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EDUCATION IN HEALTHCARE ENGINEERING: LEARN FROM, COLLABORATE WITH AND DESIGN FOR AN EXPERT USER

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ABSTRACT

Students in engineering design courses need to appreciate the need to consider user requirement early in the design phase of a project. In case of design for healthcare or medical products, they need to learn how to translate the medical needs to engineering requirements list, and to find out solutions which fit the medical usage environment. There are few organised program on Medical Engineering in Europe, and because of students background only in engineering, the major part of courses is dedicated to medical introduction such as Anatomy and Patient Safety. Considering the importance of user integration in the design process of such products, an organised structure is required to provide the opportunity to deal with the medical user for the students. In this paper, after reviewing two last related experiences, we propose a project structure for healthcare engineering in Master program of Industrial Engineering.

KEYWORDS

User integration, scenario-based approach, medical product, course design

1. INTRODUCTION

Although the education in medical engineering in European countries has been recently promoted, there already exist many courses, programs and even special departments training students for medical engineering. This kind of education, alternatively called Bioengineering and Biomedical Engineering, is a multi-disciplinary subject integrating professional engineering activities with a basic medical knowledge of the human body and an understanding of how it functions when healthy, diseased or injured. Many of the advances in this field now support medical treatments and surgical operations such as: hip replacements, pacemakers, medical imaging, and medical lasers. The courses in medical engineering generally consist of electrical

and mechanical design engineers working on projects ranging from equipment for disabled people to professional tools for surgery. The aim is to take an initial idea and turn in into a finished product. The future career of medical engineers is in the healthcare industry, the world's biggest industrial sector, which has a turnover approaching €120 billion per year and is currently growing at a rate of 7% per year. The opportunities for medical engineering graduates are enormous and because it is one of the few areas of engineering that is expected to continue to grow for many years, the demand from student for the education in this field obviously increases.

The design methodology in medical engineering is different from mechanical engineering and,

accordingly, the design practices used for mechanical design are not totally suitable for medical design. Since there is no reference or widely accepted design model, the subject is open to discussion. Thus, each institute provides its own teachers' knowledge and experiences to ensure all successful designs are made available to whoever can benefit. Direct links with local hospitals and, preferably, a medical school are essential if the course is to be truly practical and to get some clinical experience. These links, an invaluable resource for the end-of-year projects, are good practices for requirements understanding, collaboration with users and design validation which are more closely associated with the design methodology than a particular clinical problem.

In the authors' former publication, the design of medical products is augmented by including a coevolution of the design artifact and medical usage. In this article, we discuss some pedagogic elements of a desired course in medical engineering and review some experiences of such programs in one Dutch and one French university. Finally, we propose a new course for design of healthcare products.

2. EDUCATION AND DESIGN METHODOLOGY

Different approaches trying to find the optimum way to design medical instruments were proposed in the literature. To compromise the medical and technical requirements, a design method should firstly provide the environment of collaboration of different actors from different domains, and secondly, should provide some design tools to help the designers manage the development process. In this session we will review three main propositions of design methodology in the medical application which we used for our pedagogic course model. Nevertheless, a design methodology itself is not the subject of such a course, and obviously can not be taught in a single semester course. But, these methodologies are a good source to inspire an interactive program.

2.1 Clinically driven approach

Stassen (1997) distinguished between two approaches: Technology driven and clinically driven. In a technology driven approach, on the request of a medical professional or based on a bright idea of an engineer, a new instrument or system is developed. A clinically driven approach starts with the identification and definition of an existing problem in the medical environment, and aims to find a practical solution for that problem. In

the clinically driven approach, the observation of the problem situation (for example a surgery) and discussion with the user (surgeon or physician) are important. The user's activities during and after the instrument usage are discussed to detect fundamental problems and limitations occurring during the process. In this way, the functional specifications for an instrument or system can be defined.

During the entire process of defining functional specifications, the development and design of a prototype, the technical evaluation, the functional laboratory evaluation, the clinical animal experiments by the experimental doctors, the development of a series of clinical prototypes, the clinical evaluation, and finally, the design of the industrial prototype, medical input should be included.

The clinically driven approach is followed by many researchers in surgery (Dankelman *et al.* 2005). Many experiences have shown that engineers and surgeons should cooperate closely to analyze the peroperative process and to translate the clinical problems into design specifications. This translation is necessary because the clinical problems experienced and indicated by the surgeon do not automatically point to the underlying technological deficiencies (Breedveld *et al.* 1999). So, a multidisciplinary cooperation must overcome differences both in language and in discipline.

2.2 Use of scenario

Use of scenarios is mainly discussed in Human Computer Interaction and software development. Recently, scenarios have been used in the design of medical systems to deal with user activities and work situation of clinicians and surgeons. Researchers used scenarios to build a task based workflow of what the actors should be doing. Literature shows that scenarios are also used as a design tool to describe the work situation. Thomann (2007) used a scenario based approach to understand and define the requirements of surgeons for a new instrument design. In (Rasoulifar *et al.* 2009), use of scenarios in research on surgical instruments is divided into two concepts: scenario as a surgical operation procedure, and scenario as mechanical tasks for a new instrument.

Using a scenario based approach helps the designer provide a written detailed description of the desired task and the usage situation. This issue has an important impact on the design progression due to miscommunication problems between medical and engineering actors, and due to the existing tacit knowledge of both actors.

Scenario is widely used in design education, particularly in industrial design (Carroll 1995). In medical applications, scenario is a tool for clarifying the interaction between user, design artifact and the environment. Designers use scenarios to foresee all the possible happenings, and to direct the desired task.

2.3 Emulation and validation with surgeons

As briefly mentioned in the introduction, former studies of the authors proposed the design process of medical instruments as a coevolution of the new instrument and the new usage (Rasoulifar *et al.* 2007). Accordingly, this methodology proposes a step called emulation, in which the medical user examines the prototype in a realistic environment. This step, emulation, shows whether or not the prototype satisfies the user's needs. There are many reasons why user dissatisfaction happens, like malfunctions, ergonomic difficulty, etc. The cause could be the design, or the incomplete medical requirements definition. The sooner the instrument is tested, the easier it is to modify.

To organize an emulation, a scenario is needed. In the scenario, the description of the following elements is provided: the working prototype, the usage, the test situation and the observation. By analyzing an emulation the designer can extract the information needed for developing the next prototype, as well as for modifying the test situation or the observations.

The main idea of user integration in the design process exists in these three methods; while the clinically driven approach emphasizes problem identification with medical doctors, the scenario-based approach proposes some tools to formalize the usage situation and emulation provides describes the expert user validation environment during the design progression. In the following session, ideas from the literature and years in the medical design field are put together to create a medical design so students can learn how to understand user needs, how to provide solutions and how to evaluate their propositions.

3. LEARN, COLLABORATE AND DESIGN

To build a course program which contains the discussed design process elements and characteristics, the program promoter should provide a series of activities to direct students. Accordingly a good program needs an organization such as a relationship with a hospital, access to medical databases and so on. Here we review two

examples of such programs, from different departments with different foci, one from a French university and one from a Dutch university.

3.1 Surgical Instrument and Medical Safety

In the course titled Surgical Instruments and Medical Safety, held for masters students of Biomedical Engineering at Delft Technical University, for a few years in the beginning student were asked to find a subject related to surgery and patient safety, research it and prepare an oral presentation introducing the subject, functions and problems. The goal of this course is not to teach technical design principals, nor to design a surgical instrument. The aim is to teach the principal instruments (catheter, endoscope, etc) and procedures (like electro-surgery) of surgery, to enable the students' understanding of the work situation and the requirements of medical environment, and to encourage them to find technical solutions for the medical requirements.

Reviewing a five-year period of these courses' assignments, the organizer realized that less than half the studies were focused on a surgical instrument while the others were about interventions, and surgical room facilities. Although the projects were good enough from a technical point-of-view, the design aspect was missing. Unfortunately, less than 10 percent of projects went into detail about a user problem.

Last year, the students were asked to find a surgical or clinical problem, and submit a description of the problem with references before starting the project. Then, if the proposal was approved, they were asked to find the solutions in the literature and make a presentation and report on that. They were encouraged to contact medical partners, visit a hospital and provide some clinical evidence. As a result, 80 percent of projects came up with a detailed problem and 40 percent had medical contacts and did observations. Moreover, students were more motivated to discover a problem and design technical solutions.

After last year's positive outcome, this year the course assignment was modified again to better meet the design goals. Students were asked to do a three-part project: First, find a medical user (surgeon, physician, nurse...) and define a problem with him/her considering the work environmental characteristics. Second, translate the requirements to a technical abstract and look for the existing solutions. In the third part, they should go back to their user and evaluate their findings with him/ her.

In this assignment we tried to provide the situation in which students can see the problem from the

surgeon's point of view. According to the clinically driven approach, the problem definition should not be limited to the engineering desire. For this reason, this course provides the opportunity for students to find a medical problem based on the medical user's explanation. A final presentation and report are required for this course and are used to evaluate the students' ability to understand the problem, research sources for solutions and validate their final result with their user.

3.2 AE2M: Music for handicapped children

In one of the institutes specifically for handicapped children in Grenoble, France, a music teacher observed that some children had a significant response to music, and were even motivated to play. But, because of their physical limitations, these children could not use the typical instruments. This context inspired the idea for the AE2M project for engineering students (<http://projetae2m.free.fr/>) in which the goal was to develop practical solutions for to enable handicapped children to play common instruments. The project started three years ago and each year, groups of students start to work on new cases.



Figure 1 – AE2M Project; students evaluating their designed prototype by the usage of their handicapped user.

This multidisciplinary project (musical, ergonomics, social and technical aspects) tries to place engineering students in the context of reality, teach them to deal with numerous user specifications and design constraints. The students are supposed to observe the usage situation and to understand the requirements. Then they design a concept for the eventual solution and proceed to make a prototype of their solution. This step is very important because the only way to validate the design for such special users is to observe them during use and make sure that they can operate the artifact.

Although the final users in this project are disabled children, the project progresses under the supervision of a specialist physician in order to guide the medical aspects of the design. The solution, however, is an instrument for to treat disabled children and is a medical product.

4. TOWARD A SCENARIO-BASED USER INTEGRATED EDUCATION

Students in medical engineering design courses need to appreciate the need to consider user requirement early in the design phase of a project. They need to learn how to translate the medical needs to engineering requirements list, and to find out solutions which fit the medical usage environment. Medical engineering students are from different engineering background and rarely familiar with design approaches. The particular courses in instrument design could not spend enough time on this subject, so the only chance for the students to follow a given approach for their assignment.

Table 1 present a comparison between two experiments explained in the previous session. In the last column, the user integration in the process is shown. For the SIMS course, the user integration means the communication between students in designer role and surgeon

Inspiring from the concept of user integration in the design process, we designed a course of Design for healthcare for the master students in industrial engineering, University of Grenoble. In this course, student are supposed to follow a scenario-based approach to understand a medical user needs, then they should design a concept followed by a prototype and finally make their design artefact evaluated by their user in an emulation. Figure 3 shows the schematic of this project.

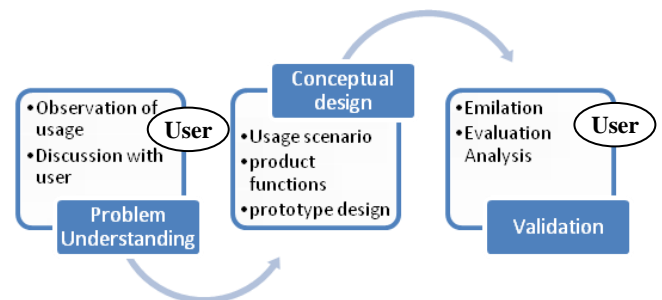


Figure 2 – Three steps of course projects for the master student of Industrial Engineering.

Table 1 - Comparison between two courses, the design steps and the user integration

	Problem definition		Design		Validation	User integration
	Understanding	Formalization	Looking for solution	Design a prototype		
SIMS	Discussion with surgeons	Themselves	Specified Literature	No	Only Conceptual	Problem definition Concept validation
AE2M	Observation the children	With supervisor	General	Yes, more than once	Emulation	Observation Validation in emulation

To support this idea, an agreement made with two surgeons of the Hospital of Grenoble, to participate in the course. After reviewing some theoretical issues in the course, the student will go to observe a common medical situation in the hospital. The observation would followed by some discussions in order to clarify the problem. In this step, each group of students will focus on a specific problem. In the next step, they create a usage scenario in which they decided to propose a new solution. The new solution passed through the idea and concept to a prototype. By the support of the university each group make a physical prototype for the emulation. In the third step, the validation, a usage environment similar to the medical situation will be set-up in order to test the prototypes. In this step the surgeon will test the prototype to evaluate their main functions. Finally, students are supposed to make an analysis of the evaluation. Although this three steps complete the course, besides there is the opportunity for students who would like to develop their design and work on the detail design and specific medical constrains.

To our knowledge this is the first initiative in industrial design engineering to provide the close contact with the medical user and to follow a scenario-based user integrated design approach for students.

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