

Emotional factors in speech based human-machine interaction in the operating room

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From surgical data synchronization to semantic workflow modelling

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Keywords Surgical workflow (SWF) · Ontology · Surgical process model · Digital Operating Room · Integrated Operating Room

Purpose

With the increase of high technologies and digital data inside the *operating room (OR)*, solutions can be developed to help surgeons managing all information in an integrated way. To translate *OR* data into information and make them helpful to surgeons, surgical processes can be abstracted and recorded into description schemes of surgical procedures, Surgical Workflows, in a way that a computer can capture them.

Surgical Workflows (SWF) can be defined from analysis of logical and/or temporal *surgical process models (SPMs)*. *SPMs* are recorded and processed to compute workflow schemes that can be used by a *Surgical Workflow Management System (SWFMS)*. A *SWFMS* is a meta-process control system for the digital *OR* of tomorrow [1].

The purpose of this work is to provide an efficient solution for generic *SPMs* recording during surgery and detailed postoperative description of *SWF* using semantic ontology language.

Methods

Our surgical process modelling method is based on the *temporal rescaling method (TR)* we developed and the use of a web ontology.

Workflow Modelling

The *TR* method provides a solution for the recording of periodical and aperiodical data during the surgery and their synchronisation after the surgical process [2]. Metadata can then be defined during the surgery to identify the procedure steps. These metadata are aperiodical information that can be manually defined by an actor of the surgery process (e.g. a surgeon) or automatically by data mining methods applied on information streams. Each metadata corresponds to an event recorded by a logging system. These metadata do not need to be explicitly defined during the process. They can just be identified as a new step and characterized, after the surgical process, using all synchronized data recorded during the surgery (e.g. videos of the microscope and the *OR*).

Semantic description

To characterize the different *SPMs* steps and their interconnection with recorded data, usage of ontology is proposed. The *Ontology Web Language (OWL 2.0)* allows the description of resources (e.g. a data file, an entity of the real life). These resources, defined by a *Uniform Resource Identifier (URI)*, can be concepts defining a *class* (e.g. a surgeon), an entity (i.e. an *individual*) of the real world (e.g. the surgeon Smith) or a physical resource (e.g. DICOM files). We can define a *surgery* class that corresponds to a *SPM*. This *surgery* class is divided in *workflow units* (i.e. a *SPM* entity contains a set of *workflow unit* entities). Each *workflow unit* is performed by an actor (e.g. a surgeon) and contains a sequence of *steps*. For each *step* entity we can

define different attributes as its start and end time or a property that links this entity to another resource. For example, if the surgeon uses a surgical instrument (e.g. a scalpel) during a step, an object property *useInstrument* (i.e. a *predicate*) is defined between a *step* entity (subject of the property relation) and an *instrument* entity (object of the property relation) [3] (Fig. 1).

Using an inference engine, a *SWFMS* can conclude that the surgeon needs this class of instrument for this class of step. Then a *Scrub Nurse Robot* as proposed by [4] could deduce, according to the surgery state (i.e. the current step), which instrument it has to propose to the surgeon.

Implementation

After surgery, each synchronized data is recorded in data files associated to *Resource Description Framework (RDF)* files, describing the nature of the recording (e.g. *URI* of the *instrument* entity, *URI* of the data). Each metadata event, representing the beginning or the end of a step, is tagged with time stamp, synchronized with recorded data and saved in a *extended Markup Language (XML)* file.

Data are then synchronized and a *Synchronized Multimedia Integration Language (SMIL)* file is created. *TR* information streams are displayed in a web browser using this file and the Quicktime player plugin. Using an *eXtensible Stylesheet Language Transformations (XSLT)* engine, *SPMs* are converted to *Scalable Vector Graphics (SVG)* file for graphical representation. The surgeon can directly access the different surgical steps (Fig. 2).

To characterize the steps and their semantic description, the surgeon will use a graphical user interface allowing to easily and graphically define ontology semantics. The basis of the ontology is designed using *Protégé* [5]. The surgeon is involved in the dynamic enhancement of the ontology using a Java engine based on the *OWL API* [6]. The inference engine is based on the *Pellet Reasoner* [7]. The Java engine can be a remote *Web Service*.

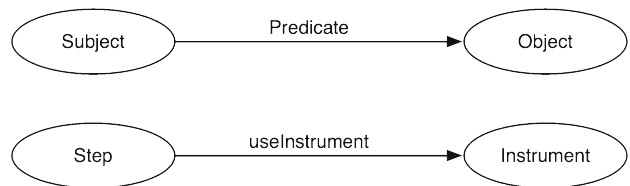


Fig. 1 Description of the use of instrument during a step



Fig. 2 Simulation of spine surgery (transpedicular screw insertion)

Results

The modelling method was tested in laboratory with a simulation of computer assisted surgery of the spine (Figure 2). We characterized the steps manually. The construction of the *SMIL* file was automated by a *MATLAB* engine that gathered recorded data files and event files. The *SVG* files of the *SWF* were created using the *Saxon XSLT Processor* [8]. We also started to implement the ontology engine as a local Java application running in console mode.

Conclusion

We demonstrated a solution for the modelling of surgical processes based on the intraoperative definition of generic steps and their postoperative semantic descriptions. The model can be build by the surgeon who can control the granularity of the model and the level of semantics to describe the surgical procedure. The model is directly linked to recorded data using an ontology language so that all data can be transformed into information for further development of expert systems with knowledge to help surgeons during their procedures.

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Workflow-Driven Touchscreen User Interface User friendly graphical user interface for workflow management during navigated robotic-assisted keyhole neurosurgery

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Keywords Surgical workflow · Navigated robotic-assisted key · Graphical user interface

Purpose

Minimally-invasive neurosurgery requires careful pre-operative planning of trajectories prior to the execution of the surgery. This work was developed within a EU-sponsored project which aims at developing an integrated solution for advanced planning and intra-operative navigation of robot-assisted neurosurgical procedures. A combination of three robots offering a large working volume with high local precision and accuracy, together with an innovative flexible probe allows for research towards novel surgical procedures such as Multi-Target Treatment procedures. In the recent years, the research community dealing with intra-operative navigation systems has identified the need for analysis of surgical workflow and context-sensitive user interfaces in the OR. In this work, we present our work-in-progress on a user-friendly user interface, which intra-operatively guides the surgeon through the execution of the pre-operative plan in form of a sequential workflow wizard. Each step of the workflow spawns a window with clear visual and verbal instructions while a state-machine in the background controls whether the correct sequence of actions is performed and which workflow transitions are allowed. Therefore, the surgeon is optimally guided through the workflow, allowing him to focus on the medical procedure at hand. The integration of further components from our overall system into the Touchscreen user interface guarantees that user input is correctly propagated within the system and that the current workflow step and surgical activity drive the internal behavior of the system, making our system partly context-aware.

Methods

The overall system features three combined robots of varying accuracy, a haptic interface for needle steering, two ultrasound systems for real-time imaging and intra-operative validation, a SensorManager module for monitoring of various tracking, imaging and sensor components, a pre-operative planning and intra-operative navigation user interface based on the open-source framework 3DSlicer as well as a High-Level-Controller (HLC) module for integration of robots into a kinematic chain. Instead of offering direct control of these system components, the workflow-driven Touchscreen user interface is designed from a surgeon point-of-view. The interface is presented in form of a sequence of buttons which have to be pressed by the surgeon in order to interact with and receive instructions and feedback by the system (Fig. 1). While Passive Actions such as suturing are only communicated to the surgeon in form of visual and verbal

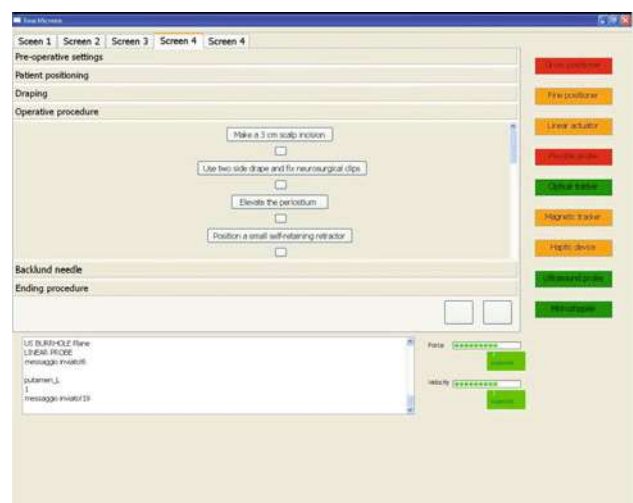


Fig. 1 The touch screen user interface is designed from the point of view of the surgeon and the workflow of the surgical procedure



Fig. 2 As the central application, the touch screen UI integrates all other central components of the overall system through various communication interfaces. In this tab, control over the 3D Slicer-based visualization interface is offered. At the right side, the availabilities and statuses of all system core components are queried and presented in form of color codes

instructions, Dynamic Actions (i.e. technical steps) like registration of objects in the OR are internally communicating with respective system components in order to query the correct information at the right time. The Touchscreen workflow management system interfaces with the robot HLC, which features a state-machine with fewer states, for workflow-driven robot control. Concerning implementation, the Touchscreen UI is based on Qt 4.6, which features a state-of-the-art state machine implementation which is fully compliant with the latest State Chart extensible Markup Language (SCXML) specifications of the World-Wide-Web Consortium (W3C). The communication of the Touchscreen interface with the SensorManager and the HLC modules is achieved by using the open-source middle-ware implementation TAO CORBA. As further functionalities, the Touchscreen UI offers full control over the image manipulation possibilities from 3DSlicer such as slice selection, scaling, rotating or windowing of medical image data (Fig. 2). Communication between the Touchscreen UI and the 3DSlicer software is achieved through the built-in socket communication between 3DSlicer and external programs, based on Tcl/Tk. Various modifications to the 3DSlicer core were made in order to adapt the software to the demands of our system's surgeon interface. Concerning hardware, a sterilizable Touchscreen is used (Puritron KM190), along with two high-resolution (2560 x 1600) 30-inch monitors (HP LP3065) for ergonomic visualization of 3DSlicer medical images inside the operating room.

Results

Workflow sequences for three different minimally-invasive neurosurgical scenarios were constructed in close collaboration with surgical partners which are both internal and external of our project consortium. The first scenario is Brain Biopsy (BB), the second scenario is Multi-Target Treatment (MTT) and the third is Deep Brain Stimulation (DBS). Between 51 to 72 workflow steps were defined, depending on the complexity of the surgical scenario. At the current state, the only evaluation concerning the usability of the workflow guidance is based on the collaborative definition of workflow together with surgeons which guarantees that the workflow steps are comprehensive and cover the entire surgical procedure. Being at the end of the second of three years project runtime, the workflow

management system is implemented and at the final stages of integration with further system components. All communication among system components has been integrated and successfully tested in mock-up scenarios.

Having just passed the implementation stage, the current paper can only reflect results concerning implementation and integration of system components and should be seen as a report on the current work-in-progress. In the upcoming year, several test cases together with surgeons are scheduled in which simulated surgeries on brain-mimicking phantoms are going to be performed. The experiments are designed towards assessing the workflow management system concerning usability, exhaustiveness of workflow steps and suitability of the state-machine approach for modeling of the manually-defined surgical workflow. At the end of the project runtime, in the case of successful phantom studies, a cadaver study is planned as a final validation of the overall ROBOCAST system.

Conclusion

This work was conducted in the course of a multi-national project comprising eleven partners from the EU and Israel, implementing a novel prototype for advanced robot-assisted minimally-invasive neurosurgery in a combined effort. In this paper, we present an approach at a workflow-driven user interface which instructs the surgeon step-by-step, guiding him through the surgical procedure at hand. While the system is user-friendly, with a strong focus on surgical activity rather than technical details, the backend implementation offers full control over the system in a context-sensitive manner. The complex technical setup of our system offers a unique test-bed for investigating the requirements of a workflow-driven user interface concerning its implementation, usability and definition of workflow sequence. With the research community putting an increasing emphasis on workflow integration into surgical navigation systems, we strongly believe our work to be a vital contribution to this field of research.

Auditory Support for Image-Guided Liver Surgery

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Keywords Auditory display · Human-Computer Interaction · Intraoperative Visualization · Image-guided Surgery

Purpose

The purpose of this work is to integrate concepts from the field of auditory display to enhance an electronic surgical navigation assistant for image-guided liver surgery. Although alarms and other auditory notification and monitoring devices are commonplace in operating rooms, audio has been a neglected modality in interaction with tools for intraoperative navigation. However, the conditions of the surgical environment present suitable opportunities for new aural modes of interaction. Surgeons and assistants are often charged with several tasks in parallel, including following a video monitor when using intraoperative planning tools. Auditory display provides a fast, flexible, and responsive system to reduce the overburdened dependence on visual input during surgery and allow surgeons to keep their eyes on the situs.

Methods

The current surgical navigation assistant allows for both preoperative and intraoperative surgical planning through the use of 3D liver models and intraoperative ultrasound data. The positions of surgical instruments (CUSA Excell, Integra Neuroscience) can be captured in real time using optical tracking and can be viewed on the 3D model. The surgeon needs to consult the planning system frequently, which creates distraction and possibly even confusion. At any rate, viewing

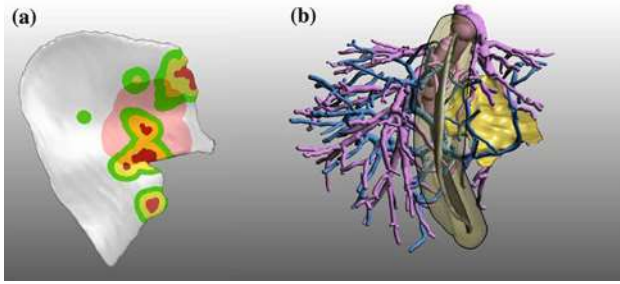


Fig. 1 (a) Risk map with shadow-like distance indicators that encode different safety margins around important vessels (dark red: 2 mm, yellow: 4 mm, green: 6 mm). The light red area encodes the proximity (10 mm) to a tumor. (b) Coronal view of the resection proposal, including hepatic vein (purple), portal vein (blue), tumor (yellow) and the safety margin around the planned resection surface (dark yellow)

the planning system's screen interrupts the surgical flow. Ideally, the surgeon would only need to look at the planning system if the instrument approaches a risk structure such as an important vessel system or tumor.

To address this issue, the auditory display for the surgical planning system makes use of risk maps (Fig. 1) with uniform safety margins surrounding risk structures such as vessels and tumors. Position data from the tracked CUSA are sent to audio synthesizer software, which references the risk map to indicate the distance of the instrument to the risk structures. The system alerts the surgeon when the instrument enters or exits each of three concentric precomputed uniform safety margins, emanating intuitive scaled layers of sounds. By using these auditory signals, the surgeon is better able to follow the preplanned resection plane, reducing dependence on the video monitor.

The routine in the operating room was taken into account when designing the auditory display. First, the sonic environments inside typical operating rooms were analyzed so that the system would not interfere acoustically with other signals in the room, enhancing detectability and discriminability. Second, sounds were chosen for the system that embody direct, representational metaphors of the instrument entering and exiting safety margins. Third, the sounds are only triggered at relevant moments, reducing user annoyance and thus enhancing acceptance and usability.

Results

Discussions with our surgical partners have indicated that an auditory display for surgical tools would be a welcome addition to the intra-operative system. Preliminary evaluations on liver phantoms suggest that the addition of auditory display does enhance recognition of uniform safety margins, thereby reducing dependence on the video monitor for clues about the instrument's distance to risk structures. In combination with the visualization of risk maps, the auditory feedback may prevent a possible damage to risk structures. Furthermore, several sound configurations have been produced, allowing for an in-depth evaluation of the design choices and modes of interaction.

Conclusions

As a rarely used modality in surgical navigation, audio shows increasing promise for computer-assisted surgery. Auditory display reduces the dependency on visual presentations, freeing the surgeon to focus his or her attention on the situs rather than on a video monitor. Our auditory display for image-guided liver surgery warns more clearly of risk structures, making them easier to identify and avoid, thus allowing the surgeon to more safely and efficiently follow a resection plan. The surgeon needs to divert less attention to the video monitor during the surgical procedure, only referencing the video monitor when notified by the auditory display. Although our system improves the recognition of safety margins being entered or exited, further evaluations are necessary to minimize undesired

emissions of sound, improve the intelligibility of the tones, create sounds that are aesthetically pleasing to the surgeon, and further enhance the system's usability in the operating room. Furthermore, registration errors must be considered and compensated in the auditory display.

Emotional factors in speech based human-machine interaction in the operating room

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Keywords Laparoscopic surgery · Emotion recognition · Speech interface

Introduction

Laparoscope positioning systems are introduced to minor access surgery in aim to augment the quality of the operation by eliminating the disadvantages of manual telescope guiding by an assistant surgeon. A user-friendly design of the human-machine interface to control such manipulators plays an important role. Implementation of an intuitive and hands free voice control interface would offer a promising solution. However, speech controlled systems proposed so far did not get acceptance due to too long reaction time, reliability and user dependent interface [1, 2]. Two decisive factors for a robust speech interface are the consideration of noisy environment in the operating room and the emotionally colored speech commands [3]. We therefore evaluated the emotional effects on speech commands during laparoscopic interventions to estimate the impact on speech control interfaces.

Material and Methods

For determination of the emotional coloring and its influence to the speech interface we recorded a total of 29 live laparoscopic surgeries at the Klinikum rechts der Isar der TU München. These records were performed under real conditions with noisy environment and unexpected influences. An AKG C 444 L headset was used for the records of seven different surgeons. The recorded operations such as cholecystectomy and fundoplication last between 30 minutes and three hours. These speech records were stored in waveform with a sample rate of 16 kHz and 16 bit per sample. In order to test and train our emotion recognition [4], the "Speech In Minimally Invasive Surgery" (SIMIS) database was created after automatic segmentation, transcription and emotional labeling within five classes for each segment (cf. Fig. 1). The recordings are segmented into speech and non-speech patterns, where the latter is classified into background noise,

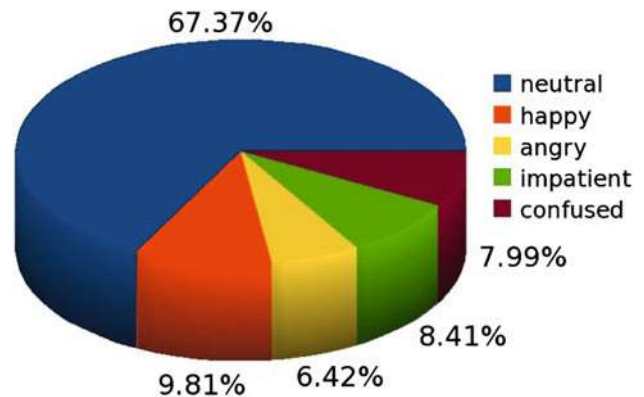


Fig. 1 Distribution of emotion classes among speech

instrument noise, background talk and breath or cough. For the training and testing of the speech recognizer, the labeled emotions were finally classified into happy as positive emotions, angry and impatient as negative emotions and neutral and confused as neutral emotions.

Results

The distribution of speech turns among emotions is shown in Fig. 1. Neutral is by far the most common emotion, making up over two-thirds of the total duration. The remaining classes lie between 5 and 10%, with happy being the most common one among them. Angry and impatient are regarded as negative emotions and constitute 14.83% of the speech.

It can be assumed that different surgeons express their emotions in different manners. Two series of experiments were accomplished to take this into account. In a first experiment a single surgeon was recorded during 20 operations whereas in the second experiment seven different surgeons were recorded during at least one operation. The classifier's performance is measured by the values

- **RR**: Overall recognition rate (Number of correctly classified cases divided by the total number of cases or weighted average).
- **CL**: Mean of the class-wise computed recognition rate (i.e. mean along the diagonal of the confusion matrix in percent or unweighted average).
- **F₁**: Uniformly weighted harmonic mean of RR and CL: $2 * CL * RR / (CL + RR)$.

As classifier for these experiments a Support Vector Machine (SVM) with sequential minimal optimization learning was chosen.

For the first experiment the recognizer was set to separate negative from non-negative speech turns, meaning that neutral and positive turns were clustered together. Since in the real-life scenario the recognizer will not be trained with data from the same operation it is tested on a leave-four-operations-out cross-validation with 5 cycles. This means that speech turns from 16 operations are used for training, while the Support Vector Machine classifier based on 37 (contours as pitch or formants) x 2 (including derivatives) x 19 (functional as mean) acoustic features (cf. [4]) is tested on the data of the remaining four recordings. As result, the RR of the recorded operations varies between 69.43% and 81.69% ($\mu = 75.38\%$, $\sigma = 4.45\%$), the CL varies between 62.27% and 66.10% ($\mu = 64.27\%$, $\sigma = 1.60\%$) and thus the F₁ varies between 65.65% and 71.18% ($\mu = 69.33\%$, $\sigma = 2.16\%$).

For the second experiment the recognizer was again set to separate negative from non-negative speech turns. Leave-one-speaker-out cross-validation was used to evaluate the performance, i.e. the data of every speaker was tested individually with a model trained on the remainder. As result, the RR varies between 70.45% and 94.87% ($\mu = 83.84\%$, $\sigma = 8.31\%$), the CL varies between 57.88% and 76.42% ($\mu = 66.89\%$, $\sigma = 7.07\%$) and thus the F₁ varies between 69.31% and 81.03% ($\mu = 73.93\%$, $\sigma = 4.15\%$).

Conclusion

The experiments showed that it is well solvable to distinguish negative from non-negative speech, if the data for testing and training both stems from the same surgeon. Recognition rates as high as 81.69% were achieved for this case and provide a reliable separation. Further, this information can be used to improve the actual speech recognition for the robot control [5].

A paramount goal for future work in this area should be to further extend the SIMIS database, specifically recording additional operations from surgeons that currently contribute only one or two interventions. This would make it possible to draw more significant conclusions on the subject of speaker independent emotion recognition.

A speech-based camera control system is a possible application of the acoustic emotion recognition. As a further step the recognizer will be implemented into the newly designed speech controlled

laparoscope positioning system SoloAssist (AktorMed, Germany) to optimize the human-machine interaction.

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OsiriX surgical navigation system using 3D mixed reality in minimally invasive surgery including NOTES, single incision surgery, and robotic surgery

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Keywords OsiriX · Image overlay navigation surgery · NOTES · Robotic surgery

Purpose

The application of virtual reality (VR) surgical assistance, in which medical images are processed to provide reference images for pre-operative surgical planning or during surgery, is being evaluated. The popularization of surgical navigation, which utilizes VR for assisting surgical procedures, is attracting much attention as a social need. When a surgeon consults an image displayed on a monitor, there is a distance arising from the actual view of the patient's operative field; hence, a technology for dynamic 3D images that fuses together the actual space and the virtual space became necessary.

Method

We have applied mixed reality (MR) consist of VR and augmented reality (AR) technology, in which electronically-generated dynamic 3D images are superimposed on the actual space in front of the surgeon, on the patient's operative field or the surface of the abdomen, and evaluated such a system as a reference for surgical navigation and education. We also described the educational aspect of MR-assisted navigation in surgery for young surgeons. MDCT was performed in 90 patients accepted endoscopic and laparoscopic surgery. Post-processing these downloaded data to a workstation, we generated anatomical VR imaging using DICOM viewer OsiriX. 3-D reconstructions (volume rendering) were incorporated on the workstation-based display and previewed on the patient body surface and operative field from the projector as MR navigation during endoscopic procedure. Moreover we are applying next application for integrated 3D images in robotic surgery.

We also applied anaglyph images to provide a stereoscopic 3D effect, when viewed with 2 color glasses (each lens a chromatically opposite color as red and cyan) using OsiriX function. Images are



Fig. 1 OsiriX three-dimensional surgical navigation system



Fig. 2 Image overlay navigation surgery in MIS and robotic surgery

made up of two color layers, superimposed, but offset with respect to each other to produce a depth effect. The main organ is in the center, while the foreground and background are shifted laterally in opposite directions. When viewed through the “color coded” “anaglyph glasses”, surgeons reveal an integrated stereoscopic image fused into perception of a 3D scene or composition (Figs. 1, 2).

Result

This 3D system provided better hand-eye coordination and accurate information for localizing the target lesions of gastrointestinal and HPB benign and malignancies with its relationship to the surrounding vessels. MR procedure, when contained virtual endoscopy, could help understanding the surgical procedures and techniques in complex minimally invasive surgical procedure including natural orifice transluminal endoscopic surgery (NOTES) and SILS [1, 2].

Conclusion

Our surgical navigation system using mixed reality by OsiriX provided accurate image guided navigation for minimally invasive surgery.

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Surgical image and video management: issues and solutions

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Keywords Surgery · Video · PACS · IHE · WADO

Purpose

During the intervention, the surgical team is handling a large number of image sources:

- surgical videos produced by camera used for minimally invasive approaches (coelioscopy, laparoscopy),
- videos from OR room camera,
- more and more radiology modalities (CR, CT or MR) acquired during the surgery for assisted surgical navigation.

Surgeons wish to store those images for multiple reasons. A first clinical motivation is to document surgical outcome as well as potential surgical incidents or complications. For instance, in gynaecology, a video may highlight the management of ureteral injuries that can be associated with vaginal surgery. In addition to static images, videos can also be useful to document the organ functions. Another motivation is to record sequences for teaching or research purpose (conference presentations).

PACS has the vocation to manage the clinical results to offer a unified access to all images and a better patient follow-up. One challenge comes from the huge amount of data to store particularly with videos. Another challenge is the implementation of a complete IHE integration profiles. Moreover, the image/video management tools need to be ergonomic to let surgeons concentrate on the operating field.

Materials and Methods

We selected the DICOM standard to ease integration with the PACS. Videos are stored using the DICOM-MPEG2 syntax transfer. Indeed the systems managing the OR imaging devices or the navigation systems more and more comply with DICOM. In case there is no integrated OR system, we interfaced the video cameras to a DICOM digital station which is able to grab signal videos and convert them to DICOM.

We also followed the IHE recommendations dealing with the administrative and scheduling chains: they define how to build study worklists and how to propagate the patient demographics to the imaging devices. However, the surgical information systems generally are not compliant with these IHE recommendations and they do not handle the concept of imaging study like it exists in radiology. Therefore there was an administrative gap to fill. Thus we decided to implement a dedicated software component to supply DICOM worklist. This component is directly interfaced to the HIS (Hospital Information System) to query the list of patients present in various ORs sectors. Each time an imaging device located in OR queries this DICOM worklist component, a DICOM study is automatically generated for each patient present in OR. By this way, the surgery staff avoids a study creation step and gain time.

At the end of the intervention, the images or videos are stored through an enterprise PACS storing all sources of images produced within the hospital. Image distribution is achieved via two complementary channels:

- Large distribution via an EPR (Electronic Patient Record) launching a free and multifunctional viewer called WEASIS [1]. This Java-based viewer can be interfaced to any PACS compliant to DICOM WADO (Web Access to DICOM Persistent Objects) to retrieve images. Its plug-in based architecture offers a wide flexibility for real-time addition of new components, like a video display interface.
- Retrieval an open source viewer, OsiriX [2], using DICOM communication. This viewer is running on Apple Macintosh. Its strength will be the multidimensional navigation capabilities to sustain further surgical planning.

Results

At the University Hospitals of Geneva, five OR rooms have been successfully interfaced to PACS for three surgical specialties: paediatric, orthopaedic and gynaecology. Two types of OR configurations are addressed: a unique integrated OR system

interfaced with PACS or multiple mobile imaging devices each individually interfaced with PACS (a low-energy CT or CR mobile units). Nurses particularly appreciated to get automated study worklists on the integrated OR system.

The video management was the most difficult issue to solve. Indeed, the complete storage of several hour interventions was unconceivable in view of the huge amount of data to handle, even if compression is applied. We reached a consensus with the surgeons and followed a hybrid strategy depending on the purpose of the data (clinical or training/research). The clinical data are a selection of relevant sequences stored on PACS. While the sequences for training and research purposes, which are much longer, are stored on DVDs managed locally by the surgical team.

An acquisition protocol has been defined for data relevant for clinical purpose: 5 to 6 static images plus 10 minutes of video (collection of short sequences of 30s to 1min) are sufficient to document a gynaecological surgery, representing approximately 700 mega-bytes of data (quality level: good to excellent). Since a post-surgical selection is not a viable option in view of the time it requires from the surgical team, selection is done directly at the acquisition level by predefining the duration of video acquisition. The surgeon launches the video acquisition via a foot pedal for instance. Export is then manually performed at the end of the intervention.

Our experience shows that integrated OR systems require further improvement to better drive the video management workflow. Ideally, the user interface would simply need to identify clinical from teaching/research data, so that export tasks would be done automatically at the end of the intervention without any further manual interventions.

Conclusion

Interfacing OR imaging devices to PACS becomes feasible and allow to complete the hospital wide PACS objective with a unified access and display. However, some improvements (user interface to better address surgical needs and workflows) are necessary especially at the level of the integrated OR system. In the future, we plan to implement video streaming between the PACS and the WEASIS viewer to have direct video display without pre-downloading of the full sequence. This streaming capability will be implemented above the WADO interface so that it can be connected to any PACS supporting WADO.

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Quality assessment of codec-based endoscopic surgical imaging transfer system in remote medicine

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Keywords Codecs · MPEG4 · H.264 · Remote Medicine

Purpose

In recent times, despite the remarkable growth in medical technology, a large section of the population still has limited access to healthcare because of shortage of medical facilities and doctors. In many countries, a conducive environment for the development of advanced techniques in diagnosis and treatment has not become established because of inadequate infrastructure. Minimally invasive surgery such as endoscopic surgery has great advantages, such as less invasiveness, decreased pain, faster postoperative rehabilitation, and reduction of medical care costs. Concurrently, broadband internet access is becoming widely available. Japan is the global leader in the build ratio of fiber to the home (FTTH) environment. Japan also offers the best price setting and usage fees for broadband internet access. In order to promote advances in remote medicine, medical image transfer systems that use the broadband network infrastructure are necessary. For use in remote medicine, ordinary images need to be digitized. However, considering their size, a bandwidth of at least 100 Mbps is required for transferring such images. Consequently, compression and decompression (codec) technologies for video images play an important role in their transfer. MPEG2 is a codec used in digital video discs (DVDs), artificial satellites, and terrestrial digital broadcasting. H.264 is the most recently introduced codec. In this study, we aimed to develop guidelines for improving interoperability between codecs required for medical imaging transfer techniques that are used in remote medicine. To clarify the potential endoscopic surgical applications of medical imaging in remote medicine, subjective evaluations were performed by medical doctors using endoscopic surgery video samples.

Methods

Brief overview of evaluation tasks for image quality assessment

The participants in the study were allowed to view the images once. A 5-level rating system was used for the evaluation of image quality. Several endoscopic surgery video samples were used for image quality assessment. For evaluation, these videos were encoded in varying bit rates using the several codecs. Decoded video samples were stored as AVI files. The image quality assessment was done by exposing the same samples to the participants in the study on a like-for-like basis. Selection of laparoscopic surgery video samples for image quality assessment

(1) Recording of video during surgery

Video of laparoscopic endoscopic surgery was recorded during live tissue training at the Minimally Invasive Training Center of Kyushu University Hospital. This video was recorded on digital video tape on VCR that was connected to the NTSC output of an endoscopic surgery system (Karl Storz Co, Ltd). During recording, the operative environment was also recorded using a small digital video camera, and this video was synchronized to that of the laparoscopic surgery.

Table 1 Select Assessment Scene










| Scene Number and Title | Scene | Scene | Scene | Scene | |
|--|--|--|---|---|---|
| No.1 Liver, Gallbladder, Small intestine |  | No.4 Stitches with needle |  | No.7 Instruction for dissection route |  |
| No.2 Expanded image of gallbladder |  | No.5 Organ borderline recognition |  | No.8 Coagulation and s |  |
| No.3 Lymph. node Spleen, Stomach Recognition of incision line |  | No.6 Making openings in the membrane using forceps |  | No.9 Instruction for steps to prevent bleeding from tissue |  |

Table 2 View point of Assessment and criteria

| Scene No | Viewpoint of assessment | Assessment criteria of degradation of image quality |
|----------|---|---|
| No. 1 | Discrimination of gallbladder color | 5. Not recognizing image degradation and no problem with discrimination 4. Recognizing image degradation, but no problem with discrimination 3. Concern regarding image degradation, but no problem with discrimination 2. Image degradation disturbs discrimination 1. Image degradation prevents discrimination |
| No. 2 | Discrimination of gallbladder color | 5. Not recognizing image degradation and no problem with discrimination 4. Recognizing image degradation, but no problem with discrimination 3. Concern regarding image degradation, but no problem with discrimination 2. Image degradation disturbs discrimination 1. Image degradation prevents discrimination |
| No. 3 | Identification of the lymph node and capillary vessels | 5. Not recognizing image degradation and no problem with identification 4. Recognizing image degradation, but no problem with identification 3. Concern regarding image degradation, but no problem with identification 2. Image degradation disturbs identification 1. Image degradation prevents identification |
| No. 4 | Possibility of instructions for handling forceps with needle | 5. Not recognizing image degradation and no problem with instructions 4. Recognizing image degradation, but no problem with instructions 3. Concern regarding image degradation, but no problem with instructions 2. Image degradation disturbs instructions 1. Image degradation prevents instructions |
| No. 5 | Possibility of instruction for fixing and cutting the suture | 5. Not recognizing image degradation and no problem with instructions 4. Recognizing image degradation, but no problem with instructions 3. Concern regarding image degradation, but no problem with instructions 2. Image degradation disturbs instructions 1. Image degradation prevents instructions |
| No. 6 | Discrimination between contact with tissue membrane and vessels | 5. Not recognizing image degradation and no problem with discrimination 4. Recognizing image degradation, but no problem with discrimination 3. Concern regarding image degradation, but no problem with discrimination 2. Image degradation disturbs discrimination 1. Image degradation prevents discrimination |
| No. 7 | Identification of the lymph node and capillary vessels | 5. Not recognizing image degradation and no problem with identification 4. Recognizing image degradation, but no problem with identification 3. Concern regarding image degradation, but no problem of identification 2. Image degradation disturbs identification 1. Image degradation prevents identification |
| No. 8 | Identification of the cause of bleeding | 5. Not recognizing image degradation and no problem with identification 4. Recognizing image degradation, but no problem with identification 3. Concern regarding image degradation, but no problem with identification 2. Image degradation disturbs identification 1. Image degradation prevents identification |
| No. 9 | Possibility of recognition of pulsating of vessels under the area of bleeding | 5. Not recognizing image degradation and no problem with recognition 4. Recognizing image degradation, but no problem with recognition 3. Concern regarding image degradation, but no problem with recognition 2. Image degradation disturbs recognition 1. Image degradation prevents recognition |

(2) Selection of laparoscopic surgery images for image quality assessments

Eighty video segments were selected as the first group of video samples from approximately 4 h of video recorded during laparoscopic surgery training. The second group of samples comprising 20 segments was selected by the chief trainer at the center. Next, segments of about 10 seconds duration were clipped from the

second set of 20 segments. Finally, from these clipped segments, the third group of samples comprising 9 segments was selected by the same trainer. The details of the 9 segments finally selected are presented in Table 1.

(3) View point of assessment and criteria

The details of the view point of assessment and criteria are presented in Table 2.

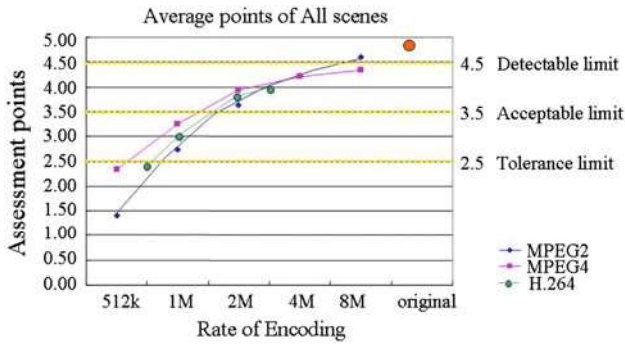


Fig. 1 Results of Assessment

Selection of coding criteria

(1) Selection of used codecs

The codecs used for the image quality assessment were as follows: H.264 low-latency codec (Wrap Vision), MPEG4 codec, MPEG2 software encoder

Selection of encoding rate

Encoding rates were limited for the H.264 low-latency codec. Thus, the used encoding rates for the H.264 low-latency codec were different from those for the other 2 codecs.

(I) MPEG2, MPEG4

The image dimensions were fixed on VGA, and the encoding frame rate was 30 fps. Performed encoding rates were as follows: 512 kbps, 1 Mbps, 2 Mbps, 4 Mbps, 8 Mbps

(II) H.264 low-latency codec (Warp Vision): 768 kbps QVGA, 30fps, 1 Mbps VGA, 15fps, 2 Mbps VGA, 24fps, 3 Mbps VGA, 30fps

Results

Ten expert endoscopic surgeons at same center were selected for image quality assessment candidates. Correlations between the image quality assessment scores and encoding rates at different assessment points for each codec are shown in Fig. 1. The assessment scores at all points were above average for all images.

Conclusion

Our results show that, for diagnosis and instructions in remote endoscopic surgery, a bandwidth of more than 1.5 Mbps is required for transfer of videos encoded with MPEG4 and H.264. However, the baseline for acceptable image quality varied between surgeons. A bandwidth of more than 3 Mbps would be required for instructions and endoscopic surgery in remote medicine.

A novel SOA based approach towards the integration of a robotic system into a modular surgical work system and IT network

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Keywords IORS · Robot · SOA · Modular surgical work system · IEC 80001

Introduction

Nowadays the number of technical systems available in the operating room (OR) is increasing. This is not limited to the standard devices such as X-ray imaging or electrosurgical-devices. Also new technologies such as navigation and smart, miniaturized robotic systems have been proposed [10], and will be introduced in the OR of the future. Robotic systems could offer advantages in surgery such as less invasive surgical strategies with increased efficiency, improvement of patient safety, accuracy, repeatability and reduction of the surgeons' workload [8].

To facilitate the use of all these devices in clinical routine, the integration into the surgical workflow is mandatory [7]. [3] states that integrated medical operating systems (IORS) can reduce costs and time and have the potential to improve human engineering by centralized control based on the integration. More advantages of IORS are discussed in [5], such as facilitating the interaction with different modules through one central control unit, to enhance exchange and integrated use of information and to resolve the classical separation of the sterile and non-sterile areas regarding communication issues within the OR. However, the integration of robotic devices is associated with highest safety requirements concerning real-time and data security especially in the context of a modular IORS. This paper presents an approach towards the integration of a modular miniaturized medical robot, which has been developed within the OrthoMIT framework.

Background

To integrate a robotic device in an IORS, the IORS must provide means for a modular and flexible integration of new devices. Available IORS are proprietary developments with only limited support for modular integration of new devices and technologies [5]. A new concept for integration has been developed within the OrthoMIT project which is based on service-oriented architecture (SOA) [4]. All the components are connected over a communication bus and managed from the Service Manager, which is responsible for access control and information management among other things. The risk analysis for the general integration architecture based on IEC 80001 [1] has shown, that it is a reasonable concept, which fulfils the high safety requirements for surgical work systems. The general approach, developed at our institute, has been adopted as use case in the framework of IEC 80001.

Approach

We investigate the integration of our modular robot system MINARO (see Fig. 1) supporting the surgeon during Revision Total Hip Replacement (RTHR) interventions. During the intervention the modular robotic system performs the following steps:

- scanning of bone cement geometry using A-Mode ultrasound [2],
- calculation of the milling path from ultrasound data,
- precise and gentle removal of femoral bone cement using a high speed milling device [9].

The integration of the robotic system into the surgical workflow and in the OR requires communication between the robotic system and needed support and interaction systems in the OR. For the MINARO robot these are a navigation and planning system for interaction with the surgeon, a tracking system for position tracking, an imaging system for scanning bone cement and milling path planning for calculation of the milling path.

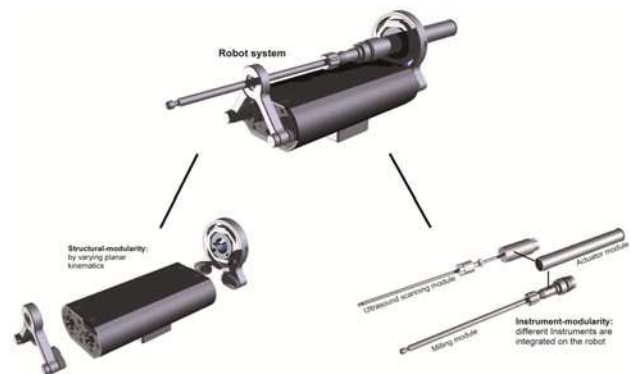


Fig. 1 Modular miniaturized medical robot system

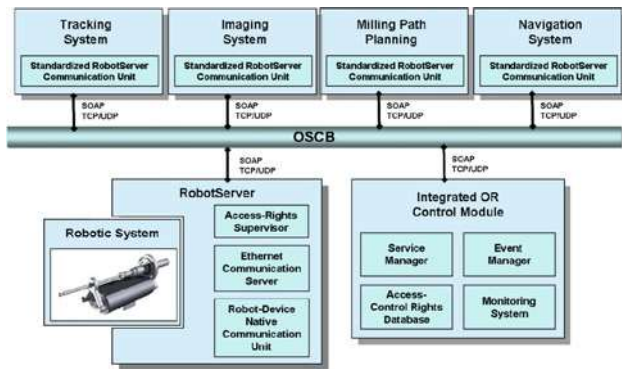


Fig. 2 Robot integration based on SOA

To allow the integration into the SOA based integration architecture and interconnection and data exchange with other systems in the OR as well as means for controlling the robotic system an interface must be defined. Therefore the so called RobotServer has been developed which provides a standardized interface for modular and exchangeable integration and encapsulates access to the robotic system.

The robot integration architecture based on the RobotServer approach is shown in Fig. 2.

Within the RobotServer an Access-Rights Supervisor is implemented to check whether a system is allowed to use the robotic system. The related information is stored in the Integrated OR Control Module (IOCM) which contains central components (Service Manager, Event Manager, Access-Control Rights Database and Monitoring System) needed by the SOA based integration approach and facilitates session management and access control as well as service discovery. Other modules, such as navigation module, milling path planning module or tracking system, use a standardized RobotServer Communication Unit (sRCU) which allows them to communicate over the Open Surgical Communication Bus (OSCB) with the RobotServer and therefore with the robotic system. The OSCB is Ethernet-based and the protocols which are used are Web-Services standards such as SOAP and XML. The integration architecture and the RobotServer will be implemented using Web-Services technologies. The general feasibility of this approach towards a SOA based infrastructure for real-time Embedded Networked Applications has been shown in industrial automation [6]. Depending on the data size and/or importance TCP or UDP is used as transport protocol. For risk critical data the reliable, connection-oriented TCP is used. Apart from this integration concept, redundant safety concepts, such as emergency shut-off and dead-man's control, can be implemented within the robot system.

Discussion

Generally there is a need for integration of robotic systems in the IORS, facilitating in particular the interaction with different modules and enhancing the exchange and integrated use of information. The modular and flexible integration of surgical robotics into the operating room is the major objective of the approach presented in this paper. The proposed integration structure for robots is one potential solution to integrate a robot in a modular way in an OR. Different modules can be connected based on the OSCB and the RobotServer can encapsulate different robotic systems as long as they have defined interfaces. Our in-depth risk analysis revealed still some bottle necks to be further analyzed. Key elements of the risk management will be presented. To facilitate integration of robots and devices from different vendors the interfaces should be standardized. Future research will be necessary concerning the system stability, security aspects and regulatory issues for medical products such as electrical safety. Additionally the risk management has to be

continuously adapted to new findings and insights concerning the integration.

Acknowledgement

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Managerial & Clinical Decision Support in the Digital Operating Room

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Keywords Anesthesia · Informatics · Decision support · Real-time · Genetics

Purpose

The digital operating room and widespread availability of real-time electronic physiologic and administrative data presents a number of

opportunities and challenges with regards to the use and provision of information for both managerial and clinical decision support.

Methods

Utilizing standard programming techniques, we have developed and implemented a customized software architecture that provides enhanced functionality for both managerial and clinical decision support. We began by performing a needs assessment within the Department of Anesthesia, Critical Care, and Pain Medicine to understand the opportunities within the realm of managerial decision support. Having obtained this information, we then generated a set of algorithms which utilize smart notification systems and customized business rules to ensure the accurate and complete generation of medical charts to facilitate and enhance charge capture. Next, we evaluated the operating room workflow to identify opportunities to provide near or real-time clinical decision support to anesthesiologists. We then set out to develop and deploy a set of robust systems, designed to improve performance on a number of measures including drug administration, maintenance of normothermia, and compliance with national standards for intraoperative physiologic monitoring.

Results

After system deployment, we achieved a number of important measurable gains in both operational and clinical areas. On the managerial side, we drove the unbillable case rate down from 1.31% (i.e. cases that were never submitted for payment because of uncorrected errors) to 0.03% – increasing revenue by \$390,000 per year. On the clinical side, we have enhanced our compliance with the Surgical Care Improvement Project (SCIP) core measures, as well as national standards for intraoperative physiologic monitoring. We have further demonstrated the ability of these systems to rapidly and reliably change provider behavior. Having demonstrated our ability to provide managerial decision support and process of care decision support, in the future we plan to provide decision support to notify clinicians about rare syndromes (i.e. malignant hyperthermia) and / or the potential impact of anesthesia that is based on patient level genomic data.

Conclusions

We have successfully utilized real-time intraoperative data to provide managerial and clinical decision support in the digital operating room. These efforts have successfully enhanced our ability to capture revenue and improve clinical performance across providers. In the future we plan to continue our efforts to provide just-in-time information at the point-of-care to include decision support that is based on individual patient level genomic data.

OR-Integration based on SOA - Automatic detection of new Service Providers using DPWS

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Keywords SOA · Integration · DPWS · IORS · Plug-and-Play

Background

In modern operating theaters, there is an increasing number of technical devices. More and more integrated medical operating systems (IORS) are available to enhance the possibility of exchange and integrated use of information for diagnosis and therapeutic treatment. Commercial IORS are mainly proprietary developments usually using proprietary communication standards and interfaces [5], limiting the possibility to integrate devices from different providers. To overcome these bottlenecks, an open standardized architecture concept (see Fig. 1) has been developed [6]. This SOA-based integration architecture uses Web Service (WS) standards, like WSDL [2] and SOAP [4] for interconnecting the different devices.

To facilitate the integration of new components into the network, and in particular of new Service Providers and their implemented Services, there is a need for a mechanism for the discovery of new devices. New Service Providers should be discoverable by the

Service-Manager, to add their function description to the Service Registry as well as to allow adding new devices to the access-rights management. Information necessary for this functionality is a Unique Identifier for each Service Provider, the “physical” address of the Service Provider, a Service Provider description, an Interface (WSDL) definition and version and optional additional metadata like serial number and manufacturer information.

Method

In the field of Web Services the OASIS [10] has standardized DPWS (Device Profile for Web-Services [10]). DPWS combines several Web Service standards to allow an auto-discovery of Service Providers (devices) and the Services which are provided by a device. Furthermore means for metadata exchange, which is further information about the Service Provider/Service, are provided. Fig. 2 shows a general example communication schema for DPWS. The main standards used are:

- WS-Discovery [9]
- SOAP-over-UDP [8]
- WS-MetadataExchange [1]
- WS-Transfer [1]

WS-Discovery in conjunction with SOAP-over-UDP provides the means for automatic discovery of Service Providers on a network. Service Providers can announce their presence when joining and leaving the network using “hello” and “bye” messages. A client obtains discovery information sending “probe” and “resolve” messages to the Service Provider, which in turn responds with a “probe match” and “resolve match” message, as defined in [9]. During the discovery the following information is exchanged:

- EndpointReference (required) - containing a unique identifier (e.g. UUID).
- MetadataVersion (required) - a metadata version number
- Type (optional) - an identifier for a set of messages a Service (endpoint) sends and/or receives
- Scope (optional) - an extensibility point allowing services to be organized into logical groups.
- XAddrs (optional) - the “physical” transport addresses where the service can be reached

WS-MetadataExchange and WS-Transfer are used to exchange further information (metadata). These specifications define how metadata associated with device and Service Provider can be represented, how they can be embedded in and retrieved from a Web Service endpoint. For retrieval of metadata the messages “get” and “getMetaData” as well as the corresponding response messages are defined. The “get” request is used for obtaining general information about the Service Provider while “getMetaData” is used to retrieve

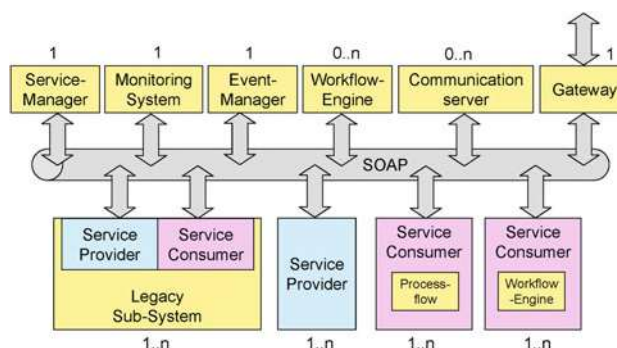


Fig. 1 SOA based Integration Framework for the Operating Room (OR) with standardized communication protocols and interface descriptions

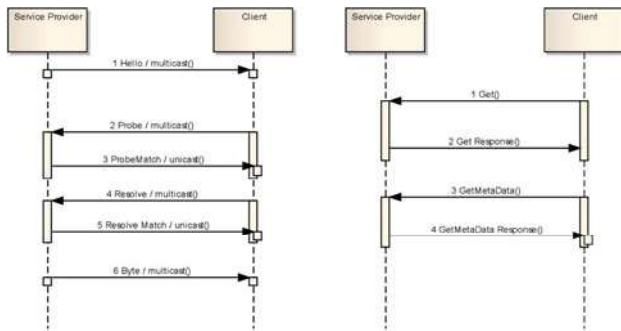


Fig. 2 Example communication schema for DPWS. Left: Discovery of a Service Provider Right: Request for Metadata of the Service Provider and hosted Services

specific information about the Services provided by the Service Provider. The metadata defined by DPWS are grouped into model and device specific data and relationship information containing the WSDL description of the services and policy information.

An OR-Table has been integrated into the SOA integration architecture in order to test DPWS auto-discovery of Service Providers in a clinical environment. Therefore a Web Service interface for the remote control of the OR-table has been developed using Axis2/Java [3] framework and the Jetty Servlet Container [7] and realized in the form of an OR-table Service Provider.

The auto-discovery of the OR-Table Service Provider based on DPWS has been implemented using the DPWS-stack from WS4D [11]. The stack supports all messages except “getMetaData” as they are defined in DPWS. To enable the auto-discovery the service description had to be edited to provide the necessary information for DPWS.

Results/discussion

We used the DPWS-Explorer from WS4D as well as a client implementation of the WS4D DPWS stack for a first test of the discovery. Both tools allow for searching for devices on the network, resolving their physical location and retrieval of metadata.

In a first test the auto-discovery was tested on the same computer device using a virtual network connection. During a second test the auto-discovery was tested on a real network. In both cases the discovery of the Service Provider and its Services succeeded without problems. Regarding the information exchanged during discovery and metadata exchange most information needed as defined in the introduction could be provided using DPWS. During the discovery phase, a Unique Identifier for the Service Provider as well as the “physical” address could be obtained.

Regarding the Service Provider description, Interface (WSDL) definition and version and optional additional details, the exchanged metadata provides only parts of this information. The response of a “get” message does provide an auto generated WSDL description, missing detailed information about data types and message descriptions. Another information missing is the version information of the WSDL file. Neither DPWS nor WSDL provides means for exchanging or providing version information of the interface description.

In conclusion we think, that DPWS is one potential solution for auto-discovery of Service Providers and their Services on a network. Regarding the required information, most of it can be provided using DPWS. Regarding the WSDL description and versioning further research is necessary, how this information could be provided. Security aspects as well as further reliability tests will be aspects of future research.

Acknowledgement

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Risk assessment of software use in computer assisted surgery

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Keywords Risk assessment · Man-machine-interaction · Software · Deep brain stimulation

Purpose

Automation in surgical context permits on the one hand broad improvements in medical care, but on the other hand its use introduces other risks such as overtrust into automation, loss of situation awareness or loss of skills. Such possible risks in the man-machine interaction need to be avoided. This study is focused on a methodical approach for risk assessment of software *use* in computer assisted surgery. Normally risk assessment according to the ISO 14971 standard [1] is focused on the software development process and potential failure modes based according technical and programming aspects. In this study the risk of the man-machine-interaction, team interaction and risk under *real* clinical conditions is assessed. As an example the neurosurgical planning software VoXim microTargeting 6.0 (IVS Solutions, Chemnitz, Germany) was assessed. This software is applied for the operation planning process of the deep brain stimulation (DBS) procedure.

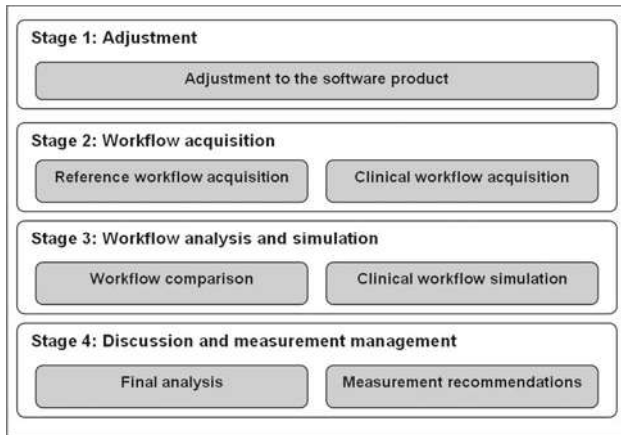


Fig. 1 Risk analysis stage concept

Methods

According to ISO 14971 the Failure Mode and Effects Analysis FMEA was chosen as a systematic procedure for risk analysis. To conduct and document the risk analysis systematically the risk management tool CARAD (SurgiTAIX AG, Aachen, Germany) was used, which was especially developed for medical devices according ISO 14971.

Risk analysis stage concept

Within the scope of this study a stage concept for the risk analysis of software use was developed and applied (Fig. 1). This concept combines the assessment of software use in real clinical setting with an extensive analysis in laboratory simulations to identify the potential risk of the man-machine-interactions as thorough as possible.

Stage 1: Adjustment

To start the risk analysis it is necessary to acquaint the researcher with the underlying software product. This process is based on the software

user guide, literature research about the corresponding clinical context and structured interviews with software developers.

Stage 2: Workflow acquisition

Workflow acquisition contains the referential workflow acquisition and the (actual) clinical workflow acquisition. Therefore the notation of Burgert et al. [2] was chosen, which was expanded by further elements for this study. The acquisition process of the workflows was executed by personal observation as well as video recording.

Stage 3: Workflow analysis and simulation

This stage contains the identification of risks in man-machine interaction. This includes (1) the comparison of the referential workflow with the clinical workflow (possible deviances can involve potential risks); and (2) the simulation of the clinical workflow in the laboratory setting.

Stage 4: Discussion and measurement management

In the final stage the identified potential risks are ranked according the Risk Priority Numbers (RPN). Further the *Risk Graph* is derived, which lead to measurement recommendations for decreasing the remaining risks.

Results

The risk analysis has shown, that VoXim microTargeting 6.0 can be categorised as secure, i.e. no unacceptable risks were identified. All identified potential risks belong to ALARP (= as low as reasonable practicable) risks or to acceptable risks. Altogether 7 remaining risks were identified, which rely on the man-machine-interaction, see Table 1.

Measures for risk reduction

Finally for every identified risk in Table 1, measurements were recommended to the clinical user as well as the software developer. This includes four measures: (a) implementation of an obligatory use of certain functions, (b) implementation of improved entry modes for values, (c) redesign of buttons, (d) use of warning windows to reduce misinterpretation or overtrust into functionalities.

Conclusion

The developed stage concept provides a systematically approach for risk assessment of software *use* in computer assisted surgery. The included risk analysis in clinical settings, the comparison with

Table 1 Remaining risks of the planning software according to the man-machine-interaction

| | |
|--|---|
| Incorrect levels of grey specification | The implemented image preview window is rather small; therefore it is difficult to specify the levels of grey for the user. There is yet no zoom function available. Incorrect specification of grey levels results in inaccurate operation planning. |
| Trajectory tracks arranged close to risk structures | The function Track Handling is <i>optional</i> but it is relevant for safe operation. This function is used for visualisation of the trajectory tracks. This allows the user to check the trajectory tracks for potential contact with structures at risk, such as blood vessels. |
| Button misinterpretation (Functional Planning) | The button Restore is used to reset the <i>complete</i> functional planning. It may be misinterpreted by the user as an Undo function, i.e. to restore only the last modification. |
| Button misinterpretation (Image Fusion) | The same as before, in another module. |
| Electrode diameter underestimation | If the values for electrode diameter are changed to values with more than one digit behind the comma, due to a rounding error, the electrode diameter may be under estimated by the user. |
| Certain buttons may be not used | All the buttons, which are not active in a certain planning step, are set to grey colors. Since certain buttons are designed in grey colors, even if active, they may be not used, even if they might be important. |
| Imprecise marker localisation | Within the module Marker Registration the surgeon can over trust the results of the automatic detection and accept them without extensive verification. This can result in inaccurate operation plan. |

referential software use and the assessment in simulation offer in combination with the risk management tool CARAD comprehensive risk analysis of man-machine-interaction. Furthermore the developed method is compliant with the ISO 14971 standard.

The executed risk analysis of VoXim microTargeting has shown that planning with VoXim is secure. However residual risks can be detected by performing risk management of software *use* in a *real* clinical setting. This residual risk can mainly be attributed to the consequences of automation and other usability problems. Many of these problems are not yet investigated well enough by scientific studies in surgical settings. Therefore it is difficult to introduce appropriate measures by the software manufactures. Some possible measures are suggested within this paper but need to be validated in future studies.

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The Integrated OR. Efficiency and effectiveness evaluation after two years use

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Keywords Assessment · Integrated OR · Efficiency · Effectiveness

Purpose

Technology evaluation is considered a must in nowadays Health Care Systems [1], especially when a significant monetary investment is required.

This paper presents an assessment study on the integrated Operating Room (OR), which is a technical solution mainly dedicated to minimally invasive surgery where environment (lights, climate, etc.), medical devices and video distribution are controlled by surgeons using a sterile touch screen. This layout can be referred to as “fully integrated OR”, while only computerized video distribution can be installed where full integration isn’t needed.

At the time being, there are many installations worldwide of such Integrated ORs although very little literature has been published on the subject, especially on system evaluation from an “operative” standpoint.

At the Varese Town and University Hospital 20 digital ORs have been recently built. 11 ORs are equipped with computerized video distribution and 9 are fully integrated.

Main objective of this paper is the evaluation of surgeons’ and staff nurses’ perception and comments on the ORs that were installed.

This results in a integrated OR solution qualitative study based on clinical staff opinion, which we considered the best parameter to be tested to judge the solution implemented.

Methods

A multiple answer questionnaire was handed to 17 surgeons and 9 scrub nurses. Interviewed people were selected among fully integrated OR users only in order to allow a complete evaluation, especially on the device control integration. Affiliations range from General Surgery (9 surgeons and 6 Scrub nurses), Orthopedic (4 surgeons), Thoracic Surgery (1 surgeon), Urology (2 surgeons, 1 scrub nurse) and ENT (1 surgeon, 2 scrub nurses).

“Multiple guided answer” questions were proposed; the interviewed had to define a level of importance by distributing 100 points among the available options.

Results

In order to assess the effectiveness of integrated OR, options ranged from reduction of patient risk to hospitalization time, rehabilitation, quality of surgery, surgical stress, surgery time. Figure 1 presents the results separately for the two interviewed groups. Enhanced quality of the surgical act has been classified as the best option in terms of total reached scores (520 points) followed by stress reduction (475 points total) and by reduction in surgical time (375 points total). In terms of classification (Fig. 1, graphics 2)), quality of surgery has been chosen as best option by 47% of surgeons vs only 11% of scrub nurses, while 35% of surgeons rank it as 2nd option, resulting in an overall 82% of surgeons stating that the integrated OR augments quality. Please refer to figure one for ranking percentages.

The fact that integrated OR can reduce risk related to surgery has been voted with 315 points, and obtained a total (1st and 2nd place considered together) percentage equal to 48% and 44% of surgeons and scrub nurses respectively.

OR layout was then analyzed to evaluate available functions such as the usefulness of computerized video matrix for images acquisition and distribution, the control system use, the utility of mounting medical devices on a single boom and the possibility to orient more than one display on independent boom arms. Results show a substantial difference in judgment between surgeons and scrub nurses. 47% of surgeons rank video acquisition and distribution most important (1st place, and a total score equal to 470 points) while, on the contrary, 78% of scrub nurses rank device control in first place with a total assigned score of 295 points. Moreover there is a different perception about the need for boom mounted devices which has been voted with 330 points by surgeons and with 145 points by scrub nurses.

As far as medical device control is concerned, options ranked from increased reactivity to events, reduced setting errors, reduced confusion, reduced displacements of devices and monitors. Fig. 2 a) assembles absolute scores for each option since the classification trend is similar for Surgeons’ and Scrub nurses’ values. Interviewed groups stated firstly that direct control can grant better reactivity to events that occur during surgery.

It has been also observed that such a system can reduce device setting errors (surgeons a little more than scrub nurses –35% as 1st place vs 22%), mess, racket and the number of displacements of devices, monitors etc. during surgery. (Fig. 2)

With regard to teaching capabilities of the integrated OR, 76% of surgeons think primarily that a better “point of view” on the surgical field can be achieved and then that a higher amount of surgeries could be viewed. A similar judgment came from scrub nurses confirming the benefits derived by using video as a pedagogic tool [4].

Conclusions

The results of the questionnaire show a substantial satisfaction, given that the installed technology grants multiple advantages to workers and patients. Among such advantages we can enumerate increased quality of patient treatment and reduced stress during surgical act (Fig. 1), reduced time for surgical act and reduced time for device setup, increased reactivity for urgent decisions and reduced setting errors and racket (Fig. 2). Such advantages are mainly obtained using features of the integrated OR like video acquisition and distribution and medical device control. Moreover the use of medical device control and availability of different types of information can improve efficiency of the surgical act, as stated by other authors [2].

Results mean that what was acquired and built in the new OR block of the Varese Town and University Hospital fulfilled the surgeons’ and scrub nurses’ need, both on the technological and organizational point of view.

What can be deduced is also a different approach to technology between surgeons and scrub nurses, the latter being more concerned about workflow and surgical process in general while surgeons appear to be more concentrated on surgical act itself. Anyway, it is clear that the Integrated OR can help overcome the usual problem of modern

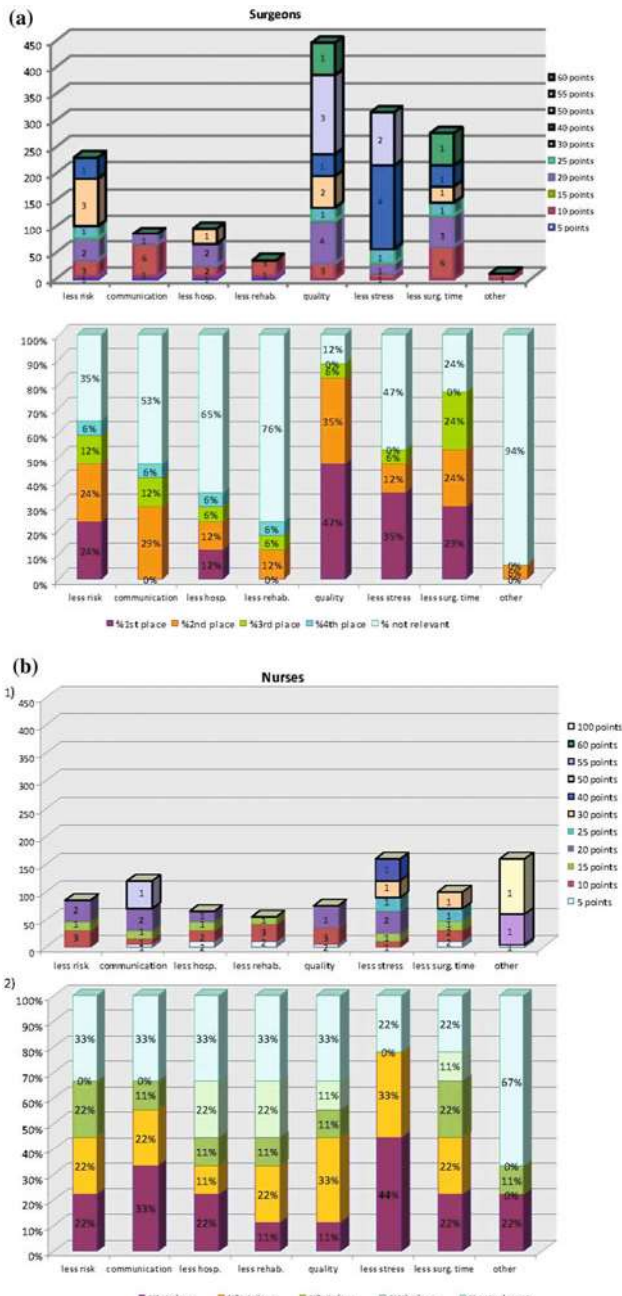


Fig. 1 Surgeons' (A1 and A2) and scrub nurses (B1 and B2) answer distribution for question "which performances are improved by integrated OR?". Graphic 1) represents the absolute scores for each choice divided in colored blocks representing points distribution. Inside the block the number of subjects that assigned that single value of points is reported. Graphic 2) shows the distribution of surgeons' percentage for each choice in terms of place classification

ORs, i.e. a conspicuous presence of high tech devices with little care to ergonomics of the OR itself.

The perception of a decreased surgical time, together with a sensible reduction of the waiting time, can be considered a data supporting the fact that the integrated OR is responsible for a long term economical save. Objective values about surgical time, hospitalization time reduction and patient quality scores (easily accessible

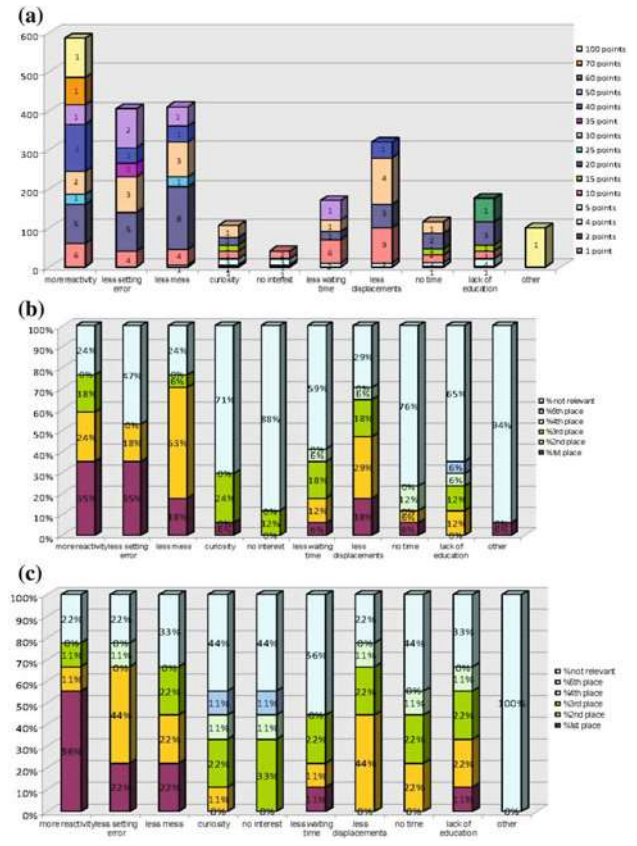


Fig. 2 Answer distribution for question: "utility of device control". Total scores are presented (a) since both Surgeons and Nurses agreed. Two graphics representing ranking expressed in percentage (b) Surgeons, (c) Scrub nurses follow

using a HIS or specific software) are not available in or institution at the time being.

An unexpected but interesting result was obtained: many functionalities available in a Integrated OR could help reduce clinical risk for patients, as stated in other works [2]. If confirmed, such answer will add even more "value" to the Integrated OR solution. At the same time, risk reduction can impact on complication occurrences which comport also an high cost.

Data presented make us state that the integrated OR is a technical solution that should be evaluated by each institution that wants to enhance its healing capabilities and its organizational structure [3].

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