Workflow Driven Decision Support Systems

A case of an intra-operative visualization system for surgeons

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Workflow Driven Decision Support Systems

A case of an intra-operative visualization system for surgeons

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For my father,

who taught me the joys of reasoning!

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CHAPTER 1 INTRODUCTION

1.1 Overview

"The image quality of the Ultrasound (US) was poor, the transducer was large, and therefore I couldn't easily reach beyond the surface of the liver. … Finally, I saw a tumor in the US. Was this the same tumor I intended to ablate? I was not sure…I had to decide; for this I needed more input. I palpated and tried to compare what I see in the US. It was "the" tumor, but the next issue was, how do I get the needle in place? It was so difficult to put the needle into place, how to decide which trajectory is optimal? Meanwhile, I turned back to see the US, the tumor was gone,….and I felt I saw another larger tumor? Or, was it a cyst? ….we feel lost sometimes…" statements of clinicians in a focus group session held at a Erasmuc MC, The Netherlands.

Science is work in progress, where unanswered questions are accepted and experimentation is encouraged. But in medical science, where lives are at stake, things are different. We want our surgeons to be perfectly skilled and informed, and for healthcare to be a field of order, knowledge, and defined procedures. Uncertainty, however, is a part of everyday life in surgical decision-making, and one of the reasons for medical errors (Gawande 2002). In the context of this thesis, these statements as quoted above refer to one such instance during an innovative surgical technique called Minimally Invasive Surgeries (MIS). While performing MIS, the lack of intra-operative visualization of the patient's anatomical structures available to the intervention radiologist leads to uncertainty in decision making, thus affecting the performance of the clinical action. Inadequate intra-operative visualization aids and the need to reduce clinical errors encourages technology engineers and designers to develop decision support systems for the visualization of patient information.

Innovative surgical techniques such as MIS (Brooks 1998) and ‘robotic surgery’ (Powell 2000) have brought about rapid change in surgical theatres, and led to technological development, especially in the area of computer aided surgical systems (Taylor et al. 1996), including (a) surgical robotics for minimally invasive surgery (Argenziano 2002) and (b) virtual reality systems for liver planning (Reitinger et al. 2006). More recently, Intra-operative Visualization Systems (IVS), which provide real-time image guidance of patient information during surgery, have been developed. Examples of these are Auto-stereoscopic Visualization for image-guided navigation in liver surgery (Vetter et al. 2002) and Augmented Reality to guide tumor ablation (Nicolau et al. 2005). Developments in the area of visualization systems for the surgical workspace are being influenced by technological trends in visualization tools like Augmented Reality (AR) and Virtual Reality (VR). However, there is often a gap between the solutions offered and those actually required by the surgeons, resulting in errors and affecting patient safety (Patel et al. 2001; Jalote-Parmar and Badke-Schaub 2008a). For example, AR as a visualization tool has been attracting attention over the past decade, but finding the right application in a decision support system in the surgical workspace remains an issue (Shuhaiber 2004).

Like other complex workspaces, for example, a pilot’s cockpit, surgical theatre is characterized by (a) dynamic and interconnected problem solving events (Rasmussen 1986; Woods 1988), (b) the unpredictability of events (Klein et al. 1993; Badke-Schaub and Buerschaper 2001; Hunink 2005) and (c) low tolerance of errors (Reason 1990; Bogner 1994; Reason 2000). Specifically, in complex workspaces such as the surgical theatre, where errors in human decision-making may affect patient safety (Bogner 1997), it is crucial that the solutions offered are driven by surgical (user) requirements and are not imposed by technological solutions. Literature states that ‘user-centered design’ aims to optimize the development of how users can, want or need to work, rather than forcing them to change how they work in order to accommodate the system or function (Preece et al. 1994). In particular, significant research in the domain of medical informatics confirms the importance and need, for understanding of cognitive processes to develop user-centered systems (Patel and Kaufman 1998; Patel et al. 2001). Previous research indicates several well established theories and various models of information processing (Rasmussen 1986; Andersen and Olsen 1998) and decision-making (Klein et al. 1993) that have been applied to design decision support systems to reduce errors and improve human performance in fields such as aviation (Baron 1988; Hopkin 1988) and healthcare (Gaba and Howard 1995; Bogner 1997; Xiao.Y et al. 1997).

Integrating abilities and limitations of human information processing to design decision support systems for complex workspaces has been a challenge for researchers over the past couple of decades. However, its application in the development of decision support systems, such as IVS, for surgical theatres is a new area of research, so it is necessary to develop scientific knowledge to inform the development. This thesis therefore proposes a framework to generate knowledge of surgical problem solving process to inform the development of IVS. It will further apply this framework to design IVS prototypes which provide decision-making support during MIS.

1.2 Research premise: pan-EU project

This research stems from the pan-European research project known as ARIS*ER-Augmented Reality in Surgery (ARIS*ER 2005), funded by the European Union as a part of the 6th framework program for research under the Marie Curie Program for Human Resources and Mobility. ARIS*ER aims to develop visualization systems to provide intra-operative surgery imaging and procedural support for MIS. During the ARIS*ER project three MIS procedures were selected for technological development: (a) Radio Frequency Ablation (RFA) (b) Endoscopic Liver Resection and (c) Endoscopic Mitral Valve Repair. IVS prototypes were developed for two procedures: RFA (Jalote-Parmar et al. 2009) and endoscopic liver resection (Lambata et al. 2008). Research was conducted in a similar manner for both the selected procedures and the development process of IVS for RFA is explained in this thesis. The multidisciplinary research team included surgeons, radiologists, technology engineers, a Human-Computer Interaction (HCI) designer and ergonomists from eight pan-European countries working in close co-operation (Fig.1). As can be seen in Fig. 1, the role of the design researcher is to establish a user-centered and collaborative design to support the development of IVS. The team had seven PhD researchers, six from the technology engineering groups and one (the author) from the human computer interaction design group. Apart from the PhD researchers, post doctoral fellows and senior scientists researched different aspects of the project. For example, at Delft there was a post doctoral fellow and a senior scientist from the field of ergonomics.

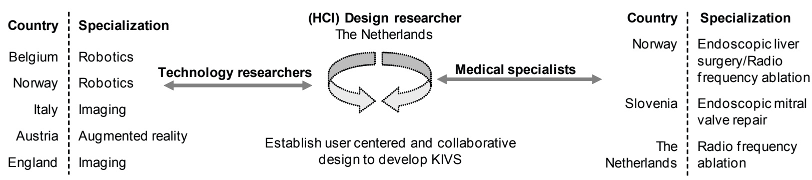


Fig.1. Role of the design researcher in the ARIS*ER consortium.

1.3 Problem case: Minimally invasive surgery

As a part of the EU project, the research presented in this thesis will focus on the design and development of IVS for MIS. MIS is conducted by making small incisions in the patient's body with specialized techniques and tools. Flexible tiny fiber-optic flashlights fixed with miniature cameras are inserted in the incisions to generate images which are displayed on high-resolution monitors. The types of MIS performed include Radio Frequency Ablation or RFA (Solbiati et al. 1999), mitral valve repair (Mehmanesh et al. 2002) and endoscopic liver surgery (Hironori et al. 2008). Although MIS has been welcomed with enthusiasm by some clinicians, others have voiced concern or even skepticism. Those supporting the minimally invasive approach point to the potential benefits, such as reduced soft tissue trauma, reduced postoperative pain, and quicker rehabilitation. Compared to the open surgery, there are several advantages for the patient undergoing MIS:

- Faster recovery and reduced pain due to less surgical trauma
- Smaller surgical incisions lead to smaller surgical scars (aesthetic reasons)
- Economic gain (shorter illness, hospital stay).

1.4 Difficulties with performing Minimally Invasive Surgery

Skeptics are concerned with the difficulties that surgeons are confronted while performing MIS in comparison to the open surgery. These difficulties, affect the quality of the surgical performance and are often the source of surgical errors. Several technological innovations are being researched to support the surgeon to cope with difficulties arising from MIS. Below is a list of issues that affect the performance of MIS and the related technological developments:

1 *High learning curve*
MIS is a completely different approach to open surgery. Even experienced surgeons require a lot of training to perform and master it. Several surgical simulators and training programs are currently being developed to introduce this technique to the surgeons (Mc Cloy and Stone 2001).

2 *Difficulty handling the instruments*
Due to restricted availability of entry ports to introduce the instruments and camera into the patient's body, there is reduced mobility and, therefore, increased risk of clinical complications. Several surgical robotic systems are being developed to support automation of instrument handling (Powell 2000).

3 *Hand-eye coordination difficulty*
The view of the patient anatomy is captured by the laproscopic camera inserted inside the patient's body. Laproscopic camera input is displayed on the monitor placed in front of the surgeon. The visualization of the patient's anatomy displayed on the monitor poses difficulties in co-coordinating the clinical action while observing the monitor. This requires enhanced spatial skills to develop hand and eye co-ordination. Several interactive simulators that provide hands-on training in endoscopic procedures with true-to-life sensations during performance are being developed (Basdogan et al. 2004).

4 *Reduced haptics*
During open surgery, surgeons can make a reasonably large slit in the patient's body to perform the intervention, allowing them to both view and feel the organs. However, while performing MIS, the surgeon has to rely on the surgical instrument and video feedback obtained from the camera (visual haptics) to 'feel' the patient's body. This situation reduces the haptic feedback by eliminating forced feedback and tactile sensation, a very important diagnostic tool which surgeons rely on when performing surgical actions. When performing MIS, the surgeon needs to become skilled enough to compensate for the loss of haptics by learning to 'feel' through the instruments and the video input. This is also true in the case of robotically performed MIS. Several innovations which explore the use of forced feedback impulse devices in virtual reality simulators, e.g. training simulators, are in development (Mc Cloy and Stone 2001; McLaughlin et al. 2001; Basdogan et al. 2004). This allows for the creation of a more realistic situation where a surgeon can learn operative skills that will readily translate into the operating room. More recently, research is being conducted into the area of tactile sensing technology for robot assisted MIS.

5 *Inadequate visualization of the operative landmarks and patient anatomy*
While performing MIS, surgeons experience a new approach to visualization of surgical tools, operative landmarks and patient anatomy. This leads to several issues with the visualization of patient data, including: (a) In order to perform the surgical action, the surgeon must be aware of the location of the surgical instrument in the patient's body. Due to the camera placed inside the patient's body the surgeons have a different view of the patient anatomy in comparison to open surgery. In open surgery surgeons view patient data directly in 3D. While in MIS the surgeon view the patient data on a 2D screen which displays the endoscopic video. This view of the patient anatomy is different and often limited as it lacks in the context view of surrounding work space and organs. This requires the surgeon to mentally reconstruct the patient's anatomy to obtain the overall picture of their location in the patient body. (b) Surgeons have a limited view of the instruments inside the patient's body. This view is dependent on the viewing angle

of the endiscopic camera. For example, if the instrument is out of the camera's view then it is not visible. This often leads to surgical errors. (c) Due to relatively small incisions in the patient's body, the visualization of the patient anatomy is restricted. The different view of the patient anatomy, together with inadequate visualization of the patient anatomy, anatomical landmarks and surgical instruments, increases operative difficulty.

Although all these issues are critical to performing MIS, in accordance with the goal of the ARIS*ER project, this thesis focuses on providing visualization support to the surgeons as a means to improve the quality of MIS.

1.5 Innovative technologies for the development of medical visualization

One of the ways to address the visualization issues like those mentioned above requires providing real-time information to the surgeon such as, context view of patient organ, location of the surgical tools. To guide task visualization and navigation during operations by improving the quality of real-time visualization of the patient anatomy is a new area of research and development, with research being conducted into medical imaging technology, which includes:

1 *Image registration*
Image registration is the process of estimating the geometrical relationship between two images which may have been acquired at different times, perhaps even from different positions (McLaughlin 2007; Milko and McLaughlin 2007). It is necessary in the development of 3D visualization of patient data acquired from different imaging modalities. Currently, research is being conducted into image fusion by registering 2D Ultrasound (US) images to Magnetic Resonance Imaging (MRI) data and Computerized Tomography (CT).

2 *Image segmentation*
Image segmentation is required to extract the necessary patient data from the imaging modality (e.g. CT) to generate a 3D model of the target organ. It involves automated segmentation of the targeted organs and classification of their tissues to generate a 3D imaging of the patient data. Research is being conducted into generating segments of liver, vessels and tumors using MRI and CT data (Casciaro et al. 2006).

3 *Visualization techniques*
There are several possibilities for visualizing patient data that is extracted from imaging modality. Several visualization techniques are being developed for visualizing surgical planning and patient data intra-operatively. An example of such a technique in development

is: ‘Augmented Reality’. This explores the application of computer-generated imagery in live-video streams as a means to expanding the real world. Advanced research includes the use of head-mounted displays and virtual retinal displays for visualization purposes (Shuhaiber 2004). It is often visible in the television broadcasting of games, for example a video image of a swimming pool is overlaid with the graphical image of the national flag representing the candidates in different lanes. Research is being conducted into its use in medical visualization in the surgical theatre.

1.6 The need for a knowledge intensive visualization system

The technological innovations as mentioned above are only a means to generate the patient data from various imaging technologies. They are however, not complete-stand alone- solutions in themselves, and while they can generate a plethora of patient information, not all of it is required by the surgeons while performing the task. This implies that these technological innovations need to be integrated into a visualization system that compiles the required real-time patient information, before presenting it to the surgeon. The development of such a system presents two main challenges:

- Integration of different technologies on a single platform to develop a real-time visualization system which is technically robust enough to function in the surgical theater.
- Visualizing critical and timely patient information which is aimed at supporting surgical decision-making.

Efforts in the development of real-time visualization systems are in their infancy and researchers are still struggling with the first challenge mentioned above (i.e. the technical integration of the different technologies). Examples of visualization systems for MIS in development are: (a) An ultrasound guided laparoscopic RFA (Bao et al. 2007), which uses an infra-red camera to track instruments, runs on a personal computer, and includes spatially registered ultrasound visualization, volume reconstruction and interactive targeting. (b) A treatment planning tool (Villard et al. 2005) which provides radiologists with a better visualization of the patient’s anatomic structures, and facilitates finding adequate treatment.

The second challenge, of visualizing critical and timely patient information, which is aimed at improving surgical decision-making has received only scant attention in literature until now and will be addressed in this thesis. Since visualization which supports surgical decision-making is dependent on the knowledge of how the surgeon solves problems and makes decisions while performing the procedure. Developing a technically robust visualization system which integrates the technological innovation may allow visualization of patient data but may not be able to adequately support surgical decision making. It is, therefore, necessary to develop a system which is not only “technology intensive” but also “knowledge intensive”. This means these systems should aim to enhance the knowledge necessary for informed decisions by providing the surgeon with the necessary patient information. To achieve this, such systems should be based on the understanding of surgical problem-solving processes to be able to visualize patient information. In this, thesis such a visualization system is termed Knowledge Intensive Visualization System (KIVS). An application case of an MIS procedure called Radio Frequency Ablation (RFA) has been selected to develop KIVS.

1.7 Application case for KIVS development: Radio Frequency Ablation

RFA is a ‘Minimally invasive procedure’ where part of the electrical conduction system of the heart, tumor or other dysfunctional tissue is ablated using high frequency alternating current. It is commonly performed to treat tumors in the lungs, liver, kidneys and the bones. Once the diagnosis of tumor is confirmed, a needle-like RFA probe is placed inside the tumor. The radiofrequency waves passing through the probe increases the temperature within the tumor tissue, resulting in its destruction. RFA is usually used to treat patients with small tumors that originate within the organ (primary tumors) or that spread to the organ (metastasis).

In order to develop the KIVS, RFA for treating tumors in the liver was selected. As a surgical alternative to the treatment of unresectable liver tumors, RFA is considered as one of the easiest, safest and most predictable procedures (Lai et al. 2009). The emission of radiofrequency from the tip of a needle-like probe heats and causes necrosis (cell death) of the cancerous cell (Fig.2). It is mainly performed by the surgeons or intervention radiologists either during laparoscopic procedures (Topal et al. 2003) or percutaneously (Solbiati et al. 1999). Percutaneous RFA can be understood as when a radio frequency needle is inserted into the patient skin to ablate a tumor in the liver, but no other incisions are made. The percutaneous approach is clinically more practical and less invasive and, at the time of commencement, it was selected on the basis of the opinions of the clinicians belonging to the partnering hospitals in the ARIS*ER project.

Percutaneous RFA is commonly an Ultrasound (US) guided procedure mainly performed by the intervention radiologist. Well known drawbacks of US such as variable sound waves caused by nature of different tissues, add confusion and limit its role in providing adequate visualization to perform RFA. The lack of adequate visualization has caused technical

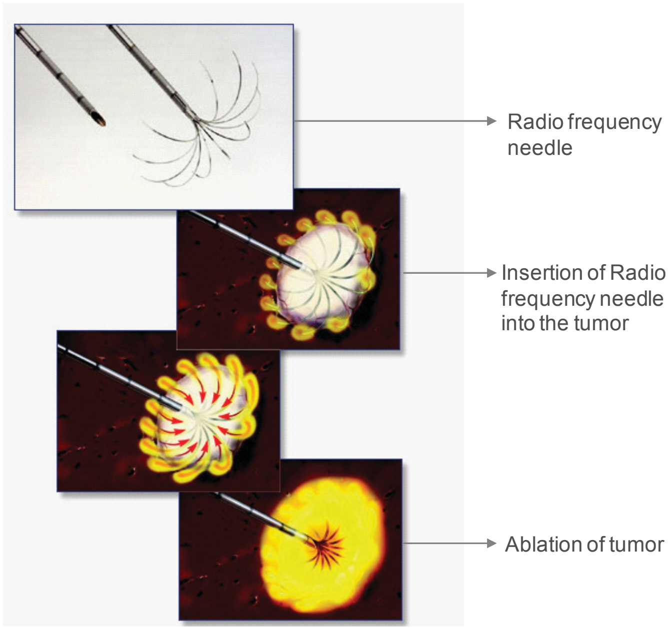


Fig.2. Illustration of RFA procedure
(photo courtesy www.sanantoniosurgery.com)

failures in the RFA procedures, thereby leading to clinical errors and hence the procedures have to be repeated (Rhim et al. 2008). Clearly, with better image guidance, the clinical quality and clinical acceptance of this procedure can be improved (Solbiati et al. 1999).

1.8 Research problem

The problem dealt within this research relates to the development of a KIVS to support surgical decision-making, thus reducing errors in MIS. In order to make informed decisions of what patient information needs to be visualized and how it needs to be visualized it is necessary to know how surgeons conduct such procedures and which factors affect their problem solving process. Access to this knowledge requires a formal mechanism to make structured inquiries into the surgical workspace. Since the development of IVS is a relatively new area of research, there is no clear reference in literature to how IVS are developed from the point of view of the surgeon, neither is there any mention of a structured methodology to be applied to support user-centered technological development. This issue is similar to the development of medical systems in healthcare, where the development is a decade or more behind other high-risk industries in its adaptation to user-centered approach to improve performance and prevent errors (Bogner 1994; Kohn et al. 1999). Recent studies on improving the safety of healthcare indicate an urgent need to build a 'knowledge base', better understood as a 'knowledge repository' of user and work context. This is necessary for the systematic development of medical systems (Buckle et al. 2006). Addressing this requirement this thesis is concerned with proposing a framework to develop a knowledge repository of surgical needs and a surgical problem solving process to guide the user-centered development of KIVS.

1.9 Research and design challenges

The development of the KIVS necessitates extracting and integrating information generated from different imaging technologies in order to visualize the patient information to support surgical decision making. Thus, the development of KIVS present the following challenges to the design researcher:

1.9.1 Analyze cognitive processes to assess surgical requirements

The development of KIVS is critically dependent on the knowledge of surgical problem solving process. To build a knowledge repository of surgical problem solving process requires an accurate assessment of surgical procedure, surgical problems and related information requirements. Research in the area of medical informatics emphasizes the importance of understanding cognitive processes to support user-centered development of decision-making systems for complex workspaces (Patel and Kaufman 1998; Patel et al. 2001; Kushniruk 2002). Since, empirical studies have demonstrated the benefits of including cognitive theories into system design and pedagogy to develop decision-making systems which lead to safer working environments and the prevention of errors (Patel et al. 2001). Therefore, it is essential to integrate knowledge of cognitive theories as a key component in the development of the knowledge repository.

1.9.2 Real-time information visualization for surgical workspace

Here, information visualization can be understood as real-time information provided as an interactive visual representation of data in order to augment cognition (Card et al. 1999; Spence 2001). Real-time patient information, such as planning information based on pre-operative patient data and real-time imaging feedback from the patient's body, may be processed from various sources within the surgical workspace. Due to the variety of information sources, there is always a bottleneck because surgeons can only pay attention to a specific information. As a consequence of scattered information, there exists a gap between the amount of data being produced and disseminated and the surgeon's ability to find the bits that are needed, to integrate them with the other bits and to arrive at the actual information needed (Jalote-Parmar et al. 2006).

Therefore, in order to support surgical decision-making, it is essential that only the relevant patient information is extracted from the various sources. Further, this extracted patient information needs to be visualized at the right level of detail and to be presented at the right time to the surgeon. Like other complex workspaces, such as aviation, the development of KIVS for the surgical workspace depends on the knowledge of the factors which influence expert decision-making in naturalistic environments (Klein et al. 1993). Theoretical concepts which provide an explanation about how to improve informational support of critical factors related to surgical procedures may thus assist in the development of better decision-making systems (Klein et al. 1993; Endsley 1995).

1.9.3 Establish collaborative design between multidisciplinary development team

The development of KIVS for the surgical workspace not only depends on the technologists or the designers but also on collaborative design between technology engineers, designers and surgeons (Jalote-Parmar and Badke-Schaub 2008a). Therefore, it is critical that the knowledge of surgical procedures and requirements is systematically communicated to members of the multidisciplinary development team at all stages of the development.

1.10 Aim of the thesis

The aim of this research is to propose a design framework to generate a knowledge repository of the surgical problem-solving process and apply this knowledge to inform a user-centered development of KIVS. This thesis focuses on answering the following research questions:

- *What are the constituents or task boundaries of the surgical workspace that influence the surgical problem-solving process?*
- *How can the knowledge of the surgical problem-solving process be incorporated into the design of KIVS so as to improve decision-making and thus the performance of the surgeons?*
- *In a multidisciplinary development team of surgeons, technology engineers and designers, what steps are required in the KIVS development process to facilitate collaborative design?*

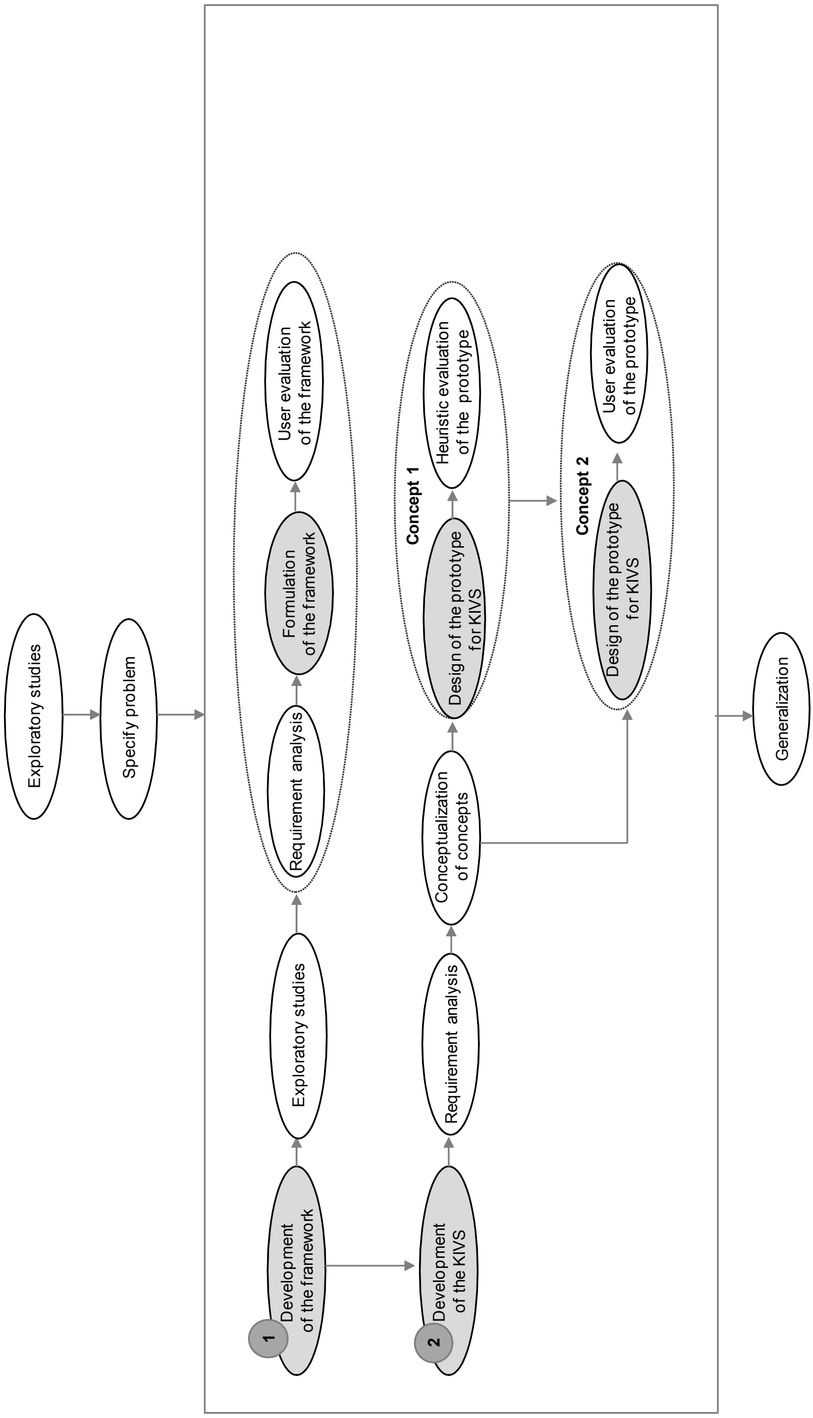


Fig.3. Scheme illustrating the research process followed in this thesis.

1.11 Research process and activities

The following key research activities have been conducted to address the above research questions (Fig. 3):

- Explorative research with the following aims: (a) to gain an overview of existing visualization systems available to the liver surgeon both at the time of surgical planning and during the surgery, (b) to explore the state of art and future intra-operative visualization systems for liver surgery and (c) to assess the surgeons' evaluation based on first hand usage of upcoming visualization systems. Findings at this phase indicated a need for a design framework to support user-centered development of KIVS.
- Studies to develop a Workflow Integration Matrix (WIM) which is an integral part of the workflow-centered framework. This aims to build a knowledge repository of the surgical problem-solving process and surgical needs.
- Studies to evaluate the framework with the users of the framework, for example: surgeons and technologists.
- Conceptualization and design of two KIVS prototypes to provide intra-operative visualization support for RFA, a MIS procedure. Two KIVS prototypes for RFA were developed during this research.
- User evaluative studies to test the two KIVS prototypes with expert intervention radiologists and medical students.

1.12 Contribution of the thesis

This thesis is an example of the role design as a discipline can play in guiding the user-centered technological innovation in the area of medical informatics, especially in the case where the development depends on creating collaborative design between different scientific disciplines: surgical, technological (medical informatics) and design.

The contribution of this thesis can be understood at two levels:

- First, the framework proposed in this thesis contributes to design (Jalote-Parmar and Badke-Schaub 2008a), and ergonomics (Jalote-Parmar et al. 2007) literature as an example of user-centered design to drive the innovation of the technological development of KIVS for complex workspaces such as the surgical theater.
- Second, it contributes to medical informatics literature by demonstrating the practical implementation of cognitive theories to guide the development of KIVS (Jalote-Parmar et al. 2009).

The aim of this thesis is to propose a design framework that can be used as a structure for the formulation of problems and the development of design guidelines in the individual fields of application; instead of proposing specific design methods and guidelines for decision support systems such as the KIVS in the surgical domain which are likely to be outdated due to new workflows and technological advancements.

1.13 Organization of the chapters

The organization of the chapters in this thesis is as follows:

1 *Chapter 2*
Chapter 2 explains the exploratory research. This includes literature research involving two studies (Study 1a & b) which aimed to investigate: (a) existing visualization systems available to the liver surgeon, (b) the future and state of the art in intra-operative visualization systems for liver surgery and (c) assessment of surgeons' evaluations based on first hand usage of upcoming visualization systems. The findings lead to specifying a need for a framework.The chapter concludes with a prosposing a workflow-centered design framework.

2 *Chapter 3*
Chapter 3 explains the requirement analysis, formulation and evaluation of the proposed workflow-centered design framework. It presents two empirical studies (Study 2 & 3), conducted in the hospitals of Klinichini- Slovenia, Riskshopitalet- Norway, and Erasmus MC- The Netherlands, to understand the surgical problem solving activities within the surgical workspace. Findings from these studies led to the formulation of the 'Workflow Integration Matrix' (WIM) which is an integral part of the proposed workflow-centered design framework. WIM assists in analyzing the surgical workflow to build a knowledge repository of the surgical procedures, problems, and design requirements, and has been evaluated with surgeons and technology engineers after its application in the ARIS*ER consortium for 1.5 years (Study 4).

3 *Chapter 4*
In chapter 4 the requirement analysis, conceptualization and evaluation of the KIVS prototype are explained (Concept 1). WIM was applied to conduct surgical workflow analysis for RFA. The findings from the studies (Study 5a & b) conducted in two hospitals (Erasmus MC, The Netherlands and Riskshopitalet, Norway) led to the formulation of the design requirements for KIVS. Based on the findings design concepts were generated and a prototype was developed. The heuristic evaluation of the demo prototype (Study 6) with the clinicians indicated the probable benefits of generating 3D visualization of patient data by image fusion in real-time.

4 *Chapter 5*
Chapter 5 describes the design and evaluation of the KIVS (Concept 2) based on the findings from the surgical workflow analysis as presented in chapter 4 and what was learned from Concept 1. The theory of situation awareness was applied in the design of the information visualization in KIVS to support the surgical decision-making. The chapter includes an empirical study (Study 7) conducted to evaluate the KIVS with the clinicians at Riskshospitalet, Norway. This study used two systems, KIVS and the conventional ultrasound guided intervention, to compare the performance of expert intervention radiologists and medical students while executing RFA.

5 *Chapter 6*
Chapter 6 discusses the implications and the limitations of the research presented and provides suggestions for future research.

Overview

This chapter positions the research in the context of improving patient safety by developing user-centered innovations for healthcare. It describes the exploratory research (Study 1a & b) conducted to analyze the state of art and the future of the visualization systems for surgical planning and intra-operative phase. These findings indicate the need for a design framework to support user-centered development of KIVS. The chapter concludes by proposing a workflow-centered framework to design KIVS.

The chapter is organized as follows: Section 2.1 describes the overview of the exploratory research. Section 2.2 describes Study 1a, which was conducted to identify the existing visualization systems available for the surgeon. Section 2.3 describes Study 1b, which aims to explore the existing and future intra-operative visualization systems for liver surgery. The study combined a literature study with observations of surgeons on first hand usage of upcoming visualization systems. Section 2.4 defines the need for a design framework and the chapter concludes by proposing a workflow-centered development framework to support the development of KIVS.

CHAPTER 2 VISUALIZATION SYSTEMS AND IMAGING MODALITIES

2.1 Exploratory research

The development of visualization systems for surgical theatres draws on knowledge from different scientific disciplines, namely medical and informatics. Consequently, when conducting scientific research, the design researcher is required not only to have a reasonable understanding of the medical terminology and surgical processes in the surgical workspace but also an understanding of the state of the art of technological innovations related to the visualization systems. This overview is necessary for understanding the issues related to the development of visualization systems.

Radio Frequency Ablation (RFA), a MIS procedure performed for treating malignant tumors in the liver, was selected as a clinical case for developing an intra-operative visualization system. RFA considered as an alternative treatment for liver resection and is performed either by liver surgeons or intervention radiologists. Surgical planning for RFA is a part of the liver surgery planning. It was therefore necessary in the exploratory phase to gain an understanding of liver surgery in general, including both the pre-operative (surgical planning) and intra-operative phases (during the surgery).

To conduct the exploratory research, a combination of methods which included surgical observations, pilot tests, visits to the technology development labs, and literature study were applied. The exploratory study was conducted as an initial exploration into the surgical workspace to define the problem space (Fig. 1). Thus, the explorative research was conducted with the following three objectives:

1 To gain an understanding of existing pre- and intra-operative visualization systems available for the liver surgeon (Section 2.1.1).

2 To explore the state of the art in visualization systems for surgical planning and intra-operative phases developed specifically for liver surgery and RFA (Section 2.1.2).

3 To obtain the surgeons assessment of the usage and utility of some of the upcoming visualization systems for liver surgery. As most of the visualization systems are still at a prototype stage in the technological labs, access to several systems was not possible. Consequently, the first hand experience of surgeons with the prototype was gained where access was possible.

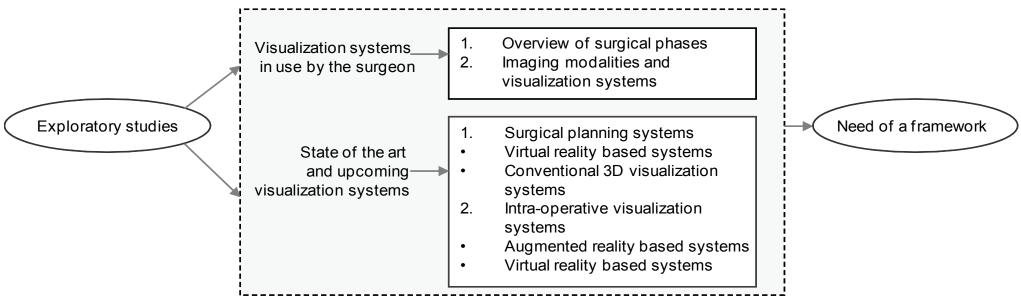


Fig.1. Schematic diagram of the exploratory studies.

2.2 Study 1a: Visualization systems currently available to the liver surgeon

The aim of this study was to gain an understanding of the existing visualization aids related to patient data available to the liver surgeon pre-operatively (surgical planning) and intra-operatively (during surgery):

Method
In total (n=22) field observations were conducted in the hospitals of Rikshospitalet, Norway; Klinichini medical hospital, Slovenia; and the

Erasmus MC, The Netherlands. The surgical applications selected for the observations were open liver surgery, endoscopic liver surgery, and RFA.

Results
The following section explains the key observations as obtained from this study.

2.2.1 Surgical phases: pre-operative, intra-operative and post-operative

1 *Pre-operative phase*

- *Planning with surgeons and radiologists*
  Surgical planning for open liver surgery, RFA, and endoscopic liver surgery is conducted together. There are weekly meetings with the clinical experts, including liver surgeons, radiologists, and gastrointestinal experts. In these meetings, the radiologists discuss their opinion about the patient considered for liver surgery. Finally, the overall surgical treatment strategy for the patient is decided on the basis of the opinion of several surgeons and clinical experts. For example, in the meeting it may be decided that the patient will undergo a liver resection or a RFA. This decision is based on pre-operative imaging data, such as Computerised Tomography (CT) scan, Magnetic Resonance Imaging (MRI), x –ray exam, patient pathological data and patient history (Hussain and Semelka 2005). The patient data is stored and can be accessed through Patient Archiving System (PACS).

- *Planning with the surgical team*
  A few days before the surgery, the main surgeon, assisting surgeon(s) and the nurses meet to discuss the surgical procedure. In this context the planning is conducted using imaging data such as the CT and MRI to share the details of the patient with the surgical team. Planning mainly includes equipment planning and any patient specific changes to the standard protocol of the surgical procedure. For example, if the patient is overweight then the placement of the equipment needs to be customized accordingly.

- *Personal planning by the surgeon*
  A day before the surgery, the surgeon mentally pre-visualizes the whole surgical procedure. This is the surgeon's personal preparation of going over the key stages of the surgery in his mind. The surgeon also develops a mental sketch of the patient's organ and goes through the anatomical details. Fig. 2 shows one such sketch made by the liver surgeon before surgery. It illustrates the location of the main vessels and the tumors. These mental visualizations are becoming a critical part of medical training (Hegarthy et al. 2007). For surgical planning surgeons currently use imaging data, such as the CT scans and MRI scans obtained through PACS.

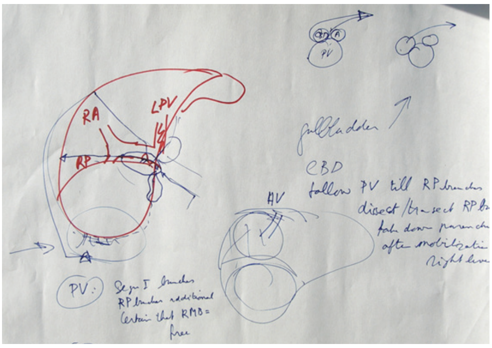


Fig.2. Mental sketch of the patient liver made by the surgeon before surgery
(Picture taken at Erasmus-MC, The Netherlands)

2 *Intra-operative phase*
The intra-operative phase involves preparing the patient, setting up the equipment, and performing the surgery. A team of nurses and an anesthesiologist prepare the patient based on specific instructions from the surgeon. The main surgeon performs the surgery together with the medical team. Fig. 3 illustrates endoscopic liver surgery, which is accomplished through small incisions. The abdomen of the patient is inflated with gas to create a space inside and a video camera is inserted into the abdomen through one of the small incisions. The video image is magnified and transmitted to a high-resolution monitor, allowing the surgeon to see the abdominal anatomy with clarity. The surgery is performed using special instruments introduced through the other incisions. Due to reasons as exemplified in chapter 1 (Section 1.4) the surgeon relies on innovative visualization techniques to help visualize the patient anatomy and navigate the instruments. During endoscopic liver surgery, the surgeon refers to the pre-operative patient data, such as the CT scans and MRI scans. This is currently displayed on the 2D monitors. Surgeons sometimes use intra-operative Ultrasound (US) attached to the endoscopic probe to get information

Fig.3. Laparoscopic liver surgery.
(Picture taken at Riskhospitalet, Norway)

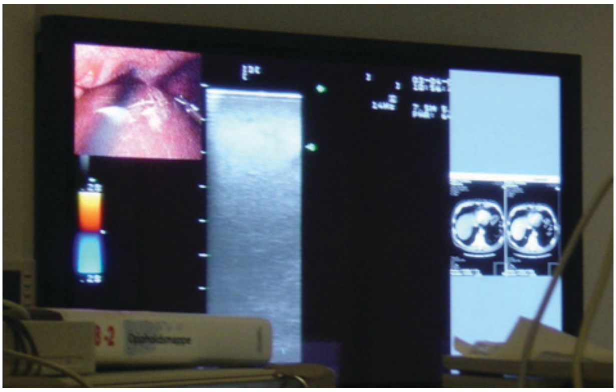


Fig.4. Monitor in the surgical theatre displaying the endoscopic image, intra-operative US and Pre-operative CT data (Picture taken at Riskhospitalet, Norway)

about the location of the vessels. As Fig. 4 shows, the patient data in the surgical theatre displayed on a large monitor during laparoscopic liver surgery. It includes a combination of pre- and intra-operative patient data which can be seen as pre-operative CT scan, video obtained from the endoscopic probe and image obtained from intra-operative US. Sometimes during a surgery, due to new findings in the patient situation, the surgeon decides to combine two procedures such as RFA along with liver resection to treat the tumors. At this point, the main surgeon may invite several experts before making the final decision. RFA is introduced as an alternative to liver resection especially for small tumors and tumors that are in locations that cannot be resected. Where possible, RFA is performed percuteanously. RFA is popularly performed on the liver as an US guided procedure in which intra-operative US is used to guide the radiofrequency needle to ablate the tumor (Solbiati et al. 1999). In some cases, RFA is also performed under CT guidance (Steinke et al. 2002).

3 *Post-operative phase*

The follow up procedure after surgery differs for each patient. In case of liver resection and RFA, the typical follow up procedure is to make new images of the MRI and CT scans of the patient to decide the subsequent course of action (Davenport et al. 2009). This data is compared to the pre-operative patient imaging data. At present, there are no special visualization systems available to compare the pre-operative patient data with the post operative data.

2.2.2 Visualization systems in the surgical workspace

1 Patient Archiving and Communication System *and imaging modalities*

Different imaging modalities provide different levels of information related to internal organs, the bones, soft tissues, and blood vessels.

For example, CT scans provide better information on soft tissue data than X-rays or Ultrasound (US). Currently, there are few dedicated visualization systems for liver surgery or RFAs that are used in pre-, intra-, or post-operative phases. The only access to patient information the surgeon has is through imaging modalities and the patient pathological data. Due to the lack of dedicated patient visualization systems, surgeons rely on the PACS for display of archived patient imaging data such as CT scans. However, PACS, as a system in itself, is not focused on visualization of patient data to provide decision support to either plan or perform the surgery.

2 *Volumetric analysis software*
In the case of a liver resection, a small remnant liver volume is a risk factor for post surgery liver failure and can be predicted accurately by using radiology image analysis software (Shoup et al. 2003). However, this software is complicated to use and usually requires support by radiologists and is, therefore, not popular among surgeons.

2.2.3 Imaging modalities

Different imaging modalities provide different information about patient data. The choice of modalities in surgical decision-making is based on the protocols followed in different hospitals and may be influenced by national policies. For example, MRI is a popular imaging modality to diagnose cancer in patients for liver surgery in the Netherlands, while CT more commonly used for the same purpose in Norway. Some commonly used imaging modalities are CT scan, US, MRI, X-ray, and Fluoroscopy. In specific US, Fluoroscopy, and CT c-arm is used for intra-operative localization and visualization of bone tissues, fractures, implants, and surgical tool positions. The clinical importance of these modalities in the diagnosis of cancer in the liver is beyond the scope of this thesis and can be further read in (Hussain and Semelka 2005; Hussain and Semelka 2005). Table 1 (See following page 34-35) briefly explains the comparison between the selected imaging modalities commonly used with respect to liver surgery.

Summary

This section provided explanation on the surgical phases and the existing visualization aids available to the liver surgeon, both at the time of surgical planning and during the surgery. Surgical planning is an integrated part of the surgical process and any visualization system introduced either in the planning or intra-operative phase affects the quality of the complete surgical procedures. The surgeon has access to an array of imaging modalities to provide patient data. These imaging modalities provide patient data, but do not always provide the surgeon with the opportunity to interact with the data from the perspective of surgical planning or performance. Visualization systems which provide the opportunity to interact with the imaging data such that it can support decision-making are therefore required. The next section reviews state of the art in visualization systems for liver surgery and RFA.

2.3 Study 1b: Future and state of the art in visualization systems for liver surgery

This section reviews upcoming technological applications in visualization for liver surgery and assesses surgeons' evaluation based on first hand usage of upcoming visualization systems. The review is conducted to understand different visualization techniques applied to visualize patient data in the planning and intra-operative phase. It does not include a technological review of visualization systems but mainly aims to understand the different functionalities offered to the surgeon to interact with the patient data.

Method
The study was conducted in two stages: (a) a literature review of visualization systems in liver surgery and RFA, and (b) obtaining the opinions of the surgeons based on their first hand user experience of three different types of innovative visualization systems. The following visualization systems were selected as representative of the upcoming technological innovations in the field of medical visualization, especially for liver surgery: Augmented reality liver surgery planner, Augmented Reality (AR) lab at Technical University, Graz, Austria (Reitinger et al. 2006); Virtual Reality (VR) lab at Erasmus MC, The Netherlands (Koning 2009); and Liver planning tool, Slevenska, Slovania (Sojar et al. 2004).

Results
A brief overview of the state of the art in planning systems and intra-operative visualization systems for liver surgery and RFA is explained in Section 2.3.1 and Section 2.3.2.

2.3.1 Planning systems

Liver surgery is still one of the most demanding fields in surgery. Planning a liver resection and RFA always presents several challenges for a surgeon in terms of patient data visualization in Three-Dimensions (3D). In order to plan an optimal resection strategy, visualization tools are required. Measurements of critical distances between vessels and tumors based on Two-Dimensional (2D) cross sectional images in CT and MRI are difficult to perform. Moreover, resection planning with current desktop based systems using 2D visualization is also tedious because of limited interaction. Several systems that can create 3D reconstructions of CT and thus enable precise surgical planning are being developed. Examples of these are: treatment planning tool for RFA (Villard et al. 2003; Villard et al. 2005); liver planning tool for liver surgery (Reitinger et al. 2006); virtual

Table 1. Usage pattern and comparison between imaging modalities: MRI,CT and US

Comparison Criteria	**CT Scan**	**MRI**	**US**
Time taken for complete scan:	Usually completed within 5 minutes.	Scanning typically run for about 30 minutes.	Usually completed within 5 -10 minutes, depends on the clinician.
Principal used for imaging:	Uses X-rays for imaging.	Uses magnets and radio waves to create images.	Uses high-frequency sound waves to produce dynamic visual images of organs, tissues or blood flow inside the body. The high-frequency sound waves are transmitted to the area of interest and the returning echoes are recorded.
Radiation exposure:	Moderate – high radiation.	None.	None which are clearly known.
Ability to change the imaging plane without moving the patient:	Not present.	MRI machines can produce images in any plane.	US imaging is flexible and can be procured from different planes. Only air and bone act as a barrier to create US images. For example US on lungs doesn't get any image.
Details of bony structures:	Provides good details about bony structures.	Less detailed compared to CT scan.	Poor.
Details of soft tissues:	Less detailed compared to MRI	Much higher detail of the soft tissues.	Muscles, tendons, and many internal organs, their size, structure and any pathological lesions with real time images.
Advantages.	Relatively low scanning time. The lungs can be imaged in less than a minute, Wide field of view, comparatively more information can be obtained. Detection of even subtle differences between body tissues.	Ability to change the contrast of the images. Small changes in the radio waves and the magnetic fields can completely change the contrast of the image. Different contrast settings highlight different types of tissue. MR images of the soft-tissue structures of the body—such as the heart, liver and many other organs— are more likely in some instances to identify and characterize abnormalities and focal lesions than	Ultrasound is widely available, easy-to-use and less expensive than other imaging methods. Ultrasound imaging uses no ionizing radiation. Most ultrasound scanning is noninvasive (no needles or injections) and is usually painless. Ultrasound scanning gives a clear picture of soft tissues that do not show up well on x-ray images. Ultrasound causes no health problems and may be repeated as often as is necessary. Ultrasound provides real-time imaging, making it a good

		other imaging methods. This detail makes MRI an invaluable tool in early diagnosis and for evaluation of many focal lesions and tumors. MRI has proven valuable in diagnosing a broad range of conditions, including cancer, heart and vascular disease, and muscular and bone abnormalities. MRI enables the discovery of abnormalities that might be obscured by bone with other imaging methods. MRI allows physicians to assess the biliary system noninvasively and without contrast injection.	tool for guiding minimally invasive procedures such as needle biopsies and needle aspiration. Unlike the strong magnetic field of magnetic resonance imaging (MRI), ultrasound is not affected by cardiac pacemakers, ferromagnetic implants or fragments within the body. Ultrasound is also an excellent alternative to MRI for claustrophobic patients. Ultrasound may actually have advantages over MRI in seeing tendon structure, which is better appreciated by ultrasound than MRI.
Disadvantage	Radiation. Need for contrast agent to obtain information on soft tissue.	Patients who have received certain types of surgical clips, metallic fragments, cardiac monitors or pacemakers cannot receive an MRI. Although the strong magnetic field is not harmful in itself, implanted medical devices that contain metal may malfunction or cause problems during an MRI exam. MRI may not always distinguish between cancer tissue and edema fluid.	Ultrasound has difficulty in penetrating bone and therefore can only provide images of the outer surface of bony structures. To visualize the internal structure of bones or certain joints, other imaging modalities such as MRI are typically used. US images are difficult to interpret. Echoes are produced at any tissue interface where a change in acoustical impedance (speed of sound) occurs. Accurate interpretation of these images requires considerable expertise, especially while performing intra-operative procedures with US image guidance.
Usage in surgical phase and future developments:	Used in pre-operative and post operative phase. CT-arm is an upcoming for of mobile CT being used in Intra-operative procedures. CT guided MIS procedures such as biopsies are becoming common, recent surgical trends suggest.	Used in pre- and post operative phases. Open MRI was introduced for use in the intra-operative phase to conduct surgical procedures but due operational limitations it did not become popular among surgeons.	Used in pre-operative, intra-operative and post operative phase. Recently, 3D US and 4D US are being used for real-time imaging.

tumor resection and computer-assisted risk analysis (Lang et al. 2005); and illustrative visualization of 3D planning models for augmented reality in liver surgery (Hansen et al. 2009). While the 3D reconstruction can be seen in several systems, not all systems allow the surgeon to simulate surgery or interact with the 3D data to plan the specific surgery. A selection of planning visualization systems using different technological approaches are explained below: (1) a virtual reality based 3D visualization system, and (2) Conventional 3D visualization based liver surgery planning tool.

1 **Virtual Reality based 3D visualization system**

VR is a technology that encompasses a broad spectrum of ideas. It is defined as "a computer generated, interactive, three-dimensional environment in which a person is immersed." (Aukstakalnis 1992). There are three key points in VR: first, a virtual environment is a computer generated three-dimensional scene which requires high performance computer graphics to provide an adequate level of realism, second, a virtual world is interactive and users require real-time response from the system to be able to interact with it in an effective manner, and third, the user is immersed in the environment (Vallino 1998). One of the identifying features of a virtual reality system is the Head Mounted Displays (HMD). These displays block out the entire external world and present a view that is under the complete control of the computer. The user is thus wholly immersed in an artificial world and becomes separated from the real environment. For this immersion to appear realistic, the VR system must accurately sense how the user is moving and determine what effect that movement should have on the scene being rendered in the head mounted display.

New technologies, in particularVR and robotics, are likely to have a major impact on health care in the next decade (Mc Cloy and Stone 2001). VR medical simulators are now available and in use across the world and other virtual reality applications are being used in mental health and emergency medicines. Three prototype level VR systems that have been developed for liver surgery are explained below:Virtual reality cave (Koning 2009).VR liver planning system (Reitinger et al. 2006), and VR planning system for RFA (Villard et al. 2003).

a *Virtual Reality (VR) cave*

The VR cave uses stereoscopic visualization techniques and immersive data analysis to support cancer research (Koning 2009). The VR cave enables clinicians to "walk through" massive volumes of genomic, chemical, and medical information and extracts more information in a shorter timeframe than conventional approaches. It enables clinicians to explore and visualize patient information obtained from imaging modalities such as the Ultrasound, CT, and MRI scans in 3D. In the VR cave, the clinician wears HMD and stands inside a cube that has four sides forming a seamless 3D virtual surrounding. A user interface is projected on one of the wall sides of the cave to enable navigation through the imaging data using an interactive device with trackers (Fig.5).

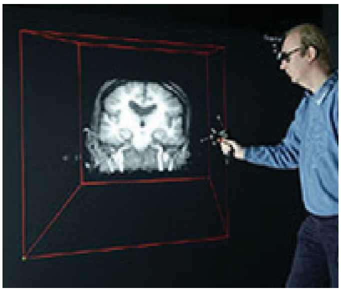


Fig.5. Virtual Reality Cave displaying the patient scan. (Picture courtesy http://www.barco.com/corporate/en/pressreleases)

User testing

To understand the applicability of the VR cave in liver surgery, a pilot test was conducted. For the study, an expert liver surgeon and a resident liver surgeon were invited by the author to interact with the cave. A pre-selected CT scan of a patient to be operated for liver resection was projected in the VR cave. The author then asked the expert liver surgeon to plan his surgery with the resident surgeon using the VR cave.

Key findings

- Specific issues related to key anatomical landmarks and key problem stages that would occur during the liver surgery were pointed out by the expert surgeon. For example, resection issues were discussed if the tumor was particularly close to a vessel.
- It was observed that both the surgeons found wearing the head mounted display (HMD) tedious. They found it difficult to orient themselves and interact with the virtual user interface in order to zoom and orient data.
- The resident surgeon found the 3D visualization of the CT slices beneficial in understanding the patient anatomy. The current visualization of CT slices displayed on a 2D screen is not sufficient enough to prepare him for the surgery.
- The expert surgeon said, "*my experience compensates the need for 3D visualization*". He mentioned that 3D visualization helped him reconfirm the model of the patient anatomy he had developed in his head on the basis of the CT slices. This reconfirmation adds to his confidence while conducting the surgery. Only at one point did he discover new information through the 3D visualization of this particular patient. As a result of age and genetics, the patient had an especially complex structure of vessels in the liver. This visualization of the vessels helped the surgeon prepare for the difficulties that he would encounter while performing the resection.
- The VR cave could not be used in the normal planning meeting as its set up is too expensive and requires a lot of space. The liver surgery planning meetings often have a group of experts discussing

the data and the VR cave does not support group interaction. Although this cave is set up in the hospital, very few liver surgeons have actually taken the time to visit it and use it for patient data visualization.

- Compared to the conventional 3D visualization of the patient data on a 2D screen, the immersive environment in the VR cave does not seem to provide additional information. It also does not offer many data interaction tools for the surgeon to plan the surgery, as it is just a 3D representation of the CT slices.

b *Virtual Reality (VR) planning tool for liver surgery*

This system has been developed at the Technical University Graz, Austria (Reitinger et al. 2006). To facilitate liver surgery planning process, different tools which allow easy user interaction in a virtual reality environment are presented. Methods for quantitative analysis like volume calculation and distance measurements are also offered through this tool.

User testing

To understand the applicability of this system in planning liver surgery, a pilot test was conducted. An expert liver surgeon belonging to the Klinichni medical center, Slovenia, was invited to use the system. A pre-selected CT scan of a patient to be operated for liver resection was projected through the VR system. The author then asked the expert liver surgeon to plan the surgery by using the different tools offered. Fig.6. illustrates the liver surgeon using the VR planning system by wearing the HMD.

Key findings

- The surgeon found certain functionalities offered in the system very useful for planning the liver surgery. Specifically, functionalities such as the possibility of virtually resecting the liver, measuring the distance between vessels and tumor, and volumetric analysis were found useful for planning the procedure.
- The HMD and virtual interface to interact with the system was not found to be intuitive by the surgeon. Specifically, the overlap in patient information and the virtual interface caused confusion in interacting with the data.
- In the surgeon's opinion, the true benefit of application of the VR reality set up using HMD was not clear compared to the visualization of the same data/functionalities on a 2D monitor. Specially, in relation to real-time task scenarios, the spatial issues caused by HMD seemed likely to create confusion and may cause serious errors.

Fig.6. Augmented reality interface for liver surgery and the liver surgeon using augmented reality system for liver surgery during a pilot study.
(Pictures taken in Graz, Austria)

Summary
It is evident that 3D visualization of the liver together with data interaction opportunities can offer benefits to the surgeon. What is not clear is the value of the VR set up for the planning tool, given that same functionalities could be displayed through 2D screen.

c *VR planning system for RFA: RF-Sim*
The VR simulation tool for RFA is developed by the INRIA research group in France (Villard et al. 2003; Villard et al. 2005; Baegert 2008). This system aims to help clinicians to have a better visualization of anatomic structures, and allows them to find an adequate treatment (Fig.6). For percutaneous RFA the clinician must choose an accurate tragectry for the insertion of the needle in order to destroy the entire tumor while preserving surrounding vital organs. This planning step is a delicate procedure that is generally performed using only 2D visualization of the CT slices or with 2D US. RF-Sim is a planning tool that integrates visualization of the tumors, allowing experimentation with various strategies, and an automatic planning algorithm that proposes optimal trajectories for the needle (Fig. 7).

In an attempt to enhance the safety of RFA, RF-sim a treatment planning and training tool has been developed. This simulates the insertion of the needle to ablate the treated area and proposes an optimal needle placement. The 3D scenes are automatically reconstructed from enhanced spiral CT scans. The system allows manipulation of the virtual needle by stimulating the needle with the hand using various interactive devices, such as data gloves or wireless fly stick.

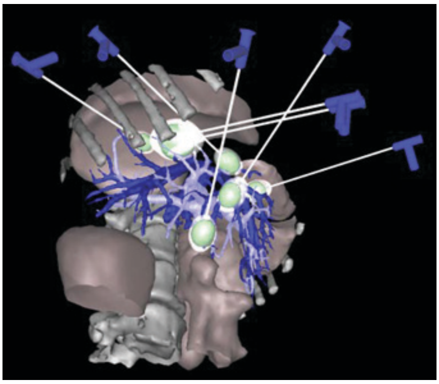


Fig.7. RF-sim system.
(photo courtesy www.ircad.org)

Summary
RF-sim involves computation of the optimal position for the needle based mainly on a volume criterion. However, according to the radiologist and surgeons, this is not the only criterion taken into account when planning an RFA. Other criteria such as the distance between needle trajectory and vital organs also need to be taken into consideration (Baegert 2008).

2 **Conventional 3D visualization liver surgery planning tool**
Another approach to developing liver surgery planning systems is using the conventional 2D screen monitors to display 3D visualization of the imagining data such as the CT slices. These systems are more focused on providing interactive tools to assist the surgeon in planning the surgery than on experimenting with different aspects of visualization. In liver surgery, the complexity and variations of the vascular and biliary systems and their relation to the tumors influence the liver resection strategy. Recently, companies like Mevis have developed a technology to generate 3D images of the liver from CT slices (MeVis 2006). Mevis provides services where the patient data can be sent online and the 3D of the liver is constructed within a few days to hospitals commercially. Although this facility exists it is still not popular among the hospitals for financial reasons. One such system is explained below:

a *Sekvenca 3D liver planning system (Sojar et al. 2004)*
This is a commercially available system which creates a 3D virtual liver manually reconstructed from the CT scans. It allows manipulation of a 3D liver and is a tool for studying the internal liver structures for all four vessels systems. The virtual environment portrays a detailed liver segmentation. The program's most important function is that it allows the performance of virtual intra-operative US on a virtual liver which can be dissected, and whose vessels can be clipped and cut. The program for 3D reconstruction from conventional CT scans has been developed so that the obtained data can be used to simulate the surgery in a virtual environment. A liver surgeon was involved in the development process.

User testing
The visualization system can be run on a normal laptop. This makes it mobile and easily accessible to the surgeon for planning surgery at home and in the surgical theatre. For the pilot test, a 3D model of the liver was constructed based on a patient to be operated for surgery.

The surgeon obtained permission from the patient to use the system as a visual aid while the surgery is taking place. Prior to surgery, the surgeon spend some time planning the surgery with the interactive tool. The visualization system installed on a laptop was placed in the surgical theatre, to observe its use by the surgeon during the surgery.

Key findings

- This system involved surgeons in the conceptualization and development process.
- Functionalities such as flexibility to rotate and resect the liver virtually were included in the system. This helps the surgeon simulate the surgery in the planning phase. (Fig. 8).
- For the intra-operative phase, the surgeon used the 3D model of the liver and the vessels as a reference point while performing the open surgery.
- This system uses manual image segmentation method to generate a 3D volume of the liver from the CT slices. This removes the reliability of the data, i.e. the 3D liver generated, especially for the intra-operative phase. Liver surgery relies on the knowledge of the distance of the vessel and the tumor. In the case of manual segmentation of image data, the generation of a 3D model relies heavily on the graphic artist for the model. Although before creating the model the radiologist assists in interpreting the data, there is always the chance of data being lost in translation and manual interpretation.

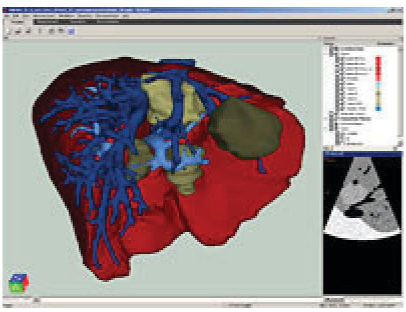


Fig.8. Sekvenca system interface showing 3D model of liver with relevant visual information
(Photo courtesy http://www.sekvenca.si)

Summary

This system is a good example of how a surgeon-centered 3D visualization of patient data and interactable tools displayed on a 2D screen can make the surgical planning effecient. The operability of the system on the laptop makes it a mobile tool for the surgeon to access information while planning the surgery, be it at the hospital, home or even in the surgical theatre. The system can be made reliable if it is made technologically robust with automated segmentation and registration of the liver in 3D from the CT slices. Currently, it is a useful training tool.

2.3.2 Intra-operative visualization systems

Tumor resections in liver are complex surgical interventions. The degree of complexity varies in different procedures like open liver surgery, endoscopic liver resection and tumor ablation through percutaneous RFA. The lack of intra-operative visualization leads to uncertainty in the surgical performance. In case of percutaneous RFA, the surgeon relies only on the US to guide the needle to ablate the tumor. In many cases, additional tumors within the liver are frequently detected during interventions using intra-operative ultrasound. These tumors are not visible in pre-operative data and their existence may require changes to the resection strategy.

The existing visualization aids, such as pre-operative CT data or intra-operative US are insufficient for the intra-operative visualization needs encountered during RFA or liver surgery. Research is being conducted into developing Intra-operative Visualization Systems (IVS). Issues such as deformation of the liver due to the patient's breathing, and registration and segmenting imaging data in real-time are some of the main technological obstacles in developing IVS. The innovation required to generate real-time patient visualization depends on the development of real-time image registration and automated image segmentation (details mentioned in Chapter 1: Section 1.5).

These are some of the IVS being developed: *Ultrasound guided laparoscopic RFA* (Bao et al. 2007): This system uses an infrared camera to track surgical instruments. It runs on a personal computer. Features of the system include spatially registered ultrasound visualization, volume reconstruction, and interactive targeting. *Augmented reality to guide tumor ablation* (Nicolau et al. 2005; Nicolau et al. 2009): an augmented reality system for RFA guidance. It superimposes, in real-time, a 3D reconstruction of the liver (from CT slices) and a virtual model of the RF needle on the patient's external views. The superimposition of the reconstructed models is performed with a 3D/2D registration based on radio-opaque markers stuck on the patient's skin.

Virtual navigator (Esaote 2007): A commercially available system developed by Esaote. It is an advanced system which allows the real-time superimposition of the US with the CT/MRI, to aid in surgical navigation. *Prototype of an intra-operative navigation and documentation system for laparoscopic radiofrequency ablation* (Hildebrand et al. 2008): An image-guided surgery system for laparoscopic liver treatments. In this system, a laparoscopic ultrasound probe and a RF needle can be navigated using an electromagnetic tracking system. *AR navigation system for endoscopic surgery* (Konishi et al. 2005): Based on creating an image fusion between intra-operative 3D-US, pre-operative 3D-CT, and laproscopic images.

Three selected intra-operative systems are explained in detail below.

1 *Augmented reality based visualization system for endoscopic liver surgery (Konishi et al. 2005)*

Augmented Reality (AR), an expanding field in virtual reality research, is now finding application in medical visualization. An augmented reality liver surgery system generates a composite view of the data, collected from imaging modalities, for the surgeon. It is a combination of the real scene of the patient viewed by the surgeon, and a virtual computer generated scene that augments the real scene with additional information based on pre-operative or intra-operative data from different imaging modalities.

The AR navigation system is based on creating an image fusion between (a) intra-operative 3D-US and endoscopic images and (b) Pre-operative 3D-CT and endoscopic images (Fig. 9). It provides real-time anatomical information, which cannot be otherwise visualized, projected on the liver. As an imaging modality, 3D-US has the advantage of acquiring real-time imaging regardless of organ shift or distortion and is available in every hospital. AR visualization is achieved by superimposing the visualized 3D-US images and the 3D-CT-based images on the endoscopic data.

Comments

- Although, it makes strong technical claims, it is as yet unclear what benefit the system achieves in increasing the accuracy of the procedure. In particular, it is not clear what the benefits are of creating a four-split screen by visualizing images created from a fusion between intra-operative 3D-US and endoscopic images and pre-operative 3D-CT and endoscopic images.
- No specific protocol was followed to gather surgical requirements related to the clinical application. Besides, several technical issues which are crucial to achieving the clinical accuracy of such a system

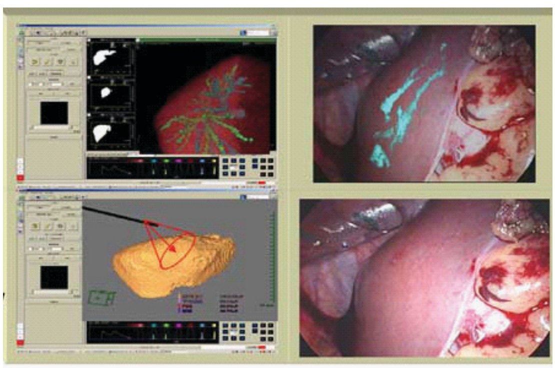


Fig.9. Integrated display of navigation system based on 3D-CT and 3D-US with calibration system of oblique viewing endoscope. Photo courtesy (Konishi et al. 2005)

remains unanswered. For example, what is the time lapse between creating a 3D volume of the US and registering it to the endoscopic image? Precisely how much time is needed to create the overlap of the 3D-US on the endoscopic image? Furthermore, in this case how are issues, such as registration and organ deformation, achieved?

- It appears that the system has focused on presenting all the created data from the image fusion of different modalities without actually focusing on which information the surgeon would require for decision making and why.

2 *Augmented reality system for RFA (Nicolau et al. 2009)*

This system is a video based augmented reality system to guide the RFA. It tracks the needle in real-time and automatically registers the 3D pre-operative patient model in the camera frame using radio-opaque markers stuck on the patient's skin. The patient model is reconstructed from a 3D CT-scan taken just before the intervention. The pre-operative CT acquisition is synchronized with the expiratory phases of the patient. The AR view is generated by creating a 3D model of the liver from the pre-operative data set and is projected onto the patient's skin (Fig.10). This system offers a three screen set up to guide the needle placement. The screens include: (a) virtual exterior view of the CT scan (Fig.11); (b) guidance interface (Fig.12); and (c) control endoscopic view (Fig.13).

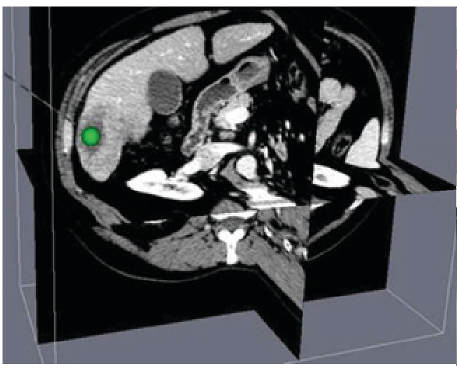


Fig.10. Patient CT image displayed in the virtual exterior view. A green sphere target placed by the user is visible.
Photo courtesy (Nicolau et al. 2009)

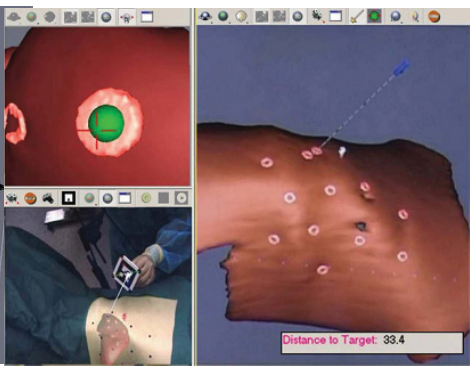


Fig.11. Three screens of the guidance interface. The bottom left image corresponds to the augmented reality screen, in which the 3D reconstruction of the liver and the virtual needle are displayed. The top left image displays the virtual needle screen (oriented towards a marker stick on the liver surface). The right image shows the main virtual screen showing the relative position.
Photo courtesy (Nicolau et al. 2009).

Comments

- In recent literature, this is technically one of the most advanced intra- operative visualization system in development for RFA.
- The technological team has tried to develop the technological competence required to develop real-time image fusion. It has, for several years, been developing the expertise required to address partial real-time registration issues like: (a) respiratory gating technique to provide motion compensation, to incorporate issues related to organ deformation caused due to the patient's breathing, and (b) needle tracking and registration.
- A phantom level testing with radiologist was conducted to test the technical robustness in simulated clinical conditions.
- A questionnaire evaluation was conducted with the radiologist to understand the usage of the information provided on the different screens. This subjective clinical evaluation study was conducted to understand the screen information usage in relation to needle placement.
- Finally, a passive evaluative protocol was conducted with patients to test the technical accuracy of image registration of the acquired patient data of the CT slices with the augmented view of the patient's liver.
- The system's development still focuses on achieving technical robustness of the system related to real-time registration issues and creating the visualizations rather than why and how it can actually help the clinicians to increase accuracy.
- US is still the key modality in the performance of RFA because it provides real-time information. There is a clear reason defined in the study as to why US was removed as the primary modality to perform the ablation and only CT was involved in the technical development.
- AR of the virtual liver is projected on the patient's abdomen. This creates several issues like lack of depth while comprehending the superimposition. It is still not clear whether it can actually aid in needle navigation or whether it creates confusion.
- The utility of visualizing the 'virtual exterior CT view' is not clearly defined.

Fig. 12. Control endoscopic view showing the markers on the liver phantom.
Photo courtesy (Nicolau et al. 2009)

- The system's development has focused on only one critical aspect of RFA, accuracy in needle insertion to the center of the tumor, and has overlooked several other critical criteria which are necessary for accurate needle insertion. These include knowledge of the critical organs in the needle's trajectory, and trajectory planning.

3 *The virtual navigator intra-operative RF Planning (Esaote 2007)*
The virtual navigator is a commercially available system developed by Esaote. It is an advanced system that allows a real-time visualization of the US with CT/MRI. The combination of the US with CT/MRI reference modalities results in an image fusion of the US and CT/MRI images, thus aiding in surgical navigation (Fig.13). The system uses a magnetic reference system (electromagnetic positioning device - fixed emitter and mobile receiver placed on the probe) to allow for correlation between US and CT/MRI images. The system allows comparison of the US with static pre-operative data from imaging modality such as the CT slices. It aims to increase the precision and accuracy of image-guided diagnosis and procedures. Specific skin markers which allow automatic spatial correlation are applied on the patient before the CT/MRI acquisitions, and are maintained during the ultrasound scan. During the real-time ultrasound modality, the user can simultaneously display the random CT/MRI planes visualized in the ultrasound scanning, thus maintaining perfect and precise spatial correlation.

Comments

- This system was developed in collaboration with the clinician. Consequently, the functionalities offered are well designed and very beneficial for improving the quality of the procedure.
- The fusion of intra-operative US in combination with the pre-operative CT, provides easy access from the point of view of intra-operative planning of RFA.
- The fusion of intra-operative US and static pre-operative CT data in real-time, allows co-relation of US data with the CT /MRI data, which are anatomically easier to grasp. This functionality is a good starting point for training the resident clinician to understand the US images in comparison to the CT data, which is particularly necessary while performing RFA.

Fig.13. Virtual navigator interface showing static pre-operative CT fused with real-time US.
(Photo courtesy http://www.esaote.com)

- It does not generate a real-time 3D image of the liver. This is critical for spatially challenging procedures such as RFA.

- The system is an intra-operative planning tool but not primarily an intra-operative navigation tool. Although the system assists the clinician in determining the optimal entry port for the needle, it does not indicate any critical organs in the needle's trajectory. The accuracy needed to hit the tumor in the center is, however, dependent on both the factors (needle trajectory and critical organs in the middle), so if the system focuses on addressing one factor and overlooks the other the overall, the the overall aim of accuracy cannot be met. overall goal of accuracy cannot be met.

2.4 Conclusions

The treatment of liver tumors by endoscopic liver surgery and RFA are performed with the image guidance of intra-operative 2D cross-sections of the liver using either US, or CT. These modalities present patient information in 2D cross section images, which is not sufficient to perform the spatially challenging MIS procedure. To provide visualization support in clinical procedures, technological development that provides intra-operative visualization of the patient data in the form of image fusions between different modalities, or superimposition endoscopic views with pre-operative imaging data is taking place.

The three components which need to be considered in the development of the IVS are:

1. Innovative technology is required to achieve real-time intra-operative visualization. To develop IVS, technological innovation is required to deal with issues such as real-time image registration while superimposing two imaging modalities or creating AR projections in real time. Furthermore, to evaluate the robustness of the technological innovation, they need to be tested in clinically simulated environments.
2. Integration of technological innovations, such as those mentioned above, is required to develop the IVS as a complete system. This requires conceptualization and prototyping of the IVS in order to integrate different technologies and test their use in the required clinical application.
3. The information flow between the various imaging modalities needs to be planned and structured in order to create a single window of integrated information providing real-time patient information. In order to support the surgical decision-making, the information visualized through these visualization systems should correspond with the 'surgical workflow' or the sequence of surgical activities performed by a surgeon to complete the surgical procedure.

The above mentioned reviews of the surgical planning and intra-operative systems illustrate that the development approaches followed are currently more focused on addressing the first two components. The third component, conceptualization of information flow to match the surgical workflow, has not yet been focused on in most of the systems as mentioned above. They have, instead, primarily focused on creating new and innovative ways of visualizing patient data. Questions, such as whether these new ways of visualizing patient data are actually useful in improving the quality of clinical procedures, and whether the patient information created by these innovative technologies actually assists in the clinical decision making, remains unanswered. As observed during the pilot tests with surgeons, several of these systems focus on creating innovative ways of visualizing patient data without understanding how the information created is useful for the surgeon in the surgical decision making. This component is critical in the development of IVS and will be addressed in this thesis.

2.4.1 Need for a design framework

In order to make informed decisions about 'what' patient information needs to be visualized, and how it needs to be visualized, it is necessary to generate knowledge of how surgeons conduct procedures and what factors affect their problem solving process. To access this knowledge, a formal mechanism is required to make structured inquiries into the surgical workspace. The two commercial systems reviewed above, Sekvenska (Sojar et al. 2004) and Esaote (Esaote 2007), have illustrated the benefits of involving clinicians in the development process. These systems offer functionalities which are found useful by the clinicians and hence may have higher chances of clinical acceptance. With respect to the existing development approaches, there is a lack of evidence in literature about how IVS are developed from the point of view of the surgeon or what methods are applied to investigate the clinical requirements or how clinicians are involved in user testing. Besides, there is little evidence of any method or framework applied to investigate surgical requirements. To support user-centered design of IVS especially in early phase of technological development, a framework is required to assist the following two development needs:

1 *Development of knowledge repository*
   Recent studies on improving the safety of healthcare through user-centered design indicate an urgent requirement to build a knowledge base or repository of user activities and work context so that medical systems can be systematically developed (Buckle et al. 2006). As can be seen in Fig.14, building the knowledge repository is the key step in developing the medical product. This product (in this case IVS) forms a part of a larger medical system which is responsible for establishing patient safety. Research conducted by Buckle et al. (2003) indicates that there is little evidence of methods or frameworks to develop a knowledge repository that is necessary for designers, ergonomists, and technology engineers to help define the design requirements for developing systems in healthcare.

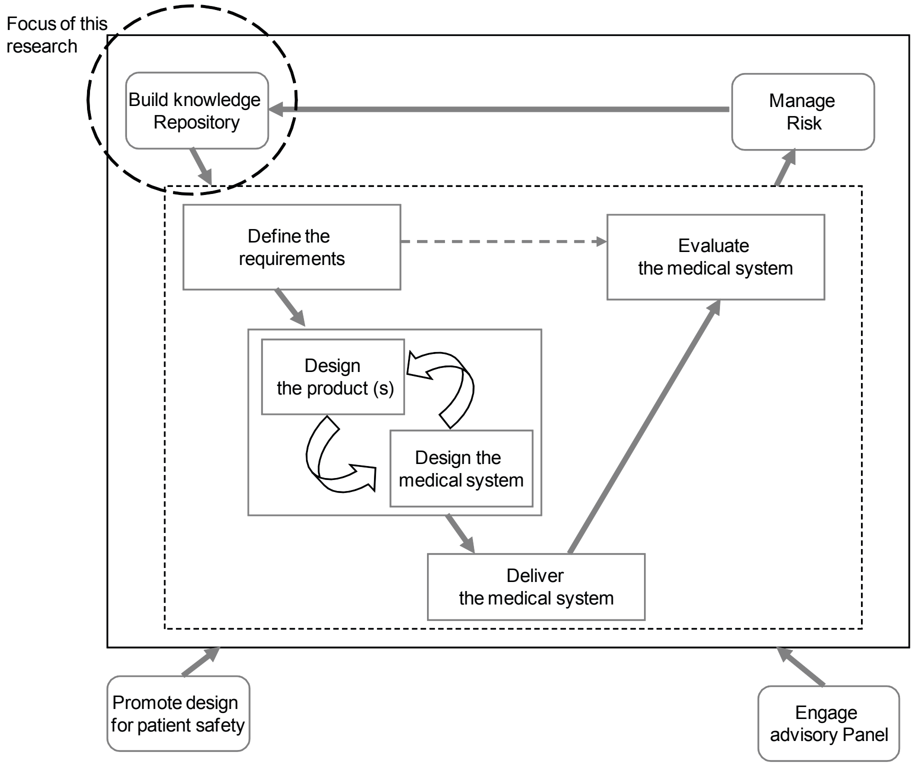


Fig.14. System based user-centered approach to develop products and systems in health care, adapted from Buckle et al. (2006)

2 *Bridging the communication between surgeons and technologists*
The multidisciplinary nature of the IVS development process underscores the need for a framework that can provide experts such as surgeons, technologists, and designers a platform to share their expertise and communicate design ideas in the early phase of IVS design process. The framework should aid in developing the knowledge repository of the surgical workflow and create opportunities for a multidisciplinary development team to share their ideas, and allow this knowledge to guide the technological development. Working towards addressing this need for a framework, the next section explains the design approach proposed in this thesis.

2.4.2 Proposing a workflow-centered approach to design KIVS

The discipline of Human Computer Interaction (HCI) design usually advocates a user-centered approach to designing products /systems for complex workplaces. This advocates understanding as a whole the complex interaction that occurs between the expert, the tool/systems, the colleagues, and the work environment (Preece et al. 1994; Norman 1998; Benyon 2005). The safety-critical industries such as aviation, have adopted a user-centered approach because they have realized the dangers of considering only certain elements of the technological system in isolation. These industries have taken into consideration what happens when and why, and how individual tasks and elements fit together and interact while designing products. However, development approaches to medical systems in healthcare are still a decade or more behind other such high-risk industries in their adaptation of user-centered approaches to improve performance and prevent errors (Kohn et al. 1999).

1 *Defining the term 'workflow'*

To support user-centered development of IVS, a workflow-centered approach is proposed. The term 'workflow centered' rather than 'user-centered' is used in order to emphasize the importance of the flow of information exchanged between the patient, the system, and the surgeon during the surgical procedure. Understanding this flow of work and information which is collectively termed as 'workflow' forms the basis of developing visualization systems which are 'knowledge intensive'. In this thesis, such visualization systems are labeled as Knowledge Intensive Visualization System (KIVS). As observed during the exploratory phase, surgical workflow depends on a dynamic information flow between the system, the surgeon, the patient, and the surgical team. Surgical workflow is also linked in time over the three surgical phases: pre-operative (before surgery), intra-operative (during surgery), and post-operative (post surgery). Literature on information processing and, more recently, medical informatics recommends analyzing human problem-solving as a means to understanding the user, the task, and the task environment (Rasmussen 1986; Andersen and Olsen 1998; Patel and Kaufman 1998; Patel et al. 2001). *In this thesis the term 'surgical workflow' is defined as: surgical problem-solving process that is determined by the task boundaries in terms of possibilities and limitations that lay conditions for pre-defined goal attainment in the three surgical phases* (Jalote-Parmar and Badke-Schaub 2008a).

In this context, the surgical problem-solving process can be understood as the sequence of physical and cognitive activities performed by a surgeon to complete the surgical procedure. This definition has been inspired by the explanation of problem-solving as proposed by Simon (Simon 1969), who explains the concept of expert behavior in a complex work environment through an interesting ant analogy: ant behavior over time is largely a reflection of the complexity of the environment in which it finds itself. He describes a situation in which an ant produced a very complex path across the terrain of a beach. A person observing only the path itself might be inclined to ascribe a great deal of intelligence to the ant. However, the complexity of the path is really produced by the complexity of the terrain over which the ant was navigating. Simon argued that human cognition is much the same. In the application of the ant analogy, the ants navigating mechanisms maps onto our work processes and the complexity of the beach maps onto the complexity of our environment.

2 *Defining the proposed workflow-centered framework*
As part of the proposed workflow-centered framework, knowledge of the surgical workflow should guide the development of the KIVS. According to the ISO standard user-centered design cycle, the key development stages can be understood as: specific context of use, analyze requirements, design prototype, and evaluate prototype. As an integral component of the workflow-centered framework, Workflow Integration Matrix (WIM) is proposed in this thesis to support the KIVS development in the following:

- Developing a knowledge repository of surgical workflow: Knowledge of surgical workflow is required to conceptualize information flow and visualization of the required patient information by integrating necessary technologies to formulate a workflow-centered solution for the KIVS,
- Creating a collaborative design platform to exchange needs and ideas between members of the multidisciplinary development team, such as surgeons, technologists, and designers.

Summary

This chapter described the exploratory studies (1a&b), which were conducted to analyze the problem space. The findings from the exploratory research raised the need for a framework to support a user-centered development of the KIVS. This framework is particularly required to conceptualize the information flow, between the various imaging modalities, that needs to be extracted, planned, and structured to create a single window of integrated patient information for the surgeon. In order to support surgical workflow driven development of the KIVS, a workflow-centered framework is proposed in this thesis. This approach has been proposed so as to systematically investigate the surgical workflow in order to develop a knowledge repository of surgical procedures and information requirements. This knowledge repository guides the development of the KIVS. To facilitate surgical workflow analysis, a Workflow Integration Matrix (WIM) has been formulated. The following chapters will first describe the formulated and evaluation of WIM (Chapter 3). Based on application of workflow centered framework, two KIVS prototypes will be developed and then evaluated (Chapter 4 & 5).

This chapter is based on the publication:

Jalote-Parmar, A. and P. Badke-Schaub (2008a). "Workflow Integration Matrix: A Framework to Support the Development of Surgical Information Systems." Design Studies 29 (4): 338-368.

Overview

This chapter explains the series of empirical studies that led to the formulation and evaluation of the proposed Workflow Integration Matrix (WIM). WIM is an integral component of a workflow-centered design framework which forms a part of the required analysis phase of the workflow-centered development approach (as explained in the previous chapter). Based on the findings from the exploratory phase, WIM aims to facilitate the development of KIVS on two levels: (a) in the conducting of the surgical workflow analysis by taking into consideration the surgical problem solving process, (b) in providing a communication platform and facilitating in the sharing of the acquired knowledge repository of the surgical workflow within a multidisciplinary development team.

CHAPTER 3 WORKFLOW INTEGRATION MATRIX

3.1 Introduction

In order to develop the Workflow Integration Matrix (WIM), which is an integral component of workflow-centered design framework the following two research questions are addressed:

- *What are the constituents or the task boundaries of the surgical workspace that influence the surgical problem solving process?*
    - a In particular, what are the task boundaries of the surgical workspace in terms of possibilities and limitations that determine the surgical workflow?
    - b What is the inter-relation of the task boundaries in the surgical problem-solving process?
- *What steps are required in the development process to facilitate collaborative design in a multidisciplinary development team of surgeons, technology engineers and designers?*

The research process that followed towards the development of WIM is illustrated in Fig 1. This chapter is organized as follows: Section 3.2 describes the literature study on existing surgical workflow frameworks as mentioned in the informatics literature. Section 3.3 explains the relationship of established task analysis methods to the formation of WIM.

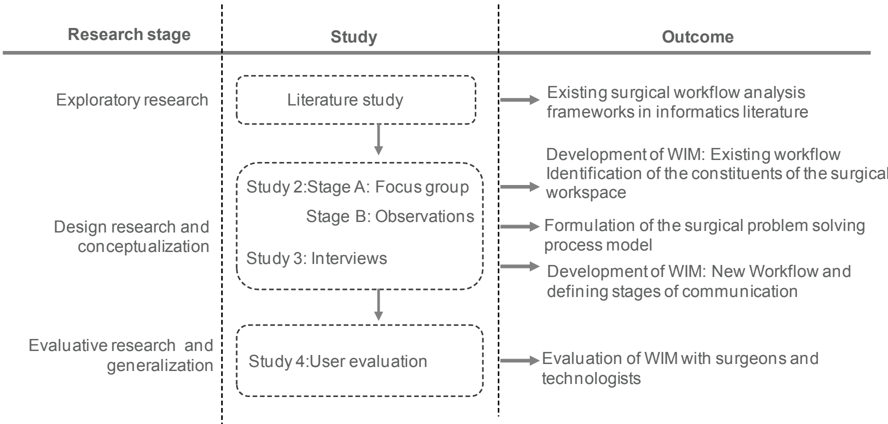


Fig.1. Research process followed in the developed of Workflow Integration Matrix (WIM).

Sections 3.4 and 3.5 explain the empirical studies conducted to formulate the proposed WIM. Of this, Section 3.4 explains Study 2, which was conducted to investigate the task boundaries that determine surgical problem-solving process in the surgical workspace, while, Section 3.5 describes Study 3 that was conducted to identify the communication gaps between surgeons and technology engineers in the product development process, specially related to surgical workspace. Section 3.5.3 explains the implication of WIM in the user-centered design cycle. Section 3.6 explains Study 4, which was conducted to evaluate the WIM framework with surgeons and technology engineers. The chapter concludes with a discussion of the application of WIM in the development of the KIVS.

3.2 Existing surgical workflow frameworks

The need for the optimization of intra-operative surgical workflow has recently emerged to support rapid technological advancements in the surgical theatre (Lemke et al. 2004; Fischer et al. 2005). Research, dealing with the development of computer aided surgical systems, emphasizes the recovery of surgical workflow as a crucial component for designing systems for future surgical theatres (Neumuth et al. 2005; Navab et al. 2007; Padoy et al. 2007). Even though there is a need, until recently few concrete efforts have been made to acquire knowledge of surgical activities by modeling surgical procedures (Jannin and Morandi 2007). Examples of existing frameworks to model surgical workflow are: (a) modeling the surgeons' physical activities to optimize surgical planning (MacKenzie.C.L et al. 2001); (b) modeling the surgical procedures for multi-modal image guided surgery (Jannin et al. 2003), (c) modeling the surgical gestures for partial robotic assistance (Botturi et al. 2005), and (d) modeling using a Extensible Markup Language (XML) to analyze the physical activities of the surgeon in the intra-operative workspace (Neumuth et al. 2005).

The frameworks mentioned above model the surgical workflow by using quantitative models to obtain information from available sensors in order to recognize objects, persons, and actions. From the informatics point of view in the existing literature the term 'surgical workflow' is explained as "the automation of a business process in the surgical management of patients, in whole or part, during which documents, information, images, or tasks are passed from one participant to another for action, according to a set of procedural rules" (Jannin and Morandi 2007). The knowledge obtained from the recovery of surgical workflow is useful in the development of a number of applications, such as optimizing the workflow, recovering regular workflows for guiding and evaluating the resident surgeons, automatic report generation, and ultimately for monitoring in a context-aware operating room (Padoy et al. 2007).

The frameworks mentioned above were primarily developed with the objective of automatic recovery of the physical actions performed in the surgical theatre: for example, by applying sensors on the surgeon. This knowledge is crucial in the development of systems where automation is the solution, for example, for developing robotic systems. To develop decision support systems such as the KIVS, these frameworks are insufficient as they do not focus on analyzing the surgical workflow from the point of view of capturing the surgical needs and surgical problem solving process. Knowledge of cognitive processes is considered critical in the development of decision support systems (Patel et al. 2001).

In addition, the frameworks mentioned above have been developed mainly by technology driven engineering groups, and therefore focus on analyzing and depicting technological requirements at a low resolution within a surgical workspace. As a result, these frameworks both do not allow the surgeons' to examine the surgical processes within the context they understand, and do not provide an overview of the surgical procedures needed to separate surgical problems which require technological solutions (Jalote-Parmar and Badke-Schaub 2008a).

In summary, although the technology-driven surgical workflow frameworks are important, the workflow analysis approach that is based on the understanding of the surgical problem-solving processes is critical. It is likely to complement the existing technological developments to solutions, which are surgeon-centered, and offer functionalities required by the surgeon. The next section explains the task analysis methods and their adoption in the formulation of WIM.

3.3 Task analysis methods and their adaptations

The development of decision support systems require analyzing how experts in a particular field conduct tasks and make decisions in their real-time environment. Integrating the abilities and limitations of human information processing to design decision support systems, such as supervisory control systems for complex workspaces, has proved a challenge for researchers over the past couple of decades. Literature on information processing and human factor engineering reveals several well established theories and methods for the analysis of expert decision making tasks in complex environments from different perspectives, such as Hierarchical Task Analysis (HTA), and Cognitive Task Analysis (CTA). Researchers have confronted the issue of investigating expert problem-solving in real-time decision-making environments from a variety of perspectives. At the one end of the spectrum, researchers from the ethnographic research tradition analyze observation data with minimal preconceptions and, at the other end, researchers from cognitive engineering begin with a formal representation of the underlying domain as a guide to the interpretation and analysis of observational data with methods, such as Hierarchical Task Analysis or HTA (Annett and Duncan 1967; Annett and Stanton 2000) and Cognitive Task Analysis or CTA (Rasmussen 1986). These methods rely on analyzing human problem-solving as a means of understanding the user, the task, and the task environment.

Annette and Duncan (1967) proposed the HTA method of examining work. HTA analyses the human activity by understanding the purpose of work in terms of the organization and the systems in which it was undertaken. It represents an accurate description of the physical steps required to complete the given tasks, and provides a practical way of identifying problems and has been used to conduct requirement analyses for complex domains such as: (a) air traffic control (Shepard 2001); (b) process control in petrochemical, power industries (Shepard 2001); and (c) laparoscopic liver surgery (MacKenzie.C.L et al. 2001).

The CTA method provides principles to map the sequence of information processes involved in decision-making in complex environments (Rasmussen 1986). It has been applied in several work domains, including (a) modeling the information processing activities for anesthesiologists (Hajdukiewicz et al. 2001), and (b) analyzing 'system life cycle' in aviation (Sanderson 2003). Several CTA methods investigate how people make decisions in complex and dynamic real-time environments (Gordan and Gill 1997) and it describes the knowledge that people 'have' or 'need to have' in order to complete the tasks. Other CTA methods, in literature, rely on the knowledge of human problem solving as a means to understand the user, the task and the task environment. Examples of CTA methods include (a) Concept mapping and expert storyboarding (Zaff et al. 1993);

(b) COGnitive NETworks of tasks or COGNET (Ryder and Redding 1993); and (c) decision making ladder: a framework for cognitive task analysis (Rasmussen 1986). These methods have been used to describe the decision-making tasks for a process controller at nuclear power plants (Rasmussen 1986), and have also been used to develop training modules for aviation pilots (Seamster et al. 1997).

Although these methods provide a foundation to conduct task analysis in complex workspaces, they do not provide the specific constituents necessary to analyze the surgical workspace. Developing decision support systems as the KIVS depends on the knowledge of surgical problem solving process. This can be understood as the sequence of physical and cognitive activities performed by a surgeon to complete the surgical procedure. In this context, several arguments persist that the HTA ignores the cognitive aspects of the tasks (Shepard 2000). Shepard (2000) argues that rather than distinguishing between cognitive and non-cognitive task analysis, it is more profitable to consider how a general task analysis strategy accommodates tasks when performance is driven substantially by cognitive tasks. He further suggests that to gain efficiency in effort and to ensure that the determination of task elements is not carried out in a vacuum, the CTA methods can be incorporated within a HTA framework. MacKenzie. C.L. et al (2001) state a similar need to add cognitive tasks in the HTA framework while conducting task decomposition of a laparoscopic surgery. Their study concludes that there is a need for domain specific framework to analyze the information that surgeons 'have' and 'need to have' in order to perform their tasks successfully.

From the above analysis it is clear that the development of a framework which can analyze the surgical workflow should be able to provide a systematic way of analyzing both the physical and the cognitive tasks of the surgeon. To do this, the framework needs to construct a combination of approaches as suggested by the CTA and HTA framework. In the following section, in order to develop the proposed 'Workflow Integration Matrix' (WIM), we first explain Study 2, conducted to investigate the domain specific task boundaries which determine the surgical problem-solving process.

3.4 Development of WIM: Existing surgical workflow

This section deals with the first research question: What are the task boundaries within a surgical workspace that influence surgical problem-solving process? To meet this objective, the study was conducted in two stages: The first stage (A) aimed to investigate the task boundaries which determine the surgical problem solving activities, i.e. the surgical workflow. Here, task boundaries are conditions, which determine the possibilities and limitations of the surgical problem solving processes within the surgical workspace. Knowledge of these task boundaries assists in the analysis of the surgical tasks required to develop a knowledge repository of the surgical procedures and information requirements. The second stage (B) focused on understanding the inter-relation between task boundaries.

3.4.1 Study 2a: Identification of task boundaries

To investigate task boundaries of the surgical workspace, the following study was conducted:

Method

The focus group method was selected to conduct the study with surgeons and intervention radiologists. The focus group method allows exploring the perceptions and understandings of people who have a common experience in a specific field, for example, surgery (Stewart and Shamdasani 1990). In combination with this, generative tools were used during the session to support and motivate the discussion. These are a combination of key words and images which allow participants to verbally and visually express themselves (Sanders 2001). During the focus group sessions, keywords and images relating to the selected surgical disciplines were used to trigger discussions, and to aid the surgeons in generating flow charts of their problem solving processes. Generative tools have previously been applied by researchers to assess the health professionals in nursing (Melles and Freudenthal 2003). Using generative tools to develop a storyboard of the problem solving events is an approach similar to the 'concept mapping and expert storyboarding' method used by Zaff (1993) to aid in the development of a CTA knowledge base.

Participants

The study was conducted with a total of (n=20) surgeons and intervention radiologists, specifically including those who perform the following procedure: (a) classical and endoscopic liver surgery (n=7); (b) classical and endoscopic cardiac surgery (n=6); and (c) percutaneous radiofrequency coagulation (n=7). Each participant had eight to twenty years of experience in his respective discipline (Table. 1).

Table 1. Participants of Study 1

Focus group	Surgeons and Intervention radiologists	Procedure	Hospital
1	7	Percutaneous radiofrequency coagulation	Erasmus MC, The Netherlands.
2	6	Classical and endoscopic cardiac surgery	Klinichini, Slovenia.
3	7	Classical and endoscopic liver surgery	Rikshospitalet, Norway.

Procedure

Three focus group sessions were conducted. The author and a surgeon moderated the sessions. In order to be an effective moderator, the author had to acquire prior knowledge of the terms and procedures of the surgical specializations. At the start of the session, the purpose and structure of the study were explained. Generative tools, including images specific to surgery, and keywords to trigger the surgical experiences (Fig. 2 a &b), were used. The participants' task was to create a flow chart of a recent critical situation that arose during the surgery and explain how they solved it. Fig. 3 illustrates the flow charts made by the surgeons by using the generative tools. Participants were given around twenty minutes to independently prepare the flow chart with the help of the images and keywords provided to them, and about ten minutes each to discuss their problem-solving process within the group. This time set up was based on the availability of the participants to be in a complete session of approximately two hours. Each presentation led to a group discussion dealing with specific surgical challenges presented by the participant.

Analysis of focus group sessions and results

All the sessions were videotaped and transcribed by the author. The data gathered from the various interviews and focus were analysed by the author. This analysis was conducted by extracting key statements from the transcribed data and semantically grouped to key categories. It is realised that this approach can lead to coder biases. As a way to overcome these biases the findings were also verified by selected clinicians. Involving another coder was not possible in this situation, as it was not feasible to find another Human Computer Interaction (HCI) expert with similar educational background and understanding of the surgical domain in the given time frame. The data was then verified by the surgeon for its medical correctness. Transcripts of all the three focus group sessions were analyzed, and key statements were identified. These statements were semantically clustered in categories by applying the affinity diagram technique as suggested by Beyer and Holtzblatt 1998) (1998). An affinity diagram

Fig.2. a- A sample focus group session and b- Generative tools used during the focus groups. (Photos taken at Rikshospitalet, Norway)

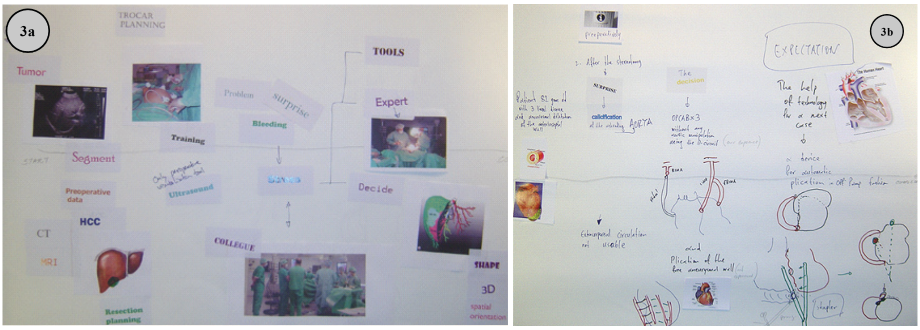


Fig.3. a- Flow charts made by the liver surgeon and b- cardiac surgeon. (Photos taken at Rikshospitalet, Norway)

helps in organizing the key statements into a smaller set of issues and themes. The affinity diagram method has been similarly used for analyzing qualitative data from interviews (Angeli et al. 2004). The frequency of occurrence of statements in each category was also marked against the category. Of course, one surgeon can make several statements; therefore, the number of frequencies can exceed the number of categories.

The analysis revealed 5 primary and 13 secondary task boundaries which the surgeon relies on during the problem-solving process while performing the surgery (Table 2). Table 3, in a later section, explains the task boundaries. The frequencies of occurrence of the task boundaries do not always indicate their importance in the problem-solving process. For example, the task boundary 'uncertainty' normally occurs once or twice during a surgical procedure. However, since even a single occurrence of uncertainty can lead to a change in the surgical strategy, its importance

Table 2. Task boundaries: primary (1-5) and secondary (a-m)

Task boundary	No. of surgeons	Frequency
1. Target state		
a. Goal	20	28
b. Procedure (Standard protocol)	20	38
c. Action (Execute, Coordinate, Manipulate)	20	36
2.Equipment		
a. Surgical tool (Selection, Set up)	20	32
b. Surgical system (Selection, Set up)	20	25
3. Communication		
a. Surgical system (Task feedback, Task input)	17	38
b. Surgical team (Protocol exchange, Decision-making, Exchange of patient data, Teaching)	14	27
4. Patient state		
a. Constraints (Anatomical)	17	42
b. Critical factor (Clinical state)	20	36
c. Feedback (Organ, Tissue, Bone, Pathology)	20	48
d. Anatomical structure (Form, Function, Location, Mental model)	20	43
5 Surprise state		
a. Uncertainty (Surprise state, Patient state)	18	22
b. Surgical strategy (Standard protocols, New pathology report, Expert advice)	20	24

cannot be ignored. Overall, the frequencies indicate that the importance of information processing activities related to 'patient state' is much higher during the problem solving process. This is because 'patient state' is the main state requiring surgical action. It involves the identification of the problem related to the physical form/function of the patient that requires the surgical action to improve the health of the patient. The 'patient state' changes as the surgical procedure progresses in time.

Verifying the findings with the surgeons
In order to confirm these findings 4 surgeons, who were not the participants of the focus group session, were asked to verify them. These surgeons were asked to explain a surgical procedure to the resident surgeons by using the task boundaries as documented in the WIM (Fig 4). Next, these surgeons were asked if they found any issue missing, which they considered as critical for their problem-solving. The surgeons found nearly all important aspects of their problem solving process covered in WIM. In their opinion, the importance of these task boundaries differs with experience in the three phases of the surgery.

3.4.2 Developing a matrix of task boundaries

In order to facilitate better design decision-making, a matrix of the task boundaries (as identified in stage A) was developed. This represents the 'existing surgical workflow component of WIM. The matrix is often used in task analysis to define the information requirements related to specific task decomposition levels (Shepard 2000). The task boundaries in the matrix represent the limitations and possibilities specific to the surgical workspace that determines the surgical problem-solving process. These boundaries allow determination of the different levels of information the surgeon relies on, while conducting surgical tasks.

WIM is structured along two axes: the x-axis represents surgical milestones, which are key surgical tasks (1/2/3…) that have to be performed in order to complete the surgical procedure (Fig 4). These milestones are placed sequentially on a time axis connecting the three surgical phases (before, during and after surgery). These are surgery specific: for example, milestone six could be understood as 'tumor coagulation', which is specific to the 'Minimally Invasive Surgery- Radio frequency' procedure. However, if the surgical procedure were a mitral valve repair, there would be a different surgical milestone. The surgical milestones for the same procedure can vary between different hospitals, but the same surgical procedure is usually followed within a single hospital and, consequently, the same surgical milestones. The y-axis includes task boundaries that facilitate the decomposition of the surgical milestones. The structure of WIM adapts to the basic HTA framework (Annett and Duncan 1967; Annett and Stanton 2000), which conducts task analysis of the physical activities of the expert by decomposing the tasks based on goals, procedures, and actions. The

Table 3. Explanation of the task boundaries of WIM for “Existing surgical workflow”

Surgical milestone	Surgical milestones are critical surgical tasks necessary to complete the surgical procedure. Surgeons may encounter certain problems while performing some of the surgical milestones. The aim of the expert system should be to support these problems in order to enhance the performance of the procedure. Surgical problems can occur for any of these surgical milestones, so it is important to identify these correctly at the start of the workflow analysis.
Time	‘Time’ is the duration taken to accomplish a surgical milestone. Time also depicts the time line connecting all the three phases of the surgery, which, in some cases, may cover days or months.
Task boundaries	Task is the problem facing the surgeon. Task boundaries can be understood as parameters which determine the possibilities and limitations of the surgical problem solving process within the surgical workspace.
Target state	Target state is the state to which the patient has to be taken by performing surgical actions.
Goal	Goal is the target that has to be attained to accomplish the surgical milestone in the given conditions (treatment plan and patient safety). Goals allow for the predictions about the actions and the preconditions for those actions.
Procedure	Procedure is a series of surgical actions performed to achieve the goal. These are based on the standard surgical protocols.
Surgical action	The surgical action includes steps and sub-steps that take place over time to transform the objects (procedure) into actions. These sub-steps may differ with each surgical case and are dependent on the personal skills and expertise of the surgeon. When creating an overview of the surgical workflow, not all details of sub-steps are required until the technological approach is selected. In the later stages of the product development process, further decomposition of the sub steps can be conducted on the basis of HTA if found necessary.
Surgical equipment	The object used to perform or support the surgical action.
Surgical tool	Surgical tool is the equipment, such as laparoscope, trocar, or needle, required to perform the surgical action. The set up and selection criteria of tools differs with surgical specialization. The surgical steps, which are not effectively supported by the current tools need to be documented along with the setup and selection criteria.
Information system	Information systems are a variety of computer aided surgical systems and imaging systems, such as intra-operative Ultrasound, Magnetic resonance imaging system, robotic system, and heart lung machine equipment, that provide information about the patient state along with imaging and procedural support to the surgical action.
Communication	Communication is the interaction between the surgeon and the system, including the team that receives the information about the state and the consequences of the surgical action.

Surgical equipment	Communication between the surgeon and the surgical equipment is necessary to communicate information about the state or consequence of the surgical action. In response to the surgical action, different systems provide critical surgical information to the surgeon. For example, the surgical action includes the following steps: the ultrasound probe is placed on the patient and assists in identifying the location of the tumor. It is important to know what information the surgeon receives from the ultrasound from the different angles of the probe.
Surgical team	Communication between the surgeon and the team is necessary to exchange information about the state or the consequences of the surgical action. Surgical staff are responsible for specific surgical actions during the surgery. The stage or the consequences of their actions are communicated to the surgeon only at critical stages. For example, during cardiac surgery, at critical moments, the surgeon requires inputs from the heart lung machine operator or the anesthesiologist. If this information is not conveyed on time, it could lead to serious surgical errors.
Patient state	The identification of the problem related to the physical form/function of the patient that requires surgical action to improve the health of the patient. The patient state changes as the surgical procedure progresses in time.
Surgical constraint	Constraint is the surgical (anatomical- form and function) limitation to the surgical action. The surgical system may be developed to avoid these limitations. For example, the organs in the path of the needle act as a constraint on the navigation path of the needle. This affects the selection of the entry port for the needle. A real-time knowledge of the location of the organs can help in avoiding this constraint.
Critical factor	The critical factor is the surgical state to be accomplished or avoided while performing the surgical action. For example, the critical factor for entry and placement of the needle is not to rupture other organs or vessels in the way of the needle placement. This indicates that the surgeon requires certain warning or visualization system to avoid rupturing the organs.
Feedback	Feedback is the response received as a result of the surgical action. It can be received from the patient body, or the system/tool in use. For example, the haptic feedback of different organs and tissues is different for different tasks.
Anatomical constraint	Anatomical structure is defined as the form, function, and location of the organs, tissues, and bones in the patient body.
Surprise state	Surprise state is the sudden (unexpected) revelation while performing the surgical action. This could lead to a breakdown of the surgical procedure.
Uncertainty	Uncertainty is the state of indecisiveness while performing the surgical action which arises as a consequence of the surprise state. For example, finding a new tumor in the liver while performing an intra-operative ultrasound. Uncertainty leads to iterations in the originally planned surgical strategy.
New surgical strategy	The surgical decision taken to solve the problem that arises as a consequence of the surprise state. In certain cases, several other surgeons may be invited into the surgical theatre and a common decision-making may take place.

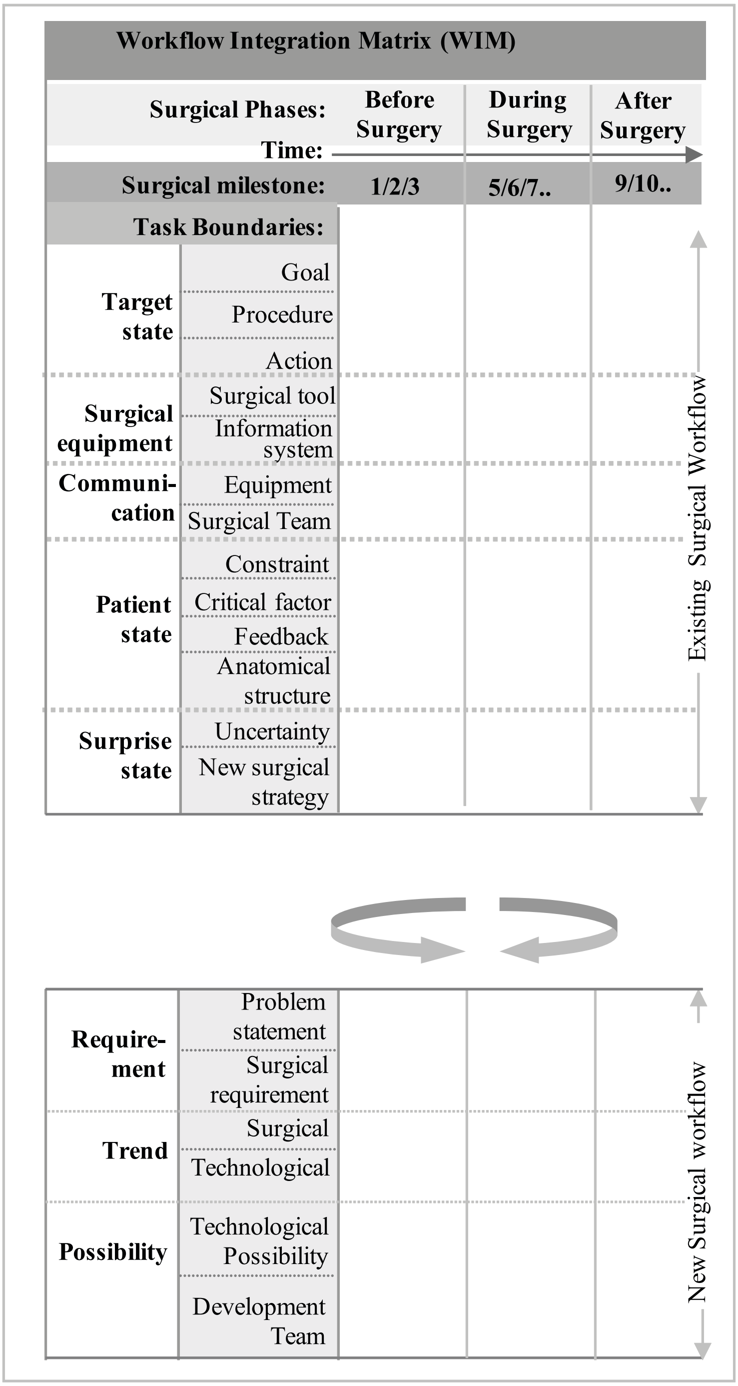


Fig.4. Workflow Integration Matrix (WIM).

basic HTA framework was not adequate for a concrete understanding of the other factors which affect the surgeons' physical and cognitive tasks. In order to analyze the surgical tasks, it is not enough to know how many times the surgeon makes a cut in the organ, it is also important to know what other boundaries or conditions determine the possibilities and limitations of performing the cut in the organ. For example, as seen in Fig.3, 'constraint' is one of the task boundary. This is the clinical limitation on the surgical action which determines surgical tasks. These constraints can be anatomical or related to the function of the organ. For example, the vessels in the path of the needle act as a constraint on the navigation path of the needle, affecting the selection of the entry port for the needle. A real-time knowledge of the location of the vessels can aid in better decision making. Therefore, in order to analyse the surgical workflow, where performance is substantially driven by a combination of both cognitive and physical tasks, the task boundaries which represent the surgical problem solving tasks (as identified in Study 2, Stage A) were integrated in the matrix. Other researchers such as Shepard (2000) have also similarly proposed an extension to the HTA in order to overcome the limitations of HTA.

3.4.3 Study 2b: Surgical problem-solving process model

This study (Study 2, Stage b) was conducted to investigate the inter-relation between the task boundaries which represent the surgical problem-solving process. This is represented as a process model depicting the information processing activities and states that form the surgical problem-solving process (Fig.5).

Method
This study was conducted thus: (a) the task boundaries and the flow charts made by the surgeons (Fig. 3), as obtained from Study 2, Stage A were re-analyzed. The task boundaries were sequentially linked to obtain the problem-solving model. (b) Ten field studies were conducted to reconfirm the task boundaries and the model. The surgeons were observed by the author for all the three phases of the surgical workflow. During the observations, wherever possible, the surgeons were asked to think aloud. In addition, in order to develop a better understanding of their problem-solving process, critical events were noted by the author during surgery and discussed with the surgeons after.

Participants
Surgeons (n=10), were shadowed by the author in the national hospitals of the Netherlands (n=6), Norway (n=2), and Slovenia (n=2) performing the following procedures: (a) classical liver surgery; (b) endoscopic liver surgery; (c) classical mitral valve repair; (d) endoscopic mitral valve repair; and (e) percutaneous radio frequency ablation.

Analysis of the findings from the surgical observations
The analysis was conducted in two steps: First, the task boundaries and flow charts, as obtained from Study 2, Stage A were sequentially documented to represent the problem solving process of each surgeon. After consolidating all the cases, a basic model of the surgical problem-solving process was developed. Second, this model was reconfirmed during the surgical observations. Here, the understanding of expert problem-solving and decision-making was explained through the decision-making ladder a CTA framework which proposed by Rasmussen (1986). This framework served as a guideline for generating the problem-solving model. Decision-making ladder is the most widely used framework to analyze decision making tasks and was selected because other CTA methods, such as COGNET (Ryder and Redding 1993),and concept mapping (Zaff et al. 1993), do not provide a process model to understand the decision making process of the user. In particular, the decision-making ladder was found to be a flexible framework and adaptable to components, such as ambiguity and complexity, which are required to describe a surgical workspace.

According to the decision making ladder', the nature of the information process changes during the problem solving activities. In the beginning, in order to identify the problem, the situation or the context needs to be analyzed. Next, a prediction and valued judgment is made, and finally there is selection and planning of the proper actions. The states of knowledge resulting from information processing activities are standard nodes between the information processing activities. Depending upon the context in which the decisions have to be made, in particular whether it is control of a physical system governed by causal physical laws or a social system governed by human intentions, the uncertainty in the decision task may result in different elementary phases.

Results
During the surgical observations, the task boundaries as obtained from Study 2, Stage A (focus groups) were reconfirmed. In addition, during the surgical observations, the 'mental model' emerged as a particularly important aspect of the surgical problem-solving process. In the following section, we first describe the surgical problem-solving process model and then the mental model.

1 *Surgical problem solving model*
The surgical problem solving process model describes the inter-relation between the task boundaries (Fig.5) and can be described by the following sequence: at the start of the process the surgeon detects a clinical symptom, which requires a surgical action. To diagnose the patient state, the surgeon conducts a set of observations. This diagnosis requires an understanding of diagnostic decision-making (Elstein et al. 1978), which is a significant area of research, but is not included in WIM. During the planning phase, the surgeon consults with several

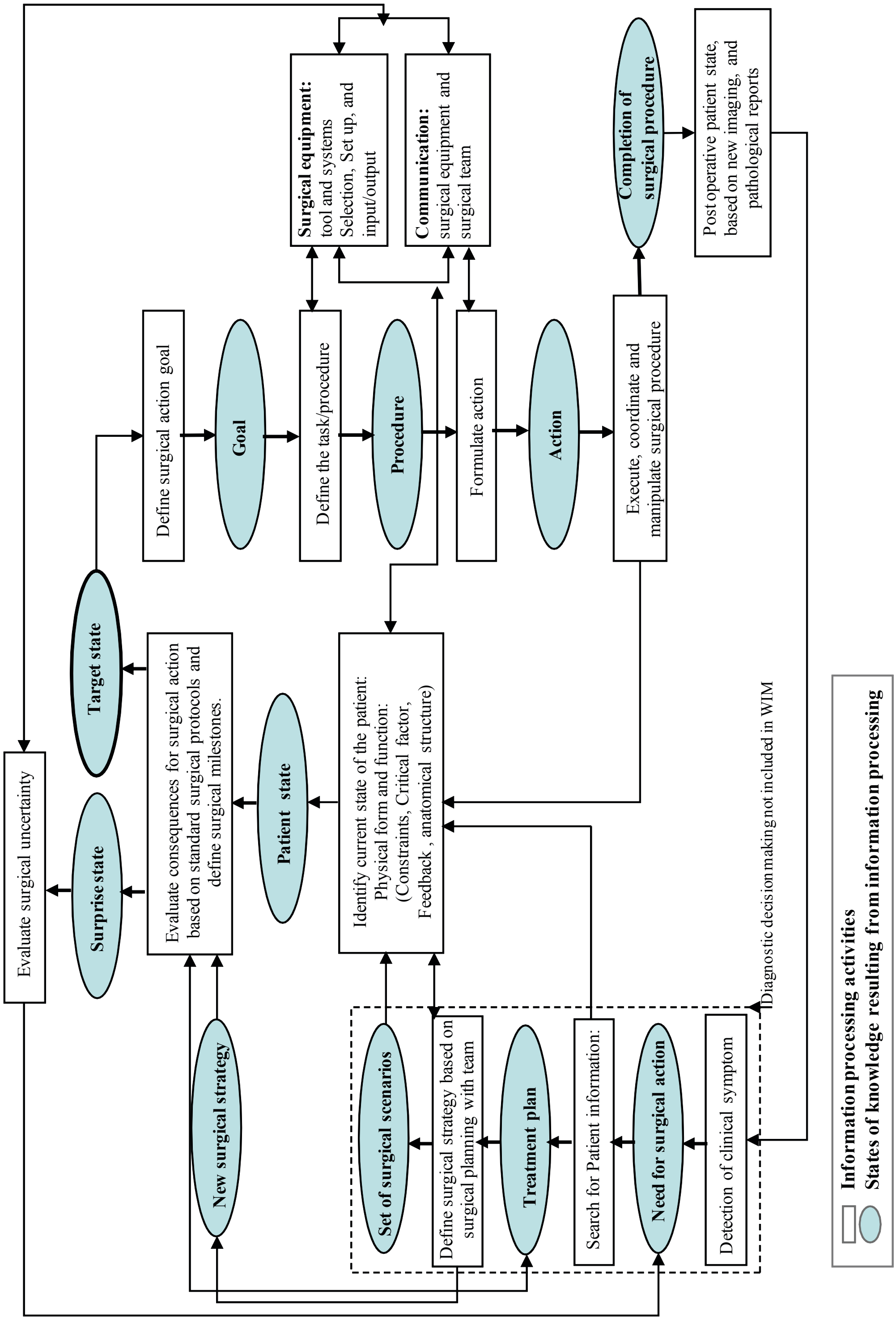


Fig.5. A model of the surgical problem-solving process.

other clinicians involved with the patient case to decide the treatment plan. Thereafter, the surgeon conducts a meeting with the surgical team to define a surgical strategy. This meeting leads to a set of surgical scenarios required to conduct the surgery. Surgical scenarios assist the surgeon to develop a mental model of the patient, which is a overview of surgical problems related to the patient and the treatment strategy currently planned. This model also includes an abstract representation of the anatomical structure of the patient, and is updated when the surgeon starts performing the surgery. This helps reduce the existing complexity of the tasks and allows for future predictions.

At the start of the surgery, the surgeon identifies the current state of the patient on the basis of his physical form and function. The surgeon then evaluates the possible consequences with reference to standard surgical protocols and defines the surgical milestones. On the basis of this information, the desired target state of the patient is planned, and the surgical procedure to accomplish the target state is defined. After the surgical strategy has been identified in terms of surgical actions, the proper procedure is planned from a review of resources available (team, tools, systems etc.). Thereafter the surgeon executes, co-ordinates, and manipulates the surgical procedures until they reach completion. Subsequently, the patient state is re-evaluated post-operatively with the assistance of new imaging and pathological reports. Depending on the type of surgery, post-operative imaging can be procured a day or several months later.

The surgeon may encounter a difference in the expected state and the current state of the patient. This may cause uncertainty, which leads to a surprise state and, therefore, the need to adapt to a new surgical strategy which can be defined by two sub stages which may occur at different stages of the surgery: First, while identifying the current state of the patient there may be a surprise relating to the heuristic findings in the physical form or function of the patient's anatomy. Second, while executing the surgical procedure a surprise due to a new finding in the physical form or function of the anatomical structure may occur. Both events require further evaluations with reference to the treatment plan and the surgical planning. The surgical problem-solving process model described can be understood at two resolution levels: First, at a lower resolution, beginning at the surgical planning and ending when the surgical procedure reaches completion. Second, at a higher resolution, the decision making loop starts from the evaluation of the patient state and cycles between the target state and back, till the completion of the procedure.

2 *Mental model*

During surgical observations, surgeons referred to the "mental model" as an important component of their problem-solving process. Literature

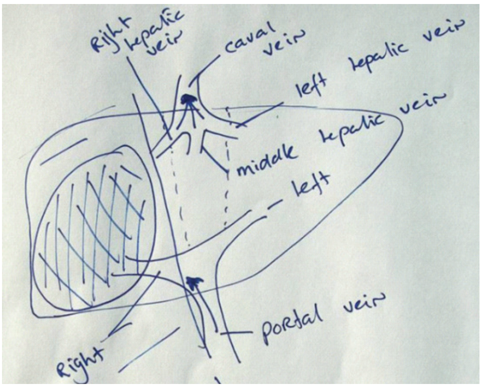


Fig.6. Sketch made by the surgeon as a visual representation of the mental model of the patient liver.

in the field of cognitive science also states that mental models are representations of the selected aspects of real-world, and are an integral part of the problem solving process (Wahlstrom 1988; Andersen and Olsen 1998). In particular, it was observed that the surgeon has a general mental model of the patient and the surgical protocol that needs to be followed for performing the surgery. This model is an abstract representation of the selected aspects of the surgical procedure applied to treat the patient. It is based on the standard surgical knowledge and the patient data provided in the planning stage. During the surgery, the surgeon focuses on or zooms into the specific aspects of the patient anatomy and updates the standard model based on the real-time inputs from the tasks. All surgeons depend on a detailed understanding of anatomy, which involves developing spatial concepts, such as the shape of anatomical structures (e.g., the liver), and the critical structures (e.g., "the hepatic portal vessel"). While performing the procedure, the internal structures of the body are not directly visible so the surgeons have to rely on their mental spatial representations of these structures and awareness of human variability (Hegarthy et al. 2007). Fig.6 shows a sketch made by the surgeon depicting the visualization of the mental model of the patient after analyzing the patient's CT scan. It shows the abstract level of 3D representation generated from the CT data. The role of visualization, as a part of generating the mental model in the surgical problem solving process, is an important area of research, but is beyond the scope of this thesis.

Summary

In the previous section, the component 'existing surgical workflow' of WIM was formulated. The 'existing surgical workflow' component of the WIM aims to analyze the surgical workflow by facilitating the decomposition of the surgical tasks based on the knowledge of surgical problem-solving. The surgical problem-solving process model aids in understanding the surgical process. The following section deals with the further development of WIM in addressing the second research challenge.

3.5 Development of WIM: *New surgical workflow*

Study 3 addresses the second challenge: What steps are required in the development process to facilitate collaborative design in a multidisciplinary development team of surgeons, technology engineers and designers? This challenge is related to the development of the KIVS, which requires a multidisciplinary team of surgeons, technologists, and designers to collaborate together. Communication within a multidisciplinary development team is critical when the product development depends on knowledge exchange across different disciplinary boundaries (Cross 1989; Milne 2000; Tzortzopoulous et al. 2006; Thomann and Caelen 2007). Cooper and Press (1995) have identified communication between teams as the main requirement for a successful design. However, literature on the communication gaps between surgeons and technology engineers in the product development process is sparse (Jalote-Parmar et al. 2006). The following section explains Study 3, conducted to identify the communication gaps between surgeons and technology engineers. Based on the findings from this study new components will be added in the WIM.

3.5.1 Study 3: Communication gaps between surgeons and technology engineers

The study was conducted to identify the gaps in communication between surgeons and technology engineers.

Method
Interviews were conducted with surgeons and technology engineers of the ARIS*ER consortium. The purpose of the interviews was to obtain information about the following issues: (1) Communication practices between surgeons and technology engineers during product development, and (2) Concerns and expectations of surgeons and technology engineers to facilitate communication in the product development process.

Participants
As a part of the study, (n=10) interviews were conducted with surgeons and technology engineers. All participants had a minimum experience of 8 years in their respective disciplines. Expert surgeons (n=5) from two national hospitals in The Netherlands and Norway and technology engineers (n=5) from the field of medical imaging and 3D visualization of medical data from technology labs in Great Britain and Norway were interviewed. These participants had prior experience with new product development in the area of medical imaging.

Qualitative analysis and results
The interviews were transcribed, and key statements were identified. The key statements were semantically clustered by building an ‘affinity diagram’ (Beyer and Holtzblatt 1998). A total of five main categories depicting communication issues were identified:

1 *Biased conceptual models of surgeons and technology engineers*
As stated by one of the surgeons,“...*This is an impressive technology, but*

I don't see where exactly it supports my tasks…even if it is given for free I wouldn't install it in my hospital." A common problem, as observed in large medical engineering organizations, is the communication gap between surgeons and technology engineers when exchanging the user requirements. In several cases, the product manager in the medical engineering organization, whose approach to the development is often more business based and technology driven than user (surgeon) driven serves as the communication link. This way of communication results in a fragmented picture of the surgical requirements for the technologist and leads to a biased technological development. As a consequence, the surgeons are unable to adapt to the technology at the surgical workspace.

2 *Unstructured approach to investigate the surgeon's requirements*
According to one surgeon, *"…We don't trust these meetings with the product managers anymore, as important conclusions from the meetings are often lost".* Due to the often unstructured approach adapted by the product managers, findings and important requirements from the discussions with the surgeons may be misplaced or only randomly documented. Thus, the critical findings necessary to provide valuable input to the product development are difficult to access, and assessing the user requirements is often ad hoc, rather than being explicitly methodology based (Darlington and Culley 2004).

3 *Inadequate verification of surgical problems*
"…What the technologist thought of as a problem was not considered a problem by the surgeons at all…": an opinion voiced by several surgeons. Despite the fact that all problems may be valid, some of them are more critical for the outcome of the surgical procedure as a whole. The process of providing signing off stages (Shein et al. 2004), where the clients (surgeons) could verify or prioritize the problems, (Cooper and Press 1995; Barrett and Stanley 1999; Bruce and Cooper 2000) appears to be missing in the product development process, particularly in relation to medical imaging systems.

4 *No room for shared understanding of surgical procedures among development teams*
A statement made by one of the technology engineers after visiting the surgical theatre for the first time: *"…I assumed that this solution may solve problems, but I now realize it might create a few others…".* At the outset of product development, it is often assumed that all members of the multidisciplinary team have a shared understanding of the surgical procedures and requirements. A lack of a common platform to exchange the problem space leads to a gulf in shared understanding (Green et al. 2004). In addition, some of the solutions, when placed in the surgical workspace, may result in changes to the existing surgical workflow. Visualizing the changes that will occur in the existing

surgical workflow when the new product is introduced can help deciding the pros and cons of technology implementation at an early stage. This can avoid solutions that do not fit the surgical workspace.

5 *Lack of opportunity for the surgeons to share innovative ideas*
A statement from one of the technology engineers: *"...attempts in exchanging the design requirements, while quite effective in bringing forward the issue of user requirements, have left to the engineering side involved in the development process the responsibility of innovation and invention"*. Thus, when designing innovative systems, technology engineers appear to be forced to disregard the surgeon and develop the technological innovation per se. The growing research on knowledge organization underscores this challenge by recognizing the knowledge boundaries within the teams working together (Brown and Duguid 2001). On the other hand, surgeons say *"we have some practical ideas related to our problems, but we don't know enough about technological options"*. In the domain of building construction, Barrett and Stanley (1999) have stated that clients need to understand the construction process and the type of input they need to provide professionally before getting involved in a project. Resolving this requires a reflective space where all the members of the multidisciplinary team can participate in exchanging processes and in the development of innovative ideas.

The above findings can be summarized into the following two key requirements:

- A component in WIM is required where the requirements, surgical procedures, and possibilities (innovative ideas) can be linked with each other to visualize the new surgical workflow.
- In the design cycle, communication stages are required where the multidisciplinary team can explicitly point to the needs of sharing and exchanging the surgical requirements, processes, and possibilities.

Based on the findings, two new additions were made to the existing WIM structure. These will be explained in following Sections 3.5.2 and 3.5.3. First, a component representing the 'new surgical workflow' was added to the 'existing surgical workflow' in WIM. Second, communication stages were added to the user-centered design cycle in order to facilitate the exchange of requirements and possibilities through WIM.

3.5.2 New surgical workflow

To form a link between the existing surgical workflow and the proposed solutions, a new surgical workflow module was added to WIM. This module includes categories for incorporating the summary of requirements, trends, and technological possibilities. Table 4 explains the categories in detail. Together, the combination of the existing and the new surgical workflow aims to provide a communication platform to deal with the following issues: (a) knowledge from the existing surgical workflow should lead to predictions

Table 4. Explanation of the categories of WIM-"New surgical workflow"	
Requirement	The information needed, identified corresponding to the task boundary for each surgical milestone
Problem statement	The definition of the key problem requiring a technological solution. These are also represented as problem scenarios among team members.
Surgical requirement	The list of the needs related to the task boundaries which correspond to each surgical milestone. These need to be verified and placed in a hierarchy by the surgeon.
Trend	Recent developments in the surgical technique or technological approach.
Surgical trend	Various surgical techniques related to a procedure which are followed in a particular surgical community or hospital or country. To compensate for the information loss in the MIS procedures, surgeons try several new surgical strategies. Since many MIS procedures are very recent, surgical protocols may differ in different countries or even hospitals. It is important to select the target surgical technique at the start of the technological development. These techniques are also help provide innovative ideas to guide future technological development.
Technological trend	The global technological advancement related to addressing the surgical problem. To avoid reinventing the technology or proposing solutions, which are excessively dependent on distant technological breakthroughs, global technological trends corresponding to each surgical milestone need to be documented.
Possibility	Alternative solutions the development team proposed for the surgical problem.
Technological possibility	Prospective technological solutions to address the surgical problem.
Development team	The development group, which includes the surgeon, the technologist, and the designer, working as a team on a particular surgical problem. Different surgical issues may require different teams and each team may be dependent on inputs from other .

about the new surgical workflow; (b) the combination of both the existing and the new surgical workflow aims to provide the multidisciplinary development team the opportunity of a structured exchange of needs and possibilities. This exchange is necessary for the surgeon to examine the development issues within the context that they understand, prioritize their problems, and select probable solutions; (c) it should allow the technology engineer an overview of the various complex procedures taking place within the surgical workspace, and focus only on the key problems that require the technological intervention.

3.5.3 Implementation of WIM

Specific communication stages have been introduced to implement WIM in the existing user-centered design cycle. These stages have been included to facilitate verifying, prioritizing, and communicating the findings of surgical workflow analysis within multidisciplinary teams. (Fig. 7). The analysis

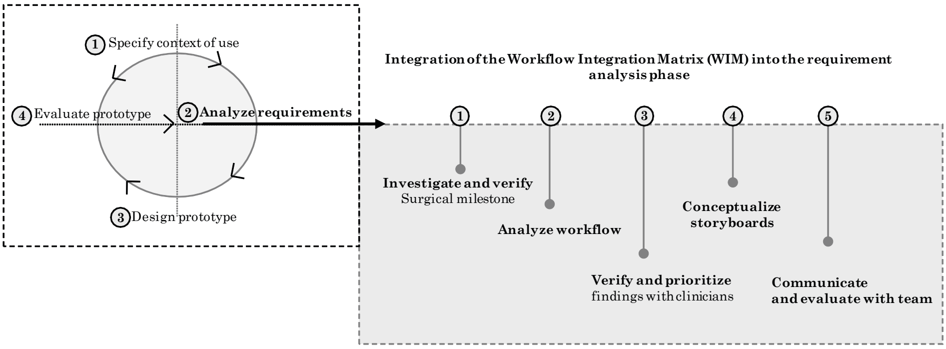


Fig.7. Implementation of WIM in the workflow-centered development framework, illustrating the 5 stages in which WIM is integrated into the requirement analysis phase to support collaborative design.

of the surgical workflow is not the final goal. It is all the same central for developing the knowledge base of surgical procedures and requirements, as the results of the surgical workflow analysis needs to be applicable to the other phases in the development. A practical example of the application of WIM in conducting requirement analyses for RFA is presented in Chapter 4, Section 4.2.2. The communication stages are as follows:

1 *Identification and verification of surgical milestones*
Surgical milestones are the critical stages that have to be completed to perform the procedure and help in defining the scope for the technological development within the surgical workflow. They are identified by observing several surgeries and consolidating the opinion of surgeons. Once identified, they are placed in the WIM (X-axis) for verification by the surgeons before the start of the surgical workflow analysis.

2 *Surgical workflow analysis*
Observation of relevant surgical procdures in the surgical workspace can be an overwhelming experience for the designer. Being a non medical-expert, the designer depends on the surgeons and other surgical staff as the main informants. The information about the procedures and the related problems can be gathered almost at any time from various sources. Here task boundaries in the WIM serve as a guideline to conduct the surgical workflow analysis for the selected surgical procedure. The findings are systematically placed in the cells corresponding to each surgical milestone in the WIM. To conduct user observations in the surgical workspace, several 'user observation methods' can be applied.

However, as it is critical not to disturb the surgical activities, it is necessary to be a passive observer, especially in the surgical theatre. Stanton et al. (1999) and Beynon (2005) provide a practical guide to several observation methods that can be applied in complex environments. In order to make accurate assessments of surgical actions and decision making, it was important to combine observation methods. Two established observations methods was selected for this purpose: (a) the contextual enquiry technique, as proposed by Beyer and Holtzblatt (1998), was used to understand the user and the context, and (b) the verbal protocols method, as proposed by Bainbridge and Sanderson (1995), was used to gain insight into the users' (surgeons') thoughts when carrying out the tasks.

3 *Verification and prioritization of requirements and processes.*
Results of the surgical workflow analysis, are documented in the 'existing surgical workflow' module in WIM. At this point, the designer(s) also marks the key problem areas in the surgical workflow where the technological intervention can make an improvement in the surgical decision-making. These findings serve as the basis for the developmental activity of the KIVS. It is therefore critical to medically verify the surgical processes. As not all surgical problems identified necessarily require a solution, the surgeons need to prioritize the specific problem areas in the surgical workflow, which require the intervention of technological solutions. Finally, the user requirements corresponding to each surgical milestone are summarized as problem statements and user requirements in the 'new surgical workflow' component in WIM.

4 *Conceptualize storyboards*
WIM is used to provide an overview of requirements and surgical procedures in the current surgical workflow, and of possible technological solutions to visualize the new or future workflow. Based on the requirements, designer(s) develop several alternative concepts for the KIVS in the form of storyboards. These represent alternative technological possibilities depicting the new surgical workflow, with each alternative illustrating how the technological assistance can address the surgical workflow in both regular and uncertain scenarios.

5 *Exchange of surgical workflow analysis and evaluating concepts*
The surgical workflow analysis, which includes the current and the new surgical workflow in WIM, is shared with the multidisciplinary development team through focus groups sessions. This exchange is conducted only after the findings have been medically verified and the requirements prioritized by the surgeon. To support homogeneous discussions between the members of the multidisciplinary team, the sessions need to be moderated, mainly by the designer(s) but with support from a surgeon and a technology engineer. This is to ensure that different aspects of the system development receive equal importance during the discussion. WIM, together with the surgical problem-solving process model, is used to explain the surgical procedures and the information processing activities for each surgical milestone at all the three stages of the

surgery. As one way of facilitating group discussion, it is proposed that the WIM is printed on an A0 sheet or projected on a huge wall for a walk-through experience of the surgical workflow. During the session, innovative ideas and possible solutions (possibilities) are documented in the new surgical workflow. Inputs on the concept storyboards are taken from the members of the multidisciplinary team as a part of collaborative design activity (Bodker et al. 1993). On the basis of the surgical and technological bottlenecks, the storyboards are further iterated with the team, leading finally to the conceptualization of the KIVS.

3.6 Study 4: Evaluation of WIM

Study 4 was conducted to evaluate how far WIM was able to facilitate the exchange of requirements, procedures and solution concepts within a multidisciplinary development team of the KIVS.

Method
For eighteen months, WIM was used by the members of the consortium, especially by technology researchers, ergonomists, and surgeons in different phases to support the development of three KIVS prototypes for the two selected MIS procedures: (1) Radio frequency ablation-2 prototypes, and (2) Laparoscopic liver resection -1 prototype. Implementation process of the workflow-centered framework with WIM as the component for the surgical workflow analysis to support the development of the KIVS can be read in detail in the chapter 4 and 5. The details for implimentation of WIM in the development of KIVS for Laparoscopic liver resection can be found in Lambata et al. (2008).

In the development of the above mentioned prototypes, application of the WIM followed two complete application cycles in each of the following stages: (a) first, the designer (author) used WIM as a component to conduct the surgical workflow analysis for the two selected MIS procedures. (b) Second, the results of the surgical workflow analysis and the user findings, as documented on WIM, were medically verified by the surgeons, (c) Third, the knowledge repository developed through the surgical workflow analysis for the MIS procedures was communicated through WIM to other members of the development team, such as technologists, and others scientific researchers. WIM was used as a communication platform by the designer and the surgeons to share the results from the surgical workflow analysis for each MIS in two different focus group sessions.

(d) Fourth, design concepts for the KIVS were made by the designer (author), and were presented to the development team in the form of storyboards which depicted the “future surgical workflow” after the implementation of the KIVS. In these sessions, the concepts were evaluated on the basis of their surgical and technological possibilities. (e) Fifth, the final concept of the KIVS, including details of the information flow and the specific user requirements for patient data visualization, were finalized by the designer (author), and (f) sixth development tasks of the KIVS developed were distributed. The author was responsible was providing design specifications for KIVS, visualizing the information content and finally evaluating the KIVS. The technology researchers were responsible for developing the technical components of the KIVS and the system integrator was responsible was bringing the technical components together.

Participants
Surgeons and technology engineers (n=28) of the ARIS*ER consortium participated in the evaluation study of WIM. The participants included: technology engineers, PhD researchers, post-docs, senior scientists from the technology engineering groups, resident surgeons, intervention radiologists, and surgeons. All participants had used WIM during the development of the KIVS and had participated in the development meetings.

Table 5 : Results of paired sample t-test conducted to compare the WIM evaluation response between surgeons and technologist

		Surgeons (n=11)	*Technology engineers (n=17)*		
Questions		Mean	Mean	f value	Sig.
How would you rate the usefulness of WIM for information presentation of the surgical workflow?					
1.	Scientific representation of the surgical workflow	4.55	3.18	6.16	0.02
2.	Link between surgical needs and technological possibilities	4.65	4.06	1.89	0.18
3.	Identification of information needs at different levels of surgical tasks	4.55	4.65	0.74	0.39
How would you rate the usefulness of WIM as a communication platform between surgeons, technology engineers, and designer?					
4.	Exchange of surgical needs and procedures	4.91	4.47	18.06	0.00
5.	Exchange of technological possibilities	4.18	3.65	6.56	0.01
6.	Exchange of ideas and concepts	3.55	4.29	0.01	0.91
7.	Exchange of detailed design solutions	1.91	2.65	6.18	0.02
8.	Verification and prioritization of the needs and possibilities	4.45	3.94	1.42	0.24

*All questions used a 5-point rating scale where 5 is the most positive rating and 1 is the least positive rating.

Qualitative evaluation of WIM
After eighteen months, an online survey was conducted to evaluate the utility of WIM and an online questionnaire created to evaluate its usability (Table 5). The questionnaire included a five-point scale, where 1 is the least positive rating and 5 the most positive rating. Each participant was requested to identify themselve as surgeons or technology engineers. Replies were received from (n=11) surgeons and (n=17) technology engineers. Independent sample t-test was used to compare the mean of two participant groups: (a) surgeons and (b) technologist for each question.

Results
Results as indicated in Table 5 show that there is significant differences between surgeons and technologists on questions 1, 4, 5 and 7. The rest are not statistically significant. In particular, the surgeons found WIM useful for obtaining structured representation of surgical procedures and analyzing surgical needs (question 1). With question 4, the high mean score indicates that both surgeons and technologists found the WIM a useful platform for exchanging needs and procedures. With respect to exchanging technological possibilities (question 5), compared to surgeons, technology engineers found WIM less useful. Low mean scores for question 7 indicate a limitation of WIM. This limitation can be understood in terms of exchanging detailed design solutions. WIM only provides an overview of the requirements and possibilities and not the development details. The results indicate that both the surgeons and technologists consider WIM a less useful tool for exchanging detailed design solutions. Interestingly, the results also indicate that at the start of the development the surgeons' requirement of exchanging the detailed design solutions of the KIVS is much higher than the technology engineers.

The surgeons and technology engineers also made some critical suggestions and comments about WIM. Technology engineers found the concept of mapping the surgical workflow based on time, which includes all the three phases, very useful because it leads to optimization in planning the technological components required for the KIVS. It was possible to conceptualize technological requirements as a whole for the pre-intra-post phase of the surgery. Based on WIM, one of the technological partners in the consortium successfully generated a framework for defining and optimizing augmented reality solutions in liver surgery (Kalkofen et al. 2006). In order to incorporate technological requirements, most of the technology engineers suggested that the new surgical workflow in WIM should include more categories. Surgeons found the structured overview of the surgical workflow an opportunity to reflect upon their own work. This is similar to the results of the HTA techniques being used in training of specialists (Shepard 2001). In the opinion of the surgeons, WIM is also likely to be useful in improving existing surgical procedures and for teaching novice surgeons.

Summary

This chapter described the formulation and evaluation of the Workflow Integration Matrix (WIM) which serves as a component of the workflow-centered design framework to analyze the surgical workflow. Knowledge of the surgical workflow is a primary requirement for the user- centered development of the KIVS in the surgical environment. Aiming to support the central role of the designer in facilitating user-centered development, the contribution of WIM towards developing the KIVS is two fold:

First, results from Study 2 , Stage A led to the formation of WIM. The study revealed task boundaries that can be understood in terms of possibilities and limitations which determine the surgical problem-solving activities. These task boundaries allow the designer to conduct surgical workflow analysis to understand the levels of information requirements that the surgeons rely on in order to perform the surgical procedures. Results from Study 2, Stage B led to the formation of a surgical problem solving model which provides an understanding of the information processing stages and activities of the surgeon in the three surgical stages (pre-intra-post).

Second, results from Study 3 outline critical issues due to communication gaps between the surgeons and the technology engineers when involved in the product development. In order to facilitate the communication of requirements within the multidisciplinary development team, two solutions have been proposed: (a) addition of a new surgical workflow component to WIM to provide a link between the current surgical workflow and the proposed technological solutions, and (b) the integration of WIM in the workflow-centered design framework to facilitate the communication of procedures, requirements and possibilities.

The evaluation study of WIM (Study 4) conducted within the ARIS*ER team showed promising results. The results indicate that both surgeons and technology engineers found WIM useful as a structured component of a workflow-centered design for generating and exchanging a knowledge repository of the surgical workflow analysis for the design of the KIVS.

Chapter 4 and 5 will illustrate the application of WIM in the development of prototypes for the KIVS for Radio Frequency Ablation.

This chapter is based on the following publications:

Jalote-Parmar, A., P. M. T. Pattynama, R. Goossens, A. Freudenthal, H. de Ridder and E. Samset (2007). Surgical Workflow Analysis: Identifying User Requirements for Surgical Information Systems. Diversity in Ergonomics. R. Pikaar, K. Ernst and K. Settels. Oxford, Elsevier: 229-241.

Jalote-Parmar, A., P. M. T. Pattynama, R. H. M. Goossens, A. Freudenthal, E. Samset and H. De Ridder (2006). Bridging the Gap: A User-centered Design Approach Towards Developing Technological Solutions. Minimally Invasive Therapies & Novel Embedded Technology Systems, ARIS*ER Summer School Book. S. Casciaro and A. Distante. Italy, Lupiensis Biomedical Publications, National Research Council. : 100-108.

CHAPTER 4 CONCEPT 1: KNOWLEDGE INTENSIVE VISUALIZATION SYSTEM

Overview

This chapter explains the development of concept 1 for KIVS and aims to address the following research question: How can the knowledge of surgical workflow be incorporated into the design of KIVS ? It is based on applying the workflow-centered design framework as proposed in Chapter 3, which includes WIM as the main component for generating a knowledge repository of surgical workflow of RFA (Jalote-Parmar and Badke-Schaub 2008a). The four design stages of this framework applied by the author in the development of KIVS are: (a) Stage 1- Specify context of use, focusing on the selection of the surgical procedure and the target user group for KIVS; (b) Stage 2- Development and communication of knowledge repository, describing the requirement analysis phase (Study 5a & b) that involves the application of WIM to build a knowledge repository of the surgical workflow for the procedure: Radio Frequency Ablation. The results of this phase aid in formulating the design, technical requirements and concept storyboards; (c) Stage 3- Design prototype, explaining the development of a working prototype of KIVS, concept 1; (d) Stage 4-Evaluate prototype, explaining heuristic evaluation (Study 6) of the concept with the medical students. The findings from the final stage guide the development of concept 2, which is explained in Chapter 5. Fig. 1 illustrates the research approach followed

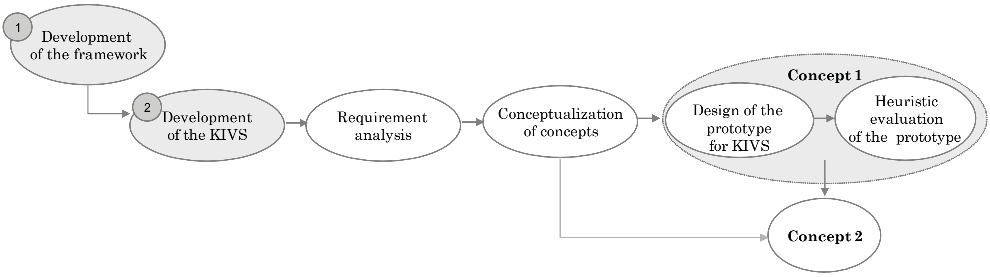


Fig.1. Research approach indicating the two phases presented in this chapter

towards development of KIVS. It also shows the various stages of the workflow-centered design approach.

4.1 Specify context of use for KIVS

In the initial phase of the development of any tool or expert system, it is necessary to specify the context in which the system will be used. Here it is crucial to specify the surgical procedure and target user group for the KIVS for RFA (details of this procedure are explained in Chapter 1, Section 1.7). Recent clinical studies have reported that a lack of adequate intra-operative visualization systems have caused failures in the Percutaneous RFA, causing procedures to be repeated (Rhim et al. 2008). These failures are mainly due to: (a) unablated cancerous cells of the tumor, (b) newly detected tumors, and (c) missed tumors (Rhim et al. 2008). Percutaneous RFA is a recent and complex MIS procedure requiring specialized skills. Consequently, the experts performing this procedure are still limited in number. Recent clinical studies indicate that with better image guidance, the clinical acceptance of this procedure can be improved (Solbiati et al. 2006). Percutaneous RFA is conventionally conducted with the Ultrasound (US) image guidance. However, well known drawbacks of US imaging, such as variable sound waves caused by nature of different tissues, add confusion in the image comprehension, thus limiting its usage (Solbiati et al. 2006). The next section explains the requirement analysis phase which includes the development of the knowledge repository for RFA.

4.2 Requirement analysis

The requirement analysis phase is a critical phase in the development of KIVS. The findings from it create the knowledge repository of the surgical workflow for RFA, which, in turn, leads to the identification of the design requirements that guide the development of KIVS. The following sections explain the implementation of WIM and the 5 stages followed to develop a knowledge repository of surgical workflow for RFA.

Fig.2. a- focus group session for RFA with clinicians and b- the generative tools which include images and keywords specific to RFA procedure that were used to stimulate the clinical experiences of the participants.

4.2.1 Study 5a: Investigate surgical milestones

Surgical milestones are critical surgical actions necessary to complete the surgical procedure. Surgeons might incur task navigation and visualization problems while performing some of the surgical milestones. The aim of the KIVS should be to address these problems in order to enhance the performance of the procedure. Since surgical problems can occur for any of these surgical milestones, it is important to identify the milestones correctly at the start of the workflow analysis. Study 5a was therefore conducted to investigate the surgical milestones for RFA.

Method
Focus group discussion was selected to investigate the surgical milestones for RFA. Details of the focus group session can be found in Chapter 3, Section 3.4.1. As explained earlier in Chapter 3, the data for this study was obtained from the Study 2. As a part of Study 2, one focus group was conducted with clinical experts on RFA. For this study the data has been re-analyzed to gain clinical insights. Fig.2a illustrates the focus group session on RFA with the participants and Fig.2b depicts the generative tools, including images and keywords specific to RFA procedure, used to stimulate the clinical experience of the participants.

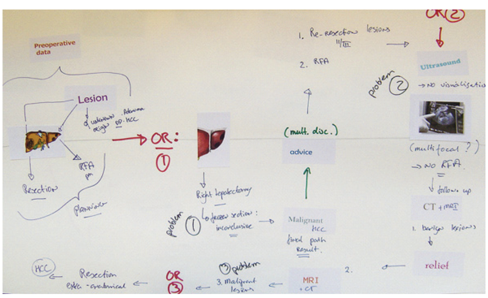


Fig.3. Flow chart made by a clinician during focus group session.

Participants
The study was conducted with a total of (n=8) surgeons and intervention radiologists practicing RFA at Erasmus MC, The Netherlands. All the participants had at least eight to twenty years of experience.

Analysis and results
The analysis of data was conducted at the following two levels

1. The transcript from the focus group session was analyzed and the key statements, which related directly to RFA procedure, were identified. During the group session, there were also general statements made by the surgeons, which were not included in the analysis. For instance, statements related to managing time in the operation theatre though it is an important clinical problem, it is more related to the hospital management than to our study. The key statements were semantically clustered by building an affinity diagram. Six surgical milestones, that are the key actions necessary to complete the surgical procedure, were identified. Two intervention radiologists who participated in the study verified the surgical milestones. Fig.4 illustrates the surgical milestones identified in the RFA procedure when considering the three surgical phases: Pre-operative (before intervention), Intra-operative (during intervention) and Post-operative (after intervention). The Surgical Milestones (SM) documented on the x-axis of WIM are:

- SM 1. *Resect or coagulate*: In the pre-operative stage the surgeons need to decide the treatment strategy for the identified tumors in the liver. The tumor can be treated either by performing RFA or a liver resection. This decision is based on the location of the tumor in the liver and the overall treatment strategy for the patient.
- SM 2. *Identification of tumor in CT scan:* In the pre-operative stage, the CT scan of the patient is taken and a particular tumor is selected for treatment by RFA. During the intervention, the surgeon has to identify that tumor in the CT scan.
- SM 3. *Identification of tumor in the liver:* After the tumor is identified in the pre-operative CT scan, it has to be located in the liver by performing an intra-operative US scan. This is done by mentally mapping the image and location of tumor on CT to what is seen in intra-operative US. Often several tumors are found in the liver of a cancer patient. Based on careful decision making, tumor(s) are selected for RFA.
- SM 4. *Entry and placement of the needle:* With the help of intra-operative US, the tumor is located in the patient body. The optimal trajectory for the needle is planned and it is finally navigated to the center of the tumor.
- SM 5. *Coagulation:* After the needle is placed in the tumor, the RFA machine is turned on to heat the needle and ablate the tumor. Once the required time for ablation is completed, the needle is taken out of the tumor.

- SM 6. *Quality check:* Normally, a month after the ablation, another CT scan is taken to verify if the target tumor has been completely ablated.

2. The statements from the session were semantically clustered for all the surgical milestones. Task boundaries were used as categories to cluster the data corresponding to each surgical milestone. These boundaries determine the information processing activities during surgical problem-solving and have been marked on the y-axis in WIM. Table 1. illustrates selected extracts of data transcribed from the focus group sessions. Each statement is categorized on the basis of the task boundaries and the surgical phase. The WIM matrix was drawn on a blank sheet at the start of the analysis and the findings were entered into each cell of WIM corresponding to the surgical milestone related to each task boundary. Fig.5. illustrates the documentation on the WIM of statements as explained in Table 1 (See following page, 86).

4.2.2 Study 5b: Surgical workflow analysis

This was conducted to assess the individual opinions of the participants (clinicians) about the problem and the process related to RFA procedure. Furthermore, study 5b was conducted to obtain field insights by observing the RFA procedures. Results from both the studies assisted in developing the knowledge repository of the surgical workflow for RFA.

Participants
Ten intervention radiologists participated in the study. They were affiliated to the national hospitals of Norway and the Netherlands. Both the surgeons and the intervention radiologists were involved in performing the RFA procedure. Due to the introduction of MIS, besides the surgeons, intervention radiologists are taking a more prominent role in conducting these procedures.

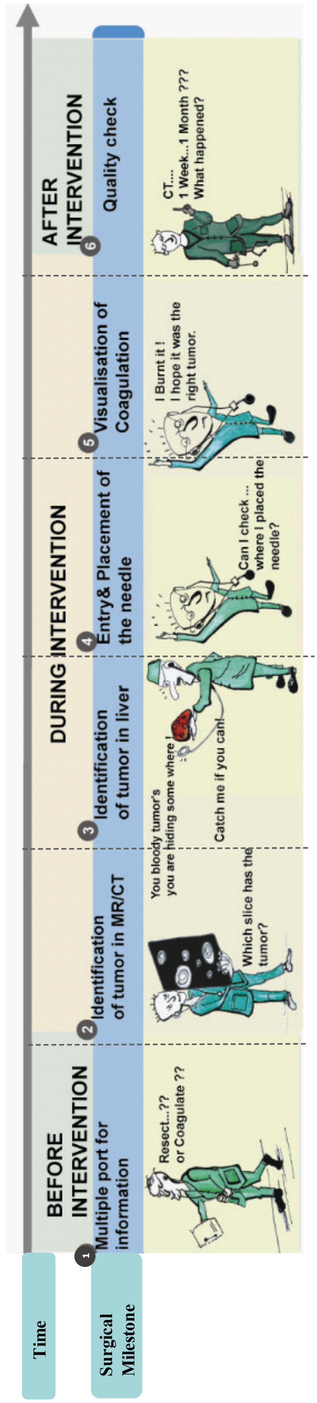


Fig.4. Surgical milestones in the RFA procedure as identified during focus group sessions.

Table 1. Extracts of transcribed data of the focus groups		
Time/ Participant	**Key Statements of the participants**	**Phase/Task Boundaries in WIM**
00:00-00:04 (1)	CT identified a tumor in the liver, we decided on percutaneous \ procedure in the planning meeting.	Pre-operative/Target State/Goal
	During percutaneous approach, the RF needle is inserted through the patient skin to ablate the tumor in the liver. Did the procedure.	Intra-operative/Target state/Procedure
	One hour later- CT	Post operative/Surgical equipment/ tool
	Lesion coagulated. seems complete coagulation	Postoperative/Patient state/Feedback
	and then we find another tumor- we find a surprise, not a nice surprise. Must have been 2 HCC, one picked by the CT, one picked up by ultrasound but they weren't the same. CT was the base.	Postoperative/Surprise state/Uncertainty
00:04-00:05 (3)	How can you be sure that the first lesion was a lesion?	
00:05-00:10 (1)	HCC base in the ultrasound….how certain?	Intra-operative/Surgical equipment/tool
	You had one lesion, coagulated single lesion with Ultrasound, very happy. Saw another coagulation. You didn't coagulate the lesion you intended.	Intra-operative/Surprise state/Uncertainty
	Second tumor is the same as the first one pre-operatively.	Intra-operative/patient state/anatomical structure
	You see the first tumor and ablation of something……… it happens a lot of time in Netherlands.	Intra-operative/Surprise state/Uncertainty
	There is a problem with Ultrasound, you can't visualize as well as in a CT or MRI.	Intra-operative/Surgical equipment/tool
	Especially in a cirrhotic liver you can't be sure...of location…..? failure	Intra-operative/patient state/anatomical structure
	One modality to image the tumor and one modality to guide the procedure.	Intra-operative/Surgical equipment/tool
	What did you coagulate-----------not sure.	Post operative/Surprise state/Uncertainty
00:10-00:11 (4)	Did you perform an Ultrasonography? Before the procedure?	Pre-operative/Target state/procedure
00:10-00:11 (1)	No	
00:10-00:11 (4)	Always do it.	
00:10-00:11 (1)	Nothing is sure. Missed the real lesion.	Postoperative/Surprise state/Uncertainty

As in the selected hospitals, the intervention radiologists mainly perform the RFA, only interventional radiologists were involved for this study. Permission were obtained from all the participants to use observation data for further analysis. The participants also obtained permission from the patients undergoing the treatment.

Method
The author observed intervention radiologists perform the RFA procedure in the three surgical phases (pre, intra and post). The existing surgical workflow component of WIM was used as a framework to document the observations. The findings obtained from Study 5b were documented on WIM, and assisted the designer in conducting observations in the surgical workspace. The observations were further added to WIM to the task boundaries for each surgical milestone. Where possible, the intervention radiologists were asked to think aloud while performing the procedure. Any critical event, such as change in the originally planned surgical scenario, was noted down by the author. After completion of the RFA procedure, the intervention radiologists were asked to explain their decision-making process in detail during the critical event. In order to avoid any disturbance in the surgical workspace, the designer avoided discussions with the intervention radiologists during the procedure.

Analysis
The task boundaries in WIM were used to categorize the observations conducted in the surgical workspace. The data from study 5 a & b was documented for each task boundary corresponding to the surgical milestones (Fig.5.). Ten observations of RFA led to repeated findings so were not documented in WIM.

Results
Results of the workflow analysis of RFA were used to complete the “existing surgical workflow”module in the workflow integration matrix. Fig. 5 illustrates a part of the workflow analysis for two selected surgical milestones 3 and 4. These milestones are explained in detail below.

1 *Surgical milestone 3 (SM-3)*
The 3rd surgical milestone in the intra-operative phase is the “Identification of the target tumor in liver”. The goal of this milestone is explained as: to identify the target tumor with intra-operative ultrasound and compare it with the one planned to be ablated in the pre-operative CT. Recent clinical studies have reported the ablation of wrong tumors (not targeted to be ablated) as one of the critical errors during the RFA procedure (Rhim et al. 2008; Lau and Lai 2009). As a treatment strategy, the intervention radiologists often decide on combining the RFA with liver resection. In such a case during the pre-operative planning, one of the target tumors is selected for RFA. Computerized Tomography (CT) or a Magnetic Resonance Imaging

(MRI) scan are the imaging modalities most frequently used to identify the tumors in the pre-operative planning phase. Another task boundary 'procedure' can be understood as: the US probe is placed on the patient and the target tumor is identified. In order to identify the target tumor in US, the intervention radiologist generates a mental mapping between the information generated from the two imaging modalities. The difficulty arises due to two main reasons:

- First, the current imaging modalities do not support the transfer of the planning data to the intra-operative phase. As a consequence, the relevant information is scattered and the intervention radiologist relies on creating a mental model which combines the two images.
- Second, due to the limitation of imaging modality, identifying the correct tumor in US is itself a very challenging clinical task. The cirrhotic (diseased) liver usually contains multiple hepatic nodules with different tissue properties that create variable echo-genicity. Echo-genicity can be explained thus: as US images are created through sound resonance affected by different tissue properties, this often causes confusion in identification of the correct tumor in the imaging data. Further details on US are explained below:

Challenges with Ultrasound imaging
Compared to the other imaging modalities in use, US is the only real-time imaging modality instantaneously created by the probe handled by the clinician. The quality of images created depends on the skills of the operator. US is highly susceptible to anatomical constraints, such as air and bone. The identification of the optimal acoustic window is crucial and relies on experience. US does not offer a large field of view especially when it comes to abdominal imaging. It presents a lower spatial resolution so identifying the most appropriate access point to reach target is a difficult task, requiring experience. The limitations mentioned above, make the US anatomy learning curve much steeper than the CT and MRI scan. Consequently, there are still very few experts who can perform RFA percutaneously. Further details on comparison between MRI, CT and US are explained in Chapter 2 (Section 2.1.1).

Table 2. Brief comparison between US and CT for task visualization

US	–Best temporal resolution (real-time) anatomic limitation –Limited field of view –Modality of choice for conducting interventional procedures (where feasible) –Appropriate acoustic window based only on experience –Bone and air a barrier
CT	–Best spatial resolution –No anatomic limitation –Large field of view

Table 2 summarizes the difference between US and CT from the point of view of task visualization.

2 *Surgical milestone 4 (SM-4)*
The 4th surgical milestone in the intra-operative phase is “choosing the right trajectory and navigating the needle to the center of the tumor”. In the corresponding task boundary on the y-axis, the goal of this milestone is explained as: to identify the optimal port of entry and acoustic window to reach the tumor and to reach the tumor without rupturing other organs. Recent clinical studies have shown that one of the reasons for technical failures of the RFA procedure is residual cancerous cells. In the corresponding task boundary on the y-axis, the procedure of this milestone is explained as: US probe and the needle size and type is selected, the optimal needle trajectory is planned, and the needle is navigated to target tumor. Guided by US images, the surgeon places the RFA needle in the center of the tumor. Before reaching the center of the tumor, the surgeons consider multiple levels of medical constraints before locating the right entry point and navigating path. The task boundary ‘critical factor’ on the y-axis is understood as: If the trajectory is not chosen correctly, the needle does not hit the tumor in the center, causing unablated cancer cells. The ablation zone is normally taken as 5 cm. The maximum tumor size selected for ablation is 3 cm, in order to leave a safety margin of 1cm around it. Fig.6 (page 91) illustrates the safety margin required for tumor ablation. Where the tumor is located 8-10 cm deep in the liver, the accepted accuracy is 5 mm from the center of the tumor.

4.2.3 Verify and prioritize findings with surgeons

Three intervention radiologists verified the completed “existing surgical workflow” component in WIM. This was necessary for two reasons (a) to verify the medical content, and (b) to identify the relevant surgical problems that require a technological solution. Although the workflow analysis can identify several requirements, not all surgical problems need technological intervention as a solution. The intervention radiologists verified and prioritized the requirements corresponding to each surgical milestone that can be seen as dots placed in the selected cells of WIM (Fig. 5, page 90). Surgical problems were summarized as problem statements and user requirements and were documented in the “new surgical workflow” component of WIM. These findings, which represent the knowledge repository of the surgical workflow for RFA, were uploaded on the ARIS*ER website for the surgeons and the technology engineers to interact with. Table 3 depicts the design and technical requirements of the KIVS.

Current surgical workflow for Percutaneous Radiofrequency Coagulation

	Surgical Phase:	Pre-Operative	Intra-operative		Post Operative
	Time:		10-12 minutes	5-8 minutes	
	Surgical Milestone:	….1/2..	3 (an example) Identifying the target tumor	4 (an example) Entry and placement of the needle	..9/10
Task Boundaries:					
Target State	Goal		To identify the target tumor with intra-operative ultrasound & compare it to the one planned to be ablated in the pre-operative CT	To identify the optimal port of entry and acoustic window to reach the tumor. To reach the tumor without rupturing other organs.	
Target State	Procedure /Action		The US probe is placed on the patient and the target tumor is located. This is done with the help of mental co-relation between the pre-operative CT scan the tumor identified in ultrasound. ●	US probe and the needle size and type selected, and the optimal needle trajectory is planned, and the needle is navigated to target tumor.	
Surgical equipment	Surgical tool		The ultrasound probe can have several transducers, depending in the position and of the tumor, the transducer is selected.	The needle has several sizes and shapes, it is selected depending on the size of the tumor.	
Surgical equipment	Visualization / Information system		Two screens: ultrasound and preoperative CT scan.	Two screens: ultrasound and preoperative CT scan.	
Commu-nication	Equipment		The real-time ultrasound communicates the real time information of the organ and the pre-operative CT scan provides the static context view of the patient anatomy.	The cirrhotic liver usually contains multiple hepatic nodules with variable echo-genicity, thus causing confusion to the clinicians of the neighboring critical structure in the anatomy	
Commu-nication	Surgical Team		The assistant helps in setting the RF set and handing the tools	In case of uncertainty, consultation with other experts ●	
Patient State	Constraint		The target tumor can be more inconspicuous than adjacent regenerative nodules or, if located in the hepatic dome, can be masked by the overlying lung or ribs.	The entry port may not be the optimal one to reach the tumor, as the tumor may be difficult to access due its location in the liver….	
Patient State	Critical factor		Identifying the correct target tumor	The needle should hit the tumor in the center, or else the cancer cells will be not completely necrotized. ●	
Patient State	Feedback		None, excepting the real time US feed.	There is a haptic feedback from the organ when the needle hits the tumor. Tumor hardness may lead to bending of the needle	
Patient State	Anatomical structure		Tumor may move from its first position once identified in the US, this movement is due to the patient breathing and movement of liver as an organ…. ●	Tumors are stiff and have various shapes. The needle may bend slightly when inserted into the tumor due to tumor density. ●	

Existing Workflow

Surprise State	Uncertainty		Not finding the target tumor due to its location in the liver. Finding many more tumors in the liver than in Preoperative CT	The tumor to be coagulated is elongated in size, it is possible that it will require two coagulation…. How to judge the center of the tumor. 1/3 or 2/3 needle placement in the tumor?…	
	New Surgical action		After consultation, in case of many new tumor, a new patient strategy needs to be made for the patient. In case of one more tumor it is to be judged if it can also be ablated.	Consultation…..patient send for Chemotherapy, to down size the size of the tumor.	

Require ment	Problem statement		To identify the target tumor in real-time US image and verify it with the pre-operative CT scan	To identify the optimal needle trajectory to reach to the target tumor and with the RF needle in the hit the center of the tumor	New Workflow
	User requirement		See Table 3	See Table 3	
Trends & Possibilities	Surgical tend		….mostly surgeons rely on real time US, some groups in Germany, use intraoperative CT….	Currently no 3D model guidance. Mostly the placement is done under the guidance of US…..	
	Technological trend		Fugo Frankfurt, IRCAD –Strasburg have developed real time tracking of needle, along with a working prototype…	Technological development to create 3D model on the basis of real time US, is in process….	
	Possibilities		Superimposition of real-time US+CT, to overlay the target tumor on US..	Real-time creation of 3D model of US and CT images and register the real time 3D model of the needle	
	Technological team		Image registration-England, Image segmentation-Italy	Image registration-England, Image segmentation-Italy, Real time augmenting the needle and the 3D model-Austria	

Fig.5. Workflow analysis of RFA.

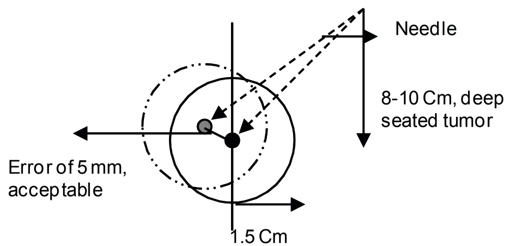


Fig.6. The accuracy required for RFA for a 8cm deep tumor.

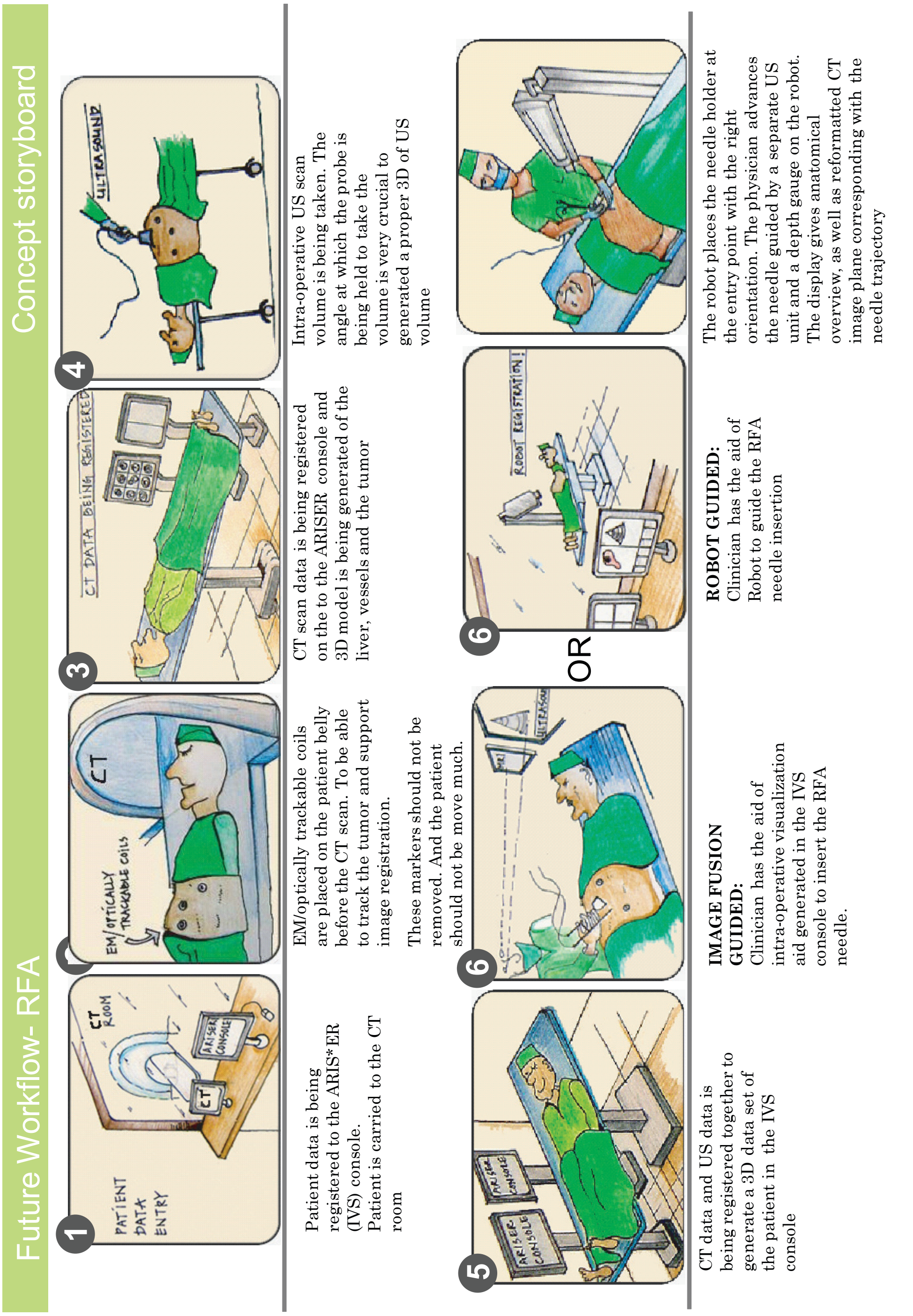
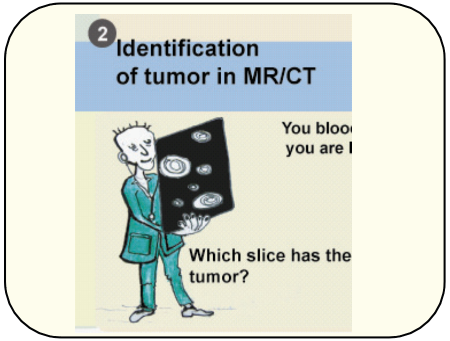


Fig.7. Storyboard two concepts depicting new surgical workflow of RFA. Concept 1 (images 1-5) illustrates the Augmented Reality Visualization System and Concept 2 (images 1-6a&b) depicts the robotic arm to insert the RF needle.

<table>
<tr><th>Surgical problem and requirement</th><th>Future surgical workflow</th><th>Proposed information visualization</th></tr>
<tr>
<td>
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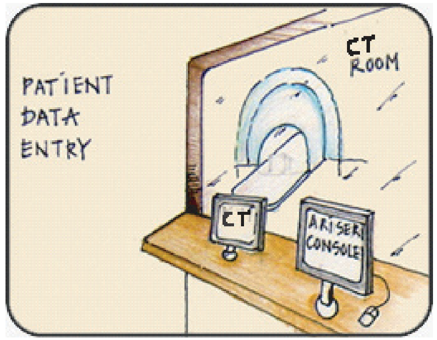
<td>
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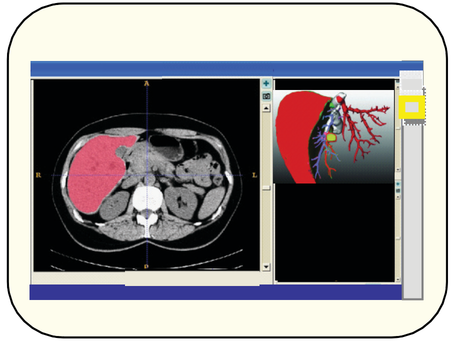
<td></td>
</tr>
<tr>
<td>SM2. Identification of tumor in CT scan: In the pre-operative stage, the CT scan of the patient is taken and a particular tumor is selected to be treated by RFA. During the intervention, the surgeon has to identify the same tumor in the CT scan.</td>
<td>Markers are placed on the patient and a CT scan (could be from CT –C arm be taken with the markers)
The patient data is entered in the KIVS console.
This data includes pre-operative CT scan. The radiologists highlights the tumor to be ablated on the CT slices.</td>
<td>The KIVS should display the specific slice the target tumors is in for the clinician before the procedure.

KIVS should provide a 3D volume of the liver with important vessels* and highlight the tumor to be ablated</td>
</tr>
</table>

Fig.8. Details of surgical milestone 2, new surgical workflow and proposed information visualization in KIVS.

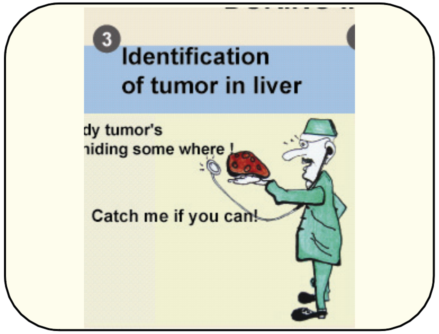
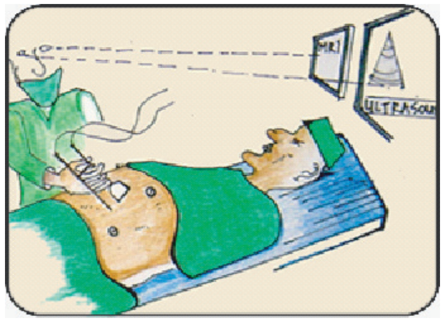
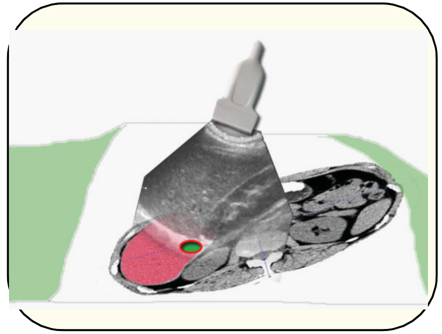
Surgical problem and requirement	Future surgical workflow	Proposed information visualization
		
SM3. Identification of tumor in the liver: After the tumor is identified in the preoperative CT scan, it has to be located in the liver by performing an intra-operative US scan. This is done by mentally mapping the image and location of tumor on CT to what is seen in intra-operative US. There are usually several tumors in the liver	Fudicial markers are retained in the same position on the patient US probe is tracked and registered with the KIVS. The clinician provides the KIVS the US volume by slowly moving the US probe over the patient abdomen KIVS now registers US volume with the pre-operative CT scan	KIVS displays the CT slice corresponding with the intra-operative US probe movement in real-time. CT slice is displayed in 2D

Fig.9. Details of surgical milestone 3, new surgical workflow and proposed information visualization in KIVS.

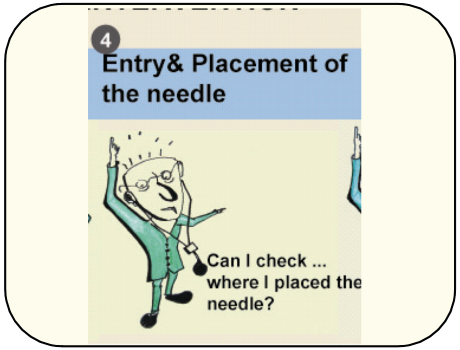
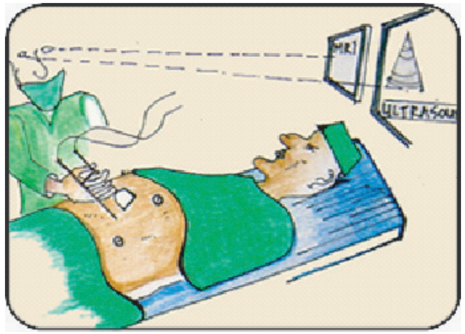
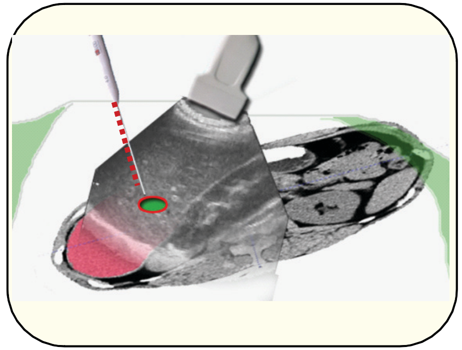
Surgical problem and requirement	Future surgical workflow	Proposed information visualization
		
SM4. Entry and placement of the needle: With the help of intra-operative US, the tumor is located in the patient body. The optimal trajectory for reaching the needle is planned and finally it is navigated to reach the center of the tumor.	KIVS tracks the RF needle.	KIVS displays the possible needle trajectory to guide the needle navigation. At this point the critical vessels and organs in the path of the needle should be visualized in 3D

Fig.10. Details of surgical milestone 4, new surgical workflow and proposed information visualization in KIVS.

4.2.4 Conceptualize storyboards

Based on the design requirements obtained from the workflow analysis, a storyboard was conceptualized by the author. This depicted the future surgical workflow of RFA. The six surgical milestones, as identified in section 4.2.1 and seen in Fig. 4, were taken as the starting point for conceptualization of the storyboard. At this level, two different technological approaches were considered:

- *Technological approach 1: Augmented reality using head mounted display*
  The KIVS provides intra-operative visualization based on image fusion between CT and US. As depicted in Stage 1-6 of Fig.8, this generates a combination of 2D and 3D visualization of the tumor, vessels and needle.
- *Technological approach 2: Robotic arm for needle insertion*
  The KIVS provides intra-operative visualization in combination with a robotic arm to insert the needle. In this scenario, the surgeon will supervise the needle positioning and the needle will be placed by the robotic arm (Stage 6 a & b in Fig.8, page 92).

As an example, details of the surgical problems, storyboards depicting the new workflow, screen visualization and probable technological approach are illustrated for SM2, 3,& 4 (Fig. 8, 9 &10).

4.2.5 Exchange of needs and ideas within a multidisciplinary development team

Both the results from the surgical workflow analysis and the concept storyboards were communicated to the multidisciplinary development team by the author, using WIM as a communication tool to present the findings in a focus group session. Fig.11 illustrates WIM printed on the A0 sheet to present the RFA workflow to the technology engineers. Clinicians (n=4) (including surgeons and intervention radiologists) and (n=14) technology engineers attended this session. The technology engineers researched the area of image fusion, image segmentation, robotics and augmented reality. WIM facilitated the surgeons, the technology engineers and the designer to engage in a collaborative design process. WIM also enabled focused discussions and systematic exchange of ideas and possibilities specifically related to KIVS.

The session included the following procedure:

a Presenting the knowledge repository of surgical workflow for RFA.
b Presenting the surgical requirements, storyboards and concept designs of KIVS (Fig. 8, 9 &10, page 93, 94 & 95).
c Discussion on the concepts and iterations based on surgical requirements and technological feasibility. Innovative ideas and possible solutions

(possibilities) were mapped during the discussions about the new surgical workflow component in WIM. Based on the discussions, the design and technical requirements of the KIVS were identified. Table 3 describes the design and technical requirement for each surgical milestone.

d The following decisions were made in the communication workshop:

- The first concept was selected from the above mentioned storyboards (Fig.7, images 1-5). This involved the augmented reality visualization as a solution to support task visualization in RFA. The robotic arm concept was not selected because the technical expertise to develop the prototype did not exist in the consortium at that moment.
- The simulated demo prototype of the concept would be developed as described in (Fig.8, 9 &10). The development team would involve technology researchers belonging to research groups such as the visualization group, image segmentation, image registration and human computer interaction design.
- Three phases of the surgical workflow of RFA would be taken into consideration in developing the working prototype. Although the planning phase of RFA is clinically important, it would not be the target for the development as it is beyond the scope of the project deliverables. In addition, the SM6 "visualization of tumor coagulation", though a very critical requirement in RFA, cannot be considered in development. The technological expertise for visualizing tumor ablation in real-time, such as thermal thermometry is still in development (van den bosch, 2008). This expertise was not available within the project.
- The purpose of the working prototype would be to present surgeons with a concept of KIVS which would act as a test bed for conceptualizing in real-time the various image-fusion possibilities.
- The working prototype would only be a simulated version for assessment of the integration of the different technical components.
- A heuristic evaluation of the working prototype would lead to conceptualization of the final prototype (Concept 2).

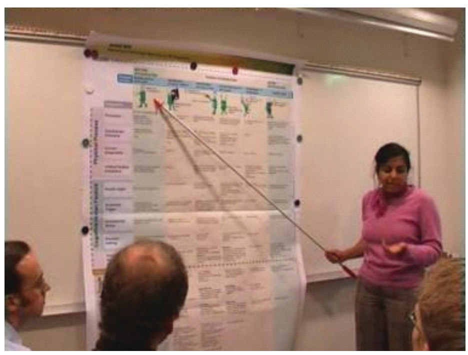


Fig.11. WIM used as a communication tool by the designer to present the surgical workflow to the technology engineers and surgeons.
(Photo taken at Rikshospitalatet, Oslo, Norway)

Table 3. Design and technical requirements for developing an KIVS for RFA	
Design Requirements	**Technical Requirements**
Surgical milestone 1: Resect or coagulate 1. Planning system to analyze the tumor location with possible needle trajectories. **Surgical milestone 2&3: Identify the target tumor in liver and Correlating CT/MRI tumor with US tumor** 1. The tumor to be ablated has to be clearly delineated in the pre-operative modality. 2. When looking at real-time US images, it should be easy to determine which tumor has to be ablated. **Surgical milestone 4: Entry and placement of the needle** 1. The system should suggest an appropriate acoustic window for US. 2. The system should suggest an optimal insertion path for the RF-probe. 3. Need real-time updates of the needle trajectory. 4. Present a warning when the needle trajectory diverts too much from the proposed insertion path. 5. Present a warning when the needle bends more than a user defined distance (i.e. 3mm). 6. Need to see the relationship between needle and relevant anatomical structures (tumor, vessels, liver). 7. Need a system accuracy of 2 mm. 8. Need possibility of adjusting trajectory intra-operatively. **Surgical milestone 4: Control of needle placement** 1. Need a 3D scene of the tumor. 2. Need zooming capability. 3. Need rotation capability. 4. Need quantitative data which describes the needle position (smallest distance from tumor boundary). 5. Need to see the tip of the needle in relation to the tumor. (3D axis). **Surgical milestone 6: Quality check of ablation** 1. Need to monitor coagulation. 2. Need the system to assure that a predefined safety margin, set by the surgeon, is reached (i.e. 1 cm). 3. Need to have the coagulated area augmented with the pre-operative MR/CT tumor. 4. Need some quantitative measure to determine success. 5. Should be able to use post-operative MR/CT to check success of ablation.	**Ultrasound machine** 1. A 3.5 Mhz US sector probe (the probe used clinically). 2. A 6 Degree of Freedom (DOF) magnetic tracker rigidly attached to US probe. 3. Video output from US machine. **Radio Frequency equipment** 4. Needs to be tracked. 5. Needs to be able to monitor the bending of the probe. **Magnetic tracking system for tracking device to obtain data from the patient and the surgeon** 6. Will need two 6DOF tracking tools, one attached to US probe and one dynamic reference frame (DRF). **Full-room tracking system for tracking devices where the tracking device can be outside the patient** 7. Will need camera redundancy. 8. Will need X tracking targets. **CT machine for acquiring pre-operative images.** 9. It needs to have be able to acquire images in various venal phases. **Image Markers** 10. Need to be MR and CT compatible. **Multi-Modal Reference Frame** 11. A reference frame which has a magnetic, optical and fiducial (placed on skin) markers integrated. **Head Mounted Display** 12. Needs to be tracked. **Data base and processing computers** 13. Computer which will drive the AR visualization. 14. Computer which will drive the screen visualizations. 15. Computer which will control and monitor the process

4.3 Design of KIVS prototype: Concept 1

The aim of the Concept 1 prototype developed at this stage was to explore the possibilities of real-time patient data visualization in relation to RFA. The findings were intended to lead to finalizing the system requirements for KIVS, Concept 2. The working prototype was a simulation of different technological components, such as real-time image segmentation. These components were not completely registered or calibrated together but were only simulated. As mentioned earlier, the technical components required to develop KIVS are still in development, so a full working prototype was not possible at this stage.

The development of the prototype was done in collaboration with the 4 technological researchers (PhD students), a system integrator and a HCI designer (the author). The researchers belonged to the following groups: (a) AR Visualization, Early Stage Researcher (ESR), Graz, Austria; (b) Image Registration, ESR, Oxford, England, (c) Image Segmentation, ESR, Lecce, Italy; (c) Research Integration Oslo, Norway, and (d) Human Computer Interaction Designer, ESR, Delft, The Netherlands.

4.3.1 System components

The following system components were integrated into the KIVS system:

1 *Image registration*
In order to accurately hit the tumor with the RF-probe, clinicians performing RFA procedures are dependent on having intra-operative real-time image guidance tools. Ultrasound is commonly used as an intra-operative real-time image modality. To be able to incorporate pre-operative surface models such as vessel structures, tumor and liver with the intra-operative ultrasound, new registration algorithms were developed, in particular, a method for registration of intra-operative US with MR.

2 *Image segmentation*
Hitting the tumor with the RF-probe guided by an intra-operative image guidance tools based on pre-operative segmentations of the structure requires very accurate image segmentation algorithms. Robust image segmentation algorithms were developed for segmentation of liver, liver tumors and liver vessels.

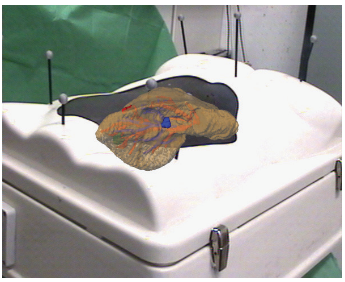
3 *Image visualization and navigation*
An integral part of any image navigation tool is how the information available in the system is presented to the user. In this research, we have developed a number of visualization tools to improve the spatial understanding of where the structures are in relation to the US probe as well as tools which warn surgeons when they are about to hit critical structures such as vessels.

4.3.2 Information visualization

The working prototype of KIVS consists of three modules which support the pre-, intra- and post-operative phases of the RFA workflow. It involved an augmented reality visualization of patient data accessible through a Head Mounted Display (HMD). Such a system generates a composite view of the data collected from imaging modalities for the surgeon. It is a combination of the real scene of the patient (in this case phantom) viewed by the surgeon, and a virtual scene generated by KIVS that augments the real scene with additional information based on data obtained from different imaging modalities, such as pre-operative CT or intra-operative US.

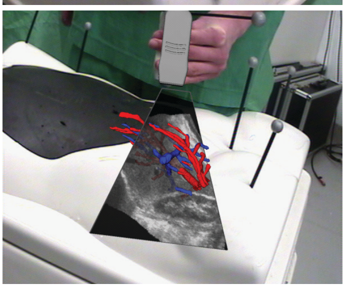
1 *Pre-Operative Module*
   Pre-operative module visualizes pre-operative CT images and 3-D model of segmented liver in relation to 2-D slices of the volumetric images.

2 *Intra-Operative Module*
   The intra-operative module visualizes a number of augmented reality image fusion possibilities projected on the patient phantom. The following combinations have been added to the system:



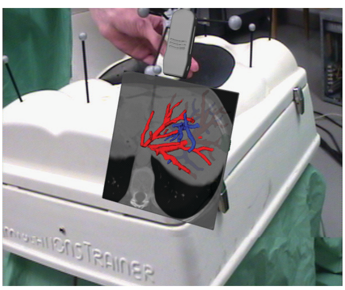
Visualization option 1
Development of 3D model of liver from pre-operative CT scan overlaid on the phantom.

Fig.12. A 3D model of liver is generated from pre-operative CT scan and overlaid on the phantom. The 3D model shows the hepatic and portal vessels, tumor and liver parenchyma.



Visualization option 2
Superimposition of US with the 3D model of liver generated from the pre-operative CT scan.

Fig.13. The visualization includes superimposition of US with the 3D model of liver generated from the pre-operative CT scan.



Visualization option 3
Superimposition of the 3D model of liver with CT slices.

Fig.14. The visualization includes superimposition of the 3D model of liver with pre-operative CT scan.

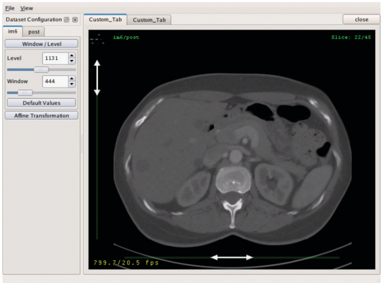


Fig.15. The system displays the post operative CT scan, superimposed with the pre-operative CT scan to compare the impact of the RFA ablation.

Post-Operative Module
After surgery it is important to validate the results so the post-operative module supports fusion of pre-operative and post-operative CT/MR images to compare the impact of the ablation.

4.4 Study 6: Heuristic evaluation of the KIVS prototype

Aim
The aim of this study was evaluation of the prototype by the clinicians, specifically to obtain their opinion of the different kinds of visualization related to different stages in the RFA workflow.

Participants
Two expert intervention radiologists (n=2) and medical students (n=4) evaluated the system.

Procedure
The purpose of the evaluation and the concept of KIVS in relation to RFA was explained to participants. Different visualization possibilities which are part of KIVS were also explained. The participants were given basic tasks to interact with the prototype with no time limit. The main tasks were (a) wearing the HMD and interacting with the three different visualization modes described above; (b) trying to insert the needle into a specified virtual target in the patient phantom using different modalities. The author observed the interaction.

Results
The KIVS prototype was not technically competent for conclusive results about the fusion of modalities and their role in improving the task accuracy of RFA. Instead, the findings lead to an understanding of the technological limitations of the prototype. For more conclusive findings, the clinician needs to be provided with the opportunity of using the system in real time with concrete tasks. This can only be achieved with a functional prototype. The findings here were made on two levels: (1) technical issues with the existing prototype; (2) issues with AR visualization. The key findings were:

1 *Issues with AR visualization*

- Oclusion is the strongest depth cue in augmented reality, especially while using HMD. The oclusion of the phantom by the surface models leads the participant to interpret that the models are floating over the phantom even though they are stereo-rendered to be located underneath the surface of the phantom. Without this depth cue, the task of navigating the needle spatially cannot be conducted accurately.

- The HMD is particularly unsuitable for the needle placement as it creates serious ocular issues especially in the context of stereo vision. The HMD set up can be developed further to improve the quality of visualization. However, the clinician did not approve its use. The visualization of patient data overlay on the phantom was too distracting for concentration on the highly spatial task such as placing the RFA needle.
- The pre-operative and post-operative visualization was important and can be included.
- For specific tasks like locating critical organs and placing the needles, fusion between US slices and 3D of liver based on CT data was found to be useful in providing a context view. Superimposition of 2D US and 2D CT slices was found confusing while conducting the task.
- There is a need to integrate a virtual window which renders the area of the video background around the surface models.
- The HMD does not accommodate adjustment of inter-camera and display positions. The static position of these parts makes it very uncomfortable for certain participants who do not have an inter-eye distance that matches that on the HMD.
- When working with structures < 0.5 meters away from the HMD, the stereo separation is so large that it is very hard to not see double.
- After >1 minute, participants gets dizzy and have to remove the HMD to rest their eyes.
- The participant needs at least 1 minute or more to get used to the stereo vision.
- AR projection using the superimposition of 3D model and US create confusion for the participant while placing the needle.

2 *Technical issues with the existing prototype*

- The area of US volume currently generated is of a very limited field of view, and therefore provides less real-time information. A new US volume with larger volume needs to be generated with the tumor.
- The current tumor is actually a cyst (seen on CT) located very near to the anterior abdominal surface.
- The tumor is not reflected clearly in the US, creating confusion. A more comprehensive model with a few more tumors needs to be built.
- Due to absence of real-time data feedback from a tangible mock up of liver and tumors, the prototype in its the current condition is less close to real time testing situation. This minimizes the navigation issues present in real life scenarios.
- US volume and the 3D surface models (liver, vessels, tumor) are not well registered.
- The off axis camera and SimVoleon software do not work well together.

At certain angles, the slice plane is not rendered, often if part of the slice plane is outside of the viewing angle of the camera.

- The current RF-probe is a tracked pen, real RF probe is necessary.
- The option of merging the CT from pre- to post-operative was considered critical by the clinicians.
- The US slices and CT slice superimposition creates confusion for the clinicians. Instead, fusion between 3D of liver based on CT data was found useful for a context view.*Summary of findings*

Although several findings have been made with respect to Concept 1, only a selected few (listed below) will be considered in the development of Concept 2 for KIVS. The selection of these findings was finalized along with project partners.

- HMD will not be used. Instead visualization for superimposition will be done on 2D monitors.
- Superimposition between 2D US and 2D CT slice will not be used. Instead 2D US and 3D CT model will be used.
- Context view of patient data is necessary but not at all moments of the tasks. The system should adapt accordingly.
- To actually test the task accuracy for clinical issues such as real-time needle placement, the phantom should realistically simulate the look and feel of clinical task.
- Only a few specific surgical tasks have to be selected to develop the KIVS. KIVS should be a working prototype with real-time exchange of patient data so that the clinician can conduct tasks and evaluate the KIVS. This is necessary to assess the role of task visualization in supporting decision making to improve task accuracy of RFA.

Summary

This chapter presented the application of workflow-centered design framework for developing KIVS, Concept 1. The following steps were followed: First, WIM was applied to create a knowledge repository of surgical workflow analysis of RFA (Study 5 a & b). This knowledge was used to identify the surgical requirements and design concept storyboards for developing KIVS. Second, these findings were shared with the multidisciplinary development team responsible for the development of KIVS. System and technical requirements for the KIVS, Concept 1 were defined based on the selected storyboard. Third, a working prototype of KIVS was developed to explore the possibilities of real-time patient data visualization in relation to RFA. KIVS was developed taking into consideration the needs of the current surgical workflow of RFA. HMD was integrated to facilitate augmented reality display of image fusion between different modalities such as intra-operative US and pre-operative CT. Fourth, heuristic evaluation (Study 6) of KIVS with medical students and clinicians highlighted issues related to technical capabilities, and issues with augmented visualization. The selected findings from the Concept 1 evaluation were considered relevant for the development of KIVS, Concept 2, explained in Chapter 5.

This chapter is based on the following publication:

Jalote-Parmar. A., P. Badke-Schaub, A. Wajid and E. Samset (2009), "Cognitive Processes as Integrative Component for Developing Expert Decision-Making Systems: A Workflow-Centered Framework", Journal of Biomedical Informatics doi:10.1016/j.jbi.2009.07.001 (In Press).

CHAPTER 5 CONCEPT 2: KNOWLEDGE INTENSIVE VISUALIZATION SYSTEM

Overview

This chapter explains the design and evaluation of the second concept of Knowledge Intra-operative Visualization System (KIVS) for the minimally invasive procedure- RFA. Fig.1 explains the research process applied to the development of KIVS, Concept 2. The workflow-centered framework developed in Chapter 3 was applied to guide workflow driven development of KIVS. This chapter will explain the development of Concept 2 for KIVS, based on the findings obtained from the surgical workflow analysis (Chapter 4) and the findings from heuristic evaluation of Concept 1.

The chapter is organized as follows: Section 5.1 describes the aims and objectives of KIVS. KIVS, Concept 2 was conceptualized on the basis of the design requirements and concept storyboards. Section 5.2 explains the information requirements for KIVS, based on findings from workflow analyses. Section 5.3 discusses the information visualization in surgical workspace. Section 5.4 chapters includes the description of how the theory of situation awareness has been applied to the design of the intra-operative visualization for the KIVS. Section 5.5 explains the design of KIVS, including explanation of system components, system architecture, and information visualization. Section 5.6 describes the evaluative study (Study 7) which compares the performance of expert intervention radiologists and

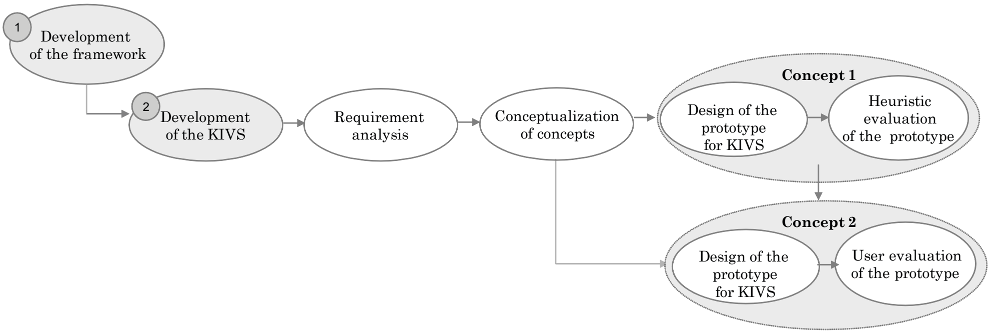


Fig.1. The research process followed in the development of KIVS.

medical students while performing RFA by using two systems: KIVS and the conventional ultrasound (US) guided intervention. The results reveal significant evidence for improved decision-making when using the KIVS. Section 5.7 reports the results of the evaluative study. Section 5.8 explains the limitations of the experimental set up and the technological limitations. Section 5.9 discusses the results and their implications. Section 5.10 provides recommendations for future development of the expert systems.

5.1 Aims and objectives of KIVS

Concept 1 was developed to conceptualize how different technological components can be integrated to formulate a solution based on the RFA workflow, specifically to gain a preliminary understanding of real-time image fusion between pre-operative imaging data and intra-operative imaging data in the context of RFA procedure. Proceeding with development activities required a more concrete understanding of the effect of specific image fusion of pre- and intra-operative data on improving the task accuracy of RFA. Therefore, Concept 2 was developed specifically to investigate the following research questions:

- *How can the knowledge of surgical workflow be incorporated into design of KIVS in order to improve decision-making and thus the performance of the surgeons?*
- *What is the role of real-time image fusion between intra-operative imaging data and pre-operative imaging data in supporting surgical decision-making in order to improve task accuracy of RFA?*

To address the above questions a specially designed working prototype of KIVS was conceptualized and developed. In order to conduct experiments with the clinicians, specially designed task scenarios were integrated into the design of prototype to simulate the clinical tasks performed during

RFA. The KIVS prototype was not developed as a complete solution for the visualization problems as identified in the workflow analysis but rather as a means of evaluating the role of real-time image fusion in improving task accuracy of RFA. The knowledge generated through this experiment should provide a basis for future technological development in the area of intra-operative visualization. Besides, it should provide an example case of workflow-driven development of intra-operative visualization systems.

The conceptualization of the prototype for KIVS, the information architecture and the experiment were designed by the author. The information architecture included designing information content on the screen and information flow between different imaging modalities. As explained in Chapter 4, the technological components for the prototype were developed by the technology engineers and several surgical requirements were identified from the surgical workflow analyses of RFA. In particular, six surgical milestones (SM 1-6, Chapter 4) were identified as critical for improving task visualization during RFA. It was decided in the testing of concept 1 that although all these surgical milestones are clinically critical, due to technological limitations, concrete solutions were only possible for a limited number of selected problems. The two surgical milestones selected were: SM 3- Identification of the target tumor in liver and SM 4- placement of the needle in the center of the tumor.

5.2 Requirement analysis

On the basis of the findings of the surgical workflow analysis of RFA, information requirements were obtained. For example, Fig. 2 depicts a part of RFA workflow for the intra-operative phase documented in the existing workflow module of WIM, describing the workflow and information requirements for Surgical Milestone (SM) 3 & 4 corresponding to each task boundary during RFA. As can be seen in the figure, when deciding the optimal entry point to insert the needle, several task boundaries determine the surgical decision making, e.g. the location of organs in the path of the needle and tumor, the size of the tumor, the depth of the tumor, approximate area of coagulation after the needle has been inserted in the tumor. The dots indicate the specific issues prioritized by the surgeon. Due to technological limitations, not all the information requirements for SM 3 & 4 can be addressed in the KIVS prototype.

5.3 Information visualization in surgical workspace

The knowledge repository of RFA workflow mentioned above and the storyboards as described in (Chapter 4) were taken as a starting point

Surgical Milestones: **Identifying the target tumor& Entry and placement of the needle**

Task Boundaries:			A part of intra-operative surgical workflow of RFA	Proposed information visualization in KIVS
Target State	Goal	SM-3	To identify the target tumor with intra-operative ultrasound & compare it to the one planned to be ablated in the pre-operative CT	-
		SM-4	To identify the optimal port of entry and acoustic window to reach the tumor. To reach the tumor without rupturing other organs.	-
	Procedure /Action	SM-3	The US probe is placed on the patient and the target tumor is located. This is done with the help of mental co-relation between the pre-operative CT scan the tumor identified in US	The US probe is swiped on the patient and US volume is scanned in the KIVS. A 3D model of liver is generated with the inputs from pre-operative CT scan and the real-time US volume.
		SM-4	The optimal needle trajectory is planned, and the needle is navigated to target tumor.	Visualization of the RFA needle in 3D and its navigation trajectory in real-time.
Surgical equipment	Surgical tool	SM-3	The ultrasound can have several transducers. Depending on the position of the tumor, the transducer is selected.	For experimental purpose a pre-selected US transducer was tracked by magnetic tracker.
		SM-4	The needle has several sizes and shapes, it is selected depending on the size and location (depth) of the tumor.	For experimental purpose a pre-selected RFA needle was tracked by magnetic tracker.
	Visualization / Information system	SM-3&4	Ultrasound	Three screens: real-time ultrasound with superimposition of preoperative CT scan, 3D model of liver and superimposition of US, pre operative CT scan (See Figure 8-10)
Communication	Equipment	SM-3&4	The intra-operative ultrasound provides the real-time information of the organ.	The pre-operative CT scan is fused with the intra-operative US. It allows the display of pre-operative data combined with real-time data of patient anatomy and the pre-operative CT scan provides the static context view of the patient anatomy.
	Surgical Team	SM-3	The assistant helps in setting up the RF machine and handing the tools.	The experimenter explains the set up.
		SM-4	In case of uncertainty, consultation with other experts.	KIVS provides visualization support for uncertain scenarios such as finding a new tumor intra-operatively.

Patient State	Clinical Constraint	SM-3	The target tumor can be more inconspicuous than adjacent regenerative nodules or, if located in the hepatic dome, can be masked by the overlying lung or ribs.	●	Superimposition of real time ultrasound with 3D CT data aids in identification of the target tumor, thus reducing the ambiguity.
		SM-4	The entry port may not be the optimal one to reach the tumor, as the tumor may be difficult to access due its location in the liver.		3D model of liver is generated from pre-operative CT scan and superimposition of real time ultrasound aids in visualizing the target needle trajectory.
	Critical factor	SM-3	Identifying the correct target tumor.	●	Superimposition of pre-operative CT data on real time ultrasound aids in identification of the target tumor, thus reducing the ambiguity.
		SM-4	The needle should hit the tumor in the center, or else the cancer cells will be not completely necrotized. Ablation zone=5cm and safety margin= 1cm	●	3D model of tumor is generated from the pre-operative CT scan, and a dot indicates the mathematical center of the tumor.
	Feedback	SM-3	None, excepting the real time US feed.		Visualization of the liver in 3D, key vessels, tumor and needle trajectory generates a context view.
		SM-4	There is a haptic feedback from the organ in the path of the needle and when the needle hits the tumor.	●	Haptic feedback is a critical issue but due to lack of technological infrastructure this issue is not addressed.
	Anatomical structure	SM-3	Tumor may move from its first position once identified in the US, this movement is due to the patient breathing and movement of liver as an organ….	●	Movement of liver is a critical issue necessary in real-time image registration, but due to lack of technological infrastructure this issue is not addressed.
		SM-4	Tumors are stiff and have various shapes. The needle may bend slightly when inserted into the tumor due to tumor density.		Bending of the needle is a critical issue, but due to lack of technological infrastructure this issue is not addressed.
Surprise State	Uncertainty	SM-3	Not finding the target tumor due to its location in the liver. Finding many more tumors in the liver than in Preoperative CT	●	The KIVS supports two levels of task complexity:
		SM-4	…. How to judge the center of the tumor	●	Routine tasks: visualization support for given information, i.e. the tumor that has been planned to be ablated.
	New Surgical action	SM-3	After consultation, in case of many new tumor, a new patient strategy needs to be made for the patient. In case of one more tumor it is to be judged if it can also be ablated.	●	Complex/uncertain tasks: real-time update of the intra-operative visualization in case new tumors are found during the procedure.
		SM-4	Consultation…..patient send for Chemotherapy, to down size the tumor.	●	-

Fig.2. The information requirements related to SM3&4 in RFA and the corresponding solutions offered in KIVS. The red dots indicate the information requirements prioritized by the surgeon.

for conceptualizing and developing the Concept 2. The analysis provided an understanding of the surgical problem solving activities and the information requirements for specific surgical tasks. These findings lead to defining the content of the information that needs to be extracted from different imaging modalities in order to be visualized. However, further reflection was necessary to investigate how the information needs to be visualized to assist surgical decision making tasks in RFA.

The surgical workspace is a complex and naturalistic decision-making environment, where the complexity can be defined in terms of: (a) dynamic decision-making that are dependent on surgical planning, (b) real-time task execution, (c) low tolerance for errors, and (d) uncertainty of events. The uncertainty is often caused by patient conditions while performing the surgical procedure. Real-time information provided to assist the surgeon in decision-making can originate from various sources within the surgical workspace, such as planning information based on pre-operative data, real-time imaging feedback from the patient body, and real-time video feedback of the endoscopic probe.

Not all information coming from the various sources is relevant at all times and unnecessary information tends to increase the information load on the surgeons. Irrelevant or redundant information may distract the surgeon from concentrating on more important information and may cause surgical errors. Therefore, to support decision-making in complex naturalistic decision-making environments such as surgical theatre, it is important to facilitate the expert (surgeon) in developing an accurate situation awareness of the critical elements required to perform the (surgical) tasks (Klein et al. 1993). Theoretical concepts which explain how to improve the visualization of critical information required for performing surgical procedures may assist in the development of better decision-making systems (Klein et al. 1993; Endsley 1995; Jalote-Parmar and Badke-Schaub 2008b).

5.4 Adapting the theory of situation awareness

In this regard, the field of Naturalistic Decision Making (NDM) has expanded on these lines by developing models of how people make decisions in the real world. A person's situation awareness becomes the key feature, dictating the success of the decision process in most real-world decision making. For developing adequate situation awareness, decision makers in these complex domains must do more than simply perceive the state of their environment. In this context, the theory of situation awareness was considered relevant (Drefus 1981; Klein 1989). This theory has been used to design systems, mainly in aviation such as for fighter aircraft (Endsley and Kiris 1994) and for pilot cockpits (Endsley et al. 1998). In complex and dynamic environments, decision-making is highly dependent on situation

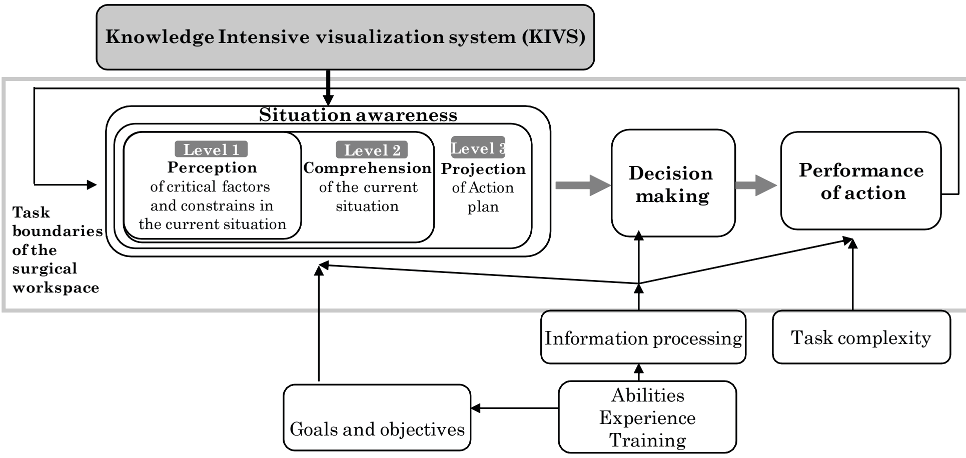


Fig.3. A model of situation awareness adapted to the surgical workspace, based on (Endsley 1995).

awareness: a constantly evolving picture of the state of the environment. Situation awareness within complex domains involves being aware of what is happening across many aspects of the work environment. For example, pilots must instantaneously keep up with where they are in space, the status of the aircraft systems, the effect of turbulence on passenger's comfort and safety (Endsley et al. 2003). Similarly, during MIS the surgeons must be adequately aware of their location inside the patient body while performing the procedure, and also be aware of the location of critical organs in the path of the surgical tasks.

Situation awareness consists of three elements of cognitive processes: (a) perception of critical factors and constraints in the environment within the given time and space, (b) comprehension of their meaning, and (c) projection of their status into near future (Endsley 1995). Obviously, the three levels of situation awareness are interrelated, i.e. there is no comprehension without perception and hence no projected plan of action without comprehension. Thus, in order to improve decision-making in the surgical workspace, all three levels have to be considered simultaneously to realize information visualization of the KIVS. The KIVS should support developing an accurate situation awareness of task boundaries such as patient state[1] and surprise state[2] which determine the surgical problem-solving activities (Jalote-Parmar and Badke-Schaub 2008a). This may lead to improved decision-making and hence to a better task performance (Fig.3.). Application details of situation awareness to design will be explained in Section 5.5.2.

1 Patient state: The identification of the problem related to physical form/function of the patient that requires surgical action to improve the health of the patient. The patient state changes as the surgical procedure progresses in time. Its sub factors are: Clinical constraint, Anatomical constraint, Feedback, Critical factor.

2 Surprise state: Sudden (unexpected) revelation while performing the surgical action. This state could lead to a breakdown of the surgical procedure. Its sub factors are: Uncertainty and New surgical strategy.

5.5 Design of the KIVS prototype: Concept 2

KIVS prototype consists of two main components:

5.5.1 System components

1 *Image integration and processing software*
This software should integrate technological components such as image registration and segmentation (Fig. 4). The main function of this software was to: (a) process the pre-operative CT slices as obtained from the diacom and generate a 3D model of liver; (b) capture, calibrate and register the real time image data as inputs received from intra-operative US; (c) create superimposition of pre-operative CT slices and real-time US. This software does not currently exist in the required form as the required technological components are still in development (Chapter 1, Section 1.5) and (Chapter 4, Section 4.3), so it was simulated for this experiment using AR framework software called Studierstube (Schmalstieg et al. 2002). This simulation was carried out by system engineers hired to develop the prototype.

2 *System architecture*
The system architecture of the KIVS is depicted in Fig 5. It includes the Aurora magnetic tracking system (Northern Digital Inc, Waterloo, Ontario), which tracks the fiducial markers on the abdominal phantom, the ultrasound probe, and the RF needle. Interventional 3D abdominal phantom (CIRS,Norflok,Va) was used. The phantom was a specially made component, consisting of a US volume of the liver and had

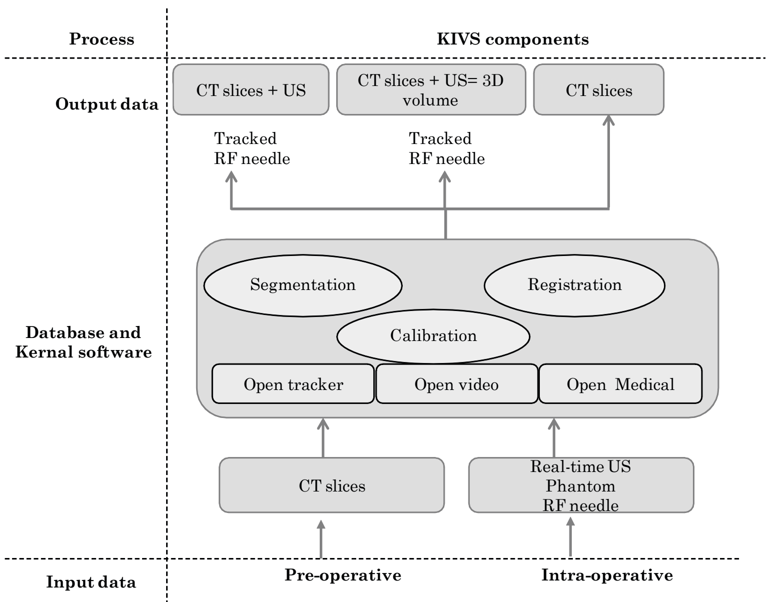


Fig.4. Scheme of KIVS system components and data flow.

multiple virtual tumors ranging from 3-4 cm in size. No large or oblong shaped tumors were present. Although oblong tumors do clinically exist in patients, for the purpose of this study, we restricted it to small oval shaped tumors. The phantom was made of specialized jelly, which imitated the human abdomen and aided in simulating the real-world clinical condition. The main workstation used the Augmented Reality software called Studierstube (Schmalstieg et al. 2002). The software grabbed the images from the US probe and the pre-operative CT scan to generate a 3D model. In addition, it integrated the tracking data from the tracking server machine to register the images and produce the video outputs in the different screens. The data were stored in the tracking server machine and the main workstation. The video input from the ultrasound machine was relayed to the tracked ultrasound probe. The pre-operative CT scan and the real time ultrasound volume were registered and fused to display Screen-1 and Screen-2. The data from the pre-operative CT scan were converted into a 3D model. The real-time registration of the 3D model to the ultrasound image has been simulated, though this technology is currently being developed (Milko et al. 2008). Functions like image zoom and rotation were provided for user interaction with the images. At present, a keyboard was used to activate these functions. Dedicated hardware with necessary keys will be developed later.

5.5.2 Information visualization

The information flow between the various imaging modalities was planned and structured in order to create a single window of integrated information providing real-time patient information. In order to support the surgical

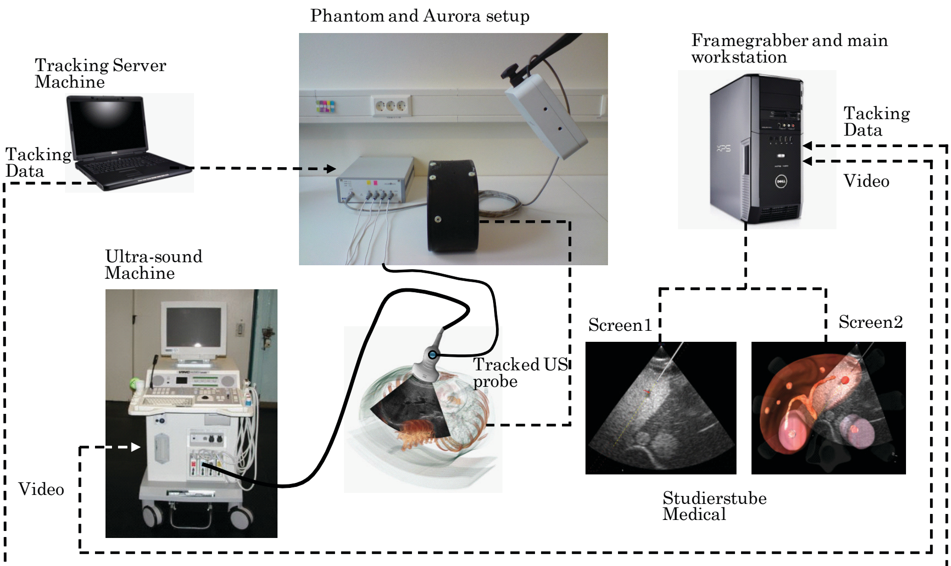


Fig.5. System architecture of the KIVS.

decision-making, the information visualized through the KIVS corresponded with the 'surgical workflow' or the sequence of surgical activities performed by a surgeon to complete the surgical procedure. Information visualization in the KIVS was intended to support the surgeon in developing an accurate situation awareness of the critical elements related to the surgical tasks. The real-time image guidance was provided through fusion between the two imaging modalities: Ultrasound (US) and Computerized Tomography (CT). These imaging modalities were selected because they ranked high in terms of the benefits from their current usage and were therefore most trusted by the surgeons to perform the RFA procedure. Detailed explanation of US and CT can be read in Chapter 4 Section 4.2.2 and Chapter 2, Section 2.1.1.

1 *Situation awareness in KIVS*

The assumed influence of the information visualization from KIVS on the cognitive processes and performance is illustrated in Fig.6. It indicates that information requirements related to task boundaries as obtained from surgical workflow analysis lead to the identification of design requirements. Based on the design requirements, information visualization was designed in KIVS to support the three cognitive processes: perception, comprehension, and projection of action plan of the surgeons. It is necessary that the information visualized through KIVS supports surgical tasks, and it is expected to result in reduced intra-operative planning time and increased accuracy during the procedure. The cognitive processes will be supported by improving intra-operative visualization of critical information for task boundaries corresponding to SM 3 & 4. Table 1 (See following pages 118-119) illustrates how the design requirements and theoretical basis of situation awareness determined the design of information visualization in KIVS. The goal of KIVS is to transmit relevant information to the surgeon as quickly as possible and without undue cognitive effort. The KIVS was designed to support three levels of situation awareness by incorporating real-time visualization inputs.

2 *Information visualization in KIVS*

The KIVS prototype includes three screens to display the required information through image fusion. The combination of the three screens assisted the surgeons in identifying the target tumor and aided in needle navigation. Real-time information visualization was achieved by fusion of pre-operative data obtained by CT scan with intra-operative data gained through real-time US. Task related visual cues of

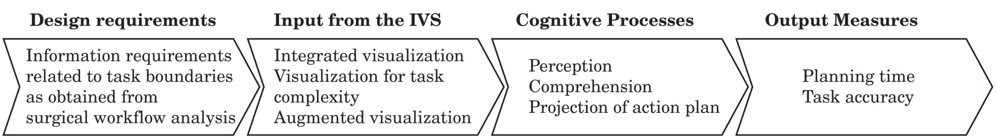


Fig.6. Assumed influence of KIVS on the three levels of situation awareness and on output measures

critical anatomical structures were augmented in 2D and 3D through image fusion between pre-operative CT and real-time data from US in screen 1&2. Both screen 1 and screen 2 can be integrated on to a single screen (large monitor). As seen in Chapter 2 Fig. 4, for intra-operative visualization requirements, the surgeons use large monitors to display a combination of intra-operative and pre-operative data. However, due to technological and financial limitations two separate screens were used and the pre-operative CT scan of the patient was displayed in Screen 3. Together, the three screens aimed at enhancing perception and comprehension of critical structures and surgical constraints to increase the situation awareness. The criteria for selecting the screen solution were dependent on the type of information provided by the two imaging modalities (CT scan and US). The CT scan provides a context view of the patient anatomy but does not provide real-time data inputs from patient anatomy. The US provides real-time inputs but does not provide context information. Thus, both modalities complement each other. Further details of the information visualization in the three screens are explained below:

Screen 1

Screen 1 assists the surgeons with a real-time view of the patient anatomy through US guidance together with augmented information. This augmented visualization is generated through image fusion between real-time US and pre-operative CT scan. The information is augmented in 2D on the US screen. This means that only the key abstracted information related to critical structures is extracted from the pre-operative data set and superimposed on the original US image. The system supports the decision-making in two levels of task complexities: Routine scenario and Complex scenario which will be explained on the following page.

- *Routine scenario.*
  The image fusion provides an augmented image of the target tumor

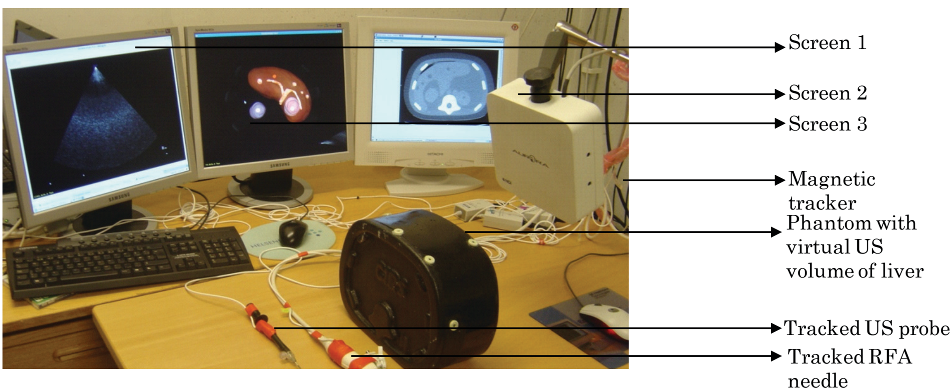


Fig.7. Physical set up and components of Intra-operative visualization (KIVS) prototype. (Picture taken at Rikshospitalet, Norway)

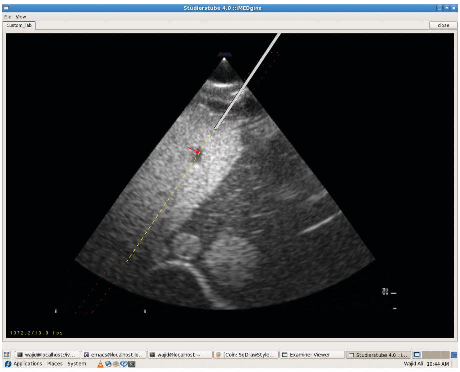


Fig.8. Screen 1 illustrates the routine scenario with the augmented needle, needle trajectory and the augmented arrow indicating the target tumor.

which is represented by a red arrow. As the surgeons swipe the US on the phantom, the system recognizes the target tumor as a result of CT and US fusion. The arrow indicates the target tumor, thus minimizing the error of selecting the wrong tumor. It provides missing patient data and reduces uncertainty caused by the noisy data of the US image. This reduces the cognitive load, enhancing perception of critical information. The system recognizes and tracks the location of the needle and generates a needle trajectory, which is augmented on the US image in real-time. This, in turn, helps needle navigation and may support the surgeon's own ability to create and accurate projection plan and thus improve situation awareness. The surgeons rely on US imaging for real-time data, so only abstracted information of critical cues is augmented on the original US image. The augmented information can be switched on and off. Fig 8. depicts the routine scenario in the screen

- *Complex scenario*
  Visualization in a complex scenario facilitates the surgeon to locate the newly detected tumor, allowing the opportunity to plan dynamically. The image fusion between pre-operative data and real-time US provides information about the newly detected tumor, represented by a blue arrow. This may reduce ambiguity caused by missing information and thus support perception and comprehension.

Screen 2

This screen provides context information about the location of the tumor, the vessels and the position of the US probe. A 3D model of liver is generated based on image fusion between CT scan and US image. The decision-making related to positioning and guiding the needle to the center of the tumor depends on the anatomical and clinical constraints. The ablation zone is normally taken to be 5 cm and the maximum tumor size selected for ablation is 3 cm, in order to leave a safety margin of 1cm around it. The anatomical constraints for the SM 3 & 4 as identified in workflow analysis (Fig. 2) have not been considered in design due to technological limitations. The screen provides the following critical cues in both routine and complex scenarios:

- *Context view*
  When the surgeon places the needle on the phantom, screen 2 displays the needle in a 3D model of the liver along with an augmented needle

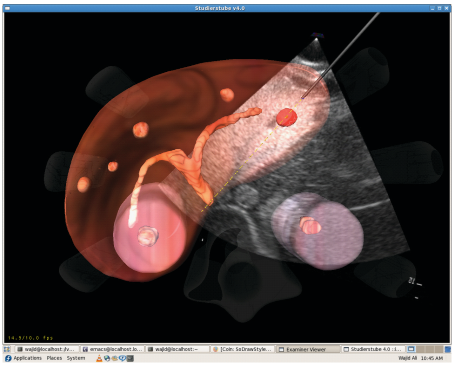


Fig.9. Screen 2 illustrates the superimposition of real-time US on 3D of liver made from CT scan. It shows the needle, tumor and critical vessels in the needle trajectory. It illustrates the context view of the patient anatomy vs. the planar view of the US.

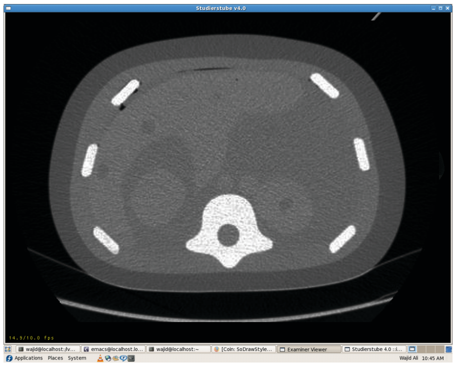


Fig.10. Screen 3 illustrates the slice of the original CT scan.

trajectory. As can be seen in Fig. 9, screen 2 only shows abstract information of the 3D model of liver and not a photo realist image. This avoids information overload of the anatomical structures not required by the surgeon for the task. This offers the surgeon a context view of the patient anatomy and spatially orient the US probe and the needle towards the target tumor. The target tumor is marked in red in the 3D model for the routine scenario. In the complex scenario, the model updates itself and the new tumor found is marked in blue. As a consequence, the surgeon is able to comprehend the task related information appropriately, thus better action planning is supported.

- *Navigation and verification*
  The liver parenchyma, tumor and main vessels are visualized in 3D. When the surgeon positions the US probe on the patient phantom, she /he knows its location corresponding to the tumor and the vessels. This assists in placing the US probe optimally and navigating the RFA needle by avoiding the anatomical structure. By visualizing critical cues related to patient anatomy, KIVS can aid in better perception of patient data thus supporting the situation awareness.

Screen 3

This screen displays the original pre-operative CT scan. This is included as during the procedure the surgeons often prefer to recapitulate the overview of the patient anatomy. No additional information is augmented on the CT scan. By providing pre-operative data, intra-operatively KIVS may reduce the mental load on the surgeon.

Table.1. Design requirements, information visualization and situation awareness in the KIVS

Design requirements as obtained from workflow analysis for SM 3&4	Realization Information visualization in KIVS	Theoretical basis Situation awareness
Visualization should support two levels of task complexity • Routine tasks: regular tasks conducted by the clinician in the planned way by applying the given information. In this case the ablation of the pre-operatively tumor that was planned. • Complex (uncertain) tasks: characterized by uncertainty, which means while performing clinical tasks unexpected revelations can occur. In this case the ablation of the new tumor identified in the intra-operative phase.	**Visualization to support two levels of task complexity** • Routine tasks: visualization support for given information, i.e. the tumor that has been planned to be ablated. • Complex tasks: real-time update of the intra-operative visualization in case new tumors are found during the procedure.	**Visualization for two levels of task complexity** Information visualization in KIVS support re-cognition of known data (=routine) and unambiguous perception and representation of complex tasks. KIVS offers missing patient data and reduces noisy data causing uncertainty. This reduces ambiguity related to patient data in real-time and increases the reliability of patient data. As a consequence the clinician is able to comprehend the task related complexity appropriately which is a precondition for better understanding and action planning.
Information visualization should be comprehensive • Integrate the information from the pre-operative into the intra-operative phase. In this case, the pre-operative imaging data of the patient anatomy needs to be presented intra-operatively in real-time.	**Integrated visualization of information** • The pre-operative CT scan is fused with the intra-operative US to display planning data compared to what the clinician sees in real-time.	**Integrated visualization of pre-operative data in real-time** KIVS will visualize aggregated data and superimposition of critical information related to surgical tasks to enhance the comprehension (Level 2 of SA). The clinician mentally superimposes the pre-operative patient data from CT image to the intra-operative US data. This superimposition is done by the KIVS to support the generation of the accurate mental model to enhance comprehension of patient data. On one hand, KIVS can reduce the cognitive load on the clinician by providing information from pre-operative stage that he/she has to carry in his head, on the other hand, KIVS supports intra-operatively generating an accurate mental model of the patient data.

<table>
<tr>
<td>Information visualization should provide critical cues to avoid ambiguity
• Identify the target tumor and critical anatomical structures related to it.
• Visualize critical anatomical cues to assist the needle navigation in the spatial space.
• Visualize optimal trajectory of needle insertion in the percutaneous procedure.</td>
<td>Augmented visualization of information of critical cues
• Visualization of critical cues to identify the target tumor and the vessels by providing augmented information of tumor and vessels on the US image.
• Superimposition of pre-operative data on real time ultrasound and visualizing the liver and anatomical structure in 3D.
• Visualization of the liver and anatomical structure in 3D to support needle navigation.
• Visualization of the RFA needle in 3D and its navigation in real-time.</td>
<td>Augmented visualization of critical cues
KIVS provides augmented visualization of critical cues related to clinical tasks such as needle trajectory, in order to support the clinicians' own ability to create accurate projections (Level 3 of SA). Augmented visualization means superimposition of critical cues related to the task on real-time imaging data (US). For example, anatomical cues on real time US image to assist the needle navigation. Augmenting information of patient anatomy on the US image reduces the complexity of data. It reconfirms the critical elements related to the tasks in the US image and thus assists in non-ambiguous perception of the data. The visualization of the critical cues supports the generation of an accurate mental model of the task, thus generating a better perception, and action plan.</td>
</tr>
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5.6 Study 7: Evaluation of the KIVS prototype

The evaluation of the technology robustness of the system on one hand and the clinical feasibility on the other are two different issues. Although the technology assessment is an important issue, it is beyond the scope of this thesis which is restricted to evaluating the clinical feasibility of the KIVS. The evaluation study (Study 7) was conducted to investigate in how far KIVS supports surgical decision-making and whether it improves performance during the procedure. An experimental study was conducted to compare whether the KIVS is better at supporting the decision-making and performance of expert intervention radiologists and medical students in comparison to the conventional Ultrasound (US) guided intervention. Both the surgeons and the intervention radiologists performed RFA procedure. Due to introduction of MIS, besides the surgeons, intervention radiologists are taking a more prominent role in conducting these procedures. In the national hospital in Norway where the KIVS prototype was developed RFA is usually performed by intervention radiologists. Consequently, intervention radiologists have been involved for this study. The purpose of the study was clearly explained to all participants. All the participants willingly agreed to participate in the study and gave permission for use of the findings for research purposes.

5.6.1 Participant selection

Experts
Eight expert intervention radiologists who were practicing RFA or biopsy procedures were selected as participants. These experts were associated with the Rikshospitalet and Radium Hospitalet Oslo, Norway and had eight to twenty years of experience in intervention radiology. Eight experts were the maximum number of experts available for the study in Oslo.

It is important to note that percutaneous RFA has been fairly recently introduced into the medical field for treating cancer in liver tumors. To perform RFA percutaneously with US guidance is a spatially challenging and complex procedure. Since it requires special expertise in understanding of US for interventional procedures, the proportion of experts practicing this procedure is limited worldwide, with each hospital having a very limited number of experts. The participants selected for the study were invited experts from two major hospitals in Norway.

Students
Final year medical students (n=8) of the Rikshospitalet Oslo participated in the study. In case of medical students, there was also a careful selection procedure. Not all medical students could be selected because a certain knowledge of image analysis was necessary to conduct the experiment. All the selected student participants were required to have primary knowledge and understanding of CT scans and of working with Ultrasound system.

This was difficult because the use of both the imaging modalities is not a part of the standard education curriculum of the final year students and those who did know, knew only as a consequence of personal interest. None had any previous training on performing RFA procedures.

5.6.2 Experiment design

Specifically designed clinical scenarios were developed in the KIVS. Each participant was given an hour of training time on the KIVS and the US. Although one hour is limited time to get acquainted with KIVS, it was the maximum time available with the experts and the students. In the case of students, half an hour more was allowed for the training as most of them were new to performing interventions by using the US. In the training period, the participants were required to hit the center of a tumor by using both the systems (Fig.11). For the final task, each participant was given two tasks (routine and complex) of hitting the center of the tumor again using both systems. The use of the system was alternated between the participants. First, four experts and four students were asked to perform the tasks using the US and then the KIVS. Then this situation was reversed for the next group of participants. Two levels of task complexity, routine and complex, were selected.

- *Routine scenario*
  This task required the participants to ablate the tumor selected for ablation during the pre-operative planning stage. To simulate this clinical scenario in the experiment, one of the tumors was highlighted on the CT of the abdominal phantom. The participants were required to ablate the selected tumor using the two different systems.

- *Complex scenario*
  This task required the participants to ablate the tumor which was newly detected while conducting intra-operative US. This newly detected tumour was not visible in the pre-operative CT, thus causing uncertainty in the originally planned clinical action. To simulate this complex scenario in the experiment, a tumor existing in the abdominal phantom was hidden in the CT scan. The hidden tumor was visible to the participants only while conducting the intra-operative US. The participants were expected to dynamically plan the RFA procedure.

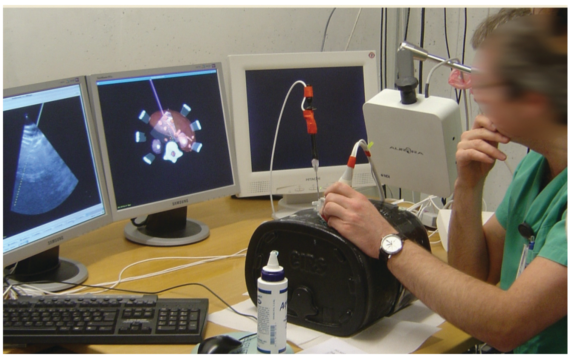

Fig.11. An expert intervention radiologist using the KIVS system.
(Picture taken at Rikshospitalatet, Norway)

5.6.3 Measurement criteria's

The data were assessed at the following two levels to compare the output of the participants:

1 *Performance measures*
The following two criteria were selected to measure task performance: (a) intra-operative planning time to execute the task and (b) the task accuracy in hitting the center of the tumor with the RFA needle.

- *Intra-operative task planning time*: The planning time was measured as the time taken by the participant to plan the procedure intra-operatively. This was measured as the total time taken by the participants for problem analysis time after explanation of the tasks until the start of task execution. Time to perceive and comprehend information to decide on an action plan is an important criterion influencing the task performance (Endsley et al. 2003). It is a well established fact that the integration of information is an important cognitive strategy to reduce information overload. It was assumed that the visualization of integrated information by KIVS reduces the mental effort and thus the intra-operative planning time.
- *Hitting the tumor in the center*: Clinical findings state that the major cause of clinical errors performing the RFA procedure is either caused by the wrong tumor hit, or by not hitting in the center of the tumor-causing unablated cancer cells (Rhim et al. 2008). In addition to information integration, the visualization of critical cues which aid in surgical tasks, such as cues related to patient anatomy, navigation tasks, are essential in supporting decision-making. To illustrate this, it was assumed that visualizing the critical cues related to the patient's anatomy would assist the intervention radiologists to identify and hit the right tumor in the center, thus improving the task accuracy and the clinical viability of the RFA procedure. The accuracy of hitting the center of the tumor was measured as the distance between the point of needle insertion by the participant and the mathematical center of the tumor. This was measured by a specially programmed software which tracked the position of the needle tip and calculated its distance from the center of the virtual tumor. This was possible because the position of virtual tumors had already been obtained from the US data of the phantom.
- *Hitting the target tumor*: The participant's accuracy of hitting the correct target tumor during the task was measured. A wrong tumor hit was measured by the distance between the needle hit and the center of the target tumor.

2 *Evaluation by the participants*
Subjective measures were integrated with performance data to gain a true understanding of self reported evaluations (Endsley et al. 2003). Follow up questions were asked to each participant immediately after

the study. A questionnaire with a 5 point Likert scale was used to evaluate the subjective opinion (questionnaire below, in Table 4). The participants were asked to rank the visualization support and the 'felt' situation awareness obtained through both the systems. Independent sample t-test was used to compare the mean of two participant groups: (a) experts and (b) students for each question and for both the systems.

5.6.4 Method of data analysis

As discussed in the previous section, experiments were specially designed to examine the performance of KIVS. The experiments were conducted with the expert group (8 participants) and student group (8 participants). They were assigned to do two levels of task complexities: Routine and complex by using KIVS. Same tasks were repeated by using conventional US. Task performances were recorded after each task. The indicators of task performance are: intra-operative task planning time and task accuracy. Intra-operative task planning time was measured as the total planning time taken by the participants after explanation of the tasks till the start of task execution. Task accuracy was measured as the distance between the points of needle insertion by the participant and the mathematical center of the tumor they hit. In addition, task accuracy was also indicated by the success rate of hitting the target tumor. To compare the performance difference between the two systems, Wilcoxon signed-rank test was applied for the following reasons: (1) we have a relatively small sample, so normal distribution assumption is difficult; (2) this method compares the median value instead of the mean value, thus partially taking care of the issue of outliers. The median is a useful number in cases where the distribution has very large extreme values that would otherwise skew the data.

5.7 Results

The results from the evaluative study were analyzed on the performance measures (as described above) are explained in the following sections:

5.7.1 Performance measures

1 *Reduced intra-operative planning time*
Both the participant groups, experts and students, show a significant reduction in intra-operative planning time for both levels of task complexity (routine and complex) using KIVS, compared to US intervention (Table 2). The planning time of the expert participants was significantly reduced when performing routine tasks ($p=0.012$, Med_KIVS=2.85 min and Med_US=6.8 min) and complex tasks ($p=0.036$, Med_KIVS=4.3 and Med_US=5,62 min). In addition, the planning time of the student participants was significantly reduced for routine tasks ($p=0.012$, Med_KIVS=5.39 min and Med_US=8.5 min) and

Table 2: Intra-operative planning time of experts (n=8) and students (n=8).

Radiologists (*n*=8)	**Planning time**		**Students** (*n*=8)	**Planning time**	
Routine tasks			**Routine tasks**		
Systems	Median	Range(min)	Systems	Median	Range(min)
KIVS	2.85	2.11-4.41	KIVS	5.39	3.54-6.34
US	6.80	5.54-10.27	US	8.55	5.67-13.65
Significance	p=0.012		Significance	p=0.012	
Complex tasks			**Complex tasks**		
Systems	Median	Range(min)	Systems	Median	Range(min)
KIVS	4.37	2.80-5.54	KIVS	5.78	4.21-6.89
US	5.62	4.33-7.40	US	9.67	5.15-14.70
Significance	p=0.036		Significance	p=0.012	

NOTE: Wilcoxon signed ranks tests ($p<0.05$)

complex tasks (p=0.012, Med_KIVS=5.78 min and Med_US=9.67 min). Results in Table 2 show that although there is a significant difference in reduced planning time between the experts and the students, the experts were quicker in conducting the intra-operative planning. Intra-operative planning involves routine but also the perception of critical situations and coping with high uncertainty (Orasanu and Connolly 1993; Rouse and Valusek 1993; Badke-Schaub and Frankenberger 1999). These scenarios required seeking alternative courses of actions, which the experts were able to acquire from the repertoire accumulated during his/her past experiences (Rouse and Valusek 1993). This can be explained as the KIVS supported the expert's experiential knowledge by providing the necessary critical cues through integrated information.

2 *Task accuracy of hitting the tumor in the center*

The results show that when using the KIVS, both experts and students show an increase in accuracy in hitting the center of the tumor as compared to the US (Table 2). The task accuracy of hitting the center of the tumor by the expert participants did not increase significantly for the routine tasks, (p<0.05, p=0.69, Med_KIVS=2.10 mm and Med_US=2.65 mm.) but increased significantly in the complex tasks, (p=0.017, Med_KIVS =1.80 mm and Med_US=3.20 mm.). The task accuracy of the student participants increased significantly while performing routine tasks, (p=0.025, Med_KIVS =1.25 mm and Med_US=5.76 mm.) and complex tasks, (p=0.012, Med_KIVS =2.65 mm and Med_US=6.36 mm).

3 *Errors in hitting the target tumor*

No wrong tumor was hit either by the experts or by the students while performing the task with the KIVS. However, experts hit three wrong tumors while performing with US. In particular, two wrong tumor hits occurred during the routine tasks and one during the complex tasks. Student participants hit four wrong tumors

Table 3: Task accuracy of experts (n=8) and students (n=8).

Intervention Radiologists (n=8)	**Task accuracy**	
Routine tasks		
Systems	Median	Range(mm)
KIVS	2.10	0.70-2.90
US	2.65	2.10-12.80
Not Significant	p=0.69	
Complex tasks		
Systems	Median	Range(mm)
KIVS	1.80	1.10-2.80
US	3.20	1.90-6.80
Significance	p=0.017	

Students (*n*=8)	**Task accuracy**	
Routine tasks		
Systems	Median	Range(mm)
KIVS	1.25	0.90-2.90
US	5.76	1.40-49.00
Significance	p=0.025	
Complex tasks		
Systems	Median	Range(mm)
KIVS	2.65	0.80-4.80
US	6.35	3.80-22.78
Significance	p=0.012	

NOTE: Wilcoxon signed ranks tests ($p<0.05$)

while using the US, with two hits for each task complexity.

The results in Table 3 indicate improved accuracy and reduced errors on two counts. First, the experts hit 3 wrong tumors and students hit 4 wrong tumors using the US, but there were no errors of hitting the wrong tumor using the KIVS. The reduced errors can be attributed to the visualization of critical cues in KIVS which guided the participants in selecting the target tumor. Second, although the experts showed an overall improved accuracy in hitting the center of the tumor by using the KIVS, significant differences between both systems were only found in the complex task scenario. Studies investigating problem solving in complex workspaces show that due to prior experience, experts can perceive underlying causes quicker (Dreyfus and Dreyfus 1986; Rouse and Valusek 1993) and this high performance can hardly be improved. Therefore, no significant difference in performing routine tasks was found for experts. The students showed significant difference in achieving task accuracy of hitting the center of the tumor for both the task scenarios by using the KIVS. The results indicate that KIVS supports the learning curve as even with almost no experience of conducting the RFA procedure, the students performed better using the KIVS.

5.7.2 Subjective evaluation by the participants

Both experts and students showed significant difference between the KIVS and US with respect to intra-operative planning (Table 4). KIVS supported the intra-operative task planning by presenting pre-operative data in 3D superimposed with real-time data from US. This integration helped the participants better comprehend the data, thus reducing the planning time. Experts rated US higher in comparison to KIVS in terms of providing visualization support for routine scenarios. This can be understood as experts being accustomed to using US for the routine tasks of performing

Table 4 : Results of independent sample t-test, conducted to compare the KIVS and US evaluation response between expert (intervention radiologists) and students (medical)

		Expert (n=8)				Student (n=8)			
Question		KIVS	US	f value	Sig.	KIVS	US	f value	Sig.
1.	Visualization support for intra-operative planning	4.00	3.13	3.16	0.09	4.50	2.50	4.47	0.05
2.	Generating mental model of critical structures of patient anatomy	4.50	3.75	0.23	0.64	4.38	2.88	1.27	0.28
3.	Visualization support in routine scenarios	3.88	4.25	12.44	0.00	4.13	3.00	7.97	0.01
4.	Visualization support in complex scenarios	4.13	3.25	0.13	0.73	4.50	3.00	25.0	0.00
5.	Ability to support your performance	4.25	4.00	0.47	0.51	4.50	3.35	2.80	0.11

*All questions used a 5-point rating scale where 5 is the most positive rating and 1 is the least positive rating.

RFA. Adapting to a new way of visualization via KIVS takes time. The significant difference in question 3, 4 and 5, on the other hand, indicates that students found the KIVS more useful than the US in visualizing data for both complex and routine scenarios. This can be understood as the students were quicker to adapt to new visualization approach and found the 3D visualization of the patient anatomy supported performing tasks and improved overall performance.

Results in Table 5 illustrate experts and students showed significant differences in rating KIVS with respect to providing visualization support for intra-operative planning. This is similar to the earlier results reported in Table 4. With respect to providing visualization support for routine scenarios, a significant difference is seen for both participant groups. Both differ in their opinion, as can be seen from the results in Table 4. The students rated the KIVS better than the US in performing routine scenarios. The students were new to the RFA procedure and as US as an imaging modality has a steep learning curve, 3D visualization in KIVS assisted the student in understanding the patient anatomy and the task criticalities, thus improving performance.

Besides from the questionnaire, the participants were also asked to provide their experience of the system usage. It was observed that the students were quicker and more open to the new system than the experts. This can be explained by the quotes of five students “KIVS reminded us of playing with a video game, therefore it’s easier to learn, where as the US requires a longer time to perform the task in 2D”. These findings support our earlier proposition of applying strategies from gaming design to design intuitive interfaces for surgical systems (Jalote-Parmar et al. 2007). The expert intervention radiologists found the visualization provided in KIVS corresponded to their workflow. Four intervention radiologists reported: *“It is impressive as the visualization corresponds to the way I think and perform my task”*. 5 students and 5 clinicians reported that “ *…display of*

Table 5 : Results of independent sample t-test to compare response between expert and student for KIVS

		Expert (n=8) Mean	Student (n=8) Mean	F-value	Sig.
Questions					
1.	Visualization support for intra-operative planning	4.00	4.25	5.60	0.03
2.	Generating mental model of critical structures of patient anatomy	4.50	4.37	0.46	0.50
3.	Visualization support in routine scenarios	3.87	4.12	5.11	0.04
4.	Visualization support in complex scenarios	4.00	4.50	3.32	0.09
5.	Ability to support your performance	4.37	4.50	1.37	0.26

pre-operative data in the intra-operative workspace assisted them in making quicker decisions". 3 expert intervention radiologists pointed out that they required more training time "*we are so accustomed to using US that it's difficult for us to adapt to 3D visualization, although the visualization aid provided seems useful*". It would be nicer if the system is placed in our lab for a longer time so that we can get trained.

5.7.3 Qualitative Analysis

Participants often made a choice of conducting the task of "needle navigation" using either Screen 1 or Screen 2. This was an interesting observation and, after the session, these participants were questioned about their choice of the screen. It was found that the choice of the screen was based on their prior experience of the types of visualization. The experts were more accustomed to using visualization similar to Screen 1 for needle navigation and Screen 2 for a context overview. The medical students, on the other hand, were more accustomed to playing video games involving 3D visualization. This made it easier for them to use Screen 2 for needle navigation. For the development of KIVS, it is critical to note that a longer training time is required in order to understand the participants' visualization preferences.

Results of the evaluative study indicate that the mean intra-operative planning time is higher for the group of the student participants. It was observed during the experiment that that several students took a long time to be spatially orientated, indicating that they had difficulties in orienting the content visualized in the screen and relating it to the patient phantom while using the US probe. Spatial cognition is central to understanding medical images, including those produced by CT, MRI, X-Ray, and Ultrasound. In this case proper training modules are required to train the students to understand 2D and 3D visualization.

5.8 Limitations of the study

Despite of promising results from the reported study, there are also limitations. The KIVS development is currently at a prototype level, and still has several technological limitations in generating real-time image fusion data. Obtaining conclusive results to guide technological development requires improving the prototype at a technological level and then conducting a longitudinal study with more experts from several hospitals. The following are the limitations of the present study:

Limitations of the experimental set up

- The virtual liver in the phantom consists of a few tumors and vessels. This may have made the task simpler for the surgeons, as in real life they are used to dealing with a higher degree of anatomical complexities and have influenced their performance. This limitation of the phantom used in the study could be changed by developing it to be similar to the anatomical structure of the human liver.
- The training time in the KIVS was kept the same for all the participants. Although the students had some prior experience with US imaging, they had no experience of performing US guided procedures. This difference in knowledge level for the US could have affected the performance of the students. This limitation can be overcome by providing additional training time for the medical students.

Limitations in KIVS set up

- The RF needle bends slightly when it is inside the liver. In future studies, we recommend tracking the bending of the RF needle by placing the sensors on the tip of the needle.
- The patient liver moves due to breathing and causes organ deformation. This is a cause of major concern when registering the images in real-time and needs to be incorporated in future studies.
- The participants found that the needle navigation in 3D space could be enhanced if the system provided visual feedback when they struck a critical structure. We recommend the incorporation of collision detection to provide the necessary feedback.
- Our observations of participants' behavior indicates that some participants preferred using 3D navigation (screen 2), 2D navigation (screen1) or a combination of both for navigating the needle to the center of the tumor. Further studies are needed to investigate the role of 2D and 3D visualization in needle navigation.
- When the needle collided with the anatomical structure even though there was a haptic feedback, there was no visual feedback provided on Screen 2. This means that the collision detection between the needle and the critical organ was not visualized in 3D on Screen 1. Lack of visualization of warnings could have created some misunderstanding

in what was felt in the haptic feedback and what was displayed in the screen. This limitation can be overcome by incorporating collision detection in the 3D visualization software and motion detection.

5.9 Recommendations

The results reported permit some recommendations for developing decision support systems which provide intra-operative image-guidance for surgical procedures. Information visualization is an important component of such expert systems. It is recommended that information visualization in the intra-operative workspace should focus on supporting the surgeon in developing an accurate situation awareness of the critical elements related to the surgical tasks. As seen in the example application, the KIVS offers visualization based on real-time image fusion between two imaging modalities, intra-operative US and pre-operative CT. These are represented in three screens in a combination of 2D and 3D visualization. The screens aid developing a context overview of the critical structures in the patient anatomy, thus helping to identify the target tumor, plan the needle trajectory and needle navigation. The system's ability to rotate 3D visualization of the critical structure and the needle trajectory in real-time enhances the efficiency of identifying the target tumor and performing the spatial task of hitting the tumor with increased accuracy.

1 *Augmentation of relevant information*
When image fusion between two modalities occurs, new data is created. Not all the information created is relevant for the surgeons. In order to avoid unnecessary cognitive overload, only relevant task specific cues should be augmented. For example, as illustrated in the results, providing augmented information of critical task related cues appears to enhance the perception and comprehension of the critical information related to performing tasks. This improvement was observable in reduced planning time. Only the information related to critical structures is extracted from the pre-operative or intra-operative data set and is superimposed on the real-time image. The development of intra-operative visualization systems is likely to benefit from consideration of the underlying cognitive processes such as perception and comprehension. In particular, improvements in generating situation awareness of critical cues may be provided by visualization of integrated information, and augmenting relevant information to reduce complexity.

2 *Selection of imaging modalities*
Different imaging modality such as CT, US, MRI, PET provide a unique level of information regarding patient anatomy. During field studies, it was observed that surgeons rely on different imaging modalities for different kinds of patient information. Removing the modality that the

surgeons are trained with and adding a new modality during intra-operative tasks may lead to confusion. The current visualization systems in development focus mainly on creating a unique way of patient data creation by fusing imaging while often disregarding the surgeon's prior experience and information dependencies on the existing modalities. For example, during RFA removing the US which provides real-time information, and merely replacing it with fusion imaging removes critical information the surgeon relies on to conduct the procedure. A detailed understanding of the information provided by each imaging modality is therefore required before generating fusion imaging.

3 *Information integration*
By visualizing integrated information (through image fusion) from the pre-operative to the intra-operative phase, KIVS supports the comprehension of interrelated information and allows quicker intra-operative planning. It also decreases mental load as the participants were not forced to rely on their individual memories. Current visualization systems in development for RFA focus mainly on providing visualization tools for the pre-operative planning phase, or on the intra-operative phase and have seldom researched on integrating the information of both phases. In terms of future development of intra-operative systems, it is recommended that the requirements in the three phases of the surgical workflow (pre-intra-post) be investigated and integrated. As this would both assist the surgeons in improving the overall efficiency of the procedure and assist the technology engineers in optimizing the development of software.

Summary

This chapter illustrated how the knowledge of surgical workflow (obtained from the previous chapter) can be applied to provide a foundation for developing KIVS. As an example, workflow-centered framework was applied to design a Knowledge Intensive Visualization System (KIVS) for an increasingly conducted minimally invasive surgery, RFA. In the first stage, KIVS, concept 2 was developed on the basis of the design requirements obtained from the surgical workflow analysis (Chapter 4) and the findings from heuristic evaluation of concept 1. The aim of the prototype development was to investigate the role of real-time image fusion between intra-operative imaging data and pre-operative imaging data in supporting surgical decision making in order to improve task accuracy of RFA. Experiments with the clinicians were conducted in specially designed task scenarios that were integrated in the design of prototype to simulate the clinical tasks performed during RFA. In addition, task scenarios were built into the system design to investigate the role of the real-time visualization as offered by KIVS on the surgical tasks. Theoretical knowledge of situation awareness was applied in the design of the information visualization component. Situation awareness was supported by improving the information visualization by offering integrated information, visualizing different levels of task complexities and augmented visualization.

In the second stage, an evaluative study (Study 7) was conducted with the clinicians. The results showed improvements in the performance of expert intervention radiologists and medical students while performing RFA by using KIVS as compared to conventional US. The evaluation of the KIVS indicates improvements in task performance by both medical experts and students in terms of three outcome measures: (1) both groups needed less intra-operative planning time, (2) both showed an increased accuracy in hitting the tumor in the center and (3) they had fewer errors (hitting the wrong tumor).
The results from the experimental study support our three assumptions:

- The development of a knowledge intensive system based on knowledge of the surgical workflow leads to enhanced task performance by the clinicians using the system.
- The visualization of the critical cues related to patient anatomy assists in the development of better situation awareness to identify and hit the center of the target tumor.
- Real-time image fusion between intra-operative imaging data and pre-operative imaging data does have apparent benefits, supporting surgical decision making and improving the task accuracy of RFA.

Further details on the generalization and limitation related to this study are discussed in chapter 6.

Overview

This chapter summarizes the research work, its implications and limitations and the scope for further research. The structure is as follows: Section 6.1 presents the main findings of the formulation and evaluation of the workflow-centered design framework for the design of KIVS. It then goes on to discuss the implications, limitations, and the scope of future research for the workflow-centered design framework. Following on from this, Section 6.2 describes the key findings from the design and evaluation of the two developed prototypes of KIVS, and finally, discusses the implications, limitations, and the scope of future research for the development of KIVS.

CHAPTER 6 CONCLUSIONS

6.1 Workflow-centered design framework

The workflow-centered design framework was proposed to support workflow driven development of decision support systems such as KIVS for surgical workspace. The framework is based on four phases of the user-centered development cycle which are synonymous with user-centered development. These are: specify context of use, analyze requirements, design prototype and evaluate prototype. To facilitate the workflow driven design, a central component, the Workflow Integration Matrix (WIM), was integrated in the requirement analysis phase of the framework. This assists in the development of a knowledge repository of surgical workflow, which is the basis for identifying information and design requirements in the surgical workspace. The formulation, implementation and evaluation of WIM can be summarized thus:

1 *Formulation of WIM*
WIM was formulated on the basis of empirical studies conducted with surgeons and by adapting theoretical concepts from existing task analysis frameworks such as HTA and CTA. Empirical studies were conducted with surgeons in hospitals in Norway, Slovenia, and The Netherlands to analyze their problem-solving activities.

2 *Implementation of WIM in five communication stages: WIM consists of two main modules*

- Existing workflow, which represents the current workflow of the surgical procedure and allows the decomposition of surgical tasks based on task boundaries. Task boundaries determine the possibilities and limitations of the surgical problem solving processes within the surgical workspace. The surgical problem-solving model, which was developed based on empirical data and surgical observations conducted in the hospitals, represents the interrelation between the task boundaries.
- New workflow, which formulates the design requirements based on knowledge of existing workflow. It allows prediction of the new surgical workflow which will be changed due to introduction of new technology in the surgical workspace.

WIM was implemented in five communication stages in the requirements analysis phase of the development cycle to facilitate collaborative design among the multidisciplinary members of the KIVS development team. These stages were: (a) Identification of surgical milestones, (b) Surgical workflow analysis, (c) Verification and prioritization of the findings with surgeons, (d) Conceptualization of the design. (e) Communication of the findings within the multidisciplinary development team. The integration of WIM in these stages aimed to facilitate verification, prioritization and communication of knowledge repository of surgical workflow to guide development of KIVS.

3 *Application and evaluation of WIM*
WIM was applied to facilitate workflow-centered development of KIVS by developing a knowledge repository of the surgical workflow of minimally invasive procedures such as radio frequency ablation (Jalote-Parmar et al. 2009) and laparoscopic liver resection (Lambata et al. 2008). The knowledge repository of RFA consists of structured decomposition of surgical procedure and its corresponding design requirements. Findings from surgical workflow analyses led to generating design concepts for the KIVS and, later, the technological development of the prototypes. WIM was evaluated after eighteen months of use by surgeons and technology engineers working as a team in the ARIS*ER consortium. The findings of the evaluative study indicated that both surgeons and technology engineers found WIM useful as a structured framework for understanding for surgical workflow and exchanging design requirements for the KIVS development.

6.1.1 Implications

The following conclusions can be drawn on the basis of what was learned during the formulation, implementation and evaluation of the WIM:

1 *Expert workflow in complex workspaces*
In a complex workspace, such as the surgical theatre, complexity is

characterized by dynamic and interconnected problem solving events, unpredictability of events and low tolerance of errors (Reason 1990; Bogner 1994). In such complex workspaces, decision making is a part of, and based on, problem solving activities linked in a specific space and over time. In order to develop decision support systems to improve the performance of a particular surgical procedure, it is critical that these systems are not only built on the knowledge of specific decision making tasks but also on the problem solving process or the surgical workflow. The surgical workflow is the problem solving process that is determined by task boundaries that set the conditions for the goal attainment in time, i.e. the three phases: pre- (planning) intra (during task execution) operative(during task execution) and post operative (after task execution).

Task boundaries differ in different workspaces. For example, an air traffic controller has a specific workspace and set of task boundaries determining his decision making activities. This implies that each expert workspace has its own set of conditions determining the limitations and decision-making possibilities. When investigating the information requirements corresponding to specific tasks, it is important to identify these task boundaries. The WIM was specifically developed for surgical workspace by incorporating task boundaries specific to that workspace. It was integrated in the requirement analysis phase of the workflow-centered development framework to develop a knowledge repository of surgical workflow. The formulation process of WIM itself is useful as a basis for the development of similar frameworks to analyze workflows and access information requirements. For example, an oil rig mud engineer is an expert working in a complex workspace and may require a decision support system particularly to support real-time visualization. When developing KIVS for a mud engineer, a similar approach can be followed to first analyze the task boundaries of the workspace and then develop a WIM to establish workflow driven development.

2 *Collaborative design in multidisciplinary development setu*p

Development of decision support systems for complex workspaces requires a multidisciplinary development team set up. The expert (in this case, surgeons) do not always have the time or the means to explain their needs in a structured way. Thus, different members of the development team develop their own understanding of the problem workspace, which are often not based on formal mechanisms. A shared understanding of the complexity of the space is a critical requirement in the development. This may provide a better opportunity to develop user-centered solutions and implies that (a) not only should the expert workflow be analyzed but it should also be systematically communicated within the development team, and (b) facilitating a shared understanding of the complexities of the problem space between members of different disciplines requires a simple representation of the workflow.

Being a part of the ARIS*ER research project, this thesis illustrates a real-world case of collaborative design of a decision-support system involving designers, technology engineers, and experts. It explains the method and the critical stages to be followed in the development cycle to facilitate verification, prioritization and communication of problems and solutions between multi-disciplinary teams. The findings from the evaluative study reveal that WIM, as a framework, was useful in systematically generating, analyzing, and exchanging knowledge of expert workflow to guide the user-centered development of expert systems. The development case presented in this thesis can be used as a case of establishing collaborative design between a multidisciplinary team, particularly in the area of medical informatics.

3 *Practical applications*

- *Workflow analysis for treatment strategy*
  WIM can be used as a framework to analyze the surgical workflow of target user group (clinical expert) for a specific procedure for which the decision support system needs to be developed. In case of the treatment strategy for the patient requiring several surgical procedures to be performed (e.g treating cancer in liver often combines treatments such as RFA, liver resection and chemotherapy), the surgical planning system in development should be able to address the planning requirements for all the three treatment procedures. This implies that WIM as a framework can be applied to conduct workflow analysis for the different surgical procedures and the resulting overview provides a holistic picture of the patient treatment strategy. This, in turn, is considered important by the surgeons in the development of planning systems and may be useful in holistic product development.

- *Design education*
  Workflow centered design framework was also used by design students of Industrial Design Engineering, TU Delft. In particular, one internship project with Erasmus MC hospital and a graduation project with Philips healthcare applied WIM to analyze expert workflow and identify requirements for product development. In both these projects, WIM was found useful by the design student in conducting of observations in the surgical workspace to analyze the surgical workflow. As previously mentioned, to our knowledge there are no specific methods other than task analysis methods available to guide surgical workflow analyses. WIM is useful as a means of enabling design students to systematically understand the surgical workspaces and generate design concepts. Further studies needs to be conducted with both design students and professionals to make WIM a generalizable framework.

- *Clinical education*
  The results of the evaluative study of WIM conducted with surgeons revealed the following three interesting findings. First,

according to several surgeons, the results from surgical workflow analysis are a means of reflecting on their existing procedures. This implies that reflection may allow them to improve their own practice of conducting the procedure. This finding is similar to that of the application of a task analysis framework in training (Shepard 2000). Second, several surgeons specifically pointed out that during education, the resident surgeons often find it difficult to visualize the various levels of complexities involved in the surgical procedure. In this context, surgeons found WIM as a structured framework to teach their students the various levels of complexities and tasks that are involved in performing the surgical procedure. Third, WIM was found useful by the resident surgeons to understand the criticalities of the procedure. In order to make the presentation of the medical content more clinically comprehensive in WIM, it was further suggested that WIM should be online and hyperlinks be added to cells in the matrix to present data such as video clips and journal data.

4 *Methodological contribution*
WIM contributes to the task analysis literature at two levels:
- It provides a method to generate an overview of the expert workflow in the complex workspace rather than generating exhaustive lists of specific tasks and sub tasks. It demonstrates the integration of CTA and HTA for analyzing complex workspaces in the design of decision support systems. WIM can also be considered as an extension of HTA specifically for the surgical workspace as it can decompose tasks at the level of task boundaries specific to the surgical workspace.
- It entails a causal relationship between the task boundaries by providing a surgical problem-solving model. This contributes to the expert decision-making literature by illustrating the complex information processing activities in the surgical workspace.

6.1.2 Limitations and scope of future research

As with all research, the proposed WIM framework has several limitations and some of these suggestions for future research arise directly from these limitations. The are explained as:

1 *Avoiding bias in data analysis*
The data gathered from the various interviews and focus group sessions were analyzed by the author. Analysis was conducted by extracting key statements from the transcribed data and semantically grouping it to identify key categories. As this approach may have lead to single coder biases, the findings were also verified by selected clinicians. For real-time development projects, a team of HCI experts and medical experts should be involved for further validation of the findings for real-time projects.

2 *Amalgamation of technology and user- centered approach to workflow analysis*
The need for intra-operative surgical workflow optimization has recently emerged, supporting rapid technological advancements in the surgical theatre. In contrast to the technological approach, a user-centered approach to the development of decision support systems requires an understanding of how experts in a particular field conduct tasks and make decisions in dynamic real-time environments. Consequently, WIM relies on the knowledge of surgical problem-solving as a means to understand the surgeon, the task and the complex surgical workspace. Both the technological and user-centered approaches are equally critical to support development of systems to improve performance in the surgical workspace. In future research, the amalgamation between the technology and the surgeon driven workflow frameworks could compliment the existing development.

3 *Generating overview vs. in-depth workflow analysis*
Another limitation is that WIM generates an overview of surgical workflow taking into account the problem-solving tasks in the three phases of the surgery. Although the overview of the surgical workspace has its benefits in generating design concepts, it has its limitations in terms of allowing in-depth analyses of the surgical tasks. Insight into this issue could be provided by design concepts based on the findings from WIM, using, wherever necessary, a detailed understanding generated by applying HTA. For example, based on WIM analysis, if there is a need for a robotic system to assist "Surgical milestone no. X", then a detailed HTA could be conducted for that particular task.

4 *Analyzing the workflow of other clinical experts*
The surgical workspace is a composite of several workflows such as the workflow of nurses, anesthesiologists, surgeons and others. WIM does not incorporate the workflow of other experts, at present it only provides a structured method to describe the surgical workflow from the surgeon's point of view. If an expert system needs to be developed for an anesthesiologist, WIM will need to be customized. This can be achieved by investigating the specific task boundaries that determine the problem solving tasks of the anesthesiologist.

5 *Capturing decision making in the surgical workspace*
Another limitation is related to the question of how to capture critical decision-making events in WIM. These are currently captured using think-aloud protocols during surgery and verbalized explanation by the surgeon after the surgery. While this approach was perhaps sufficient for developing intra-operative visualization systems which provide visualization and procedural support, in future the decision support systems might also suggest alternate surgical strategies in situations of uncertainty. The development of such systems should be built upon databases of clinical decision-making strategies. Research to support the development of these databases would require the development of

quantitative /statistical models of documenting decision making.

6 *Improving interactivity of WIM*
During the workshops with technology engineers and surgeons, WIM was used as a communication platform. In order to facilitate the documentation of the findings and easy access to data WIM needs to be made "interactable". One possibility is to program the matrix in a hypertext format, allowing all the members of the multidisciplinary team to add and edit data. Video clips were found necessary to illustrate specific stages or issues of the surgical workflow to the team members and hypertext would allow linking of necessary information related to specific surgical tasks.

6.2 Knowledge intensive visualization system

Development of real-time visualization systems depends on technological innovation. However, while technological innovation itself may be able to provide the means to innovatively visualize patient data, it may not be able to adequately support surgical decision making. Visualization of the patient information which supports surgical decision making is critically dependent on the knowledge of how surgeons solve problems and make decisions while performing the procedure. In order to develop systems which are not just "technology intensive" but which are "knowledge intensive", the systems should aim to provide the knowledge required to make informed decisions by providing the surgeon the necessary patient information.

The workflow-centered design framework was applied to guide the innovative technology development of KIVS for Radio Frequency Ablation or RFA. The goal was to incorporate the knowledge of surgical workflow to design KIVS to improve surgical decision-making. Two KIVS prototypes were developed. The aim of the prototype development was to investigate the role of intra-operative visualization to support the surgical decision-making and improve task accuracy for RFA. Empirical studies were conducted in the surgical theatre by applying WIM to analyze the surgical workflow of RFA. The findings led to the development of a knowledge repository of RFA, which was used to identify information and design requirements to conceptualize the design of the KIVS. Storyboards depicting the future workflow of KIVS were conceptualized and iterated. Based on the conceptualized workflow, a demo prototype of KIVS, concept 1 was developed to provide visualization support to RFA. Concept 2 was developed to understand the patient data visualization possibilities created by superimposition of imaging modalities such as intra-operative US and pre-operative CT. The following conclusions can be drawn based on the findings made from the development and evaluation of the two prototypes for KIVS:

6.2.1 Implications

1 *KIVS prototype as a link between development labs and surgical workspaces*
Innovative surgical interventions, such as MIS, are giving way to technological developments in the area of real-time patient data visualization, intra-operative imaging modalities, robotic systems and surgical instruments. The introduction of new systems and tools in the surgical workspace is a critical link affecting surgical performance and hence patient safety. It is therefore necessary that these developments are guided by the surgical requirements to ensure that the solutions fit in the surgical workflow. At a higher level, these systems and tools not only become a part of the surgical workflow but also of the patient and hospital workflow, thus playing an important role in ensuring improving healthcare in general.

As mentioned above, the rapid technological advancements present a challenging situation for companies and development teams. On the one hand the development team doesn't necessarily have the accurate understanding of the problem workspace. For example, the new surgical intervention involves complicated clinical procedures which must be understood before designing a system to support them. This situation leads to a mismatch in the solutions offered and those actually required by the clinician to improve the quality of the performance. On the other hand the clinicians are not able to conceptualize the solutions in the same resolution as verbally explained to them, unless a tangible set up of the innovative technological application is demonstrated with respect to the specific clinical problem. This is especially critical for intra-operative systems for the clinical workspace such as intra-operative robotic and visualization systems.

In order to support the knowledge exchange between the development team and clinical experts, this thesis proposed a workflow-centered design framework. This contributed to the development of a knowledge intensive system at two main levels. First, it integrates WIM as a central component to develop a knowledge repository of the surgical workflow for the clinical procedure requiring technological development. This knowledge repository consists of a structured decomposition of the surgical problem-solving process and the corresponding problem and requirements and it can be used to draw up design and technical requirements. Second, the proposed framework facilitates the involvement of the development team and clinical experts in collaborative design processes of the prototype development. Evaluative studies conducted with the clinicians led to the formulation of guidelines necessary for further development.

- *A concept level simulated prototype*
  The development of decision-support systems depends on different

kinds of technological components that need to be integrated together to build the system. As there are often several development groups engaged in this activity, creating simulations of the prototype are necessary to visualize the concept of the system concretely. Development teams can learn how different components can fit together and create specifications for the system, while clinicians can concretely visualize the role of the system in supporting the clinical procedure. In this thesis, Concept 1 was developed as a simulated prototype with a similar objective. The exercise of integrating the prototype was beneficial to the development team. The clinicians had a tangible understanding of the KIVS and the role it can play in supporting the surgical workflow of RFA. In addition, the development groups gained hands on experience of how different technological components work towards generating real-time image fusion for RFA. While the prototype at this stage allowed the clinicians to interact with different imaging possibilities, it did not engage them in a real-time task scenario. A heuristic evaluation with experts provided critical insight into the selection of the technological approach to resolving the specific clinical issues. Therefore, having a concept level prototype evaluation at this stage is recommended.

- *Clinical task specific working prototype*
  A clinical task specific prototype development is required to investigate in detail how the different functionalities of the proposed system will correspond with the requirements of the clinical workflow. It is important that the prototype provides the clinicians the opportunity of conducting tasks in real-time in a simulated clinical setting. At this stage, both the development and the evaluation of the prototype will offer insights into the pitfalls and benefits of the system related to clinical task environment. Experiments with functional technological components are likely to provide the opportunity of judging the actual role of the system in improving the clinical performance. The evaluation of the KIVS prototype with the clinical experts as illustrated in this thesis indicated the potential of real-time image fusion by combining different imaging modalities. Furthermore, it indicated the benefit of combining pre- and intra-operative imaging to improve surgical decision-making, thus improving the RFA task performance. The KIVS currently developed for RFA is still constrained by several technological limitations in the generation of real-time image fusion of pre- and intra-operative imaging data. The findings from the evaluation of the KIVS, Concept 2 cannot be generalized but should be taken as an indicator for guiding further development. Conclusive results to guide technological development requires improving the prototype at technological level and conducting a longitudinal study with other experts from several hospitals.

For companies and organization involved in developing of decision support system, it is important to invest in such prototypes at an early stage of system development. This will ensure that the system developed are synchronous with the clinical requirements and a greater likelihood of clinical acceptance. Many prototypes of existing technological developments in the area of RFA as mentioned in literature have not been tested with clinicians. The evaluation study of KIVS concept 2 (Chapter 5) contributes to the literature of developing KIVS for RFA by providing an example of conducting evaluation studies with clinicians. In addition, the development case of KIVS prototype as presented in thesis can serve as an example for developing workflow driven KIVS for MIS procedures such as RFA.

2 *Information visualization to increase situation awareness*
Information visualization is an important component of KIVS. Real-time communication of critical data to assist the expert in decision-making can originate from various sources within the surgical workspace, such as planning information based on pre-operative data, real-time imaging feedback from the patient body, and real-time video feedback of the endoscopic probe. Not all information coming from the various sources is relevant at all times and unnecessary information tends to increase the information load on the surgeons. Irrelevant or redundant information may distract the surgeon from more important information and may cause surgical errors. Consequently, to support decision-making in complex naturalistic decision-making environments such as the surgical theatre, it is important to facilitate the expert (surgeon) in gaining accurate situation awareness of the critical elements required to perform the surgical tasks (Klein et al. 1993).

Developing accurate situation awareness of the critical information in intra-operative workspace is essential to improve decision-making and, hence, better task performance. The KIVS Concept 2 demonstrated how critical information related to RFA was visualized to enhance the situation awareness of the surgeons. This was achieved by providing visualization support for two levels of task complexity: routine and complex tasks (triggered by uncertainty). Patient information visualized through KIVS was based on the combination of patient data obtained from the pre-operative (static) phase and that obtained from the intra-operative (real-timed or dynamic data) phase.

Situation awareness can be supported through improving the information visualization by offering integrated information, visualizing critical cues and augmenting information. This leads to improved perception, comprehension and action planning, thus improving decision-making of the surgeons. The evaluation of the KIVS indicates an improvement in task performance by medical experts and students in comparison to the conventional US guided procedure in three outcome measures: (a) both groups needed less intra-operative planning time, (b) both showed increased accuracy in hitting the tumor in the center and (c) both had fewer errors in hitting the wrong tumor. The results indicate that visualizing critical cues related to patient anatomy help the surgeons to develop better situation awareness in terms of identifying and hitting the center of the target tumor.

Accurate and timely visualization of patient data is an important link supporting surgical tasks. Knowledge of the surgical workflow can provide an understanding of the information that needs to be visualized to support each surgical task. In this context, SA can play a role in visualizing information in such a way that it can improve surgical decision making and hence the performance of the surgeons. In future, the development of intra-operative visualization systems, such as robotic consoles, should include situation awareness as guiding framework in creating effective visualization of patient data. Literature on the theory of situation awareness shows that this approach has been mainly applied to the development of information systems and trainings in the aviation industry (Endsley 1993; Endsley and Kiris 1994). Only a selected few studies have mentioned its application in healthcare (Gaba and Howard 1995). This thesis contributes to medical informatics by demonstrating the application of the theory of situation awareness to the design of information visualization for the surgical workspace.

6.2.2 Limitations and scope of future research

Despite promising results related to the development of KIVS, it has certain limitations that need to be taken into consideration for future research. These are:

1 *Experimental tasks close to clinical setting*
The experimental set up was planned carefully to at least partly simulate the clinical setting. However, improvements need to be made to improve the reliability of the findings. The phantom used in the KIVS study consisted of liver, vessles and a few tumors. This may have made the task simpler for the surgeons during the experiment, as in real life they are used to dealing with a higher degree of anatomical complexities and may have influenced their performance. As the phantom plays an important role in conducting experiments with clinicians when designing an intra-operative visualization system, it should be developed to be more similar to human anatomical structure.

2 *Training time with prototypes*
The training time with the KIVS was the same for all participants. Although the students had some prior experience with US imaging, they had no experience of performing US guided procedures. This difference in knowledge level for the US may have affected the performance of

the students. This limitation can be overcome by providing additional training time for the medical students. In addition, obtaining conclusive results to direct technological development requires improving the prototype at a technological level and conducting a longitudinal study with a larger number of experts from several hospitals. As hospitals often follow different protocols to perform the same surgical procedure, designing a system compatible for several, requires a longitudinal study in a number of hospitals. Such research would further inform the future development of KIVS.

3 The role of mental models in surgical decision making

During the surgical observations as stated in Chapter 3, surgeons were observed to refer to their "mental model" as an important component of their problem solving process. Literature in cognitive science also states that mental models are representations of the selected aspects of real-world and are an integral part of problem solving process. In particular, the surgeons referred to developing a mental model of the patient anatomy while conducting critical tasks. When performing the procedures the internal structures of the body are not directly visible therefore, the surgeons have to rely on their mental spatial representations of these structures. Surgeons depend on a detailed understanding of anatomy, which involves spatial concepts, such as the shape of anatomical structures (e.g., the liver) and the critical structures (e.g., "the hepatic portal vessel").

Research states that spatial cognition is central to developing an understanding of medical images, including those produced by CT, MRI, X-Ray, and ultrasound. These are essentially two-dimensional slices of three-dimensional objects. When interpreting medical images, specialists have to infer the three dimensional structure of the anatomy of a specific patient based on the two-dimensional view provided by the image and their own knowledge of anatomy. Interpretation of medical images therefore relies centrally on spatial representations and processes. Basic research is needed to describe the precise nature of mental images and their use in clinical reasoning. Further research into understanding the role of mental model in surgical problem solving is likely to be relevant in developing intra-operative visualization systems especially when generating real-time 3D visualizations.

SUMMARY

As a consequence of innovative surgical techniques such as robotic arms and Minimally Invasive Surgeries (MIS), surgical theatres are changing rapidly. Reduced visualization of operative landmarks in MIS compels the surgeons to rely on advanced medical imaging technologies which can improve task visualization during the operations. Inadequate visualization during MIS has led several technology research labs to develop decision support systems such as Intra-operative Visualization Systems (IVS). This focuses on providing surgeons with real-time imaging support to improve task visualization and navigation. Though exciting, this emerging field also presents challenges in terms of design, development, implementation and integration of various technologies in the surgical workplace.

This thesis is concerned with the development of IVS to support surgical decision making and thereby reduce errors during MIS. The development of IVS presents two main challenges. The first is related to the development of technologies which can extract and integrate patient data from various imaging sources and produce a real-time visualization system. For example, extracting real-time patient data by superimposition of intra-operative Ultrasound (US) data with pre-operative Computerized Tomography (CT) data is indeed a development challenge. However, dealing with the core technological aspects is beyond the scope of this thesis (I will spare you the grueling algorithms!). The second challenge is: How can the knowledge of

surgical problem solving process be incorporated into design the of IVS to improve decision-making and thus the performance of the surgeons? This challenge, which has until now received scant attention in the context of the development of IVS, is addressed in this thesis.

Visualization of the patient information which supports surgical decision making is dependent on knowledge of how surgeons solve problems and make decisions while performing the procedure. Consequently, while developing a technically robust visualization system which integrates various imaging sources may help visualizing the patient data, it may not serve its true purpose: to adequately support surgeons in making the right decisions. Development of IVS should therefore be not just “technology intensive”; but “knowledge intensive”. This means that these systems should aim to provide the knowledge to make informed decisions by providing the surgeon with the necessary patient information. In this thesis, such visualization systems are called Knowledge Intensive Visualization Systems (KIVS).

For informed decisions on what information needs to be visualized and how it needs to be visualized, it is necessary to know how surgeons conduct surgeries and which factors enhance their problem solving process. Accessing this knowledge requires a formal mechanism to make structured inquiries into the surgical workspace. Since the development of KIVS is a relatively new research area, there are neither clear guidelines in literature about how KIVS are developed from the point of view of the surgeon, nor is there a description of a structured methodology which can be applied to support user-centered technological development.

Recent research in the area of medical informatics highlights the importance of understanding cognitive processes in developing user-centered systems to improve decision-making in complex workspaces. Integrating the abilities and limitations of human information processing to design decision support systems for complex workspaces has been a challenge for researchers for the past couple of decades. Nevertheless, its application in the development of decision support systems, such as KIVS, for surgical theatres is a new area of research and it is necessary to develop scientific knowledge to drive its development.

To this end, this thesis proposes a ‘workflow-centered framework’ to generate a knowledge repository of surgical problem solving process. The knowledge gained from the surgical workflow analysis can be applied to visualize critical patient information through KIVS to improve surgical decision-making. As an application case, this framework was applied in the development of two KIVS prototypes. A KIVS was developed to support task visualization and navigation to treat cancerous tumors in liver through a MIS procedure called Radio Frequency Ablation (RFA).

The research process followed in this thesis is as follows:

1 *Exploratory phase*
First, an exploratory study (See Chapter 2) was conducted to gain an understanding of the following: (a) existing visualization systems available to the liver surgeon both at the time of surgical planning and during the surgery, (b) state of the art and future intra-operative visualization systems for liver surgery, and (c) surgeons' opinions about emerging visualization systems based on their first hand use of the system. Findings from this phase provided the requirements for developing a framework to support user-centered development of KIVS.

2 *Formulation and evaluation of the workflow-centered design framework*
A workflow-centered design framework is proposed to drive user-centered development of KIVS. A component called Workflow Integration Matrix (WIM) forms a key part of this framework and is integrated in the requirements analysis phase to facilitate analysis of the existing surgical workflow by taking into consideration surgical problem solving activities. Surgical workflow analysis leads to the development of the knowledge repository of surgical procedure, information and design requirements for the KIVS.

WIM was formulated on the basis of empirical studies conducted with surgeons and by adopting theoretical concepts from existing task analysis frameworks such as cognitive task analysis and hierarchical task analysis (Chapter 3). Empirical studies were conducted with surgeons to analyze their problem solving activities in the hospitals in Norway, Slovenia, and the Netherlands. WIM consists of two modules:

- Existing surgical workflow, which represents the conventional workflow of the surgical procedure. It allows the decomposition of surgical tasks on the basis of task boundaries. Task boundaries aid in determining the information flow during the surgery and hence the requirements for each specific task. A surgical problem-solving process model was developed to represent the inter-relation between the task boundaries. This model was developed based on empirical data and surgical observations conducted in the hospitals.
- New surgical workflow formulates the design requirements based on the knowledge of existing workflow. It allows prediction of the new surgical workflow as a result of introduction of new system in the surgical workspace. The design of KIVS necessitates the involvement of a multidisciplinary development team including surgeons, technology engineers and designers. To support collaborative design, WIM is implemented in five communication stages in the workflow-centered development framework. This, in turn, provides a communication platform that facilitates an exchange of the acquired knowledge repository of the surgical

workflow and technological possibilities within a multidisciplinary team.

Workflow-centered design framework was applied to guide the innovative technology development of KIVS for RFA. The framework was evaluated by surgeons and technology developers after its application to guide the development of KIVS in a European Union project called Augmented Reality in Surgery (ARIS*ER). Findings indicate that both surgeons and technology engineers found WIM useful as a structured framework for exchanging the knowledge of surgical workflow to guide the development of KIVS.

3 *Development and evaluation of the Knowledge Intensive Visualization system*

The workflow-centered design framework was applied to guide the innovative technology development of KIVS for RFA (See Chapter 4 & 5). The goal of this research was to incorporate the knowledge of surgical workflow to design a KIVS that improves surgical decision-making. RFA is a MIS procedure performed for treating cancer in liver. Clinical studies indicated that, with better image guidance, the clinical performance of RFA can be improved. RFA is performed with the image guidance of an intra-operative 2D cross-sections of the patient using either ultrasound (US) or computed tomography (CT). These modalities present patient information in 2D cross section images which is not sufficient to perform the spatially challenging RFA procedures. Lack of adequate intra-operative visualization systems have caused technical failures in RFA, resulting in clinical errors and the procedures having to be repeated. These failures in RFA are caused due to unablated cancerous cells of the tumor, newly detected tumors and missed tumors.

Two KIVS prototypes were developed to investigate the role of intra-operative visualization to support the surgical decision-making and improve task accuracy for RFA. Empirical studies were conducted in the surgical theatre by applying WIM to analyze the surgical workflow of RFA. The findings led to the development of a knowledge repository of RFA which was used to identify information and design requirements to conceptualize the design of the KIVS. Storyboards depicting the future workflow of KIVS were conceptualized and iterated. Based on the conceptualized workflow, a demo prototype of KIVS (Concept 1) was developed to provide visualization support to RFA (See Chapter 4). Concept 1 was developed to understand the patient data visualization possibilities that can be created by superimposition of imaging modalities such as intra-operative US and pre-operative CT. The heuristic evaluation of the demo prototype indicated the probable benefits of generating 3D visualization of patient data by image fusion in real-time.

Concept 2 of KIVS was developed on the basis of the findings from Concept 1 and requirements generated from the surgical workflow analysis (Chapter 5). Theoretical concepts of situation awareness were applied to design information visualization in the KIVS to support the surgical decision-making. The prototype was developed in collaboration with the technology engineers who were responsible for real-time image segmentation, image registration and system integration. Specially designed scenarios were built into the KIVS prototype to simulate surgical scenarios closely resembling the clinical setting. An evaluative study was conducted to compare the performance of expert intervention radiologists and medical students while performing RFA using two systems: KIVS and the conventional Ultrasound (US) guided intervention. The results from the evaluative study showed significant improvements in the performance of expert intervention radiologists and medical students while performing RFA using KIVS compared to US. In particular, intra-operative planning time and task accuracy of hitting the right tumor in the center showed significant improvement. The findings demonstrated the importance of workflow driven patient data visualization in improving surgical decision making.

The contribution of this thesis is, on the one hand, the design process of the KIVS and, on the other, the design of the KIVS itself. It embeds "design" as a research means to evolve scientific knowledge to develop decision support systems for complex workspaces such as the surgical workspace. This thesis is an example of the role design as a discipline can play in guiding user-centered technological innovation in the area of medical informatics, particularly where the development depends on creating collaborative design involving different scientific disciplines: surgical, technological, medical informatics and design.

The framework proposed in this thesis serves as a means to generate the scientific knowledge required to drive user-centered development of KIVS. The contribution of this thesis is at three levels:

- The framework proposed in this thesis contributes to design and ergonomics literature as a practical example of application of user-centered design to drive innovative technological development of KIVS for complex workspaces such as the surgical theatre.
- It contributes to the medical informatics by integrating cognitive theories as a foundation which guides the development of KIVS.
- The KIVS prototype serves as a development aid to guide future technological innovation in the area of intra-operative visualization system for RFA and for MIS in general.

SAMENVATTING

Operatiekamers veranderen in een snel tempo als gevolg van innovatieve chirurgische technieken zoals robotica en minimaal invasieve chirurgie. Beperkter visualisatie op oriëntatiepunten bij minimaal invasieve chirurgie (Minimal Invasive Surgery, MIS) maakt het noodzakelijk voor de chirurg te vertrouwen op geavanceerde medische beeldtechnologieën om het zicht op de taak gedurende de operatie te verbeteren. Onvoldoende visualisatie tijdens MIS heeft diverse technologische onderzoekslaboratoria ertoe gebracht besluitondersteunende systemen zoals Intraoperative Visualation Systems (IVS) te ontwikkelen. IVS is gericht op het bieden van 'real time' beeldondersteuning aan de chirurg om de taakvisualisatie en navigatie te verbeteren. Hoewel interessant, roept dit opkomende vakgebied ook moeilijke uitdagingen op met betrekking tot ontwerp, ontwikkeling, implementatie en het integreren van diverse technologieën in de chirurgische werkomgeving.

Dit proefschrift heeft betrekking op de rol die ontwerp kan spelen bij het aanjagen van ontwikkeling van IVS met het doel de chirurgische besluitvorming te ondersteunen om zodoende fouten tijdens MIS te reduceren. De ontwikkeling van IVS omvat twee belangrijke uitdagingen. De eerste uitdaging hangt samen met de ontwikkeling van technologieën die patiëntgegevens uit diverse beeldbronnen kunnen verzamelen en integreren zodat een real time visualisatie systeem ontstaat. Zo is bijvoorbeeld het op elkaar leggen (superimposition) van intra-operatieve Ultrasound (US) data en pre-operatieve Computerized Tomography (CT) data om real time patiëntgegevens te verkrijgen een ontwikkelingsprobleem. Echter, de behandeling van de kern van de technologische aspecten valt buiten het bereik van dit proefschrift (ik bespaar jullie de moeizame algoritmen!). De tweede uitdaging met betrekking tot de ontwikkeling van IVS is: op welke wijzen kunnen essentiële patiëntgegevens in real time worden weergegeven om de chirurgische besluitvorming te ondersteunen? Deze uitdaging heeft tot dusver beperkt aandacht gekregen in de literatuur over de ontwikkeling van IVS en zal in dit proefschrift worden behandeld.

Visualisatie van patiëntgegevens die de chirurgische besluitvorming ondersteunen is in sterke mate afhankelijk van de kennis over hoe chirurgen problemen oplossen en besluiten nemen gedurende chirurgische ingrepen. Derhalve kan het enkel ontwikkelen van technische robuuste visualisatiesystemen die de diverse beeldbronnen integreren, op zich wel leiden tot het visualiseren van patiëntgegevens, maar leidt niet tot de daadwerkelijke doelstelling, namelijk het adequaat ondersteunen van de chirurg bij diens besluitvorming. Ontwikkeling van IVS is niet alleen ‘technologie-intensief’, maar dient voor de ondersteuning van chirurgische besluitvorming ook ‘kennisintensief’ te zijn. Dit betekent dat deze systemen moeten zijn gericht op het leveren van de kennis voor het nemen van gefundeerde besluiten door de chirurg te voorzien van de benodigde patiëntgegevens. De systemen moeten daarom zijn gebaseerd op kennis van chirurgische probleemoplossingprocessen. In dit proefschrift worden deze visualisatietechnieken aangeduid als Kennis Intensieve Visualisatie Systemen (KIVS). Als ontwikkel casus is hierbij de MIS-procedure “Radio Frequency Ablation” (RFA) gekozen.

Teneinde gefundeerd te kunnen besluiten over welke data gevisualiseerd moeten worden en op welke wijze, is het nodig te begrijpen hoe chirurgen daadwerkelijk chirurgische ingrepen plegen en welke factoren hun probleemoplossend vermogen aanvullen. Het kunnen benaderen van deze kennis vergt formele, gestructureerde procedures om de praktijk van werken in de operatiekamers te onderzoeken. Omdat de ontwikkeling van KIVS een relatief nieuw onderzoeksveld is, zijn er noch heldere richtlijnen in de literatuur over hoe KIVS kan worden ontwikkeld vanuit chirurgisch perspectief, noch is er een beschrijving van een gestructureerde methodologie die kan worden toegepast als ondersteuning bij de ontwikkeling van op gebruikers gerichte technologie.

Recent onderzoek op het gebied van medische informatica benadrukt het belang van het begrijpen van cognitieve processen bij het ontwerpen van systemen gericht op verbetering van besluitvorming in complexe werkomgevingen en bij het ondersteunen van op gebruikers gerichte ontwikkeling van besluitondersteunende systemen. De menselijke beperkingen om informatie te integreren en te verwerken vormde in de afgelopen decennia voor onderzoekers een uitdaging bij het ontwerpen van besluitondersteunende systemen voor complexe werkomgevingen. Niettemin is de toepassing van menselijke informatieverwerking bij de ontwikkeling van besluitondersteunende systemen voor operatiekamers, zoals KIVS, een nieuw onderzoeksterrein en het is noodzakelijk wetenschappelijke kennis te genereren om de ontwikkeling te stimuleren. Om een gebruikersgerichte ontwikkeling van KIVS te stimuleren, wordt in dit proefschrift een werkstroom gericht raamwerk (workflow centered framework) voorgesteld om een kennisbank ("repository") te genereren met chirurgische processen voor probleemoplossing. De kennis die wordt verkregen uit analyse van chirurgische werkstromen kan worden toegepast om essentiële patiëntgegevens via KIVS zichtbaar te maken om zodoende de chirurgische besluitvorming te verbeteren. Als praktijk casus werd dit raamwerk toegepast bij de ontwikkeling van twee prototypen. KIVS was ontwikkeld voor een MIS bij behandeling van kanker tumoren in een lever via een proces dat bekend staat als Radio Frequency Ablation (RFA).

Het onderzoeksproces gevolgd in dit proefschrift luidt als volgt:

1 *Verkennende fase*

Allereerst is verkennend onderzoek verricht (zie Hoofdstuk 2) om inzicht te verkrijgen in het volgende: (a) bestaande visualisatiesystemen waarover de leverchirurg kan beschikken, zowel bij de planning van de ingreep als tijdens deze ingreep, (b) de huidige en toekomstige intra-operatieve visualisatiesystemen voor leverchirurgie en (c) verkrijgen van de mening van chirurgen op basis van feitelijk gebruik van opkomende visualisatiesystemen. De bevindingen uit deze fase van de studie wijzen op de behoefte aan ontwikkeling van een raamwerk om op gebruikers gerichte ontwikkeling van KIVS te ondersteunen.

2 *Opstellen en evalueren van het op werkstroom gericht ontwerpraamwerk*

In dit proefschrift is een op werkstroom gericht ontwerpraamwerk voorgesteld als stimulans voor op gebruikers gerichte ontwikkeling van KIVS. Een component genaamd Werkstroom Integratie Matrix (WIM) vormt een belangrijk onderdeel van dit raamwerk. WIM is geïntegreerd in de fase van analyse van voorwaarden om de analyse van de bestaande chirurgische werkstromen te faciliteren door rekening te houden met chirurgische probleemoplossingactiviteiten. Analyse van de chirurgische werkstroom leidt tot de ontwikkeling van de kennisbank met chirurgische procedures, informatie en ontwerpeisen voor de KIVS.

WIM was opgesteld op basis van empirische studies verricht in samenwerking met chirurgen en met toepassing van theoretische concepten uit bestaande raamwerken voor taakanalyse, zoals cognitieve taakanalyse en hiërarchische taakanalyse (zie Hoofdstuk 3). Empirische studies zijn verricht met chirurgen in ziekenhuizen in Noorwegen, Slovenië, en Nederland, om hun probleemoplossingactiviteiten te analyseren. WIM bestaat uit twee modules:

- Bestaande chirurgische werkstroom, wat staat voor de conventionele werkstroom rond de chirurgische ingreep. Het maakt het mogelijk om chirurgische taken te onderscheiden op basis van taakbegrenzingen. Taakbegrenzingen helpen bij het vaststellen van de informatiestromen gedurende de chirurgische ingreep en daarmee ook van de eisen die aan de specifieke taken worden gesteld. Een chirurgisch probleemoplossend procesmodel is ontwikkeld om het verband tussen de onderscheiden taakbegrenzingen weer te geven. Dit model werd ontwikkeld op basis van empirische gegevens en chirurgische waarnemingen die werden uitgevoerd in ziekenhuizen.
- De nieuwe chirurgische werkstroom formuleert de ontwerpeisen, gebaseerd op kennis van bestaande werkstromen. Het maakt voorspellingen over de nieuwe chirurgische werkstroom mogelijk, door de introductie van nieuwe systemen in de chirurgische werkomgeving. Het ontwerp van KIVS vereist de betrokkenheid van een multidisciplinair ontwikkelingsteam onder andere bestaande uit chirurgen, ingenieurs en ontwerpers. Om de samenwerking bij het ontwerpen te ondersteunen, wordt WIM toegepast in vijf communicatiestadia van het werkstroomgerichte ontwikkelingsraamwerk. Omgekeerd voorziet dit in een platform voor communicatie dat uitwisseling van de verkregen kennis over de chirurgische werkstromen en technische mogelijkheden binnen een multidisciplinair team faciliteert.

Een werkstroomgericht ontwikkelingsraamwerk is toegepast om de innovatieve technologieontwikkeling van KVIS voor een specifieke Minimale Invasieve Chirurgische ingreep genaamd Radio Frequency Ablation te begeleiden. Het raamwerk is met de chirurgen en de technisch ontwerpers geëvalueerd, na toepassing ervan ter begeleiding van de ontwikkeling van KIVS in een project van de Europese Unie onder de naam “Augmented Reality in Surgery” (ARIS*ER). De bevindingen duiden erop dat zowel de chirurgen als de technisch ingenieurs WIM bruikbaar vonden als een gestructureerd raamwerk voor kennisuitwisseling over de chirurgische werkstromen als leidraad bij de ontwikkeling van KIVS.

3 *Ontwikkeling en evaluatie van het Kennis Intensieve Visualisatie Systeem (KIVS)*
Het werkstroom gericht ontwikkelingsraamwerk is toegepast om de innovatieve technologische ontwikkeling van KIVS bij Radio Frequency Ablation of RFA (zie Hoofdstuk 4 en 5) te begeleiden. Het doel van dit onderzoek was de kennis van de chirurgische werkstroom te incorporeren om KIVS te ontwerpen die het chirurgische besluitvormingsproces verbeteren. RFA is een MIS procedure die

werd uitgevoerd ter behandeling van leverkanker. Klinische studies hebben laten zien dat met een betere beeldbegeleiding de klinische prestatie van RFA kan worden verbeterd. RFA is uitgevoerd met de beeldbegeleiding van intra operatieve 2D dwarsdoorsneden van de patiënt, die ofwel zijn verkregen met Ultrasound (US) ofwel met Computed Tomography (CT). Deze modaliteiten geven patiëntgegevens weer in 2D dwarsdoorsneden, wat onvoldoende is om RFA procedures uit te voeren in een beperkte taakomgeving. Het ontbreken van adequate intra operatieve visualisatiesystemen heeft geleid tot technische fouten bij RFA, hetgeen klinische fouten en de noodzaak tot herhaling van de procedure tot gevolg had. Deze fouten bij RFA zijn ontstaan als gevolg van kankercellen die niet zijn weggebrand, nieuw ontdekte tumoren en tumoren die over het hoofd zijn gezien.

Er zijn twee KVIS prototypes ontwikkeld. Het doel van de ontwikkeling van deze KVIS prototypes was te onderzoeken wat de rol van intra operatieve visualisatie is ter ondersteuning van de chirurgische besluitvorming en ter verbetering van nauwkeurigheid van taakuitvoering bij RFA. Empirische studies in operatiekamers zijn verricht met de toepassing van WIM om de chirurgische werkstroom bij RFA te analyseren. De bevindingen hebben geleid tot de ontwikkeling van een kennisbank met betrekking tot RFA. De kennisbank is gebruikt om vast te stellen wat de informatie- en ontwerpeisen zijn voor het maken van een conceptontwerp voor KIVS. Storyboards die de toekomstige werkstromen van KIVS weergeven werden geconcipieerd en herhaald. Gebaseerd op dit concept werkstroom is een demo prototype (concept 1) ontwikkeld, om visuele ondersteuning te bieden bij RFA (zie Hoofdstuk 4). Concept 1 is ontwikkeld om te begrijpen welke mogelijkheden kunnen worden gecreëerd om informatie over de patiënt te visualiseren door het bundelen van beeldtechnieken zoals intra-operatieve US en pre-operatieve CT. De voorbereidende evaluatie van het demo prototype duidt op mogelijke voordelen van het genereren van 3D visualisatie van patiëntgegevens door samenvoeging van beelden in real time.

Concept 2 van KIVS werd ontwikkeld op basis van de bevindingen uit Concept 1 en de eisen die werden gegenereerd uit de analyse van de chirurgische werkstroom (zie Hoofdstuk 5). Theoretische concepten van omgevingsbewustzijn (situation awareness) zijn toegepast om visualisatie van patiëntgegevens in KIVS te ontwerpen ter ondersteuning van het chirurgische besluitvormingsproces. Het prototype is ontwikkeld in samenwerking met de technisch ingenieurs, die verantwoordelijk waren voor de real time beeldsegmentatie, beeldregistratie en de systeemintegratie. In de "phantom level" van het KIVS prototype zijn speciaal ontworpen scenario's ingebouwd om chirurgische scenario's vergelijkbaar met de klinische omgeving te simuleren. Een evaluatieve studie werd uitgevoerd om de prestaties van deskundige interventie radiologen en medische studenten te vergelijken bij de uitvoering van RFA met gebruik van twee systemen: KIVS en een conventionele, door Ultrasound (US) begeleide ingreep. De resultaten uit deze evaluatieve studie laten zien dat de prestaties van deskundige interventie radiologen en medische studenten gedurende de uitvoering van RFA, bij gebruik van KIVS significant beter zijn dan bij gebruik van Ultrasound (US). Met name de planning van de voor de intra operatieve benodigde tijd en de taakaccuratesse bij het centraal raken van de juiste tumor laten een duidelijke verbetering zien. De bevindingen laten het belang zien van werkstroom gedreven visualisatie van patiëntgegevens ter verbetering van het chirurgische besluitvormingsproces.

De bijdrage van dit proefschrift is enerzijds het ontwerpproces voor het KIVS en anderzijds het ontwerp van het KIVS zelf. Dit proefschrift is een voorbeeld van de rol die ontwerp als discipline kan spelen bij het begeleiden van technische innovaties op het gebied van de medische informatica. Het werkstroom gericht ontwerpraamwerk, zoals in dit proefschrift wordt voorgesteld, dient als middel om wetenschappelijke kennis te genereren die nodig is om gebruikersgerichte ontwikkeling van KIVS te stimuleren.

Het raamwerk dat in dit proefschrift is voorgesteld dient als middel om de wetenschappelijke kennis te genereren die nodig is om de ontwikkeling van gebruikers gerichte KIVS te stimuleren. De bijdrage van dit proefschrift kan op drie niveaus worden beschouwd:

- Het raamwerk dat in dit proefschrift is voorgesteld draagt bij aan de literatuur over ontwerpen, literatuur over ergonomie als praktisch voorbeeld van de toepassing van gebruikers gericht ontwerpen ter stimulering van innovatieve technische ontwikkeling van KIVS voor complexe werkomgevingen zoals operatiekamers.
- Het draagt bij aan de literatuur over medische informatica door de praktische implementatie te laten zien van cognitieve theorieën als basis om de ontwikkeling van KIVS te begeleiden.
- Het KIVS prototype dient als een hulpmiddel voor ontwikkeling, om toekomstige technologische innovatie op het gebied van intra operatieve visualisatie voor RFA en voor MIS in het algemeen te begeleiden.

REFERENCES

Andersen, H. B. and S. E. Olsen (1998). Tasks, Errors and Mental Models. Bristol, P.A, USA, Taylor & Francis, Inc.

Angeli, D. A., U. Athavankar, A. Joshi, L. M. Coventry and J. Graham (2004). "Introducing ATMs in India: A Contextual Inquiry." Interacting with Computers 16 (1): 29-44.

Annett, J. and K. Duncan (1967). "Task Analysis and Training in Design." Occupational Psychology 41: 211-221.

Annett, J. and N. Stanton (2000). Task Analysis. London, Taylor and Francis.

Argenziano, M. (2002). Robotically Assisted, Minimally Invasive Cardiac Surgery, Presbyterian Hospital, New York.

ARIS*ER. (2005). "Augmented Reality in Surgery (ARIS*ER)." Retrieved 1/10/2009, http://ariser.info.

Aukstakalnis, S. and D. Blanter. (1992). Silicon Mirage - The Art and Science of Virtual Reality. Berkeley, CA, Peachpit Press.

Badke-Schaub, P. and C. Buerschaper (2001). Creativity and Complex Problem Solving in the Social Context. Decision Making: Social and Creative Dimensions. C. M. Allwood and M. Selart. Dordrecht Kluwer: 177-196.

Badke-Schaub, P. and E. Frankenberger (1999). "Analysis of Design Projects." Design Studies 20(5): 465-480.

Baegert, C. (2008). "Trajectory Optimization for the Planning of Percutaneous Radiofrequency Ablation of Hepatic Tumors." Computer Aided Surgery 12(2): 82-90.

Bainbridge, L. and P. Sanderson (1995). Verbal Protocol Analysis. Evaluation of Human Work. J. R. Wilson and E. Corlett, N. London, Taylor and Francis: 169-201.

Bao, P., T. K. Sihna, C. C. R. Chen, J. R. Warmath, R. L. Galloway and A. J. Herline (2007). "A Prototype Ultrasound-Guided Laparoscopic Radiofrequency Ablation System." Surgical Endoscopy 21: 74-79.

Baron, S. (1988). Pilot Control. Human Factors in Aviation. E. L. Wiener and C. D. Nagel. San Diego, California, Academic Press.

Barrett, P. and C. Stanley (1999). Better Construction Briefing. UK.

Basdogan, C., S. De, J. Kim, M. Muniyandi, H. Kim and M. A. Srinivasan (2004). "Haptics in Minimally Invasive Surgical Simulation and Training." IEEE, Computer Graphics and Applications 24(2): 56-64.

Benyon, D., P Turner and S.Turner (2005). Designing Interactive Systems People Activities Contexts, Technologies. Essex, England, Addison-Wesley \ Pearson Education.

Beyer, H. and K. Holtzblatt (1998). Contextual Design: Defining Customer Centered Systems, Morgan Kaufmann Publishers, Inc.

Bodker, S., K. Gronbaek and M. Kyng (1993). Cooperative Design: Techniques and Experiences from Scandinavian Scene. Participatory Design: Principles and Practices. D. Schuler and A. Namioka. Hillsdale NJ, Lawrence Erlbaum Associates: 157-175.

Bogner, S. M. (1994). Human Error in Medicine. New Jersey, Lawrence Erlbaum Associates.

Bogner, S. M. (1997). Naturalistic Decision Making in Health Care. Naturalistic Decision Making. C. Zsambok and G. Klein, Lawrence Erlbaum Associates.

Bosch van den, M., B. Daniel, V. Rieke, K. Butts-Pauly, E.Kermit and S. Jeffrey (2008). Journal Magnetic Resonance Imaging 27(1):204-8.

Botturi, D., P. Fiorini and G. Fracastoro (2005). Task Level Model for surgical Environment. Proceedings of surgetica, Chambery, France, Sauramps Medical, Montpellier.

Brooks, D. C., Ed. (1998). Current Review of Minimally Invasive Surgery, Springer.

Brown, J. S. and P. Duguid (2001). "Knowledge and Organization: A social practice perspective." Organizational Science 12: 198-213.

Bruce, M. and R. Cooper (2000). Creative Product Design: A Practical Guide to Requirements Capture Management. Chichester, Wiley.

Buckle, P., P. J. Clarkson, R. Coleman and J. Ward (2006). "Patient Safety, System Design and Ergonomics." Journal of Applied Ergonomics 37(4): 491-500.

Card, S. K., J. D. Mackinlay and B. Shneiderman (1999). Information Visualization: Using Vision to Think. San Francisco, Morgan Kaufmaan Publishers.

Casciaro, S., L. Massoptier, E. Samset, E. Casciaro and A. Distante (2006). A Method for Fast and Automatic Segmentation of Soft Organs from CT and MR Images. 20th International Congress on Computer Assisted Radiology and Surgery CARS 2006 Osaka, Japan, Int J CARS.

Cooper, R. and M. Press (1995). Design Agenda. Chichester, Wilney and Sons.

Cross, N. (1989). Engineering Design Methods. Chichester, John Wiley & Sons.

Cuscheri, A. (2003). "Medical Errors, Incidents, Accidents and Violations." Minimally Invasive Therapies & Allied Technologies 12 (3-4): 111-120.

Darlington, M. J. and S. J. Culley (2004). "A Model of Factors Influencing the Design Requirement." Design Studies 25(4): 329-350.

Davenport, M., E. Caoili, et al. (2009). "MRI and CT Characteristics of Successfully Ablated Renal Masses: Imaging Surveillance after Radiofrequency Ablation." American Journal of Roentgenology 192: 1571-1578.

Drefus, S. E. (1981). Formal Models vs. Human Situational understanding : Inherent Limitations on the Modeling of Business Expertise. Berkeley, Operations Research Center, University of California.

Dreyfus, H. and S. Dreyfus, Eds. (1986). Mind Over Machine. New York, The Free Press.

Elstein, A., S, L. Shuman, S and S. Sprafka, A (1978). Medical Problem Solving: An Analysis of Clinical Reasoning Cambridge, Mass: Harvard University Press.

Endsley, M. (1993). “A Survey of Situation Awareness Requirements in Air-to-Air Combat Fighters.” International Journal of Aviation Psychology 3(2): 157-168.

Endsley, M. (1995). “Measurement of Situation Awareness in Dynamic Systems.” Human Factors 37(1): 65-84.

Endsley, M. (1995). “Towards a Theory of Situation Awareness in Dynamic Systems.” Human factors 37(1): 32-64.

Endsley, M., B. Bolte and D. Jones (2003). Designing for Situation Awareness- An Approach to User-Centered Design. New York, Taylor & Francis.

Endsley, M., T. C. Farley, W. M. Jones, A. H. Midkiff and R. J. Hansman (1998). Situation Awareness Information Requirements for Commercial Airline pilots(ICAT-98-1). Cambridge, MA, Massachusetts Institute of Technology International Center for Air Transportation.

Endsley, M. and E. O. Kiris (1994). “Information Presentation for Expert Systems in Future Fighter Aircraft.” International Journal of Aviation Psychology 4(4): 333-348.

Esaote. (2007). “Virtual Navigator.” Retrieved 1/10/2009, http://www.esaote.com.

Fischer, M., G. Strauss, et al. (2005). ENT. Surgical Workflow as an Instrument to Asses the Efficiency of Technological Developments in Medicine. Computer Assisted Radiology and Surgery (CARS), Berlin, Germany, Elsevier B.V, Amsterdam.

Gaba, D. M. and S. K. Howard (1995). “Situation Awareness in Anesthesiology.” Human factors 37(1): 20-31.

Gawande, A. (2002). Complications: A Surgeon’s Notes on an Imperfect Science. New York, Metropolitan Books.

Gordan, S., E and R. Gill, T (1997). Cognitive Task Analysis. Naturalistic Decision Making. C. Zsambok and G. Klein. Mahawah, New Jersey, Lawrence Erlbaum Associates: 131-140.

Green, S., R. Newcombe, S. Fernie and S. Weller (2004). Learning Across business sectors: Knowledge Sharing Between Aerospace and Construction. Research report, University of Reading.

Hajdukiewicz, J. R., K. J. Vicente, D. J. Doyle, P. Milgram and C. M. Burns (2001). “Modeling a Medical Environment: an Ontology for Integrated Medical Informatics Design.” International Journal of Medical Informatics 62: 79-99.

Hansen, C., J. Wieferich, F. Ritter, C. Rieder and H.-O. Peitgen (2009). "Illustrative Visualization of 3D Planning Models for Augmented Reality in Liver Surgery." International Journal of Computer Assisted Radiology and Surgery 10.1007/s11548-009-0365-3.

Hegarthy, M., M. Keehner, C. Cohen, D. Montello, R and Y. Lippa (2007). The Role of Spatial Cognition in Medicine: Applications for Selecting and Training Professionals. Applied Spatial Cognition. G.Allen. Mahwah, NJ, Erlbaum.

Hildebrand, P., Schlichting, et al. (2008). "Prototype of an Intra-operative Navigation and Documentation System for Laparoscopic Radiofrequency Ablation: First Experiences." The Journal of Cancer Surgery 34.

Hironori, K., T. Masaru, et al. (2008). "Laparoscopy-Assisted Hepatectomy for Giant Hepatocellular Carcinoma." Surgical laparoscopy, Endoscopy & Percutaneous Techniques 18(1): 127-31.

Hopkin, D. V. (1988). Air Traffic Control. Human factors in aviation. E. L. Wiener and C. D. Nagel. San Diego, California, Academic press: 639-663.

Hunink, M. M. G. (2005). "Decision Making in the Face of Uncertainty and Resource Constraints: Examples from Trauma Imaging." Radiology 235(2): 375-383.

Hussain, S. M. and C. R. Semelka (2005). "Hepatic Imaging: Comparison of Modalities." Radiologic Clinics of North America 43: 929-947.

Hussain, S. M. and C. R. Semelka (2005). "Liver Masses." Magnetic Resonance Imaging Clinics of North America 13: 255-275.

Jalote-Parmar, A. and P. Badke-Schaub (2008a). "Workflow Integration Matrix: A Framework to Support the Development of Surgical Information Systems." Design Studies 29 (4): 338-368.

Jalote-Parmar, A. and P. Badke-Schaub (2008b). Critical Factors Influencing Intra-operative Surgical Decision -Making. IEEE, Man Machine and Cybernetics. Singapore,12-15 October, IEEE.

Jalote-Parmar, A., P. Badke-Schaub, A. Wajid and E. Samset (2009). "Cognitive Processes as Integrative Component for Developing Expert Decision-Making Systems: A Workflow-centered Framework" Biomedical Informatics doi:10.1016/j.jbi.2009.07.001

Jalote-Parmar, A., P. M. T. Pattynama, R. Goossens, A. Freudenthal, H. de Ridder and E. Samset (2007). Surgical Workflow Analysis: Identifying User Requirements for Surgical Information Systems. Diversity in Ergonomics. R. Pikaar, K. Ernst and K. Settels. Oxford, Elsevier: 229-241.

Jalote-Parmar, A., P. M. T. Pattynama, R. H. M. Goossens, A. Freudenthal, E. Samset and H. De Ridder (2006). Bridging the Gap: A User-centered Design Approach Towards Developing Technological Solutions. Minimally Invasive Therapies & Novel Embedded Technology Systems, ARIS*ER Summer School Book. S. Casciaro and A. Distante. Italy, Lupiensis Biomedical Publications, National Research Council. : 100-108.

Jalote-Parmar, A., P. M. T. Pattynama, A. P. Van der Plas and d. Heer P (2007). Towards Intuitive Surgical Interfaces: Strategies from Video Games New Technology Frontiers in Minimally Invasive Therapies. S. Casciaro and A. Distante. Italy, Lupiensis Biomedical Publications, National Research Council.

Jannin, P. and X. Morandi (2007). "Surgical Models for Computer-Assisted Neurosurgery." Neuroimage 37(3): 783-91.

Jannin, P., M. Raimbault, X. Morandi, L. Riffaud and B. Gibaud (2003). "Model of Surgical Procedures for Multimodal Image-Guided Neurosurgery Computer Assisted Surgery " 8 2: 98-106.

Kalkofen, D., B. Reitinger, et al. (2006). Integrated Medical Workflow for Augmented Reality Applications. In Proceedings of AMI workshop, Copenhangen.

Klein, G. (1989). Recognition-primed decisions. Advances in Man -Machine Systems Research. W. B. Rouse. Greenwich, JAI. Press, Inc. 5: 47-92.

Klein, G., J. Orasanau, R. Calderwood and C. Zsambok (1993). Decision Making in Action: Models and Methods. Norwood, New Jersey, Albex Publishing Corporation.

Kohn, T. L., J. M. Corrigan and M. S. Donaldson (1999). To Err is Human Building a Safer Health System. Committee on Quality of Health Care in America. Washington, D.C, National Academy Press.

Koning, A. H. J. (2009). Volume Visualization Using Virtual Reality Medical Applications of Volume Rendering in Immersive Virtual Environments Advanced Imaging in Biology and Medicine, Springer Berlin Heidelberg. 2: 257-269 (in press).

Konishi, K., M. Hashizume, et al. (2005). "Augmented Reality Navigation System for Endoscopic Surgery Based on Three-Dimensional Ultrasound and Computed Tomography: Application to 20 Clinical Cases." International Congress Series 1281: 537-542.

Kushniruk, A. W. (2002). "Analysis of Complex Decision-Making Processes in Health Care: Cognitive Approaches to Health Informatics." Journal of Biomedical Informatics 34(365-376).

Lai, E. C. H., C. N. Tang, P. Y. J. Ha and K. W. M. Li (2009). "Laparoscopic Liver Resection for Hepatocellular Carcinoma: Ten-Year Experience in a Single Center." Arch Surg 144(2): 143-147.

Lambata, P., A. Jalote-Parmar, F. Lambata and J. Deckleric (2008). "The Resection Map, A proposal for intra-Operative Hepatectomy Guidance." International Journal of Computer Assisted Radiology and Surgery 3(3-4): 299-306.

Lang, H., A. Radtke and M. e. a. Hindennach (2005). "Impact of Virtual Tumor Resection and Computer-Assisted Risk Analysis on Operation

Planning and Intra-Operative Strategy in Major Hepatic Resection." Arch Surg 140 (7): 629-638.

Lau, W. Y. and E. Lai, C. H (2009). "The Current Role of Radiofrequency Ablation in the Management of Hepatocellular Carcinoma: A Systematic Review." Annals of Surgery 249 (1).

Lemke, H. U., C. Trantakis, K. Kochy, A. Muller, G. Strauss and J. Meixensberger (2004). Workflow Analysis for Mechatronic and Imaging Assistance in Head Surgery. International Congress Series 1268, Leipzig, Germany, Elsevier.

MacKenzie. C. L, J. A. Ibbotson, C. G. L. Cao and A. J. Lomax (2001). "Hierarchical Decomposition of Laparoscopic Surgery: A Human Factors Approach to Investigating the Operating Room Environment." Minimally Invasive Theory and Allied Technologies 10(3): 121-127.

Mc Cloy, R. and R. Stone (2001). "Science, medicine and the future-Virtual reality in surgery." British Medical Journal 323: 912-915.

McLaughlin, M. L., J. P. Hespanha and G. S. Sukhatme (2001). Touch in Virtual Environments: Haptics and the Design of Interactive Systems, {McLaughlin, 2001 #102}.

McLaughlin, R. A. (2007). An introduction to Image Registration. Novel Technologies for Minimally Invasive Therapies. C. S and E. Samset. Lecce, Lupiensis Biomedical Publications: 107-110.

Mehmanesh, H., R. Henze and R. Lange (2002). "Totally Endoscopic Mitral Valve Repair " J Thorac Cardiovasc Surg 12: 96-97.

Melles, M. and A. Freudenthal (2003). Next Generation Equipment in the Intensive Care Unit: Data Collection for Design Guidelines. EAM 2003, the 22nd European Conference on Human Decision Making and Manual Control., University of Linköping.

MeVis. (2006). "Distance Services Liver Planning." Retrieved 1/10/2009, http://www.mevis.de/mms/en/Distant_Services.html.

Milko, S. and R. A. McLaughlin (2007). Registration of 2D Ultrasound to MR Volumetric Data. Novel Technologies for Minimally Invasive Therapies C. S and E. Samset. Lecce, Lupoensis Biomedical Publications: 67-74.

Milko, S., E. Samset and T. Kadir (2008). "Segmentation of the Liver in Ultrasound: a Dynamic Texture Approach " International Journal of Computer Assisted Radiology and Surgery 3(1-2): 143-150.

Milne, A. J. (2000). Analyzing the Activity of Multidisciplinary Design Teams in the Early Stages of Conceptual Design: Method and Measures." Collaborative Design" Proceedings of Co-Designing 2000 Conference. , Coventry, U.K., Springer, London.

Navab, N., J. Traub, T. Sielhorst, M. Feuerstein and C. Bichlmeier (2007). Action- and Workflow-Driven Augmented Reality for Computer-Aided Medical Procedures. IEEE Computer Graphics and Applications 27 (5):10-14

Neumuth, T., A. Pretschner, C. Trantakis, M. Fischer, H. U. Lemke and B. Oliver (2005). An Approach to XML-based Description of Intra-operative Surgical Workflows. Berliner XML Tage: 147-152.

Nicolau, S., A. Garcia, X. L. Pennec and S. Ayache, N (2005). "An Augmented Reality System to Guide Radio-Frequency Tumor Ablation." Computer Animation and Virtual Worlds 16 (1): 1-10.

Nicolau, S. A., X. Pennec, et al. (2009). "An Augmented Reality System For Liver Thermal Ablation: Design and Evaluation on Clinical Cases " Medical Image Analysis 13(3): 494-506.

Norman, D. A. (1998). The Design of Everyday Things. London, The MIT Press.

Orasanu, J. and T. Connolly (1993). The Reinvention of Decision Making. Decision Making in Action: Models and Methods. G. Klein, J. Orasanau, R. Calderwood and C. Zsambok. New Jersy, Albex Publishing Corporation: 3-20.

Padoy, N., T. Blum, I. Essa, H. Feußner, M. O. Berger and N. Navab (2007). A Boosted Segmentation Method for Surgical Workflow Analysis Medical Image Computing and Computer-Assisted Intervention (MICCAI 2007), Brisbane, Australia.

Patel, V., L, J. Arocha, F and D. Kaufman, R (2001). "A Primer on Aspects of Cognition for Medical Informatics." Journal of American Medical Informatics Association 8 324-343.

Patel, V. L. and D. R. Kaufman (1998). "Medical Informatics and the Science of Cognition." Journal of American Medical Informatics Association 5(6): 493-502.

Powell, Y. C. (2000). Robotics Transforming the Operating Room. Technology and Trends for International Optical Engineering Community, SPIE. 201.

Preece, J., Y. Rogers, H. Sharp, D. Benyon, S. Holland and T. Carey (1994). Human Computer Interaction. Workingham, Addison Wesley.

Rasmussen, J. (1986). Information Processing and Human-Machine Interaction. New York, Elsevier.

Reason, J. (1990). Human Error. Cambridge, Cambridge University Press.

Reason, J. (2000). "Human error: models and Management." British Medical Journal 320: 768-770.

Reitinger, B., A. Bornik, R. Beichel and D. Schmalstieg (2006). Livery Surgery Planning Using Virtual Reality. IEEE Computer Graphics Applications. 26: 36-47.

Rhim, H., Y. S. Kim, D. Choi, D. Lim, H. K. Lim and K. Park (2008). "Percutaneous Radiofrequency Ablation of Hepatocellular Carcinoma: Analysis of 80 Patients Treated with Two Consecutive Sessions." European Radiology 18(7): 1442-8.

Rouse, W. and J. Valusek (1993). Evolutionary Design of Systems to Support Decision Making. Decision Making in Action: Models and Methods. G. Klein, J. Orasanau, R. Calderwood and C. Zsambok. New Jersey, Albex Publishing Corporation: 270-286.

Ryder, J. M. and R. E. Redding (1993). "Integrating Cognitive Task Analysis into Instructional Systems Development." Education Technology Research and Development 41(2): 71-96.

Sanders, E. B. N. (2001). Harnessing People's Creativity: Ideation and Expression Through Visual Communication. Focus Groups: Supporting Effective Product Development. J. Langford and D. McDonagh-Philp, Taylor and Francis.

Sanderson, P. M. (2003). Cognitive Work Analysis Across the System Life cycle: Achievements, Challenges and Prospects in Aviation. Alderschot, UK Ashgate.

Schmalstieg, D., A. Fuhrmann, et al. (2002). "The studierstube augmented reality project." Presence: Teleoper. Virtual Environ 11(1): 33-54.

Seamster, T. L., R. E. Redding and G. L. Kaempf (1997). Applied Cognitive Task Analysis in Aviation. Aldershot, England, Ashgate Publishing Ltd.

Shein, Q., H. Li, J. Chung and P. Hui (2004). "A Framework for Identification and Representation of Client Requirements in the Briefing Process." Construction Management and Economics 22: 213-221.

Shepard, A. (2000). HTA as a Framework for Task Analysis. Task Analysis. J. Annett and N. Stanton, A. New York, Taylor and Francis. : 9-24.

Shepard, A. (2001). Hierarchical Task Analysis. London, Taylor & Francis.

Shepard, A. (2001). HTA and Training. Hierarchical Task Analysis. S. Andrew. London, Taylor & Francis.

Shoup, M., M. Gonen and M. D'Angelica (2003). "Volumetric Analysis Predicts Hepatic Dysfunction in Patients Undergoing Major Liver Resection." J Gastrointest Surg 7(3): 325-330.

Shuhaiber, J. H. (2004). "Augmented Reality in Surgery." Arch.Surg. 139: 170-174.

Simon, H. (1969). Science of the Artificial. Cambridge, MIT Press.

Sojar, V., D. Stanisavljevic, et al. (2004). Liver Surgery Training and Planning in 3D Virtual Space. CARS 2004 - Computer Assisted Radiology and Surgery. Proceedings of the 18th International Congress and Exhibition International Congress Series.

Solbiati, L., S. N. Goldberg, T. Ierace, M. Dellanice, T. Livraghi and G. S. Gazelle (1999). "Radio-Frequency Ablation of Hepatic Metastases: Post Procedural Assessment with a US Microbubble Contrast Agent-Early Experience." Radiology 211(3): 643-649.

Solbiati, L., M. Tonoloni and T. Lerace (2006). Guidance of Percutaneous Tumor Ablation. Enhancing the Role of Ultrasound with Contrast Agents. R. Lencioni, Springer.

Spence, R. (2001). Information Visualization, Addison-Wesley, ACM press.

Stanton, N., and M. S. Young (1999). Guide to Methodology in Ergonomics. London, Taylor and Francis.

Steinke, K., J. Habicht, S. Thomsen, M. Soler and A. Jacob (2002). "CT-Guided Radiofrequency Ablation of a Pulmonary Metastasis Followed by Surgical Resection " CardioVascular and Interventional Radiology 25(6): 543-546.

Stewart, D. W. and P. N. Shamdasani (1990). Focus groups: Theory and Practice. London, Sage Publications.

Taylor, R. H., S. Lavallée, G. S. Burdea and R. Mösges (1996). Computer-Integrated Surgery: Technology and Clinical Applications Massachusetts, The MIT press, Cambridge.

Thomann, G. and J. Caelen (2007). Proposal of a New Design Methodology Including Participatory Design and Scenario Based Design in Minimally Invasive Surgery 12th IFToMM World Congress, Besançon (France).

Topal, B., R. Aerts and F. Penninckx (2003). “Laparoscopic Radiofrequency Ablation of Unresectable Liver Malignancies: Feasibility and Clinical Outcome.” Surgical Laparoscopy, Endoscopy & Percutaneous Techniques 13(1): 11-15.

Tzortzopoulous, P., R. Cooper, P. Chan and M. Kagioglou (2006). “Clients’ Activities at the Design Front -End.” Design Studies 27(6): 657-683.

Vallino, R. J. (1998). Interactive Augmented Reality. Department of Computer Science, The College Arts and Sciences. Rochester, New York, University of Rochester. Doctoral Thesis.

Vetter, M., P. Hassenpflug, et al. (2002). Superiority of Auto-stereoscopic visualization for Image-Guided Navigation in Livery Surgery. In Proceedings of SPIE.

Villard, C., L. Soler and A. Gangi (2005). “Radiofrequency Ablation of Hepatic tumors: Simulation, Planning and Contribution.” Computer Methods Biomech Biomed Engineering 8(4): 215-27.

Villard, C., L. Soler, et al. (2003). RF-Sim: A Treatment Planning Tool for Radiofrequency Ablation of Hepatic Tumors. Proceedings of the Seventh International Conference on Information Visualization (IV’03), IEEE Computer Society.

Wahlstrom, B. (1988). On the Use of Models in Human Decision-Making. Tasks, Errors and Mental Models. L. P. Goodstein, H. B. Andersen and S. E. Olsen. London, Taylor &Francis Ltd: 160-170.

Woods, D. D. (1988). Coping with Complexity: The Psychology of Human Behavior in Complex Systems. Tasks, Errors and Mental Models. Basingstoke, Hampshire, Taylor & Francis Ltd: 128-143.

Xiao,Y, P. Milgram and D. J. Doyle (1997). Capturing and Modeling Planning Expertise in Anesthesiology: Results of a Field Study. Naturalistic decision Making. C. Zsambok and G. Klein, Lawrence Erlbaum Associates.

Zaff, B. S., M. D. Mc Neeese and D. E. Snyder (1993). “Capturing Mutiple perspective: A User-centered Approach to Knowledge and design Acquisition.” Knowledge Acquisition 5: 79-116.

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Ashis was born on 14th August 1975 in Dodoma, Tanzania, East Africa. In 1998, she graduated as a designer with a degree in visual design (advertising design) from College of Arts and Crafts, Lucknow University, India. At the same time, she also worked as a visualizer in Mudra Advertising for clients such as Samsung, Pepsi and Nestle. In July 2000, she received her Masters Degree in Industrial Design, specializing in visual communication (Human Computer Interaction/Information design) with Cuma Laude, from the Indian Institute of Technology (IIT), Bombay, India. She also received best graphic design award from the industry for her master's thesis.

Soon after graduation, she was invited to Germany on a Hildegard- Fürst scholarship, to the Hochshule, Mannheim, where she researched in the area of knowledge management (2000-2001). In the 2001-2002, she joined SAP AG, Waldorf, as a user interface designer/usability expert in Customer Relationship Management/New Area Development (CRM/NAD). She then joined the Industrial Design Center IIT, Bombay as a senior lecturer in visual communication and HCI (2003-2004). Later, for one semester, she joined the User-centered Interaction design lab in Korean Advanced Institute of Technology as a researcher and was also involved in teaching and supervising student projects in the area of product planning and design.

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PUBLICATIONS BY THE AUTHOR

Journal

Jalote-Parmar. A., P. Badke-Schaub, A.Wajid and E. Samset (2009), “Cognitive Processes as Integrative Component for Developing Expert Decision-Making Systems: A Workflow-Centered Framework”, Journal of Biomedical Informatics doi:10.1016/j.jbi.2009.07.001 (In Press).

Jalote-Parmar. A and P. Badke-Schaub (2008). “Workflow Integration Matrix: A Framework to Support the Development of Surgical Information Systems”, Design Studies, 29 (4): 338-368.

Lambata. P., Jalote-Parmar. A, Lambata. F and Deckleric. J (2008). “The Resection Map, A Proposal for Intra-operative Hepatectomy Guidance” International Journal of Computer Assisted Radiology and Surgery, 3 (3-4): 299-306.

Book Chapter

Jalote-Parmar. A., Pattynama. PMT, De Ridder. H, Goossens. RHM, Freudenthal. A and Samset. E (2007). “Surgical Workflow Analysis: Identifying User Requirements for Surgical Information Systems”, In: Pikaar R, Ernst K, Settels, (Eds), Diversity in Ergonomics, Oxford, Elsevier: 229-41.

Jalote-Parmar. A., Pattynama. PMT, Van Der Plas. AP and Heer. P D (2007). “Towards Intuitive Surgical Interfaces: Strategies From Video Games”, In: Casciaro S, Distante A (Eds), New Technology Frontiers in Minimally Invasive Therapies, Italy: Lupiensis Biomedical Publications, National Research Council:101-111.

Jalote-Parmar. A., Pattynama. PMT, Goossens. RHM, Freudenthal. A, Samset. E and De Ridder. H (2006). “Bridging the Gap: A User-centered Design Approach Towards Developing Technological Solutions”, In: Casciaro S, Distante A, (Eds). Minimally Invasive Therapies & Novel Embedded Technology Systems, Lupiensis Biomedical Publications, National Research Council, Italy: 93-101.

Freudenthal. A., Pattynama, P. M.T, Samset. E, Jalote-Parmar. A, B.Gersak and S. Casciaro (2006). "Design Approach to Bridge the Gap Between Surgeons and Technologist in Minimally Invasive Surgery". In: Casciaro S, Distante A, (Eds). Minimally Invasive Therapies & Novel Embedded Technology Systems, Lupiensis Biomedical Publications, National Research Council, Italy:180-188.

Morvan. T., Martinsen M, Jalote-Parmar A, Reimers M, Elle.Ole Jakob, and Samset. E (2006). "A Generic Monitoring System for Surgical Robotic Manipulators". In: Casciaro S, Distante A, (Eds). Minimally Invasive Therapies & Novel Embedded Technology Systems, Lupiensis Biomedical Publications, National Research Council, Italy: 158-165.

Conference Papers & Presentations

Jalote-Parmar. A and P. Badke-Schaub (2008). "Critical Factors Influencing Intra-Operative Surgical Decision-Making". IEEE International Conference on Systems, Man, and Cybernetics (SMC 2008), Singapore, 12-15 October.

Jalote-Parmar. A and P Badke-Schaub (2008). "Surgical Decision-Making: Insights for Developing Expert System for Minimally Invasive Surgeries" 27th European Annual Conference on Human Decision-Making and Manual Control, Delft, The Netherlands, 2008.

Lambata. P., Jalote-Parmar, Lambata. F and Deckleric. J (2008). "The Resection Map, A Proposal for Intra-operative Hepatectomy Guidance" CAR, 2008, Barcelona.

Jalote-Parmar. A., Van Alfen. M and Hermans. J (2008). "Workflow Driven User Interface for Radiological System: A Human Factors Approach" CAR, 2008, Barcelona.

Jalote-Parmar. A., Pattynama, P.M.T, Goossens, R.H.M, Samset, E and De Ridder, H (2007). "A Surgeon Centric Framework Towards Analyzing The Surgical Workflow". International Journal of Computer Assisted Radiology and Surgery, CAR,2007, Springer, 2(1):154-156

Jalote-Parmar. A., Pattynama, P.M.T, Goossens R.H.M, Freudenthal. A, Samset . E and De Ridder H (2006). "Exploring A User Centric Methodology to Investigate and Integrate Information Gathered During Medical Intervention". In Proceedings of The 16th World Congress on Ergonomics (IEA), Maastricht, The Netherlands: International Ergonomics Association.

GLOSSARY OF ACRONYMS

ARIS*ER	Augmented Reality in Surgery
CT	Computerized Tomography
CTA	Cognitive Task Analysis
HCI	Human Computer Interaction
HMD	Head Mounted Display
HTA	Hierarchical Task Analysis
IVS	Intra-operative Visualization System
KIVS	Knowledge Intensive Visualization System
MIS	Minimally Invasive Surgery
MRI	Magnetic Resonance Imaging
RFA	Radio Frequency Ablation
NDM	Naturalistic Decision Making
US	Ultrasound
WIM	Workflow Integration Matrix
2D	Two dimensional
3D	Three dimensional