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Proposal of a New Design Methodology including PD and SBD in Minimally Invasive Surgery

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Abstract— *In all the production domains, we usually notice a difference between the user's idea and the designer's proposition product. This variable difference often depends of the design process methodology used by the company.*
Nowadays, more and more surgical interventions are carried out in Minimally Invasive Surgery, to make the post-operative constraints less painful for the patient. New surgical tools are designed after informal discussions between surgeons and designers. Medical terms, often used by surgeons and employed to explain their needs, don't allow for an instantaneous understanding by designers. Unfortunately, this relation causes a dysfunction in the definition cycle of the product.
Our aim is to modify the design process for better understandings and more complementarities between surgeons and designers. For that we have the objective to propose a design methodology which takes the user into account more effectively in the process design.
After introducing the "Participatory Design" and the "Scenario-Based Design" methodologies, we will develop[1] a surgeon-centred method-design proposition. Then, we will organise some needs expression scenarios and creativity scenarios to test some surgical tool design solutions.

Keywords: Design Methodology, Participatory Design, Scenario-Based Design, Minimally Invasive Surgery

I. Introduction

Currently, the consequences are very handicapping after hard classical surgical interventions. Scientific progress of the last decades makes more and more possible to satisfy the needs for the surgeons in terms of surgical materials and more precisely of surgical tools. Thus, the Minimally Invasive Surgery (MIS) made its appearance in operating rooms in the years 1990. MIS has the main objectives to make the post-operative constraints less painful for the patient, mainly by modifying the operative process with the aim of introducing miniaturized or modified tools inside the human body.

Following this observation, the surgeon with whom we are working has explained his need concerning the use of minimally invasive surgical tools. These new devices should allow the lumbar arthrodesis intervention not by making large incisions (25 cm), but by making serval small incisions (2 cm) in the back of the patient's back.

Today, surgical tools are designed after informal discussions between surgeons and designers. Medical terms often used by surgeons and employed to explain their needs don't allow an instantaneous understanding by the designers. Unfortunately, this relation causes a dysfunction in the product definition cycle.

Our aim is to modify this design process for better understandings and complementarities between surgeons and designers. Questions concerning methods, tools and organisation supporting the process design will be explored to support the expression of this need with the aim of increasing the surgeon point of view during the design process of the tools.

In a first step, using an immersion in the medical environment, we will realise some tasks analysis. Then, we will organise some needs expression scenarios and creativity scenarios with surgeons to propose some design solutions.

In this paper, we will show methodologies to better include the user to the surgical tool design process. Initially we will focus on the "Participatory Design" (PD) and the "Scenario-Based Design" (SBD) methodologies which are mainly used in Web Development. Then, we will present the adaptation of these techniques to the design of surgical tools and explain the scenario configurations adopted. Since this scenario has already been experimented, we will detail our first conclusions and evolutions.

Later on, the concrete in situ application of the new design process methodology (integrating PD and SBD) will allow us to experimentally validate the procedure. Our aim is clearly to reorganise the current process design with the goal of simplification and performance.

Currently, there were no documents that provided an overall view of the integration of validation with device design, process design and production [1]. In recognition of the need for more practical guidance that encourages integrated design, development and validation, research has been carried out in the field of "Design for Validation"

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which can be combined with other good practice techniques such as design for manufacture, design for reliability and design for usability.

II. What is "Participatory Design" and what are the advantages of use?

A Participatory Design (PD) workshop is one in which developers, business representatives and users work together to design a solution [2]. PD workshops are most effective early in the design process, when ideas can be less constrained by existing code or other infrastructure.

Recently, issues have been explored in PD and three of them have dominated the discourse in the literature: the politics of design, the nature of participation and the methods, tools and techniques for carrying out the design projects [3]. During the last 20 years, the PD projects have been more centred to the last arena: the individual project arena.

The PD term appeared in the beginning of the 1980s, concerning software development. Early in the PD movement, this was not an issue: Platform-independent software was not significant until the 1980s; Systems were built for one organization. In the mid-80s, more and more industrials used software systems, so it was the beginning of the design for users [4]. This revealed the complexity of working closely with users on a possible new product.

Then, the "Collaborative Analysis of Requirements and Design" (CARD) approach was proposed in 1992 and refined into a well-understood practice in 1993 [5]. CARD can be assimilated as a macroscopic PD technique [6]. CARD sessions are conducted informally as a kind of semi structured brainstorming session. Participants are people who want to combine their different point of view to reflect their diverse workplace needs and constituencies.

In PD, the users are involved in development of the products; in essence they are co-designers. A great number of projects are currently made around Software, Web and Human-Machine Interface development [7] [8] [9].

The major advantage of the user centred design approach is that a deeper understanding of the psychological, organizational, social and ergonomic factors that affect the use of computer technology emerges from the involvement of the users at every stage of the design and evaluation of the product [10]. The involvement of users assures that the product will be suitable for its intended purpose in the environment in which it will be used. This approach leads to the development of products that are more effective, efficient, and safe.

The User-Centred Design (UCD) methodology allows designers to imagine and create an appropriate product to the user. Unfortunately in some cases, this product can become too much specific and adapted only to one user, not to a whole of users. For these reasons and to avoid the case of a too specific tool, we will discuss in the next section, the proposal to experiment the Scenario-Based Design methodology.

III. Towards the creation of scenarios

Many papers deal with the advantages of the Scenario-Based Design (SBD) and with the way of creating scenarios [11] [12] [13]. In SBD, descriptions of situations become more than just orienting examples and background data, they become first-class design objects. Scenario-based design takes literally the adage that a tool is what people can do with it — the consequences it has for them and for their activities that use it.

In SBD, scenarios of established work practice are constructed. Each scenario depicts actors, goals, supporting tools and other artefacts, and a sequence of thoughts, actions, and events, through which goals are achieved, transformed, obstructed, and/or abandoned. The scenarios are iteratively analyzed, revised, and refined.

Two types of scenarios in the design process are proposed in [14]: the first, high-level *day-in-the-life scenarios* are used to map the typical sets of usage patterns and behaviours of the key personas by developing a narrative that describes their use of the product or service. These scenarios, which are created iteratively, bridge the gap between user goals and user tasks by exploring minimal sets of steps necessary to achieve particular goals.

The second type of scenario is the *key path scenario*. Key path scenarios employ concept sketches and storyboards that explore the structural and navigational paradigms of the design in sufficient detail to validate the coherence of the design for all major interactions. When the key path scenario has been iterated to the point of coherence, it can be used as the basis of a *communication scenario* which is used to communicate the design to recipients of the design.

However, *Bordeleau and al.* explain that, to the best of their knowledge, there exists no patterns that address the difficult problem of integrating a set of possibly concurrent and interacting scenarios into a set of component behaviours [15]. They describe one of the several behaviour integration patterns they have identified to help designers define communicating hierarchical state machines from scenario models.

More specifically in the medical domain, the subject of the study made by *Sawyer* [16] is the impact of design upon safe and effective use of medical devices. Errors in the use of such devices often are caused, at least in part, by the design of the user interface, i.e., those features with which healthcare practitioners and lay users interact. Mistakes made during device operation not only can hamper effective patient treatment, monitoring, or diagnosis but in some cases can lead to injury or death. It is important that medical devices be designed with consideration of the impact of design on safe use. This study discusses human factors problems, general design principles, and human factors engineering methods and uses examples and illustrations for clarification.

In the second section, we have detailed the PD methodology. It allows designers to create new tools and devices with user participation during all the primary phases of the design process. Secondly, the introduction to the SBD shows us the significance of such experimentation. Prototypes simulate the user interface, they are used to select alternative designs and uncover problems. Written scenarios help provide the structure for what test participants actually will do. In all cases, scenarios have to be clearly written to help ensure consistency across participants and test conditions. Healthcare professionals are the ones that can provide scenarios and check them for realism and accuracy [17].

In the section below, we will first detail the SBD methodology in the medical context, than, we will introduce the surgical domain we are working on and the methodology used with the user to express its needs.

IV. The surgical application domain and the usage of the surgeon

A. The proposed design procedure

In the current study about the design of new surgical tools using the SBD methodology, we propose the following simplified diagram as our general design procedure (figure 1).

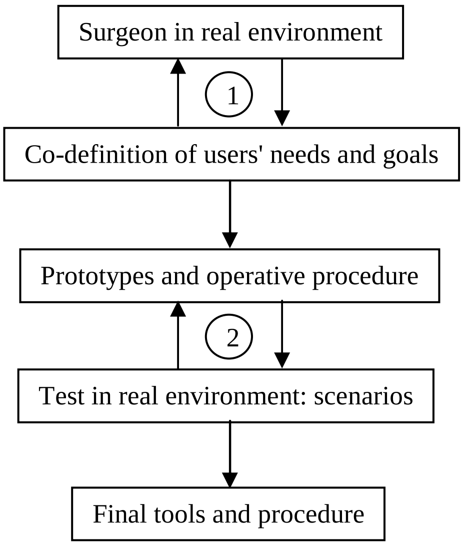

Fig. 1. Diagram of the new design methodology in the surgical domain

This strategy begins from the observation of the surgeon in its real environment. The loop numbered 1 is explained in the next section and allows a better definition of the client needs and goals by its integration in this stage. The second loop concerns the design and the test of prototypes during scenario. This specific work of creating and playing scenario will be describe later

B. The surgical application domain

Our aim is to apply the PD methodology in the surgical domain, to propose new surgical tools adapted to the requirement of MIS.

For the detection and the analysis of the surgeon needs, we have to understand the surgical operation, the goals and use of the target user in its real environment.

In the specific surgical application studied, a particular lumbar fracture is caused by 50% of the serious sport accidents (falls of motorbike, ski, parapet, etc.). Currently, the "classical" lumbar arthrodesis operation (placed an implant on the L1 vertebra) is carried out by tools introduced against the patient's back through a 25cm large incision. It is a heavy surgical operation consisting in reforming the vertebra fractured, while having beforehand repositioned the adjacent vertebrae with their origin positions - the post operative consequences are very handicapping.

Following this observation, the surgeon has explained his need concerning the use of minimally invasive surgical tools.

Fig. 2. Picture of the implant placed on the lumbar vertebra of the patient

C. First step of the PD methodology: the surgical needs

Videos, pictures, discussions with user, observations, and classifications of the information have been done to collect and to appreciate the usage of the surgeon [18]. Specific diagrams of the current operative procedure, with picture of all the surgical tools used, have been proposed and discussed with the specialist.

Through this first step (loop 1 in the figure 1), it has been possible for us to discuss with an appropriate language and to better understand the goals of the user: "new surgical tools adapted to the requirement of MIS" means "new surgical tools and a new operative procedure adapted to these tools". Indeed, placing an implant on the spinal column by multiple little holes requires another approach than placing it by making a 25cm large incision. This approach actually doesn't exist and the designer has to imagine it (with the user) with consideration of the entire surgical environment.

Using SBD methodology is then the only one possibility to test this operative procedure and the associated surgical tools.

In the next sections, we explain our choices concerning the application of this SBD strategy with the surgeon. The installation of a scenario needs lots of preparation especially in the medical domain.

V. Proposition of a Scenario-Based Design procedure in the surgical domain

The second loop of the diagram proposed in figure 2 concerns the test of prototypes and operative procedure in real environment. Prototypes simulate the user interface, they are used to select alternative designs and uncover problems [16]. A prototype's fidelity, or resemblance to a working device, is determined by its physical and/or conceptual attributes. If installation, control and display layout, or manual operation (e.g., of surgical tools) are of special interest, mock-ups should be used for physical simulations, or "playing". Users can perform the procedural steps to confirm or repudiate the design or layout details.

A. The design of prototype and associated operative procedure

As we have explained in the *Section IV.C.*, some specific diagrams of the current operative procedure have been written in collaboration with the user. Starting from this diagram, we have identified specific heavy surgical acts where the surgeon uses "classical" surgical tools. This operative part of the complete operative procedure must be modified and adapted to the new surgical tools proposed.

Currently, implant represented in figure 3 is set up through a 25cm large incision. That is why the main stem can be "easily" inserted in the three screw heads.

Fig. 3. Picture of on part of the current implant placed on the lumbar vertebra of the patient

In MIS, the multiple holes don't allow this "simple" action. In agreement with the surgeon, it has been decided to design a prototype inspired from another surgical tool used from femur fracture. It consists of an L-shape tool the surgeon can easily hold in one hand (figure 4). The tip of this tool represents the stem which must cross the three screw heads.

The associate operative procedure is thought from the realisation of the holes to the final placement of the implant on the vertebrae.

The difficulty resides in the fact that there is no visibility inside the human body during all this new established operative procedure. The precise placement of the holes (located compared to the vertebrae) depends of the knowledge and the experience of the surgeon. The delicate insertion of the screws through the skin, muscles and grease, without damages caused to the patient, requires the design of complementary surgical tools.

Fig. 4. Picture of the first surgical tool prototype

B. Scenario preparation

Healthcare professionals are the ones that can provide scenarios and checking them for realism and accuracy.

The surgical tools must be tested under conditions that are as realistic as possible.

Depending on resources and the nature of the test, a modest usability laboratory may suffice. A limited facility might consist of a room containing a table, chairs, electrical outlets, and adequate lighting. An increasingly elaborate setup would include a one-way mirror, observation room, video camera(s), adjustable lighting, tape player for noise presentation, an automated data-logging system, a microphone, and other medical equipment. Finally, testing in medical facilities is another possibility but participants should be reminded that it is the device, not themselves, being tested.

In the case of small, iterative, prototype evaluations conducted throughout development, two or three participants per test may be sufficient [16]. Employees such as clinical staff may be used, although repeated use of the same individuals can bias the findings. Full usability tests require larger samples drawn directly from the user population. If a device is intended for a fairly homogenous population, data obtained with about 10 individuals' representative of that population may be sufficient to eliminate most problems.

To write a scenario, it is necessary to describe in a simple language the interaction which needs installation. It is important to put of references to technology, except when technology represents a constraint of design which must be represented [12]. It is thus always necessary to have the scenario read again by a user to be sure that it is representative of the real world in which he evolves.

In agreement with the surgeon, we have decided to begin the scenario at a certain stage of the new established operational procedure. Then the scenario makes it possible to mainly test the prototype of tool proposed (figure 4).

The decision of SBD and the specific scenario implies a particular preparation of a mannequin which represents the patient. Due to this specific surgical operation, the mannequin must integrate a fractured column and due to the scenario prepared, the surgeon has to preliminary placed three screws in three vertebral pedicles (figure 5).

To recover a maximum of information at the end of 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 and record its remarks.

Fig. 5. Preliminary placement of three screws in vertebral pedicles by the surgeon

C. Course of the scenario

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. He could use the radiographic images to see the prototype in the mannequin (3D location and orientation). In figure 6, the surgeon is manipulating the prototype and looking at its photographic images in the monitor.

D. Results analysis and improvement of the scenario condition

Thanks to the information collection equipment installed in the operating room, a large part of the work consists in organising and analyzing the recovered data. Several improvements were considered, mainly starting from the films and the speech recorded during the scenario.

Fig. 6. Surgeon manipulates the prototype during the scenario

This scenario informs us about the user manipulations of the prototype. As a result of this experiment, it is possible to observe how the surgeon apprehends and handle the surgical tool compared to the comments he had before the experimented scenario.

Thus, by using *The Observer XT* software [18] with the video films recorded, it is possible to classify all the events by the definitions of *subjects*, *actions* and *modifiers*. It is clear that the configuration of this software is directly in link with the scenario proposed and the objectives wanted. Tanks to this analysis, it is for example possible to isolate all the sequences where the surgeon is using the prototype while he is watching on the monitor.

Following this first scenario, we can underline parameters to be modified to make it more effective:

- the positions of the video cameras and the micro tie are relatively optimum and will be certainly the same for the next scenarios,
- we detect (based on a qualitative assessment) bad choices of materials for the design of the mannequin, in particular with regard to the matter representing the muscles in the back of the patient,

- the designed tool is compatible with the guidance equipment used during the surgical operations (radiographies for 3D location and orientation),
- the first designed prototype meets the principal needs expressed by the user, but it has to be more finished and used in complement with other tools for the future scenarios proposed,
- finally, a more precise scenario and more targeted on a specific action of the user will enable us to refine our research on a particular requirement of the surgeon.

V. Conclusion

In this study, our aim is to improve the process design with a better integration of the user. The research concerning "Participatory Design" and "Scenario-Based Design" show us the advantage of these methodologies.

Many authors in the literature explain that PD proposes to associate the users in the design process, as soon as possible in the beginning of the project, with the principle that they know what they need, but that they can also have innovative ideas.

SBD methodology is defining by a person who makes things in a certain context. Using scenarios during design ensure that all participants understand and agree to the design parameters, and to specify exactly what interactions the system must support.

The first step of our study was to identify the needs and the goals of the surgeon. Due to observations in its real environment and discussions with users, the conclusion was the design of "new surgical tools adapted to the requirement of MIS associated with a new operative procedure adapted to these tools".

Currently, the experimental part of our study is placed in the second loop of the figure 1, concerning the improvement of the prototype proposed with the help of the scenarios developed. *The Observer XT* software will allow us to better understand how the user expresses his needs and his reaction concerning the use of the prototype during the scenarios.

The future work concerns more specifically the observation of the current design process in the industry. Then, it consists in a more precise analysis of the actors' chain and the tools which support the communication and needs expressions.

This analysis will allow the evaluation of the risks and the reasons of the differences between the surgeon needs and what the tools currently uoffer. It will be possible to propose methods, tools and a new process organisation only after identifications of the actors and their rules.

Questions concerning methods, tools and organisation supporting the process design will be explored to support the expression of this need with the aim of increasing the point of view of the surgeon during the design of the tools by integrating the UCD and the SBD methodologies.

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