable as good access to the surgical field makes the procedure easier, on the other hand, the patients obviously prefer the benefits of MIS which in some cases are enormous. In the same text, Wickham reports a dramatic decrease in mortality in the removal of bladder stones, from 40% in the invasive way, to 1% in the minimally invasive way. Since then, surgery has seen considerable developments and almost all procedures have minimally invasive alternatives.

From the patient point of view, the benefits of having smaller incisions are very attractive: less trauma, less pain, smaller risk of infection, shorter hospital stays and quicker return to normal life [2-5]. And, the impact is not only on the patient: with shorter hospital stays, the costs per patient can be reduced and the ability to treat more patients, time- and money-wise, is increased. This is especially important for the healthcare system in a time where the healthcare expenditure rises to astronomical levels [6].

But these benefits come at the expense of increased workload for the surgeon and his team: in MIS there is no direct vision and no access with the hands inside the patient and this poses significant problems. One of the common ways of coping with the lack of vision is the use of an endoscope as seen in Figure 1c. But, depending on the complexity and type of procedure, other imaging techniques must be used. As a consequence, image guided surgery technology gained increased importance in MIS as will be described in the next section. Lack of direct access with the hands has also important consequences as haptic feedback, or sense of touch, is an important tool in diagnostics and guidance [7]. The hand is capable of distinguishing mechanical properties, temperature or movements [8] and this ability makes it a valuable tool for guidance, complementing vision, aiding for instance in the identification of tumors that hide under healthy tissue. Also, the instruments used in MIS and how they are used pose a challenge, first because their design doesn’t comply with ergonomic guidelines [8;9] and second because of the unnatural movements the surgeon must perform. As instruments have a fixed point at the port, movements to the left translate to movements to the right in the patient.

Because of these difficulties and the additional workload they imply, in many cases it is not clear if MIS is a better approach than open surgery. If the benefits come at the expense of too long learning curves and higher surgery times ultimately resulting in increased risk, it is still preferable to use a conventional open technique. So, in some cases, where this balance is clear MIS became the gold standard as is the case in cholecystectomy [10] while in other cases, like in minimally invasive mitral valve replacement, the balance is unclear [11-14] and using the minimally invasive approach is still not common practice.

1.2 Image guided surgery

Image guided surgery (IGS) aims at supporting the surgeon by providing him with guidance in situations where direct vision is impossible or impaired. The field saw its first development with the appearance of the stereotactic frame in 1908 introduced by Horsley and Clarke and tested on animals [15]. The device, fixed to the patient's head, allowed localization of targets inside the skull based on atlases. This was the first form of image-to-patient registration. Some decades later, in 1947 a version of the device was used for the first time in humans. Two versions appeared almost at the same time one by Spiegel and Wycis in the United States [16] and one by Leksell in Sweden [17]. This can be considered as the birth of IGS in human medicine. Since then, interventions guided by different imaging modalities developed rapidly. Nowadays, fluoroscopy is used to guide stent placement [18;19] or to guide the insertion of needles in vertebroplasty (for delivering cement-like biomaterial to the spine) [20]. Ultra sound (US) is used during RF-ablation of liver tumors, to guide needle insertion to target the tumor precisely [21] and also to guide and monitor the position of catheters [22;23]. Intraoperative magnetic resonance imaging (MRI) is used to navigate endovascular catheters and deliver stents, vena cava filters, embolization materials, and septum closure devices [24]. Numerous other examples exist. Building on this, computer assisted surgery (CAS) systems emerged, where not only images directly guide the procedure but image processing techniques are used to enhance the perception and navigation. These navigation systems assist the surgeon in achieving his goals in an easier way much like a car navigation system helps the driver arriving at his destination. In general, at the basis of all applications is the acquisition of a three-dimensional dataset of the patient for creating a patient model. Depending on the surgery and pathology, different types of images might be required: computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET) or three-dimensional ultrasound (3DUS). Visualization techniques allow the surgeon to manipulate and interpret the 3D patient dataset, improving diagnostics and allowing the detailed planning of interventions. Surgical planning is essential in complex interventions as it allows careful analysis and strategy definition in a moment which is neither time- nor safety-critical. Example planning tasks include definition of target structures and surgical paths [25], definition of optimal port placement for MIS [26] or definition of dental implant placement [27]. CAS applications also provide real-time intra-operative guidance. With the advent of tracking systems capable of sensing the position of instruments, patients and surgeons with sub-millimeter accuracy, applications show the position of instruments within the pre-operative images in real-time as guidance to the surgeon. Image registration also grew in importance as aligning the tracking data, the patient and the images became crucial for the reliability of CAS applications.

Figure 2 shows the typical setup in the operating room (OR) for a computer assisted surgery system and Figure 3 an example of an existing software tool, used for planning and intra-operative guidance of port placement in minimally invasive cardiac surgery.

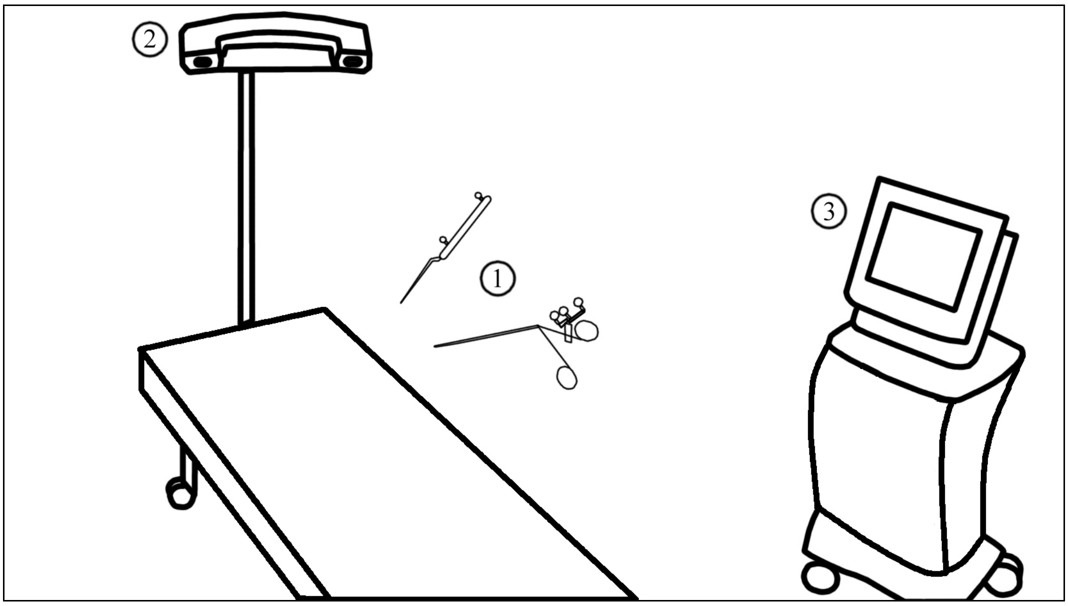

Figure 2 - Typical computer assisted setup in the operating room. In this case the instruments (1) have small embedded spheres so they can be detected by the optical tracking device (2) and seen on the screen (3) normally overlaid on an image of the patient

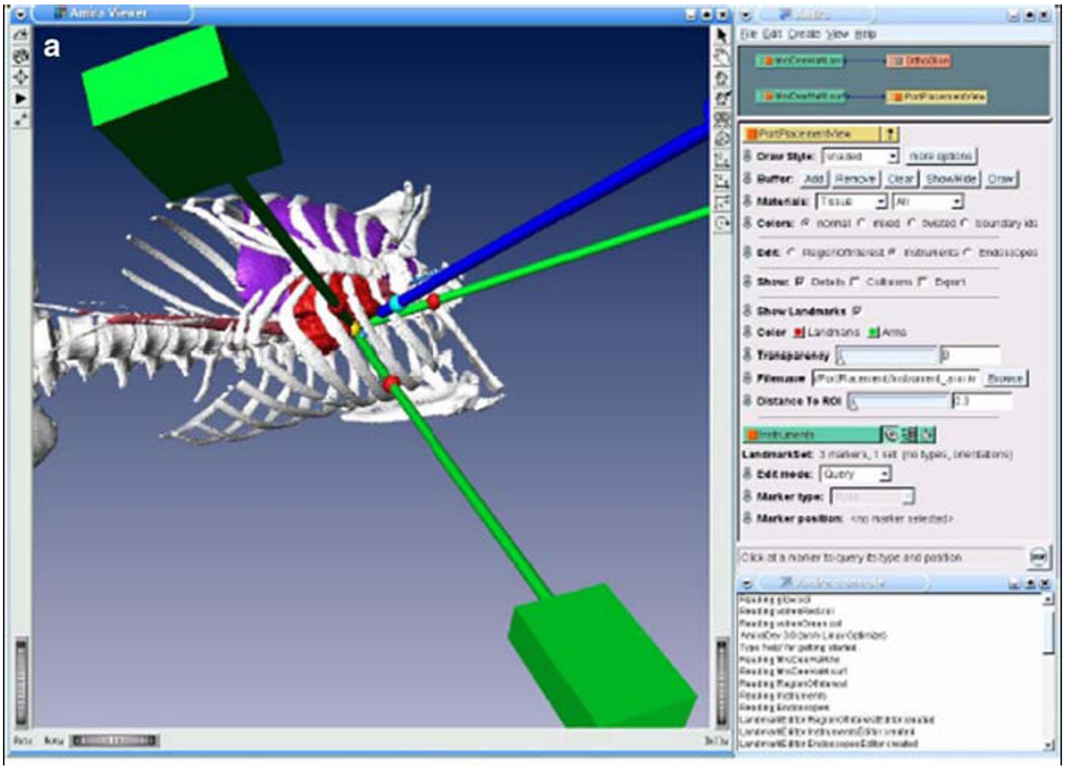

Figure 3 - Screenshot of an application for port placement optimization and guidance in minimally invasive cardiac surgery (taken from [26]).

To date, hundreds of CAS applications have been developed. Most of them are academic research prototypes but some commercial systems are used in current clinical practice. While academic applications exist for almost all types of surgery, commercial applications still remain on the domain of neurosurgery, ENT, maxillofacial surgery and orthopedics. This is mainly due to non-rigid registration methods still being an open research topic, limiting the safe use of CAS application in procedures where soft tissue deformation is considerable.

1.3 Wireless Sensor Networks

Wireless sensor networks (WSN) are among the most popular technologies of the moment. A wireless sensor network consists of a collection of autonomous sensors capable of wireless data transmission. These sensors (network nodes) are normally distributed along a certain space with the purpose of acquiring measurements at the different points and sending these measurements to the users. A typical wireless node (usually called "mote") is equipped with at least one sensor, a power source, a micro controller and a radio transceiver. The general idea is that each sensor, having limited radio range, sends its data routed through the other sensors in an ad-hoc fashion, until it reaches a sink where it can be gathered and analyzed. Figure 4 depicts the general concept.

One of the most popular applications of WSN technology is in environmental data measurement where hundreds of sensors can be used to collect high density meteorological information (as opposed to the traditional data collection by very sparse stations) with the purpose of building better weather models [28] or to investigate specific geological parameters [29]. Even if originally motivated by military surveillance applications, WSNs are now applied to many other domains [30].

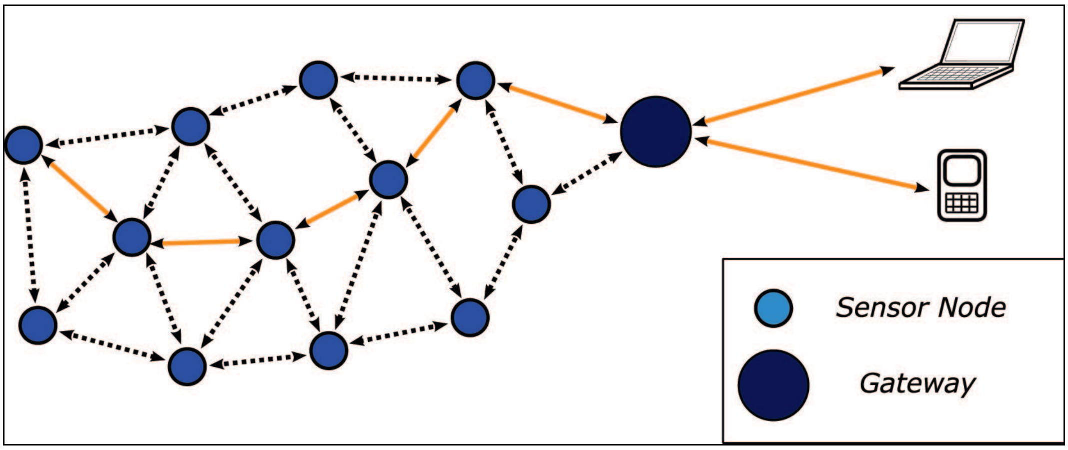

Figure 4 - Typical topology of a wireless sensor network. In orange we see the path of a data sample routed through several nodes until it reaches its destination.

In medicine there are also many prototype applications which leverage the power of WSNs. In general, three subsets can be identified, depending on their range of application. Wireless body area sensor networks (WBAN) consist of several physiological sensors (ECG, oximetry, temperature, etc.) scattered in the body, sending these measurements to an off-body personal terminal, which is used for gathering and visualizing data and possibly sending them to other, more powerful servers. This typical architecture for WBAN applications was implemented to support rehabilitation [31], prevent ulcers [32], or simply inform the doctors at remote locations of the state of patients at home [33] which is especially beneficial for elder patients. Figure 5 shows the typical setup for a WBAN application.

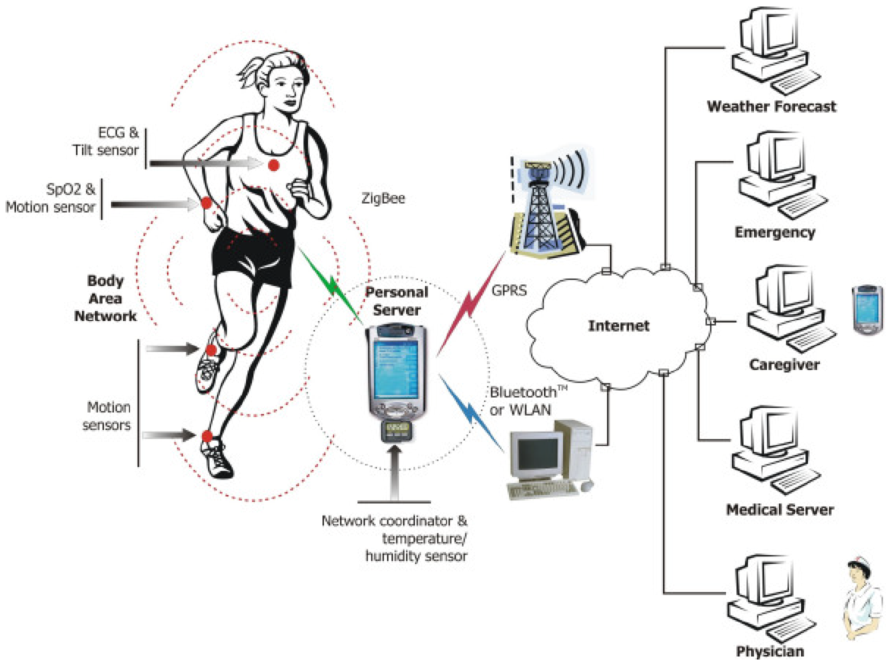

Figure 5 - Typical body area network architecture. The sensors are scattered around the body and communicate via low power radio with a gateway. In turn the gateway distributes the data over a wide area network (taken from [34]).

Other applications cover a wider area, typically spanning from whole hospitals where medical staff and equipment is tracked to increase efficiency of the medical care process [35] to an entire city, to optimize the management of medical response in disaster scenarios [36].

In between, some applications are dedicated to support the medical team in the operating room as is the case in [37] where radio-frequency identification (RFID) sensors are used to locate medical staff, patients and equipment in the OR and a context-based application that increases safety by warning the team of unusual situations (e.g. wrong blood bags are present).

From these three categories, OR applications are the least explored but for MIS, they are the most interesting. Perception problems associated with MIS can be better tackled by gathering as much knowledge as possible from the patient state and from the surgical workflow state. As this cannot come at the cost of introducing cumbersome equipment attached to the patient, WSNs can offer the benefits of better patient data with minimum impact on the surgical process.

One of the possible reasons for the small amount of WSN applications for the OR might be the challenges posed by safety issues associated with medical applications [38]. If these challenges are met, WSNs can become a powerful technology to collect better quality data for use as input in CAS applications.

1.4 Hypotheses

The purpose of this dissertation is the study and design of systems that support the surgical team during minimally invasive surgery, aiming at minimizing or solving some of the problems described in Section 1.1. The ultimate goal is to demonstrate that with an adequate use of technology, the safety of the procedure can increase making it common practice. The work was done focusing on a specific procedure: minimally invasive mitral valve repair or replacement (MIMVRR). Our objectives were:

- Analysis of the procedure and definition of a new surgical workflow, including careful translation of the medical requirements into technical requirements.
- Implementation and evaluation of a prototype for visualization and control of a balloon catheter position and pressure.
- Evaluation of the impact of the new prototype in the safety of the surgical procedure as well as in the time taken to complete the procedure.
- Study possibilities for the integration of wireless sensing technology in the prototype by developing and evaluating a framework for seamless interoperability of WSN technology in computed assisted surgery applications.

In the case of MIMVRR the major problem is associated with the visualization and placement of a balloon catheter in the ascending aorta. This catheter, named the *endoclamp* catheter, is used to occlude the aortic arch, that is, block the blood flow from the ascending aorta to the heart, which plays the same role as the external aortic cross-clamp used in the open procedure. The endoclamp is currently placed under real-time visual guidance using trans-esophageal echocardiography (TEE). The placement has to be very precise to avoid damage and occlusion of nearby structures. At a later stage in the surgery, TEE is no longer usable as the heart is open and filled with air and monitoring of the balloon position is very poor. Figure 6 shows the endoclamp balloon placed in three different positions. The challenge is to avoid a) and c) maintaining the balloon as far apart as possible from the aortic valve in the distal direction and from the brachiocephalic trunk in the proximal direction.

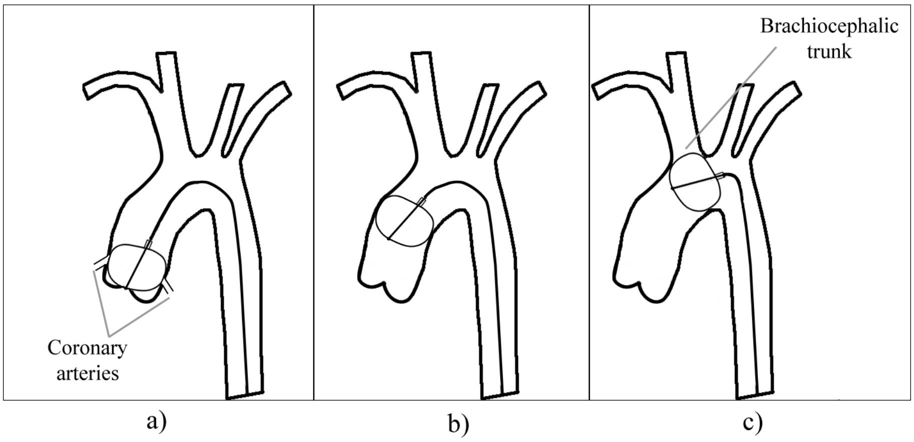

Figure 6 - Different positions of the endoclamp balloon catheter in the aorta: a) occluding the coronary arteries, b) correct position and c) occluding the brachiocephalic trunk

At the moment, better monitoring of the balloon position at placement time as well as during the surgery will be a major benefit as monitoring is very poor, especially during the time where the surgeon operates on the heart. As a consequence of this poor monitoring, there is an ongoing discussion whether the endoclamp brings added value against other, slightly more invasive approaches. Our aim was to deliver a solution to the problem with the aim of making the endoclamp the technology of choice for this procedure. With this study and implementation we had a chance to cover all the phases of development of a medical application.

We based our work in the following set of hypotheses:

- **H1**: local rigidity conditions can be assumed for the structures of interest in this specific procedure. It is then possible, based on this, to superimpose the tracked balloon position on pre-operative three-dimensional imagery of the patient using rigid registration methods.
- **H2**: Providing the medical team with such visualization will increase the safety and reliability of the procedure. It will also reduce surgery time with the potential of making the procedure more common practise.
- **H3**: the position information and pressure measurements of the balloon and aortic root are enough data to realize a stable control loop for the position and pressure of the balloon catheter.
- **H4**: it is possible to implement an information exchange architecture that holds network context about connected sensors and data transfers without imposing too much burden on the normal data transfer. It is then possible to seamlessly integrate heterogeneous sensors in a seamless way with computer assisted surgery applications.

1.5 Methodology

Several methods were used to achieve the results described in this thesis:

- **Design**: we followed user centered design (UCD) principles throughout the development of our solution. The surgeon and the medical team (the users of the system), were involved in all phases of the work from concept to evaluation. The development was an iterative process consisting of design **workshops**, individual **interviews**, surgery **observations** and **prototyping** and **evaluation** rounds. In all phases, a multidisciplinary team was involved consisting of medical doctors, technology engineers and human factor specialists.
- **Implementation:** augmented reality (AR) technology was used to implement the prototype for visualization of the endoclamp balloon. We used a magnetic tracking system to track the position of the catheter in real-time and used this data to superimpose a 3D model of the balloon in a pre-operative 3D patient dataset. For alignment we used a rigid registration method based on fiducial points. As for the control of the catheter's position a robotic inserter was developed. The control was done using a proportional-integral-derivative (PID) algorithm using the tracked balloon position and a target defined by the surgeon.
- **Evaluation:** *usability tests* were performed where we compared user performance in placing the balloon catheter in a silicon phantom under different visualization conditions. We measured time and accuracy while placing the catheter by hand when the user had full visualization, the current TEE visualization and the system visualization. *Automatic placement* vs. *human placement* was done, comparing also time and accuracy of similar displacements by both methods. The users filled out *evaluation questionnaires* rating the support they got from each of the visual aids. *Animal tests* were done with the aim of evaluating the feasibility of the approach in close-to-real conditions.
- **WSN:** design of the wireless sensor network integration was done taking into account existing solutions in the literature and adaptation of technology from different domains to fit our solution. Evaluation was done by measuring the impact that the addition of a new architecture and the consequent communication overhead would have in regular communications.

1.6 Contribution

The work presented in this dissertation produced results which are relevant in different scientific domains: medical technology, augmented reality and wireless sensor networks.

The most important contribution was the development of an augmented reality based application for minimally invasive surgery which is described in detail in Chapter 3. The application solves the specific problem of **poor visual support** and **difficult maneuvering** during aortic occlusion in minimally invasive cardiac surgery. At the moment there is no application addressing these specific difficulties. Existing applications typically focus only on visualization, showing locations of tools or organs which are covered by tissues. The novelty of our work lies in the combination of tracking data and planning to visualize at all times the catheter used for occlusion and to drive an automatic robotic inserter that controls the catheter.

The results of our evaluation have shown that the prototype is relevant for the medical community. We demonstrated that the users perform better, faster and more accurately, when using this system than with the current TEE guidance. Also, according to the user questionnaires, the system supports the task much better than the current method. This translated a **decrease in surgery time** and **increased safety** in MIMVRR which is of extreme importance.

We also studied how wireless sensor networks can be used to support the team in the OR. Despite the growing development of WSN technology, no applications focus specifically on supporting minimally invasive surgery. We bridged this gap by designing a framework that allows WSNs to seamlessly integrate in CAS applications with the aim of supporting this type of surgery.

1.7 Collaboration and publications

The work presented here was done in the context of two European projects: ARIS*ER (Augmented Reality in Surgery) and ProSense (Promote, Mobilize, Reinforce and Integrate Wireless Sensor Networking Research and Researchers). The ARIS*ER project had the aim of developing technology building blocks to support minimally invasive surgical interventions, while the ProSense project has the aim of bringing WSN research further and to integrate these developments in West Balkan countries by creating excellence centers in local institutions.

With results of such collaborative nature, it is important to discriminate which are the direct contributions of the author of this thesis and which come from other project participants.

The work presented in **chapter 3** is one of the projects of the ARIS*ER consortium. Within this project two other people other than the author have made major contributions and thus deserve special mentioning.

Thomas Stüdeli, a post-doc researcher of the Technical University of Delft (Netherlands) was the human factor specialist assigned to guide the formal analysis and design of the procedure. He was the main contributor to the new clinical workflow and conducted the usability questionnaires during the prototype testing. He was also co-responsible, together with the author, in the design of the test setups, in particular in the definition of the test views.

Mauro Sette, a PhD student at Katholieke Universiteit Leuven (Belgium), implemented the control software in LabVew, designed and built the two mechanical actuators that were used in testing and modified the syringe pump used for automatic balloon inflation. He also collected the pressure measurements and designed and implemented the pressure control algorithm for balloon inflation.

The rest of the work presented is a direct contribution by the author: the implementation of the software, the design of the user interface, the implementation of the user tests and the data collection during testing and subsequent analysis. The author had also an important contribution in the general solution design process. At the University Medical Center of Ljubljana, Slovenia, his workplace, he conducted several surgical observations and many informal interviews with the surgeons. From these observations and interviews the author extracted several formal requirements which were used in the final surgical workflow definition and in the design process of the whole prototype.

The work presented in **chapter 4** is a direct contribution from the author. This includes the architecture design, selection of software components, implementation of new software and data collection and analysis.

During the course of this work many relevant publications were achieved:

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- H. Furtado and P. Lamata, *Registration techniques for catheter guidance*, Minimally Invasive Technologies and Nanosystems for Diagnosis and Therapies, Lupiensis Biomedical Publications, ISBN 978-88-902880-2-9, pp. 187-195, 2008
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- H. Furtado, T. Stüdeli, A. Freudenthal, P. Lamata, S. Milko, H. Rutten, *Advanced rectal cancer treatment: Augmented reality system for support of navigation in the pelvis, guidance for IORT and treatment documentation for an evidence-based surgery*. Proceedings Abstract, IGRT Vienna 2008 - Visions and Perspectives in

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1.8 Outline

This dissertation is organized in five different chapters including this one. Chapter 2 describes in more detail the motivation and background to our work. Chapter 3 is an in depth view of the design, implementation and evaluation of our solution to the problem described in Chapter 2, the endoclamp balloon visualization and placement system. Chapter 4 describes the design, implementation and evaluation of an architecture for the integration of wireless sensor network technology in minimally invasive surgery application. Finally, Chapter 5 concludes the dissertation with an overall discussion on the subjects studied.

2 Background

In this chapter we provide a detailed description of the state-of-the art in the areas that are relevant for the work presented in the following chapters. First the medical background is introduced, then a discussion on the technologies for the development of computer assisted surgery applications and finally, relevant applications using wireless sensor technology are reviewed.

2.1 Minimally Invasive Cardiac Surgery

In many procedures in cardiac surgery the heart has to be stopped. In this case, the blood flow and oxygenation is done with the help of a cardio-pulmonary bypass (CPB) machine, commonly known as heart-lung machine. In this situation, as the name indicates, the machine replaces the function of heart and lungs, pumping oxygenated blood into the arteries, receiving venous blood from the body, oxygenating it and pumping it back into the body. This can be seen as if the heart is out of the circuit so it can be stopped and operated on. Venous blood is pulled out of the superior and inferior vena cava and the oxygenated blood is returned to the body through a cannula, inserted in the aorta. The blood must not flow towards the heart but should flow normally to the rest of the body. Because of this, the aorta has to be occluded that is, the circulation must be interrupted in the aortic arch, preventing the blood flow towards the aortic valve and the coronary arteries. The point of aortic occlusion is represented in Figure 9a. This is called aortic cross-clamping, as in the open procedure, the occlusion is done with a clamp. Figure 7 shows a simplified diagram of the implementation of CPB circulation.

Cardiac surgery is following the general trend and being increasingly performed in a minimally invasive way. In this case, the differences in incisions are quite visible. In the open procedure, a sternotomy (an incision that splits the sternum in two) has to be performed to expose the thoracic cavity (Figure 8a). In the minimally invasive case, as in other procedures, the surgeon operates through ports. These incisions are done between the ribs and inflict damage only to soft-tissue, as opposed to the open case (Figure 8b).

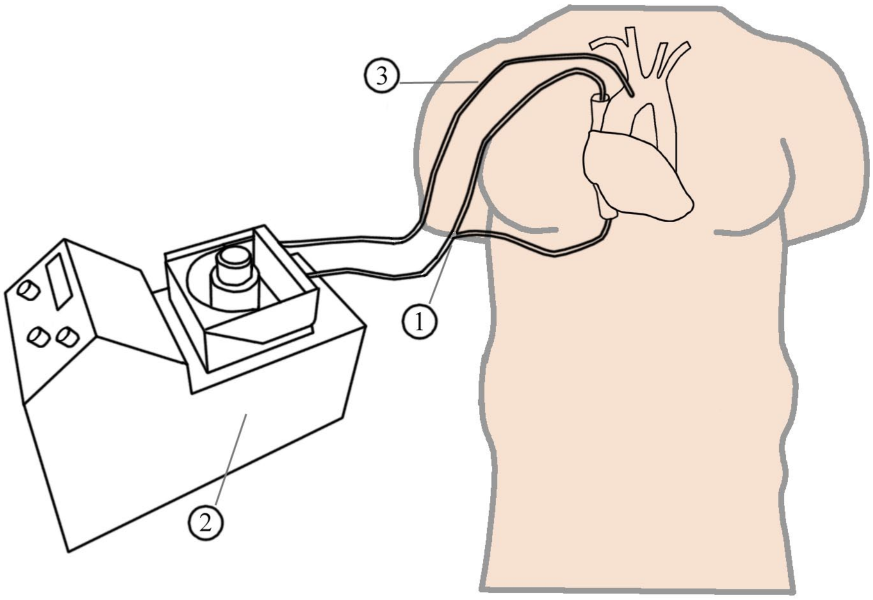
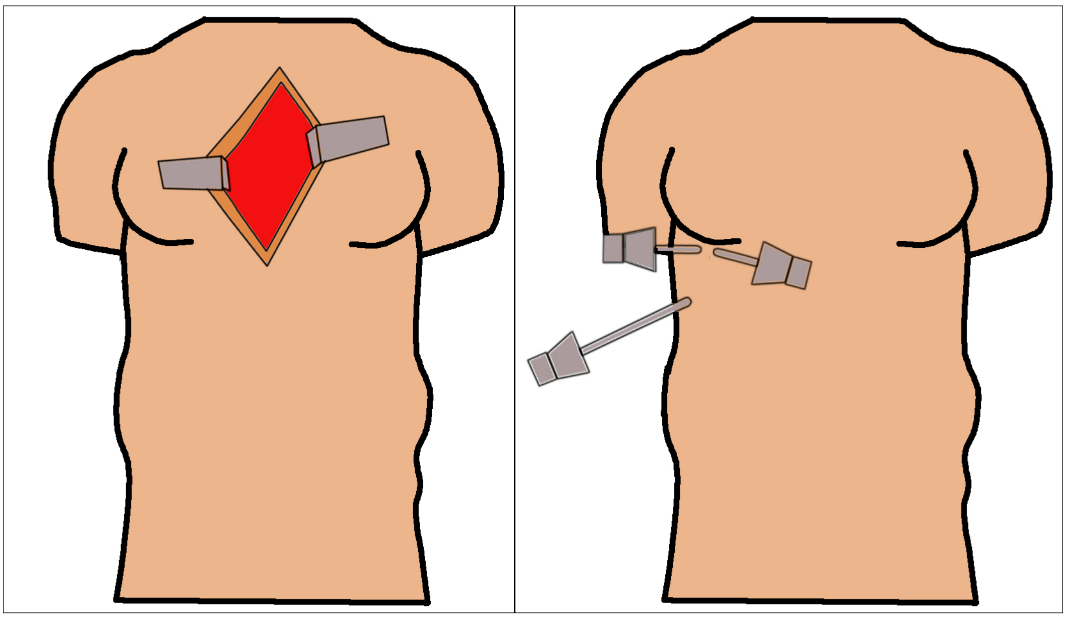


Figure 7 - Implementation of cardio-pulmonary bypass. (1) the oxygen-poor blood is taken from the heart and enters the machine, (2) the heart-lung machine oxygenates the blood and pumps it and (3) the oxygenated blood reenters the body through the aorta, skipping the heart and lungs



a) b)

Figure 8 - Location and type of incisions for different types of cardiac surgery. a) in open surgery a sternotomy is used to open the chest and expose the heart, b) in the minimally invasive approach, a small skin incision is open in the 4th or 5th intercostal space for the insertion of trocars. A separate incision is open for insertion of the endoscope.

Mitral valve repair or replacement is not an exception and the minimally invasive alternative of this intervention is also becoming popular [3;39]. Studies show great benefits for the patient, especially reduced pain, less risk of infection and faster return to regular activities [2;3]. This technique has been also used with success in reoperations [40]. When compared with the classical procedure, the minimal invasive approach shows longer cardio-pulmonary bypass (CPB) and aortic cross-clamping times but reduced stay in the intensive care unit, earlier extubation, shorter hospital stay times and reduced total hospital costs [12]. After some initial less encouraging results [14;41] this approach is now mature enough to be the standard choice for many surgical teams [13]. The outcome can be similar to those of the sternotomy approach as shown in some controlled trials [42].

There are many choices of specific techniques available to perform minimally invasive mitral valve repair or replacement[43]. In what regards aortic occlusion for CPB there are three choices: a trans-thoracic cross-clamp (TTCC) [44], a portaclamp (PC) [45] or internal aortic occlusion with an endoclamp balloon catheter, either the Port-Access (PA) from Edwards Lifesciences or remote access perfusion (RAP) from ESTECH [46;47]. Internal occlusion (PA or RAP) is less invasive than the TTCC because in the latter, an extra incision has to be made for insertion of the clamp. Also, in reoperations, it has the advantage over the external clamping in that it requires less aortic dissection to achieve aortic control [48]. On the other hand, there have been some reports of endothelial damage at the site of aortic balloon occlusion [49], but no clinical correlation has been shown [50]. So, using an endoclamp is a good choice if we want to keep the number of incisions to the minimum [13;50] . Nevertheless, difficulties associated with the endoclamp technique make it still unclear whether this is the optimal choice in comparison to the TTCC. Figure 9 shows the location where the aortic occlusion should occur, and how the endoclamp should be placed in order to achieve the same effect as the cross-clamp.

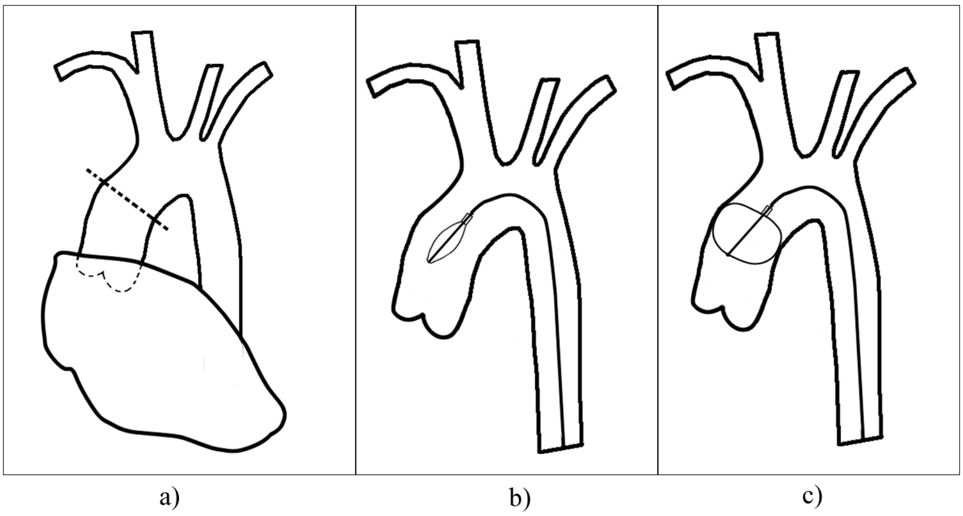


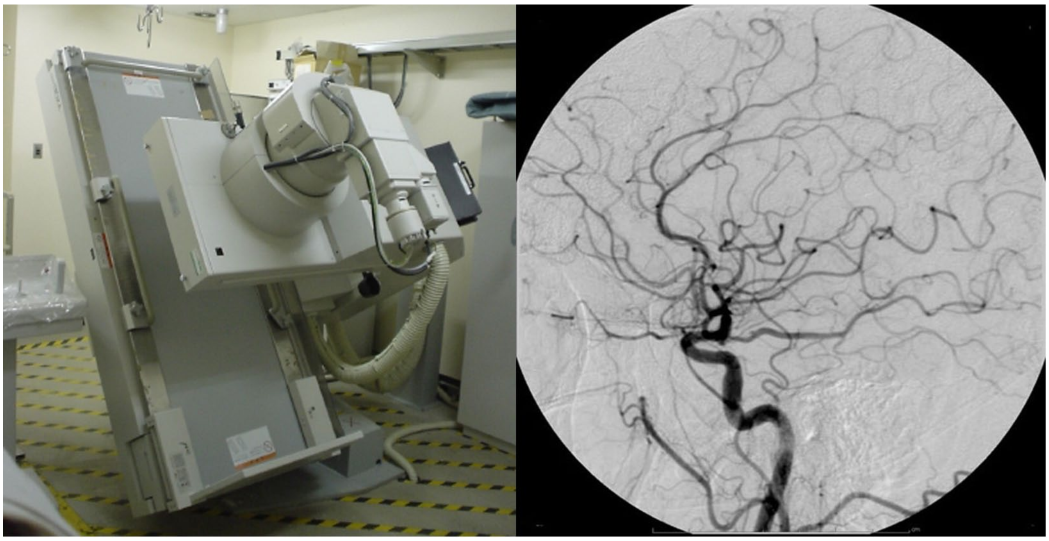
Figure 9 - Clamping the aorta: a) location where the clamping should be done, b) deflated endoclamp balloon catheter in the clamping position and c) inflated balloon performing the same function as the cross-clamp

Initial balloon placement is normally done under visual guidance using trans-esophageal echography (TEE) with good results [51] (Figure 11). Still, placement is a hard task leading to increased procedure times mainly due to difficulties in maneuvering and visualizing the balloon [11]. Studies also show that risks of aortic disruption [14], balloon disruption [52] and balloon migration [51;53] are small but not negligible. Most of these complications could be attributed to the beginning of the learning curve, which is quite long in case of Port-Access surgery [54]. Nevertheless, they still present a real danger and have to be considered seriously. Monitoring of migrations during the intervention is still not solved adequately. Quality of TEE visualization is much worse once the left atrium is open so migrations are detected by monitoring right radial artery pressure where a decrease of this pressure indicates brachiocephalic trunk occlusion [51]. Monitoring of balloon migration is extremely important as there can be severe consequences. In case of distal migration, damage to the aortic valve and occlusion of the coronary arteries can occur. The coronary arteries must not be occluded as they must be periodically perfused with cardioplegia, a solution to cool down and protect the myocardium. On the other hand, in case of proximal migration, there can be damage to the central nervous system due to hypoperfusion and ischemia as a result of brachiocephalic trunk occlusion. In any case, a repositioning of the balloon has to be performed immediately. Figure 6 in Chapter 1.4 shows the possible balloon migrations.

When compared to PA, the use of the TTCC requires almost no training, it is less costly and there are no displacement risks [11]. But aortic cross-clamping also has its disadvantages: beyond the extra incision, there can be damage to the aortic wall [55] and the risk of aortic dissection is not excluded [11]. Better monitoring and control of balloon position and better balloon pressure management are needed to fully exploit the benefits of PA. The comparison between both approaches suggests that better monitoring and control of balloon position and better balloon pressure management are needed if we want to take advantage of the less invasive characteristics of the PA technique.

2.2 Image guidance for cardiac interventions

X-rays have played a key role in imaging the cardiovascular system and today, fluoroscopy is still the most used modality to guide cardiovascular interventions. Röntgen discovered X-rays in 1895 and since then, the development of technology led to this discovery being used to build different versions of the fluoroscope to image the human anatomy in real time [56;57]. The first fluoroscopes consisted of a source of radiation and a target with materials that scintillated in the presence of X-rays. The resulting images were of very low intensity and therefore doctors had to look at them after having their eyes accustomed to the dark. Later on, image intensifiers were used so images could be seen in an easier way. Nowadays flat-panel detectors (solid-state detectors using a principle similar to the detectors in digital cameras to capture visible light) allow for better image quality, less radiation dose and allow also the physician to be in a separate room from the patient. Modern fluoroscopes (Figure 10) are used in endovascular image-guided interventions such as balloon angioplasty, placement of stents and insertion of catheters [58]. This is the primary imaging modality in interventional therapies for vascular diseases and an important treatment modality for cancer. The main problems with this solution are that it only provides a 2D image of the anatomy, the bulkiness of the imaging device and most importantly, the radiation doses for the patient and physician [59;60]. For a review and a vision of the future of this field, the reader is referred to [58;61].



a) b)

Figure 10 - a) A modern fluoroscope and b) an image of the brain obtained using fluoroscopy

Another common imaging modality used in diagnosis and interventional guidance for cardiac procedures is ultra-sound (US). US is commonly used to assess valvular function, guide insertion of catheters in the heart chambers and in the vascular system in general [62;63]. An array of transducers generates acoustic pulses that are reflected from points where the acoustic impedance of tissues is different (e.g. at the border between two types of tissue). By measuring the time-of-flight and the intensity of the reflections, a 2D image can be formed. A 3D US can also be formed, commonly by scanning a sequence of 2D US slices. US is considered harmless and scanners are less bulky then fluoroscopes but the downside is the poorer image quality and the fact that it doesn't work well with solid means (e.g. bone) or gases, limiting its application range. For cardiac imaging there are two major approaches, trans-thoracic US, in which the probe is in contact with the patient's chest or the trans-esophageal approach (or trans- esophageal echography - TEE) in which the probe is inserted in the patient's esophagus providing a better quality image of the heart and surrounding vasculature as the probe is much closer to these structures. Figure 11 shows an US image taken with a TEE probe revealing a part of the heart's anatomy. In this image the inferior resolution when compared to fluoroscopy can be seen. Nevertheless, and because of its harmless nature, US is the imaging modality of choice in many interventions.

Intra-operative magnetic resonance imaging (MRI) guidance appeared as a high image quality alternative to the modalities described before. Intra-operative MR is used to navigate endovascular catheters and deliver stents, vena cava filters, embolization materials, and septum closure devices [64-67]. Benefiting from high quality images and from its harmfulness to the patient, this modality has the potential of helping the development of new minimally invasive techniques that cannot be performed with conventional guiding techniques. It is currently limited by the available set of ferromagnetic compatible devices and by the bulkiness and cost of scanners. These are of course not as widely available as US. For a review on recent advances of endovascular interventions under MRI guidance the reader is referred to [24].

a) b)

Figure 11 - a) Trans-esophageal echography image of a part of the heart's anatomy and b) the same image with annotations. The endoclamp balloon described in the last section is clearly seen.

As seen in section 2.1, at the moment the insertion of the endoclamp balloon catheter is guided by TEE. This technique, while effective, suffers from the problems mentioned above: 1) its low quality makes it a hard task to perform an acceptable placement without a lot of training both on the side of the surgeon and on the side of the anesthesiologist, whom is responsible for finding the right plane to show on the TEE, and 2) it is limited to the time of initial placement, when the chest is closed. After that, during actual heart surgery, there is air inside the chest and the TEE images are unusable. Looking at the other available imaging modalities, none of them provides with enough advantages to justify their usage: fluoroscopy is used in repositioning but the radiation dose delivered to the patient and team is not acceptable to make it a standard imaging option for every insertion. As for inter-operative MRI, it is definitively too cumbersome and cost ineffective to use this modality just to make the procedure less invasive.

2.3 Computer assisted surgery

All the image guidance methods described in the last section provide raw intra-operative imaging, that is, without any kind of enhancement external to the imaging devices. Computer assisted surgery (CAS) applications emerged, enhancing raw imaging with the aim of providing better guidance [68].

CAS applications can support the surgical team throughout the different surgical phases: pre-operative planning, intra-operative guidance and post-operative quality assessment. Planning has an important role in cardiac surgery, especially in minimally invasive cardiac surgery (MICS). An example of one of the most important planning tasks in MICS is optimal port placement. In general, the surgical protocol defines the typical placement for the ports but, depending on the specific patient anatomy, the optimal location can change as the ports must allow access to all the structures that need to be operated in a way where the instruments do not collide. Software applications provide a way to calculate the optimal port placement based on pre-operative images and the clinical target, so they are a patient-specific, case-specific approaches [26;69]. Planning has also an especially important role in the definition of effective surgical strategies in cases where the heart anatomy is atypical. Tumors for instance, change the anatomy, and it is not always evident for the surgeon how to navigate in this “modified” heart avoiding damage to healthy tissue. Planning is also valuable when the cardiac anatomy is extremely altered as is the case in patients with complex congenital malformation diseases. In all listed cases, 3D imaging and visualization and also 3D rapid prototype printing, provide with valuable input to assist the surgeon in planning an optimal intervention [70;71].

Intra-operative guidance aims at assisting the surgeon in coping with the lack of sensorial information, guiding him in real-time through the surgical process. This guidance can be in the form of an assistance system to ensure the surgeon follows the planned tasks (as is the case with some of the planning tools mentioned before) but applications can also enhance the images to better see structures that are hidden [72]. Augmented reality (AR) technology became a popular choice to deliver image guidance. AR is the technology in which human perception is enhanced by superimposing computer generated information in real world images. Milgram derived a taxonomy for mixed-reality systems known as the real-virtual continuum [73]. It the mixed-reality space applications range from a completely real to a totally virtual environment (Figure 12). Applications containing mostly real information with some computer generated information are said to be augmented reality. The opposite, where some bits of real information are superimposed on a virtual environment, is called augmented virtuality.

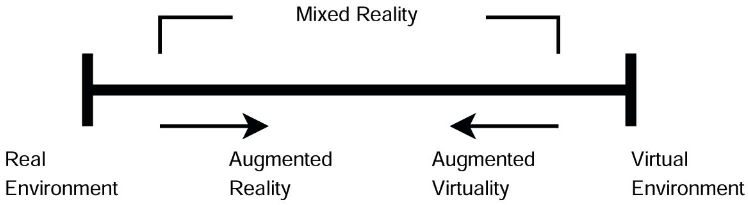


Figure 12 - Milgram's mixed reality space ranging from a completely real environment to a completely virtual environment.

AR became a popular choice for guidance as it enables for example to embed visual cues in real imagery or to mix real-time images like US augmenting these with off-line 3D models coming from CT or MRI. To correctly superimpose information in the scene, a patient model has to be properly defined. In cases where the anatomy is rigid, the problem is simple but this is hardly the case when surgery is being performed on the beating heart. Even if surgery is performed on the stopped heart the preoperative images do not always correspond to the reality in the OR because the heart will be deformed after it is stopped. Efforts have been made to model heart's deformation using ultra-sound [74] or to model its motion using a variety of image modalities [75]. In general, AR applications augment the surgeon's information but this information is not used in closed loop to automatically actuate on the patient. Robotic actuators do exist in combination with AR systems and are used in clinical practice [76] but these are teleoperated by the surgeon and not driven by the application.

CAS applications leverage a number of different technologies including:

- **Tracking**: where the position of surgical tools, the patient, instruments or the surgeon is measured in 3D space
- **Image processing**: *registration* provides alignment between data in different coordinate frames and *segmentation* provides methods to discriminate between different structures, e.g. bone and organs
- **Modelling**: where organs or structures are modelled to take into account their biomechanical properties, motion possibilities, etc.
- **Visualization**: where patient data and extra guidance information are presented to the users

2.3.1 Tracking

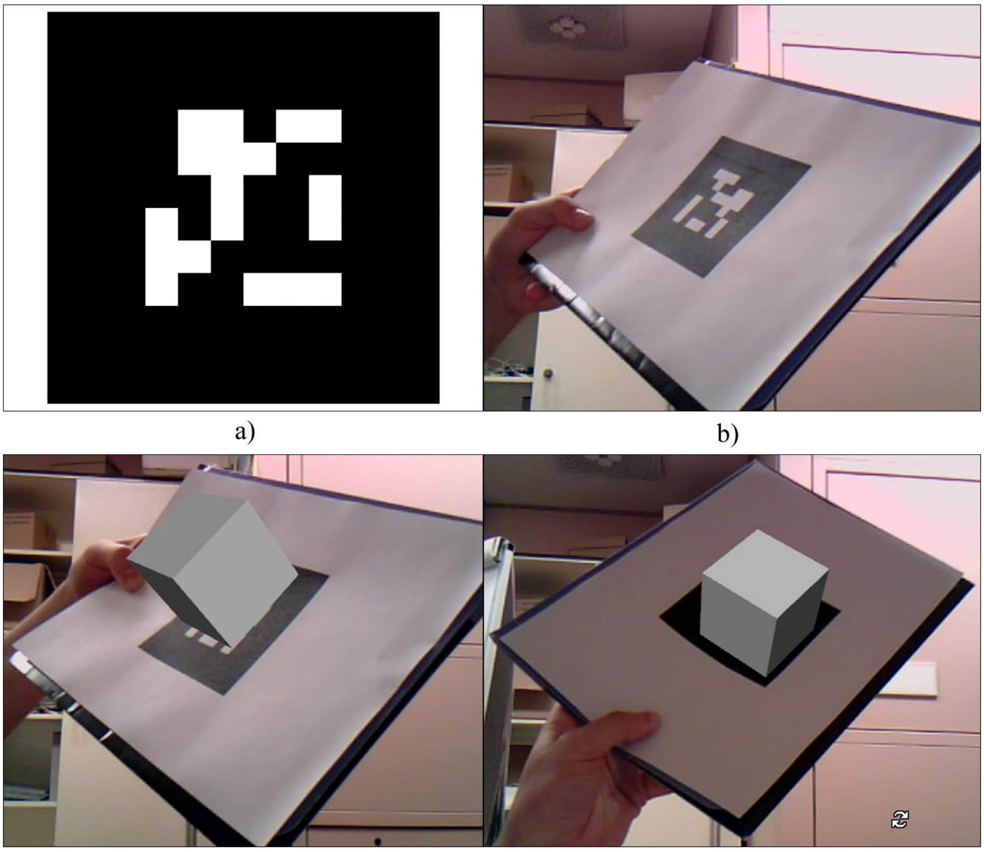
Knowing the position in space of surgical tools, catheters and other objects in the OR is essential to display information about them to the user. Measuring their position and orientation in space - called *tracking* - is a fundamental process in CAS applications and can be achieved using a number of different principles. Other than knowing the spatial coordinates of surgical tools and catheters, it is sometimes also desirable to measure the position and orientation of the surgeon's head, to provide him with visual information in the correct viewing angle, tracking the patient or parts of his anatomy, e.g. tracking the chest to compensate for breathing motion, and tracking the position of imaging devices like an US probe head which would for instance provide information to align the image coming from the US with another image. In summary, tracking is used to provide information about the spatial relation of all the objects of interest in a scene and is essential as all the other methods depend on how precise the spatial measurements are.

From all the tracking technologies the most popular are optical and magnetic. These two have a clear trade-off in what regards accuracy versus flexibility: while optical trackers are the gold standard in what concerns accuracy they require line of sight so they cannot be used to track objects which are occluded, e.g. inside a vessel. Optical tracking relies in a set (one or more) of cameras generating images of the scene of interest. By using image processing techniques, the position in space of the objects of interest can be calculated. One of the possibilities to do so is to attach sets of markers defined specifically to be easily identifiable to the objects of interest. The image processing will then extract the position and orientation of the markers (and consequently of the objects) from the images. Consider as an example the 2D marker in Figure 13. Using the ARToolkit+ it is possible to track its positions and orientations in space using a conventional camera (even with a simple laptop integrated camera) allowing the superimposition of a virtual object aligned with the location and orientation of the marker.

While this option for optical tracking is not the one with higher precision (it is in fact quite poor) it illustrates the principle well and is used in non-critical applications such as AR games. In the medical domain, options with higher accuracy must be employed. An example is NDI Polaris which consists of a body with a source of infrared light (IR) and detectors (cameras) which sense the reflection of the IR light from spheres implanted in surgical tools. Figure 14 shows a picture of the system and the tools it can track. Other commercial optical tracking systems exist in the market, which can be chosen depending on the budget and necessary precision.

Magnetic tracking uses sensor coils placed on the objects as a base for tracking. A field generator creates a time varying magnetic field in space which induces current in the sensor coils. These, are connected to a detector unit that, through signal processing, can relate the induced current with the position and orientation of the sensor coils (Figure 20).

The big advantage of such systems is that line of sight is not required as opposed to optical trackers. This makes magnetic tracking a perfect choice to measure the position of objects which are constantly occluded as is the case of the balloon catheter we described in section 2.1 or any other tool or catheter that is inside the patient’s body during surgery. The disadvantage is that the accuracy of these systems is not as high as the optical ones. Moreover, magnetic trackers suffer from potential field distortions induced by moving ferromagnetic materials within the volume of measurement [77] which makes it even more challenging when high accuracy is needed, even if these distortions can be managed.



a) b) c) d)

Figure 13 - Example of the ARToolkit+ library. a) Id marker for video based tracking. b) video image of the marker printed on an A4 sheet. c) and d) a superimposed cube which is aligned in position and orientation with the marker.

a) b)

Figure 14 - Polaris optical tracking system from NDI. a) position sensor and b) tracked tools

Apart from optical and magnetic, other solutions exist. These are by far not as popular but worth mentioning and include:

- mechanical tracking, where mechanical arms with angular encoders in their joints allow to calculate the position of their tip
- ultra-Sound, where the time-of-flight of ultra sound waves coming from an acoustical source, the target to track, is measured by an array of highly sensitive microphones
- Inertial trackers which, after an initial calibration step to define the current position, report their updated position based on accelerometers. These are quite inaccurate and their use is discarded in medical applications but they are

extremely popular in personal applications, e.g. they are part of many smart phones on the market nowadays.

In general, manufacturers provide software APIs to allow access to tracking data coming from the hardware. Developers can use these software development kits directly to integrate data in their applications. The research community has developed robust libraries that can also be used to interface with tracking hardware. These are compatible with a wide variety of hardware including the most popular products available. Two popular such libraries are Opentracker [78] and VRPN [79]. These are open source libraries that manage tracking data while providing abstract interfaces to the hardware. Taking into account the level of distribution of applications and the fact that sensors also will no longer be monolithic, the *Ubitrack* architecture was recently proposed [80;81] with the aim of easily supporting combinations of heterogeneous position sensors, i.e. sensors employing different kinds of sensing technology. It is based on a central server and peer-to-peer data transport for low-latency data transmission. It is also probably the first one to have a graphical tool, *trackman*, to manage the tracking hardware configuration and to monitor network status.

2.3.2 Registration

Images coming from different modalities, or scans at different moments in time are in different coordinate systems. Spatial data measured by the tracking systems are also referring to their own coordinate system. This data have to be “registered” in order to be represented in the same coordinate system with the aim of coherently identifying similar structures or overlaying tracked objects in them.

Registration is the search for a transformation between one coordinate system and another so that points in one image (or dataset) best match points in another image. Depending on the source of the data, we can talk about image-to-image registration, when we want to align images at different points in time (e.g. the same patient imaged on two days) or between two imaging modalities (e.g. PET and CT), or image-to-patient registration (e.g. correspondence between patient anatomy and the images). An excellent taxonomy of medical image registration is presented in [82]. Two great categories of methods exist, extrinsic and intrinsic registration methods. The stereotactic frame, briefly mentioned in the introduction, was a first way of obtaining image-to-patient registration. It was a first solution to have a set of points visible on the patient and on the image with the purpose of clearly matching them. Similarly nowadays, fiducial points can be introduced in patients before imaging. These can be screwed to patient’s bones or simply glued to the skin. As long as they are clearly visible in the images they provide the explicit point correspondence needed. These methods are often called extrinsic as they rely on the introduction of external markers to drive the registration [82;83]. The markers have to stay implanted in the patient throughout the whole treatment which may be for several days or weeks in the case of radiation therapy. Intrinsic methods use the structures that pertain to the patient to drive the registration. These can be prominent anatomical features like bones or bifurcations in the bronchus, whole structures obtained by segmentation or whole images (based for instance on voxel intensity) in which case they are called content-based registration methods. The choice of particular methodology will depend on the type of imaging employed in the procedure and the existence or not of easily identifiable structures that can be used as landmarks. Another characteristic to consider is the rigidity of the body to study which will determine the nature of the transform to search for. In case of totally rigid bodies (or regions of interest) a rigid or an affine transform are sufficient. This is generally the case in neurosurgery and orthopedic surgery as well as other cases where rigid conditions can be assumed [84-86]. Given the relative simplicity of the problem, reliable real-time registration methods exist and this is probably the reason why systems for this type of surgery were the first to be developed as commercial products. An example, in the field of bronchoscopy, shows that internal anatomical landmarks give more accurate results compared to external fiducial markers. In this case, the anatomy is not strictly rigid but rigid condition can be assumed. The work [87] compares accuracy of using external fiducial markers or intrinsic anatomical markers. This solution is currently implemented in a commercial product, superDimension Bronchus system (superDimension, Ltd; Hertzliya, Israel), with some first positive clinical results already reported [88]. A similar approach for patient-to-image registration is used in [89;90]. The aim is to accurately track a bronchoscope in order to represent its position in pre-operative CT images. The registration is computed using a modified version of the iterative closest point (ICP) algorithm [91] where, instead of matching two clouds of points, one cloud is matched to the bronchus tree. The bronchus tree is calculated from segmenting the pre-operative CT data. One of the problems with this approach is that it assumes that the sensor (which in this case is sitting in the Bronchoscope) runs along this centerline of the airways which is not a completely realistic constraint. An extension of this idea is to make the registration without the need to find centerlines or segmentation of the pre-operative dataset [92].

One of the practical uses of registration is to allow the complementing the poorer quality intra-operative imaging modalities with high quality pre-operative images. Intra-operative images, coming from US or fluoroscopy provide two-dimensional views of the anatomy and the surgeon has to build a 3D mental map of the anatomy to effectively deliver treatment. Preoperative models and intra-operative modalities can be registered to enhance the intra-operative visualization. The problem is usually formulated as 2D/3D registration. As an example, high spatial resolution roadmaps derived from MRI are overlaid onto conventional X-ray fluoroscopy and used in clinical practice [93]. In this work, authors used external fiducial markers to drive the registration, but intensity based registration algorithms also provide accurate results in similar applications [94;95]. The detailed but static CT volumes used as roadmaps for the navigation can be augmented with the segmented myocardial borders from a real time US [96]. In [97] the authors propose fusing MR images and C-arm fluoroscopy images in what they call a hybrid magnetic resonance (MR)/X-ray suite. This guidance system acquires X-ray images and displays the previously acquired and registered MR derived anatomy. The C-arm is tracked by an optical tracking system and automatically registered to the MR images.

All these approached assume rigid conditions but in many cases in cardiovascular surgery, these cannot be assumed. When this is the case, non-rigid registration methods compensate for the additional deformations. These methods generally consist of adding an additional deformation model to the affine transform present in rigid methods. The search for the transformation is usually done by minimization (or maximization) of a merit function which measures how well the two images match after transformation. Several possibilities for modeling the deformation of the image data to be registered exist – these range from elastic deformation and group-wise registration of image compartments [98-100] to statistical shape models [101-103] and finite-element models [104;105]. Common applications of these might be to model the heart deformation using a 3D+t model of the heart and register this to endoscopic images [72;75].

2.3.3 Visualization

Both the patient datasets and 3D models of objects that are embedded in a scene need to be efficiently rendered on screen to display the application output to the user. The large volume of data and complexity of the scenes demand for efficient use of graphics cards acceleration features to provide real-time visualization of data and objects. OpenGL is the industry standard open source application programmer interface (API) to expose graphics cards acceleration features. Still, when creating applications developers should not be concerned with specific low-level features with the implementations but rather with getting higher level access to the accelerated rendering pipeline. To solve this, high level three-dimensional graphics rendering libraries appeared. They provide simple APIs in which the developers can worry about how their scenes have to be shown to the users rather than focusing on how the low level implementation works. Two libraries that are popular in the scientific and industrial community are the visualization toolkit ([106] VTK, *Kitware Inc.*) and Coin3D (*Kongsberg / SIM*), a reimplementation of the Open Inventor (*silicon graphics*) library. Many scientific visualization and virtual reality applications rely on one of these two.

VTK is perhaps the most popular visualization library available. It provides the means to easily read data in different formats (including DICOM), render these volumes on the screen using a number of different visualization algorithms (scalar, vector, tensor, texture, and volumetric methods) and modeling methods (implicit modeling, polygon reduction, mesh smoothing, cutting, contouring, and Delaunay triangulation). It is highly extendible with bindings for Python, Java and TCL and is under Kitware's quality software process to build, test and package it.

Coin3D is a 3D graphics API designed as a higher level interface to OpenGL functionality using the scene graph concept as data structures [107]. It consists of a set of C++ classes abstracting the underlying OpenGL architecture allowing the programmer to easily access high performance features in an easy and convenient way. The scene graph is a data structure storing an internal representation of the scene to be rendered. The scene is organized in a graph or tree structure. Nodes can be object primitives like a cube, a sphere or a mesh of polygons, action primitives like a position transform or other types like a camera or a light source. When applying actions, like a position transform, rendering or updation, these have an effect on all the children of the node they apply to. Figure 15 illustrates the concept for rendering, illuminating and viewing a simple table.

It is important to mention the *sister* library to VTK, the Insight Toolkit (ITK). It is not performing any direct visualization or rendering but is rather a collection of established methods to perform registration and segmentation [108].

Finally, an important topic is the way how information is displayed to the medical team. The most common and popular way to display visual information is on LCD screens that are now standard equipment in many ORs. Still, to visualize overlaid information (typical in AR systems) head mounted displays [109;110] are a more appropriate choice. Nevertheless, the proper way to display information to the medical team is a subject of intense study and discussion [111-114].

2.3.4 Implementing applications: toolkits and frameworks

As indicated in the beginning of this section, CAS applications are a combination of the different technologies that have been described throughout the previous subsections. Connecting all these technologies (tracking, visualization, registration, etc.) in one application is a huge software engineering task. As a result from this challenge, several software toolkits and development frameworks appeared so that the integration can be done in an easier way. The frameworks can be seen as being one abstraction level up in the hierarchy of tools for application development in relation to the libraries described before. The toolkits effectively combine software libraries in a transparent way leaving space to the developer to focus on application functionality rather than focusing on software integration tasks. This allows rapid prototyping and testing of applications which is (as we will see later on) crucial for iterative co-design of medical applications.

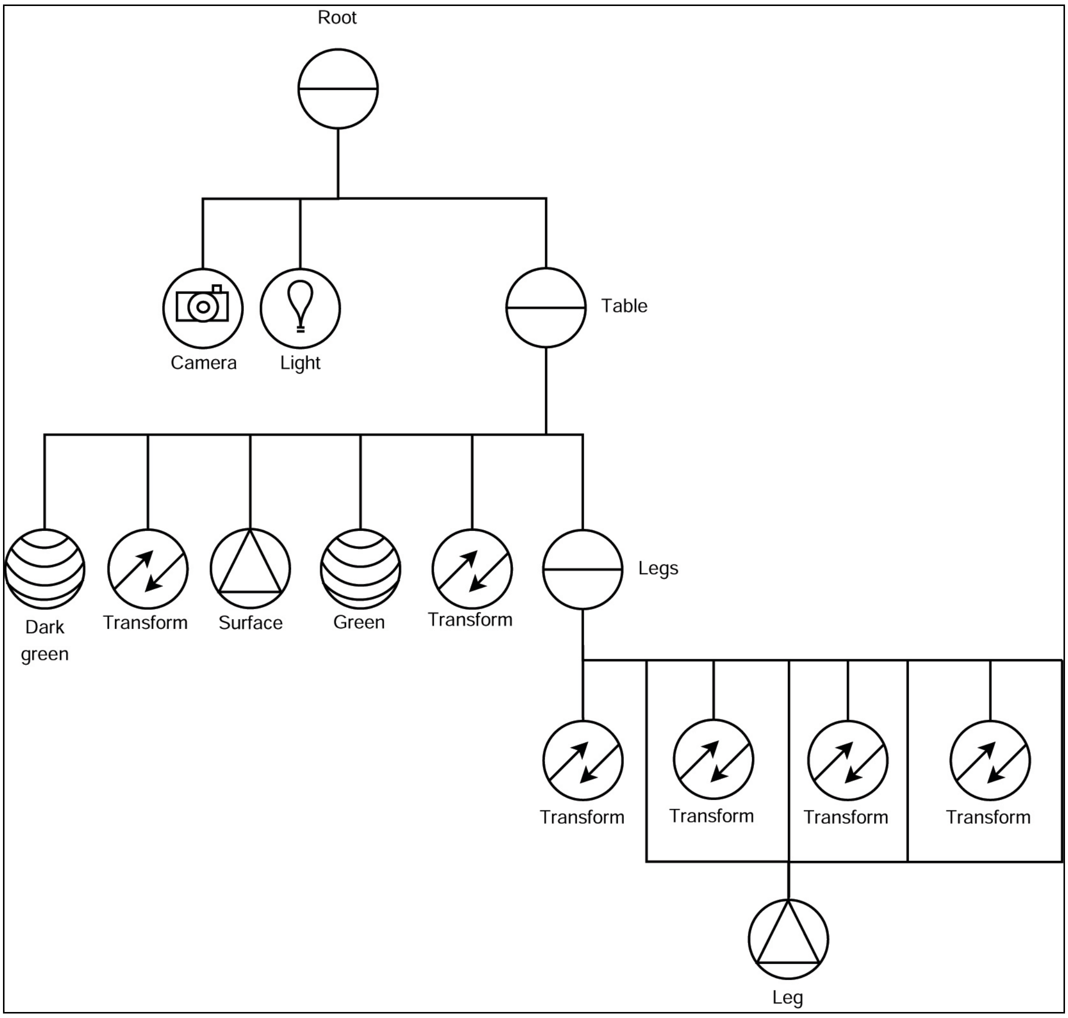


Figure 15 - Example scenegraph detailing the rendering of a table.

One such framework is *Studierstube*, the one that was used in the development of the prototype described in this dissertation. *Studierstube* is a collaborative augmented reality development framework that has been under development for over 10 years. The framework is designed as a set of classes built over open inventor (using the Coin3D implementation) so graphics rendering is closely tied to this library. Moreover, it integrates a component to manage tracking sources in a configurable and abstract way (using extension classes from Opentracker), possibility of video overlay using "Openvideo" (one of *Studierstube's* components) and easy integration with third party components like ARToolkit+, a library for optical tracking of card-shaped markers (Figure 13) also developed as a component of *Studierstube*. The component based architecture makes it easily extensible. Creating a new component (e.g. registration management component or a specific display component) is a matter of overloading a set of defined classes. *Studierstube* is a general purpose framework so it was not designed specifically for medical applications. *Studierstube medical* [115] is a derived project that adapted the framework including new components having the medical domain (specifically minimally invasive surgery) in mind. The RF ablation project [116] from the

EU ARIS*ER network [117] is an example of an application developed with this framework.

Apart from *Studierstube* which we used there is a number of choices, general purpose or dedicated to the medical domain. The image guided surgery toolkit (IGSTK) [118] combines VTK and ITK capabilities and adds support for tracking hardware and common user interface design. The slicer image guided navigation (SIGN) [119], also combines VTK and ITK and uses a modified version of opentracker (NaviTrack) for managing tracking hardware. Applications are defined through configuration of MRML (application defined markup language) and extensible markup language (XML) files. The distributed wearable augmented reality framework (DWARF) [120] is particularly focused on component distribution over a network and applications are designed as *services* (providing specific functionalities, e.g. registration) or *needs* (consuming functionalities). Common object request broker architecture (CORBA) [121] is used as the communication platform between the components. The medical imaging interaction toolkit (MITK) [122] was specifically designed to extend the capabilities of VTK and ITK beyond their low level functionality. MITK integrates the visualization and algorithmic capabilities of these two libraries extending them with interaction and user friendly visualization. Finally, another interesting framework is the extensible imaging platform (XIP) builder [123] which uses the rapid application development paradigm allowing the used to design scenegraphs using a drag-and-drop interface. The toolkit is based on openinventor and features native integration of VTK and ITK algorithms.

Interesting is the report about the integration and cooperation of the described frameworks. *Studierstube* and DWARF developers coded an interconnection between the two frameworks based on two different approaches as a way to demonstrate how easy it is to extend and integrate both of the frameworks with other applications [124]. Another of such efforts was done by the integration of MITK functionality in XIP builder [125]. The number of choices and the possibilities of integration between all of the frameworks makes the selection of one of them not an obvious one. Still, all these tools take a long time to master and the developer's objective of creating a robust fast prototyping environment is still not achieved which means that developing applications is still not possible to developers without expert programming skills, a difficulty felt for instance by human computer interaction specialists when studying and prototyping interfaces.

2.4 Wireless Sensor Networks

CAS applications are heavily dependent on information gathering. Basically they can be seen as a pipeline of **sensing** (object tracking, head tracking), **processing** (registration, collision detection, etc.) and **display** (on a screen, head-mounted display, on top of the "real" world, etc.). They are applied nowadays to solve the problems associated with MIS

- they try to *augment* reality so the surgeons recover their "lost" senses. Still, improvements provided by the applications are in general limited to spatial measurements and offering visual guidance. In the OR there are a number of other information sources from which CAS applications might benefit. These can include physiological measurements from the patient but also from the surgical team themselves as well as sensing which members are present and which material is present. The question arises: are these measurements not often taken into account because they are not useful or is it too cumbersome to equip the patient and members with a pack of sensors?

Wireless sensor networks (WSN) are a rapidly developing technology that can effectively increase the power and usefulness of CAS applications. Being small and unobtrusive, wireless sensors provide a simpler hardware solution that can be used to acquire data during MIS without adding too much complexity. But still, at software level the complexity remains: there is no simple way to bridge networks of sensors into CAS applications and their already complex development frameworks.

There are many applications of WSN to medicine in very different perspectives. They can range from Body Sensor Networks (BSN) where a collection of wireless on-body sensors communicate with external servers with the aim of supporting rehabilitation [31], prevent ulcers [32], or simply inform the doctors at remote locations of the state of the patients residing at home [126] to applications spanning across whole hospitals where medical staff and equipment is tracked to increase efficiency of the medical care process [127]. The former is normally based in custom-developed wireless sensor boards that measure physiological quantities, perform some local processing and send the data to a sink. The sink can be either a personal device like a personal digital assistant (PDA) or a PC. The latter kind of applications is normally based on a more complex architecture where local networks (sensors detecting doctors with RFID tags) communicate with central servers using normal local area network (LAN) infrastructure and manage this information in a central database. In the WILHO project [128] RFID tag readers that can communicate with a central server are used to order clothes in a hospital. The developed framework abstracts the RFID reader (treating it just like a general sensor) and the architecture could be used with other sensing technology. In [36] the authors developed a number of different vital sign wireless sensors intended to acquire information from patients in case of accidents or of a massive disaster. The sensors relay their information to PDAs or ambulance based stations using short range wireless communications. The data can be integrated into a pre-hospital patient record. On another perspective, some applications are dedicated to support the medical team in the operating room (OR) [37]. In this case, the patient, the medical team, the tools and blood bags are equipped with RFID tags. Using a rule-based approach and the readings from the sensors that are present or not, the system generates warnings in case something is wrong e.g. the blood bags are of the wrong type. Other applications of WSNs to medicine are discussed in [129-132].

The topic of connecting different sensor data in AR applications has been addressed before. Notably, the opentracker [78] and VRPN [79] libraries provide abstract interfaces to connect applications to different kinds of sensors in a transparent way. These are usually tracking sensors (spatial measurements) but integration of other sensors is dependent on writing device drivers which would make integration with WSNs possible. Still, sensors that will be available to the application must be configured at design time and no changes can be made at runtime. There is also no mechanism in these libraries to address quality of service requirements.

Middleware systems bridge two (or more) layers of software that normally don't interact out-of-the-box. According to [133] middleware is "...software that lies between the operating system and applications running on each node of the system. Generally, middleware is expected to hide the internal workings and the heterogeneity of the system, providing standard interfaces, abstractions and a set of services that depends largely on the application". In [134;135] existing solutions are surveyed and challenges of using middleware in WSNs are discussed. Faced with the task of interfacing these two worlds our current approach was inspired by two points of view pointing in the same direction. The first is depicted in [136] where the authors present a complete network architecture IPv6-based architecture for WSN. In most of the reviewed applications communication architecture is not IP compatible. In this work the authors show that, whereas before it was thought that IP is an old standard not suitable for WSNs, with careful design the performance can be better that the custom based approaches that were designed for each of the applications. This led us to believe that the design of a custom network stack should be left for later, if needed, and focus on a middleware component will be more important. Such a decision is supported by [137] where their review of possible distribution schemes for WSNs shows that an approach via middleware can be an interesting one. Also for others [138] middleware is a good choice to provide high level abstraction when interfacing heterogeneous sensors and applications. Having this into consideration, we concluded that middleware based architectures are instrumental to combine the power of WSN sensing capabilities with the enhancing capabilities of CAS applications with its already proven benefits to medical interventions.

2.5 User Centred Design

The main focus of the work described in this dissertation was the implementation of a software application to support the procedure described in section 2.1. Design, implementation and evaluation of the application was done in the context of the European research training network ARIS*ER - Augmented Reality in Surgery [117]. Even if the focus was on software development the work was done in cooperation with all of the eight partners of the network, following user centered design (UCD) principles [139].

This proved to be instrumental in designing an application that effectively addressed the needs of the surgical team rather than being a mere demonstration of technological capacity.

Bridging the technical and medical domains is not trivial and UCD is a growing topic as a result of the complexity technology has to offer and the lack of appropriate interfaces and targeted functionalities to address requirements of the users. In medicine, factors taken into account in the design include cognitive workload, decision-making, human control, human learning, levels of professional expertise, professional strategies during treatment, visual and haptic strategies, physical workload, and team work. Classical ergonomics methods to analyze these factors include observations of interventions, interviews and literature studies but these are insufficient and newer techniques such as focus groups [140], focused brainstorms and/or generative techniques [141] have proven to be efficient. The innovation is that not only all partners are involved in generating requirements but also in the design process, contributing to the solution finding process equally. The process is termed co-design.

3 A visualization and control system for the endoclamp catheter placement

In this chapter we describe in detail the prototype implemented for visualization and control of the endoclamp balloon catheter. We describe our design approach, detail the implementation of the system and present the results from user studies.

Targeting the specific problem of the endoclamp balloon management described in Section 2.1, we designed an application to assist the surgical team during initial placement and throughout the surgery. The application was developed within the framework of the European research network "Augmented Reality in Surgery" (ARIS*ER). ARSIS*ER created technical building blocks in augmented reality (AR) and robotics to overcome common problems in minimally invasive surgery (MIS): lack of visual information and lack of haptic (tactile) information. In the context of this project, we created a combined information and positioning system based on augmented reality technology and robotics to support minimally invasive mitral valve surgery (MVS) using the port access (PA) technique. The system provides continuous, real-time monitoring of balloon position during the entire procedure, automatic position control to a specified target, useful for initial placement and to correct intra-operative migrations and automatic balloon pressure control, keeping the pressure level to the minimum required for occlusion while protecting the aorta from disruption. As such a system addresses the key safety issues in the current surgical workflow we expect that it has the potential to make PA the technique of choice for minimally invasive MVS and so, profit from the smallest incisions possible. In this chapter we describe the design and implementation of the system as well as user studies we performed to evaluate the technical feasibility and the clinical benefit of introducing such system in the clinical workflow.

The system is simple and effective: we measure the balloon position in real time with the help of a magnetic sensor. The position is superimposed on a three-dimensional scan of the patient's thorax, showing it 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 throughout the surgery. If still there is a migration, the system automatically takes care of repositioning in the correct location. Balloon pressure levels are also controlled automatically. Our design follows a similar path as other systems implemented for the support of medical interventions both for cardiac [142] and other procedures [143]. In both cases, the authors use like us, a pre-acquired 3D dataset and track surgical instruments and an Ultra Sound (US) probe with a combination of magnetic and optical tracking. The tracking data is used to superimpose the virtual surgical tool reconstruction on the US images, guiding the surgeon.

We extended existing work in two ways: first our system is the first to address and solve the difficulties with occluding the aorta using the endoclamp in MVS; second, our system not only provides information to the surgeon but also supports automatic robotic placement that relies on the position data. To our knowledge our system is the first to combine such techniques providing a complete solution for monitoring and automatic placement specifically to supporting minimally invasive MVS.

3.1 Design

We followed a user centered design (UCD) approach with engineers, clinicians and human factor specialists involved in all the development phases. The main purpose of the user centered design approach is for the user (the surgeon) to be involved in the design process from the beginning, avoiding that the final solution be driven by the availability of technology rather than by the specific needs of the surgical team. Since these projects are highly interdisciplinary, knowledge from different technical fields as well as from medical sciences has to be integrated with the aim of designing a single application. This raises the need of very specific and focused design methodologies reason for which, the involvement of human factors (HF) specialists is essential to guide engineers and medical doctors throughout the design process.

UCD is an iterative process going several times through the design cycle. The essential concept is that initial solutions are based on technology opportunities, i.e. on technology that is yet unavailable because it is subject of research. Then, throughout several iterations, the application requirements are redefined taking into account the technology progress up to that point and the possible future expectations. In our project we can identify three major iterations that can be summarized as follows:

- 1st iteration: initial procedure analysis and direction proposal

  An initial workshop was held with surgeons, engineers and human factor specialists with informal brainstorming sessions about options for combining available modules into the desired system. Three months after, meetings were held, with HF specialists and engineers of different domains - robotics and software (AR) - in search of an appropriate technical solution. The following months were dedicated to design refinement and implementation.

- 2nd iteration: first prototype evaluation and problem redefinition

  Ten months after the first kick-off meeting an initial prototype was ready. The prototype contained already all the main functionality of the final solution which gave all the involved parties an opportunity for assessment: the engineers investigated the feasibility of the solution, the medical staff evaluated the suitability of the solution in terms of functionality and the HF specialists had the chance to interact with both, refining the design process and planning the next steps. Formal user studies as well as informal brainstorming sessions were held.

- 3rd iteration: detailed evaluation and final prototype targeting

  On the second year of the project, there were several re-design and re-implementation steps that contributed for the refinement and convergence to the final version presented in this thesis.

Each of these three major iterations consisted of sets of workshops and meetings. Table 1 shows a list of all the workshops realized during the project with a summary of the key findings.

Event	Summary
1 - Workshop Telemark, Norway Dec 2006	Procedure analysis and first technical solution finding **Major outcome**: high level directions to follow
2 - Surgery observation Ljubljana, Slovenia 12-19 Feb 2007	Surgical observation, interviews, current clinical workflow definition and modification to take the new system into account **Major outcome**: first conceptual system design
3 - Technical meeting Leuven, Belgium 26 Feb 2007	Solution finding for the functionality of the catheter actuator. **Major outcome**: requirements for the actuator (force, stroke, etc.)
4 - Workshop, technical meeting Ljubljana, Slovenia 30 May-2 Jun 2007	Limited initial implementations were available. Initial discussions about integration were conducted. **Major outcome**: integration and test strategies (mainly which kind of phantom to use) were defined.
5 - Tech. meeting, evaluation Oslo, Norway 19 Nov - 3 Dec 2007	First physical assembly of the full working prototype. **Major outcome**: usability tests were conducted. Future directions were explored.
6 - Workshop, evaluation Sils Maria, Switzerland 10-14 Mar 2008	Second physical assembly of the system with new functionalities (syringe driver for balloon inflation). **Major outcome**: second round of usability tests.
7 - Brainstorming, tech. meeting Leuven, Belgium, 4-7 Jul 2008	Testing of the second robotic inserter and automatic pump inflation. Definition of the requirements for the automatic intra-operative balloon repositioning. Preparation for animal testing including ethical issues discussion with the surgeon.
8 - Animal testing Oslo, Norway, 14-24 Oct 2008	Animal studies. Clinical feasibility. Data gathering.

Table 1 - Summary of ARIS*ER workshops

Following we detail the major findings of the two first workshops which contributed most to the beginning of the development process.

Event 1 - Workshop

Telemark Norway - *First problem analysis and conceptual solution finding*

Safety aspects were initially analyzed in this workshop [144] held at the project kick-off meeting. In the meeting, the key problems were identified and high level requirements derived. Table 2 bellow summarizes these requirements which are related to specific problem solving. These requirements were later refined throughout the rest of the project's workshops.

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

Table 2 - High level requirements for the positioning system

At the Telemark workshop, a group consisting of 2 surgeons, 10 engineers and 1 HF specialist who coordinated the session, worked on the initial conceptual solution finding (Figure 16). The first step was to start the exchange of knowledge by going virtually through the procedure (method: *usability walkthrough*). In a second step, a discussion on tasks that cover key requirements such as information exchange in the surgical team, security relevant tasks and surgeons workload, helped defining on which problem the team needs to focus on (method: *task analysis* and *critical incident analysis*). The final step consisted of the technology assessment with the aim of finding an initial technical solution for solving the defined problem (method: *brainstorming*).

From the task analysis and based on the descriptions in [145-147] a matrix (inspired by [148]) was created in an A0 sheet (Figure 17) depicting the occurring main tasks of the surgical procedure in columns, and roles of the team and the actual equipment of the system in rows. First, different tasks and subtasks during the procedure had to be identified and described and then, descriptions of the subtasks for the different roles were placed in the appropriate cells (roles as defined by [149]). From the tasks defined using the matrix, a draft of the medical workflow for the minimally invasive mitral valve procedure was derived.

Figure 16 - First human centered design workshop in Telemark, Norway

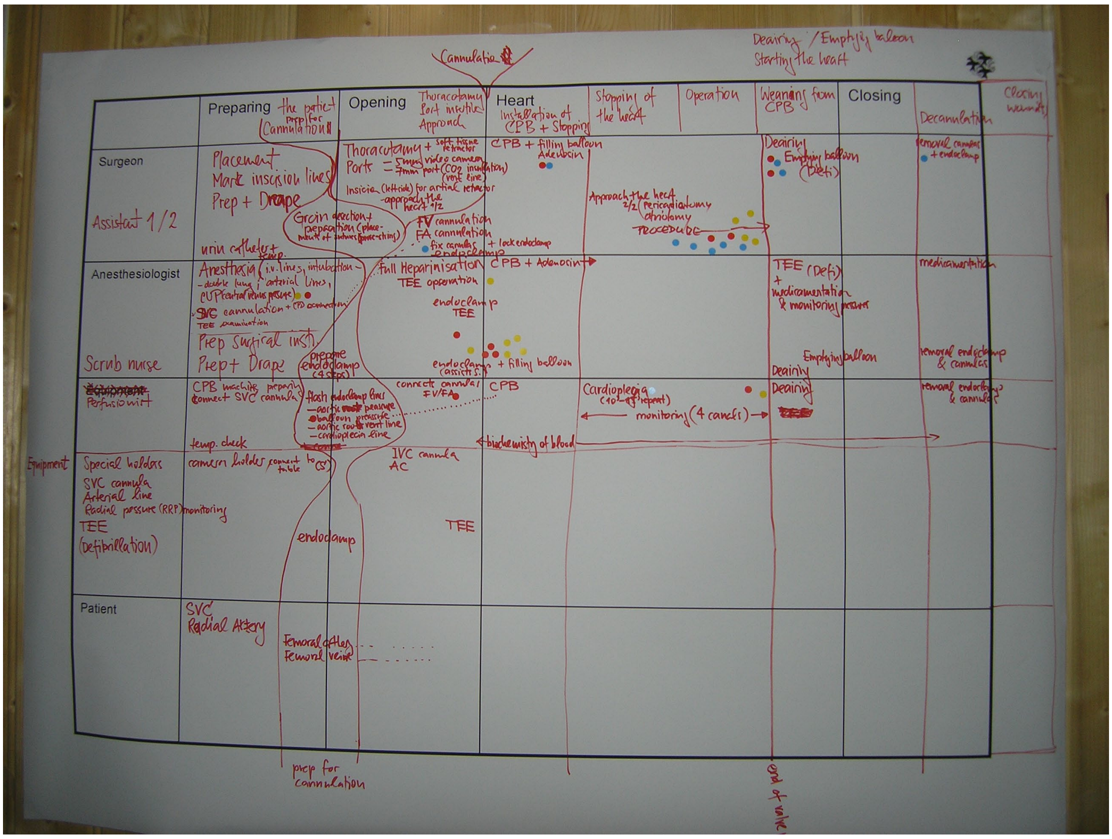


Figure 17 - Workflow matrix with identification of critical tasks

The *critical incident analysis* was also performed using the matrix to analyze the workload for the surgeon and the team in each part of the procedure. Each of the participants of the workshop (regardless of their background) was asked to select critical subtasks and to mark the corresponding cell on the grid with colour coded stickers. This served as a tool to identify which issues should be addressed by the future system and to drive the subsequent analysis. The most important conclusion from the analysis was that **to effectively increase the safety of the procedure and reduce the cognitive workload on the surgeon and his team, the specific task the technological support should focus in, should be aortic occlusion.** Even if this was intuitively the part of the procedure which seemed to need better support from a technical solution, the analysis was extremely helpful in identifying the importance of supporting the balloon placement during aortic occlusion.

The second part of the workshop focused on brainstorming to find technical solutions for coping with the difficulties in the endoscopic aortic occlusion. Again, all the participants gave their input so, **from the very beginning** solutions were accepted or discarded as being feasible or unfeasible on a medical and technical level. The early agreement on a direction to follow was determinant for the success of the solution proposed later on.

Event 2 - Brainstorming / surgery observation
Ljubljana, Slovenia - *Clinical workflow refinement*

The second design iteration had as participants 1 engineer, 1 HF specialist and a group of 9 medical doctors 7 of which were cardiac surgeons and 2 anesthesiologists. The purpose was to refine the clinical workflow description that had been the outcome of the first workshop. The refinement was done through a matching of the descriptions mentioned before and by observing the procedure and discussing it with the doctors. As a result of the workshop, a high level clinical workflow for MIMVRR was derived and new steps inserted at the points where the new system would have an impact (Figure 18).

The subsequent 6 workshops were refinements of the design and the results will be presented on the next subchapters as we present the details of the implementation of our prototype.

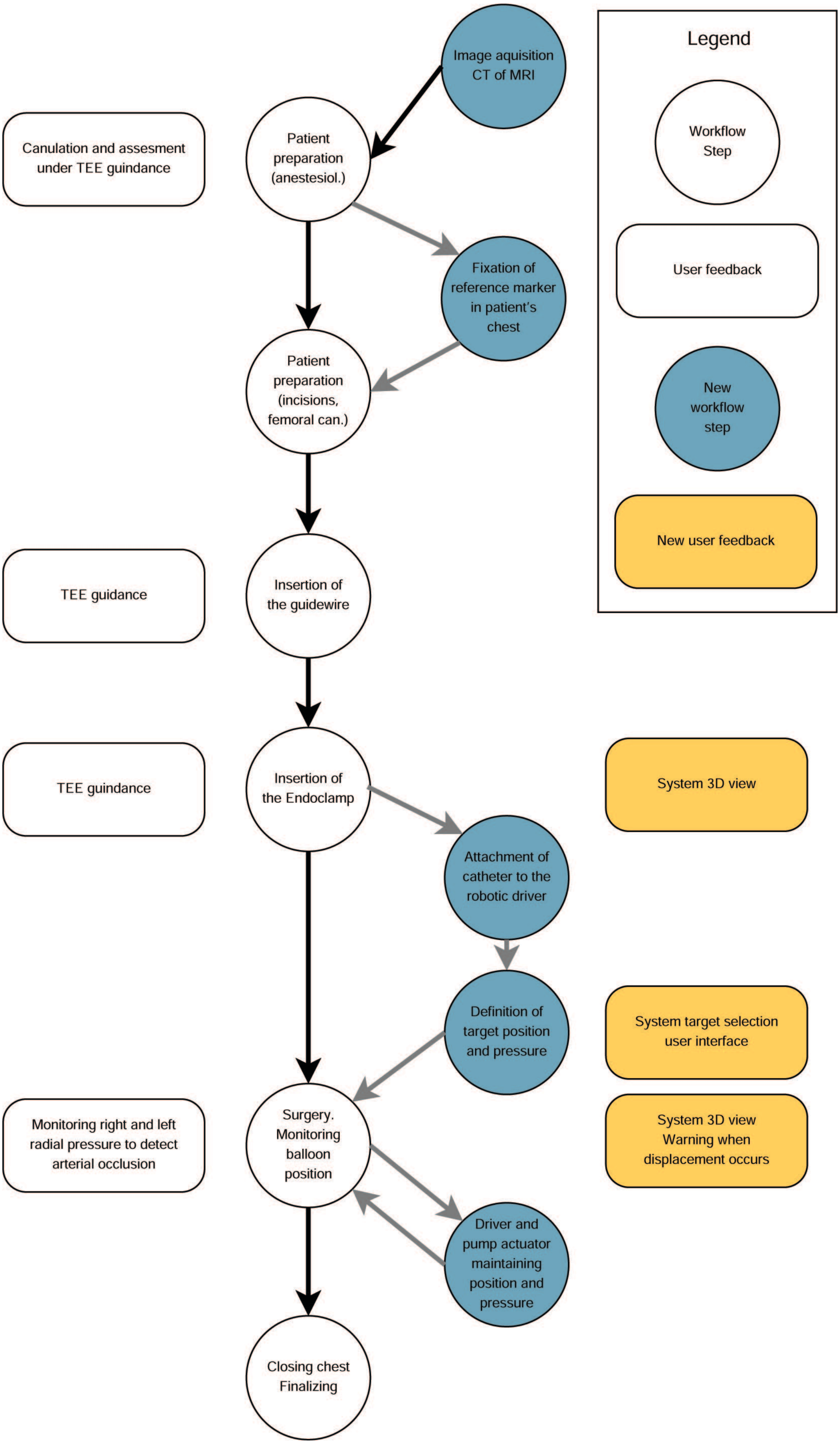


Figure 18 - Surgical workflow

3.2 Materials

3.2.1 Hardware

The EndoClamp™ balloon catheter manufactured by Edwards life sciences (simply referred to as endoclamp) is at the center of our design (Figure 19a). It is a 10.5 Fr three-lumen catheter with an elastomeric balloon near its tip (Figure 19b). The balloon was specifically designed to occlude the ascending aorta during cardiac procedures. The central lumen has two purposes: to deliver cardioplegia solution to the aortic root and to vent air and fluid from the aortic root. The central lumen also accommodates space for a guidewire to be inserted in the beginning of the procedure (Figure 19d and e). The guidewire is first inserted before the catheter to serve, as the name indicates, to guide it as it advances through the vessel serving as a sort of rail where the catheter goes through smoothly. The other two, smaller lumens, are used to inflate the balloon and to measure the pressure at the aortic root (Figure 19c shows a section of the balloon seen at the microscope). Inflating the balloon is done using a 35ml syringe (Figure 19f). The pressure of the balloon can also be measured connecting the lumen used for inflating to a pressure sensor. The balloon and aortic compliance, and the catheter's hydraulic resistance, disturb the reading as the system behaves like a capacitance + resistance system. This was the motivation for the design of a pressure control algorithm which estimates the balloon pressure taking these parameters into account [150].

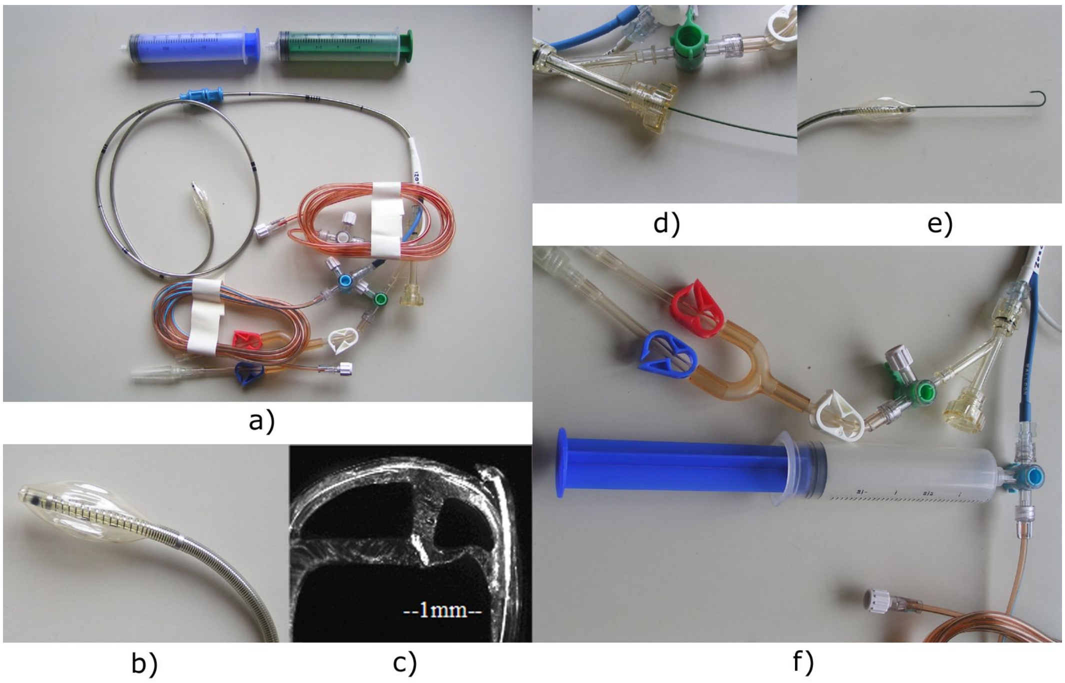


Figure 19 - The EndoClamp™ balloon catheter system. a) general view. b) close up of the balloon. c) microscope view of the three lumens. d) and e) insertion of the guide wire and f) syringe used to inflate the balloon

The tracking hardware was the Aurora magnetic tracking system from Northern Digital Inc.. The system consists of a magnetic field generator (Figure 20a) a processing unit (Figure 20b) and sensor coils (Figure 20c). The generator induces current in the sensor coils which depends on the position and spatial orientation of the sensors. The processing unit reads the current and calculates the position and orientation of the sensors, up to four at the same time. The system can track 5 degree-of-freedom (DOF) mini-coil sensors of 8 mm x 0.55 mm (length x diameter) with an accuracy of 0.9mm which is appropriate for our application. It is also possible to track coil sensors with 6DOF but these are slightly larger and would not fit in the catheters lumen. The tracking system is fully approved for medical use.

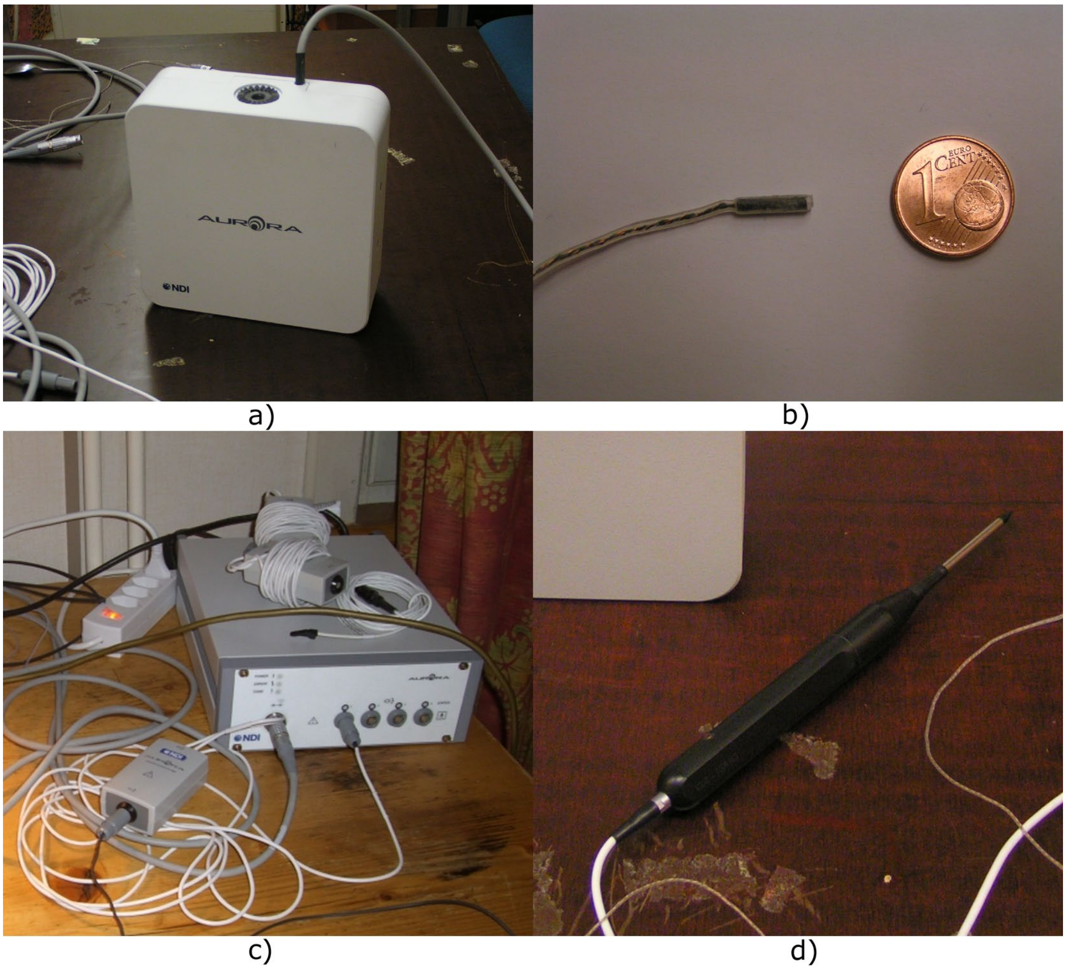
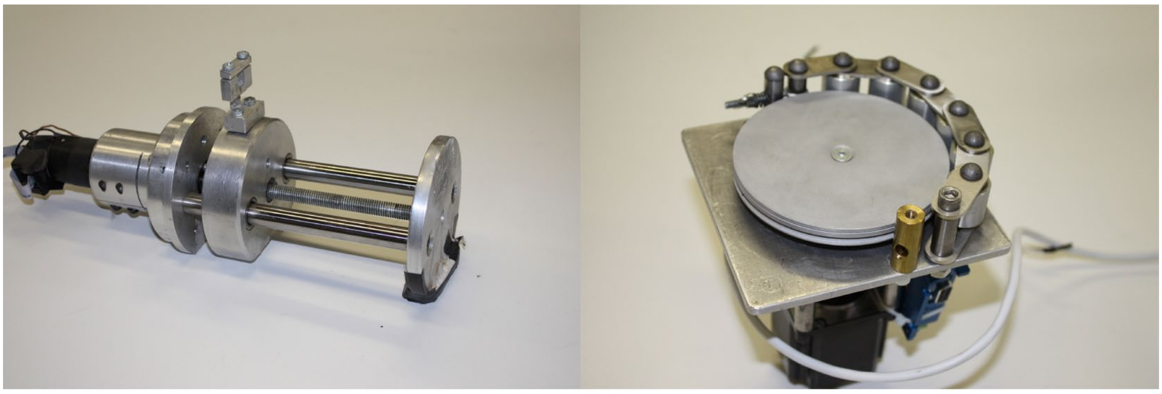


Figure 20 - The Aurora magnetic tracking system. a) magnetic field generator, b) processing unit, c) close view of a sensor coil and d) pointer sensor used for registration.

For the automatic positioning of the catheter different robotic inserters were custom designed. Two main versions were implemented. The first version (Figure 21a) consists of a stepping motor connected to a spindle which slowly and precisely moves a central disk where the balloon is attached. The need for a different design arose from the first tests where it was seen that the first version did not have enough stroke to deal with catheter slack. The second version consists of a spinning wheel connected to a stepper motor and free spinning wheels that guide the catheter (Figure 21b). Since the stroke is infinite, the problem we found with the first version was eliminated.



a) b)

Figure 21 - The two versions of the robotic inserter. The first version (a) was abandoned as the maximum travel distance was very limited. In the second version (b) the stroke is unlimited.

To control the balloon inflation, an automatic syringe driver was also developed by modifying an existing electrical syringe driver by embedding custom electronics so it became possible to control it by software (Figure 22).

For the evaluation tests, a flexible, transparent, silicon aortic phantom with real size anatomy was used (Shelley Medical Imaging Technologies, model T-S-N-002+ (Figure 23a). The phantom was designed so it is possible to perfuse it with water or other fluids and to insert catheters in a conventional way. In the cases where perfusion was required we used conventional pulsatile pumps (Figure 24a: experiment Sils, model Sarns 7400; Figure 24b: experiment Oslo, model Stockert).

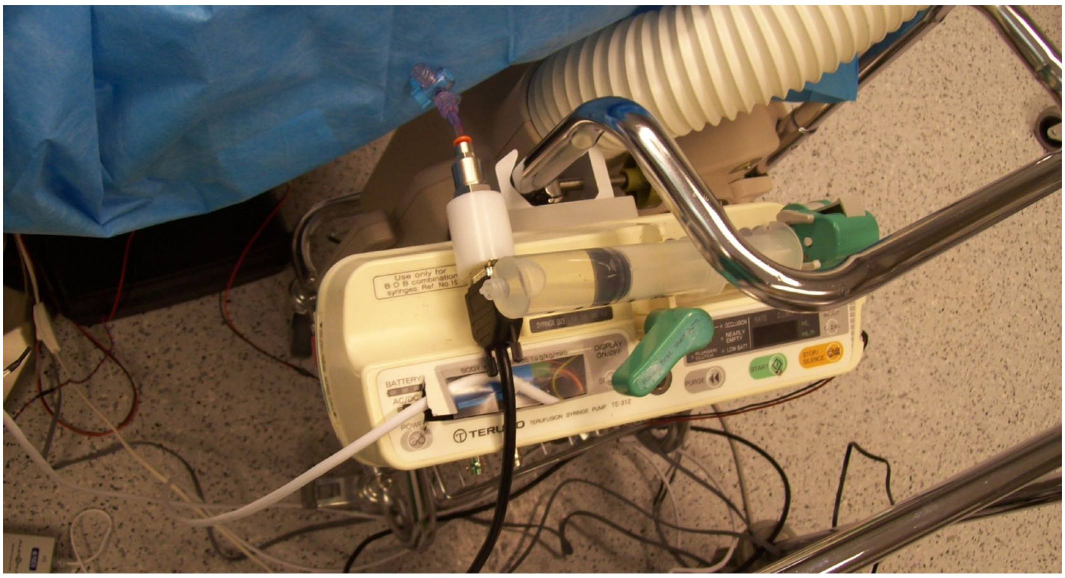
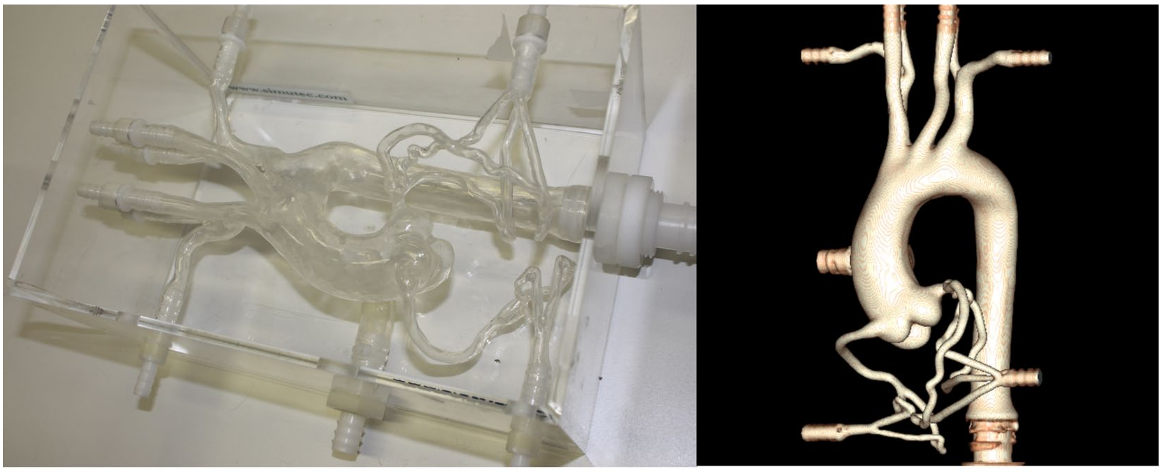


Figure 22 - Syringe pump for automatic balloon inflation



a) b)

Figure 23 - Silicon phantom used in the tests (a) and 3D dataset obtained by CT scan (b)

a) b)

Figure 24 - Conventional rotary pumps used during testing

3.2.2 Software

3.2.2.1 *Tracking management*

The tracking data in our application is managed using the open source component Opentracker (OT). OT uses the pipes-and-filters design pattern to handle tracking data. The important concepts are the ones of tracking ***events*** and of ***nodes***. A tracking ***event*** is one sample of tracking data. Each sample is converted in a data block with 6DOF (x,y,z, yaw, pitch, roll), a confidence value between 0 and 1 and space for arbitrary data. The data ***nodes*** are organized in an arbitrary graph with data flowing from source nodes, which acquire data from physical devices (events), through filter nodes, finally ending in sink nodes, which deliver the data to applications. This organization is very flexible, allowing the use of different filter paths to the same acquired data, combination of different sources, easy reconfiguration of tracking sources and easy deliver of data to the applications (Figure 25).

Source nodes acquire data from the tracking hardware and push it into the pipeline. Each node encapsulates a device driver interfacing specific tracking hardware acting as the bridge between the hardware and the data pipeline. A number of nodes exist built in the library for popular tracking hardware, 2D or 3D input devices and gaming input devices. In our case, we used source nodes for the Aurora tracking system developed in the NaviTrack project which is based on OT source code and implements device drivers for NDI tracking hardware like the Aurora and the Polaris optical trackers.

Filter nodes, transform data in various ways and then pass the data along to the next step of the data graph. The filters can be any numerical operation on the data including different kinds of matrix transforms, arbitrary digital filters and data modifiers based on user input.

Finally, **sink nodes** receive data from the pipeline and push them into applications.

The *console* and *network* nodes are two useful kinds of source and sink nodes. *Console source* allows the user to directly input data in the tracking tree via the keyboard. The *console sink*, sends the data directly to an operating system (OS) terminal which is useful for debug purposes. The *network source* and *sink* provide an OS independent way of sending the tracking data over the network which is extremely useful if the connection to the tracking hardware in one computer and the application on another.

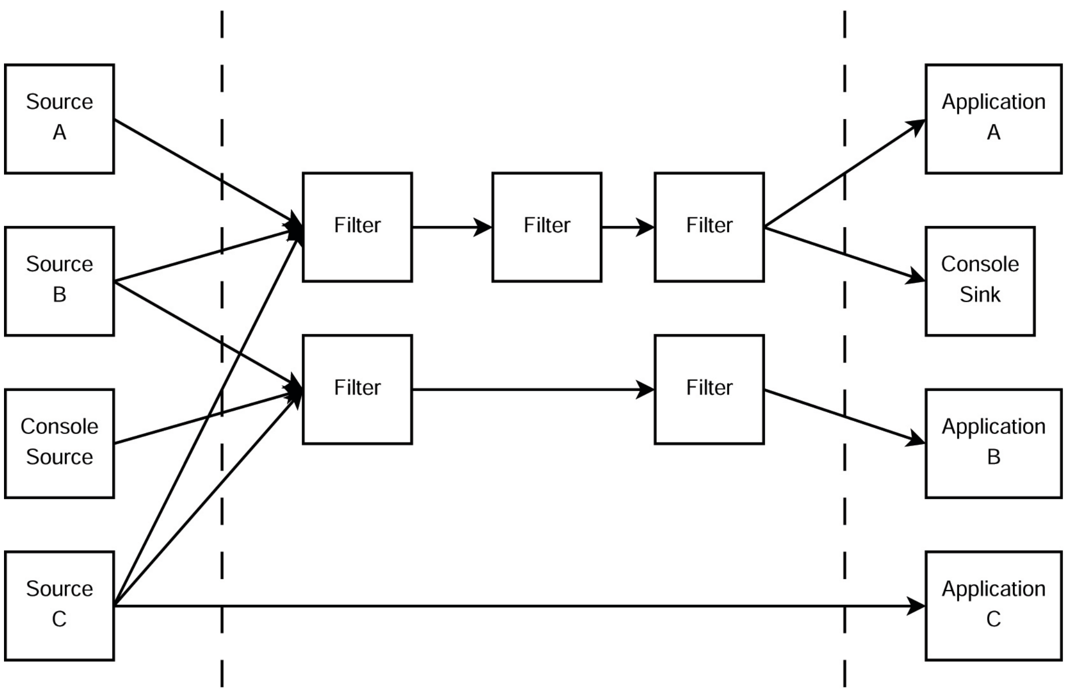


Figure 25 - General opentracker pipes-and-filters data flow. The sources can be combined in different ways and can finally feed different applications after having gone through specific filters.

3.2.2.2 *Main application*

The main application was implemented using *Studierstube* which is a framework designed for the development of augmented reality applications. *Studierstube* is implemented as a set of extension nodes to the open inventor (OIV) graphics rendering library and a set of objects intended to provide advanced runtime functions with AR applications in mind. One of the important features is the ability to handle three-dimensional events. Using the OT library it supports interaction based on 3D tracking events, that is, the objects in the 3D scene react to events generated by OT in contrast to the simpler 2D event handling present in most applications and in OIV. The framework allows several components and applications to load at runtime. It also provides a runtime context through which the applications and the components can share data like for example the scenegraphs of interest. The components and applications to be loaded as well as their configuration files are defined in a main XML file. An application designed with the *Studierstube* framework normally comprises of one or more *Application* components and several extension components. These are normally the *Event*, the *Viewer* and the *Video* components.

- The *Application* component is where all the main application specific functionality is coded and where the scenegraphs for the 3D rendering of the main scene are loaded from separate configuration files which contain the scenegraph definition.
- The *Event* component is an instance of OT with some extensions and so provides the interface to the tracking devices. It implements two additional OT nodes dedicated to interfacing *Studierstube* data context allowing the tracking data to be connected with the scenegraphs. These are the *StbSink* and *StbSource* nodes. The first one pushes an event from the OT tracking tree into an OIV scenegraph node and the second one connects data from a scenegraph node and pushes it into the OT tracking tree.
- The *Viewer* component defines the behavior of scenegraph presentation to the user. There are specific bindings for the WindowsAPI or for QT.
- The *Video* component offers the possibility of adding video background in applications allowing overlay of virtual objects in real scenes using the openvideo library.

This architecture makes *Studierstube* easily extendable. Developing a new component is a matter of inheriting from the *Component* base class and implementing specific functionality. All the components that are loaded and make part of an application will have access to the runtime context and thus can share data among them.

3.2.2.3 *2D desktop interaction*

The standard 2D widget interaction user interface for the application was developed using *QT Designer* from Nokia. The *Designer* is a graphical tool to define standard desktop user interfaces. It is a standard and mature tool that can simply be used to define *forms* (user interaction panels) and callbacks following user interaction on the different widgets such as buttons, slider bars, etc. The details of the connection between the *forms* and the application subsystem will be described in the methods section.

3.2.2.4 *Hardware control*

The control algorithm and the interfacing to actuator and syringe pump were done in LabVIEW. LabVIEW is a popular platform for interfacing PCs with instrumentation and for data acquisition. It uses a dataflow programming language paradigm where the program is modeled as a graph with the data flowing trough the nodes. The visual programming language, also called “G” is inherently tied to GUI developments and offers the benefit of easy interfacing hardware.

3.3 Methods

The high level concept of our implementation lies in creating a model of the patient pre-operatively, measure the position of the balloon intra-operatively, correlate (register) these two and represent the balloon position in real time in the pre-operative model. Also, with the position information, control a robotic arm automatically which will move the balloon and position it on a target position defined by the surgeon. Figure 26 shows a schematic representation of how the system was implemented.

3.3.1 Tracking

For tracking we used two sensor coils. One was inserted in the centre of the balloon trough one lumens of the catheter so that the spatial position could be measured in real time (Figure 27a, b). The second sensor was placed on the patient (in our tests in the phantom, Figure 27) to serve as reference frame. That way, we could compensate for patient movement without losing registration. We chose magnetic tracking because there is no line of sight to the inside of the patient during the surgery and because 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.

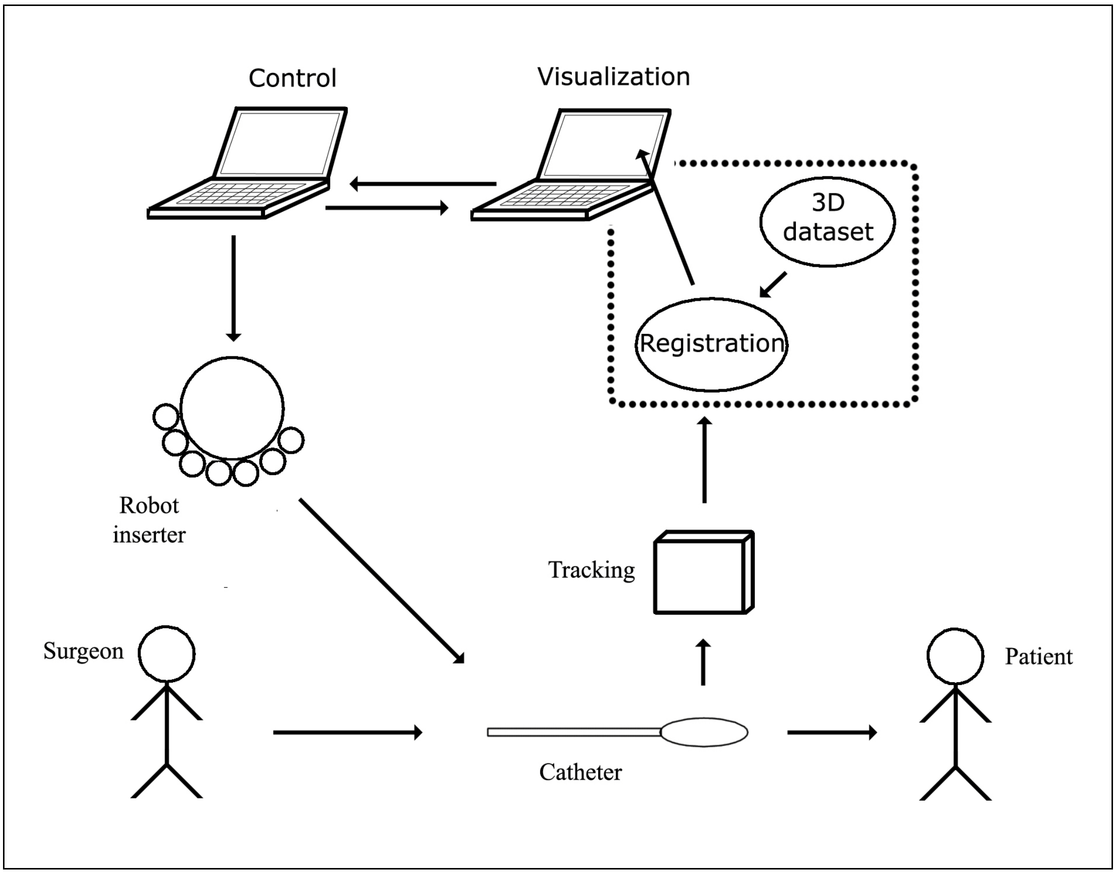


Figure 26 - System overview

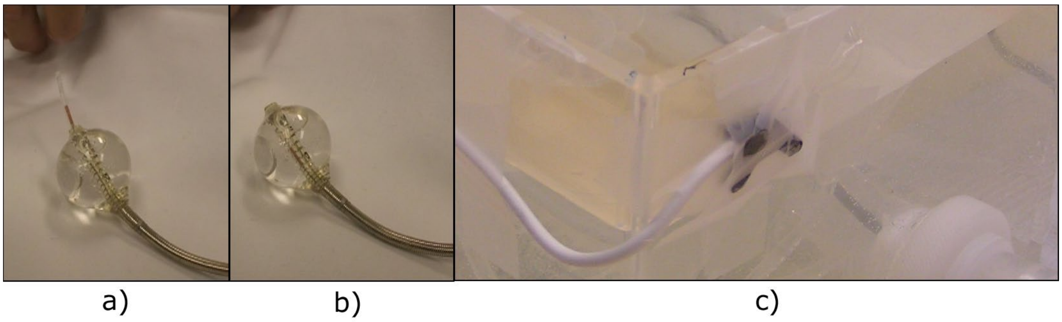


Figure 27 - Balloon and reference sensors: a) outside the balloon, b) inside the balloon in the correct position for the application and c) reference position sensor on the body (in this case in the phantom)

Open tracker allows for easily dealing with using the second sensor as a reference frame. We used a *dynamic transform* node, where the data coming from the second sensor serves as transform base for the data coming from the sensor of interest which sits in the balloon. Figure 28 shows the tracking configuration file and a simplified corresponding graph we used in our implementation. In the graph we see that the tracking nodes which interface the hardware are implemented in a different computer than the main application. Each of the sub-graphs enclosed in dashed line is a separate instance of OT. The configuration files for the simpler graphs enclosed in blue is not shown as it consists only of the source node interfacing the hardware and the network sink node. The tracking data

```xml
<?xml version="1.0" encoding="UTF-8"?>
<OpenTracker>
  <configuration>
    <ConsoleConfig headerline="Sample Tracking Input" interval="1" display="off"/>
    <FileConfig append="true" loop="true" realtime="false"/>
    <EventConfig keyevents="on" mouseevents="on"/>
  </configuration>

  <ConsoleSink comment="Transformed coordinates" active="off">
    <EventSink tracking="otTrack">
      <EventOrientationTransform rotationtype="euler" rotation="0 -1.5708 3.1416">
        <EventMatrixTransform matrix="0 0 1 85 0 -1 0 -2.64 1 0 0 26.37">
          <EventDynamicTransform baseevent="true">
            <NetworkSource mode="unicast" number="2" address="149.148.77.151" port="12058"/>
            <TransformBase>
              <EventInvertTransform>
                <NetworkSource mode="unicast" number="1" address="149.148.77.151" port="12057"/>
              </EventInvertTransform>
            </TransformBase>
          </EventDynamicTransform>
        </EventMatrixTransform>
      </EventOrientationTransform>
    </EventSink>
  </ConsoleSink>
  <ConsoleSink comment="Pointer sensor" active="on">
    <EventOrientationTransform rotationtype="euler" rotation="0 -1.5708 3.1416">
      <EventDynamicTransform baseevent="true">
        <NetworkSource mode="unicast" number="0" address="149.148.77.151" port="12056"/>
        <TransformBase>
          <EventInvertTransform>
            <NetworkSource mode="unicast" number="3" address="149.148.77.151" port="12059"/>
          </EventInvertTransform>
        </TransformBase>
      </EventDynamicTransform>
    </EventOrientationTransform>
  </ConsoleSink>
</OpenTracker>
```

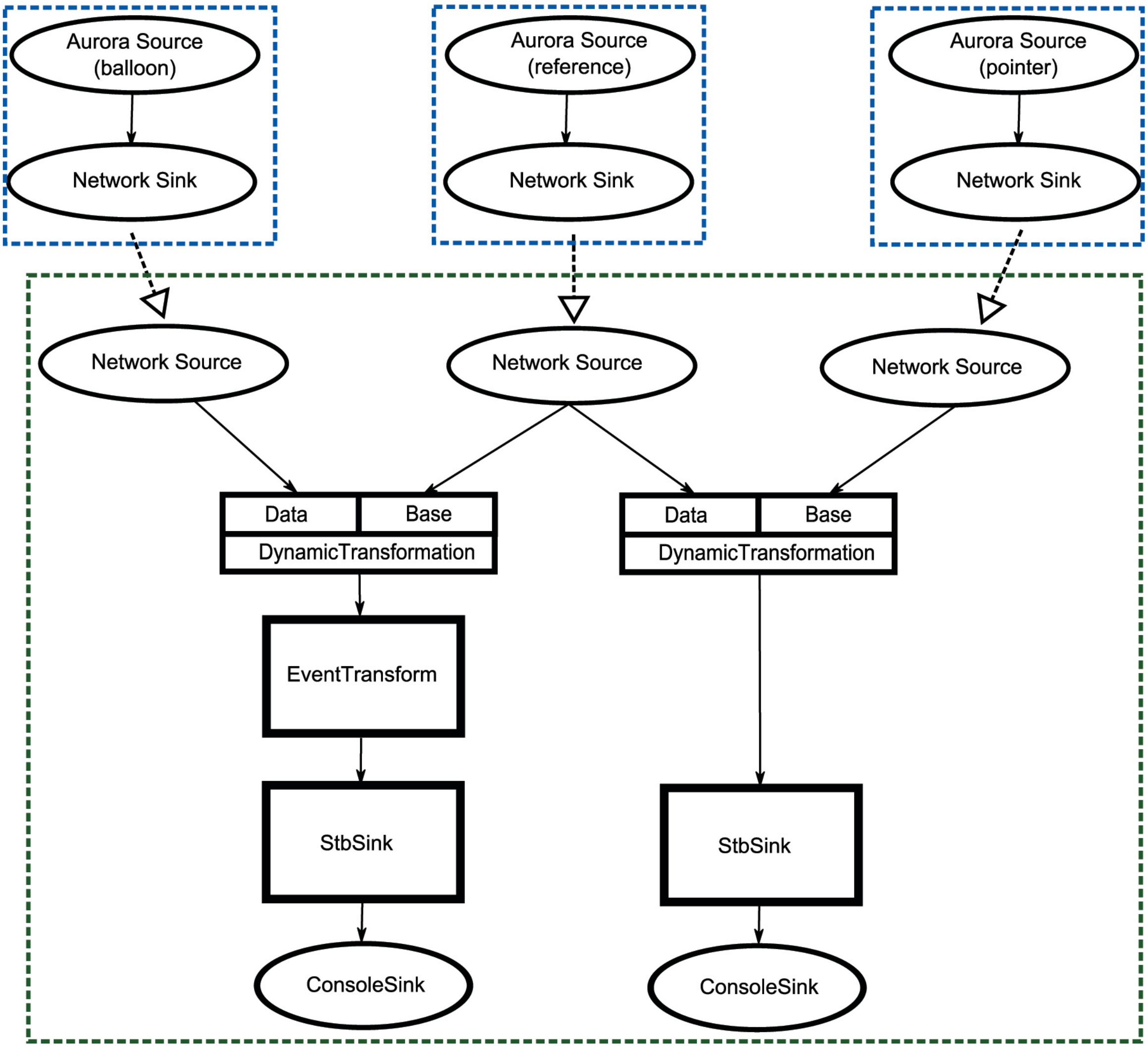


Figure 28 - Opentracker configuration used in our implementation. Each part enclosed in dotted lines represents a separate instance with its own configuration file and the dotted arrows represent network connections. The XML code is relative to the graph enclosed in green.

was transferred over the network from these separate instances using *NetworkSink* and *NetworkSource* nodes. The pointer (Figure 20d), indicated in the top right of the graph was used for the registration procedure. After the registration transform, the tracking data is pushed into *Studierstube* by means of the *StbSink* node which is connected to a *SoMultimodalEngine*. In the current implementation, after the registration transform is found, it has to be inserted by hand in the OT configuration file followed by an application restart. Such an approach is undesirable and one possibility to overcome it is to use a *StbSource* OT node to feedback the matrix calculated in the application to calibrate automatically the registration matrix in OT. The *StbSource* inserts data in OT from the application. In OT it can be connected to the *DynamicTransformation* directly and the transformation will take the value of the transform which is present in the application. In the beginning the transform in the application is the identity which means that the *DynamicTransformation* leaves the data untouched. As soon as the registration procedure is complete, the value that was calculated in the application will be directly connected with the *DynamicTrasformation* without the need to restart.

3.3.2 Scene graph

Figure 29 shows a simplified diagram of the scene graph used for our 3D scene (corresponding to what is seen in Figure 31a) 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 by the green dotted line. The connection is done using the *SoMultimodalEngine*, a *Studierstube* specific node that receives tracking data from OT and, by connecting the *trackingTransform* node to the engine. The engine nodes can be connected to other nodes in the scenegraph to animate them. 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.

In the case where volume rendering was needed, we used axial CT slices in DICOM format. The volume rendering is done using the SimVoleon library, an extension to the Coin3D implementation of OIV. This library renders volumes from files with the "VOL" format which consist of a header followed by the raw data slice by slice, therefore the original DICOM images were first converted to raw 8 bit images and then compiled in a file in the proper VOL format by means of a MatLab script.

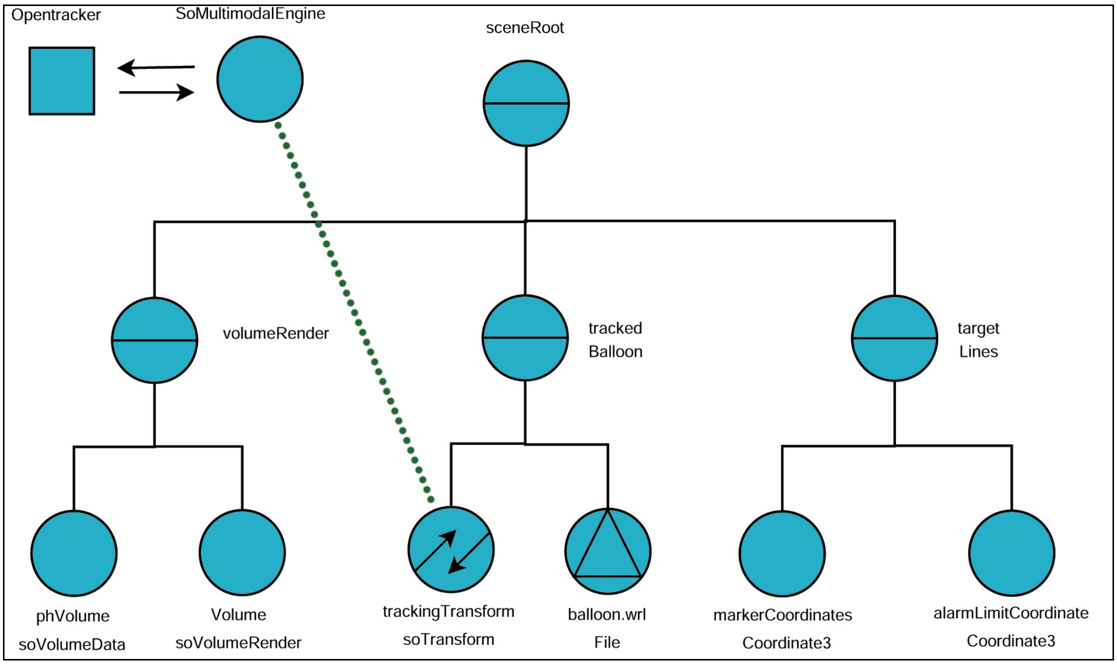


Figure 29 - Scenegraph for the cardiac application

3.3.3 Main Augmented Reality application

Figure 30 shows the software architecture of the system. We used two additional components apart from the typical ones already mentioned in Section 3.2.2.2: *CARegistration* and *CASceneManager*.

CARegistration handles all the registration calculations outputting a registration matrix.

CASceneManager is responsible for maintaining a list the different scenes used in the application which is useful for data sharing between the other components in a blackboard fashion.

qtEmbeddBalloon is our *Viewer* component inherited from *QtEmbedd*, an existing class intended for binding the application with the QT graphical user interface design framework. *QtEmbedd* allows attaching the viewports, where the scenegraphs are plugged in, to QT frames which is the important connection from the Coin3D viewers to QT. The *Viewer* component also implements the callbacks to all 2D widget user input.

qtSimpleApp is our *Application* component which implements all the application specific behavior. In particular:

- Reads the main scenegraph and the registration scenegraph from the configuration files.
- Implements the three state machines needed for managing actuator and pump control and for user tests
- Implements the TCP/IP server needed to interface the control software
- Handles 3D user input events used on the registration procedure

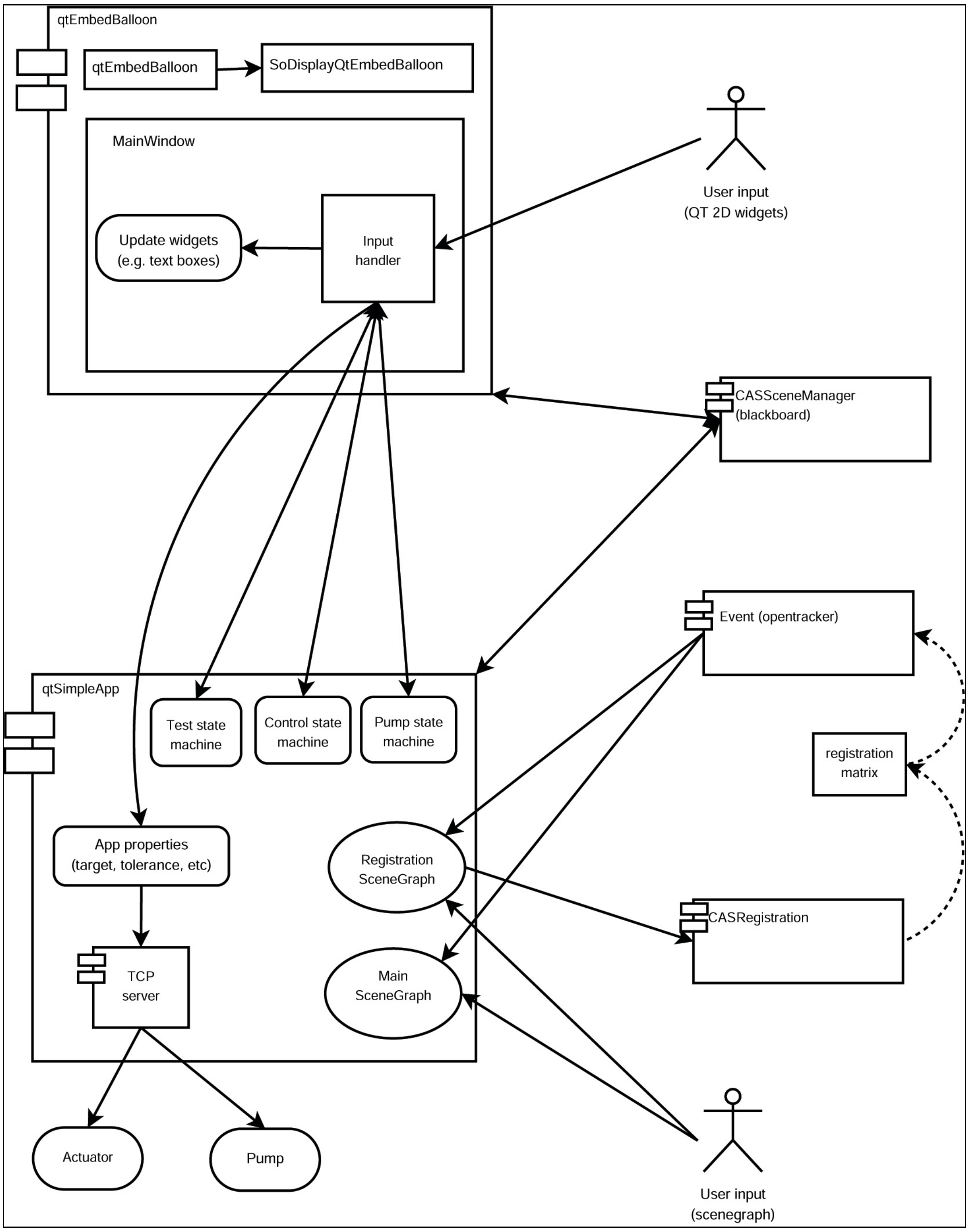


Figure 30 - Main software architecture

3.3.4 Registration

A rigid point-based registration algorithm is used to align the tracking data with the 3D pre-operative dataset. The registration procedure is done by selecting two collections of N fiducial points, x_i and y_i, i=1,2,...N, one on the 3D images and one on the patient. A matrix transform, consisting of a translation and a rotation is found by minimizing the distances d_i in the root-mean-square sense between two corresponding points in the collection.

The ICP registration method [91] was also implemented. The method finds the registration between a point cloud obtained by segmentation of the aorta and a point collection acquired from the magnetic tracking. The idea is that the user sweeps the aorta with the catheter a number of times to get a significant amount of points. This method is implemented but not extensively tested.

3.3.5 Control

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 [150]. 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. Both the actuators were interfaced with a laptop PC through a National Instruments Digital Acquisition (NIDAQ) controller.

3.3.6 Inter-application communication

To communicate between the main application and the control application a TCP/IP connection was implemented using a client / server architecture. The server resides on the main visualization part and the control part implements the client in LabVIEW. The client 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.

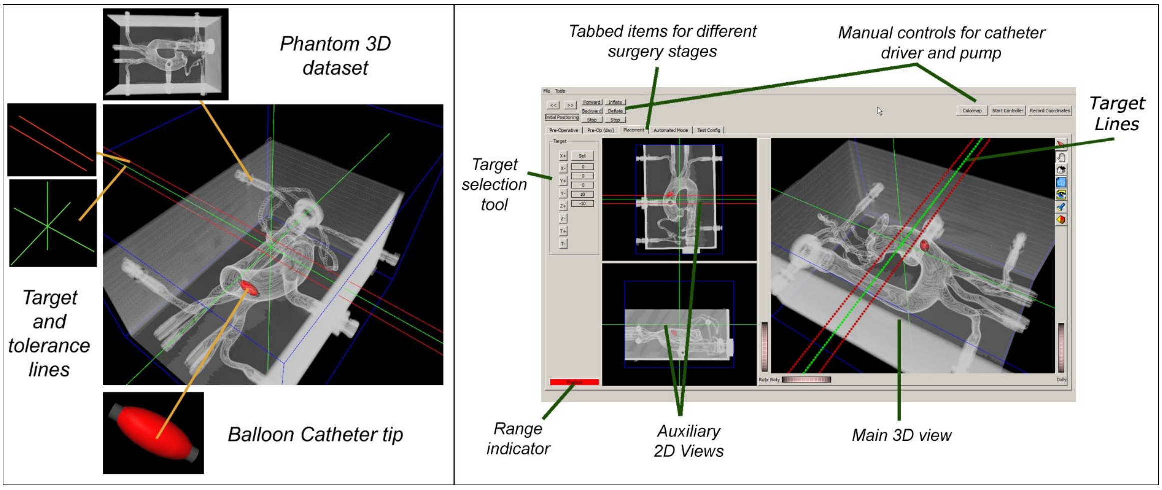
3.4 Results

In this section we present the main results obtained for this part of our work. In particular we describe the *look and feel* of the software, the way how it should be used and finally describe the results from user and animal evaluations we performed.

3.4.1 User interface and usage

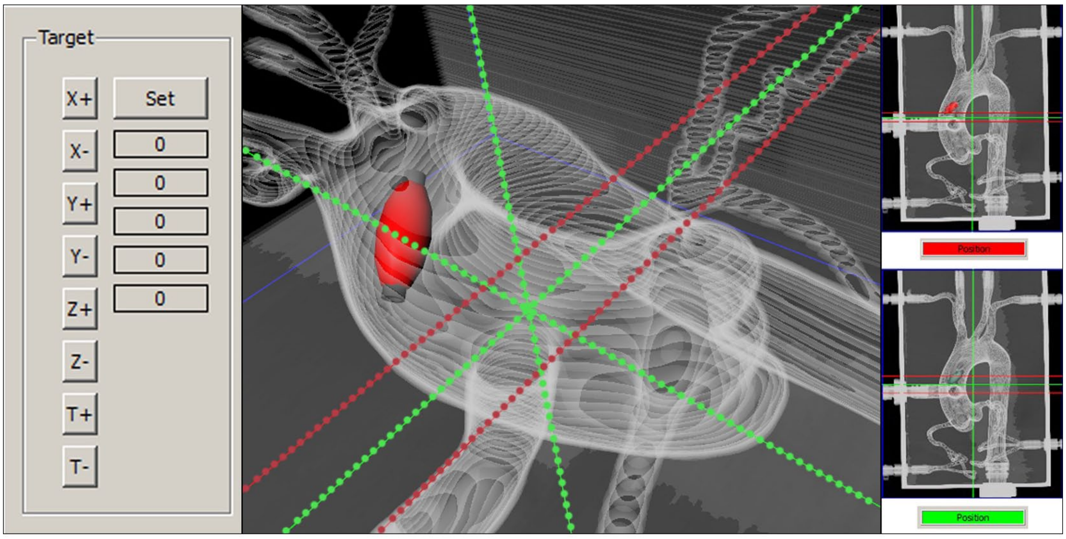
The main visual feedback is given to the user through a 3D scene with the tracked balloon superimposed on the rendered aorta model. Figure 31a describes the main concepts in the scene. The scene is shown in three different views: 3D, coronal and sagittal (Figure 31b). Different parts of the surgery are selected using a tabbed selector.

Here the user can select the pre-operative stage, where he performs registration, intra-operative, the main view to visualize the balloon in real-time, or select a screen for test configuration. In the intra-operative view there is a tool for selecting the target location for the balloon a range indicator and manual controls for the robotic actuator and for balloon inflation. The user can define a target position and a tolerance region using a target selection tool. The target and tolerance lines will move and the range indicator will be activated. The range indicator turns green when the balloon is within the tolerance (Figure 32). Finally it is possible to control the mechanical actuator and pump directly using the manual controls.



a) b)

Figure 31 - Overview of the visual feedback. a) main objects in the 3D scene and b) user interface of the system with explanation of the key concepts.



a) b) c)

Figure 32 - Close up and explanation of the target selection. a) Target and tolerance selection controls, b) target and tolerance lines and c) tolerance indicator turns green when the balloon is in range

Figure 33 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 with the slider 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 corresponding points in the patient using a tracking pointer (shown in the OT configuration in Figure 28) and calculate the transform based on the matching pairs of points from the two collections.

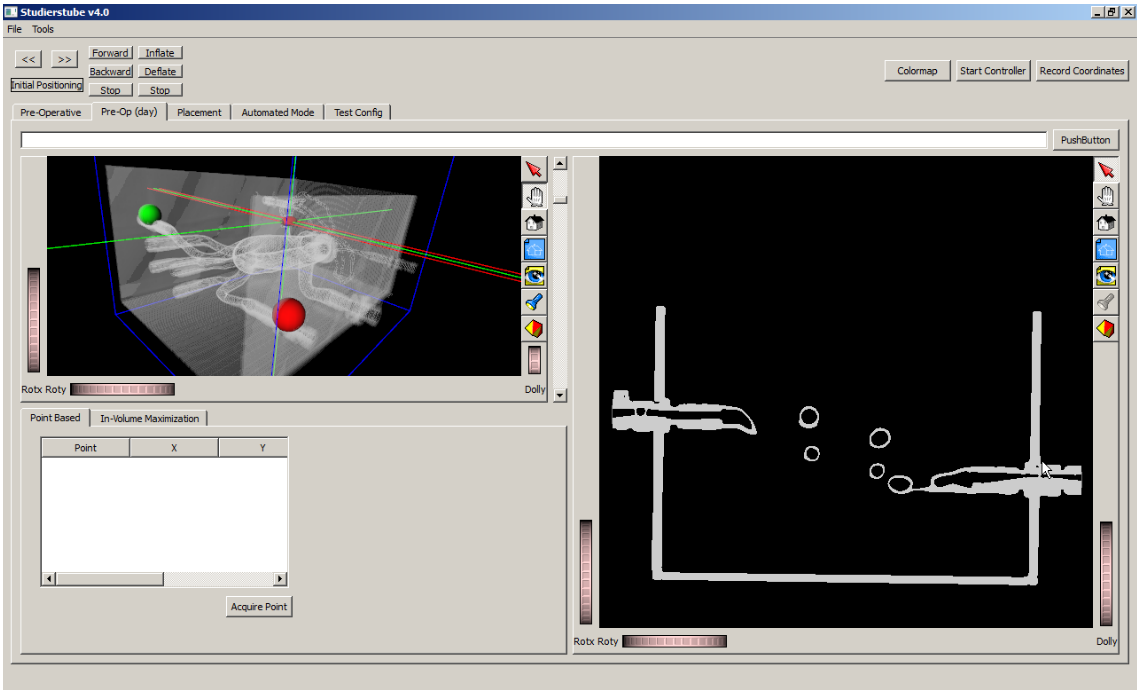


Figure 33 - The registration interface. On the right the user selects a slice and points to a location in the 2D image. The selected point appears as a colored sphere in the 3D image on the left. Once a collection of points is acquired, the user acquires points from the tracking system at the same location selected in the images by using the pointer sensor.

3.4.2 User tests

3.4.2.1 *Test setup*

The user studies were done with the silicon phantom model seen in Figure 23a. The phantom was perfused with water with a flow rate of 5 l/min. The main questions addressed in the user tests were "*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, in order to assess the visual support provided by the system we defined 3 different ways of visual guidance in order to compare the performance of the subjects under different visual support. These were:

- **Total view**: the phantom is transparent, so the users placed the catheter looking directly through the vessel (Figure 34a).
- **US view / Restricted view**: First test - we simulated the TEE image seen in the real surgery. The phantom box was filled with water and a US probe inserted so that an image similar to the real surgery TEE was obtained (Figure 34b). In the second test, a US probe was not available so we used the system to simulate the TEE view (Figure 34d). In this view the medically relevant information provided is equal to the US version in first test.
- **3D view** (system): the phantom was covered with black plastic and the subjects only used the information on the computer screen (Figure 34c)

The subjects had the task of performing rounds of catheter placements on the aortic phantom to a defined target place in the ascending aorta using the different views. Each placement started with the balloon in the descending aorta and finished with the balloon inflated on target in the aortic arch. The aim was to be as fast and as accurate as possible. In both tests we measured speed, placement accuracy and subjective comfort in using the system. We briefed all the subjects regarding the target position and the objective of the test. The limits were roughly ±25mm, indicated qualitatively in the phantom. The subjects were asked to rate their actual psychological state before and after the test and they had to fill in a questionnaire on aspects of usability and visualization.

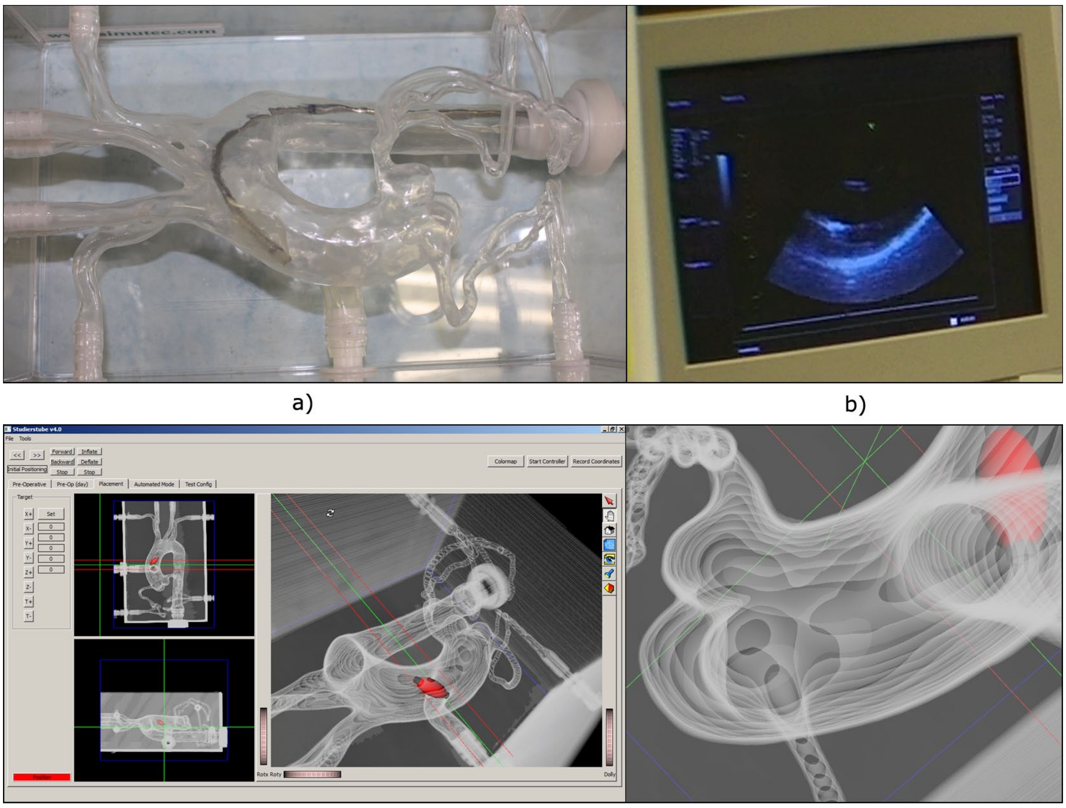


Figure 34 - Test views: a) total view, b) US view, c) system view and d) simulated US view

Two sets of tests were performed. First test: 3x6 placements (3 views, 6 trials) with 8 subjects (four MD, four engineers, age 28-46, mean 34) and Second test: 3x3 (3 views, 3 trials) placements with 9 subjects (one MD, eight engineer, age 28-46, mean 34). The results of these tests are presented in the next section. To answer the second question we performed series of fine tuning placements using the robotic actuator. The series consisted in setting a target close to the aortic valve and one close to the brachiocephalic trunk moving between these two. The experiment was repeated 20 times and in two variants, with and without flow. We also did a series of tests (12), measuring 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.

3.4.2.2 *Test 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. Figure 35 shows a user performing an insertion using 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. We collected data files containing the tracking points of all the insertions during all the tests. These, from which samples are shown bellow, allow further study on the way the subjects perform their insertions. Figure 37 shows the data for one single insertion. The values shown here should be interpreted taking into account the reference axes of Figure 36. On the left, the data is the progression of the catheter in time of only in the Z axis. On the right we see the XZ projection of the sensor progression which, as expected, has the shape of the vessel. It is interesting to see on the left side, different parts of the insertion. First, the subject inserts the catheter until the aortic arch (segment I). Then, the user advances the balloon until the ascending aorta, where he performs a first inflation (segment II). This is seen by the concentrations of points, denoting the balloon was in this location for some time. Because of the flow, the now partially inflated balloon is dragged towards the heart (segment III). Finally, the user gently pulls back the balloon and finishes the inflation (segment IV). Figure 38 shows a comparison of the insertion strategy of four different users in the total view. Here it can be seen that while some followed the steps described before in a very pronounced way (c) others (a and b) don't allow the balloon to advance towards the heart and gently pull it to stay in its final position throughout the whole inflation time. Figure 39 shows the way how experienced and inexperienced users cope with the different views. The experienced user, a surgeon (left side, a,c and e) has a similar insertion pattern in all the three views. On the other hand, the inexperienced user (right side, b, d, f) clearly reacts differently to the different visual feedback he gets.

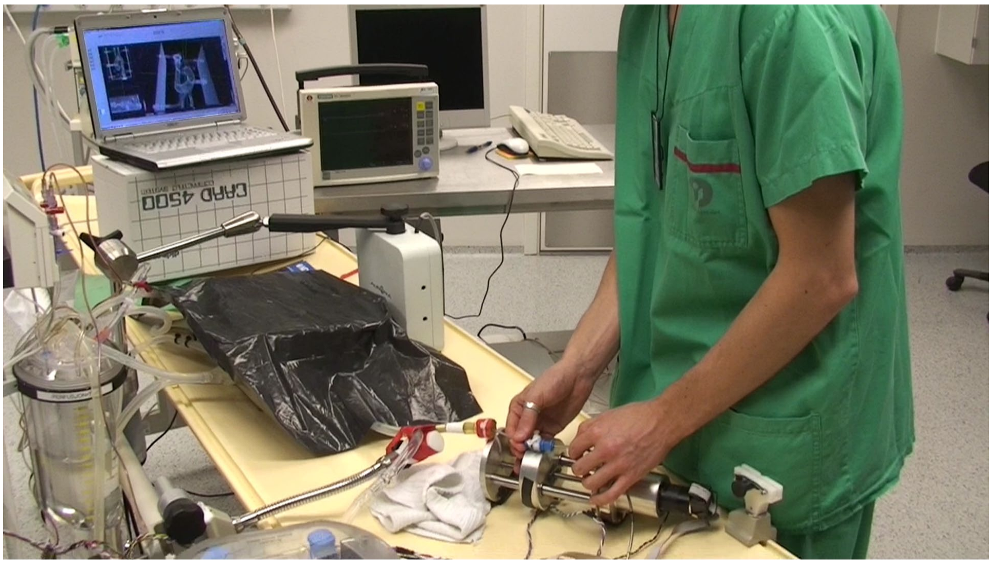


Figure 35 - User testing the system

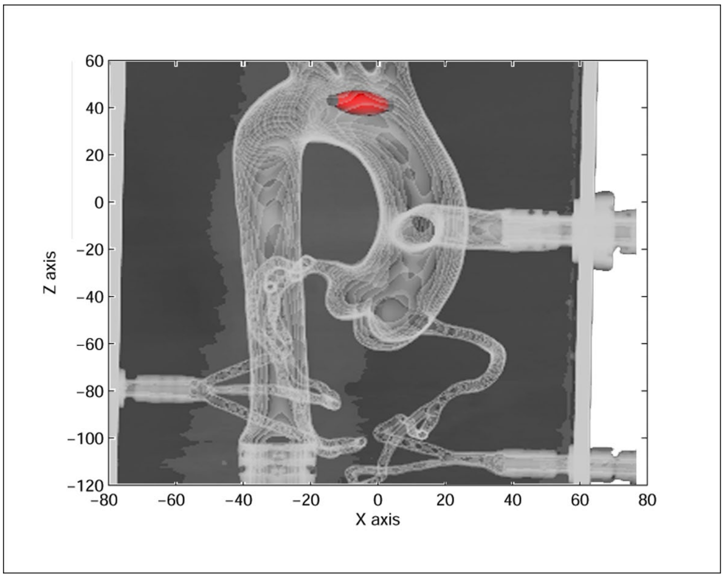


Figure 36 - Indication of the axes relative to which the data was acquired. These axes are the ones that should be taken into account when analyzing the data shown later.

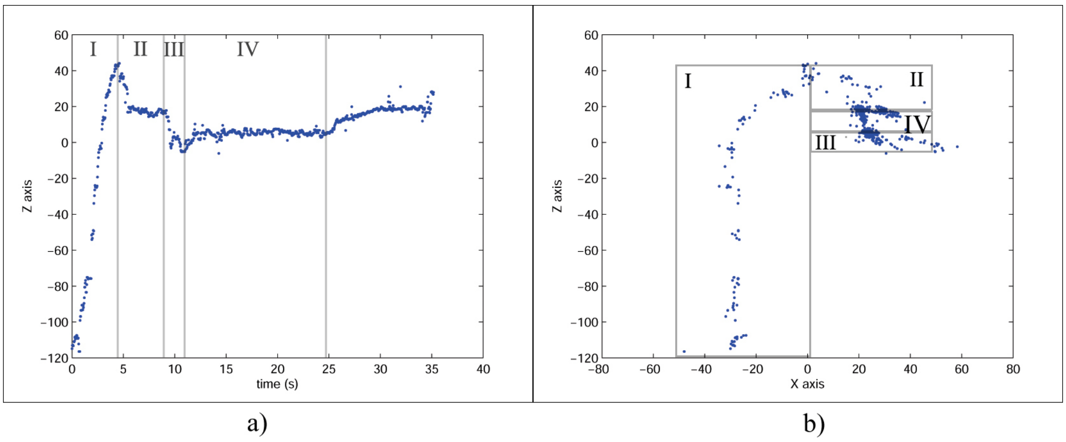


Figure 37 - Data for one insertion. a) shows the z-axis value while b) the xz projection. The data is divided in four different sections representing four different parts of the task. (I) is the first advancement of the catheter in the descending aorta, in (II) the user performs a slight balloon inflation, in (III) the user brings the balloon to the final position and in (IV) the inflation is finalized.

Placing Time

All the subjects could perform the task in each of the three views. We defined a successful placement as one being within ±25mm of the target (this is an accepted range, considering safety and effectiveness of placement, in concordance with the medical team). In the first test (Oslo, Norway, November/December 2007) there were 92.4% successful placements within reasonable time (all under 1 minute). Better performance would be expected when using direct vision and this was confirmed. We measured the following average placing times: 26±11s in the total view, 27±8s in the restricted view and 27±8s in the 3D view, expressed as mean ± standard deviation. In the second test (Sils Maria, Switzerland, March 2008), we experienced even clearer trends. The placement times were of 34±20s in the total view, 48±20s in the 3D view and 56±29s in the restricted view.

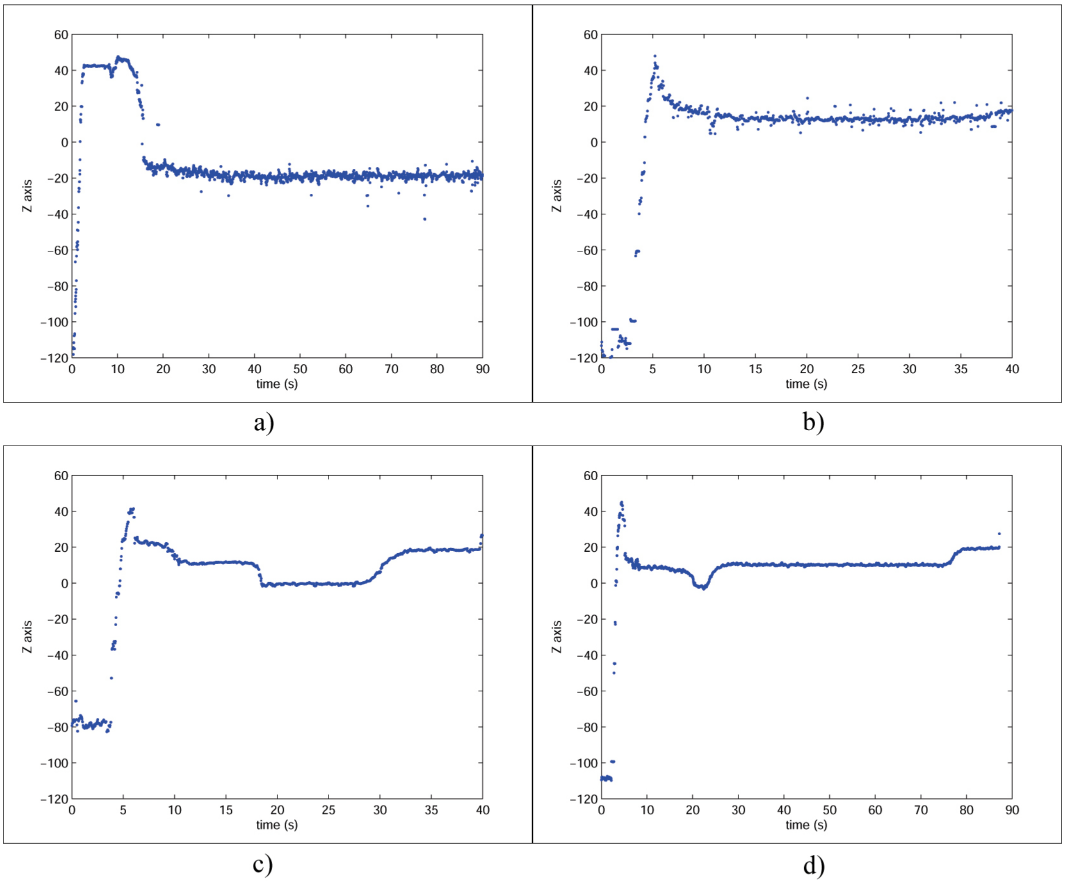


Figure 38 - Comparison of the strategy of four different users in the total view

Accuracy

Human accuracy (no robot): In terms of target accuracy, in Oslo, the average placement was done 1.3±10mm away from the target (considering the target as position 0mm) in the total view, 0,5±12mm in the 3D view and 9.6±14mm in the restricted view. In Sils, the average placement was done 12±3mm away from the target in the total view, 4±7mm in the 3D view and 7±9mm in the restricted view.

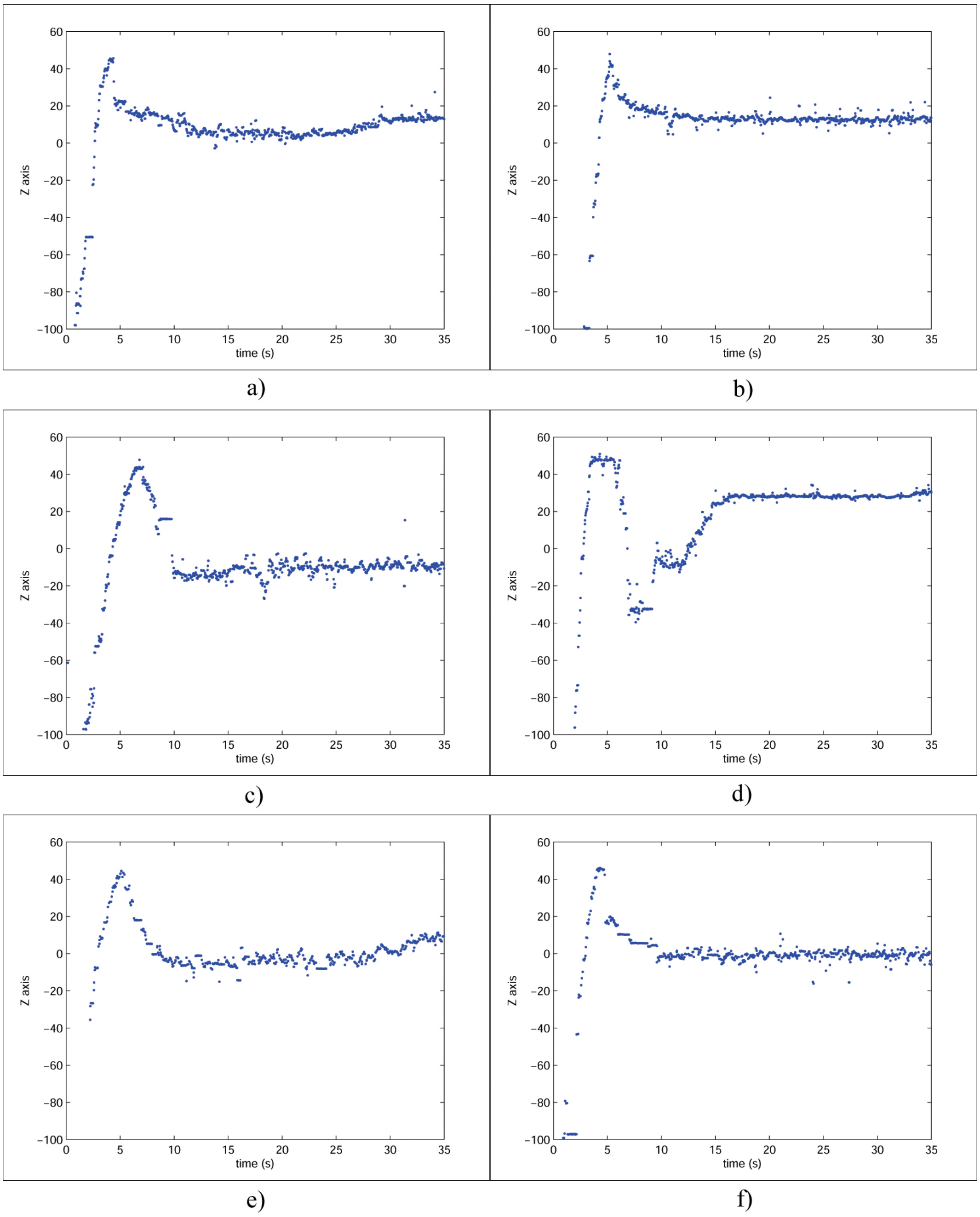


Figure 39 - Differences in how an experienced (a,c,e) and inexperienced (b,d,f) user deal with the different views.

User rated support

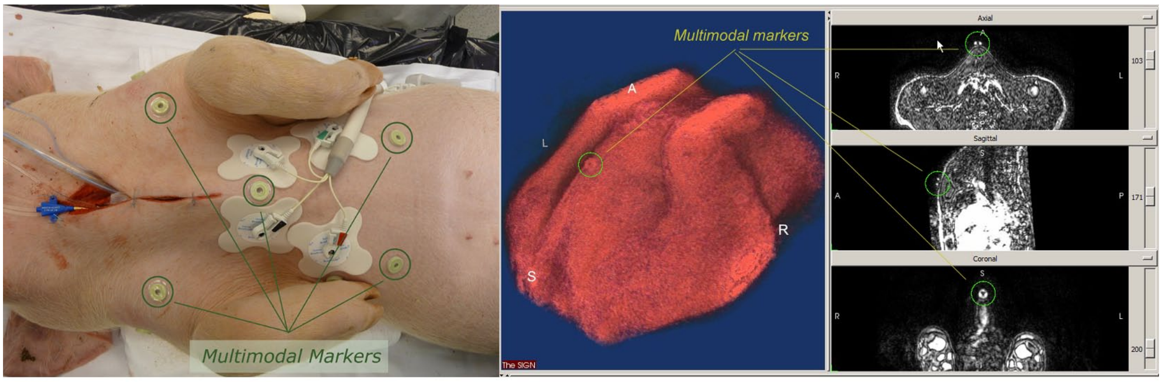
The users rated the total view as the one supporting them better: 9,25±0.75 points in a scale of 1 to 10. The 3D view was rated 7.75±1.25 points and the restricted view was rated 4.5±2 points. In appendix 1 the reader can find the questionnaire the users filled in.

Robot accuracy and placement times

The automatic placement was done with an average error of 1.4mm away from the target when there was no flow and 1.9mm with flow. Regarding placing times, the driver could push the catheter (total displacement distance always around 25mm) in 25±11s and pull it in 15±2s for the case with no flow and in 17±3s and 11±1s with flow, for push and pull, respectively.

3.4.3 Animal tests

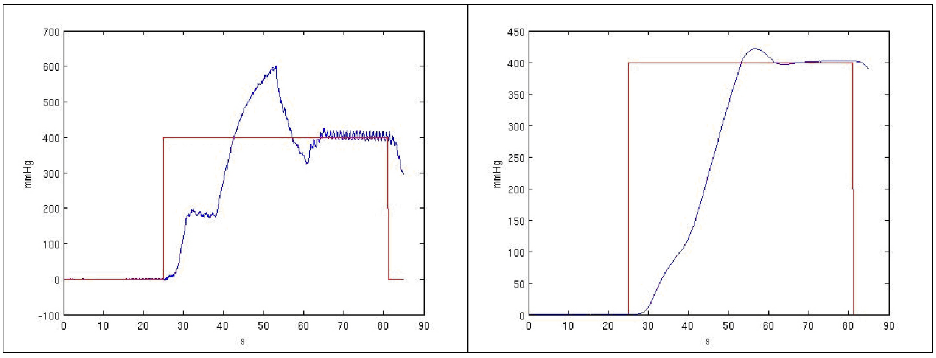
Animal tests were performed with two porcine subjects. These tests were done with the purpose of simulating a normal surgical workflow using the system in a harder environment. The aim was to understand and study the difficulties that would arise in a close-to-real clinical setting. Datasets from both animals were acquired 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 40 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" [119].



a) b)

Figure 40 - Multimodal markers in the body (a) and how they are seen in the images (b).

A first animal test using the ARISER system took place at the Oslo interventional center on a pig of 52 kg. Operating time was around 3h 15 min. Due to problems with a non appropriate MRI datasets, the catheter positioning has been effectuated with the help of two additional electromagnetic (EM) tracking sensors placed on the aorta, US (external), and after sternotomy also with direct palpation (fingers). Once the position of the balloon in the target region of the aorta was secured, a sequence of balloon inflations (manual and automatic, full or semi inflation up to different pressures) could be effectuated. Data was used for optimization of the syringe driver control. Figure 41a and b show the step response graphs of the measured and real pressures inside the balloon. From these experiments it was concluded that this model of the system is robust enough to control the pressure inside the balloon. It can be said that this approach leads to new concepts of bio-controllers in which the controlling systems to be used in medical environment take into account physiological quantities [150].



a) b)

Figure 41 - Step response of measured and real pressures during the first animal test. a) Ps - measured pressure, b) Pb - real pressure (taken from the data presented in [150])

The second animal test of the ARISER system took place at the Oslo interventional center on a pig of 55 kg (Figure 42). Operating time was around 2h. The registration tests could be effectuated and positioning of the eight multimodal fiducial markers on the abdominal wall has been proven good. This led to the important finding 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. The driver could place the balloon in a single attempt into the target position and reacted without delay on manual displacements of the catheter. Additional tests will have to be performed to prove reliability and the advantages of the system during real surgical practice.

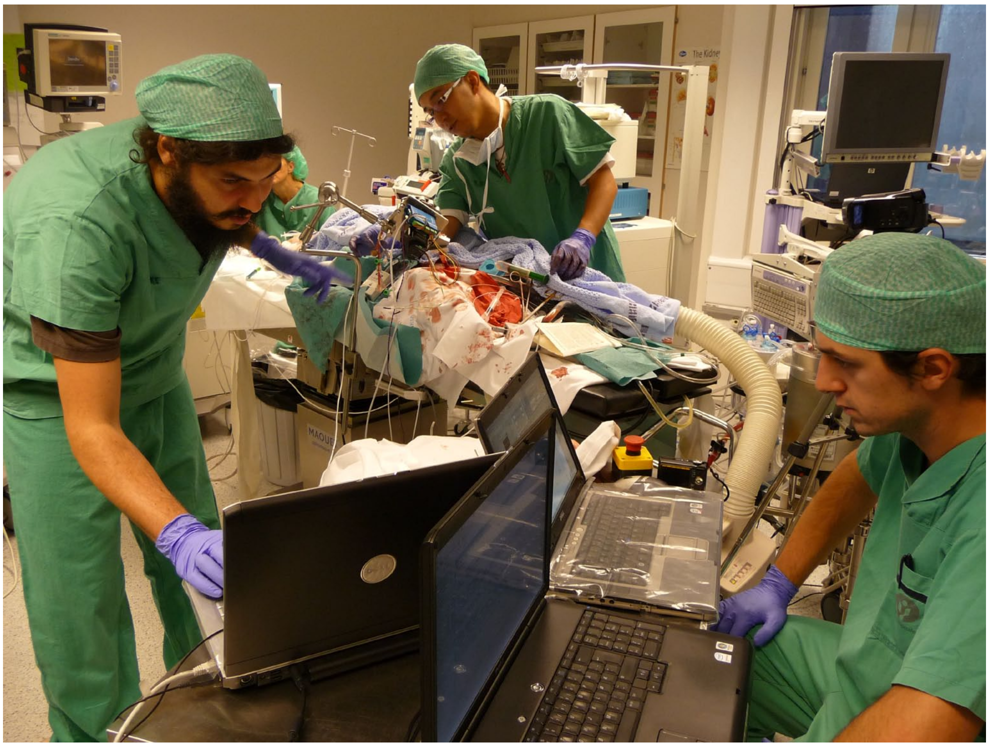
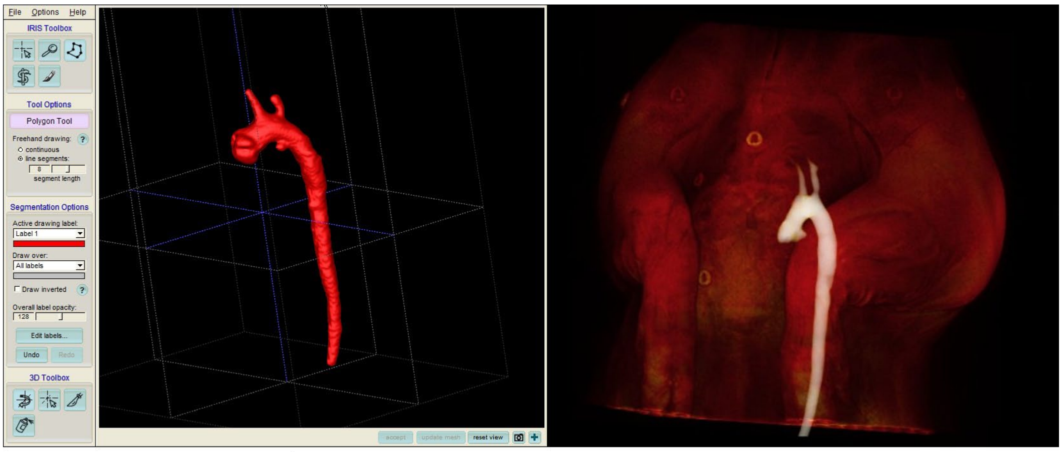


Figure 42 - Operating room at the Oslo interventional center during the second animal experiment

The following figures show several steps of the workflow during the experiment. For the animal tests, an extra segmentation task was needed 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 with the balloon superimposed. For the segmentation, ITKSnap (www.itksnap.org) was used. The multimodal markers seen in Figure 40a used for registration, can also be seen in the MRI scans and in the reconstructed 3D dataset (Figure 40b and Figure 43b). The segmented aorta can be seen in Figure 43a and in Figure 43b we see the aorta fused with the 3D reconstructed surface of the animal. Figure 44 shows what could be seen in the visualization software during the procedure and Figure 45 shows the progress of the balloon as it advanced up the aorta until the aortic arch.



a) b)

Figure 43 - a) aorta segmentation with ITK snap and b) fusion of segmented model with 3D rendering

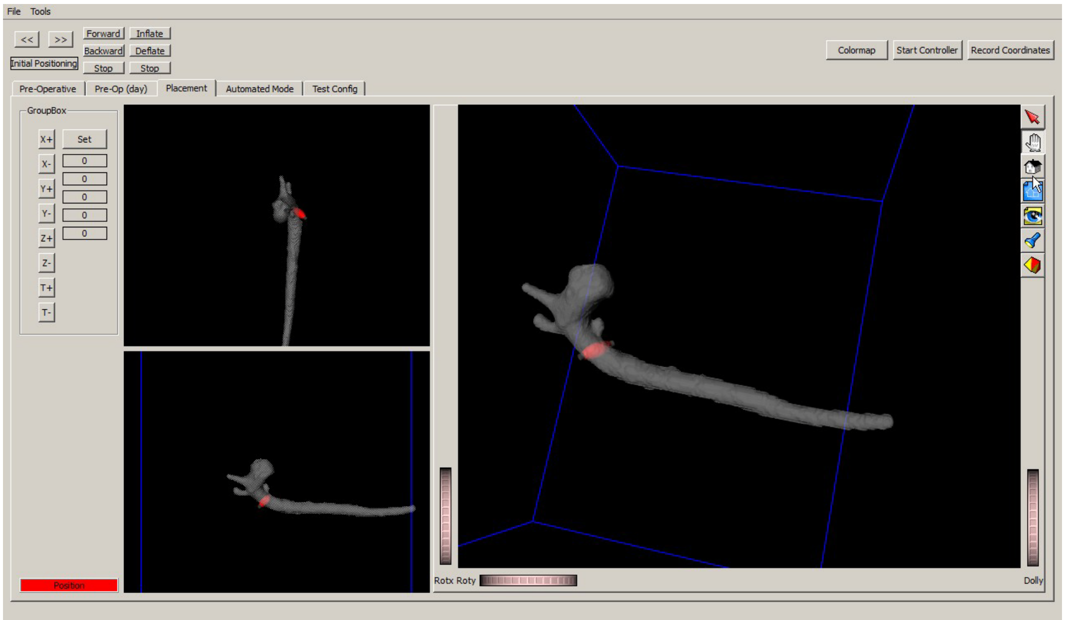
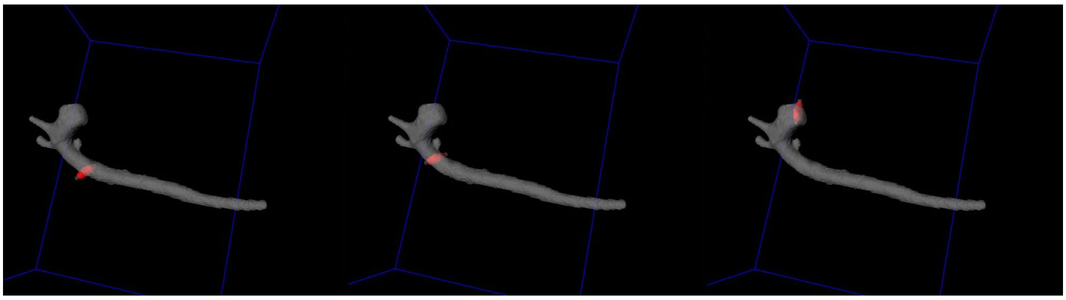


Figure 44 - The visualization system during the second animal operation. Here only the segmented aorta is shown instead of the full three-dimensional image volume



a) b) c)

Figure 45 - Progression of the balloon in the aorta as seen from the visualization system. a) at the end of the descending aorta, b) entering the aortic arch and c) in the ascending aorta

3.5 Discussion

The obtained results demonstrate the advantage of using the system. Comparing placing times and accuracy, the subjects perform always better with the total view and, as good or slightly better when using the 3D view compared with the restricted view. 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. These results were backed up by the user questionnaires where there was a clear statement that support was better in the 3D view, against restricted view, and by our own observations. For instance we observed that, during some insertions, the catheter got stuck in the brachiocephalic trunk. In this situation, the users needed to pull it back a little and then try to advance again. This is a common situation in real cases, where catheters or guide wires can go into the wrong vessels. 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 there) 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* of what was happening because it was difficult to advance the catheter.

All the automatic fine placements using the actuator were done under 30s and with less than 5mm error. These results fall well inside our specifications. Combining this with the good manual placements we can say that the system's visual support enables a fast and safe manual rough placement with an accurate fine placement done automatically.

It is important to note that we do not provide here hard evidence on the system's behavior nor it was our intention. Instead, our aim was to test the clinical feasibility of such a system by technically proofing the concept and by getting feedback from the potential users of the system, the surgeons. So far, we were given very clear positive feedback relative to the ability of the system to make the procedure safer and quicker. We have many challenges to face but we have a good indication on the feasibility of such a system and guidelines on directions to follow.

The first proof-of-concept tests also showed us that the driver was insufficient for the task in terms of stroke (maximum distance of pushing and pulling). As the initial idea was to use the driver only for fine adjustments it is limited to 20cm displacements. But, due to the catheter slack, the driver is required to push or pull much more than that. This led to the design of a new driver, which proved to be adequate for our needs. The specified accuracy of the magnetic tracking system is suitable for the application but we observed sensitivity to mechanical vibrations, present when perfusion is administered. These vibrations introduced visible errors that need to be studied in more detail. The system also aims to have minimal impact on the clinical workflow as it should be easy to integrate in the operation room. For this also further development on the user interfaces of the different parts will be necessary especially the integration of the robotic actuator.

One of the limitations of the 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. For the time being, this assumption has proven to be correct for all the cases we tested. In the animal tests, under harder conditions, we could use the system under this assumption, using the multimodal markers to perform rigid point-based registration. This was one of the most important qualitative finding during these tests. Still, should the system need to cope with more serious deformations, like retracting the heart and aorta, this limitation has to be addressed in the future. Future work directions should be aimed at solving these limitations as well as increasing robustness at the software level, maturing the prototype towards actual operating room usage.

The results achieved so far represent a major step towards 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.

4 Middleware for integration of body sensor networks in surgery

In this chapter we describe the analysis, design, proof-of-concept implementation and evaluation of a formal architecture for the integration of body sensor networks in minimally invasive surgery. In particular we analyze the requirements of medical applications for the operation room and propose a solution for the inclusion of wireless sensing technology in surgery, based on results obtained by studying different possibilities.

The system we described in the previous chapter relies mostly on spatial data collection so it has geometrical information on the location of the objects of interest, in our case, the balloon catheter. But the system also relies on pressure measurements, notably the pressure inside the balloon catheter and the pressure in the aortic root for automatic control during the surgery and during balloon repositioning. In the current implementation, these measurements are extracted from the pressure lines, through the lumens of the catheter, and read through interfacing an analog acquisition board to standard measuring equipment. Even if this is sufficient and not too cumbersome, it would be desirable to measure the pressures in a more effective way, with sensors at the measurement location avoiding the delay induced by the length of pressure lines. With the advent of miniature pressure sensors [151] comes the opportunity of acquiring these data in a more straightforward fashion. This fact was part of the motivation for the architecture we propose. Another drive for designing a formal communication scheme was the fact that the system is implemented in practice in three different workstations communicating through the network (wired or wireless) but has no mechanisms to deal with failures should they arise. Failure might include a communication breakdown, too latent data or one of the modules crashing. In any of these situations, actions should be taken to ensure that the other components of the system behave properly, avoiding risk to the patient. This was also part of the motivation for designing the communication scheme.

In short, in the future we would like to support AR systems with sensor information, taking advantage of new developments in miniature wireless sensors, as is the case for our system with the pressure measurements. If the systems are distributed among several network nodes then a formal scheme of communication has to exist allowing this type of setup to be used reliably in the context of a medical application. The following Sections describe the study, design, first implementation and analysis of the impact of a scheme we designed to address medical AR sensing needs. The implementation is not intended to be exhaustive but rather to open the door for future developments as innovative design in this domain has to be done in a careful and timely fashion. Nonetheless, the designed system shows that it is feasible to support AR medical applications with tiny wireless on body sensors while maintaining reliability requirements which are extremely important.

4.1 Design requirements

An architecture that addresses the operating room (OR) needs to be focused on three main requirements for a medical application: **safety**, **security** and **flexibility**. We will discuss these requirements more in detail.

Safety is a key factor in a medical application. The consequences of system failure can be permanent body damage or death, so it is of extreme importance that safety is taken into account when designing a system to support medical interventions. When talking about communications, the various aspects to consider are maintaining the data rate to the acceptable level, avoiding communication breakdown and what are the consequences when it is not possible to guarantee one or the other. Maintaining the data rate and avoiding breakdown can be seen as a guarantee of a certain level of quality-of-service (QoS). QoS is reviewed specifically regarding wireless sensor networks (WSN) in [152]. After reviewing QoS research under different perspectives (application specific and network QoS) the authors mention, as an open research issue of great interest, an approach to QoS through middleware that negotiates with the applications and with the network. A QoS-aware middleware architecture is described in [153]. The work is not specifically for WSNs but rather for heterogeneous distributed systems. But the interesting idea is that the authors consider QoS as application specific and their architecture provides support since the application development phase, to runtime phase. Similarly, we wanted to provide the means for the applications in our network to decide about their QoS policy. In our case we intended to provide a scheme to monitor the connections taking into account certain criteria defined by the applications. Applications tell the middleware to warn them in case of specific events, like a failure in a sensor or a lowered data rate, and we leave it up to them to implement mechanisms to deal with the consequences. These mechanisms can be for instance, popping up alarms or stopping certain actions according to the severity of the problem (e.g. an actuator stops when the position information is not reliable anymore).

When designing a WSN architecture for the OR it is also of importance to have **security** in mind. Security (as well as reliability) is underlined by many to be a key issue to address [32;34;126;154]. It should be avoided that data leaks out of the network as privacy sensitive information about the patient might be disclosed to a third-party. On the other hand, the network must be protected from intrusion, where an impersonator node might generate fake data or might corrupt the real data, potentially compromising the surgery. Encryption schemes can provide the necessary security in what regards avoiding data "sniffing". Despite mentioning its importance, in many prototype applications security mechanisms are seldom implemented. In [154] for instance, the authors propose an authentication based scheme using secure channel communication [155]. In [36], the authors propose a similar authentication based scheme where authenticated users can also pass on access rights to others in the network. An interesting approach to the security issue is presented in [156] where the characteristics of the physiological signals are used to generate keys to identify (authenticate) sensors belonging to a certain individual. Still, in the applications reviewed, we found no work that focuses on the problem of sensors being accepted or rejected in a certain network. This is corroborated in [133] where the authors state that security is an issue of great importance and is in general not addressed.

Flexibility of the network is of utmost importance in medical environments as the type of sensors that might be required can vary greatly. Just as an example, nowadays, a surgical team relies on all kinds of inputs: pressure, temperature, oximetry, ECG and imaging (ultra-sound, endoscopic cameras, etc.). In the future it is expected that position tracking moves to the OR as an integral part of many applications. Also, it is expected that wireless sensing of different kinds gains more acceptance and thus will have a more marked presence in the OR. To cope with these kinds of different possibilities a system must be designed to be easily extendable and not rely only on certain kinds of predefined inputs. Also, applications themselves may function as sensors as their output data can serve as input in an actuator, itself acting as a network node or as input to other applications. So, as already stated in [157], a mechanism for easy **plug-and-play** of sensors and applications into the network must be derived and one that doesn't compromise the previous requirements (safety and security). This vision is also shared in other efforts like the European research network SENSEI [158], aiming at building the framework for the "internet of things" through the design of a general network architecture. Based on these considerations we shortly summarize in Table 3 the requirements of a network architecture to support MIS.

Topic	Description
Safety	Sensing must be reliable. Special care must be put so that: • data are accurate • communication flow is continuous (at the needed rate) • must cope with faulty sensors (evaluation of consequences, actions)
Security	Security must be guaranteed from several points of view: • data cannot be corrupted by external agents • data cannot be sniffed by external agents • only trusted sensors and other resources can be part of the network
Flexibility	Participating sensors must be allowed to be heterogeneous and must be able to join and leave the network in a simple way

Table 3 - Overview of requirements for a WSN medical application

A new component will be in charge of deciding which sensors are allowed to participate in the network, of monitoring the quality of the sensing data and the connections and of maintaining "network context" having centralized information about which nodes are part of the network at a certain time, which ones are exchanging information, and the quality of the data being exchanged. Our approach comes from the integration of similar approaches in the literature combined with new ideas. In fact, the proposed solution is in part inspired by the *muddleware* communication platform presented in [159] used in online gaming. Large scale gaming is influenced by unreliable communication and requires heterogeneity, persistence and scalability. In our case, we have not been so concerned with the latter. The authors use a real time XML database server that can be queried through the network with XPath using several different communication interfaces. They maintain the state of the game in the server, which players are participating, which non-player characters are in the game, which objects are in possession of certain players, etc. The use of XML as the core technology allows for rapid prototyping of applications and eases up the proof-of-concept phase.

In our case, such a database will allow us to maintain the current state of the network regarding active network nodes, which is useful both to inform client applications of the available sensors and for the QoS monitoring. Since our aim was proof-of-concept and the study of the feasibility and utility of the proposed system, and not the efficiency for the time being, XML was a good choice because it is a well established human readable protocol and implementation is simplified.

4.2 Proposed architecture

The most important concept is that the services we propose have to be transparent to the applications. The idea is that an application can use a wireless sensing infrastructure in the OR almost without additional programming effort. For this purpose, we add an intermediate layer of logic in the network communication, a **middleware** component which will transparently negotiate with a **central database server**. Conceptually, logging in the network (registering), finding available nodes, establishing data channels and storing meta-data (like latency data, checksums, etc) about data transfer, are processes that are managed by the middleware component. The component acts as a broker between applications, sensors and actuators giving all of them access to information about the network but hiding the underlying logic. The concept is illustrated in Figure 46 where we see how data flows as usual between nodes but with the addition of a middleware component which manages operations. The middleware component is in practice implemented as two separate concepts: a local part, which resides in the network communication stack, between the application layer and the lower layers in the network nodes and, a central server which is a real-time database storing context about the network and all the service logic. In summary, the local component provides nodes an application programming interface (API) that encapsulates the communication with the server making the services transparent to them. The API also provides access to some features that should be exposed to applications such as queries about network status or available sensors. Following we detail the behavior of these two parts of the middleware, the central server and the local client.

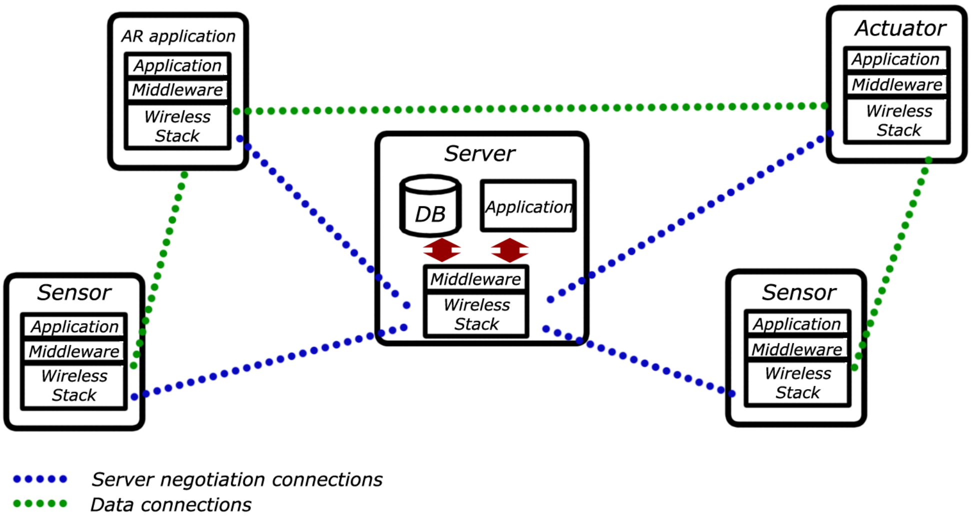


Figure 46 - General architecture overview

4.2.1 Central middleware component

The central middleware component manages the network. It is responsible for **accepting or rejecting network members**, **provide information upon request of the status of the network** (how many sensors are connected, which kind, etc.), **connecting two or more nodes together for efficient data exchange** and providing **QoS**, what we see as safety mechanisms. To provide these services, the database at the server holds as much information about the network status as possible. Figure 47 shows one possible option for the database specification. By querying the database, any trusted node can have information about the status of the network at a point in time.

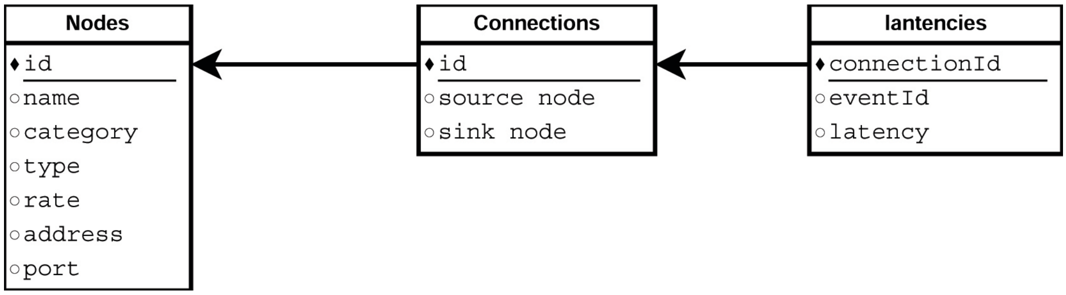


Figure 47 - Database tables in central server

Based on the data it holds, the server can provide a number of services with the aim of achieving the specifications derived in the design. The server should offer three main services:

- **Node authentication**: the authentication will be done at a node's request. The node wanting to participate in the network must log in by doing a request to the server. An example of how a sensor can request to join the network is shown in Figure 48. The sensor sends a request to join the network and the server asks for authentication. If authentication is successful, the sensor is accepted as part of the network and an entry is created in the server database. The server holds at all times a database with the table of the participating nodes and also with their characteristics (type of measurement, reliability, etc.). The server will then broadcast a notification to all, previously participating nodes indicating that a new sensor just joined the network. The nodes have then the choice to update their local sensor tables. After updating, the sensors can accept connections with any other nodes from the table. By enforcing this mechanism, there is the guarantee that all nodes that are listed on the server's database are trustworthy.

- **Connectivity**: the server maintains a list of all connected nodes. It is then possible for any node to query the server looking for available sensors. Typically applications will look for sensors from which they can request to receive data. Because the database holds all the sensor's characteristics as seen in Figure 47, excellent flexibility is achieved: the application can get information about which type of data is generated by the available sensors, the network address of the sensors, amongst other things and can create its own custom network of information tailored to its needs.

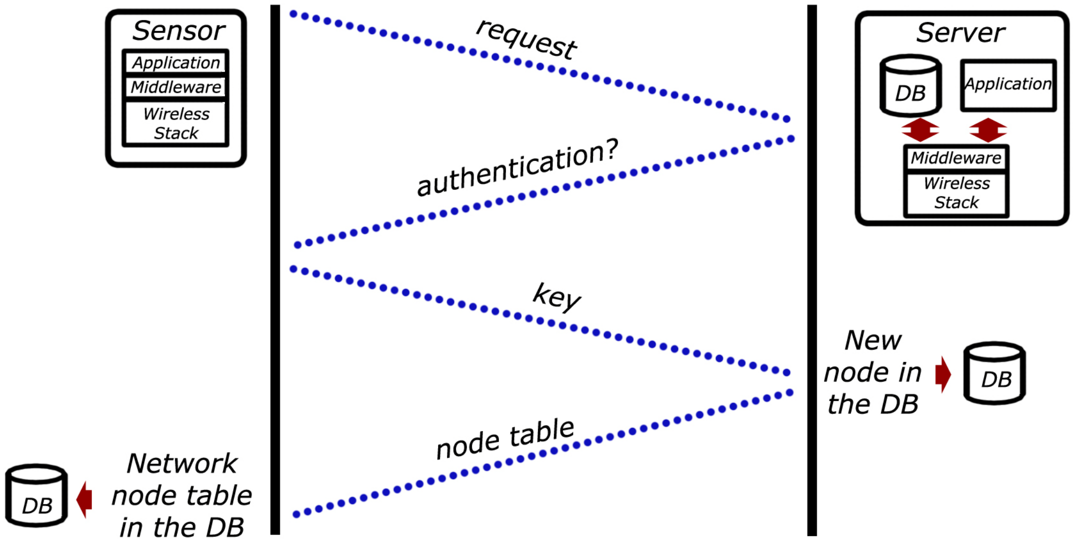


Figure 48 - Node authentication

- **QoS mechanism**: The architecture can offer two QoS features, monitoring of **connection interruption** and the monitoring of data transmission **latency**. To offer these services, the central server relies on information coming from the node side middleware. As explained, applications wishing to get data from a certain sensor must request a connection to the server. When the connection is established, the server will add an entry in the connections table of the database (Figure 47). This means that the server has constant updated information about which nodes are holding active data transfers. Then, the server receives from the node middleware periodical messages regarding the state of the connection. If a certain timeout is elapsed and the server doesn't get a message it assumes the connection is broken. It then notifies the applications that requested to be informed so the applications themselves can implement recovery mechanisms. The timeout is of course application dependent and thus should be configurable. As for latency, it is measured when data transfer is occurring between two nodes. Several mechanisms can be implemented. We propose a mechanism based on data timestamping. For instance, when transmitting a data sample, the sensor adds a timestamp. Then, the receiving party calculates the latency and adds an entry in the database with the obtained latency. In this way, the database server has a history of the transmission latencies for that connection. Based also on a configuration parameter, if the value is too high, a warning is triggered and sent to the applications that registered to be warned about that particular connection. Such mechanism not only allows applications to be warned about broken or highly latent connections but allows a third party application to monitor the status of the network as the information is all held at the central database. These statistics can be used in the future when other applications join and request nodes with certain QoS criteria.

4.2.2 Node middleware component

The node middleware component is the key element in hiding the architecture function from the network nodes. Normally, in a sensor node, the application layer will be responsible for the data acquisition and processing. Then the data is passed on to the network by calling functions of the lower network layers. On applications, the application layer will deliver the data received from the lower layers of the network stack to the application logic.

Our architecture, inserts a new layer in the network stack, between the application layer and the lower layers. Instead of calling functions from the lower network layers, the application layer will call functions from the middleware to send or receive data to and from the network. This layer will implement some common functionality and some node specific functionality. Common to all nodes is the implementation of a server authentication mechanism at node startup as all nodes that participate in the network need to be authenticated. Also common is a time synchronization mechanism as the QoS services rely on timestamping and thus the nodes need to have synchronized clocks. The middleware layer will implement different functionalities depending on the type of node. If the node is a sensor, the middleware implements a timestamping mechanism for each data sample which will be used later on for latency calculations. In the case of an application node receiving data, besides passing the data on to the application layer, the latency calculation will be done at the local level. Finally the latency value will be registered at the database (Figure 49). Alternatively, the sensor node can also register the source timestamp in the database. Such functionality should be feasible to implement in limited resource sensor nodes. In [160] the authors present their own implementation of an existing server middleware. The component was reduced to achieve the small footprints required to fit in sensor node hardware. Their work shows that tiny implementations of middleware that are compatible with industrial standards (e.g. CORBA) are possible on sensor nodes. As for the lower layers of the communication stack we will, for the time being, focus on using an already developed stack instead of designing a new one. There are already IPv6 compatible stacks developed that have shown good results in medical applications [161;162].

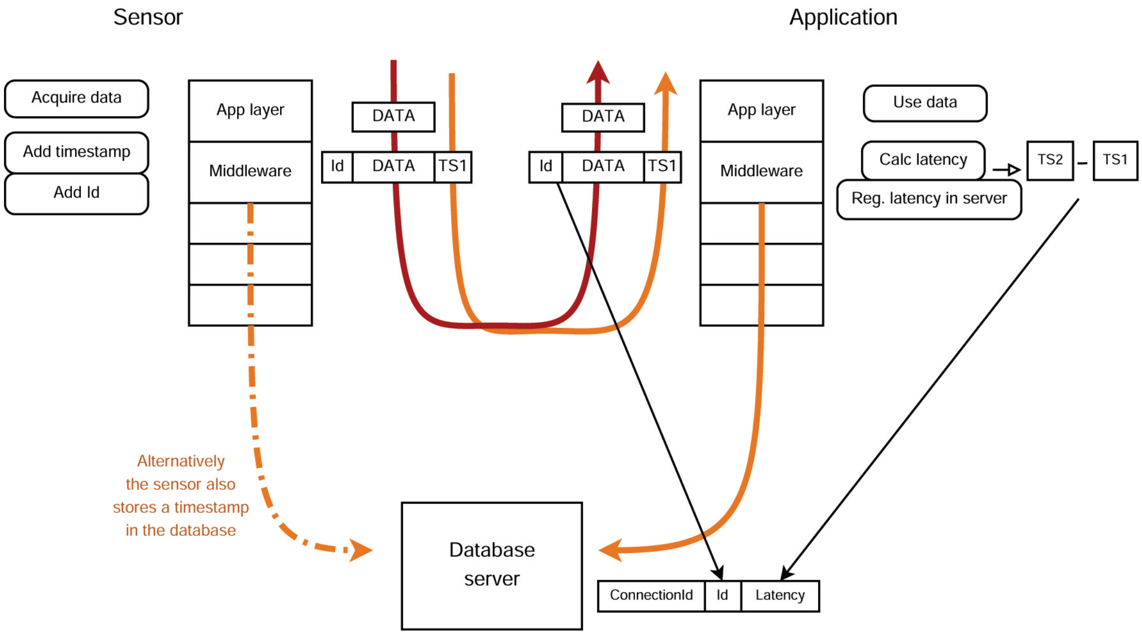


Figure 49 - Function of the node level middleware. The application layer, in a sensor acquires a data sample, inserts a timestamp and sends it to the network. The receiver (application) calculates the latency, sends the data to the top level layer and registers the latency value in the database.

4.3 Standalone implementation

The purpose for the standalone implementation is to evaluate the feasibility of the architecture we propose. The aim is to assess what is the impact of the communication with the server in the normal data transmission. If we discover that the architecture is feasible and useful, then the way is open for a real hardware implementation.

In our implementation we did not use real hardware sensors but simulated sensors implemented in software components in the PC. For the server database we used the *muddleware* component, which was already mentioned in the design section. *Muddleware* is very versatile and provides with a number of out-of-the-box functionality which is extremely useful to evaluate if our solution is feasible. In fact, all of the mechanisms we need for the time being are present. In particularly:

- Real time database accessed through the network using C++ interface
- XML database, queried using XPath which is extremely useful in a prototyping stage,
- Watchdog mechanism: a client of the database can register to get an asynchronous warning every time a certain node is modified which is useful to implement our warning mechanisms,
- State machine that can execute specific actions according to the state of the database. This would be useful to implement a database cleaning and logging functionality which we describe later but which was not implemented.

As for the sensor and application nodes we implemented simulated software components which simulate the behavior of their real counterparts. The final implementation doesn't include all the features we propose but it is sufficient to prove that the concept is interesting and feasible. Using the *muddleware* component, we implemented the database server, which can accept connections from clients that can be sensors or applications. These, register themselves in the database by adding a new entry with the XML tag <Node> and with attributes showing their characteristics. Applications will look for available sensors by querying the database. If they find a sensor of interest they will connect to it using a dedicated connection. When this happens, a new line in the database with the XML tag <Connection> is created with the characteristics of the connection. In Figure 50 we see an example of a database with three sensors, one actuator and one application connected to it. These are all under the <Nodes> tag and can be seen in the figure highlighted in green. Since in the example, the application "mainVisualization" is receiving data from the tracking sensor with name "TestSensor", a line, highlighted in yellow, under the tag <Connections> reflects this.


```xml
<?xml version="1.0" standalone="no" ?>
<DemoMiddleware>
    <Nodes>
        <Node name="Pressure1" category="sensor" type="pressure" rate="20" address="localhost" port="10000" />
        <Node name="Tracking1" category="sensor" type="tracking" rate="40" address="localhost" port="15000" />
        <Node name="mainVisualization" category="application" />
        <Node name="catheterInserterV2" category="actuator" type="position" />
        <Node name="TestSensor" category="sensor" type="Tracking" address="localhost" port="13000" />
    </Nodes>
    <Connections>
        <Connection dataSource="Pressure1" dataSink="mainVisualization" status="active" />
    </Connections>
</DemoMiddleware>
```


Figure 50 - Server database in one of our showcase examples. Here there are three sensors, one application and one actuator in the database all under the <Nodes> tag. The single connection highlighted in yellow reflects the fact that "mainVisualization" is receiving data from "Pressure1".

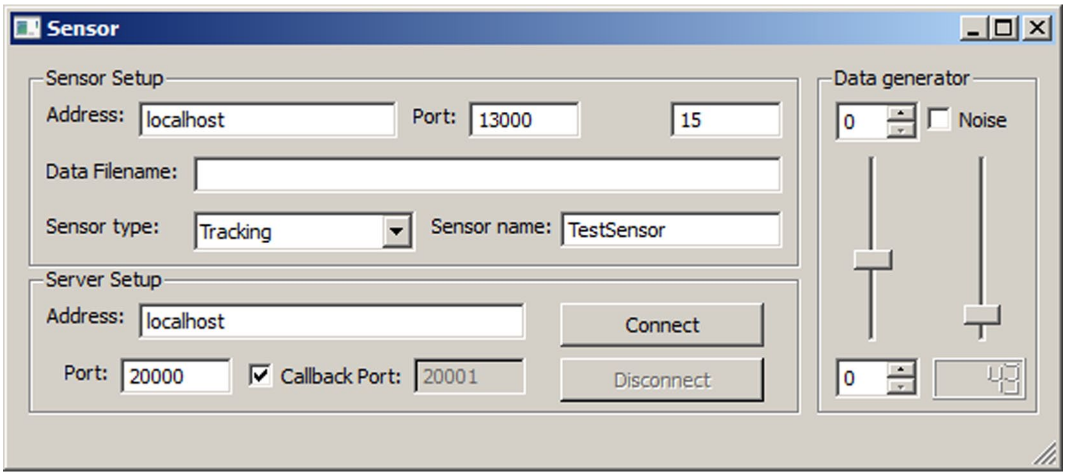
There are different ways to access the *muddleware* server. We chose to use the available C++ API, integrating it in our client software. The API provides a complete interface to the server allowing all the operations in the database (add, modify and remove elements and attributes) and registering of watchdogs.

Sensors

Sensors register their capabilities (type of measurement, data rate) and their network location (address) in the database. In Figure 51 we see a screen of our test sensor. We can run multiple instances to simulate several sensors connecting to the network. Each sensor implements a separate TCP/IP server where its data will be available to applications. The address of the server is configured with the address and port text boxes. When the user presses the "connect" button the sensor contacts the middleware server and creates a new entry in the database. The new database entry is shown on the lower part of Figure 51. Each sensor consists of only one XML tag their characteristics are stored as attribute-value pairs.

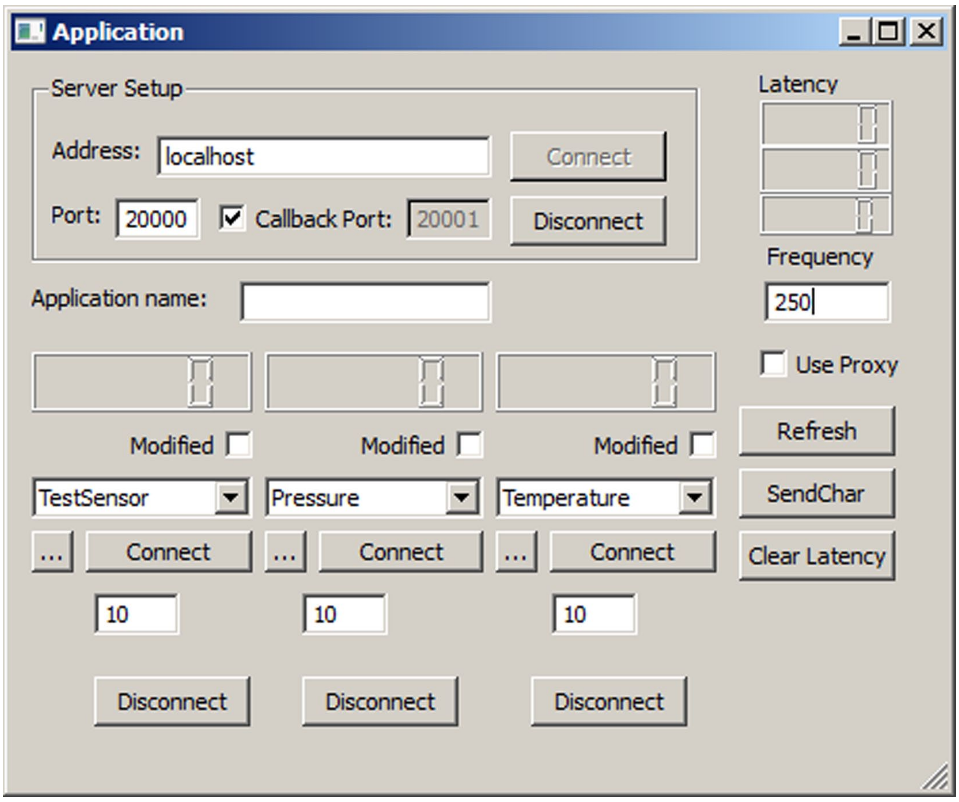
Applications

Applications register themselves in a similar procedure as sensors and then look for available sensor nodes. In the beginning, applications register also an asynchronous watchdog in the <Nodes> tag. In this way, every time a sensor joins in or leaves the network, the application is warned and the available sensor lists seen in the "combo boxes" of the application user interface is refreshed (Figure 52).




```
<Node name="TestSensor" category="sensor" type="Tracking" address="localhost" port="13000" />
```

Figure 51 - Screenshot of the example sensor. The server setup group should be filled with the database server details. The sensor group should be filled with the characteristics of the sensor we wish to simulate.




```
<Node name="mainVisualization" category="application" />
```

Figure 52 - Screenshot of our example application

The user can then choose to connect to a certain sensor to start getting data from it. The connection will be done to the sensor's dedicated network port. Since the address and port of the sensor is available from the database, the connection is initiated automatically and data flows from the sensor to the application. When this happens, a new tag on the <Connections> tag is created as seen in Figure 50 which ensures that applications are able to know the state of their active connections at all times. Whenever there is an error with the connection, e.g. a broken connection, the QoS mechanism performs a change in the database entry marking the connection as inactive or broken. If the application registers a watchdog linked to the <connections> tag it will be warned as soon as there is some change in the connection. Then it can implement actions depending on the change, e.g. can try to connect again if the connection was broken.

4.4 Integration with the visualization system

Since the application described in Chapter 3 receives all the spatial sensor information from the opentracker (OT) component we developed extensions to the software which implement the functionality required to interact with the database server.

As explained before, OT has modules and nodes. A module is essentially a configuration to the node behavior. A node, depending on its type, receives tracking data from the tracker tree, performs some operation and pushes the data forward in the tracker tree. We implemented a new module and a new node. The module is loaded at configure time in OT. When the module is created, the connection to the server is done in a similar way as in the stand alone implementation. By now the OT instance is registered as a sensor or as an application in the database, depending whether it produces or consumes data. After that, the new node we created would, in principle, add a timestamp to the data just like the node middleware in the implementation described in the last section. But, since all OT events already contain a timestamp, additional timestamping is not needed. All that needs to be guaranteed is that the machine running OT is properly synchronized with a time server. This can be achieved in the initialization step, when the module is created. Then, in practice, the new OT node doesn’t perform any operation on the OT event on the side of the data source. On the other hand, on the side of the application (data sink, or receiver) the new OT node performs a similar operation as the stand alone nodes. The difference is that the stand alone nodes have to extract the timestamp from the newly arrived data, make the latency calculation, deliver the clean data to the application and register the latency at the server. Here, on the other hand, since the event with the timestamp is what the application is expecting, the timestamp is not stripped out. The node, reads the timestamp from the arrived event, calculates the latency and registers it on the server. The behavior is quite similar to the standalone version except the timestamp is already included.

4.5 Simulation results

Regarding the discovery of available sensors, the proposed architecture behaved very well. Using the proposed scheme it was possible to always find the list of trusted sensors and, through the attributes present in the database it was easy to connect to them and proceed with data transfer.

In what regards the quality of service mechanisms, we needed to evaluate the impact of the constant writes in the database, in particular for high data rate connections so we could decide on a database access policy.

The tests were done with the simulated sensors and applications described in the last section and with the *muddleware* database server. In all tests, both sensors and applications start by registering in the DB and, after that, the application requests data from one or more sensors. We wished to investigate the best DB access policy: how much information to store, and which nodes should store information: sensors, applications or both. As described in Section 4.2.2, there are two options for storing latency relevant information in the DB. Either the only application registers the calculated latency after receiving a data sample or, in addition, the sensor also registers the timestamp value when sending the data sample. Every time a node writes a value in the DB, a new entry is created, increasing its total size. The purpose is to evaluate the different schemes, measuring the influence of DB size (total number of entries), number of writes per second and number of connected nodes. The important requirement is, obviously, that the DB read and write operations should not interfere with normal data transmission.

The tests were done in an Intel Core2 Duo 2GHz with 2 GB RAM on a Windows Vista 32 bit operating system. In all tests, we recorded a number of consecutive data sample transfers with the application requesting the data and the sensor replying (polling). Where it was convenient we measured:

- Data latency: the time taken from a sample to go from the sensor to the application,
- Time between requests: the time elapsed between two consecutive data requests from the application, measured as they arrived at the sensor,
- Time between replies: the time elapsed between the arrival of two consecutive data samples, measured as they arrived at the application,
- DB write time: the time taken in a write operation

The first test had as objective to understand the impact of the size of the database on the write latency. Figure 53 shows the results obtained for this relationship with one single application getting data from one single sensor. We measured the DB write time and the time between replies. This last measure shows the influence of the delay caused by the database access. In a normal situation, the time between replies from the sensor should be equal to the data period (the period, T is the inverse of the data rate, f). As we will see in many cases, this is not always true and the main reason is that writing in the database blocks code execution and delays the process. For this reason, measuring this parameter is a good indicator of the impact of the database access in our architecture. It should be noticed that blocking execution would not be a problem if the write time would be very small. But if the time is comparable to the data period then, blocking writes will delay the normal data flow.

Figure 53a) and b) show the results obtained for a data transmission with 40Hz rate. We can see that the DB write times grow non-linearly with the number of entries, that is, the larger the amount of data in the DB, the longer it takes to write. In b) we also see that as a result, the application receives the data later and later as the curve follows a similar trend than in a). This makes sense as the sensor only sends the data after writing the timestamp value in the DB. Figure 53c) and d) show the results obtained when the transmission rate is of 4Hz. In both these measurements the sensor and the application were writing in the database. In e) and f) we show the results when only the sensor writes. We can see that the latency is mostly proportional to the number of entries and is fairly independent on the number of access per second as in this case, since only the sensor writes, there are half the entries than in a) for the same number of transmitted data samples. It can also be seen in f) that since only the sensor writes, the influence of the delay on the data exchange is lower because the application does not have to wait for a write access to request for a new data sample. The minimum write latency value found is around 20ms when the database is practically empty which poses a problem should we wish to write values for every data sample. Obviously it will not be possible with this DB server. This is of course dependent on the setup, i.e. CPU speed and probably other factors. In any case, the setup is fairly fast but the value is still quite high. Worst, we can see that already with 1000 entries the writing latency is as high as 60ms. This clearly indicates that we cannot write one entry per data sample during surgery where many sensors and several applications will be expected to function for a few hours. It is interesting to see that the write latency is independent of the data rate.

Another interesting option is to maintain only the last data transmission latency value in the database. This would imply that there would be one database access per data sample, in case only the sensor writes in the DB or two, in case both the sensor and application write. Here, the advantage is that the DB doesn't grow and so the write latency dependency seen before would be avoided. Figure 54 shows the data obtained after 5000 data samples transmitted when only the sensor is writing the last latency value in the database. As it can be seen the DB access latency doesn't grow as before, strengthening the assumption that the access time is dependent mostly on database size. Nevertheless, and as seen before, the typical access time value is between 25ms and 50ms. While these times are acceptable for sensors with a low sample rate, for "realtime" data (f=40Hz / T=25ms) they would be unacceptable. If we write in the DB for each data sample transmitted, we would fall in one of two problems: 1) either the write is blocking execution and we delay the data transmission, which is what we have been experiencing so far, or 2) the DB writing is scheduled to a separate execution thread, thus not blocking node code execution, so there will be no influence on the data transmission. In 2) the database writes would still be slower than required but buffered, so all information would be written properly. But, the data would not be immediately available to other applications. Moreover, depending on the parameters of transmission, the size of the buffer would have to be huge.

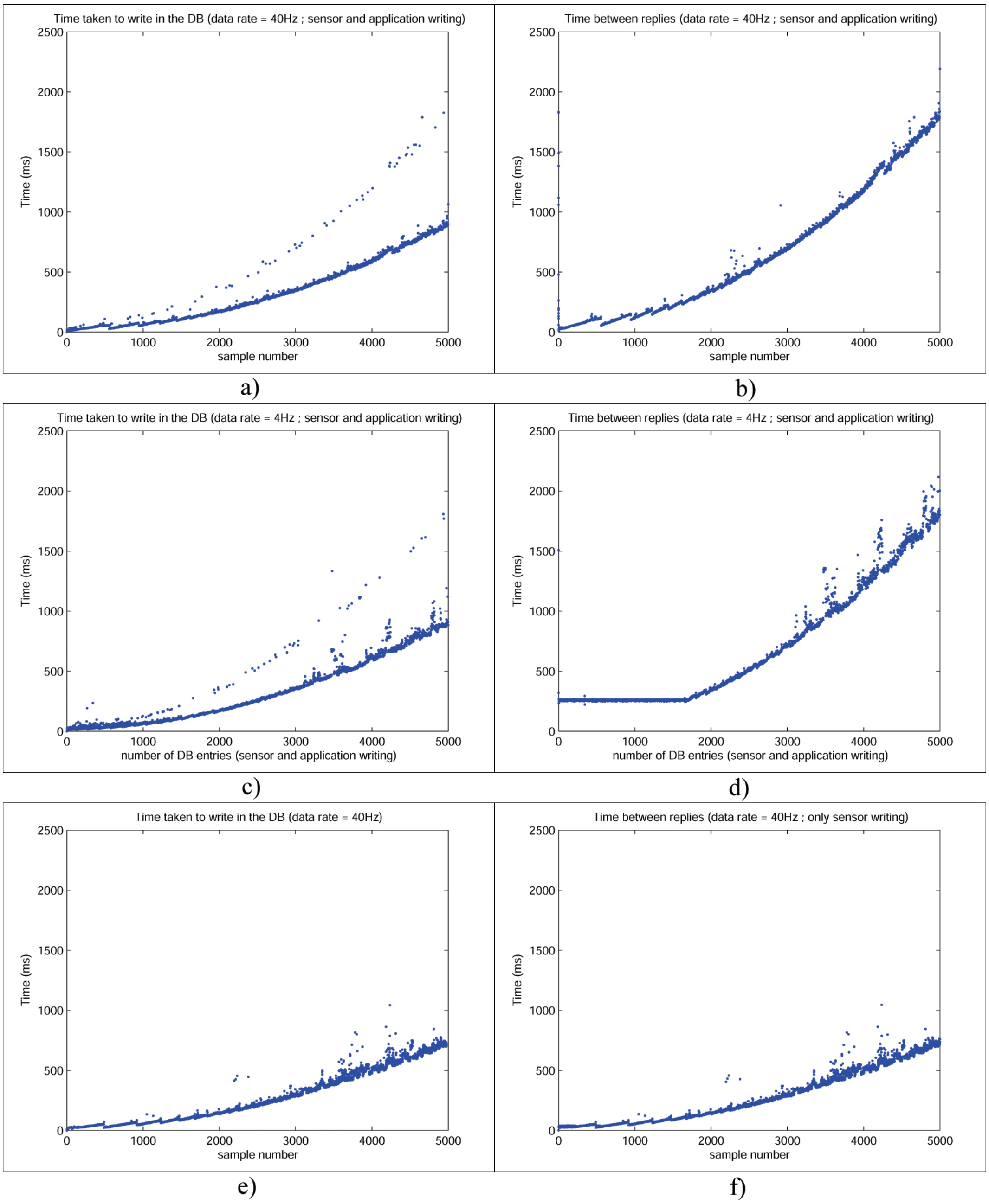


Figure 53 - Influence of the size of the database on the writing latency. It can be seen that the factor that most influences latency is the size of the database. The left column shows the writing times while the right column shows the time between data samples arriving at the application. In all cases the total number of entries written in the database is the same.

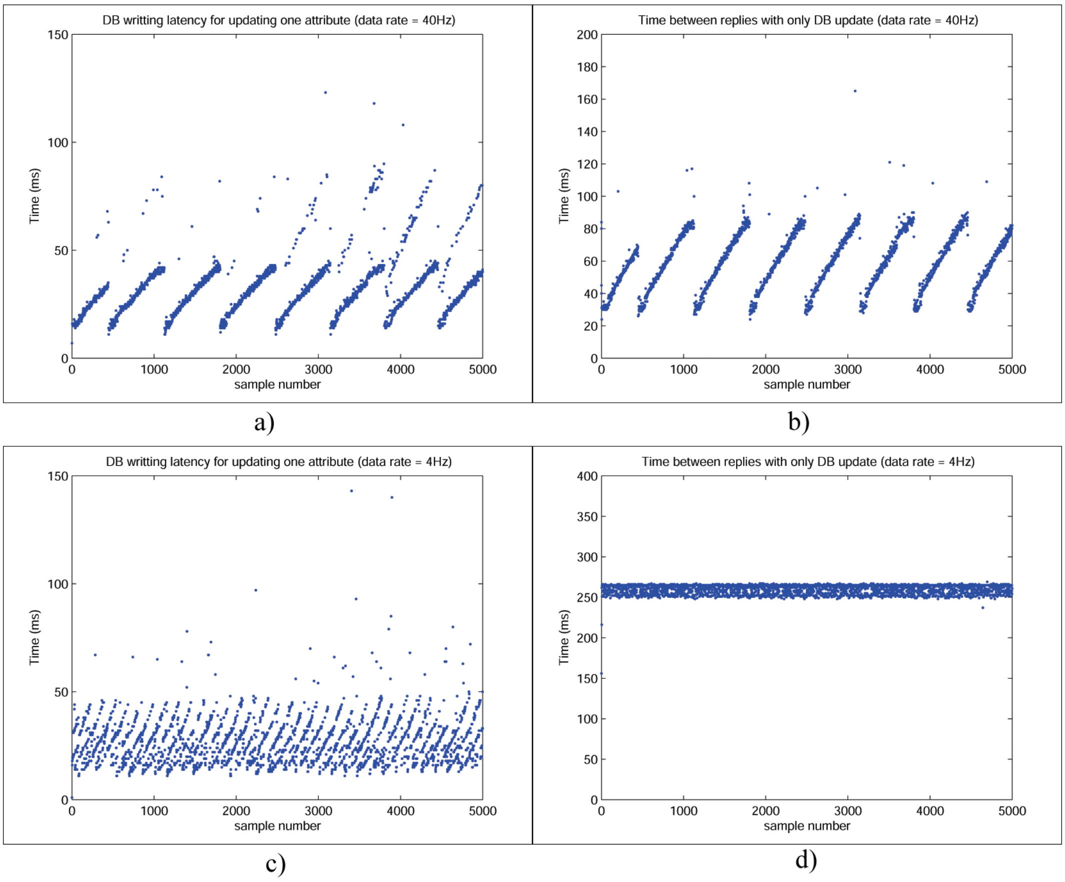


Figure 54 - Database access latency when the sensor only updates one DB entry for each value instead of adding a new entry. For higher data rates 40Hz - (a) the write latency doesn't grow beyond a certain value but it is still high enough to delay data transmission (b). For lower data rates - 4Hz (c) the writing latency is small enough not to disturb the data transmission (d).

Another factor that might influence DB write time is how many sensors are connected and writing at a given time. In Figure 53 e) and f) we have already seen that the influence is not high but we measured write times with two and three sensors sending data simultaneously to one application to better assess the influence. The results are shown in Figure 55. In all cases, all the sensors as well as the application were writing values in the DB. On the left column - a), b) and c) - the data was obtained with one application getting data from two sensors. On the right column - d), e) and f) - there were three sensors and one application connected to the DB with the application getting data from all three sensors. It can be seen that there is a slight influence on write times. The more sensors, the longer it takes to write in the DB. Still, the influence is not too high.

Finally, we found the DB write time to be also dependent on weather nodes register for watchdog warnings or not as can be seen in Figure 56. Here we see an influence indicating that having a node registered for watchdog warnings, as we need to have in our case, increases the database write time.

From the previous results, it is seen that it is not feasible to write a new entry on the DB for each data event received. Thus, we investigated the behavior of the architecture when writes were executed only at periodical intervals.

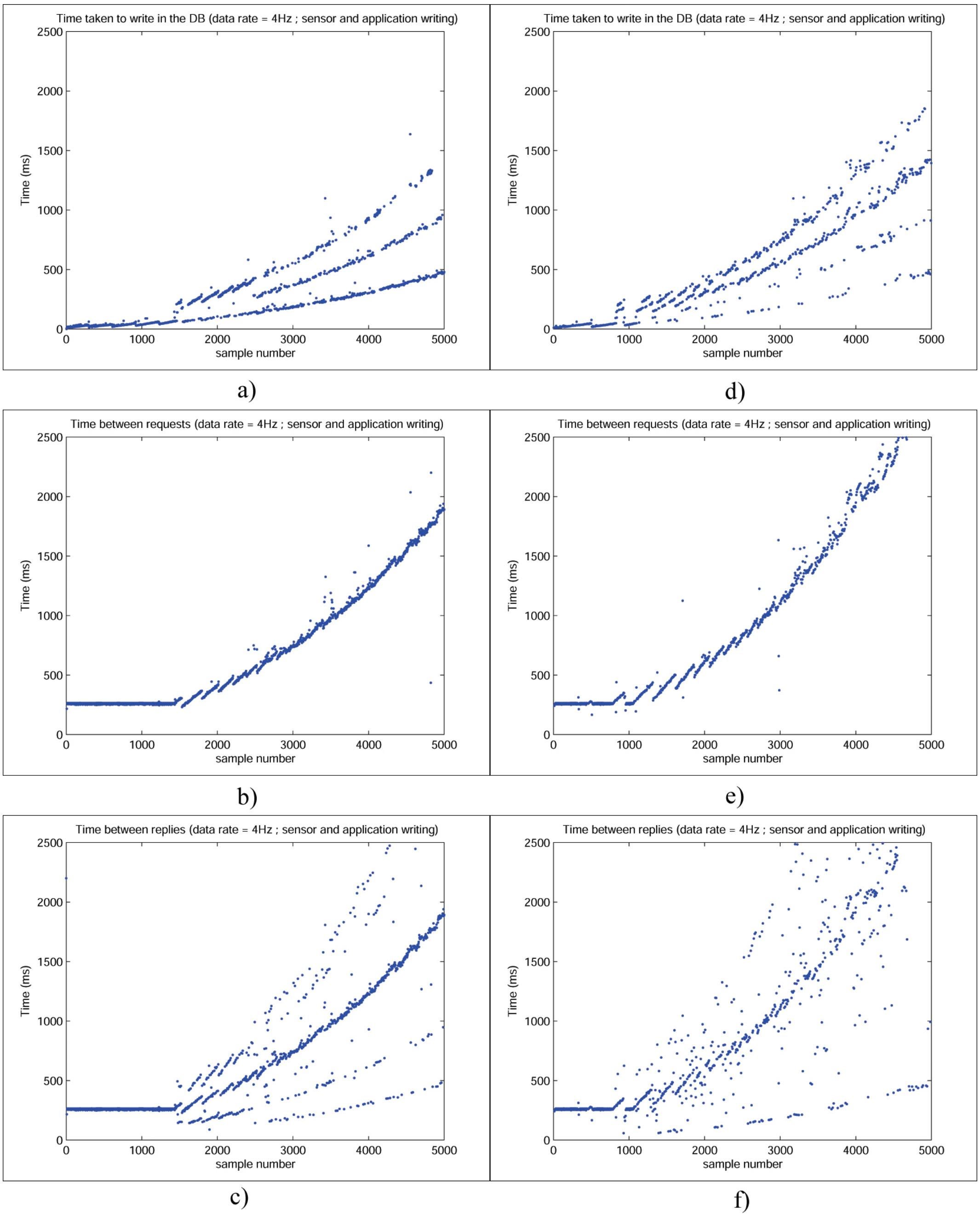
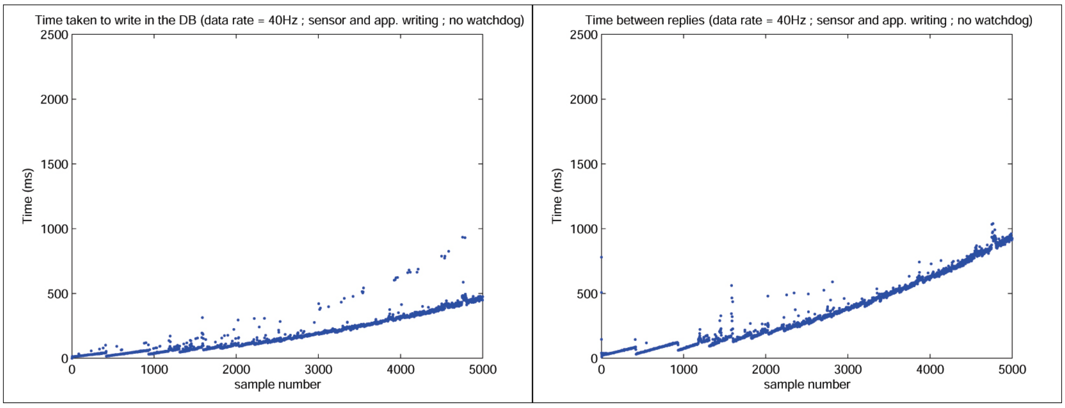


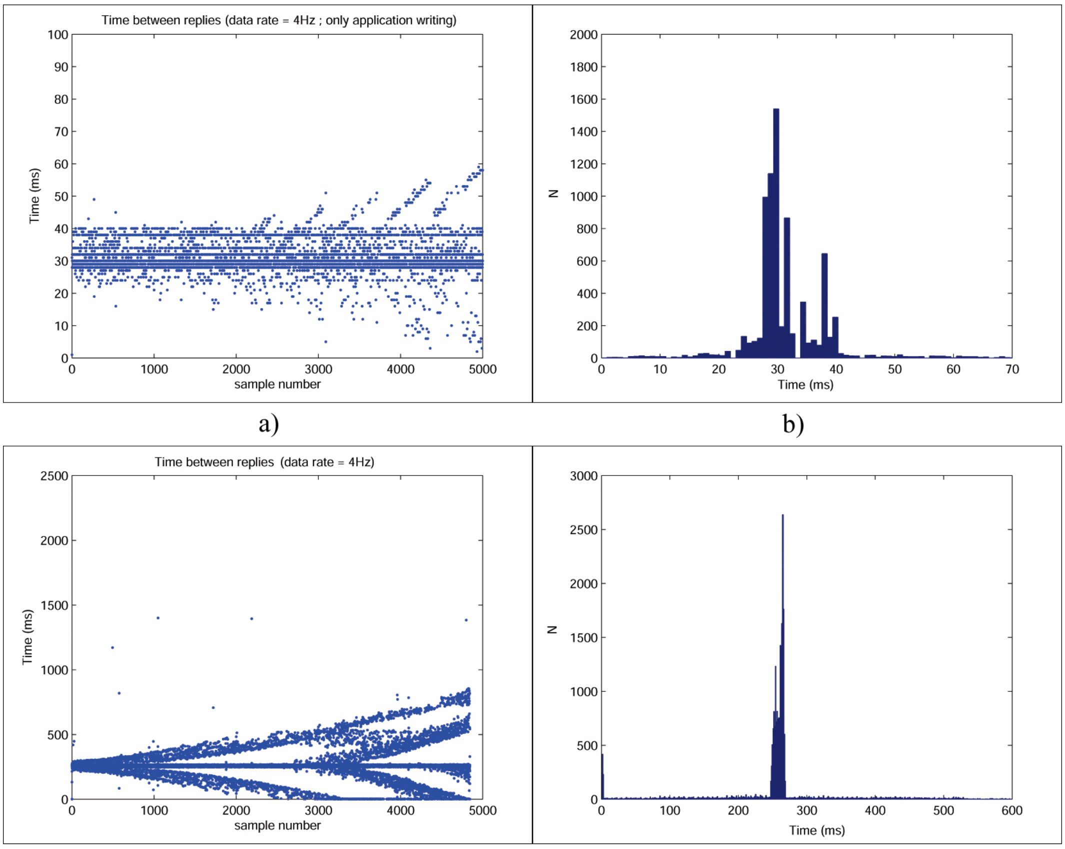
Figure 55 - Influence of the number of connected and accessing nodes on database access times. The left column shows results obtained when there were two sensors and the application connected. The right column show similar results with three sensors and one application.

The idea is to write latency values after a number of N data samples are transmitted, where N is a divider depending on the intended number writes per second. The results are presented in Figure 57 showing measurements for 40Hz data rates - a) and b) -, with N = 150 and 4 Hz data rates - c) and d) -, with N = 15. Here, we can see that the behavior is acceptable, that is, the time between replies is close to the sampling period, as it should (around 25ms for f = 40Hz and 250ms for f = 4Hz). But, there are still many samples arriving late as can be seen in the histograms. This is due to the fact that each write in the DB is blocking sensor and application code execution, thus delaying data delivery. We thus performed similar measurements using a separate execution thread which was in charge only of database writes. The results are presented in Figure 58. It can finally be seen that the system is stable for a long time, even when the data rate is 40Hz. It is also shown that even if the database writing latency increases as expected (Figure 59 b), the data transmission latency does not (Figure 59 a).



a) b)

Figure 56 - Database access latencies when the application doesn't have a watchdog registered



c) d)

Figure 57 - Database access latency when performing only periodical writes. In the left column we show the time between consecutive data values arriving at the application. We see that in both cases, most of the data arrive on time. The histograms on the right side help seeing this. Nevertheless, a significant number of data samples arrive out of the foreseen time.

We conclude that these results have to be carefully taken into account when implementing the system. From Figure 59 b) we can see that the database server queues the requests and that in the end, all the data is well written, despite being too late. Nevertheless, care has to be taken not to design a system that writes too many entries. The database writing strategy should be designed such that the writing latency is kept to a minimum. From the results we see that the latency is acceptable when we are under 3000 entries. Taking into account the number of connected sensors and their sample rates, we can decide on a proper writing interval that holds for some time. Still, surgery typically lasts for several hours, ranging from shortly bellow one hour to, sometimes, 10 hours. Possibly, keeping the entries bellow 3000 would mean that we would be limited to having 300 entries per hour which would be far too less if we want the system to hold more comprehensive data. This would be 30 samples per sensor per hour if we would have 10 sensors connected which might be acceptable just to implement the immediate QoS mechanism but is quite low if the idea is also to keep a log of the data transmission quality which can be useful for documentation. A possibility would be to have a separate application which handles data housekeeping. The application could periodically read the database contents, storing them in a separate file and cleaning the database which would be back to a low writing latency state (Figure 60). With careful choice of timings, such a system could function well for many hours and record a proper amount of data.

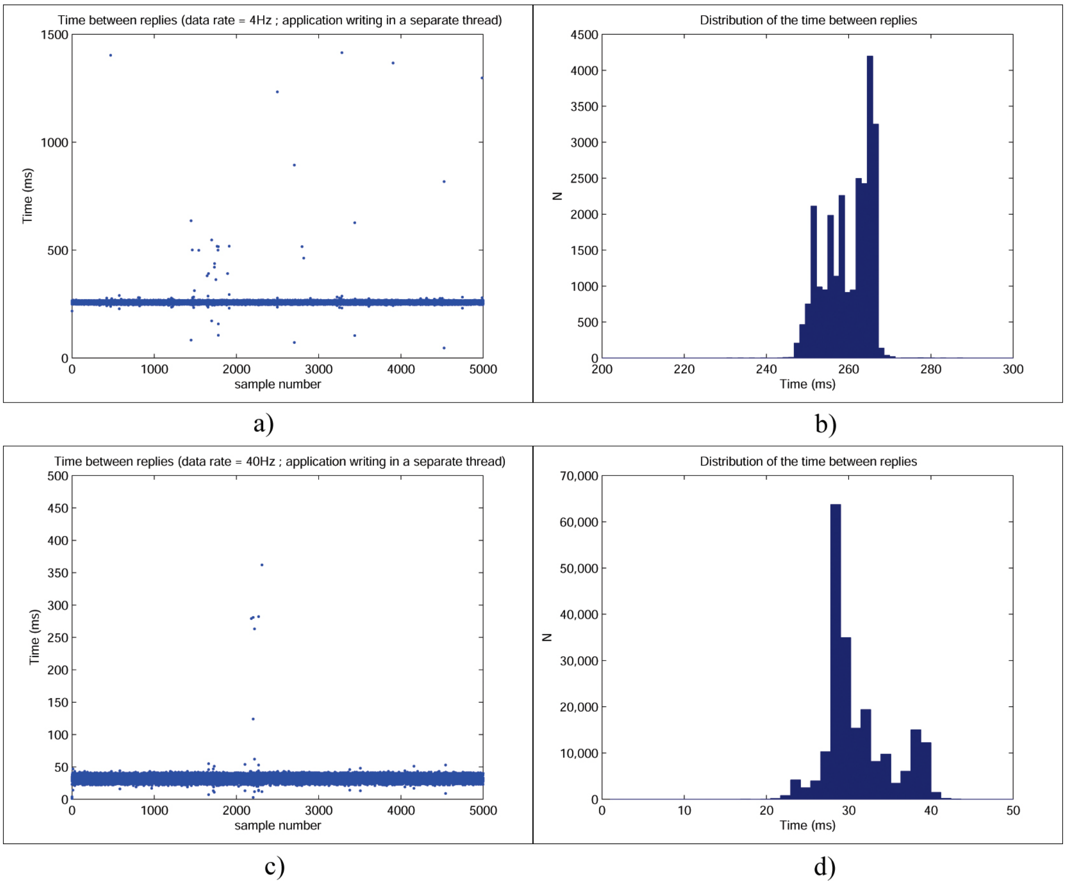
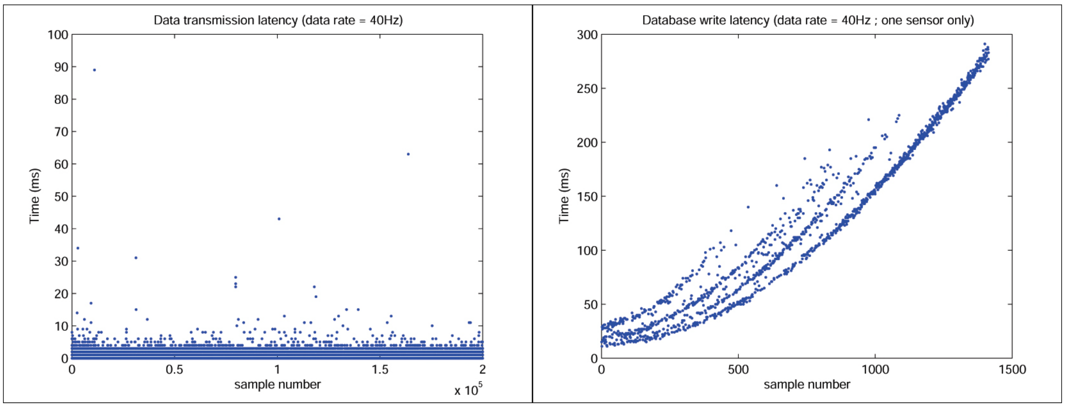


Figure 58 - Results while writing in the database with a separate thread. In this case, the interval between consecutive samples arrive at the destination is consistent with the data rate which is what is expected.



a) b)

Figure 59 - Relationship between the data transmission latency and the database writing latency. We see that the data transmission latency doesn't increase a) even if the database writing latency does b).

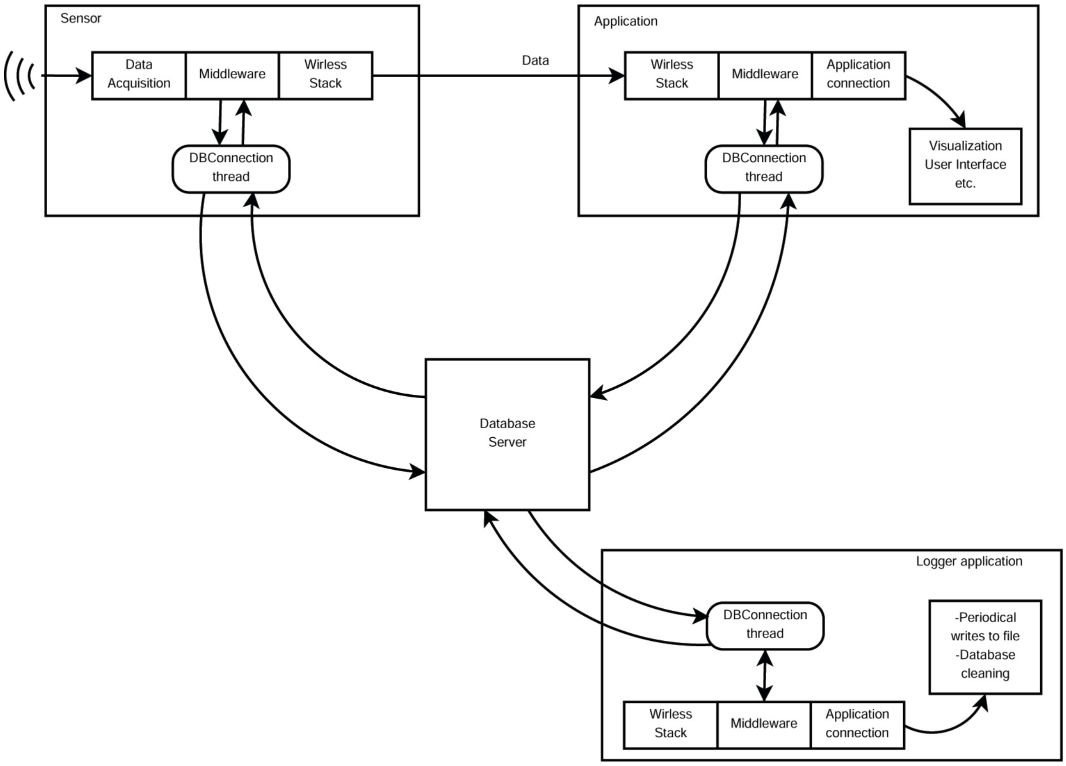


Figure 60 - Example of application and sensor connection showing the middleware communicating with the database server through separate tasks and the logger application, used for logging data to file and cleaning the database to achieve low access latencies. In this case the sensor also connects to the DB through a separate thread whether it is only for initial DB registering or to log timestamp values.

4.6 Foreseen scenarios

Figure 61 shows a vision of one foreseen scenario on how the application could be interfaced with the wireless sensors. The pressure sensors as well as both of the application's actuators are interfaced to the PCs through low power wireless networks.

Note that, in the picture, only data connections are shown for simplicity but these are managed though server negotiation connections as always. The exemplified scenario can be seen as a natural extension to the application described in Chapter 3.

A separate application is also included. The context-aware application depicted in the image has access to the data present on the database server and can use the data to derive contextual logic about the state of the surgery and warn the team about unusual situations, in a similar way as described in [37]. The interesting point is that the cardiac application is unaware that a separate application is running and using data produced by it. Both applications can coexist without a single modification to the cardiac application. This possibility for indirect collaboration by sharing data through the server is very interesting.

On another perspective, the current architecture can also be used to implement typical CAS applications in different ways. In fact, processing blocks like registration could be implemented as separate applications instead of tying them intrinsically in the main application. Normally, the main application receives spatial information data from position sensors and performs registration calculations based on this data and user input. A separate application, dedicated only to registration, could receive the data and perform calculations. The application would have as sensor inputs the spatial data and the user input. Then, after calculation, the application would publish its data on the network, as a regular sensor. The main application could then receive the already transformed data, not having to worry about registration. Such setup can be very useful to test different registration algorithms as developers could concentrate only on this without having to worry about the complex frameworks for CAS application development.

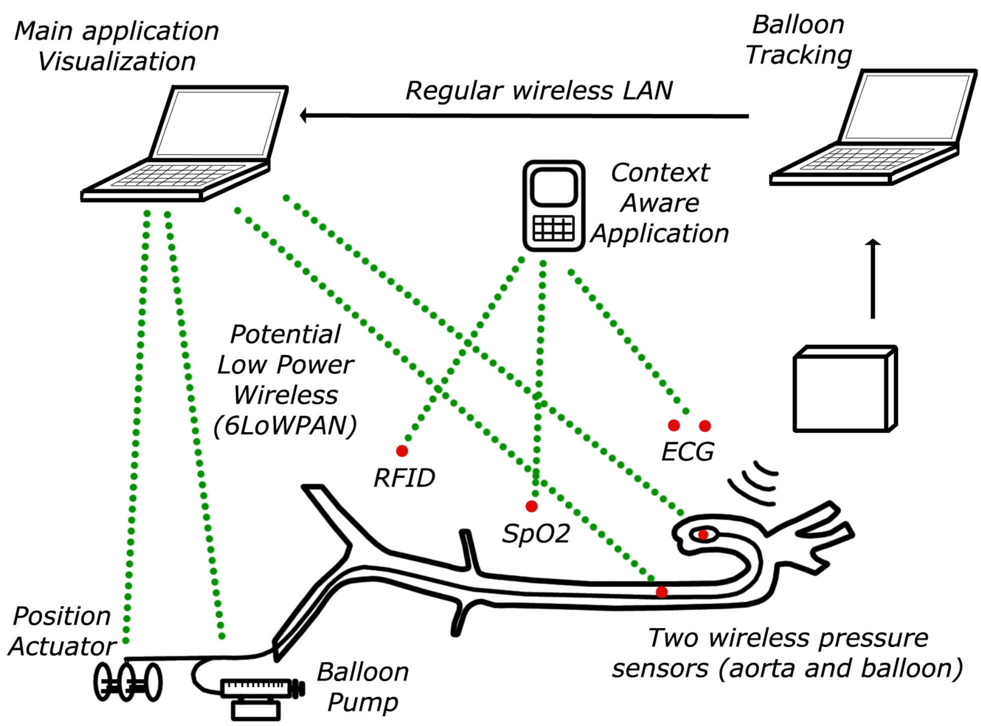


Figure 61 - Foreseen integration scenario

4.7 Discussion

Our proposal aimed at implementing a formal architecture for the integration of wireless sensor networks in minimally invasive surgery. The motivations for this were to profit from new wireless sensing technology and the opportunity it presents for MIS while also achieving better safety for applications that are distributed and communicating over the network. We expect that this would foster the development of new applications due to the flexibility and increase application acceptance due to an increase in safety.

We chose to approach the problem in a simplified way. The reasons were mentioned in Section 2.4: on the one hand, it is feasible to approach the problem only with a middleware component and on the other hand, at the moment available IPv6 compatible network stacks lead us to believe that this is the best choice for interfacing wireless sensors with existing applications. Our main objective was to test whether it would be feasible to implement such an architecture.

Our design has shown the intended flexibility as it allows for any kind of sensor to be interfaced with applications. Sensing data types are registered in the database and applications subscribe to them based on their needs. The complexity of the underlying network is hidden by the middleware and the applications only see data that they can subscribe to. Because of this flexibility, applications can be designed to depend on a variable number of sources of information of different kinds. Data connections can even change at runtime as an application, automatically or through user input, might request new sources of data at any point in time. The sensors can be combined in any way and so, more complex applications can easily be developed on top of the architecture. Applications can feed on several sensor data, process it to produce higher level information, and output these results as new data to the network. Also, several applications can reside side by side, using the network infrastructure without interfering with each other. The conceptual separation of network from applications provides the necessary modularity so that development of new products is much easier.

From the simulated results, it is also shown that it is easy to store meta-data about the data connections taking place, to constantly ensure data transmission quality. This is important in AR applications for medicine as surgeon's reactions are dependent of the quality of received data. Too high latency or too frequent interruptions in sensitive data (like the pressure of a balloon catheter for instance) might cause discomfort or might even make it unfeasible to use the system. These real-time constraints differ from typical WSN requirements where power consumption, for instance, is one of the main constraints.

The existing *muddleware* server was sufficient for our first implementation. In what concerns registering nodes and connections in the database and generating warnings when these nodes change, database access are very smooth and the mechanism work flawlessly. But to address the QoS issue, our measurements of simulated scenarios have shown that care has to be taken on choosing a proper database writing policy, so that the architecture doesn't add unnecessary delay on the data connections and so that the data is available in the database in a timely fashion. It was seen that for very fast sampled data the *muddleware* server cannot cope with registering a new entry for every data sample. In any case it is sufficient, depending on the application requirements, to register only periodical information about the connection, e.g. once every minute. This has to be decided case by case. The time values obtained are of course dependent on the platform where we simulated the architecture. So, to better understand the impact, in the future simulations have to be executed in different platforms. Nevertheless, the writing times are quite high for our purpose even in a fast platform such as the one we used. This means that either a dedicated database server should be used or, as depicted in Figure 60, special writing strategies have to be adopted so the server access doesn't interfere with normal data transmission.

There are also many open possibilities on which metadata to calculate and store. Over the period between two database writes, statistics about the transmitted data samples can be made. For example, the maximum, minimum and average latency can be calculated and also registered on the DB server. Another interesting possibility could be for the sensor to calculate a checksum of the data transmitted between database writes and register the checksum in the server. The application would also calculate the checksum of the received data, and comparing it with the one stored in the DB. Like this, a mechanism for detection of corrupted data could be in place. Usefulness of these mechanisms has to be further investigated.

Extending the *muddleware* server with other server-side functionalities is easy. A good approach is to design blocks of logic acting also as clients. Since all the information about the network nodes is in the database, any client application has access to all the data. Reasoning on the available data, a safety policy can be enforced, decisions made based on the available information and actions taken. This can be in the form of generating more warnings or adding new database entries so that applications can decide on their own actions when safety is not guaranteed. Important in a future implementation, is adding new tables in the database where applications can specify their own safety requirements. Being able to define which parameters are important allows for maximum flexibility so different kinds of applications can benefit from the middleware.

In our work we assume that IP connectivity is achievable for the wireless nodes. While this is not always the case for many available hardware platforms, we focused on solving the safety and connectivity issues assuming this simplification mainly for two reasons. First, hardware restrictions for OR application will be different that typical restrictions for other applications. Especially, power consumption will probably not be one of the main concerns, as consecutive operating time before a recharge is generally under one day (the time of a surgery). On the other hand, it is argued that with careful design, the performance of an IPv6 based stack can be comparable or better than other existing custom approaches [136]. As an example, the NanoStack, a commercial 6LoWPAN implementation from Sensinode [163] shows good results. This has nevertheless to be further investigated as for instance in [164] the authors show that the 6LoWPAN stack is unable to meet the requirements for some medical applications. For our application, the matter has to be further investigated, in particular through better definition of the requirements for the OR and with an implementation and evaluation in real hardware.

5 Conclusions and final considerations

In this chapter we summarize the main results obtained during the course of this thesis work. The results are matched with the research directions defined in beginning of this document. We finish with some general considerations.

5.1 Outline of main results

In the previous chapters we presented our solutions for supporting minimally invasive procedures which resulted in a fully working computer assisted surgery prototype and in an architecture design for integration of wireless sensors with this type of software. The work presented before follows the directions established in Chapter 1.

Implementation and impact of the prototype. A system for visualization and control of the position and pressure of the endoclamp aortic balloon catheter was implemented. It is a simple and pragmatic solution conceived to enhance the safety of sealing the aorta during cardio-pulmonary bypass in minimally invasive mitral valve procedures. The user tests demonstrate the advantages of the visualization system: in the tests performed using a phantom, 92% of the users performed the tasks successfully. From these, the majority placed the catheter faster and more accurately than when using a visual support similar to the one used at the present time. The users also rated the system as supporting them much better than the current visual support, with 7.75 points against 4.5 points out of 10.

Regarding automatic placement of the catheter, the mechanical actuator could always position the balloon catheter in the targets within a range of ±5mm, as specified. Also, it was faster and more accurate than similar human placements. These results show that the system we designed acquires enough information to implement a **robust control loop** for automatic balloon placement.

Thus, the proposed system presents clear benefits in comparison with the current situation. 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. The results demonstrate that the system has the potential to make the port-access technique **safer**, **reducing surgery times** and the **learning curve** for the surgical teams.

Animal studies. Results form the animal tests are preliminary. One important finding is that rigid registration with fiducial markers, where the error was less than 5mm, is sufficient to provide good alignment for intuitive visualization of the balloon within the porcine aorta. This is an important verification of the assumption of local rigidity during this surgical procedure.

Integration of wireless sensing technology in minimally invasive surgery. We proposed an architecture for the integration of wireless sensors in computer aided surgery applications in a transparent manner. From our simulated results, we can draw two important conclusions. First, it is straightforward and useful to have a sensor discovery and connection mechanism for applications. In this way, applications can easily receive data from any kind of sensor. Second, is feasible to provide quality-of-service monitoring mechanisms in a useful way, without interfering in normal data transmission. The measurements were made with simulated sensors and a component which was not specifically designed for performance under these conditions. They show that with an adequate choice of parameters it is possible to include enough information about data transmission quality in the database, so that quality-of-service monitoring mechanisms can be in place. This demonstrates the feasibility of the mechanism, which was the main contribution of the work presented in chapter 4.

5.2 Final considerations

The work presented on this thesis is focused on systems that provide technology support for surgery. In particular, we were concerned with systems designed specifically for the operating room, to aid in coping with the limitations that surgeons and surgical teams face while performing minimally invasive surgery.

The presented results and analyses are relevant to different fields: medical, computer and wireless communication sciences. The philosophy with which each of the parts of the work was approached was also different.

The work presented in Chapter 3 focused on the development of an information technology system to support a very specific medical procedure. As such, the results are very concrete and the future direction to follow is very obvious. On the other hand, the work presented in Chapter 4 is of a more theoretical and exploratory nature. It has the intent of opening the way for future developments based on technology opportunities rather than on a specific need. Thus, the final result as a whole is an interesting combination: a concrete system that effectively supports the surgical team during minimally invasive cardiac surgery and, an architecture proposal to enhance the system with different kinds of wireless sensors in an almost transparent way. Given that this type of sensors are expected to be ubiquitous in a few years, exploring the best ways to easily interconnect computer assisted surgery applications with this technology was an important step.

We would finally wish to stress that the user centered design methodology, used to analyze and derive a conceptual solution for the medical problem was a key factor for the success of the prototype presented in Chapter 3. This kind of structured design methodology is extremely important in a multidisciplinary environment, as finding effective ways to communicate and exchange knowledge across such different domains is a big challenge. This difficulty is many times underestimated.

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Appendix 1: Usability questionnaire

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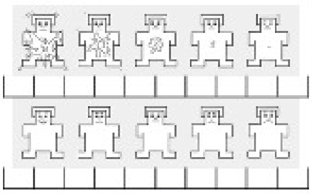
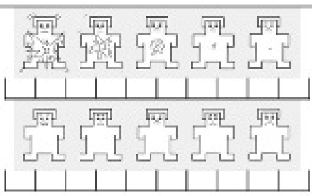
experimental setup

Task	Where, what	
Warm up: Get to know the cardiac phantom. Please ask the study coordinator as soon as you feel unsure about anything.	1. Let you explain the task. 2. Get used to the system and it's functionalities	Warm up
Test(s): Do the insertion and the placement of the ballon at it's target place as fast and as accurate as possible.	1. **Total view** (6 placements) Either **System** (6 placements) Or **Restricted view** - target possition (6 placements)	Test
Review	3. Fill in the usability questionnaire 4. Any other remarks? Feel free to comment	Conclusive session

actual psychological strain

"Now I feel like..."			
Base line	released worried relaxed skeptic comfortable	oppressive mindless restive trusting unwell	
After test	released worried relaxed skeptic comfortable	oppressive mindless restive trusting unwell	

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questionnaire

Warm-up or learning phase:	
How difficult was it to learn the different functions of the system e.g. CT views, 3D view, tracking info?	Please rate 0 1 2 3 4 5 6 7 8 9 10 not at all very much
How much confident were you after the warm-up phase to fullfill the tasks successfully?	Please rate 0 1 2 3 4 5 6 7 8 9 10 not at all very much
Placement:	
How much did the **total view** support you to do the task?	Please rate 0 1 2 3 4 5 6 7 8 9 10 not at all very much
How much did the **system** support you to do the task?	Please rate 0 1 2 3 4 5 6 7 8 9 10 not at all very much
How much did the **restricted view** support you to the task?	Please rate 0 1 2 3 4 5 6 7 8 9 10 not at all very much
How **efficient** (efficiency = time x output, here accuray) have you been with the **total view**?	Please rate 0 1 2 3 4 5 6 7 8 9 10 not at all very much
How **efficient** (efficiency = time x output, here accuray) have you been with the **system**?	Please rate 0 1 2 3 4 5 6 7 8 9 10 not at all very much
How **efficient** (efficiency = time x output, here accuray) have you been with the **restricted view**?	Please rate 0 1 2 3 4 5 6 7 8 9 10 not at all very much
System: How important were the **different views** for you?	3D 0 1 2 3 4 5 6 7 8 9 10 not at all very much 2D - transversal 0 1 2 3 4 5 6 7 8 9 10 not at all very much 2D - sagital 0 1 2 3 4 5 6 7 8 9 10 not at all very much
System: How much did you **like** it personnally to use the system (satisfaction, personal preferance)?	Please rate 0 1 2 3 4 5 6 7 8 9 10 not at all very much
System: How good was the tool to define the **final placement** of the balloon?	Please rate 0 1 2 3 4 5 6 7 8 9 10 not at all very much

Appendix 2: Publications related to this thesis

The conditions for defense of this thesis were fulfilled by the following publications:

- Furtado, H. ; Geršak, B., Sette, M. ; Famaey, N. ; Stüdeli, T. ; Samset, E. Automatic Catheter Positioning System, *Patent Application number* PCT/NL2009/050314

- Furtado, H. ; Stüdeli, T. ; Sette, M. ; Morita, T. ; Trunk, P., Freudenthal, A. ; Samset, E. ; Bergsland, J. ; Geršak, B. Endoclamp Balloon Visualization and Automatic Placement System, *The Heart Surgery Forum*, **13** (4) 2010