Engineering Design in surgery: An analyze model for prototype validation

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Abstract
Many surgical instruments consist of basic mechanical components which are common in mechanical design. New surgeries performed with better results thanks to these instruments, but the question is how these instruments were designed and developed? How the confrontation between surgical needs and engineering solution can end to a well designed instrument? One experimental stage in surgical design is prototyping and validation by the surgeon in the real use situation, we call it emulation. In this article we study a new surgical instrument design as a design process, and try to make out the details from observed emulation steps. The main object is to develop an analyse model for detailing surgical procedure, in order to have a focused vision on prototype validation. This model aims also to provide some helps in requirement analysis for the designer in conceptual design.

Keywords:
Participatory observation, requirement analysis, surgical design

1 INTRODUCTION

Design in medical and surgical domain is one the best example of multidisciplinary elements and approaches. Development cycle of a new product necessitates collaboration between expertise of surgery and engineering, to build an adequate understanding of requirements and to result suitable design conceptions. Moreover, in this domain, user requirements will not being well defined if there where no prototype testing in real situation. There are many reasons for that, but by the considerable distance between engineering and surgery, a strict design process model could not respond the new collaborative needs. As we will describe further, some user-centred approach should be take the challenge of change. On the main entry as we supposed in this paper is a way to make out the needs of user in this case.

In this article we study a new surgical instrument design as a design process and try to make out the details from observed sub-processes. The research is based on observation of a design team of surgeons and designers, in a development a new instrument for a new kind of surgery. By organizing the project, we prepared some simulations in which the interaction between surgeon and engineer in use situation can be observed. A scenario based model was used and modified to be fitted for this kind of simulation. Finally, professional commercial software is used to demonstrate the result of this method.

2 ENGINEERING DESIGN IN SURGERY

Modern technology has transformed the practice of surgeons. We can now see where we could not before, conduct surgery with minimal trauma, intervene at the genetic level, replace whole natural organs with functional artificial ones, make rapid diagnoses, and peer into the workings of the brain [1]. More patients are surviving, and those who do are living better. Much of the credit for these advances goes to the engineers, physicians, and physiologists who together decided what needed to be done, the science required to support it, and how it could be made practical.

A new design starts with the idea of responding new requirements. Comparing the new requirements list with existing solution or situation makes out new problems, and design process solves these problems. An essential part of problem solving method involves step-by-step analysis and synthesis. The systematic approach of engineering design [2] proposes to proceed from the qualitative to the quantitative, each new step being more concrete than the last even in the first stage, requirement understanding.

Design in surgery, unlike conventional design deals with patient life and a performing design of special instruments and operation techniques results in a reduced patient-trauma. The usually long and thin instruments and a camera (endoscope) are inserted through small incisions into the patient’s body. The surgeon performs the intervention by looking at a monitor device where the images from the endoscope are displayed. On patient-side, the advantages of MIS are numerous, including reduced pain, lower risk of infection and a rapid recovery resulting in shortened hospitalization.

There are also some practical experiences which led to analytical model which does not clearly belong to one category. For example, [3] propose a model to analyze the preoperative surgical process. In general, in most of researches in instrument development, the development of new technologies to improve new surgical operations (such as minimally invasive surgeries) starts with task analyses followed by problem assessments, instrument design and evaluation of new technologies.

Scenario-based design (SBD) is one of the methodologies proposed to allow designers to create new tools and devices with user participation during all the primary phases of the design process in software engineering [4].

3 INTRODUCTION TO MINIMALLY INVASIVE SURGERY

Minimally Invasive Surgery (MIS) is a new kind of surgery which gets more and more common nowadays, started in past decades and well-known as 'endoscopic surgery'. The whole idea of this kind of operation is to avoid cutting the mussels the mussels are rarely separated, the patient has less pain, less bleeding and will recover quicker. With this method, a surgical operation is performed by the help of a small endoscopic camera and several long, thin, rigid instruments through natural body openings or small artificial incisions ('keyhole surgery'). In comparison to the usual, open surgery, there exist several advantages for the patient such as less pain, less strain of the organism, faster recovery, smaller injuries (aesthetic reasons), and also economic gain (shorter illness time). On the other hand, there exist some important disadvantages for the surgeon, too:

- restricted vision
- difficult handling of the instruments
- very restricted mobility
- difficult hand-eye coordination
- limited tactile perception

Minimally Invasive Spine Surgery (MISS) has rapidly come of age due to the explosive development of bio-computer technology, digital video imaging, laser application and much better medical/surgical instruments. Medical professionals expect that up to 85% of spinal surgery will soon be done with MISS. However, the goal of MIS must be the same as surgery performed with a formal open procedure. The incision and tissue dissection to the spine may be less, but the surgical procedure cannot be less.

When a surgery is performed with a large incision the dissection leads the surgeon directly to the spine. The approach enables the surgeon to touch the spine and manipulate the spine manually as is often necessary. Instruments for performing open surgery are traditionally made short allowing the surgeon better control and tactile feel. The implants and the tools used to insert the implants are often very large and bulky, because the incision size allows a large access.

The development of such instruments is therefore preferably done by a clinically- driven approach [5, 6]. The clinically-driven approach can best be described as a design process where the physician (in this case the orthopaedic surgeon) and the designer (in this case the engineer) analyze specific needs and problems independent of a technical solution [7]. For a successful analysis, they have to understand the background of their respective disciplines. Such a multidisciplinary problem analysis guarantees that development is done for clinically-relevant topics, resulting in new instruments that fulfil clinical requirements [8, 9].

The participative observation is described in following section as our selected approach to provide data from and with the surgeon in design process stages.

4 PARTICIPATORY OBSERVATION

4.1 Definition: participatory observation serves the artefact evolution

Besides of the complexity of use of medical instruments, one proposition for design medical systems as close as possible to the idea and needs of the users is to design with them and not only for them.

The participative design (PD) is a collective process in which the actors collectively transform an artefact. In the project, everybody is an actor and the user is retained for its competence in the project. The artefact, which is at the beginning only one idea, becomes a concept then a virtual model which is concretized progressively during the design process and is transformed into the end of cycle in a prototype. This artefact is considered as the focusing point the design which makes it possible to each actor to deploy his practices and its skills. The participatory design uses the paradigm to conceive collectively.

Than a collective design process is a PD activity where all the actors are considered as experts and their participation are based on their knowledge. In this case of collective design, the designers and the users don't use

Figure 1. One participatory observation experiment: Designers are in the operation room discussing with the surgeon. Surgeons acts are being captured by an eye-tracker and a general camera.

the same mean of communication and the same knowledge reference. The user communicates almost exclusively with words while the other actors use at the same time words but also their capacity of technical expression.

4.2 Methodology and necessity of observation step(s) in the design process

The observation technique is an investigation method used in physics and natural sciences, and transposed to human and social sciences. It consists in recovering information on the social agents by "collecting" their comportments and their remarks. The initial finality of the observation is to conclude to a diagnostic, from the analysis of the recovering information.

A Participatory Design (PD) workshop is one in which developers, business representatives and users work together to design a solution [10]. PD workshops are most effective early in the design process, when ideas can be less constrained by existing code or other infrastructure. In PD, the users are involved in development of the products; in essence they are co-designers. The first projects using this PD methodology were applied in the Software, Web and Human-Machine Interface development [11]. In these projects, the main idea of the PD is to observe the user is situation of use.

The goal of using video-based observation is to anticipate user behaviour as much as possible in real situation, using the artefact, and the videotape record was extremely helpful in that [12]. The analysis of videotapes of use in conjunction with design has two parts: the analysis itself and the derivation of design implications. Sometimes an observation has an obvious counterpart in an interesting system. However, more often, considerable work must be done to understand and assess the design implications of the observations.

In the medical domain and to examine the features of Emergency Medical Service work and technology use in different emergency situations from the perspective of multiple actors, researchers propose qualitative research and PD [13]. They explain that purpose of PD is to create a process that will support researchers/designers and practitioners in producing innovative, high quality results. An important aspect of this is to achieve, maintain and continuously develop a common understanding across the disciplines.

Another application in this domain presents an observational study that was conducted to guide the design and development of technologies to support information flow during nurses' shift change in a hospital ward [14]. This study shows clearly that the methodology of observatory design is essential to collect a rich set of complex information.

Videotape allows us to capture much more of the richness of the real situation than we have ever had access to before, which opens up important observational possibilities. Handling all this information can be a problem, but the benefits of success could be important. We believe that video lets us catch many serious problems early in the process, often perhaps even before the mistakes are made.

4.3 Application

The purpose of an observation is to try to understand an event or behaviour by watching and also by recording (filming), by taking notes etc. It's not up to the actor to explain what he does, the observer is in charge to understand, and to validate his findings. There are also some researches that shown that in many cases, the actor is not aware of his/her behaviour [15].

In our case of designing innovative surgical tool for a new kind of surgical intervention in Minimally Invasive Surgery, we have firstly decided to observe the surgeon several times in the operating room This phase allows us and the designers to understand the operative conditions and to clarify the surgeon propositions and requirements. Some discussions between the expert user and the engineering designers allow proposing a first prototype of the surgical tool.

Then, the ideal condition is to apply the participatory observation phase in real conditions to make the surgical tool progress. The application of a specific scenario implies a particular preparation of a mannequin which represents the patient. Due to the specific surgical operation we work on with the surgeon, the mannequin must integrate a fractured column. Based on the prepared scenario, the surgeon has to preliminary placed three pares of screws in six vertebral pedicles.

To recover a maximum of information during this experiment, instructions were clearly notified to the surgeon. Frontal and general video cameras and a micro tie were installed to clearly observe the user gestures and movement and record its remarks.

Even without a patient, performance testing in healthcare facilities adds substantial realism. We had the possibility to test the proposed surgical tool during scenario directly in the operating room. Under these ideal conditions, the surgeon had the opportunity to use all the equipments which are usually used during surgical interventions and the know-hows of the expert user is automatically taken into account. He could use the radiographic images to see the prototype in the mannequin (3D location and orientation). In figure 1, the surgeon is manipulating the prototype and looking at its photographic images in the monitor. In the same time, engineers and researchers take pictures and notes to complete the video camera image.

We repeated this emulation three times with two different surgeons and while the prototype and the surgical procedure was modified according to the results of the first emulation. The operation scenario was developed for examination more utilities. Finally, the condition of emulation was improved like the mannequin, and the observation setting.

5 DATA CATEGORIZATION AND ANALYSIS

To establish a new analysis method, at the first level the knowledge and applications of the interventions should be clarified during the design process. This knowledge is often consists of the order of know-how used by experts and the applications derived from specializations done in the field. For this reason, task analysis modelling is used adapted from software engineering, artificial intelligence, and robotics in order to set up human-machine dialogues. Therefore, first researches on analysis of surgeons' act came from the task analysis of human machine interaction [16, 17], and some methodologies are proposed to describe and to analyze of surgical process [7].

The first step in surgical process analysis is to distinguish the different subsystems, the parameters of process (type of procedure, tasks, and basic actions), their mutual interactions, and the disturbances acting on the sub systems [3, 18]. Subsystems are surgeon, assistant, instrument, etc.

In the applied case of new surgical instrument design, we prepared a data collecting form in order to bring together all the possible information from observation in the operating bloc. The forms have been filled in four steps:

- First, before the operation, asking the surgeon to explain successive objectives of the operation,
- Second, during the operation with the prototype, we asked him to describe what he does and his complement about the instrument. Both of his act and voice were recorded with two different cameras, one established on his head for recording what he sees,
- Third, just after the operation, he asked to summarize his operation and advantages and disadvantages

Operation phases	no	Operation sub-phases	No	Task
Positioning the screws (3 pair of screws on 3 vertebras)	1	Insert guide wire	1-1	Incision
			1-2	Insert guide wire
	2	Insert working channel	2-1	Insert 1st dilator
			2-2	Insert 2nd dilator
			2-3	Insert 3rd dilator
			2-4	Insert 4th dilator
			2-5	Insert working channel
			2-6	Remove 4th dilator
			2-7	Remove 3rd dilator
			2-8	Remove 2nd dilator
			2-9	Remove 1st dilator
	3	Insert pedicle screws	3-1	Push down screw
			3-2	Turn
Inserting and fixing rod (2 times)	4	Positioning rod	4-1	Incision
			4-2	Insert the rod
			4-3	Aligning the screws
			4-4	Pass trough the rod
	5	Stabilize	5-1	Aligning vertebras
			5-2	Fix rod in the screws heads
			5-3	Release the rod holder

Table 1. Task analysis of two main phases of the MIS protocol.

- Forth step: some days after, he watches the film of the operation and clarify what he did. In the same time, the filled part of form was verified with the surgeon.

For the analysis of surgeon's work, task analysis seems not sufficient. The designer become familiar with the surgical protocol, but what he needs to have more focus, is how surgeons do the tasks, and what undefined factors which affect their action are. To provide an easier analysis of the surgeon actions during the surgery, we made a categorization concerning surgeons two hand's act, based on researches in this filed. Moreover, we add main functions of the instrument in the category. It means to note the certain time in which the instrument is used for a special function. However, because of the nature of MIS since to entrance of instruments into the body, the observation is no longer possible visually. Surgeons use to use x-ray machine called a fluoroscope to locate and navigate the instrument. For this reason, the third class added to the analyze frame is shown in table 2.

Subject class	Action class	Sub-class	Variable
Surgeon, Assistants	Hands' Act	Right Hand Left Hand	In movement Out movement Left movement Right movement Up movement Down movement Rotation Clockwise Rotation Counter clockwise Grasp
	Control Act		Hand touch Watch Radiography
Main instrument (Protige)	Main functions		Plug and Hold rod Insert and navigate rod Unplug rod
Other instrument	Main functions		

Table 2. Grill of Analyze: Classes and variables

The next step is to finding a software to annotate the video stream of the surgical operation. There are some studies on annotation schemes and tools in natural interactivity domain, and a number of tools in support of natural interactivity and multimodal data annotation, i.e. tools which support

annotation of spoken dialogue, facial expression, gesture, bodily posture, or cross-modality issues, were reviewed in the surveys (see [19, 20] The long-term vision of natural interactivity envisions that humans communicate, or exchange information, with machines (or systems) in the same ways in which humans communicate with one another, using thoroughly coordinated speech, gesture, gaze, facial expression, head movement, bodily posture, and object manipulation [21].

For this study and in view of the expected analysis of video stream a particular selection criteria was set up except that it should be possible to somehow to develop and to enrich the observation from different aspects. With this exception, a survey was performed for reviewing the accessible software in two research centre partners G-SCOP (Grenoble – Sciences for Design, Optimisation and production) and LIG-IMAG (Institute of Informatics and Applied Mathematics of Grenoble). Finally The Observer XT® (from Noldus Information Technology) was chosen for data annotation and analysis. The Observer is the professional software package for the collection, analysis and presentation of observational data with capability of define independent variables and link them to an observation.

One of our aims in annotation of the surgical operation observation was to gather feedback from the surgeon about the surgical instrument in the use situation. Moreover, as described in section four, the argumentation and discussion between engineer and surgeon is also important to be captured and be added to analyze frame. For this reason, the audio steam of the discussion during the surgical operation was separately transcribed into text and added to analyse stream. The framework in which we intend to perform analysis is better known as product validation, or usability testing, and could be used for two well-known techniques of development: engineering and ergonomics.

Although the annotation process is very time consuming and deal with some technical problems, the annotated stream is very useful for focusing on both the use aspects and design aspects of the instrument.

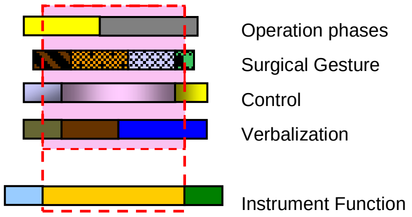

Figure 2. A schematic form of the analyze model for annotation

For example as shown in the figure 2, by simple calling an annotated phase of the operation, or an special gesture of surgeon, the different period in which the phase performed or the gesture figured is accessible. Moreover, what make this analysis more interesting and usable for engineers, is the possibility of demonstration of what is happening during the actualisation of each (or combination) of instrument's functions.

Subject			Behavior	Modifier
Surgeon	Hands Act	Right Hand	Left movement	Protige
		Left Hand	Nothing	
	Control	Watch		
	Verbalization		Critics	The handle is heavy

Table 3. Analysis of 4 to 6 second of operation in second phase, task 4-2A

Table 3 show an analysis of 4 to 6 second of operation in second phase, task 4-2 (see table 3). For more explanation, what is important for the designer is to focus on the use situation of the instrument in details, for example the hands' position of the surgeon, the control acts and also the possible comments on the instrument. However, the result of analysis of the operation is very robust, and can not been published in a conference article. Moreover, some technical issue of the discussion concerning the instrument mechanism is subject of confidentiality.

6 CONCLUSION

The overall concept of generation and classification of an observation of a surgical operation in MIS was presented. This analyze model can be used for providing a functional validation of a surgical instrument, as well as evolution of surgical protocol for a new operation. Selected approach of observation was described and the case study of a new instrument in minimally invasive spine surgery introduced for supporting the analyze model. For extracting as much information as possible from the observation of a surgery, a robust annotation of the surgeon's act (operative and control), verbalization and also instruments' functions was implemented and presented. The resulting trajectory provides necessary information which can be used to segment the surgical skill into elementary operators and confront them to the instrument's function. The next step will be the test of this model on different MIS observation.

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