Scenario based user centred design process: application on innovative surgical instruments design for Minimally Invasive

Rahi Rasoulifar

UNIVERSITÉ JOSEPH FOURIER – GRENOBLE

T H È S E

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Processus de conception centé utilisateur à base de scenario : application à la conception d'instruments chirurgicaux innovants en chirurgie mini-invasive

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Abstract

This PhD research is a contribution to the design process of innovative surgical instruments, particularly for minimally invasive surgery (MIS) for which the collaboration of surgeons and engineers is inevitable. Reviewing the literature shows that there is a gap between what surgeons need and what the engineers design. An approach to fill this gap is to build a design process which enables surgeons and engineers to work together, or in other words, enables the designer to integrate the surgeon in the design process. Taking the action research as the research method, this thesis went through the action of a 2-year design project of an MIS instrument, Protige, and observed and captured the experiment. The analyses of the corpus of observation showed new aspects of design process: the coevolution of product and usage during the process, and the role of the expert user in the design progression. These results led to propose new descriptions of design process, such as emulation step and expert-UCD, and provided bases for proposing a descriptive design process model for innovative surgical instruments. The validity of the proposed model was examined by applying to another MIS instrument design, and an informatic structure was proposed as a support for the process model.

Résumé

Cette thèse est une contribution au développement du processus de conception d'instruments chirurgicaux innovants, plus particulièrement pour la conception d'instruments dans le domaine de la chirurgie minimalement invasive pour lesquels la collaboration du chirurgien et de l'ingénieur est indispensable. L'objet de recherche de cette thèse est de mieux connaître la pratique de conception dans ce domaine particulier dans le but de proposer un modèle amélioré de processus de conception. L'étude bibliographique montre l'écart important entre l'approche médicale (validation clinique) et l'approche de l'ingénierie (conception innovante). Pour combler cet écart, un moyen peut être la mise en place de nouvelles méthodes de conception permettant une étroite collaboration entre l'ingénieur et le chirurgien. Dans ce contexte, il s'agit de trouver un équilibre entre les méthodes d'ingénieries pures et les méthodes centrées utilisateurs.

Nous basant sur la recherche-action comme méthode de recherche de ce travail, nous nous sommes lancés dans l'action de conception d'un instrument chirurgical innovant, le projet Protige, afin d'observer et de capturer cette expérimentation. Les différentes analyses du corpus de ce projet nous ont aidés à découvrir et identifier de nouveaux aspects du processus de conception, comme la coévolution du produit et de l'usage et le rôle de l'utilisateur expert dans le processus. Finalement, nous avons proposé une modélisations descriptive de processus de conception, incluant les concepts d'émulation et de Conception Centrée Utilisateur Expert (Expert-UCD) pour ensuite formaliser une méthode prescriptive de processus de conception pour les instruments chirurgicaux innovants. Ce modèle a été éprouvé sur un nouveau cas de conception d'un instrument pour la chirurgie minimalement invasive. Une architecture informatique a été proposée comme support de cette proposition de modèle.

Jenny Dankelman, Guillaume Thomann, Jérôme Tonetti, François Villeneuve, Jean-François Petiot, Rahi Rasoulifar, Jean Caelen, Alain Di-Donato, Brigitte Meillon

2/12/2009 - Grenoble INP

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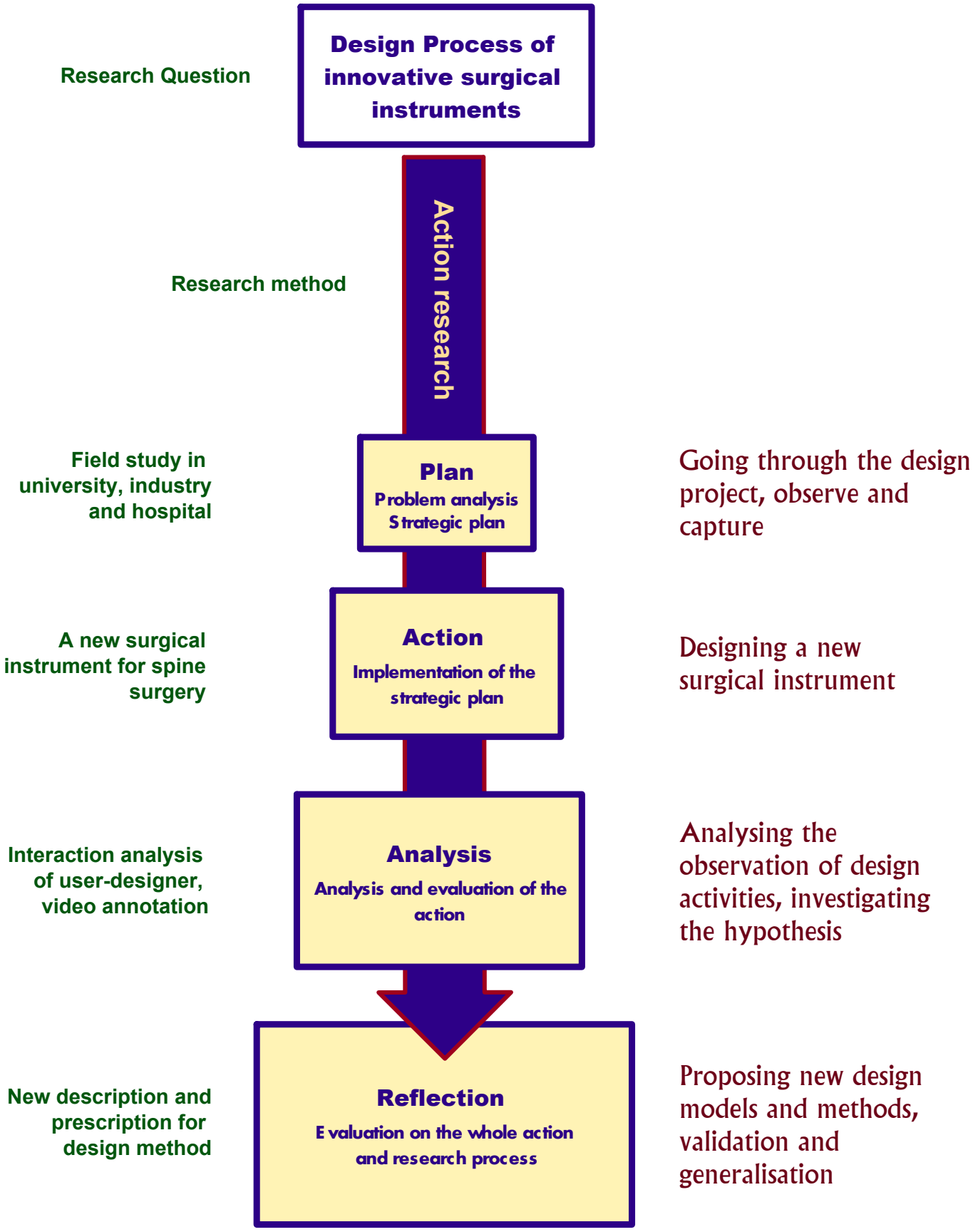
Et enfin, à ma sœur et mes parents, pour le bonheur et l'énergie qu'ils me donnent chaque jour.


Research Question
Design Process of innovative surgical instruments
Research method
Action research
Field study in university, industry and hospital
Plan
Problem analysis
Strategic plan
Going through the design project, observe and capture
A new surgical instrument for spine surgery
Action
Implementation of the strategic plan
Designing a new surgical instrument
Interaction analysis of user-designer, video annotation
Analysis
Analysis and evaluation of the action
Analysing the observation of design activities, investigating the hypothesis
New description and prescription for design method
Reflection
Evaluation on the whole action and research process
Proposing new design models and methods, validation and generalisation

A note to the reader

Before beginning to read the dissertation, I would like to mention some points to the reader. I shall start with the scientific comments:

1. The main line of this report can be simplified to: a bibliographic review on how new surgical instruments are designed (chapter 1), what design approach may serve the design of innovative surgical instruments (chapter 2), my research approach (action research) and how I participated in action of design (chapter 3), observation and analysis of the design experience in order to locate design phenomena (chapter 4), and finally the reflections on action, and propositions for design process of surgical instruments (chapter 5).

2. Some claims and some hypothesis have been made, which are better to be clarified from the beginning: First, innovation in surgery has two approaches: medical (clinical validation in trials) and engineering (innovative design). These two approaches need to become closer, in order to provide the possibility of designing new instruments which enable new (and better) surgeries. The review of chapter 1 shows such a methodology does not exist in the literature. Chapter 2 shows in the design sciences, engineering design methods do not concern the user integration, and user-centred approaches are far from formalization design tasks for design a mechanical product. Though, the demanded design method should be situated between, and has both aspects of engineering design and user-centred design approaches.

3. In this dissertation, the difference between *research method*, and *design method* is defined as follows: my research approach, action research, is how I carry out my study to find the answer of my problematic. In chapter 3 this choice is explained and later in general conclusion is justified. On the other hand, the design method in this dissertation is the method for design of surgical instruments, proposed in chapter 3 as a first draft, and later being used in the experiment. The analyses and reflection on this method brings the discussion first to describe in detail the design phenomena, and then to propose a prescriptive model for the design process of surgical instrument, in chapter 5.

4. “Emulation” is a word that I employed in this dissertation in order to describe the situation in which the user has the physical prototype in his hand and manipulates it, following a usage scenario, to validate the functionality of the solution. What makes the difference between simulation and emulation is the very existing of the physical prototype, and the usage environment. Examples of emulation are given in chapter 3, and conceptualization of such a moment in design process is explained in chapter 5.

5. *Annotation* is a technique used for data analysis, and I did use this technique for adding data to video stream which I had captured from observation in operating room and design meetings. Annotation includes building a framework, adding data and visualisation of the results. This process can be done using video annotation software. I used a video annotation software to annotate the captured data for further analysis. The annotation and analyses is the subject of whole chapter 4. Since the subject of analysis is the design

activity, this subject is also explained in that chapter.

6. This thesis ends with some propositions for design process, in chapter 5. These propositions are divided into two parts: *descriptive* and *prescriptive*. In descriptive part, I propose two descriptions for the design process, coevolution of product-usage, and expert user integration. At the same place I rediscuss the emulation step. Then, based on these perceptions, I propose a *prescriptive model*, that can help the design process of innovative surgical instruments. *Extended Scenario* is a tool proposed in this model to prepare and manage emulation steps. This model is validated by being examined in design of another surgical instrument. An informatic structure is also proposed to support the design process model.

Besides, there are some general remarks, I would like to make. This thesis is a subject of design research study, however, because of the strong application in surgical innovation as a typical user involvement design, it goes through the medical and surgical issues, which have their own vocabulary and semantic. I tried not to leave out any unfamiliar words without some short explanation, either in the text or in the Glossary. Moreover, despite of two chapters of literature review, I included new subjects in chapter 4, such as design activity analysis as the employed analyze method, which in my opinion needed to be supported by literature references. For this reason I provided some concise bibliographic notes in footnotes.

I propose the reader to use also the electronic version (pdf file), because of the simplicity of the navigation, and the access to the cross references (Tables, Figures, references, sections, etc.) just by clicking. In Bibliographic section, at the end of the dissertation, the numbers at the end of each reference indicate the page(s) at which the entry has been referred.

And finally, English is not the mother tongue of the author, neither is for his PhD supervisors. Being a French PhD candidate, it has been already a challenge to write the dissertation in English and much effort was put to prepare an understandable document. So, please feel free to report any discomfort due to the language to the author; your comments are more than welcome.

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Literature Review
State of the art

Chapter 1

Innovative Surgical Instruments Design

Chapter 2

Design methods and models

Action research

Chapter 3

Action of research: Protige design project

Plan

Action

Chapter 4

Exploring design phenomena:
Observation and analysis

Analysis

Chapter 5

Propositions for the design
process of surgical instruments

Reflection

This PhD's contribution

- New description of the design process
- A prescription model for the design process
- Model validation by application case

Product - usage coevolution

Emulation

Extended Scenario

Expert UCD

Introduction

In this evolving society of design innovation and application, I have enjoyed three years of doing my PhD, studying the concept of design, the design methods, and the design application in surgical innovation. Without getting any complexity, I tend to define design as Simon (1969) did "Courses of action aimed at changing existing situations into preferred ones". The surgical innovation involves any attempt that brings a better cure and care for patients.

From the beginning, the objective of my PhD was to investigate the design process of surgical instruments, particularly those who enable surgeons to perform new operations. I was not supposed to design a surgical instrument, neither to help particular surgeons making the order of what they need for new operation to the engineers. I was supposed to study, observe, and understand the design process of surgical instruments. Accordingly, one aim of my PhD study was to describe the design activity in this domain, and if possible, contribute to ameliorate the existing methods and practices.

For a PhD - practice-based or classical - one expects to answer a question, interpret or challenge prior knowledge, or in some way make an "original" contribution to the knowledge of the field. How else might we do this than through some form of organized inquiry? And how might we present what we develop, discover, or learn other than through some kind of logical structure?

Since the beginning, I had two parallel tasks to do: studying design research, and being in the action of designing. The first task brought me to understand how the design science was constructed, and how the design researchers discover the design phenomena and publish their results. The second task was an amazing experience of working with surgeons, observing the design progressions for satisfying the clinical needs, and accordingly, was an opening to the new world in which design and innovation had a whole new meaning.

In my view of a young design researcher, a design PhD remained primarily a training to become a researcher, someone with a broad knowledge of research methods, a knowledge of how to apply which methods under what conditions, and the ability to do all this independently. PhD seemed a process of learning by doing research practically.

But, there was an issue that made my PhD study different from a "normal" research practice. By the end of the first year, I came up with the question of whether the practice of designing can be a part of a PhD process. Until then, I had two clearly separated images of design studies. First, studies which propose a new solution, help, or guide to design an artifact. These studies were dealing with the action of design, no matter the field, and classically addressed the problems and proposed the new solutions. Nonetheless, I was hardly occupied by this kind of research in the domain of minimally invasive surgery. The second group was the studies which investigate how the design progress, what the

relations between actors are, which trends in design discussions are, etc. This notion was very interesting for me, because I have already started to observe and analyze what was happening in the practice of surgical instruments design, looking forward to understanding why things happen. Yet, it was not clear for me what my research methodology was.

In this sense, I had accepted that several kinds of research methods regrouped under the title of case study were meaning to help my PhD research. This idea encouraged me to extend my research domain to visiting hospitals, discussing with surgeons, interviewing surgical instruments industries, and finally a scientific visit abroad, in a group of minimally invasive surgical instruments designers. These efforts put together my knowledge about the research on design process of surgical instruments.

In this direction, I found the convenient research approach: research through design. This concept known also as action research, proposes a cycle of plan, action, observation and reflection. I found this approach suitable to what I needed to do for my research. I planned my research, went through the design of a surgical instrument in collaboration with surgeons, observed the experiment and finally reflected on the process of design and research. Let's see how all these can be written in a scientific manner; in a PhD thesis.

This dissertation begins with the questioning about the design and innovation of surgical instruments. Chapter 1 proposes the state of the art in design of innovative surgical instruments, particularly the minimally invasive surgical instruments. The reason of this choice, as it will be explained, is that this subject brings together the innovation in technology, and the innovation in surgical operation technique. First chapter ends with the claim that in the literature, there is no design methodology dealing with both engineering and medical aspects of innovative surgery.

My objective was to describe the design process, thus I needed to define what the design is, and what design processes are created for. Moreover, it was important to see whether the design literature can propose an appropriate method for the problematic of surgical instruments design. This is the subject of chapter 2. I performed a review on design definitions, methods and models. This chapter concludes with the proposition I made for a hybrid process model, which puts together some approaches from the literature, in order to point out the position of the desirable method of surgical instruments design.

The next step was action research. Chapter 3 starts with discussing about the action research method, and why this method can be useful for my study. Then the plan is explained: I am going through the design of a surgical instrument for minimally invasive spine surgery, in collaboration with the Hospital of Grenoble. The instrument is called Protige and it was originally defined as one of the undergoing projects in research program called DESTIN[1]. Afterwards the action of design, the Protige project is explained in details, from the idea to the final prototype, and clinical validation. Protige was a successful design experience, and the instrument was patented in the spring of this year.

[1] DEsign for Surgical and Technological INnovation

The action is done, the analysis is up. Different kinds of data acquired from the Protige experiment are explained in chapter 4, particularly the design evaluation meetings and surgeon validation in the operating room, so called *emulation*. This chapter also introduces my analytical framework for design evaluations and then shows the results of different analyses on the experiment corpus. This chapter comes up with interesting results supporting the importance of expert user integration in the design process, and the dual nature of the design artifact: product and usage.

Thereby the chapter 5 is the moment of reflecting on the design action and on the research approach. My reflection on the design process is explained in two sections: descriptive models and prescriptive models for the design process. Therefore, I discussed the validation challenge, and explained the application of the proposed method into an MIS instrument. Then, my research ends with bringing the subject to develop software tools based on new proposed methodology in order to help designers in this context. A proposition for a structure in informatic for such a tool is the last issue in this last chapter.

Having necessary reflects on the design action, in the conclusion of this dissertation I return to the action research method, and evaluate this method according to my experience. Accordingly, some modifications on action research approach are proposed.

Chapter 1

Innovative Surgical Instruments Design

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In this chapter you will find :

- *How the innovation and the design are defined and being used in surgical community literature*
- *What Minimally Invasive Surgery is, and why it is an important innovation*
- *How new surgical instruments have been designed, according to the scientific publications*
- *If there is any methodology for designing the new surgical instruments*

1.1 Introduction

The story of surgical instruments goes back to long time ago, when surgeons made their instruments by themselves. This is one of the most basic characteristics of surgeons: they invent a wide range of techniques, tools and other artifacts[1] to suit their purposes. The technology improves, surgeons reflect on the currently available facilities, such refinements are made to create and use the new artifacts, and different kinds of improvements are conceived and made.

Over the last two decades, surgery faced a fundamental evolution: the surgical endoscopic techniques. Endoscopy means looking inside, and typically refers to looking inside the body for medical reasons by using an instrument called an endoscope. The idea was simple and brilliant: surgeon can look through the body and perform the operation by special instruments passing through a small hole. So, there is no more need to make large incisions, and consequently the patient experiences less damage, less pain, less anaesthesia, and shorter recovery period. Endoscopy was the beginning of the new minimally invasive procedures for different kinds of surgery such as laparoscopic surgery, heart surgery, orthopaedic surgery and etc., known today under the title of Minimally Invasive Surgery (MIS).

According to a recent market analysis, the global market for MIS devices and instruments was worth $14.8 billion in 2008. This should reach $15.8 billion in 2009 and $23.0 billion in 2014, for a compound annual growth rate of 7.8% (McWilliams, 2009). However, these achievements could not be made without the active participation of hospital and industry in the product lifecycle, mainly in design and manufacturing phases.

The desire to do a better surgical operation is in the nature of being a surgeon, and finding a better way is not necessarily regarded to require special design or engineering abilities. In traditional experienced-based surgery, "innovation" was not particularly separated from performing new surgical techniques with actual instruments. That is to say there was usually no prior activity of observation, drawing, modeling or prototyping before the usage of an instrument for a new trial on operation technique during a series of surgeries. As a result, the process by which surgical innovation applies new ideas to clinical needs, took the equivalent position as what can be called design process. Riskin et al. (2006) quoted: "the history of surgery is comprised largely of individual, widely respected surgeon innovators".

Perhaps a way toward understanding what is behind the innovation in surgical instruments design is to look from two different points of view: clinical and technological aspects. Clinical aspect in general takes place in the hospital and operating room (OR) and regards new operational techniques. Clinical study using surgical instruments is always a source for creativity and innovation, and in many cases come up with propositions for future products. Obviously in this step, surgical instruments are commercialized and are no more under the

[1] For artefact versus artifact debate please check the website:
http://www.worldwidewords.org/qa/qa-art1.htm

design and development process.

On the other side, technical design happens in the office, starting with the requirement list and using schemes and mathematical models to find out a solution responding the problem's criteria. Thus, the design description may look totally different in these two points of view, and needs to converge in certain points in which the actors from both aspects communicate and work together.

This chapter provides more information about the design and innovation from both clinical and technological aspects. Since the focus point of my research in this dissertation is the design of innovative surgical instruments, MIS instruments were considered more particularly. In section 1.2, the design and innovation in surgery is reviewed, and MIS as the new big thing in surgery is explained. In section 1.3, I make a review on the innovative surgical instruments from the design and engineering literature. This review will show how the subject was treated from the research point of view. Finally, this chapter comes up to this discussion: Is there any design methodology for innovative surgical instruments? The details and the answer are presented in section 1.4.

1.2 Design and innovation in surgery

"The abdomen, the chest and the brain will forever be shut from the intrusion of the wise and humane surgeon." So opined Sir John Ericksen, extraordinary surgeon, to Queen Victoria in 1837. However, today surgeons perform an average of 80,000 operations each day (Riskin et al., 2006), on different parts of human body. According to the report of US National Center for Health Statistics, 46 million operations were performed in the United States in 2006, almost 11 million of them were advanced operations and highly dependent on new technological developments (DeFrances et al., 2008). Table 1.1 shows the variety of these surgical procedures.

An increase in multidisciplinary research by surgeons, engineers and scientists has produced an explosion of new surgical devices and implants. This has caused rapid changes in clinical practices, many devices have been introduced some succeeded and some failed even before they have been evaluated in controlled trials (Gross, 1993). Nonetheless, many good examples of design can be found, and most manufacturers care deeply about users' needs.

To get involved in solving clinical problems, it is necessary to become familiar with this world. Therefore, in this section we try to look from the clinical point of view to the innovation and design of new instruments. Accordingly, references and citations are selected from the literature in surgery such as: Annals of Surgery, Journal of Bone & Joint Surgery, Minimally Invasive Therapy and Allied Technologies, and Surgical Endoscopy. First the concept and the insight of innovation are reviewed; afterwards, Minimally Invasive Surgery (MIS), the famous recent innovation is explained.

Table 1.1: Variety of surgical procedures, from National Hospital Discharge Survey (2006) - digits are the number of each type of surgery per year, in USA

Type of Surgery	**Number per year**
Arteriography and angiocardiography using contrast material	1,700,000
Cardiac catheterizations	1,100,000
Endoscopy of small intestine with or without biopsy	1,000,000
Endoscopy of large intestine with or without biopsy	522,000
Computerized axial tomography (CAT scans)	740,000
Diagnostic ultrasound	888,000
Balloon angioplasty of coronary artery or coronary atherectomy	661,000
Hysterectomy	569,000
Cesarean section	1,300,000
Reduction of fracture	627,000
Insertion of coronary artery stent	652,000
Coronary artery bypass graft	444,000
Total knee replacement	542,000
Total hip replacement	231,000
Total	**10,976,000**

1.2.1 Innovation in surgery: concept and approach

Many terms and definitions are used within innovation research, in general according to "the act of introducing something new" and "the use of a new idea or method" (Jones et al., 2004). The coupling of new ideas and hands-on use is also a central tenet of surgery, partially explaining the historical success of surgeons as innovators and the progress that their innovation created. Riskin et al. (2006) made a historical perspective on innovation in surgery, in which the role of surgeon in innovation, and the role of technology changes and market share is discussed. Here is what I extract:

> *"Surgeons have historically been idea generators and creative practitioners within their craft. Because surgeons understand clinical needs, they may anticipate future advances and opportunities. However, surgeons are increasingly under pressure to achieve a fiscal report card that is black and not red. Workload increases, reimbursement decreases, and extra time, which was traditionally dedicated to teaching, research, and innovation, becomes harder to find. Accordingly due to the observation, surgeons have lost their effective active position in the innovation leadership in surgical instruments."* (Riskin et al., 2006)

As the history shows, in early 18th century the clinical research on the endoscopic surgery was undergoing. Philipe Bozzini invented the first effective lightening system for endoscopy in 1805, and Antonin Jean Desormeaux put a lot of effort on the new surgical

techniques, so he was able to build and generate interest in an effective endoscope in 1865. But more than 100 years later in the mid-1980s, laparoscopic technique had little use in major operations, and the introduction and deployment of this technique in the surgery waited up to recent decade. What is the reason? At least, one explanation would be that the surgeon is not the only actor in the new market of surgical instruments.

Riskin's study concludes that body of knowledge on technology innovation has been developed over the last decade but has not been applied largely to surgery, and suggests to the community of surgeons to savvy not only in medicine, but also in technology and business. Gross (1993) proposed a phased clinical trial for prospective assessment of the new devices or methods before they are released to be used by the surgical community (see Table 1.2). Perhaps the successful innovation can be traced from the result: from the surgical procedures or the new instruments. Thus, the above mentioned classification can be extended, considering the process view of design.

Strasberg and Ludbrook (2003) proposed two main characteristics for the innovation in surgery: clinical and technical. Clinical innovation varies from minor changes that are inherent and appropriate in individual practice.Technical innovation starts from small technical changes in instruments, up to fundamentally technologies that are allowed for general uses only after their safety and efficacy have been proven in extensive trials using human subjects.

Table 1.2: Surgical equipment or implant validation process, adapted from Gross (1993)

Phase 1 Laboratory study	An exploratory investigation of the principles involved in a new implant, or a new method of fixation. It may require equivalent animal models for the biological response and human cadavers for the study of biomechanics
Phase 2 Cohort study	It Involves a strictly controlled prospective investigation in selected consenting patients. It is designed to determine the value and viability of the new procedure according to a predefined set of endpoints.
Phase 3 Randomized controlled trial	This tests the hypothesis that the new procedure, method or implant is superior to the current standard treatment in a much larger predefined population, treated by surgeons other than the originators.
Phase 4 Surveillance study	This continues the careful assessment of a treated population by follow-up of all patients to detect any unexpected complications. The length of time will depend on the procedure or device. For total joint replacements, it would be reasonable to make a preliminary assessment at five years and again at ten years.

Clinical trial as shown in Table 1.2 is the only formalized process of innovation from clinical point of view. In other words, the effort on technical innovation in the clinical literature is put on using new technologies for better performing surgery, and not to con-

tributing to develop the new technology. I would like to bold this remark, because as it will be explained in the history of MIS, almost all new instruments were invented by surgeons, and were validated in some kind of clinical trial. However, I have some comments about the clinical validation to point out here:

1. The validation process takes the design artifact (system or device) as a solid input, so the process leads to a Yes/No answer without considering the possible feedbacks from clinical users in order to improve the design. Thus, in the case of failure it would not be clarified why and whether or not the failure originates from the design concept, from the manufacturing, or from the usage. In the same way, in case of approval, the process could not guaranty that the artifact is optimized and meets the engineering requirements.

2. Having passed the laboratory study, the validation process enters the situation in which the design artifact should be clinically qualified. Applying an instrument on patients necessitates the healthcare standards and also the approval from the ethical review committee. These requirements imply much the restriction and limitation on the design, so the test prototype should be functional, safe, and healthcare-approved.

3. As mentioned, the final surveillance study could take up to 5 years. This time is too long comparing to the design phase. Considering that the industry does not risk to produce a non-validated instrument, this delay makes the situation complicated. In general, once a surgical instrument passed the preliminary clinical evaluation, the design owner(s) patent the instrument to provide intellectual protection. It means that the design is finalized and is not subject of any modification due to the feedback from clinical surveillance.

Nonetheless, the major surgical innovations include both clinical and technical major changes. Thus, I propose to extend the clinical-technical classification to these new classes:

1. Innovation in clinical usage, without employment of new instruments

2. Innovation in technology, without change or considerable modification in clinical usage

3. Innovation in both technology and clinical techniques which enable a new surgical procedure using the new instruments.

Figure 1.1 shows some examples of this classification. To conclude, from the clinical view, the surgeon is the innovator, either by providing evidences from clinical trial, or by designing a new surgical instrument and proves its efficiency by clinical evidences. In the next section, the history of MIS is review. MIS instruments are the best example for the third class innovation, in which the innovation resulted in new technologies for new and various surgical operations.

(a) (b) (c)

Figure 1.1: Examples of clinical-technical classification; (a) Two cardiac surgeons performing a cardiac surgery known as coronary artery bypass surgery, (b) Technician monitoring a patient's CAT scan, (c) Da Vinci surgical robot surgeons to manipulate tools through four tiny incisions in the patient's chest during the surgery

1.2.2 Minimally Invasive Surgery

Minimally invasive surgery (MIS) known also as keyhole surgery, is an operation containing any procedure that is less invasive than open surgery used for the same goal. MIS is the most important recent development in surgery and intervention. The idea is to access the patient's body via a few number of round cannulas (called trocars), inserted through the small incisions in the skin. In result, surgery becomes more difficult than having direct access and view on the operation site. Surgical instruments need to become thin, rigid, and multifunctional to allow the surgeon to perform the procedure in the small restricted cavity. Instead, many benefits come to the patient like small skin incision, less bleeding, and short hospitalization time.

Table 1.3: Minimally invasive surgery - problems, challenges and benefits. Data gathered from the website of American Academy of Orthopaedic Surgeons and Dankelman et al. (2005)

Difficulties in surgical procedure performing	**Benefits for the patient**	**Challenges for instrument design**
Indirect observation (through camera and monitor)	Short skin incisions	Manipulation restriction in degree of freedom
Eye-hand coordination	Minimal tissue dissection	Scaling the hand movement and the tip forces
Training for new techniques	Decreased blood loss	Poor tactile feedback
Longer operative time	Fewer peroperative complications	Force transmission
Physical fatigue	Accelerated rehabilitation	Small size
	Preferred by patients of all ages	Rigid and simple
	Reduced anaesthesia	

Table 1.3 shows the MIS benefits and difficulties from three points of view: Surgical operation, patient safety and instrument design.

1.2.2.1 History of minimally invasive surgery (MIS)

Here a short history of MIS is narrated. Data are generally extracted from medical university online publications such as http://www.mssm.edu/misc/introduction.shtml and http://www.endo-kiel.de/.

The early history of MIS is unknown to many surgeons, but a main step forward is credited to Philipp Bozzini (1773-1809) who developed a light conductor which he called "Lichtleiter" to avoid the problems of inadequate illumination. This early endoscope directed light into the internal cavities of the body and redirected to the eye of the observer.

John D. Fisher (1798-1850) in Boston described an endoscope initially to inspect the vagina, but later he modified it to examine the bladder and urethra. In 1853, Antoine Jean Desormeaux, a French surgeon, first introduced the "Lichtleiter" of Bozzini to a patient. For many he is considered the "Father of Endoscopy". This instrument had a system of mirrors and lenses, with a lamp flame as the light source; the endoscope burned a mixture of alcohol and turpentine. Burns, as might be imagined, were the major complication of these procedures. Desormeaux had initially contemplated using electricity, but abandoned that idea.

The technique of laparoscopy was first reported by George Kelling (1902) and by Jakobeus (1910). Kelling, a surgeon from Dresden, coined the term "coelioskope" to describe the technique that used a cystoscope to examine the abdominal cavity of dogs. Kelling also used filtered air through sterile cotton to create a pneumoperitoneum, aiming to stop intra-abdominal bleeding (ectopic Pregnancy, bleeding ulcers, pancreatitis), but these studies did not find any response or supporters. Kelling noted that the abdominal cavity could store more than 2.5 liters of blood. He also considered intra-abdominal adhesions a contraindication for the procedure[2].

Since this innovation, many surgeons looked for new opportunities to use laparoscopic techniques in new operations and to develop a new instrument and use it in surgery. Table 1.4 shows a time line of there progression.

In 1981, rules and requirements to perform laparoscopy were adopted by many hospitals

[2]During late 1910 and early 1911, H.C. Jacobaeus, from Stockholm, used the term "laparothorakoskopie" for the first time. He published his report on laparoscopy and thoracoscopy in humans in Münchener Medizinische Wochenschrift. He also suggested employing similar techniques to examine body cavities endoscopically. A response by Kelling appeared two months later in the same journal, disputing Jacobaeus' claim to be the first to perform the procedure in humans, stating that he had successfully used celioscopy in two humans between 1901-1910. Unfortunately, Kelling had made a mistake: he did not publish his work. Interestingly, in Jacobaeus' paper in 1911, he viewed thoracoscopy as a more promising procedure than laparoscopy.

Table 1.4: Historical timeline of surgical innovation in MIS, extracted from http://www.mssm.edu/misc/introduction.shtml

Year	Innovation	Surgeon innovator	Country
1806	Light conductor	Philipp Bozzini	Germany
1853	introduced the "Lichtleiter" of Bozzini to a patient	Jean Desormeaux	France
1887	Electrical light bulb as the source of illumination	Maximilian Nitze	Germany
1902	"coelioskope" : the technique of using a cystoscope to examine the abdominal cavity of dogs	George Kelling	Germany
1911	ilaparothorakoskopiei : laparoscopy and thoracoscopy in humans	H.C. Jacobaeus	Sweden
1911	"organoscopy", proctoscope of a half-inch diameter using the ordinary lignt	Bertram M. Berheim	USA
1918	automatic pneumoperitoneum needle	Otto Goetze	Germany
1920	first large series of peritoneoscopies (42 cases), sharp pyramidal trocar point	B.H. Orndoff	USA
1929	135-degree lens system and a dual trocar approach	Heinz Kalk	Germany
1934	built-in forceps instrument with electrocoagulation capacity	John C. Ruddock	USA
1938	spring-loaded needle	Janos Veress	Hungar
1944	performed gynecological examinations using laparoscopy	Raoul Palmer	France
1948	rod-lens system and fiberoptics.	Harold H. Hopkins	England
1966	automatic insufflator	Kurt Sem	Germany
1971	technique performing laparoscopy through a miniature laparotomy incision	H.M. Hasso	USA
1980	perform laparoscopic procedures in the operating room under sterile condition	Patrick Stepto	England
1987	performed the first video-laparoscopic cholecystectomy	Phillipe Mouret	France

and surgical societies. The American Board of Obstetrics and Gynecology made laparoscopy training a required component of residency training. The first solid state camera was introduced in 1982. This was the start of "video-laparoscopy". Nothing had caused more revolution and had led to so many other developments during the past twenty years than the first laparoscopy cholecystectomy on a human in 1987, by Phillipe Mouret in Lyon, France. The year after, Dubois (Paris), Perissat (Bordeaux), Nathanson and Cuschieri (Scotland), McKernan and Saye (Marietta, Georgia), and Reddick and Olsen (Nashville, Tennessee), had performed laparoscopic cholecystectomy at their institutions on both sides of the Atlantic.

Since then, many contributions of hundreds of surgeons have brought a new approach to surgery to the benefit of the patients. Many procedures are reported in minimally invasive, such as hypodermic injection, air-pressure injection, subdermal implants, endoscopy, percutaneous surgery, laparoscopic surgery, arthroscopic surgery, cryosurgery, microsurgery, keyhole surgery, endovascular surgery (such as angioplasty), coronary catheterization, permanent spinal and brain electrodes, stereotactic surgery, The Nuss Procedure, radioactivity-based medical imaging methods, such as gamma camera, Positron emission tomography and SPECT (single photon emission tomography). As the table shows, historically the credit of the innovation in MIS goes to the surgeons up to the recent decades when the engineering and the industry became interested in the new generation of surgical devices and instruments.

1.2.3 Minimally invasive versus open surgery

In open surgery, access to the internal organs is provided via a large incision. The incision allows the surgeon and assistant surgeon to have direct vision of anatomy and direct contact with their hands with the tissues. The surgeon normally uses his hands to palpate and manipulate the tissues. The exposure of the operating site is created by mechanical wound spreaders (called retractors) and the surgeon has largely enough space for manipulating surgical instruments.

In minimally invasive surgery the principal difference is the access; the surgeon does not have the direct touch access anymore, neither do have a direct view on the anatomy. This limitation causes some problems and difficulties during the surgical procedure. Stassen et al. (2005) compared the consequences of the operation procedures in open, assisted and minimally invasive surgery. A summery of his work is shown in Table 1.5. As the table shows, the actual procedures in MIS causes many problems and difficulties to the surgeon. The ideal perspective in this respect would be changing all negative signs to positive ones for the patient, as well as for the surgeon.

The introduction of the new technologies to surgery, initiated the new concepts and practices for surgeon; image-guided surgery, robotic surgery and interventional radiology are the main examples of this development. Besides the everyday innovations and scientific publications about new improvement in surgery in the surgeons' community, this subject

Table 1.5: Minimally invasive versus open surgery due to surgeon and patient. (- : negative, + : positive; O : no negative or positive consequence)-adapted from Stassen et al. (2005)

	Operative technique			
	Open		Minimally invasive	
Aspects	**Patient**	**Surgeon**	**Patient**	**Surgeon**
Operation wound	-		+	
Hospital stay	-		+	
Recovery time	-		+	
Operation complexity		+		-
Observation		+		-
Handling		+		-
Operation time	+	+	-	-
Disturbances		+		-
Wound infection	-		+	
N° of persons in OR		+		-
Training surgeon		+		-
Online teleconsulting		O		+
Medical cost of surgery	+		–	–
Overall cost of treatment	–		+	+

has been studied and discussed by the design researchers. Although the advantages of minimally invasive surgery have been clearly established for the patient, the studies have shown that the surgeon has faced with numerous disadvantages caused by poorly designed instrument handles, including the potential of harm to the surgeon due to uncomfortable postures, high repetition and high force exertions and the likelihood of harm to the patient due to the poorly designed tools (Trejo et al., 2006). Thus, there is a crucial need to look at this subject from design and engineering point of view. How the design can help the new instruments to fully address the needs of minimally invasive surgery and its surgeons? In the next section, a literature review of current design studies and engineering publications is presented.

1.3 Design researchers and surgical instruments

I classify the research and publications on surgical instruments in non-medical publications into two different categories: The first category contains either pure scientific or technical developments of technologies which have application in medical and surgical domain, such as imaging and analysis, biopolymers, organ modeling, and etc. The second category includes the studies credited by the word design, which try to provide an engineering design orientation on the surgery and operating room, to find out problems and propose solutions.

This dissertation is inline with the research topics in the second category, though it is better to have an overview of the studies in this category and clarify the position of my research. I provided a particular literature review in the following paragraphs. To be mentioned, there are a limited number of scientific journals and international communities which support this kind of research. The following study is made considering different topics and various publications from design journals to surgical journals.

Let's call the instruments and the systems used for surgery, directly in operation or for helping surgeon, as the surgical products. To provide a better understanding of the problematic and the research trends in the literature, I propose to have a primary classification: 1) Studies focused on the design of the surgical products 2) Studies focused on the process of the design of the surgical products. This classification helps to have a better objective of what we are looking for in the literature review.

1) Surgical product design

These studies in general focus on the usage of the actual surgical instruments and tools, trying to provide technical solution for an existing problem or to evaluate an under-usage instrument and to find the benefits or the problems. The design and the evaluation of the surgical instruments and ergonomics are the main subjects. Section 1.3.1 provides more details.

2) Design process of surgical products

Studies in this category focus on how the design of surgical products progress. Researchers in this category basically regard the design as a process which passes through some main steps. Accordingly subjects like actors, design communication, decision making and workflow in OR are among the main topics. More details are presented in section 1.3.2.

Although the final goal of this dissertation is to propose a design process, reviewing the literature on both categories seems to be necessary. Studying the literature on design of surgical products shows how engineers, designers or surgeons accomplished bringing a new design to world. Obviously nobody is obliged to use a predefined method to design a new product. The studies of next category show the characteristics of the design process in the field of surgical products, and provide suggestions to improve the research and the design in this field. The review and analysis below regards the design of surgical products with focus on MIS products.

1.3.1 Instrument design and evaluation

In order to find out what the literature proposes on MIS instrument design, I scanned the ISI Web of Knowledge indexed publications, updated in May 2009. At the first glance, three types of journals have been identified: Medical Engineering journals, journals in MIS, and journal of Applied Ergonomics. Unfortunately the journals of design community were not present in the databases, so I decided to make a selection and add it to this review

papers. Five main design journals were selected and scanned.

Hopefully with this basis, I can demonstrate the actual research on the surgical instrument design and development. The search was in full text record through their websites, regarding the keywords such as: surgery, surgical instruments, and medical device. Our main goal of this literature review was to find out in which cases this subject was discussed in the publications, and how different researchers studied the design issues. The results are summarized as follows:

a) Design journals

Journal of Design Research, Journal of Engineering Design, Research in Engineering Design, Design Studies, and CoDesign journal have been scanned looking forward to finding out the design research and studies in the surgical domain. In results, less than five related papers have been found, only one on product design (Frost et al., 2003) and another on measuring during surgery (Attfield and Wilton, 1995). It implies that either this subject has not been interesting for the design researches, or researchers prefer to publish in other journals.

b) Ergonomic journals

Searching in the ISI Web of knowledge by design of surgical instruments keywords, a considerible number of publications have been found, published in the Journal of Applied Ergonomics. Martin et al. (2008) indicated the role of ergonomics in design and development of medical devices and surgical instruments. Accordingly, many trends are found in this direction: Error finding and prevention (Joice et al., 1998; Lyons, 2009), instrument safety evaluation (Wu et al., 2009), ergonomic design (Dan, 1997; Trejo et al., 2007), evaluation of technical skills (Gonzalez et al., 2007), design and development (Karlqvist, 1998; Serra and Waterworth, 1997) are the examples.

c) Medical engineering journals

A total number of 47 papers have been found, among 34 journals and transactions. Three main categories have been recognized: 1) instrument design and evaluation, 2) helping surgeon in positioning the dates, or by robotic supports, 3) measurement, tracing and modeling of instruments. Looking through the papers concerning the two first categories (21 papers), I tried to find out how the designers made their design. In other words, I investigated these publications as cases to find out if any methodology for design have been used or not, and, in any cases what the main steps are to progress the design. Results are shown in the Table 1.6. Papers in the third category indeed presented a very fundamental and useful approach and result in design of surgical instruments. However, in order to be focused on instrument development, those papers have been excluded from the detail review.

While some papers presented the process definition to clinical evaluation, some focused on only one phase. In all cases, the evaluation was reported from engineering point of view

and in a few cases it was simply mentioned that clinical usages of new designed product did not cause any problem.

Table 1.6: Design phases and methods, extracted from 21 papers on surgical instrument design, refined research in ISI Web of Knowledge data base, May 2009. One paper may contain more than one issue.

Design phase	Methods	# of papers	Example
Requirement specification	From literature	10	(Duchemin 2005)
	Observation in OR	2	(Yoshimitsu 2007)
	Feedback data capture and analysis	8	(Canestri 1999)
Conceptual design	New mechanical functions, or improvement	5	(Sun 1997)
	New technology applications (MEMS, thin films, RFID)	3	(Rivera 2008)
	Comparison to existing device	2	(Ramrath 2007)
	Simulation and data analysis	2	(Li 2008)
Evaluation	Proof of concept prototype	5	(Sauvee 2008)
	Clinical laboratory test (in vitro)	4	(Jerosch 1999)
	Operating room, in surgery (in vivo)	6	(Urban 1990)

d) Surgical journals

The primary search for the surgical instrument design in the ISI Web of knowledge returns more than 1170 records in 94 journals. I used the "Refine Results" to narrow down to 573 results in surgery and then to 37 results in MIS (3 journals) and Laparoscopy (3 journals). These six journals have been selected due to the correlation of the subject to design for less invasive surgeries. Looking through these papers, I tried again to find out in first place, what aspect of the surgical instruments design has been studied, and in second place which design methodology has been used.

Table 1.7 shows the results of our analytical review. I identified four main focuses for the papers; in fact, I took three classes of part c, and extended the evaluation phase to in-vitro an in-vivo. Thus four focuses in view of design process are: 1) Requirement analysis, 2) Conceptual design and prototype production, 3) Experiments on in-vitro Study, 4) Clinical evaluation in OR. To be mentioned that some of the papers had more than one focus.

In addition, some interesting points were found. The papers in the first category showed some research techniques such as surgeon interviewing (Berguer et al., 1997), surveys using questionnaires (Bergner and Hreljac, 2004; Van Veelen and Meijer, 1999) and the systematic literature review (Magdy and Eric, 2003). Concerning the design, among twenty papers focusing on design, in nine cases, the design was followed by an in-vitro experimentation, while six others have reported the OR evaluation. This implies that almost a half of the evaluations in OR papers (eight out of seventeen) proposed a new operational technique using a conventional instruments.

Table 1.7: Analysis of published papers in surgical journals according to the design process; Data extracted from ISI Web of Knowledge, May 2009

	# of papers	% of 37	Design phase			
			Study, requirement identification	Design	Experiment	OR evaluation
Journal of the American association of gynecologic laparoscopists	13	35.1	4	7	5	4
Minimally invasive neurosurgery	7	18.9	1	6	2	3
Journal of minimally invasive gynecology	6	16.2	1	2	1	3
Minimally invasive therapy & allied technologies	4	10.8	1	2	1	2
Surgical laparoscopy & endoscopy	4	10.8		3	2	2
Journal of laparoendoscopic & advanced surgical techniques	3	8.1				3
Total			**7**	**20**	**11**	**17**

I conclude the following terms with reformulating the findings from detail reviewing of the existing literature on the surgical instrument design: First, a surgical innovation contains two sides: technological design and development, and operative technical performance. Second, the design evaluation is not limited to an engineering validation of the concepts, and needs the clinical evaluation, in-vitro and/or in-vivo. This fact struggles the design progression; On one hand design has only reached the first prototype, and still is immature. On the other hand clinical evaluation needs a performing functional product, and in many cases the obligation of the healthcare and safety standards. Therefore the clinical evaluation of the design artifact would not be a simple step in the progression.

In the next part, I magnify our focus from the instrument design to the design process, to find out what the literature can offer in term of design organization.

1.3.2 Design process of surgical products

There have been many examples to explain a unique design approach in the literature, but very few attempts to draw up the maps or the model of the design process of surgical instruments. Researchers, however, reported their research techniques; for example, direct observation (Mondada, 2002), questionnaires and interviews (Trejo et al., 2007) has been reported on the anticipation of the users' behavior for the requirement definition and the product evaluation. In this section, I discuss those researches that attempted to build a

guideline, to propose a generic approach or to describe the sequences of activities in the design of the surgical instruments. Accordingly, I choose two main titles to go through in more detail: workflow analysis and engineering for patient safety. While workflow concerns what happening in the OR, which is an important issue in the beginning of the design process, engineering for patient safety provides some practical guides and helps about the design of surgical instruments.

1.3.2.1 Workflow analysis in OR

The term "Surgical Workflow" is used in a variety of contexts and for different purposes, each having one thing in common: modeling the processes in the operating room. In the operating room several parallel workflows are going on, including the surgical procedure, anesthesia, usage of instruments and patient monitoring. Together, they make a complex workflow which includes all actors and devices to reach the objective of accomplishing a successful surgery. Workflow analysis is a method to understand about the problems in the OR, and to propose solutions for helping surgeons. These solutions aim at providing sufficient information support for surgeon, and assist the surgeon to do the procedures. The current trends in developing and applying workflow technologies in minimally invasive surgery are in Image-guided surgery (Lango et al., 2008; Zhang et al., 2006; Fosse et al., 1999), component automation (Wong et al., 2003), automation (Punt et al., 2005) and so on.

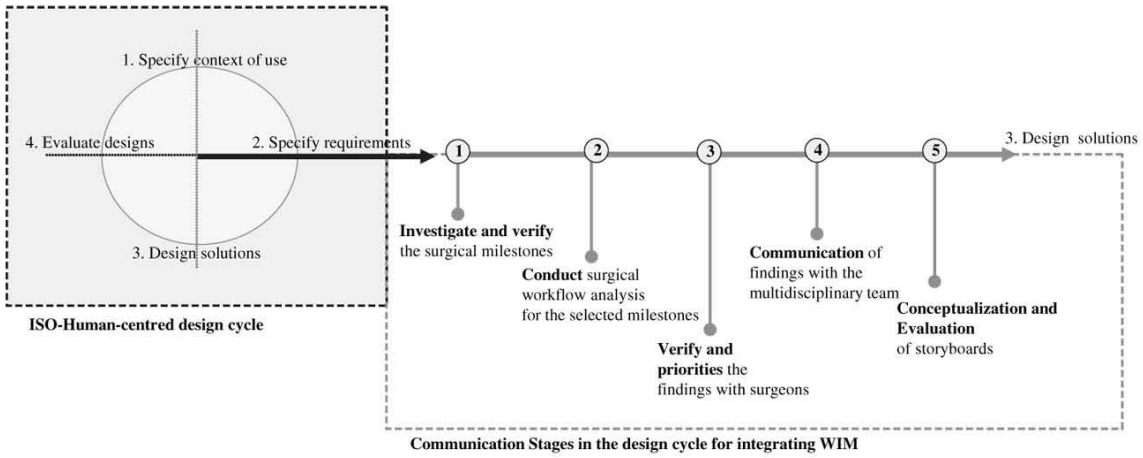

Figure 1.2: Workflow integrated in product development cycle (Jalote-Parmar and Badke-Schaub, 2008)

In an interesting study about surgical workflow, Jalote-Parmar proposes a workflow analysis framework to be integrated into the design process (Jalote-Parmar et al., 2006). In this model shown in Figure 1.2, a communication stage is proposed to be added to ISO- Human-centered Design model, in order to develop the knowledge base of the surgical

processes and requirements, which are essential for the design and success of the surgical information system. However, no argument is proposed supporting why the design process in surgical systems is considered as a human-centered design.

In conclusion, improving the knowledge of the surgical workflow is a primary requirement for the development of the surgical products and systems. By analyzing the surgical requirements related to the surgical workflow, the communication with design team can be improved by validation and prioritization of the requirements. Studying and analyzing the surgical workflow provides the means for better understanding of the surgical problems, surgical techniques and surgeon interactions with the OR workspace.

1.3.2.2 Engineering for patient safety

In the Engineering for patient safety (Dankelman et al., 2005), two principally different approaches to clinical problems are discussed: technology driven and clinically driven approaches (Stassen, 1997). In a technology driven approach, on request of a medical professional or based on a bright idea of an engineer, a new instrument or system is developed. The MRI is a good example of what can be realized by technology driven approach. In this field there is no vital need for surgeon interrogation, the target product is not depending on surgical knowledge base and the target market is very general. However if the available technology is chosen as the starting point for improving surgical techniques, the risk exists that the new instruments do not fulfill clinical needs (Grimbergen et al., 2001). In a clinically driven approach, the surgeon is observed in his work environment, for example performing a task analysis. The surgeon's activities during and after the actual operation are discussed to detect the fundamental problems and the limitations occurring during the operation process.

Studies with clinically driven orientation pointed out the notion of collaboration between surgeons and engineers to design new surgical instruments (Dankelman et al., 2005). Setting up a fruitful communication between surgeons and engineers (Tuijthof et al., 2005) and a combination of observations - discussions with surgeons resulted in the definition of the design issues in the design projects. The clinically-driven approach can be best described as a design process where the surgeon and the engineer analyze the specific needs and problems independently of a technical solution (Sjoerdsma, 1998). The development of the surgical instruments is therefore preferably done by a clinically-driven approach (Stassen, 1997; den Boer et al., 2002; Dankelman et al., 2005).

Having this overview, I notify the lack of a generic and holistic framework for the design process in the surgical products. In other words, no clear activity list can be found to cover the whole process of surgical instruments design. Before asking about the possibility of the existence of such a method, I remind note the lack of research and study in this concern. In the final section, we summarize our findings so far, and clarify our target position and strategy of research in the dissertation.

1.4 Looking for a design methodology for surgical instruments

How to design innovative surgical instruments? Under which methods surgical instruments have been designed so far? In a sense, any identifiable way of working, within the context of designing, can be considered as a design method. Thus, in our context, any procedure, technique, aid, or tool for designing a surgical instrument is a design method (section 1.3.1). Although some design methods can be conventional and normal procedures of design, such as identifying a clinical problem, drawing a concept, some others, such as conceptualisation and evaluation, designing of innovative surgical instruments showed as unconventional procedures. The main intention of seeking a "surgical instruments design method" would be an attempt to bring rational procedures into the design process. Many design methods have been shown in section 1.3, some methods seemed to be a new invention, some adapted from the operational researches, the decision theory, engineering design or other sources.

On the other hand, there are some fundamental problems and difficulties concerning the design of the surgical instruments. During the product development process, there often exist communication gaps among the surgeons (users) and the engineers (Dankelman et al., 2005), new technologies are imposed rather than what the surgeons would require (Patel et al., 2001), and in result many new surgical products do not integrate in the hospital usage (Gross, 1993). For example, surveys on minimally invasive and laparoscopic instruments showed many difficulties and problems for surgeons using the new instruments (Berguer et al., 1997; Bergner and Hreljac, 2004; Van Veelen and Meijer, 1999).

Not only the road of design is particular and unclear in this field, but also no evidences confirms an appropriate outcome in case of using certain methods. That is the tentative question behind our research: What does the generic design process of innovative surgical instruments look like? What should be acquired to make a successful design?

Thus, there is need for a more systematized approach to the design, the evaluation, the implementation and the general release of new surgical procedures or implants (Gross, 1993). It seams that from the literature, observations and design contributions, a formalized methodology can be drawn out to help the design process of innovative surgical instruments. To help who? The answer can be the designers, the engineers, the surgeons, or the patient individually, or even help them to collaborate in design activities.

The challenge that the present dissertation will deal with is to build-up, examine and formalize such a methodology. The focus of this research is on the design process of minimally invasive surgical instruments, though the proposed methodology should take into account the specific characters of design in such a context, and it should envisage the extension to the innovative surgical instruments design in general.

To propose a design methodology, it is necessary to clarify in the first place the definition of the concepts and the objectives of having a methodology. In the second place, it is

important to study the existing design methodologies, to see whether or not the existing methodologies can help to satisfy the need in the innovative surgical instruments design. This discussion is the subject of the next chapter.

1.5 Conclusion

Innovation in surgery always targets a better care and cure for patients. From long ago up to this century, the surgeons were innovators. They discovered many techniques and brought it to innovation by performing surgery. They used to design and fabricate the instrument they needed by their own. The new century comes along with the new technologies and, very soon, technologists turned to medical and surgical applications to solve the problems. Many new solutions are developed, in day-to-day advancement, to provide better facilities for surgeons in order to offer the safer and less invasive interventions and operations. MIS and Natural Orifice Surgery (NOS) are experiencing the day-to-day changes, and became, as a matter of fact, highly dependent on various technologies. In the same way, surgeons face the new challenge of integration and use of those new technologies.

In a closer look, design of new surgical instruments contains many complexities in engineering design as well as in operation techniques, and necessitates the collaboration between engineers and surgeons. This later according to what we found in the literature is not always the case, and in result many brilliant ideas from surgeons do not reach out from wishes, and many technically preferment instruments do not provide any help in the OR. To solve this problem we need in the first place to know about the state of the art in design of surgical instruments.

In this chapter, we firstly entered the medical atmosphere to see how the notion of innovation and design in the surgical world was defined. As shown, from the clinical view, either the surgeon designs a new surgical instrument and proves its efficiency by clinical evidences, or a new well designed and healthcare-qualified instrument reaches the hospital for clinical evaluation. However, the new trends in design and development of the surgical instruments point the innovation in new technologies which come from collaboration between the surgeons and the engineers. MIS innovations, as a representation for the disciplines including an innovation in both surgical instruments and operational techniques, was explained in the second section.

On one hand surgeons are looking for the new techniques and supports to make a better operation. On the other hand engineers, designers and technologists are looking for new solutions in their field, to help surgeons in diagnostics and surgical performance. In section 1.3 we reviewed the literature to see how the innovative surgical products have been designed. This review had two focuses: the studies concerning the design of the surgical products, and the studies concerning the design process of the surgical products.

Various design methods were used for design of surgical products, also some guidelines

were provided to improve the process of design in the literature. However, my systematic review showed there is no adequate design methodology adapted for the design process of surgical products. At this moment, we need to take a further step and look for the methods and tools for the design progression in total. The main intention of seeking such a methodology would be the attempt to bring rational procedures into the design process.

Considering the lack of design process view or method for surgical instrument as the problem. One coherent solution is to look for it through the design and engineering design sciences, where many design method independent of the product, has been proposed. And this is what we are going to do. In the next chapter, I try to clarify what a design process and design methodology look like. Then, by reviewing design methods/models in the literature, we will find out the main characteristics of a method for design of innovative surgical instruments.

Chapter 2

Design methods and models

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2.6 Conclusion 50

In this chapter you will find :

- *What the design is about, and what those confusing combinations like design process, design method, design model are*
- *If design process, is to describe or to prescribe*
- *How the design process has been described in the literature*
- *What differentiates engineering design approach from human-centered approach*
- *Where the surgical instruments design's place is*

2.1 Introduction

I finished the previous chapter with questioning about the design methodology in design of surgical instruments. Reviewing the literature of medical and surgical instruments design drew two conclusions:

First, there are various approaches to the design of the surgical instruments, some methods have been used, and some general guidelines and generic proposition are made. However, most of the propositions are context-based and highly dependent on the own case.

Second, although few design studies tried to look at the surgical instruments and the surgical task from a holistic, systematic or process point of view, there is no methodology proposed in this field. In this chapter, we look for the concept and the structure of a methodological framework in engineering design, in the literature of design and more specifically the product design and the mechanical engineering approach. To do so I review existing propositions on design "process" and "methodology" to clarify our basis of knowledge of design.

Methods of design – considering design as a scientific discipline – according to Hubka and Eder (1995) are divided into two main branches[1]:

1. Knowledge about the design process and its operators, (the design system)
2. Knowledge about the designed objects (process and real systems)

Each of these branches contains descriptive (theory) and prescriptive knowledge. Although the debate on the fundamental concept of science, knowledge, theory and methodology is not the objective of this chapter, but to provide a common understanding of the notion of these terms in design research, I propose a general overview in the beginning of the next section.

What I am looking for in this chapter is a methodological approach for design and innovation in user-dependent domain, particularly such as the surgical instruments. Therefore, I review the design literatures with focus on engineering design methods (section 2.2), user-integration methods (section 2.3) and evidence-based methods (section 2.4). In engineering design there are two approaches to design methods: descriptive and prescriptive. While the descriptive approach tries to explain what is happening during the design, the prescriptive model provides some guidelines for designers to improve their design organisation. Nonetheless, the notion of the user and user integration is not undertaken in the engineering design, and though the concept of 'design as a social activity' is needed to traverse to the human-centered design and user-centered design studies. This approach is originated in the Human-Computer Interaction (HCI) science and software engineering discipline. I try to show why this approach can be specified and enriched for the context of innovative surgical instruments. The last category, experimental approaches, is less formalized than

[1] They defined the scientific method as "the way of gaining knowledge and insights, starting from a hypothesis, which scholars usually pursue".

the methods in engineering design and user integration. However the design in medical and surgical domain has never been far from experimentation and evidence-based approaches. For this reason it would be wise to have a look into the design studies in this field.

Finally in this chapter, I look back to the literature study of the previous chapter to figure out the structure of a design methodology due to the specifications in surgical instruments design context.

2.2 Engineering design methods

Accepting design as a scientific discipline (some accept it with no doubt), I should bring an order to demonstrate the interaction between design elements – what can be identified in a design activity – and their mutual casual relationships. This requires a theory and a framework which takes care of design interactions.

One can discuss the engineering design on a different level of abstraction, leading to a stratification around engineering design sciences (Eekels, 2000). He used Engineering design methodics to refer to the collection of methods and rules for designers. Nigel Cross in his book with the same title as I chose for this section, quotes "Design methods are any procedures, techniques, aids, or tools for designing" (Cross, 1998). The design methodology is the science of methods that are or can be applied in designing, quoted by Roozenburg and Eekels (1995) and Eekels (2000).

Let's look from the highest level, from the engineering design science. Design science is a collection of many different logically connected knowledge and disciplines. By crossing the classification of Hubka from the introduction with methodological classification, a classification for engineering design statements will be obtained. This matrix was proposed by Eekels (2000) shown in Table 2.1. In this matrix the subject can refer to the design object or to the design process, and the methodology statement can be descriptive (theoretical) or prescriptive.

Table 2.1: The matrix of engineering design science statements by Eekels (2000) adapted from Hubka and Eder (1995)

		Knowledge category	
		Design object (products, manufacturing processes)	**Design process**
Methodological category	Prescriptive (practical)	Product and process knowledge from the various technical trades	Design methods and methodics
	Descriptive (theoretical)	Theory of technical systems (products, machines mfg., processes)	Theory of engineering design processes

Engineering design science is therefore a science concerning an important area of action. As Eekels (2000) proposes, engineering design is a specific type of action, though it exhibits the structure of a general interaction model of action: action subject, action process, action object. Figure 2.1 shows the engineering design science structured in the action model.

Making action to do the task is what the engineering design is all about. Engineering design however has a fundamental task: to transform an initial collection of loose elements, facts, views, procedures etc. into an ordered set (Hubka and Eder, 1992).

In summary, the engineering design is known to us as a science which has its own knowledge and methodology. The engineering design follows the interaction model, defined in action theory and though, all propositions on description and prescription for design activity and interactivity is considered as a design method. I come back to the descriptive and prescriptive classification later.

At this level, I can question the engineering design in practice: How to design in an engineering manner? How the engineering design process helps to make an effective and efficient design? These questions are answered as follows, by reviewing the methods and models proposed in the literature.

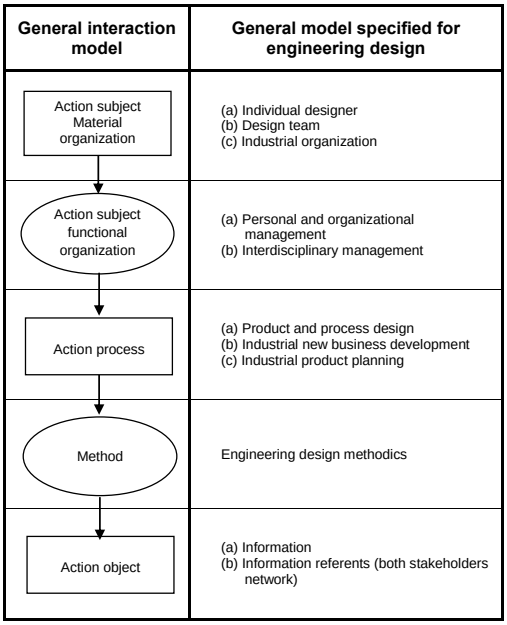


Figure 2.1: The general interaction model of action specified for engineering design (Eekels, 2000)

2.2.1 Modeling the design process

To the date, the design is widely considered as a series of sequences, called process. The process of designing can be performed in systematic, methodical, structured ways, but also intuitively with no obviously followed structure (Hubka and Eder, 1995). One can find conflict in these different appearances, but structuring can be and is used to support the intuitive and creative leaps, design procedures, knowledge and information. Let's start with the simple descriptive model of the design process, proposed by Cross (1998), based on the essential activities that the designer perform. This simple four-stage model is shown in Figure 2.2 . Descriptive models of the design process usually emphasize on the importance of generating a solution concept early in the process. Assuming that the evaluation stage does not always lead directly to the communication of a final design, but that sometimes a new, more satisfactory concept has to be chosen, an iterative feed back loop is shown from the evaluation stage to the generation stage.

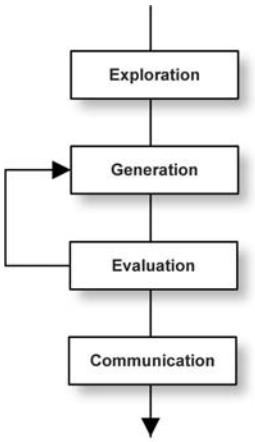


Figure 2.2: Simple four-stage model of the design process (Cross, 1998)

Descriptive models of the design process usually emphasize on the importance of generating a solution concept early in the process. Assuming that the evaluation stage does not always lead directly to the communication of a final design, an iterative feedback loop is provided to return evaluation results such as unsatisfied needs to the generation stage.

Models of the design process are often drawn in the flow-diagram form, showing the development of the design proceeding from one stage to the next, also containing the feedback loops. Almost all design processes start with the definition of the problem. The analysis of the problem is a small but important part of the overall process. Thus French (1985) proposes to start the process with an initial statement of a need. Analysis of the problem ends to a problem statement which contains goals (proper design problem), constrains (limitation placed upon the solution) and criteria (criterion of excellence to be worked to). French's model of design process in presented in Figure 2.3(a).

The design assignment defines the design problem very superficially. So, in the first step the designer should perform a more detailed analysis of the design problem posed, from which he will identify a number of criteria by which design should have to be approved.

In other point of view, the design finishes with the final decision of solution selection. Roozenburg and Eekels (1995) propose a basic design cycle to show the steps and activities in design. Starting from the analysis – which is considered as a reasoning act – design process enters the step of synthesis. The basic reasoning pattern of synthesis is innoduction (the pattern of reasoning from function to form), and is heavily depended on the creativity of designers. The diagram of this design process is shown in Figure 2.3(b).

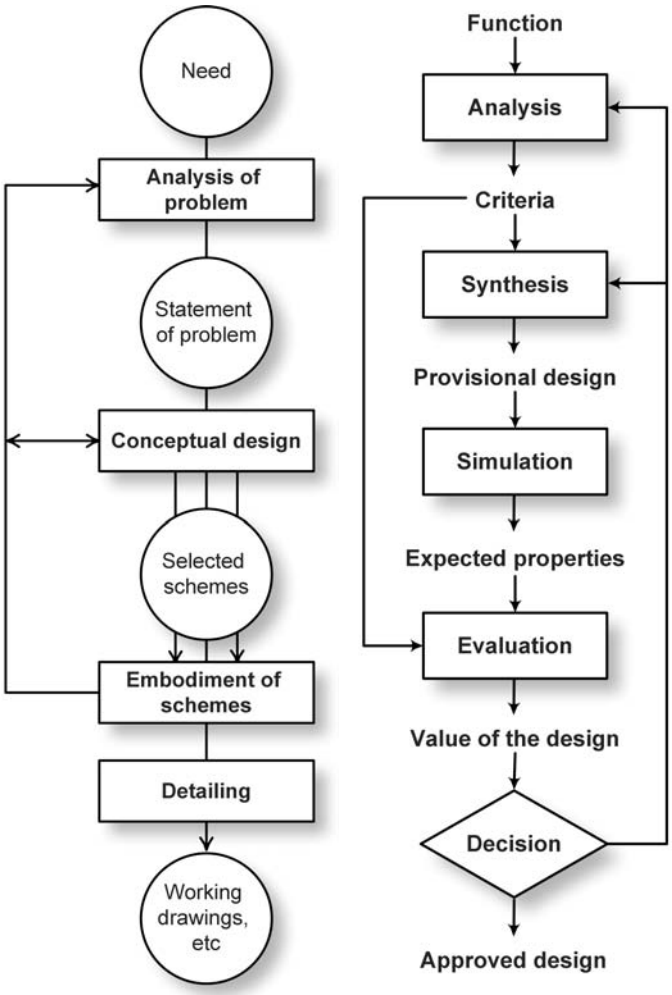
Like the model of Cross (Figure 2.2), here evaluation is the step in which the value (properties) of the expected design should be compared with the criteria established in the analysis step. The final step is a decision. Dependent on the result of the evaluation, acceptable or not, the design provisionals (come from the simulation step) will be selected to be promoted or rejected to go back to the synthesis step or even analysis step.

2.2.2 From descriptive to prescriptive methods

Beside many models that simply *describe* a more or less conventional process of design, there have been several attempts to build *prescriptive* models of the design process. Prescriptive models principally attempt to propose an improved way of working, and also try to encourage the engineering designers to follow the algorithm they propose.

In the first volume of "Research in Engineering Design" journal, Finger and Dixon (1989) published a landmark review of design theories and methodologies in the mechanical engineering domain and categorized various theories and methodologies into six categories, two first are descriptive and prescriptive models of design processes. They divide the descriptive models into two categories: protocol studies of individual designers (by gathering data from how designers design) and cognitive models. In both categories researchers attempt to describe what is happening during the design process and try to identify some dominant characteristics. Table 2.2 provides an extraction and make bold some of these findings from the Finger and Dixon's review.

As they have observed, most of the protocol studies have been done during the preliminary design stage by direct observation, recordings, etc. One major criticism to the descriptive models underlies on the data reliability. The requirement to verbalize may interfere with the design process itself. In the design protocols for example, designer's words cannot reveal those processes that are inherently nonverbal, for example, geometric reasoning. Moreover, while there is a consensus that during all phases of design from preliminary and early steps to detail design steps, designers exhibit the range of design strategies, this assumption has never been tested. In addition, few formal protocol studies have been done on the design teams. These factors must be taken into account when studying the results of the design protocols.



(a) French (1985) (b) Roozenburg and Eekels (1995)

Figure 2.3: The design process model

Table 2.2: Design descriptions extracted from the literature

Author(s)	Finding
Uflman and Dietterich (1986)	designers pursue a single design concept, and they will **patch and repair their original idea** rather than generate new alternatives
Waldron et al. (1987)	experienced designers **handle visual data more efficiently** and they use information at a higher symbolic level
Esterline et al. (1988)	the process of **problem formulation could not be separated** from the design process
Schon (1988)	designers work from **underlying types, such as *pavilion*** or, which are general and yet concretely particular
Marples (1961)	designers reuse familiar solutions and will not explore alternatives or innovative ideas **unless their new design fails badly** and cannot be salvaged
Allen (1989)	the **design itself changes and influences the environment** within which it evolves
Bucciarelli (1988)	language and multiple representations of design **shape the description of an artifact**
Stults (1986)	Design is a fractal-like process in which **the stages of design repeat continuously** at different times and at different levels of detail
Rzevski (1981)	Every design solution (that is, every artefact produced as a result of design) **will inevitably change equilibrium relationships within its environment** and thus create unforeseen problems
Fitzhorn (1988)	The design artifact is **an enumerated string from a formal grammar**, and the **rules of design are formal state** changes that govern the string enumeration

Unlike the descriptive models, the prescriptive models are more about what to do and how to do, and provide some systematic procedure to follow. In one sense, they are often regarded as providing a particular design methodology (Cross, 1998). Finger and Dixon (1989) divide prescriptive model into two categories: those that prescribe how the design process ought to proceed and those that prescribe the attributes that the design artifact ought to have. In the following paragraphs, I review some of these propositions, from the generic model of Jones and Archer to the detailed systematic model of Pahl and Beitz.

Jones (1981) suggests a basic structure for the design process: analysis, synthesis and evaluation. This simple conventional design process summarizes what should be done along the progress.

> ***Analysis.*** *Listing of all design requirements and the reduction of these to a complete set of logically related performance specifications.*
> ***Synthesis.*** *Finding possible solutions for each individual performance specification and building up complete designs from these with least possible compromise.*
> ***Evaluation.*** *Evaluating the accuracy with which alternative designs fulfil performance requirements for operation, manufacture and sales before the final design is selected.*

Some later, Archer (1984) proposed a more detailed perspective model of design, setting-up a search strategy for designers. This includes inputs and outputs, which connects the design process to the outside world. Archer's model is shown in Figure 2.4.

Some earlier, in a paper made for the first volume of the Design Studies journal Archer had explained the notion of provision in the relation between the problem and solutions (Archer, 1979):

> *"The first thing to recognise is that 'the problem' in a design problem, like any other all-defined problem, is not the statement of requirements, nor is 'the solution'. The means ultimately arrived at to meet those requirements. 'The problem' is obscurity about the requirements, the practicability of envisageable provisions and/or misfit between the requirements and the provisions. 'The solution' is a requirement/provision match that contains an acceptably small amount of residual misfit and obscurity. Thus, the relationship between design problem and design requirements, and design provision lies along one axis and the relationship between design problem and design solution lies along another axis."*

Many more complex models have been proposed, by various researchers and from various points of view. Although all the models tend to obscure the general structure of the design process by swamping in the fine detail of the numerous tasks and activities (Cross, 1998), a comprehensive and practical model should bring some clarity to the design tasks, and on the other aspects of rationalizing the design process.

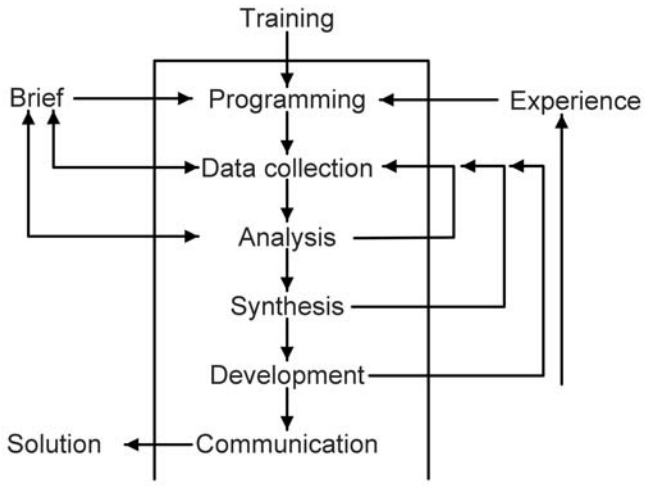


Figure 2.4: Archer's model of the design process; Programming: establish crucial issues, propose a course of action; Data collection: collect, classify and store data; Analysis: identify sub-problems, prepare performance (or design) specifications, reappraise proposed programme and estimate; Synthesis: prepare outline design proposals; Development: develop prototype design(s), prepare and execute validation studies; Communication: prepare manufacturing documentation (Archer, 1984).

Among numerous proposition for the prescriptive design methods, after having a review on the structural design methods and their classifications, to finish this part I chose to explain two important methodologies: the systematic design approach developed by Pahl and Beitz, and the design process of Cross. These two approaches are worldwide known and are being commonly used as dominant methods for exploration, refinement, specification, and education in the design research.

2.2.3 Engineering design, a Systematic approach

Pahl and Beitz propose a structure for describing the engineering design (Pahl et al., 2007). The flow of work during the process of design has been described in general terms as well as domain and product-specific terms. The systematic approach provides an extensive description of this flow of work, focused on mechanical engineering. In this objective, they divide the planning and design process into the following main phases:

- *Planning and task clarification: specification of information*

  The product development task is given to the engineering department by the marketing department, or a special department responsible for product planning. The purpose of this task clarification is to collect the information about the requirements that have to be fulfilled by the product, and also about the existing constraints and

their importance. This activity results in the specification of the information in the form of a requirements list that focuses on, and is tuned to, the interests of the design process and subsequent working steps.

- *Conceptual design: specification of the principle solution (concept)*

  The conceptual design phase determines the principle solution. This is achieved by abstracting the essential problems, establishing function structures, searching for suitable working principles and then combining those principles into a working structure. Conceptual design results in the specification of a principle solution.

- *Embodiment design: specification of the layout (construction)*

  During this phase, designers, starting from a concept (working structure, principle solution), determine the construction structure (overall layout) of a technical system in line with the technical and the economic criteria. Embodiment design results in the specification of a layout.

- *Detail design: specification of the production*

  This is the phase of the design process in which the arrangement, forms, dimensions and the surface properties of all of the individual parts are finally laid down, the materials are specified, the production possibilities is assessed, the costs is estimated, and all the drawings and other production documents are prepared.

The description above is a generalization of the existing processes. In practice a clear distinction between the working steps and their results cannot always be made, nor is it necessary to do so. However, this approach is useful for the designers to be aware of the main process flow and the tasks described in order to plan their work and to avoid leaving out something. Some details of four mains steps are given in Figure 2.5.

The systematic approach deliberates step-by-step procedure, and ensures that nothing essential has been overlooked or ignored, and is therefore indispensable in the case of the original designs. However, it is not impossible in real practice to face unforeseen consequences. Clearly this model has the primitive definition of the task and starts by acquiring the information about the requirements from outside, and then progressing through the steps. The approach does not contain prototyping and evaluation, which seems important for innovative design.

In the following part, I present the Cross's work in formalizing the engineering design process, but not focused on the mechanical engineering aspect. A brief comparison between these two approaches is given in the last part.

2.2.4 Model of Cross

"Certainly it seems that, in most design situations, it is not possible, or relevant, to attempt to analyze the problem, ab initio and in abstract isolation from solution concepts; the

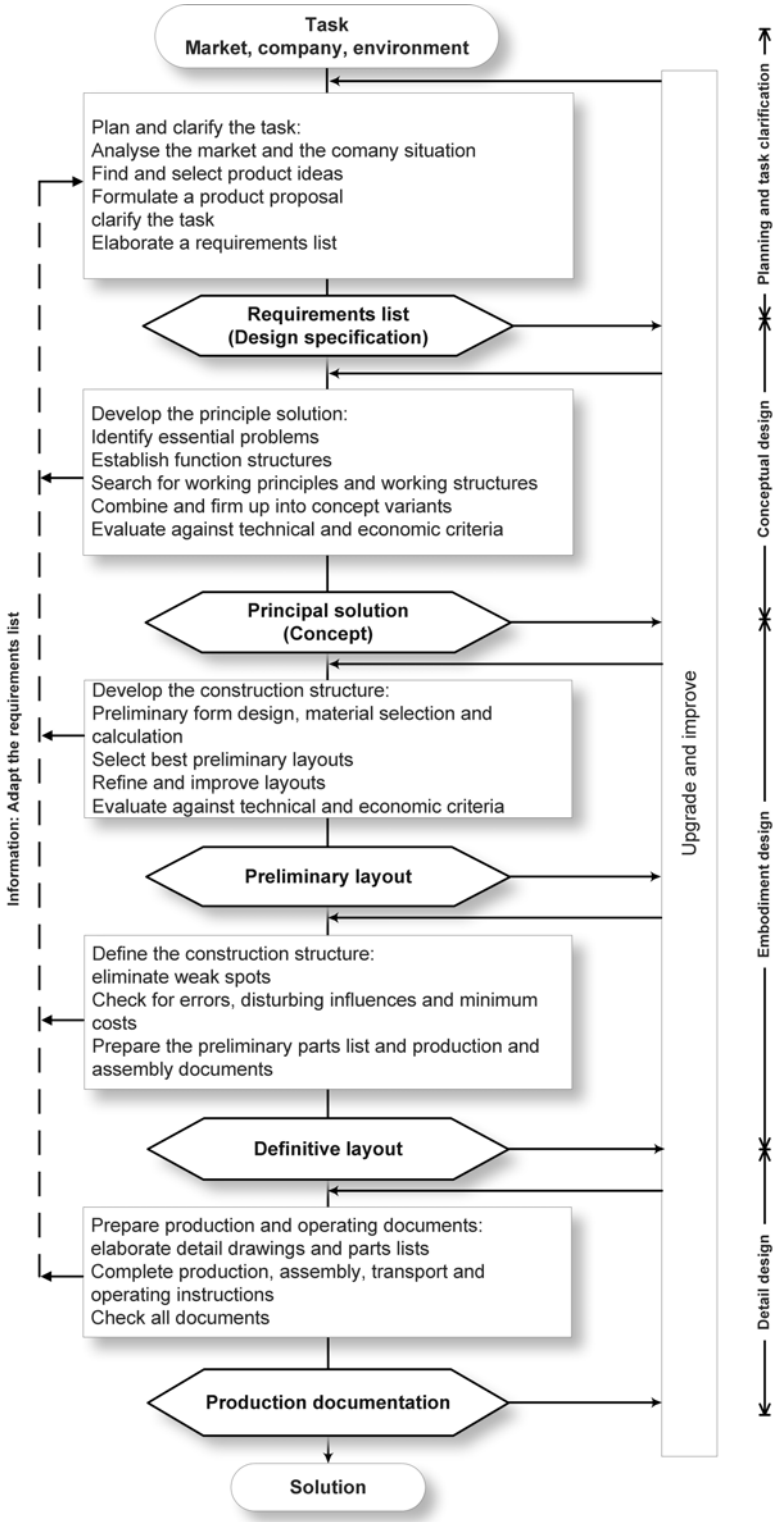


Figure 2.5: Systematic approach for engineering design (Pahl et al., 2007)

designer needs to explore and develop problem and solution together" (Cross, 1998). In this perspective Cross proposes some logical progression from problem to sub-problems and from sub-solutions to solution, as illustrated in Figure 2.6.

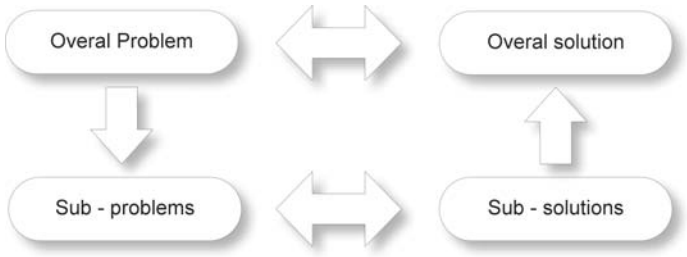


Figure 2.6: The symmetrical relationship of problem, sub-problems, sub-solutions, solution in design (Cross, 1998)

Aligned with this descriptive model, Cross proposes seven steps covering all aspects of the problem clarification to detail design. A short explanation of each step is given below. Figure 2.7 demonstrates how these steps are related to each other and to the symmetrical problem solution model (Figure 2.6). The explanation of each step is given in Table 2.3.

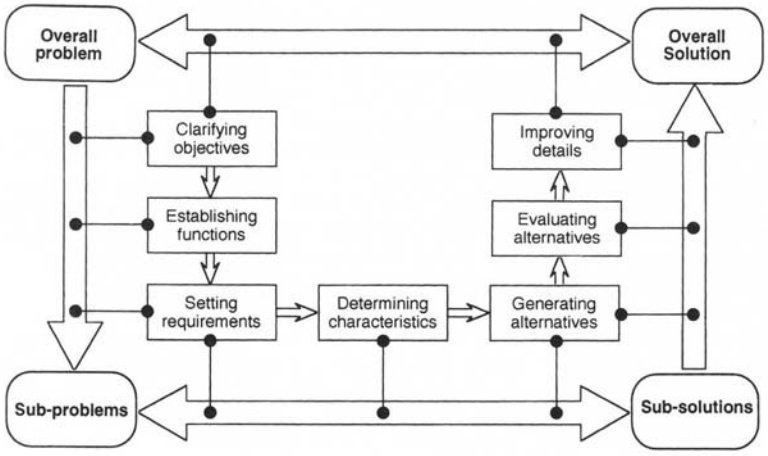


Figure 2.7: Seven stages of the design process positioned within the symmetrical problem-solution model (Cross, 1998)

This model of designing integrates the procedural aspects of the design problems with the structural aspects. The procedural aspects are represented by the sequence of methods and the structural aspects are represented by the arrows showing the commutative relationship between problem and solution, and the hierarchical relationship between problem/ sub-problems and between sub-solutions/solution.

Table 2.3: Description of design steps in Cross model (Cross, 1998)

Stage in the design process	**Method relevant to this stage**
Clarifying objectives	**Objective Tree** Aim: To clarify design objectives and sub-objectives, and the relationships between them
Establishing functions	**Function Analysis** Aim: To establish the functions required, and the system boundary, of a new design
Setting requirements	**Performance Specification** Aim: To make an accurate specification of the performance required of a design solution
Determining characteristics	**Quality Function Deployment** Aim: To set targets to be achieved for the engineering characteristics of a product, such that they satisfy customer requirements
Generating alternatives	**Morphological Chart** Aim: To generate the complete range of alternative design solutions for a product, and hence to widen the search for potentiel new solutions
Evaluating alternatives	**Weighted Objectives** Aim: To compare the utility values of alternative design proposais, on the basis of performance against differentially weighted objectives
Improving details	**Value Engineering** Aim: To increase or maintain the value of a product to its purchaser whilst reducing its cost to its producer

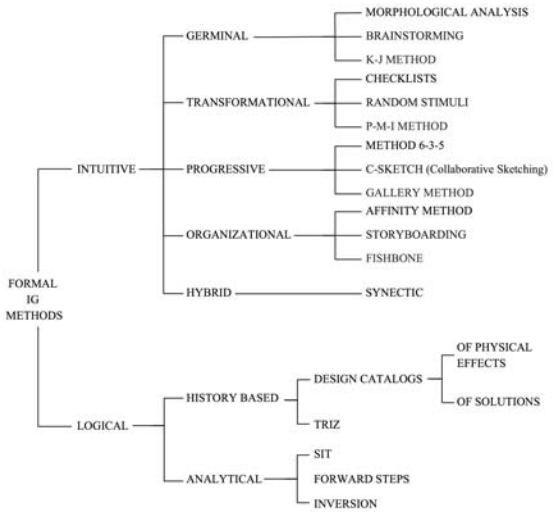
2.2.5 Toward a classification for existing methods

In the engineering design research, the design process is identified as a targeted move from the problem to the solution. While the different design methods agree on the nature of the design process and the trends in analysing the problem and making synthesis for the final solution, the representation of the process and highlights on importance of steps varies from one model to another.

As a result, there are many propositions (partial or generic) targeting the design activity, all tried to help the designers to solve the design problems and reach the solution in a shorter time and with a better organisation of sources. This section re-asks one part of the main question of the dissertation: "How to find out a proper design methods of doing design?" One preliminary answer would be an effort to find out what methods are proposed for, or which method matches which situation. In the first chapter I tried to find the answer among the surgical instrument literature. In this chapter I looked through the design glasses and found many interesting interpretation, characterisation and systematisation to help organising a design activity. To finish my exploration in this area, it seems relevant to refer to an interesting classification proposition on the design methods.

DTM Category		**Examples**
DTM to generate a new design solution		
Creativity-based Design	Pure invention (intuitive)	• Intuitive invention • Emergent Synthesis
	Stimulation methods	• Brainstorming • Bio-inspired design
Combination-based Design	Combining known knowledge	• Abduction
	Systematic	• Pahl & Beitz
Modification-based Design		• Traditional • TRIZ • Emergent synthesis
DTM to enrich information about functional and attributive information		• Optimization • Engineering analysis • QFD, FMEA • AD • DfX • Emergent Synthesis
DTM to manage design processes		• AD • DSM
DTM to represent design knowledge		• GDT • Solid modeling • Product modeling

(a) Classification of DTM (Tomiyama, 2006)



(b) Classification of idea generation methods (Shah et al., 2000)

Figure 2.8: Design theories and methodologies classifications

In a classification of design theories and methodologies (DTM) by Tomiyama (2006), two categories have been identified: DTM to generate a new design solution, and DTM to enrich the information about the functional and the attributive information. In this regard, the design is considered as a knowledge operation process, so two more categories in the DTM classification can be identified: DTM to manage the design process and DTM to represent the design information and knowledge. The classification and examples are summarized in Figure 2.8(a).

According to this classification, the design methodology which can respond to my interest -designing of the innovative surgical instruments - is situated in the first category, DTM to generate a new design solution. In another classification, the formal idea generation methods are broadly classified into two categories–intuitive and logical (Shah et al., 2000). Intuitive methods work by stimulating the unconscious thought processes of the human mind. The outcome is rather unpredictable, yet they may facilitate finding a novel solution. Logical or rational methods involve systematic decomposition and analysis of the problem. These methods make use of the science and engineering principles and/or the catalogues of the solutions or procedures. The subcategories of both intuitive and logical methods are shown in Figure 2.8(b).

2.2.6 Summary: Would the engineering design methods suffice?

So far in this review, the design process is treated as a knowledge manipulation process (Yoshikawa, 1981) which follows an essentially mental operation (Eekels, 2001). However, limitations of such design methods became apparent more or less quickly, both in general and in the specific context of this thesis. The knowledge involved in the design phases is contextual, dynamic and perpetually evolving, so it would be futile to hope to integrate it into the design office context in the form of the tools (Prudhomme et al., 2003).

In the engineering design, the nature of the design process is identified as the coordination of the single acts of the designer, and the collaboration of a group of the actors using interaction tools to solve a problem, or, to shift from a problematic situation, in which the needs are unsatisfied, to an objective situation in which they are. This group is not consisted only of the engineering designers, and as a result there are many activities and interactions that would overtake the technical design tasks and activities. Thus, as Brissaud and Garro (1996) point out, the design activities are distributed in particular among the different actors involved in the product life-cycle, and the integration of those actors from the earliest stages of the design is explicitly intended. It is critical to the success of a company to understand and to meet the requirements of their customers and end users, in the product design.

Moreover, almost all of the engineering design methods begin with a defined problem and/or defined tasks to accomplish, which is not the case in many medical and surgical design assignments (see chapter 1). The knowledge gap between engineering and medical professions involved in the design development implies the necessity of user integration, and an integrated design process to provide the multi designer reasoning. The technical or conceptual design in surgical context needs to be communicated and evaluated with the user (surgeon or OR technician) and this communication shows difficulties and requires intermediary objects and methods. Thus, choosing an engineering design method and a systematic approach, at least with respect to these definitions are not straightforward issues. It would thus appear that the methodological options to design should be opened to other approaches. In the following part, I look at the design in regard of a social and a

human-centered activity.

2.3 Design and the human-centered approach

In the anniversary of forty years of the design research, Cross (2007) quoted:

> *"Where the first generation of design methods was based on the application of systematic, rational, 'scientific' methods, the second generation moved away from attempts to optimize and from the omnipotence of the designer (especially for 'wicked problems'), towards recognition of satisfactory or appropriate solutions and an 'argumentative', participatory process in which designers are partners with the problem 'owners' (clients, customers, users, the community). However, this approach seemed to be more relevant to architecture and planning than engineering and industrial design, and meanwhile these fields were still developing their methodologies in somewhat different directions."*

Although some engineering design researchers put forward the idea of need integration into the design process (Prudhomme et al., 2003), the subject of user involvement in the design process was initiated by the studies in human-computer interactions (Bekker and Long, 2000; Karat, 1997), and widely accepted as a principle in the development of the usable and useful products and systems. In this section I review user-centered design, participatory design and scenario-based design which are main design approaches in this domain.

2.3.1 User-cenetred design

User-Centered Design (UCD) was introduced in the format of the standard ISO 13407: Human-Centered Design Processes for Interactive Systems (ISO13407, 1999), and accordingly several methods for capturing user requirements during the early design stage were proposed (Luck, 2003; Jokela, 2002). Figure 2.9 shows the UCD process model proposed by the standard.

To *understand and specify the context of use*, the characterizations of users, the tasks and the environment (physical and organizational) should be identified in detail. For the potential user the characteristic includes knowledge, competency, experience, education, training, physical characters, habits, preferences and aptitudes. For the consigned tasks, the description of the sensitive and responsive effects on usability such as the frequency and the run time is necessary. And, the environment contains material elements, software, and employed products.

The process of *specify the user and organizational requirements* distinguishes an ex-

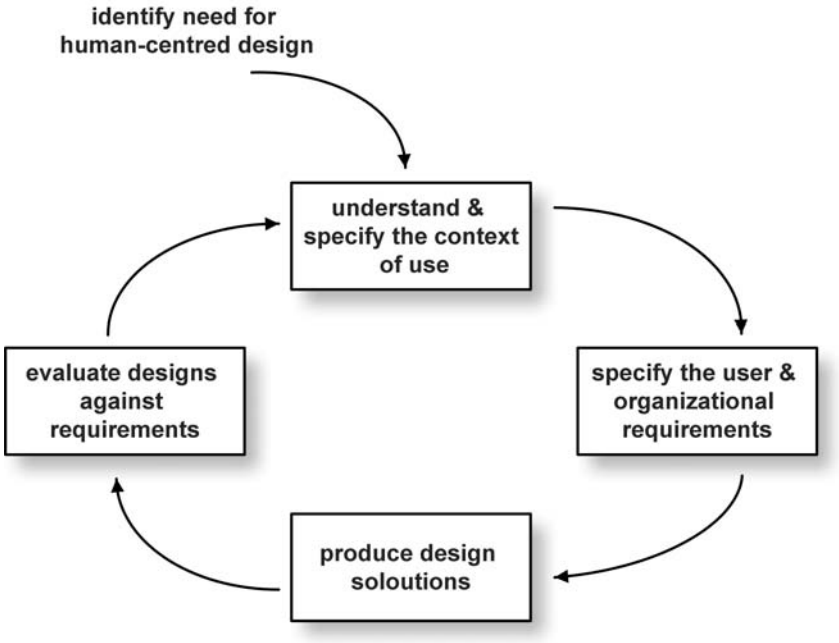


Figure 2.9: Processes for user-cenetred design in ISO 13407

plicit statement of user and organizational requirements in relation with the context of use description. Despite of the ambiguity of the definition of process in this step, there are some considerations in order to identify relevant requirements, such as the required performance of the new system against the operational and financial objectives, co-operation and communication between the users and the other relevant parties, management of change including training and personnel to be involved.

However, ISO proposes less detail about the other steps: The process of *Produce design solutions* is about producing the potential design solutions by drawing on the established state of the art, the experience and the knowledge of the participants and the results of the context of usage analysis. The process of *Evaluate designs against requirement* according to the ISO is an essential step in human-centered design and should take place at all stages in the system life cycle.

The main advantage of the UCD approach is to make a deeper understanding of the psychological, organizational, social and ergonomic factors that affect the use, but I still need some intermediates to identify, capture, and analyze these inputs understanding from the user. Although the ISO 13407 describes each process in detail, it takes an informal way. It is not clear that how a process defined by sub-sequences and is it just between two phases or also in one phase. This ambiguity encourages the researchers to meet the formality of process definitions set which ends to development of many models improving the UCD concept such as work of Jokela (2001) and also to look for other user anticipation

approaches from various points of view.

2.3.2 Participatory Design

So far, the user was not really a part of the team, but is spoken for the designer by the intermediates. By the end of 1999, many participatory experiences showed that the roles of the designer and the researcher blur and the user becomes a critical component of the process. It was a shift in attitude from designing for users to one of designing with users (Sanders, 2002). This new concept is called differently such as user-design, post design and participatory design (Carr-Chellman et al., 1998). Clement and Van den Besselaar (1993) outlined three basic requirements for participation: 1) Access to relevant information, 2) The possibility of taking an independent position on the problems, and 3) Participation in decision making.

Design processes that involve user participation have evolved among several design uses and professions, in both product and software engineering (Sanders, 2002). User should not be neglected anymore, and the designers should be prepared for dealing with user integration issues. "The new rules call for new tools" quoted from Sanders that addresses the users: "Users want to express themselves, and to participate directly and proactively in the design development process" (Grudin and Pruitt, 2002).

Caelen proposed Moment Theory as an approach in the participatory design, and accordingly proposed a model of the design process. This model formalizes the user contribution to the design, and helps the organization of design activity during the project considering the cycle of capture, observation, conceptualization and capitalization (Caelen et al., 2005). Thus, the participatory methods had some efforts from product developers to adapt and extend the elements of the participatory design approach. Some of these issues which are mentioned as low-fidelity mock-ups and prototyping, increased the engagement and the communication with potential users, and the emphasis on site visits and understanding the work context. Reich et al. (1996) identified four key issues in participatory design projects as the key for extending participation activities:

1. The recording of historical data on participation activities
2. The provision of educational material
3. The articulation of informal knowledge
4. The support of asynchronous communication among participants

However, the choice to participate is limited by a given participant's experience, understanding, motivation, and the pressing need to get things done.

2.3.3 Scenario and design

A substantial amount of current research and development activities is focused on creating a more usage-oriented perspective on the new product development. One key element in this perspective is the user interaction scenario, a narrative description of what users do and experience as they try to make use of the new products. Thus, the first question would be what is the scenario and how does it look like?

Scenarios are the stories about people and their activities (Carroll, 2000), and these stories are more and more attractive for the researchers who try to find the logic of the design by studying the essential aspects of the problem and the birth of the solution. First researches about the scenario was about to characterize the story by a setting of elements (Propp, 1958). In the same context, researchers made effort to discover new aspects of the scenario: Agents and actors, goals and objectives, and actions and events were being included as the main notions and in different domains, researchers started to use the scenario as a tool for design or introduce it consciously to the design process. Historically, strategic gaming and military were the first use of scenario (Becker, 1983; Brown, 1968). In management and economy, scenario has been used for analyzing the consequence of actions and policies. By the first proposition of the use of scenario in Human-Computer Interactions (HCI) (Young and Barnard, 1987), researchers have employed scenarios as representation of system requirements to improve the communication between developers and users. The idea to recognize some consequences in the description of activities involving actors and details of the situation of manipulation makes the researchers use the "scenario-based" term in their methodologies. A superficial search leads to find lots of scenario-based methodologies in variant disciplines, such as decision making (Bontemps and Schobbens, 2007; Blanning, 1995), technology (in software) development (Weidenhaupt et al., 1998), requirement analysis (Jintae et al., 2006), accounting (Pacharn and Zhang, 2006), and finally the design as the Scenario-based Design (Carroll, 1995; Hertzum, 2003; Yin-Leng et al., 2005).

As some observation recognizes the scenarios like "one of the least understood recent success stories in the information technology (IT) and management areas" (Jarke et al., 1998), there are some main domains in which use of scenario stands out. Jarke et al. reviewed scenario from three major disciplines: strategic management, human-computer interaction and software and system engineering, and propose an interdisciplinary framework for scenario management. They also concluded that despite of some diversity in terminology and use, two particular qualities emerge from their study. First, a scenario is a context-dependent and purposeful description of the word with the focus on task interaction. Second, scenarios are a mean of communication among stakeholders. Their findings are summarized by Hertzum considering the underlying role of scenario: to ground decisions in a sound and communicable understanding of the use situation (Hertzum, 2003).

The scenario is supposed to capture and explore the finer structure of the operative psychology in the situation of use (Carroll, 1995). Kurakawa proposes situation as the

one of the three essential components of a scenario, and he defines the situation as "the setting surrounding the actor/agent and the state before and after the actor/agent takes a particular action or there occurs a particular event." (Kurakawa, 2004). Mostly, description of the situation of use is given by the scenario. This description desired to be narrative, detailed (Carroll, 1995), and to be written very carefully (Diaper, 2002), but unfortunately there is no accurate study about the situation of use, except for the issue of task analysis. The specification of the environment or the different elements of use situation are very important, particularly when we need to realize that an artifact could not be used free of environmental elements. Scenario-based design provides a framework for managing the flow of design activity and information in the task-artifact cycle (Carroll, 2000). Designers can see their work as artefacts-in use and, through this focus, to realize usage and other use-related constraints in the design process. Moreover, researchers can use scenarios to analyze the varied possibilities afforded by their designs through many alternative views of usage situations. This concept is represented in Figure 2.10.

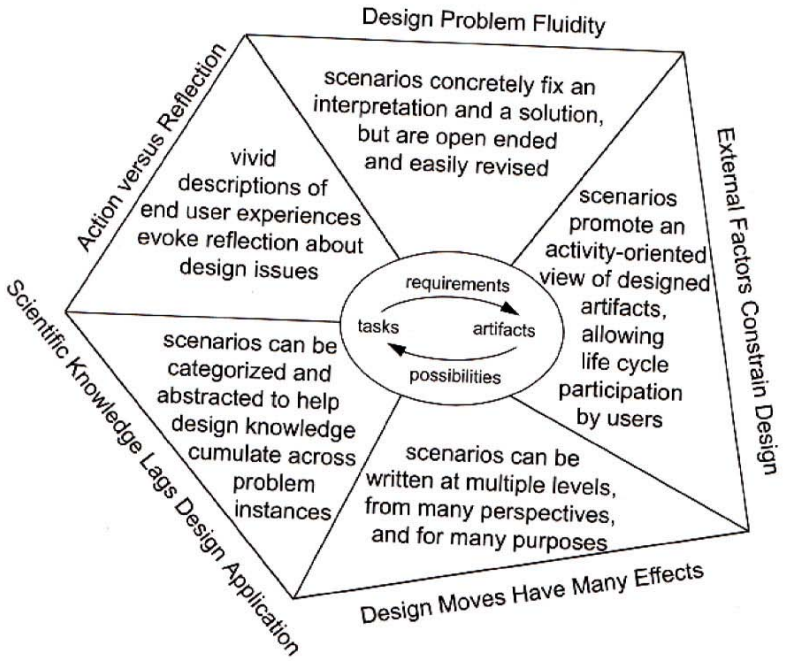


Figure 2.10: Challenges and approaches in scenario-based design from (Carroll, 1995)

We should point out a question here: "How does the scenario help designers to make a good design?" The answer is not strict, and depends on the nature of the product (a software versus a mechanical device). A Scenario helps to clarify what the usage supposed to be and how the design can satisfy the predicted use. In the design of the surgical instruments, a scenario can be the description of the operation procedure. It can also serve as a research tool in surgeon's act analysis. I come back to this discussion in chapter 5.

2.3.4 Conclusion

There are many insights to use participatory design as a design method for product development (see Design studies and CoDesign journals). However, the problem in many participatory design projects is that the user participation is commonly based on, for example, description of the current work practices and testing or evaluating of the existing products, but users' design-related ideas and decisions are left out (Kensing and Blomberg, 1998). Iterative and adaptive processes in creativity are in conflict with typical design development methods (Edmonds, 2006). The absence of a common vocabulary can limit the dialogue between the designer and the user (Luck, 2003). Moreover, most of design studies concerning user needs have been based on novices or, at best, accessible users of relatively modest talents. The reason is somehow obvious: it is easier to obtain such people as subjects of the study and they seem to provide enough data.

Hence, such a discussion implies that the integration of a "special user" in the design process cannot be covered by actual propositions and methods. Olson and Bakke (2001) reviewed some experiences of using the 'lead user' method. von Hippel (2005) studied the lead users in co-creative activities, and Visser et al. (2005) proposed (each) the user is a part of the design team as the 'expert of their experiences'. The concepts of the experts and the expertise are debated within the field of epistemology under the general heading of the expert knowledge. In contrast, the opposite of a specialist would be a generalist, somebody with expertise in many fields. The word experience means direct observation of or participation in events as a basis of knowledge and the fact or state of having been affected by or gain the knowledge through direct observation or participation (Merriam-Webster). Expert is the person who supposed to have the experience. When designers design for a use situation, they usually put themselves in the role of the user (Buur, 1993). A designer or an engineer can hardly be representative for the user, and this role is almost invalid in case of the expert users with professional knowledge. It is also necessary to give more attention to users' cognitive ability as the key element in information processing.

2.4 Experimental models for design

Evidence-based design is the process of basing decisions about the built environment on credible research to achieve the best possible outcomes. This approach is used by architects, interior designers, facility managers, and more recently by health care practitioners. An evidence-based designer, together with the user, makes decisions based on the best information available from research, from project evaluations, and also from evidence gathered from the user' activity. In health care, the evidence-based design used for three main categories:

1. Treatment modalities (models of care, technology);
2. Quality & safety (infections, errors, falls);
3. Exercise (exertion, rehabilitation).

Until recently, researchers seemed not very interested in this approach. However the debate exists on the intuition-driven approaches versus evidence-based design. Harbour shows the use an importance of a systematic review of the scientific evidence for preparing clinical guidelines (Harbour and Miller, 2009). Sadler et al. (2009) discussed the role of the evidence-based design in building future hospitals, enhancing the safety and quality.

To conclude, the evidence-based design can be considered as a design method, but this method does not propose a process view or model. The large application if this method in clinical and healthcare studies brings the hypothesis that this method respond sufficiently for such studies. And, the terminology of design may differ from what was considered in engineering design. However, I scanned two design journals for evidence-based design and came up with no relevant results.

2.5 A framework of design approaches from literature

So far in this chapter, I looked at the descriptive and prescriptive propositions for the design process with two considerations: first a rational, formalized and systematic approach to technical design which can roughly called engineering approach, and second the user centric and participatory approach. In the focus of this dissertation, design of the surgical instruments, developing a multifunctional optimized mechanism is the main goal of the design. This is particularly true for the innovative surgery, where the innovative procedures by which surgeons aim to make a better performance depends on the new instruments. In such a product, the usage issues – like usability and ergonomics – which can alter the favorability of the product, may fade. To stay competitive and successful, therefore many surgical instrument designers are driven by the pressure to keep the user convinced and satisfied. Accordingly, the design process I am looking for to develop should have an arrangement of both approaches.

Two questions arise here: First, is it possible to put together and confront the both general design approaches – engineering design and user-centered design – in order to find a modified appropriate method of design for the design of the surgical instruments? In case of a positive answer, the second question is how to develop, validate, and enrich such a method? In this section as follows I try to draw a rough proposition for the first question, by bringing together and comparing the steps and the elements of the reviewed models. The answer to the second question will take the whole next chapter.

What happens if I draw some connections between two approaches? On one hand, as it is shown in the previous chapter, surgical instruments are complicated, multifunctional and very precise. Thus the design is multidisciplinary and various expertises should collaborate. The design has a great share of innovation and all of the expected issues necessitate having adequate design methods and tools to support the new product development. On the other hand the importance of the usability and the user side issues are largely studied and reported in scientific publications.

Putting together the two approaches, three main phases can be identified in common for both models:

1. Understanding and specifying the context of use
2. Conceptual Design
3. Evaluation with user

These three steps are shown in Figure 2.11, together with the methods proposed in the literature. While the systematic approach proposes a formalized way for conceptual design, the UCD shows the steps for understanding and specification of use, looking forward to extracting the needs and usage tasks, and translate it to a requirement list. Moreover, UCD considers the evaluation of the solutions against the usage tasks. Thus, a first idea would be to have both point of views, and list the methods and techniques proposed in the literature for each side in this way: 1) UCD and participatory design methods for understanding the requirements, and for usability evaluation. 2) Engineering design methods for technical design and evaluation. In this way, the boundary connection of two approaches becomes very sensitive and important (see Figure 2.12)

As a result, the first proposition for the design model for surgical instruments can be drawn. The main steps and tasks are listed below. As I shall discuss later, this model provides nothing critically new, but a basic structure to perform a research project and obtain observation and results.

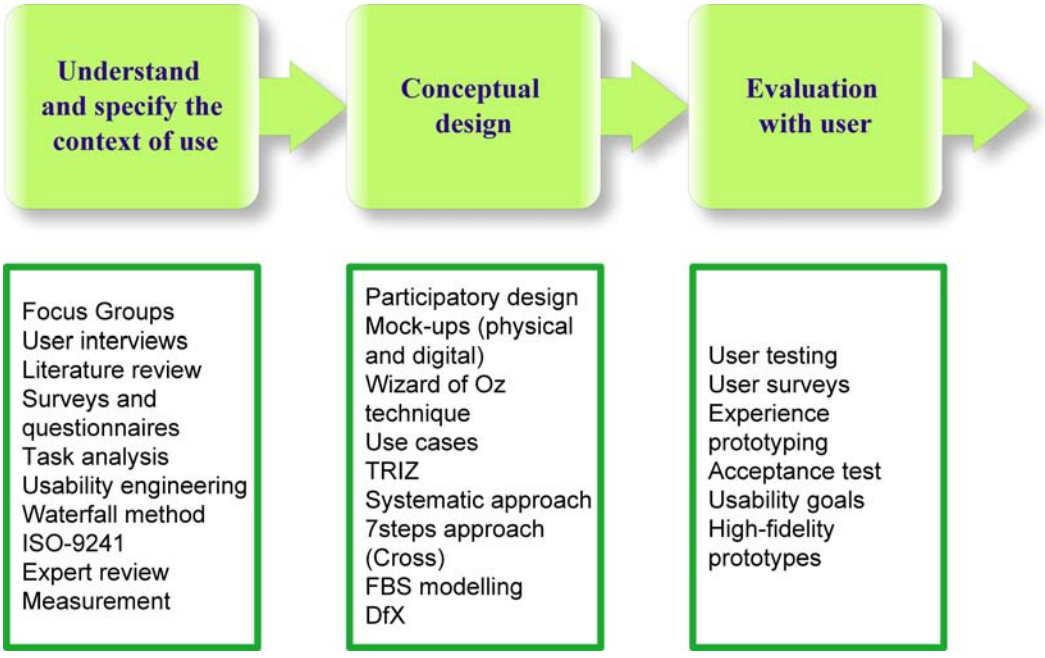


Figure 2.11: Design main steps and proposed methods

Understanding Problem

- Actual operation
- Scenario for new operation
- Translate the operation scenario to mechanical functions
- Make (technical) requirement list
- Identify usage limitations according situation (OR)

Conceptual Design

- Generate alternatives
- Classify the alternatives and find interrelation
- Evaluation alternatives (technical)
- Evaluate alternatives due to usage
- Select the best solution

Evaluation with the user

- Prepare a simple mockup
- Prepare a usage scenario
- Emulate (physical simulation) for usage situation
- Ask the user to manipulate and comment
- Observe and capture of usage

Detail Design

- CAD modelling and layout structure
- Prototyping with clinical standards
- Detail evaluation (technical and usage) in clinical satiation
- Finalize the design solution

Clinical evaluation

- Prepare healthcare authorisation for the instrument
- Prepare ethical authorisation
- Prepare precise usage scenario
- Ask user to manipulate the instrument in real situation and comment
- Observe, capture for further analysis

This method of designing aims at integrating the user and participatory aspects with the engineering design aspects. I leave the details of this method here, and will come back to the model and explanation of each step with a real case of design, in Chapter 3.

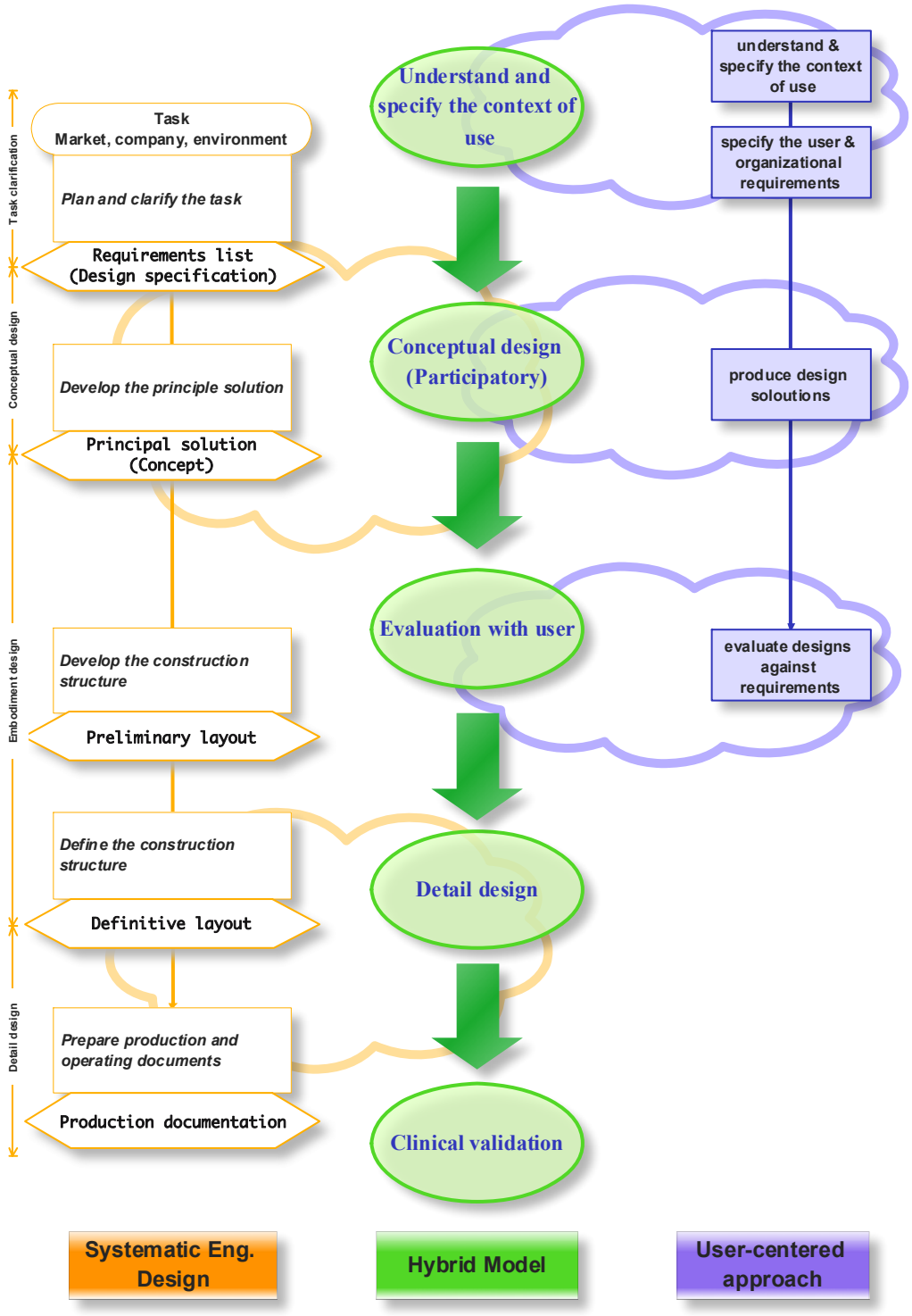


Figure 2.12: Design steps placement between systematic and user-centered approaches

2.6 Conclusion

This chapter provided a literature review on design methodologies, with two main focuses on engineering design and user integration. The overall approach and the specific methods described in this chapter have been applied in many studies. The third type studies such as design for patient safety confirm the importance of evidence-based methods as well as theoretical literature of design.

In conclusion, as I could point out from this review, the engineering design models and UCD models could be used in completion form to provide a structure for the design in the context of new surgical instruments.

According to Swann (2002), "design is for human consumption and not bounded by the quantifiable certainties of the physical world. ... Design deals in human interactions with artifacts and situations that contain a great deal of uncertainty." This research, however, is dedicated to a design process of products which are at the same time highly complex in technical aspects, and are fundamentally user-dependent and participative for actors of the different domains. Thus it does deal with human interactions and uncertainties.

In this chapter, I put emphasis on the characteristics of the design methodology for design of innovative surgical instruments, according to the literature on engineering design and user integration in design. A design model proposed to cover most aspects designer face in designing of surgical or medical products. Nonetheless, this design model provides a basis for research and experimentation in term of surgical design project.

In the next chapter, I will describe my research approach and methodology to attack the design problematic in the field of the surgical instruments. I explain the research approach which guides us to organize and anticipate a design project, in the context of MIS, to see the application of the explained model and to examine the relevancy and suitability of the hypothesis in practice.

Chapter 3

Action of research: Protige design project

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In this chapter you will find :

- *What the action research is, and how I used it as my research methodology*
- *How I gathered data from academia, hospitals and industry*
- *The Protige project, my action in the design of a surgical instrument*
- *The details of design progression in university as well as in hospital*

3.1 Introduction

Design as a discipline has various characteristics, and as the previous chapter showed, it has been a challenging subject for researchers in the field to identify, characterize, and prescribe design activities from the problem statement to the final solution. Design is a human activity. To drive from one step to the next (for instance from the requirements to the functions), we should distinguish human operations by their orientation in time, target, share, etc. Design models could not always tell us how these steps happen. They may not always propose a good strategy for moving forward, because of the dissimilarity in the design subjects, the design contexts, or the design environments. There is much to know and learn about the design, and the way forward is the design research. There are many theoretical studies and design frameworks in the literature. But, can a design research be limited to the theoretical studying and establishing models? Does such a strategy work for interpreting any design context? One can imagine that those questions have been asked and re-asked many times and caused a turning point in the design research. That may be the reason why the interpretive nature of the design became important, and as a result, the epistemology of practice based research formed the movements like “action research”.

The action research arises from a problem, dilemma, or ambiguity in a situation in which the practitioners find themselves (Swann, 2002). It is a practical research methodology that usually is described as requiring three conditions to be met. First, its subject matter normally is situated in a social practice that needs to be changed; second, it is a participatory activity at which the researchers work in equitable collaboration; and third, the project proceeds through a spiral of cycles of planning, acting, observing, and reflecting in a systematic and documented study (Kember and Kelly, 1993).

The action research was first conceptualized by Lewin (1952) and further developed by Kolb (1984), Carr and Kemmis (1986) and reoriented to design by Swann (2002). Swann explains action research as a spiral of cycles of action and research consisting of four major moments: plan, act, observe, and reflect. These steps are shown in the Figure 3.1

Figure 3.1: Action research diagram (Illustrated by the author based on (Swann, 2002))

In this approach, the plan includes problem analysis and a strategic plan; action refers to the implementation of the strategic plan; observation includes an evaluation of the action by appropriate methods and techniques; and reflection means reflecting on the result of the evaluation and on the whole action and research process, which may lead to the identification of a new problem or problems and hence a new cycle of planning, acting, observing and reflecting.

Swann (2002) points out that the action research and the action of designing are so close, thus it would require only a few words to be substituted for the theoretical frameworks of action research to make it applicable to design. A very similar idea to action research was promoted by Bruce Archer, termed out as "research through design" and "evidence-based design". For design practice he argued that there was a need for method and rigor, and for decisions to be recorded and explained so they could, if necessary, be defended and explained (Archer, 1981, 1995).

Inspired from all these motivations in practice-led research, we chose, as a demarche for this PhD work, to setup a design project to have a mode of enquiry. This design practice will be used to create an evidence basis for something demonstrated or found out.

Coming back to Kember's conditions, let's see if this research can be a action research.

First, the subject of innovative surgical instruments design is a collaborative practice when the actual situation needs to be changed. In other words, as it is explained in detail in the first chapter, the problematic of the innovative design in surgery could no longer be studied in an isolated field of engineering or surgery. So the design in surgery is a developing

social activity in which many actors take part.

Second, concerning the participation of research, the high rate of innovation and publication in the field of surgical instruments design shows that in this context the role of designer does not really vary from the role of researcher (in contrast with designing a car, furniture, or industrial products). Thus in a design project, researchers have a participatory activity and also a fair collaboration with designers.

Third, like the surgery itself, design of surgical instruments is a spiral cycle of planning, acting, observing and reflecting. The project is documented by sketches, 3D models and also operation protocol and clinical data.

In this perspective, it seems authentic to base our research methodology on action research to start this study and looking for reliable answers to our problematic. So, this chapter piles up the whole experimental part of this thesis. Considering the action research diagram (Figure 3.1), the plan, action, observation and reflection will be defined.

Section 3.2 brings our plan: the general demarche to refine the research questions about the design methodology of surgical instruments. Section 3.3 is about the action, and though delineates why and how the subject of action has been selected, and then describes our case study background which is the design of a spinal surgery instrument for transforming actual open surgery to minimally invasive.

Being still in the detail of action, the section 3.4 explains in detail how this project went on and what was our contribution to organize this project and drive the progression process. I finish this chapter by summing up our project results and our research findings in section 3.5. The observation and reflection on the action are the subjects of two next chapters (chapter 4 and chapter 5).

3.2 Demarche and the research question

The integration of personal design project within research is not new, and almost common in design PhDs, but rare in publication. Every research method starts with exploration. The simplest and the most common way of exploration is solving questions, principally, asking them, even when lacking an answer. By asking major questions like “What needs the design methodology should satisfy?” or “Who are the user of the design methodology and how could they be helped by?”, I was encouraged to find out everything about my research, through exploring, observing, thinking and verifying.

The meta-structure of design in this PhD study is the global and holistic conceptualization of the actions and the environment, so every activity in the design and use of the surgical instruments, in the culture of design innovation. Since I will turn back to action following the action research approach, now I can make statement about the environment: Where should I look and how to look, to find the answers to my research questions?

3.2.1 Research environment

For deeply understanding the problematic of the surgical instruments design, I investigated different kinds of concerned environments. In this section, my research environment including academia, industry and hospital is explained. After explaining each of these environments, I put forward what I have learned from, and the way I summarize the main issues.

3.2.1.1 Academia and university

For a deeper understanding of design, I needed to know the application of design theories, methods and models in the daily life of design research centers. My PhD employment was located in the Integrated Design department of the G-SCOP Laboratory (Grenoble research center of sciences for design, optimization and production) where I built up my vision of design, explained in detail in the previous chapter. In brief, the notion of collaborative activity, the need integration into the design process and the analysis of the designers' activities are some good examples of our research context in G-SCOP laboratory. However, the action research method was one of the discussion subjects of monthly laboratory meetings.

Besides, I had the opportunity to work with the "Design and Evaluation of Interactive Systems" team of Grenoble center of informatics (LIG). There, I learned about the man-machine interaction issues, the participative design, and about the interaction with user and associated techniques. A synthesis of this vision was presented in the previous chapter.

Scientific visit at TU Delft Despite of the good opportunity to learn from and work with design researchers, I had no chance to be in contact with designers of surgical instruments, which seemed important and necessary for this research. For this reason, I applied for a scientific visit at a research group of surgical instruments designers. Very fortunately, I went to the Department of Biomechanical Engineering, Delft University of Technology, and I stayed with Minimally Invasive Surgery and Interventional Techniques (MISIT) group. The aim of MISIT is to provide the facilities to offer a better healthcare. Using a clinically driven approach, MISIT aims to improve minimally invasive techniques through the development of new instruments and training devices.

This visit gave me the opportunity to be with designers, to observe them, to discuss with them and to ask my questions. Under the supervision of Professor Jenny Dankelman, I was introduced to four projects. Since MISIT has a strong collaboration with hospitals and surgeons, I took the advantage of contacting the medical side, which is explained further.

What I faced in the first place was the clinically driven approach, which was a strategy to fill the surgeon-engineer gap. This strategy comes from the fact that the engineers would not be able to understand the medical needs and problems unless they actually observed the medical process. Furthermore, just producing a device or a system on demand of a

surgeon or a doctor may not result in a suitable instrument. There are several reasons lying on the gap between the engineering and the medical domain, for example medical doctors may not have enough knowledge about the technological possibilities and limitations, and engineers do not have expertise on anatomy and organs characters, even if they gain enough knowledge about the targeted medication or operation.

Therefore, I looked forward to finding the answer of the principal question: What should be done to fill the gap? I organized a little series of interviews of the colleagues of MISIT. I preferred not to use questionnaires for this job. The reason was that those four projects were different enough not to be interrogated in the same manner. Moreover, I noticed another gap between the ontology of design researchers and designers. So I kept it simple by trying to capture what I was looking for through the descriptive and sometimes technical talk of the interviewee, and confirm it with re-questioning.

Here are the main questions:

1. Who is the user in your design? How do you identify and characterize his requirements?
2. How often do you need to contact the user, what are the contact reasons? How do you make the contact?
3. How do you evaluate your ideas, propositions or design solutions facing with the user?

At the first glance, the interviews didn't show critical findings against what the literature had showed. Designer needs to understand the clinical problem, though he/she contacts the user to have an observation in the clinical situation, and to ask some questions. In some cases, a series of observations is needed to clarify problem and gather some evidences. In the next step of design, once an idea came to realization, the designer likes the design to be evaluated by the user. However, this little investigation showed the cognitive synchronization between the user (surgeon) and the designer takes a long time. In addition, there is no methodology to follow for innovative design. Surgeon is mostly welcome to test and examine new ideas, in clinical situation (in vitro), and the non-written rule is to go to take surgeon's time once you have a worthy idea.

Table 3.1 shows a summary of the findings from the interviews at Delft University. Since the focus was on the user, I tried to find out more about the reasons for contacting user, how the contact is made, and how the user evaluates the design solutions.

This table presents a preliminary, but very interesting preview of surgical instruments design projects at the university. At the first place, the contact with the surgeon started from the beginning of the projects and OR visits provided the best opportunity to know the surgeon's workplace and understand the environmental facilities and constraints. However, the university research is not always supposed to reach a final product, though there is not much effort to have OR tests. In the case of the MISIT program, the considerable number of patents coming from the research and then spin-offs commercializing those ideas, showed the strong capacity of finding the clinical problem and responding the demand by the

Table 3.1: User contact and design evaluation methods in PhD projects at MISIT, TU Delft

		Reason for user contact			**How to contact**			**Design evaluation**			
Project	**User**	Understanding the clinical problem	Observation of clinical situation	Asking for clinical information	Project meeting	In hospital/OR	Regular	Idea	Physical prototype	Clinical/In-vitro test	OR test
Shape memory Colonoscope	Colonoscopy surgeon	✓	✓	✓		✓			✓	✓	
Breathing control system for immature infants	Nurses		✓			✓				✓	
Laparoscopy trainer	Surgeon, trainees			✓		✓		✓	✓	✓	
Operating room design - Lighting & Instrumentation - Flexible	Surgeon, assistant, other surgical team	✓	✓	✓	✓	✓					

innovation design.

To sum up, the academic environment provides some important initiations for the design research in the specific field of innovation in the surgical application, which I listed below:

- A big picture of the industrial design and production methods, the different approaches and pros and cons, and a large set of different experiences and case studies
- The basic knowledge about the design in surgical domain, the state of art and current problems
- An infra-structure to develop my research question
- Initiation of a scientific approach to design process of surgical instruments, a hybrid of different methods such as engineering design (in G-SCOP), user-centered (in LIG), and clinically-driven approach (in MISIT)

3.2.1.2 Industry

The academic environment offers a theoretical, scientific view of what design process should be, and what are the main problems in the industry and the solution approaches. But going to the industrial world and discussing with the people in the actual workflow can demonstrate some overlooked issues. With this idea, we tried to establish some connections with related industries to have meetings and to exchange ideas, etc. The main objective for this work was firstly to understand the industrial needs, and to verify our understanding of the industrial problem. Second, I tried to evaluate the approach with the industrial point of view. However, because of – more than expected – security and confidentiality issues, the discussions couldn't proceed in many details and stood at general information level.

I had some meetings with four enterprises, active in four different levels from an international leader to a spin-off, and I could discuss and clarify some interesting issues. A summary of this discussion is presented in Table 3.2. First, some general data about each contact is shown, then a brief synthesis about the discussion and the important findings.

1) **Medtronic** The meeting with Medtronic took place when I had started the observation in the operating room and was looking for a framework of analysis and formalization. My main hypothesis was that engineers need to watch some operations to understand the actual operation and identify the problems, and also to see the usage of a prototype. The second hypothesis was that in industry, it was not always possible for many engineers to go to OR quiet often, thus, a system of observation and capture could help. Furthermore, I was wondering if there was already a technology (software/hardware) in industry to help image processing and automatic annotation of video observations.

The first hypothesis was confirmed by the R&D manager: "In practice there are many visits into hospitals". The discussions also implied that there were many video captures. But, in absence of any technical solution, almost all of video captures were stored, somehow

Table 3.2: Industrial contacts and interviews

Name, Location	Speciality	Contact person	Contact	Reference
Medtronic, Lausanne (Ch)	Various surgical instruments	R&D manager	Meeting	http://www.medtronic.com/
Biomet, Valence (Fr)	MIS, Customised prosthesis,	R&D manager	Meeting	http://www.biomet.fr/
Kiscomedica, St. Priest (Fr)	Spine and orthopaedics products	Production manager, Marketing manager	2 meetings	http://www.kiscomedica.com/
DEAM, Amsterdam (Nl)	MIS instruments	CEO, Technical manager	Meetings, interviews	http://www.deamcorporation.com/

useless. The interviewee approved that the any attempts to make use of video capture such as image recognition, automatic annotation and database generation would be welcome for the industry.

2) **Biomet** In my contact with Biomet, I would like to know about how a new design project starts and progresses. In their approach, a team of surgeons and engineers started the project under the direction of a project manager in the industry location. They discuss about the problem and the possible solutions, and agreed on a certain strategy. Two months later, the engineers prepared a simulation and a prototype, so they met again to evaluate the idea. If the idea seemed promising, the legal process such as patent and healthcare certification began. In parallel, surgeons prepare a set-up for clinical validation.

However, according to their experience, this typical process was not feasible when the new product was a totally new concept, or had revolutionary innovation. In other words, this generic process is possible for small modifications on existing instruments. According to the company, most of the new products were in response to the requirements of the surgeons in their practice.

3) **Kiscomedica** Kiskomedica is focused on the niche of the spine products, such as spinal fusion system for surgery (screw, rod, and related tools) and not really targets big innovations in design, but in production. With this strategy, they work more on the aspects such as packaging, ergonomics, logistics, etc. and interestingly they have close relation with surgeons, and irregularly OR visits and work meeting. The discussions with Kiscomedica clarified that integrating the surgeons in the design process was not limited to the design and design innovation issues and could go much further in the product lifecycle.

4) **DEAM** I had the chance of meeting and interviewing key persons of DEAM Corporation during my visit in TU Delft. DEAM has been started as a spin-off from TU Delft, by a team composed of a professor, a PhD graduated from TU Delft Biomechanical Eng. and

an investor with great experiences in surgical instrument design. It was a good opportunity to see and study a structure, right in the middle of the university projects and the industrial environment.

The interviews I had with DEAM showed a very close relation with surgeons and hospitals. It was very relevant because the main product of DEAM was a revolutionary innovation in MIS instruments structure, and together with clinical needs, it presents adequate instruments for new surgeries.

This contact helped me to familiarize with the industrialization process of a surgical instrument, start with the innovation and patent issues at university, up to making professional prototypes, selling patents and dealing with large industries on research contracts.

In short, what I did learn from the contact with the industry are:

- Design process for non-revolutionary innovations (which is a stable strategy for most SMEs) initiates based on the surgeon's requirements. A team of engineering and surgery competencies is set to narrow down on the requirements, find functional and technological solutions, evaluate the solutions with the surgeons (one or two clinical test) and go to production. This process takes almost 18 to 24 months, from the beginning to the end (product in market).
- In an industrial production process, the role of the surgeon is not limited to bringing the idea or evaluating some prototypes; it is important in sales and marketing as well.
- Unlike the companies in Information Technology industry, the large enterprises are very interested in investigation on radical innovations. However, many innovative products and systems come from spin-offs and start-ups, and the successful one's are bought or contracted by the large industries.
- It doesn't seem that the industry produces ideal products, neither uses ideal production process. There are not many researches on these corporations (unlike the car industry or aviation) ongoing at universities. However the industry is very profiting and is in growth, though until now there is no such a motivation from industry to undertake the university research concerning design studies.

3.2.1.3 Hospital and Surgeons

Hospital is where users work, and is the final place where the design artifact in this field will be used. I did pay a special attention to visit different hospitals and talk with the surgeons. The three years of a PhD provided this opportunity for me to visit environment of the end users, and also the design collaborators. My first amazing finding was that I had entered the environment in which the very same words of technique, innovation, validation, etc. were being used for totally different meanings from what I used to know in engineering background.

I visited different hospitals and discussed with surgeons of various specialties, mostly those who were involved in design projects. Some of these contacts are listed below. Moreover, I never missed the opportunity to speak to the surgeons about my research and approaches during the conferences and a summer school that I have participated. One interesting point in this last was how surgeons face the new complex technologies. Basically, they are interested to know how it can be used in their OR, and how it will improve the operation. But, according to what I've observed in both hospitals and conferences, surgeons hardly find any relevance between what the engineer speakers propose and what he/she could make use for the surgery. For this reason they have many critics on the concept and functionality of the instrument.

I have tried to find out more about how surgeons evaluate a new technology, so I organized some communications and small talk in conferences to interviews at hospitals. Table 3.4 summarizes some of these communications.

Table 3.3: Summary of communication with surgeons and hospitals

Location	**Surgeon Expertise**	**Hospital**
Grenoble, France	Orthopaedic traumatology	*CHU de Grenoble* *http://www.chu-grenoble.fr/*
Leiden, The Netherlands	Laparoscopic surgery	*Leiden University Medical Center* *http://www.lumc.nl/*
Groningen, The Netherlands	BioMedical Engineering	*University Medical Center Groningen* *http://www.umcg.nl/*
Amsterdam, The Netherlands	Eye surgery,	*VU medisch centrum* *http://www.vumc.nl/*
Tehran, Iran	Orthopaedic	*Tehran Hospital* *http://www.sbmu.ac.ir/*
Wien, Austria	Heart Surgery	Allgemeines Krankenhaus http://www.akhwien.at/

The theme of the question I've asked relays on the surgeon facing new technology at the first place. Second, I was interested to know how the collaboration with engineers is defined from the surgeon's point of view. Here is a summary of my findings:

- From the beginning, the surgeons were considered as very qualified and skilled professionals, and they used their fingers like pianists and violinists. The finger sensation is of utmost importance in diagnosis and for performance in many operations. The introduction of new technologies like MIS changes many issues: surgeon does not look to the operation site but the monitor, and he/she holds an instrument. This issue causes a philosophical problem to surgery, which is not easy to solve (see (Stark and Benhidjeb, 2008) for more discussions).
- Not all of the surgeons are open to try and error for the design of new instruments.

In general, what they like is to explain in brief what they need and then receive a well designed, simple, and standard instrument to use in the operation. Neither could all of the designers give a simple explanation of the solution mechanism. Communication in engineer-surgeon relation is a critical subject, because of the complexity of the subjects, the difference between the domains, the professional vocabulary and so on. The communication problem, and the overloaded time of the surgeons' – which prevent the time to solve the problems – are two main obstacles for being involved in the design projects.

- On the other hand, there are many surgeons open and interested in the design and the development of new surgical instruments, and they accept the time sacrifice and other problems. Particularly in the context of the university research projects, I found surgeons who spend hours to perform an operative scenario on a phantom, animal or cadaver to evaluate the concept of a newly designed prototype. The point here is that the surgeons can comment on the idea or the paper drawings, but these comments remain superficial. What he/she really needs is a physical prototype that can be used in OR. In this way both surgeons and engineers achieve a better understanding of the usage.
- Maybe a suitable organization for surgical instruments design is an atelier (small workshop) situated in the hospital, where the OR observation, the communication with the surgeons, and the access to the conventional surgical instruments and OR devices is facilitated. Such an organization has been experienced in some hospitals and medical centers for instance in Groningen, The Netherlands, and the results seem promising. However, management of this project-based structure and providing ethical and legal agreements would not be easy.

In summary, in spite of the interest of many surgeons to use new surgical instruments, there are some problems in the way of production from idea to a prototype in surgeons' hand. The communication problems, the distance between desired requirements and a perfect tool, and the necessity of a synchronized understanding of the product and the usage are some of these obstacles.

3.2.2 Toward a University-Hospital-Industry organization

Hospitals are always welcoming new solutions for the patient care problems and they like to change the position from the end consumer to the initiator of the new technologies. In this way they would have the technologies responding to their requirements, defined and clarified by themselves.

In surgical instruments industry, the objective is to get as much as possible out of their investments. To be able to do so, they need to actively manage the innovation and competition ensuring that they do not loose the market share.

University is the place of doing research, without any economical pressure. The main

difference between the research in the university and in the industry in the surgical products and services is that in the industry, the most valuable assets such as human resources, physical assets, and other resources are organized for the profit. Thus it makes difference in objectives and strategies. In an optimistic view, an effective and appropriate management of surgical technology in the industry will contribute to improve the efficiency within the health sector and will result in the improved and increased health outcomes, and a more sustainable health service. So, the requirement of the healthcare actors such as surgeons, physicians, nurses and even patients are not necessarily well satisfied. They are somehow obliged to use what the industry provides and as some study in the first chapter showed, there is a significant distance between the technological assets and their application in the surgical instruments. More discussion on this subject can be found in one of my publications (Rasoulifar et al., 2008a).

Let's take back our research objectives. For us to explore the design process of the surgical instruments we need to have the notion of these three partners. We have to have a clinical requirement, and the industrial support for engineering and production, and the university research support. Swann indicates that action research requires the research process to be made visible. Thus, a design project that can involve the hospital and the industry will provide a support of study and research. This strategy looks quiet good for my research. In the next section the details of a design project of a surgical instrument is explained.

3.2.3 Research questions

Now I can formalize the research question of my PhD, in order to have a clear objective of what I am going to find, and also through which demarche. Here are my research questions

- What are the characteristics and elements of a design process, which can help the design progression of innovative surgical instruments?
- How to employ such a model to build collaboration between different design actors, particularly the engineer and the surgeon?
- What are the techniques and tools that provide help for the design progression?

Looking forward to find the answer of these questions, I chose the action research as my research method. The first question was asked and discussed to some extent regarding the literature in chapter 2. In the following, I will use the action research to plan my study in order to answer these questions.

3.3 Action research plan: setting up the design project

Here the organization of my research project is presented. In the objective of action research, a practice-led study is designed to provide an environment of research, and also a specific case to analyze. This approach makes the research process visible and capable of being analyzed from different points of view. The framework of this project is as follows:

Subject Subject of the project is the design process of a surgical instrument for the transformation of a specific open surgery to a minimally invasive form. The context of the project is explained in detail in the next section. In brief, the project is about finding a solution in the form of a new product, to help surgeons to perform traumatic spinal operation, which actually is on open surgery, using minimally invasive technique.

Objectives This project has not only the design objectives, but also the research objectives. The design objectives are set to conduct a real design project with tangible results. On the other hand, this project serves as a support for the research, so the research objectives according to the methodology (action research) should be provided.

Design objectives:

- To design a new surgical instrument from A to Z, starting from the problem identification to realization and clinical evaluation,
- To make a scientific contribution to innovative instrument design
- To promote the results, and eventually to apply in the form of a patent,
- To communicate the designed solution and the product in the form of a publication, presentation, etc. with the industry and the hospital

Research objectives:

- To observe, capture and document the design process and activities
- To analyze the design activities and procedures
- Devise improvement in the design methods, following one or some methods and to develop the modifications or new design procedures, information, organization, priorities, etc.
- To propose a new methodology for design in this discipline supported by the appropriate tools and techniques
- To communicate the research contribution and to publish in the design community

Organization Accordingly, the project is organized to make collaboration between the University of Grenoble (researchers, designers) and the hospital of Grenoble (surgeons). On the university side, two research laboratories supported this collaboration: G-SCOP and LIG. While G-SCOP had the competency in the production engineering and the prototyping

machinery, LIG provided the competency in the activity observation and the analysis, and they provided the project by the professional cameras and a set-up for operating room. Moreover, a grant was allocated from G-SCOP to outsource the prototyping to a certificated fabricator. The preliminary prototypes fabricated in the GI NOVA workshop in Grenoble INP, under the supervision of Alain Di-Donato.

In the hospital, two surgeons from the clinic of orthopedic traumatology joined the project, Prof. Dr. Jérôme Tonetti and Dr. Hérvè Vouaillat. The basic idea of the project explained in the next section comes in fact from the experiences of these surgeons. The hospital accepted to provide the facilities for experimentation in OR and also to have access to the anatomy laboratory for experiments such as on cadaver.

3.4 Protige project

Protige is the name given to the instrument, which we started to design for minimally invasive operation on the spine. The reason of giving that name was that in French the word “tige” stands for the english word “rod”. Before starting this section, I could imagine that the readers of this dissertation are not necessarily surgeon; neither do necessarily have the knowledge and information about the anatomy of the spine and the protocols of the spine surgery. Here is a brief introduction to the spine surgery and the minimally invasive surgery techniques, in a simplified language. Some parts of the text and the images below are extracted from more than 20 public websites such as www.back.com , www.allaboutbackpain.com, and www.spine-health.com. I have gathered some complementary information about this subject that is provided in Appendix 1.

3.4.1 Background

The spine in the human anatomy usually consists of 24 vertebras, which corresponds to the different region of the column, called cervical, thoracic, lumbar, and pelvic (see Figure 3.2). Between 70% and 85% of all people experience back pain during their lifetime (Anderson, 1999). Some patients fear the worst, especially when pain is severe. Although back pain can be caused by fractures, disc disorder, or tumor, the most common cause is sprain or strain.

Spine surgery is rarely an initial treatment for the back pain; however, there are some cases and some emergencies that may require the surgical treatment. According to the statistics, 151,000 patient undergo a lumbar fusion each year (Lipson, 2004). Lumbar fusion is one of the surgical options to eliminate the motion between the adjacent vertebrae. The goal of the lumbar fusion surgery is to relieve the pain, numbness, tingling and weakness, to restore the nerve function and to stop or prevent the abnormal motions in the lumbar spine. This is done by fusing the vertebrae together.

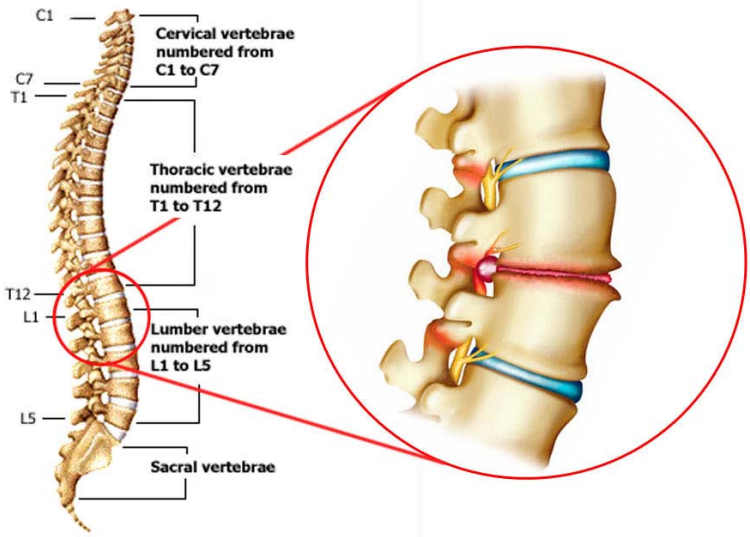


Figure 3.2: Anatomy of the spine and mechanical pain in lumbar vertebra

The spine fusion may be done in order to treat a problem such as unstable spine (spondylolisthesis), or it may be done because of the extent of other surgery on the spine (such as a laminectomy). In Grenoble, the city of alpinism sports, a considerable number of the accidents end to lumbar vertebral displacement or fracture. According to the hospital's observation, 50% of the serious sport accidents (falls of ski, parapet, or motorbike) result in the vertebral T12-L1 fracture and thus need the lumbar fusion surgery.

The lumbar fusion can be done in the front or the back of the spine. If the fusion is performed in the front of the spine, the surgeon will remove the disc (cushion between vertebrae) and any arthritic areas, and place a bone graft between the vertebrae where it eventually fuses to the surrounding vertebrae to stop abnormal motions. If the fusion is performed in the back of the spine, a bone graft will be placed on the sides of the vertebrae where it will grow together with the vertebrae to stop abnormal motions.

The bone graft can be one of two types: an autograft (bone taken from your own body usually your pelvis) or an allograft (bone from a bone bank). Sometimes metal rods, screws or hooks are also used with the bone graft to stabilize the spine further. This is referred to as "instrumentation". When the vertebrae have been surgically stabilized, the abnormal motions are stopped and the function is restored to the spinal nerves.

In the instrumented surgery, the surgeon may use some type of metal screws, plates, and rods to hold the vertebrae in place while the spine fusion heals. Designed to stabilize and hold the bones together while the fusion heals, these devices have greatly improved the success rate of the fusion in the lower back. Figure 3.3 shows some of this devices and the installation on the spine.

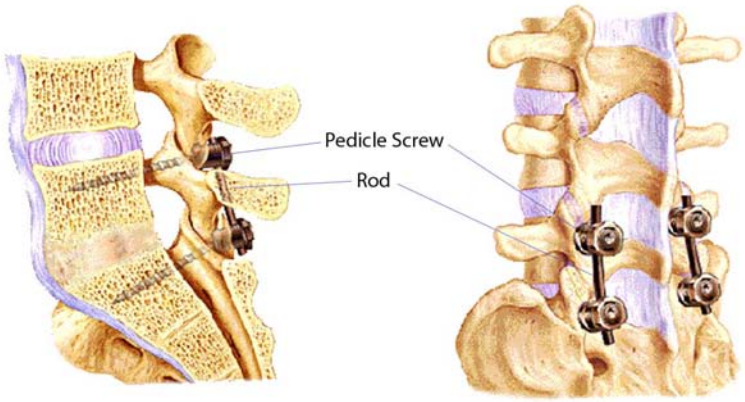


Figure 3.3: Screw and rod system positioning on the lumbar vertebras

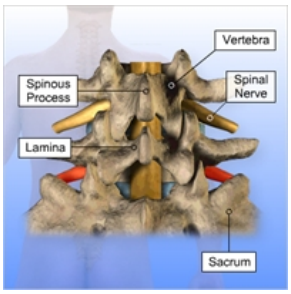
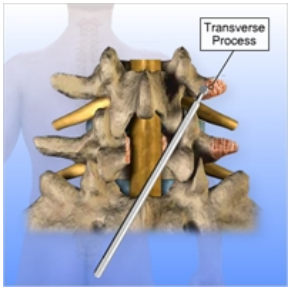
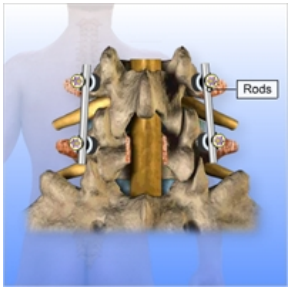
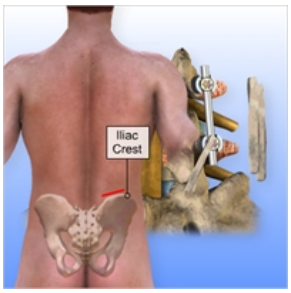
What should be done in lumbar fusion surgery can be simplified in this way: Pedicle screws are placed through each of the pedicle bones on the back of the spinal column. The screws are inserted through the pedicle and into the vertebral body, one on each side. The screws grab into the bone of the vertebral body, giving them a good solid hold on the vertebra. Once the screws are placed they are attached to the metal rods that connect all the screws together. When the rod-screw system is bolted together and tightened, the combination creates a stiff metal frame that holds the vertebrae still so that healing can occur. The bone graft is then placed around the back of the vertebrae.

This operation is used to be, and in some cases still is, performed in the classic open surgery. It means that an incision is made in the middle of the low back. After the spine is exposed, the surgical instruments are used to remove the spinous process, lamina, and any bone spurs that may be intruding into the spinal canal. Before bone grafts are added, the instrumentation (screws and rods) is introduced to stabilize the spine. A drill is used to make holes in the pedicle area of the vertebrae, and the screws are placed in the drilled holes. Afterwards, the rods are positioned between the screws and fastened in place. The rod and screw instrumentation provides stability to the spine and prevents the vertebrae from moving while the bone graft fusion takes place. See Table 3.4 for more details.

There are some risks to surgery for lumbar spinal fusion, including:

- Bleeding
- Infection
- Blood clots
- Reaction to anesthesia
- Tearing of the sac covering the nerves (dural tear)
- Failure to relieve symptoms
- Return of symptoms after some time
- Failure of the bone fusion to heal

Table 3.4: Open lumbar fusion procedure. Figures from internet site: UnderstandSpineSurgery.com

	**Incision and Laminectomy** An incision is made in the middle of the low back. After the spine is exposed, surgical instruments are used to remove the spinous process, lamina, and any bone spurs that may be intruding into the spinal canal. The spinal nerves now have more space with less pressure on the nerves.
	**Preparing for Fusion** To prepare for the fusion that will stabilize the vertebrae, a motorized instrument is used to remove the top (cortical) layer of the transverse processes. This is the site where the bone grafts for the new fusion will be added.
	**Stabilizing the Spine** Before bone grafts are added, instrumentation is introduced to stabilize the spine. A drill is used to make holes in the pedicle area of the vertebrae, and screws are placed in the drilled holes. Then, rods are positioned between the screws and fastened in place. The rod and screw instrumentation provides stability to the spine and prevents the vertebrae from moving while the bone graft fusion takes place.
	**Bone Graft** Bone grafting can be done with pieces of a patient's own bone (autograft), processed bone from a bone bank (allograft), or a bone graft substitute (demineralized bone, ceramic extender, or bone morphogenetic protein). To harvest a patient's own bone for grafting, a second incision is made over the back of the pelvis. Bone is removed from the iliac crest and placed along the prepared site where the top layer of bone was removed. This bone eventually grows in place, fusing the spine and providing additional stability.
	**Summary** The incisions are closed and dressed to complete the procedure. Adding the instrumentation to the laminectomy with bone graft fusion increases the strength of the spine directly after surgery, and may decrease the need for a post-operative brace. Patients often remain in the hospital for one to four weeks following the procedure and should avoid heavy lifting, bending, twisting, and turning for six to twelve weeks.

- Failure of the screws or the rods
- Need for further surgery
- Injury to the nerves

The risks of the surgery depend on the patient and the exact procedure being performed. After the surgery, the patients may be hospitalized for several days, depending on the patient and the procedure performed. Relatively healthy patients who undergo only decompression may be discharged from the hospital the same day, and may return to the normal activities after only a few weeks. Patients who undergo spinal fusion are hospitalized for several days. They usually receive an outpatient physical therapy program. A lumbar corset or brace may also be prescribed after the surgery. The patients generally return to normal activities after 2 to 3 months.

3.4.2 Objective: Toward a new operation with minimally invasive technique

The surgery of the spine continues to be a challenging and difficult area. The vertebrae are small, so there is not much room to place small instruments. Also, many nerves can get in the way of putting the screws into the vertebral body. It means that a large amount of stress is put on the lower back, so finding a metal device that is able to hold the bones together can be difficult. Moreover, this operation is a large invasive operation, from 10 up to 25 centimeters, and needs the muscle stripping. Large bands of back muscles are stripped free from the spine and pulled off (retracted) to each side for visualization of the spine and the easy access to the bones for instrument implantation. This stripping and retraction can cause considerable back pain, and the muscles, to some degree, are permanently scarred and damaged. Thus the postoperative consequences are very harmful.

What if we can avoid the large incision? What if we provide all accesses from some small holes – which is what MIS is all about – and find a feasible solution for the surgeon to perform the operation and reach the goal without any incision?

By looking to some other spine surgeries, we found some interesting issues. Modern spinal surgery has already some solutions for the minimally invasive access to the spine; the operations such as Discectomy (disk removal) and the screw insertion in minimally invasive manner. The problem lies in the introduction of the rod, placing in the screw heads and fixation.

At the beginning of the project, the surgical team had the idea to insert the rods percutaneously (parallel to spine, via needle-puncture of the skin) and pass them through the screw heads. From this point the project starts: to design an instrument or a system to deliver the rod into pedicle screws. In the next section, the project progression is explained.

3.5 Action in progression

I started this project reading a master project report on the necessity and the possibility of such an operation in minimally invasive manner (Verdier, 2006). In the report, the author made an observation in the OR to understand the actual operation situation. I had decided to start with the same idea, but at the first place, I should establish a design methodology. This hybrid of engineering and usage methodology was inspired from the systematic review on the design literature, presented in chapters 1 and 2. Having such a basis, we could drive our design and enrich it with experience from real performance.

The surgical instruments design and development has been described, in chapters 1, to be complex both in method and application. The designer needs to move toward an understanding of where and how to obtain the information, and then how to apply it in a desired situation. The designers need to deal with different aspects of knowledge, user anticipation, technical design, and evaluation.

To start the project, I explain in detail the design steps from the previous chapter (chapter 2). This design model will be applied on the Protige project as follows.

In the next section, we explain our initial model of design process, coming from the synthesis we made in the end of the second chapter, and which is our guideline for the project progression.

3.5.1 Design process model

Let's recall the three main steps, shared in both engineering and the user-centered approaches:

- Understanding the problem (in usage context)
- Design (conceptual and detail)
- Evaluation (with user and use situation)

It is obvious that there are many interrelations between these steps. The actor of design is not the designer alone, and there should be many collaborative tasks to be developed. The iteration between the design phase and the evaluation phase produces the first evaluation of the concepts after the conceptual design, and then one step of the clinical evaluation after the detail design step. These steps were roughly mentioned at the end of the previous chapter. Figure 3.4 shows the design process in schematic and each step will be explained by the example of the Protige project as follows.

The rest of this chapter presents the detail description of the presented model, together with the progression of our design project. The explanation is supported by the photos,

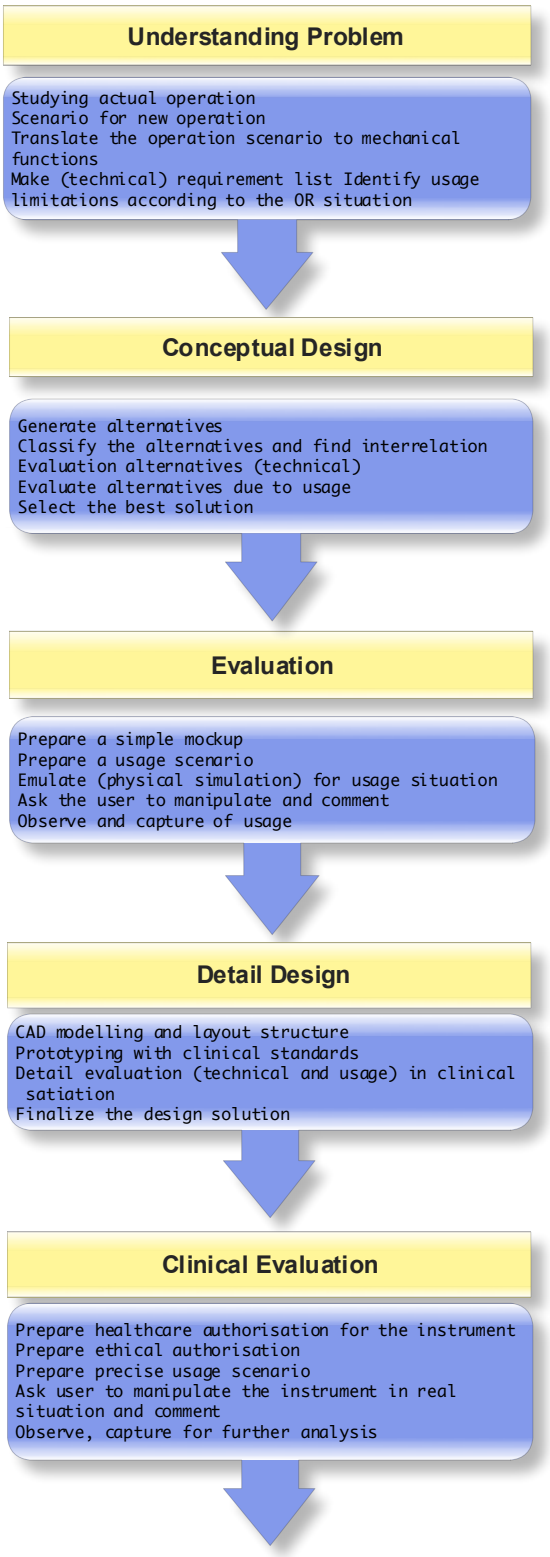


Figure 3.4: Design process model for the Protige project

movies (accessible in the electronic version) and the clinical data, all prepared by the author, and under the agreement of the Hospital of Grenoble.

3.5.2 Understanding the problem

This step is the beginning of the process, and starts with the identification of the current situation. Before going to the details, I may remind that some anatomical and surgical information is needed here. This information is accessible in the literature and reference books. An extract of the necessary information was presented in section 3.4.1.

In order to understand the actual situation of the operation, we firstly explored the literature to acquire the main framework. Then, an observation in the OR was organized to capture (video, voice, and photo) and to analyze in detail to identify the list of the activities. Today, the access to the information about surgeries is incredibly changed and has become simple. There are many websites that provide very useful information, the animations and the live operations. The observation explained as follows took place in Hospital of Grenoble, Orthopedic surgery bloc.

3.5.2.1 Observation of the surgical operation

The objective of this observation is to define the phases of the operation, to decompose the actions into the tasks and to provide complementary information about the tasks like actor, time of action and task alternatives. Before going to the result, I propose to have a look at the environment of the research: the operation room.

Figure 3.5 shows one of the ORs in Hospital of Grenoble, fit out by fluoro-navigation system. Surgical operation room is a complex system, and there are various systems and actors interacting during an operation. For the lumbar fusion surgery, which is the subject of our study, I have participated in several surgeries, and captured some of them, to provide further study and analysis.

3.5.2.2 Surgical phases and protocol tasks of actual lumbar fusion

The surgeon is the leader of the surgical team and has the ultimate responsibility for performing the surgery in an effective and safe manner. He is dependent upon other members of the team for the patient's emotional well-being and physiologic monitoring. As it can almost be seen in Figure 3.5, the surgical team consists of four types of actors:

a) Surgeon

b) Scrub Nurse (or Scrub Assistant): prepares the setup and assists the surgeon by passing instruments, sutures, etc.

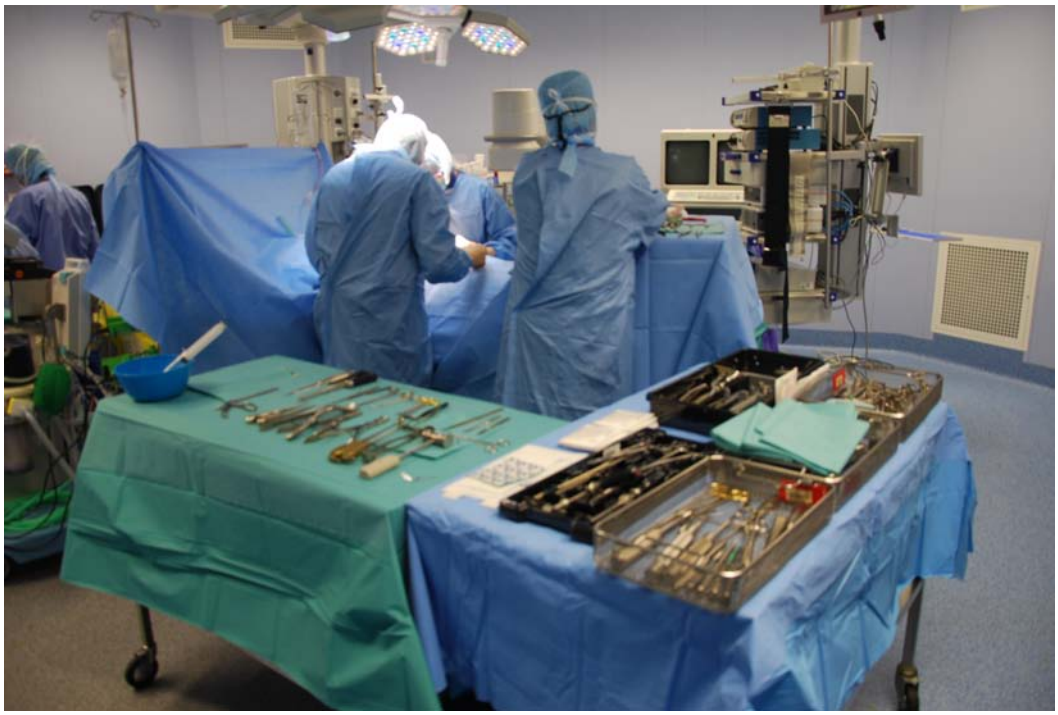


Figure 3.5: OR at Hospital of Grenoble – Surgical team performing a spinal fusion operation

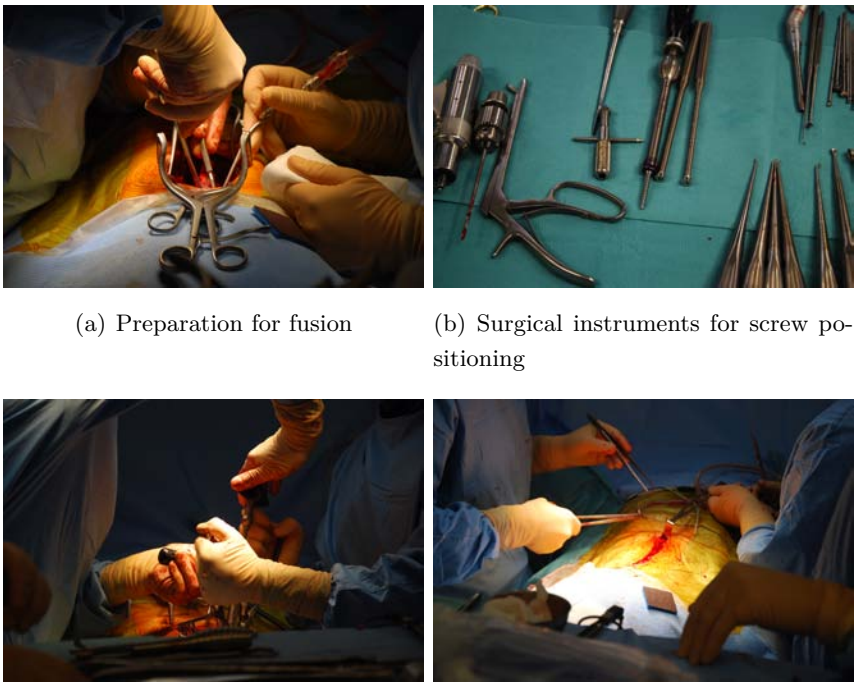
c) Anesthesia team (anesthesiologist/anesthetist)

d) Circulating Nurse: professional registered nurse who is free to obtain supplies, answer the anesthesiologist/anesthetist requests, deliver supplies to the sterile field, carry out the nursing care plan, etc.

Our focus is on the first group, the surgeon. In transforming the actual operation to MIS, the other groups are less concerned, and their activity is not critically the subject of change.

The operation starts with the anesthesia, and once the patient is ready, the operating protocol begins. In the Figure 3.6 main steps of the procedure are shown by photos taken during the operation. Afterwards, a simple analysis of this operation is proposed (see Table 3.5). This analysis consists of the tasks due to each phases, the detail of each task such as cooperation, OR device, surgical instrument and also time and frequency of the use is extracted.

The objective of this analysis is to go through the details of the operation. The reason is the new operation aims to accomplish the same surgical goals, but with different techniques and tools which prevent the large incision.



(a) Preparation for fusion

(b) Surgical instruments for screw positioning

(c) Fixing the rod by using nuts

(d) Suturing

Figure 3.6: Spinal fusion procedure - Photos from an operation in Hospital of Grenoble

The analysis shown in Table 3.5 is made using an observation and annotation software. More information about annotation and analysis is provided in the chapter 4 section . The

Table 3.5: Task analysis of the open spinal fusion; note: SA1: Scrub Assistant on operation site, SA2: Scrub Assistant preparing instruments, CN: Circulating Nurse. The last column shows the duration of the actions.

	Phase		Task	Co-actors			Instrument	Device	Time(s)
No.				SA1	SA2	CN			
1	Incision	1.1	Localization of the site	✓			Probe pedicle channel	X-ray	5
		1.2	Make the incision				Scalpel		2
		1.3	Put the retractor	✓			Retractor (small and large)		3
		1.4	Put the suction tip	✓			Suction device	Suction tube	5
2	Laminectomy	2.1	Get and place pedicle prob	✓	✓		pedicle prob		10
		2.2	Cut bonny arches	✓			Bone Rongeurs		300
		2.3	Cut opening in the ligament	✓			Bone Rongeurs		40
		2.4	Exit and unload the bone peaces	✓			Bone Rongeurs		20
3	Prepare for fusion	3.1	Order (size) and get motorized instrument	✓	✓	✓			5
		3.2	Remove the top (cortical) layer of the vertebra	✓					420
4	Screw placement	4.1	Make the target point		✓		Probe pedicle channel		10
		4.2	Insert and screw down				Screwdriver		8
		4.3	Control the position			✓		X-ray	5
5	Rod placement	5.1	Measure the distance and angle		✓				12
		5.2	Prepare the rod (Rod contouring)		✓	✓	Bending pliers		15
		5.3	Place the shaped rod	✓			rod crimping pliers		42
		5.4	Control the position			✓		X-ray	8
6	Rod fixation	6.1	Pick up and place the nut	✓	✓	✓	Universal handle + sleeve		10
		6.2	Loosely tighten the Nut	✓			Universal handle + sleeve		45
		6.3	Position adjustment	✓	✓		Spreader Forceps		54
		6.4	Firmly tighten the Nut	✓			Counter torque		30
7	Washing and sterilisation								140
8	Suturing								34

images and detail of surgical instruments were excluded from this table, in order to avoid unnecessary complexion. A list of spine surgery instruments with images and details is provided in Appendix 2.

After participating and observing several operations, analyzing the observation in the OR, and discussion with both surgeons of the project, we start to find the solution for transforming the open operation to MIS. A basic issue here is to make sure that the new operation doesn't change the clinical results of the open surgery. Accordingly, the detailed and strictly defined list of operative tasks and goals should be taken into account during for the new design. However, the promising results for instrument final validation only come from statistics of clinical evaluation.

3.5.2.3 Scenario for new operation

Scenario making, as a recommended tool in UCD and PD approaches, seems helpful to be used in this step in order to imagine the new operation. To avoid the large incision, our surgeon had the idea to make a small incision on lower back, and insert the rod laterally from this incision into the screw heads. Since the main step here is the rod insertion and placement, we can imagine the scenario of the operation with focus on this step, and then with looking for the preceding and the succeeding tasks. In this way, it is possible to know the feasibility of the new rod insertion technique due to the other operation tasks. We first consider the states and then find out the activity and tools needed. Table 3.6 shows this scenario:

Table 3.6: Scenario prepared for the new operation

Status	**Procedure**
Screws placed in the vertebras	
	Locate the insertion point, Incision, Insert and guide the rod to pass through the screws head
Two rods in the screw heads	
	Insert nut and fix the rod in the screw head
Rods fixed in the screw heads	
	Expand the system, Verify (X-ray image control)
System adjusted and repositioned	

In this way, we have a scenario for new operation, and it helps to start the conceptual design of the new instrument. Once the user's objectives and needs are clarified, our design method proposes to finish this step with the requirement list. The clarification of the tasks

with the help of a requirements list can help to focus attention on the problems. Elaborating the requirements list may thus be said to have prepared the way for following steps. Table 3.7 shows the requirement list for Protige.

Table 3.7: Requirement list for Protige

Surgical site	
	Lumbar spine
Geometry	
	Shape fixed and rigid Form: body + handle
Material	
	Stainless steel, Titanium
Technical	
	Mechanical plug and unplug of rod
Usage	
	Compatible with spinal lumbar fusion operation instruments Compatible with sterilization process
Ergonomy	
	Ergonomic handle
Test requirement	
	Phantom in laboratory
	Examination on cadaver
Production	
	Small scale production

3.5.2.4 Conceptual Design

According to the procedural plan outlined in section 2.5, the conceptual design phase follows the clarification of the task and turns them to the functions. Functions are broken into sub-functions. In order to determine the main function, one should first select some preliminary physical effects or working principles using intuition-based methods, literature and patent searches and previous products. The relationship between the functions in these solutions should be analyzed to identify other important sub-functions for which physical effects and working principles need to be found.

A function structure can be created based on the requirement list. The advantage of setting up a function structure is that it allows the clear definition of existing subsystems

or of those to be newly developed, so that they can be dealt with separately. In the case of new surgical instruments the compatibility with the other instruments and tools of surgeries need to be considered.

The definition of the function is not unique and has been struggling within the last forty years of the design research. However, the formulation given under Function Behavior Structure (FBS) modeling seems stable and in line with our design approach: Functions are those physical dispositions of an artifact that contribute to the purposes for which the artifact is designed (See (Vermaas and Dorst, 2007)).

Table 3.8: Main functions of Protige

User (surgeon)	**Clinical**
Receive and hold the rod	Biocompatibility of material
Insert and guide the rod (in push forward manipulation)	Small size for entering part
Release the rod and remove the instrument	Smooth form for entering part
Adaptability to receive different rods (diameter and geometry)	Minimum ruggedness for cleaning and sterilization procedure

I used a function analysis method called "Diagramme pieuvre" to determine the functions[1]. Table 3.8 shows the results, classified in two classes, according to user (surgeon) and usage situation (clinical).

Although the receive/release functions are not technically complicated to design, but under constraints such as small form, robustness and biocompatibility, conceptual design becomes very difficult. Moreover, the instrument's functions are highly dependent on the manipulation behavior of the surgeon. This surgical act is not producible without surgeon, and out of OR. At the same time, to realize it, a prototype is needed. Therefore, we decided to design and prepare a preliminary prototype, providing the function "Insert and guide the rod". The receive/release functions are not complicated to design, but are highly dependent on the manipulation behavior of the surgeon.

I also needed to prepare a mannequin on the usage situation: the spine, the screws and a box to simulate the lower back of the body, with a resisting cover presenting the skin. I explain the phantom preparation later in section 3.5.2.5.

Fortunately we could use the OR for this experiment, so the usage scenario became closer to the real operation, considering the OR facilities such as operation table, C-arm, and real surgical instruments. Moreover, the limits in the OR could be observed and be taken into account. The scenario for this simulation was simplified to insert the rod and to fix it in the screws. Therefore, I added a pre-emulation step to ask the surgeon fixing three

[1]For more information about the Diagramme pieuvre see http://fr.wikipedia.org/wiki/Methode APTE

screws on the spine model.

We decided to name this prototype evaluation by user in the real situation, **emulation**. Emulation sounds like simulation, but, with the difference that simulation is generally implies a virtual environment. Emulation is the act of imitating the behavior of some situation or some process by means of something with physical properties.

First emulation The first emulation took place on 23/06/2006, and was captured by camcorders. The emulation is an opportunity to discuss more with the surgeons and discover his usage activities and corresponding requirements through the discussion and observation. Some photos of this emulation are shown in Figure 3.7. Table 3.9 shows the scenario of operation in the right column and the operative activity of the surgeon during the emulation in front of each task of the scenario.

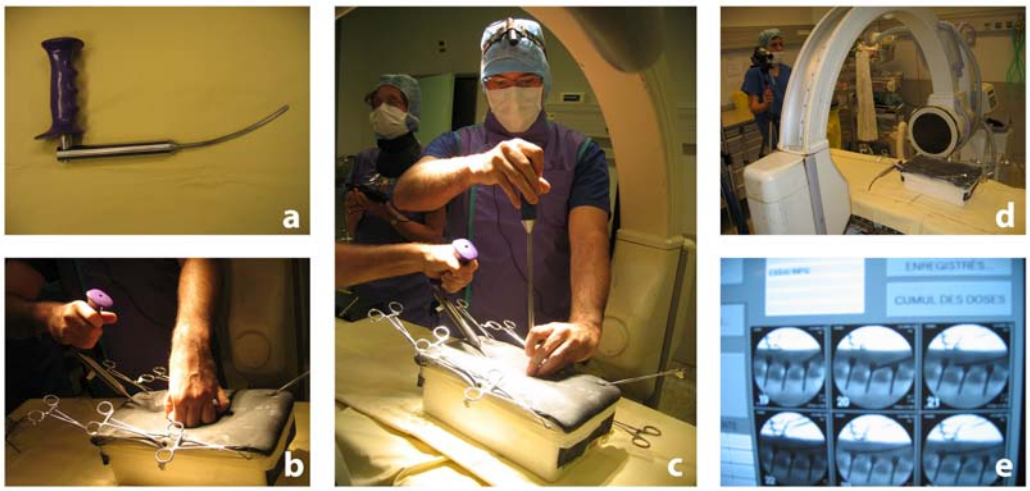


Figure 3.7: First emulation, (a) First Protige prototype, (b),(c) Surgeon is performing the scenario, (d) C-arm device, (e) X-ray image of the phantom

Table 3.9: First emulation – scenario and analysis

Phase	How to / tool	Time(s)	N radio
Locate the position	Finger sensation Imaging	26	3
Incision	Scalpel	30	-
Rod insertion	Protige	37	7
Locate the screw	Pedicle Probe	10	3
Incision	Scalpel	3	-
Rod fixation	Rod pusher, screwdriver	180	12

Following this first emulation, we have found some problems and also propositions for new usage scenario. The main problem was that the rod fixing step was not performed in

reality, because the screws had been placed before, and no incision and instrumentation was made. Thus it was difficult to bloc the rod in the screw heads. Moreover, there were some practical problems to be fixed, such as the phantom size was too small.

In a new scenario, I needed to start from placing screws. The minimally invasive way of doing this operation is to use tubular retractors. Tubular retractors are a series of tubes which are inserted progressively from the smallest to the largest through a small incision and dilate the muscle fibers gently, to provide access to the operative site. Using specialized instruments and microscopic visualization, surgery is performed through the tube.

Actually, some operations on the vertebral column use tubular retractors to provide an MIS operation. I took this option and planned the next emulation scenario with these tubes. The reason was our surgeon knew this technique, and evaluated that as the less invasive access provider, comparing with other retractors.

To prepare the second emulation I needed to fabricate a tubular retractor series. Once I prepared the scenario I realized one operative technique that may affect the tubular retractor. In doing MIS, surgeon inserts the retractors progressively to access the spine. Then he removes the ones inside and holds the largest to have the space for performing operation. The stay of the tube makes the rod insertion impossible. To solve this problem the largest tube should have a transversal groove. The diameter of the groove matches the diameter of the rod.

Second emulation Fabricating the tubular retractors and modifying the spine mock-up the second emulation took place on 17/01/2007. For this emulation I improved the observation system and tried to use a frontal camera for the surgeon. The reason was that from the first emulation I realized that an important part of usage is X-ray control, and without capturing this part there a part of information would be missing. I also asked to another surgeon in the team to do the operation, to monitor the differences. Some photos of this emulation are shown in Figure 3.8. Table 3.10 shows the second scenario in the right column and in front, the detail of operative techniques.

Table 3.10: Second emulation – scenario and analysis

Phase	How to / tool	Time(s)	N radio
Locate the position	X-ray	50	7
Incision	Scalpel	2	
Tubular retractor insertion	Placing the Broche	64	3
	Insertion of tubes	165	1
Locate the entering point	Imaging	4	2
Incision	Scalpel	3	-
Rod insertion	Protige	5	3

For this emulation I changed the filling material of phantom box. In the first one chalk powder was used to fill around the spine model, but it was not suitable for the OR. For the

(a) (b) (c)

Figure 3.8: Second emulation (a) locating the vertebra by radio images, (b) insertion of tubular retractor (c) insertion of Protige through the screw's head

second emulation the box was filled by steel sand. However, another problem appeared: the sand made the vertebral column invisible by the X-ray. That is the reason why the surgeon took many X-ray images from different angles.

For the rod insertion task there is a considerable time difference between two emulations. According to the surgeon, it was because three tubes allow seeing the screw heads and it became very simple to guide the rod in line. In addition, the tubes I made were too large, so in result the incision extended and was no more MIS. In this emulation we figured out some more details about the operation; such as it is technically possible for the surgeon to insert the rod top-down instead of bottom-up, and in placing three pairs of screws, the procedure make no clear difference between putting pair by pair, or three on one side and then three on the other side of vertebras. The surgeon preferred the pair by pair.

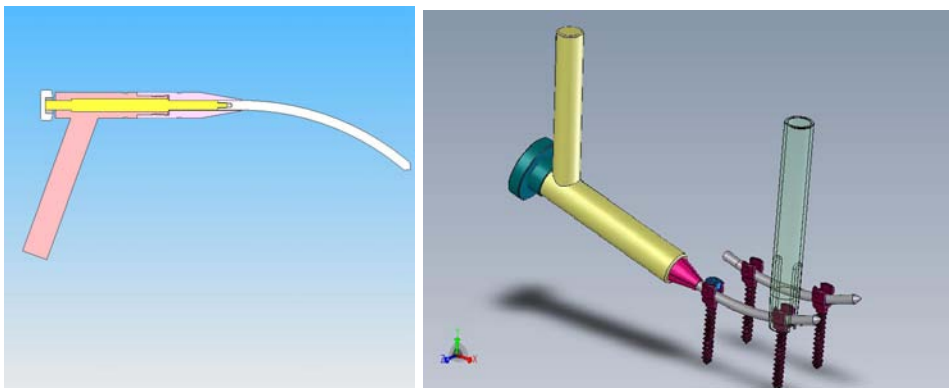
Following this emulation, and a meeting afterward to discuss about the principal concepts, the development of concept and making a prototype was previewed to finish the phase of conceptual design.

Development of the concept The principles elaborated in the previous part are not concrete enough to lead to the adoption of a definite concept. This is because the search for a solution is based on the functional structure, and so it is aimed at the technical function.

Important characteristics of the working principles were decided in this way: Protige should have few parts, to be assembled and disassembled easily. Figure 3.9(a) below shows the first CAD design of Protige. Look at the part in which the rod is kept in the instrument. The inside rod contact provides a quite strong contact and by turning the roundel, surgeon can plug and unplug the rod. However, this solution necessitates the pre-operation rod preparation with new device and procedure, which is not preferable by the surgeon.

To avoid this problem, we focused on the outside contact mechanism to plug and unplug

the rod. We finally came up with the following mechanism: Protige body has a conical shape at the end (where the rod is inserted). By pushing forward the grip in the con, the grip laps converge inside and fix the rod. To unplug, it's enough to turn inverse. Figure 3.9(b) shows the new solution in CAD model.



(a) (b)

Figure 3.9: Three dimensional designed model of Protige, (a) side view, (b) Assembled in the solution

3.5.2.5 Evaluation

The solution has to be evaluated against the functional criteria and also against the usage requirements. For this purpose, the evaluation condition for the user should be prepared. In other words, this evaluation, we called emulation, needs a prototype of the instruments, a phantom for performing the operation, and preparing the OR.

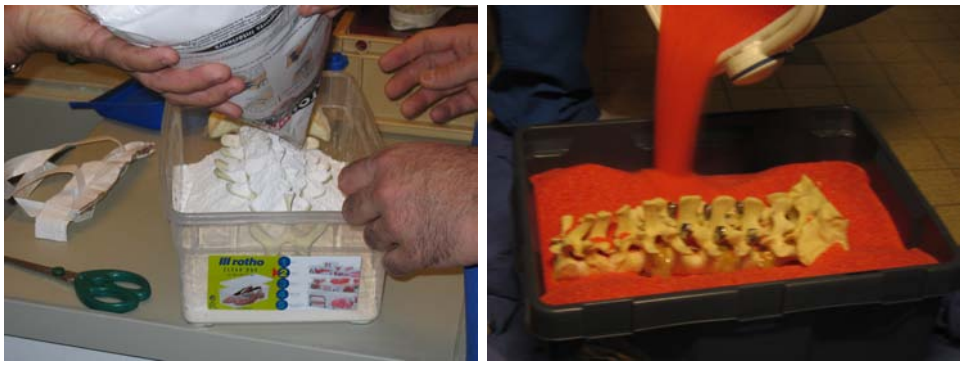
The CAD model was sent to outsource dealer for prototyping. Moreover, as mentioned in the previous part to perform this scenario, we needed to prepare the modified tubular retractor with groove which was ordered to be fabricated. Meanwhile, we focused on the phantom preparation. Some problems were observed from the two first emulations concerning the phantom:

Phantom Preparation **Spine position in the box:** spine model did not have a good position in the box, and was too far below the surface. As a result, the surgeon faced problem since during the insertion of the Protige, handle touched the box edge.

Filling material: for the first emulation we used chalk powder as the filler. The problem with chalk was that it presented too much resistance, and didn't have a fluid characteristic. For the second emulation we tried to sterilize sand which was much better in terms of resistance and viscosity but caused other problems. First, sand is radio-opaque, so made the spine invisible. Second sand is very light and flies everywhere and is not very

welcome in the OR.

Skin cover: in both emulations the texture used for skin representation was not evaluated positively. The fixation of the texture on the box and its tension was another problem. The skin issue was very important because the whole project was about minimally invasive, so the emulation should give a good idea about the size of the incisions. To avoid these problems, we needed to spend more time on phantom design and preparation. For this part we had a temporary colleague, Bérangère Guicherd, to help in this subject. Finding the anatomical dimensions, testing various materials in OR against X-ray, and finally designing a fixation system, an adequate phantom was prepared (see Figure 3.10). For more details on the phantom development and the choice of radio transparent materials, see the Bérangère's report (Guicherd, 2007).



(a) (b)

Figure 3.10: Phantom preparation (a) first emulation using chalk powder, (b) Third emulation using synthetic granules

Third emulation The third emulation took place on 13/06/2007. The scenario of operation is shown in Tables 3.11 and 3.12. The main objective was to use the Protige to insert the rod through the screw heads, fix the rod, and release the rod. Although there were some problems using the prototype, the design solution was positively evaluated by the surgeon.

The phantom was also satisfying according to the surgeon. Like other emulations, a very useful discussion happened between surgeons and engineers around the features of the prototype and the tasks of the operation. By this, the conceptual design phases reached to end and detail development would be commenced.

Table 3.11: Photos from the third emulation

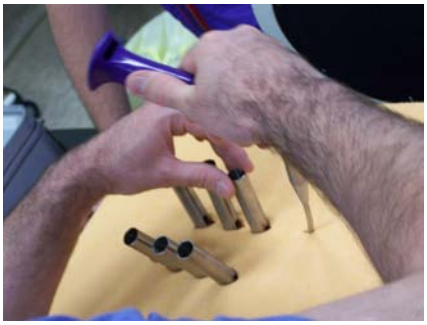
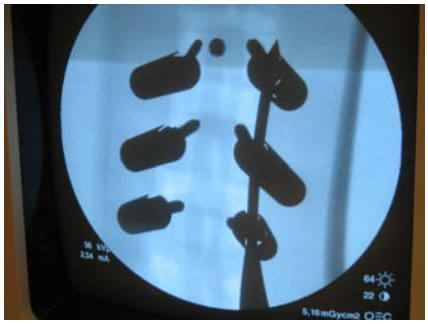
	Protige prototype: This prototype provides the functionality of plug and unplugthe standard rods
	Preparation for screw insertion: surgeon uses tubular retractor to stretch. The last tube has the transversal groove in order to let the rod pass through
	Rod insertion using Protige
	Protige stable position

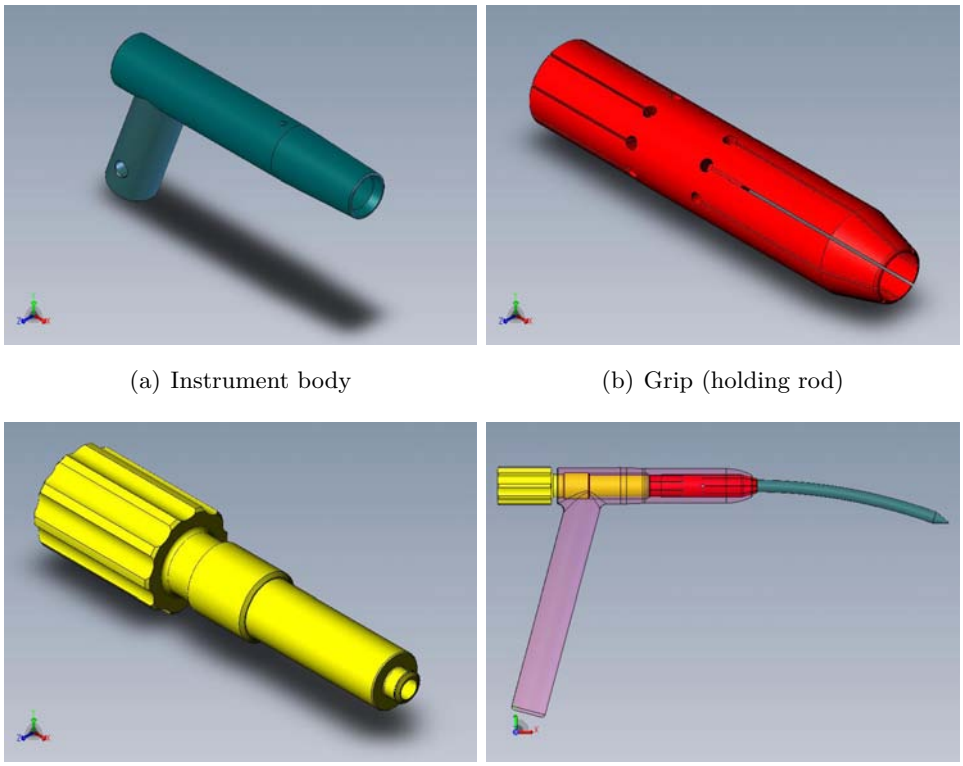
Table 3.12: Photos from the third emulation (continued from Table 3.11)

	Rod fixation in the screw by using nuts
	Mechanical plug and unplug of rod
	Phantom when all tubes are taken out, one of rods can be seen through the holes
	Radiography image shows the rod in all the three screw heads

3.5.2.6 Detail Design

For detail design of the instrument, we needed to finalize the geometrical dimensions of Protige, choose the material and make sure about the functions and behaviors of all parts. For this reason, beside of individual engineering advancement, two meetings were held to finalize the design decision. First meeting was an engineering evaluation meeting in which the final design was discussed by the technical team members. Second meeting was with the surgeon, to synchronize the last modification and have last verification before prototyping. A detailed explanation of these two meetings is given in the next chapter (see section 4.4.1).

In the last meeting, there are two main modification subjects. First, as usual, surgeon demands to minimize the diameter of the conic part (which enters in the body). Second, there was a risk that the grip was blocked in the instrument body because of the blood and tissues, and since the unplug mechanism needed a certain distance between the grip and the conic part, that might cause a problem. To overcome this problem, a small cylindrical top is added to the roundel body (where it contacts the grip). Figure 3.11 shows the 3D model of the final design.



(a) Instrument body (b) Grip (holding rod)

(c) Roundel (d) Assembled instrument

Figure 3.11: 3D model of the final design of Protige

3.5.3 Clinical validation

Many medical devices do not require clinical trails as the regularity for the certification. However, as the FDA guidebook for medical devices points out, all devices require clinical evaluation and should be tested in the actual or simulated use environment as a part of validation (Kimmelman and Trautman, 1996). Clinical validation has the same role as process and contains different steps (see Table 1.2). Clinical validation should be designed, analyzed and documented.

For the Protige project after many discussions with surgeons we have decided to prepare a cadaver test. With this opportunity we could have realized the operation from the beginning and could have examined the reliably of Protige usage against the real vertebra and resistance. The administrative authorization was needed in order to borrow a cadaver from the Anatomy laboratory.

Fourth emulation The emulation was planned for 08/02/2008 at Hospital of Grenoble. For the preparation, the last design (modified after the third emulation) has been outsourced for fine fabrication. To be mentioned that for all the research team it was the first time to see a cadaver, but fortunately there no problem happenedduring the emulation.

Tables 3.13 and 3.14 show the emulation scenario together with photos from the emulation. Like other emulations this one has also been filmed to further analysis.

The discussion during and after the forth emulation showed the surgeons satisfaction of the design of Protige. Though, this emulation was the last validation step for the Protige project before starting the clinical trails in which Protige would be used in real operations.

3.5.4 Main results and summing up

Protige project was started at April 2006 by the master thesis of Morgan Verdier (Verdier, 2006) under the supervision of Guillaume Thomann on preliminary study of new operation for MIS in spine surgery. I joined the project in summer 2006, a little before beginning my PhD. In spring 2008 TuAnh Pham joined the project for her Master thesis and helped me to work on healthcare certification and standardization process of surgical instruments issues. In her master thesis, the patenting procedure was discussed and a framework was proposed to help designers to anticipate patenting procedure during the design process (Pham, 2008). In the spring 2009 we submitted the patent documents for Protige instruments, and some later the instrument was patented, owned by the Grenoble hospital and the Grenoble university (Tonetti et al., 2009a). Figure 3.12 shows a timeline of this design project mentioning the emulations date and also the meetings with surgeons.

Table 3.13: Photos from the fourth emulation

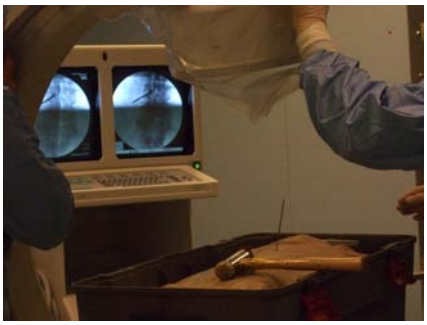
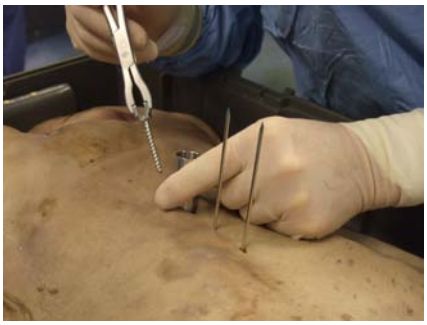
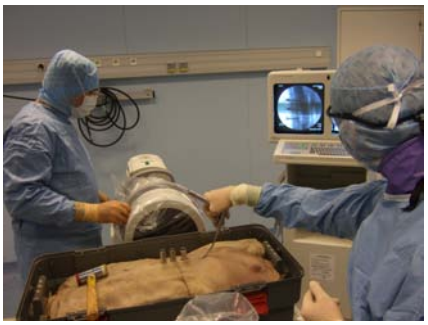
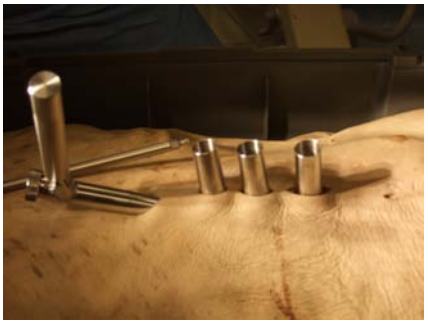
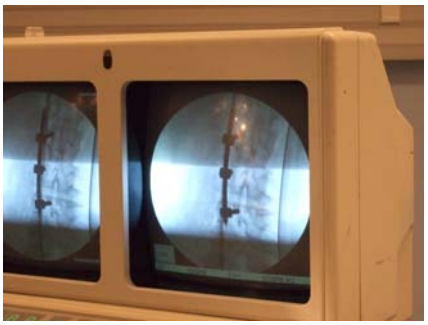
	Locating vertebra and incision
	Preparation for screw insertion: using tubular retractor to stretch the muscles
	Screw insertion and placement

Table 3.14: Photos from the fourth emulation (continued from Table 3.13)

	Rod insertion using Protige
	Final position of Protige before releasing the rod
	Radio image of the position of the rod in the screws' heads

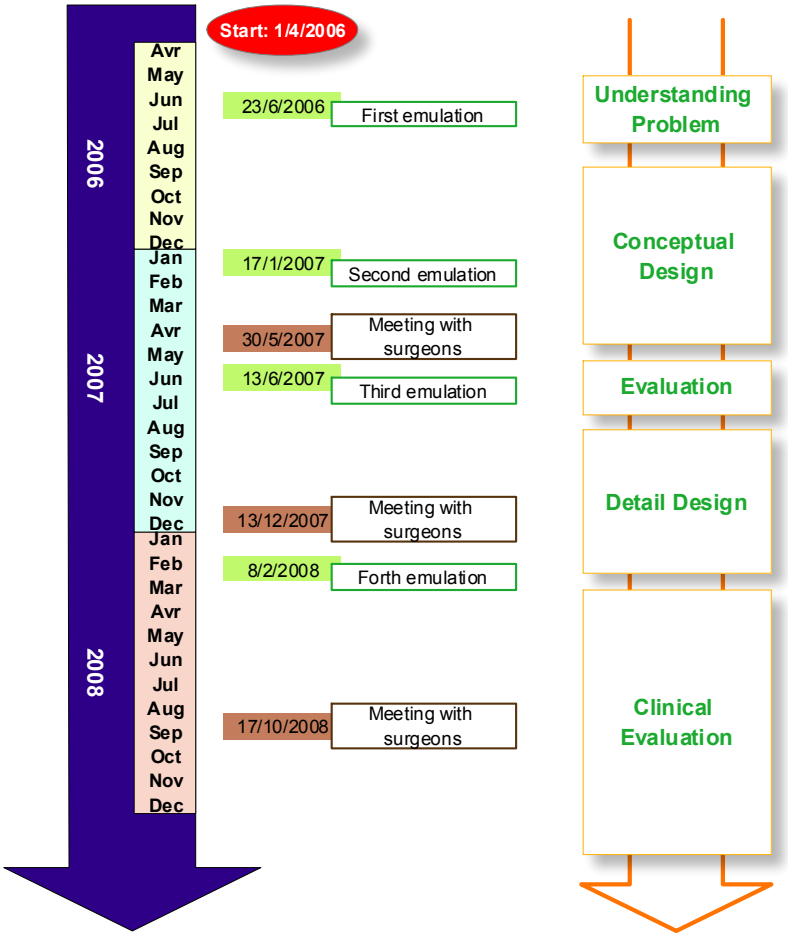


Figure 3.12: The timeline of the Protige project

3.6 Conclusion: designing own research

Action research has to be strengthened in order to stabilize the delicate dynamic balance between action of designing and observation and reflection. The iterative process of plan–act–observe–reflect entails reflection in-action as a description of how members deal with the act of doing things, followed by the reflection on-action as a more considered hindsight view. The research on design parallels the conventional design approach, but is enhanced by the transparent structuring.

In this chapter, I defined my research methodology inspired from action research. Section 3.1 explained in detail what the action research is about and why our research project fits in this methodology. After that in section 3.2 the demarche taken to do the research was explained.

Sections 3.3 and 3.4 brought the plan in to action: the Protige project, the design and development of a surgical instrument for MIS in the action of our demarche. The progression of design was followed in section 3.5.

The Protige project was an exercise of having no outsiders in the collaborative process. The integration of surgeon in the design process was a main challenge for this project because of many problems such as communication problems, project organization, professional vocabulary etc.

To conclude, the approach of action research has been followed, so an application of this approach in design of surgical instruments. Design goals have been achieved: Protige satisfied the surgeons' requirements and has been patented for clinical application.

In the next chapter, I continue on the next step of the research: observation. Since the Protige project has not only design objectives but also research objectives, the project was documented and traces were caught. The next chapter explains the observation, data sources and then enters the analysis of captured data.

Chapter 4

Exploring design phenomena: Observation and analysis

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In this chapter you will find :

- *Observation data sources and how the Protige project was observed and captured*
- *Design activity analysis and the method I used to analyze my observations*
- *New analysis framework and the video annotation techniques and tools*
- *Corpus analysis of design evaluation meeting and emulation, two main moments in the design progression*

4.1 Introduction

The history of the design research testifies that there are not straight forward answers to what to study, what to focus on, and how to choose the ways to study. Obviously, it is valuable to capture and analyze own design activities, not only the claims made from empirical work, but also the methodical choices made to advance such claims. In this dissertation so far, a claim about the lack of methodology of surgical instruments design has been made through the state of the art in the first chapter. Then, the discussion on what the concept of method and methodology is in design, led us to review the design literature to find out the appropriate tools and methods to approach our goal. Afterwards, the context of the practice-led research (particularly action research) has been chosen to study the design methodology and a design assignment in the context of innovative surgical instruments was performed. The next step is to look back at the design assessment and, as the action research proposes, observe and reflect.

The focus of our observation and further analysis is the *design activity*. Design activity embraces various intellectual activities including thinking, decision-making, communicating, as well as practical activities such as information exchange, model making, and result evaluation. Accordingly, the main goal of studying design activity in this chapter is to investigate the role of the surgeon in decision making and evaluation during the design progression. For this reason the design situations, in which the designer and the user collaborate, are identified and analyzed in detail. In particular, two design evaluation meetings and all emulations of the Protige project will be analyzed in this chapter.

In this chapter, first I explain how the data have been gathered from the project (section 4.2). Then, I describe my analytical method to analyze and interpret the data (section 4.3). And finally, I present the analysis results from the application of the methods on the project corpus (section 4.4). The result of these analyses led us to describe the design process and propose descriptive and prescriptive models which will be discussed in chapter 5.

4.2 Observation, Capture and Analysis

Considering the design activity as a data source, the observation of the design activities takes a holistic view of the relationship among the designers' communication, designed

artifacts, the socio-cultural context of the design situation, the position of the observers and the techniques they use for the observation. The term "capture" is used because the ordinary design activities are highly transient and become lost in time. Moreover, in many cases such as our experience, the design activity includes various parallel processes and uses different supports, though it is not always possible to clearly understand what is going on in the situation. While the observation-analysis studies are developed outside of the design studies and mainly in psychology and the natural interactivity sciences, their approaches and results did interest the design researchers in different aspects like the argumentation analysis and the human-machine interactions.

Tang proposed to record the design activities in his Observe-Analyze-Intervene methodology (Tang, 1989). Video recordings provide maximal data of the subject and the situation. It can be replayed and reinterpreted, and can provide the access to the behaviors and the interactions that could have been missed by direct observation. Moreover, some studies showed that video recording can reduce the observers' bias and improve the corroboration (Carrizosa et al., 2002). Thus, video recording is being used widely for research on design in the research workshops. The technology advancement facilitates the use of the video streaming. The real-time audio and video recording have widespread use in academic research.

Unlike the natural interactivity community, the design interaction fully recognizes itself as a "design disciplin", in that the objective is to create new interactive systems and change the existing ones for better (Fallman, 2003). There is an increasing interest in the design community to observe and analyze the design activities in the industrial situations, student experiments, and the international research workshops (Rasoulifar et al., 2009). Although there is no generally accepted approach or research methodology, each study uses its own "observe - hypothesize - analyze - verify" method to obtain result.

Having the posterior research objectives, I have provided the observation and capture systems during the Protige project, explained as follows (section 4.2.1). Afterwards, I summarized what I have learned from observation and capture in the OR from the project (section 4.2.2).

The design activity as a data source provides a multitude of information about the design phases including design-thinking, decision-making, collaboration using intermediary objects, and the design evaluation. The external activities can be observed, recorded, archived for analysis, etc. whereas the externally imperceptible (Pedgley, 2007) activities are far harder to capture. Accordingly, various methods and tools were used by researchers to collect the design activity data such as archiving and reports, questionnaires, interviews and so on.

For our research, in order to obtain information around the design activities, several data collection methods have been used and various data sources were collected. I focused on the design meetings, emulations in OR, design documents and design objects as data sources. In the following section, I explain these data sources and the capturing techniques

that I used for our research in detail.

4.2.1 Design meetings

In the first place, all of the design meetings in which the surgeons and the engineers discussed and made decision about the project were recorded in audio and video formats. Besides keeping a trace of the discussion, there were some other objectives for capturing. In three different design meetings, we have used different intermediary objects, such as the paper sketches, CAD models, and the prototypes. Table 4.1 shows a summary report of these meetings. Although this list does not cover the short communications such as phone calls and light discussions with the surgeon in his office, but it provides a useful source of data of the collective and official discussions and decisions. I come back to some of these meetings to make a detailed analysis in section 4.4.

Since the Protige project was designed and organized also for research objectives, we examined several ideas and techniques to provide additional data for further analysis. For example in one of these meetings (30/5/2007), the surgeon was asked to wear an eye-tracker, during the session of discussion with the engineers. The objective was to see whether the engineer-surgeon communication contains some misunderstanding. The Eye-tracker had a system to point out with an acceptable error, the exact point of the surgeon's gaze, so an afterward analysis would make clear if the surgeon followed the engineers discussion. In the same meeting the surgeon was asked to explain the video capture of another surgeon's operation. The objective was to measure the correlation of a scenario for two surgeons, and to find out if there are serious differences in performance of a certain technique[1].

Furthermore, in one of the last detail design meetings the engineers used a design annotation system to manage the design. The design annotation tool has been used in order to document the discussion between the designers, and to provide the traces of argumentation on technical issues and usage issues for further analysis. Figure 4.1 presents three design evaluation meetings of Protige project.

4.2.2 Emulations in OR

Likewise, the emulation steps in the hospital in which a design prototype was supposed to be evaluated were recorded in a semi-professional manner. For example, in one emulation I set up the video capturing system, voice-recording system, and photographing and the saved X-ray images taken during the operation. Two digital camcorders were fixed in the operation room, on the lighting system, focusing on the emulation scenery from two different angles, covering the whole scene. These camcorders had their own MPEG2 video encoder

[1] Although the cognitive aspect of surgeons work was not in the focus of this research, some observation such as what mentioned brought very interesting discussion with researchers from the human and social sciences (SHS in French) and opened new windows to the future research.

Table 4.1: A summary of design meetings during the Protige project

	Date	Subject	Surgeon participation	Tools	Duration	Observation
1	19/06/2006	a)Preparation for the first emulation in the OR, b) phantom preparation	Dr. Vouaillat	-	1h10	Camera
2	30/5/2007	a) Explanation of the surgery, b) comment on another surgeon's operation , c) Discussion about prototype	Dr. Vouaillat	CAD model	2h	Camera, Eye tracker
3	13/12/2007	Discussion on the new solution, Preparation for cadaver emulation	Dr. Tonetti	CAD model, last prototype	1h30	Camera
4	1/10/2008	Detail design meeting	-	Annot'Action	1h40	Camera + Software Logfile
5	17/10/2008	Finalization of design, Preparation for real operation	Dr. Tonetti	CAD model	1h	Camera

(a) (b) (c)

Figure 4.1: (a) Discussion about the design, (b) The surgeon comments on the previous operation, (c) Engineering meeting on the detail design of Protige

and hard disk recording system.

The preliminary test showed that using only global scene camcorders did not capture the operation in detail. For instance, the scene was not captured if the operation site was covered by the surgeon's hands. Moreover, a system to capture the X-ray images, and a solution to synchronize the activities of the surgeon (operational and control) with the X-ray images were needed. To solve these problems some different set-ups were tested during the experiments and progressively an observation set-up created. In that set-up, in addition to two other camcorders, I used an eye tracker plus another camcorder. By using an eye tracker, it became possible to monitor where the surgeon looked. Accordingly, an eye tracker was provided and, after giving instructions to the surgeon and some tests for familiarization, he was asked to wear the eye tracker. The system is called "Mobile eye" from ASL Company, and consists of an eyewear (spectacles) with light and unobtrusive optics. It is able to record and interleave the scene and the eye image. This device provides relevant information concerning the visual strategy of the surgeon performing his task (scene video through the surgeon's point of view, and scan path superimposed on the video). In addition, the system has an integrated microphone to record the surgeon's voice that is connected to the data storage system.

Figure 4.2: Observation setup in the operating room

Figure 4.2 shows the set-up and the surgeon in the operating room. I used a scenario-based approach to be certain about the observation recordings: A scenario was used to clarify what the usage situation was supposed to be, and how the observation could capture the feed data for further analysis.

To be mentioned, there was also an evolution in the observation techniques and system I used in the OR. Inspired from the other works and learning from our own experiences, I improved the observation and the data gathering. As these findings may serve other

researchers in the field, section 5.6 is dedicated to this subject. Table 4.2 summarizes the emulations of Protige projects.

Table 4.2: Summary of emulations during the Protige project, took place in Grenoble Hospital (CHU de Grenoble). The asterisk indicates the role of assistant

	Date	**Main goal**	**Operation time**	**Total emulation time**	**Surgeon**
Emulation 1	23/06/2006	Idea evaluation of Protige	15 min	30 min	Dr. Vouaillat
Emulation 2	12/01/2007	Evaluation of Protige-tubular retractor system	25 min	50 min	Dr. Tonetti
Emulation 3	13/06/2007	Proof of concept	40 min	60 min	Dr. Vouaillat, Dr. Tonetti*
Emulation 4	08/02/2008	Idea evaluation of Protige	45 min	90 min	Dr. Tonetti, Dr. Vouaillat*

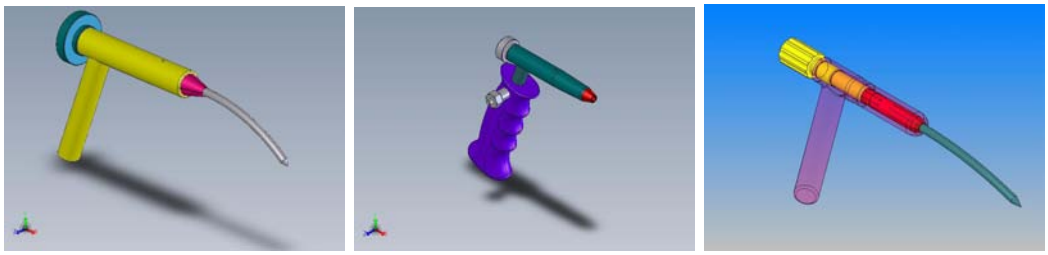
4.2.3 Design documents (scenario, CAD models)

Since I have used a scenario-based approach for the usage (new operation), and there were progressive versions of a usage scenario, this document provides a trace of progression during the design process. Scenario contains lots of information such as the usage tasks, actors, instrument and devices, duration time and frequency of each task. Examples of these scenarios are presented in the previous chapter.

Although the design representation in the Protige project could reach from a sketch to a physical prototype from the early stages, the importance of the 3D CAD modeling is not negligible. The design prototypes explained in the following are made from the CAD modeling. Moreover, 3D model in this project has been used as a communication and discussion support among the engineers in the technical meetings, and among the engineers and the surgeons in the design and the evaluation meetings. Figure 4.3 provides some examples of the 3D modeling from the Protige project.

4.2.4 Design objects

As explained, the prototyping in our experience was like a center for the iterative processes of creating new solutions and evaluating them, and then using the feedback to create a new prototype. Like any project, a designed artifact can be broadly interpreted in terms of the three variable groups of function, structure, and behavior. A design prototype brings together these three groups and the relations between them. The design prototype also shows the processes for selecting and obtaining values for variables. As a result, the design



(a) (b) (c)

Figure 4.3: 3D models of the different versions of Protige

object itself provides much valuable information about the design process, in form of the progressive prototypes.

4.3 Methods for design activity analysis

In this section I explain the analysis method of design interaction. A very short introduction to interaction analysis is provided in order to refresh the basics and give some notions from the literature. My focus is on the collective mechanisms involved in collaborative design. Design methodologies distinguish two kinds of meetings that typically involve collaborative design: design meetings and design evaluation meetings (e.g. inspection or review meetings). Both design meetings and design evaluation meetings contain collaborative activities, but their objectives as prescribed by design methodologies are quiet different. In design meetings, the prescribed objective is to search for a solution to a problem, though the accent is on solution development. In design evaluation meetings the prescribed objective is to evaluate and validate the design solutions that are the input to the meeting. Though the accent is on solution evaluation, and, most of the time, design activities are supposed not to happen.

Since the focus of the study behind this dissertation was the designer-user collaboration, the study presented in this chapter examines the collective mechanisms involved in collaboration of engineer and surgeon, through analysis of design evaluation meetings. While there are many studies and publication focusing on the analysis of design meetings, very few of them analyzed activities involved in evaluation meetings.

There are many studies in the literature concerning activities involved in the evaluation meetings[2]. Nevertheless, most of these studies are focused on the designers' role, and not

[2]The subject of the activity analysis has been originated in the ergonomics studies. The activity analysis, according to Garrigou, refers to a methodology aimed at understanding the behaviour and the operating strategies of the participants through the processes and interactions with others in a given situation (Garrigou et al., 1995). This may include task analysis, which has been used as a method to retrieve the data, including a detailed description of both manual and mental activities,

the users'. From this point, my study distinguishes from existing literature and though I develop my methodology of analysis for the design evaluation in which the expert user has an active role in the evaluation (see section 4.3.2). During the Protige project two kinds of design evaluation meetings have been observed: evaluation of concept in a meeting through the CAD models, and evaluation of the solution prototype in an emulation. Accordingly I explain the difference between these two evaluation steps and then I propose my proper analysis framework for each (section 4.3.2.1 and 4.3.2.2). Afterwards, I explain the concept of annotation and techniques of using annotation software that I have used for my analysis (section 4.3.3). The details of the application of the analysis methods on the corpus of the Protige project and the results will be shown in section 4.4.

4.3.1 Design evaluation activities and methodologies

Very few studies have examined collaboration activities during evaluation meetings, mainly the meetings concerned with validation of conceptual proposition. In absence of design activities, three main activities have been identified (Letovsky et al., 1987):

- Evaluation
- Cognitive synchronization
- Negotiation

D'Astous extended this categorisation to a data coding and segmentation method, in which verbal interactions are Move, Exchange and Sequence (D'Astous et al., 2004). A move is the contribution of a single speaker to a given sequence and is characterised by one activity and the subject (theme) that is the object of the activity. An exchange is characterised by one functional activity rather than by one theme. A sequence is composed of one or more exchanges. Accordingly, the authors propose a classification for activities, initiated and validated within corpus application (see Table 4.3).

There are two issues that distinguish my research context from what has been studied in the literature, and bring us to build a new classification. First concerns the nature of

and to identify the characteristics such as the duration, frequency, allocation, complexity and so on. Design researchers have shown a very special interest to study, describe and analyze the activities in the design situation. More than 770 papers only in the Journal of Design Studies show the importance and pertinence of the activity analysis in design research. Lloyd and Scott (1994) collected protocols and imposed an external structure based on the models of design. (Akin and Lin, 1995) proposed an activity-based model to analyze design protocols. Cross and colleagues, in several publications, have proposed different aspects of analyzing the design activities. Most of them used the Delft Workshop corpus, in which a video recording and transcriptions of a design session were given, and participants were asked to analyze the protocol. (Gero and Mc Neill, 1998) developed and applied some methods to provide the basis for articulating different aspects of the behavior of the individual designers and for distinguishing between the designing behaviors of the different designers.

Table 4.3: Classification of activities for evaluation meeting from (D'Astous et al., 2004)

Activity	Definition
Management	Coordinating and planning the different tasks at the project or meeting level.
Introduction	Introducing a new subject into the discussion
Development	Presenting a new idea in detail
Evaluation	Judging the value of a subject. An evaluation is negative, positive or neutral.
Hypothesis	Expressing a personal representation of a subject, using phrases such as 'I believe that . . . ', 'I think . . . ' or 'Maybe . . . '.
Information	Handing out new knowledge with respect to the nature of a subject
Justification	Arguing or explaining the rationale of a choice
Acceptance	Considering a subject as being valid
Rejection	Discarding a subject as being invalid

design solution in the context of surgical instruments, and the second is the particularity of evaluation during the emulation.

Firstly, the design solution in the context of Protige project is not only a surgical instrument, but also the operation protocol of using the instrument. For this reason, a considerable part of the discussion turns around the usage issues. So, in order to have a better understanding of the activity, the focus (usage or technique) should be considered. This discussion will be developed later in the analysis by giving some examples from the corpus.

Secondly, as it is observed during the project, a main part of validation takes place in the emulation step, in the OR. The primary difference between a meeting and an emulation is, in the emulation, the evaluation has a new element: manipulation. The surgeon uses the prototype following the scenario and makes a clear evaluation of the usability of the prototype. Thus, the analysis could not be complete if it only focuses on the verbalization and neglects the manipulation and gestures. In the following section, I explain my proposition to overcome this problem.

4.3.2 Frameworks for analyzing design evaluation

Methods for design evaluation meetings fall within the perspective of the process model. The preliminary process model of Protige project, explained in the previous chapter (section 3.5), distinguishes different phases occurring in design, from understanding the problem to clinical evaluation. For each phase, the model proceeds to decomposition into tasks, which may affect both engineers and surgeons. In Protige project, the evaluation meeting occurred after a technical design progression and before the emulation. In fact, the evaluation meeting

was supposed to evaluate the design through a CAD model, and then a prototype was made and the next step of validation took place in an emulation.

In general, in the design project of new surgical instruments, validation meeting requires the presence of the designer(s) and the expert user(s), takes certain amount of times (see Table 4.1 for meetings of Protige project), and may take place at any phase during the development process. In fact, this characteristic of the evaluation meetings, the user presence, makes them different from the engineering evaluation meetings.

On the other hand, evaluation during the emulation needs to take into account the non-verbal activities, which according to the author knowledge, has never been considered in design studies. Therefore, the two following sub-sections present my proposition for analysis in meeting and emulation evaluations.

4.3.2.1 A framework for design evaluation meetings

Inspired from the framework proposed and examined in previous studies (D'Astous et al., 2004; Detienne et al., 2004; Robillard et al., 1998; Vacherand-Revel, 2002), a preliminary framework has been proposed in one of our former publications (Rasoulifar et al., 2008b; Hisarciklilar et al., 2009).

Table 4.4: Proposed coding scheme for activity classification in design evaluation meetings

	Description	**Example**
Cognitive synchronisation	Introducing a new subject, or presenting an idea. Making sure that team members share a common representation of a concept	Engineers explain the designed solution to the surgeon
Argumentation	Describing why the solution should or shouldn't be adopted. Arguing or explaining the rationale of a choice	Surgeon justify why the instrument should have the function F.
Evaluation of solution(s)	Evaluating positively or negatively a proposed solution	Surgeon accepts or reject a solution or a part of a solution
Assessment of constraint(s)	Evaluating positively or negatively a constraint	Engineer makes an assessment about the usage constrains
Proposing solution(s)	Proposing, explaining a solution or an alternative solution	Engineer or surgeon proposes a new solution
Enhancing a solution	Enunciating supplementary and complementary ideas to develop a solution	Engineer or surgeon goes through the lately proposed solution and proposes modifications

All five recorded meetings of the Protige project were reviewed for the initial recognition

to see whether or not the framework is adequate with the activities during the meetings. Since the annotation results seemed promising, after some modifications, the new framework was prepared and is shown in Table 4.4.

This coding scheme follows the same logic of categorisation as those proposed in the literature. There is a new issue I propose to add to the conventional coding scheme is to take into account the notion of focus of activity. For all of the activities explained in Table 4.4, there is a focus that alters among technique, usage and scenario. In other words, each activity of Table 4.4, assessment of constrains for example, take the focus on usage, meaning that the subject (surgeon or engineer) assess the usage issues. Table 4.5 below shows some examples of the activity focuses.

Table 4.5: Introducing the focus of activity into coding scheme

Focus	**Activity (e.g.)**	**Example from the corpus**
Technique	Evaluation of solution	"The instrument body it too heavy"
Usage	Enhancing a solution	"I would insert the rod top-down"
Scenario	Cognitive synchronization	"What should I do next"

Although the division seems clear, attention is needed in practice of analysing. Further in this chapter I will use this framework to analyse two evaluation meetings, on with and the other without the surgeon (see section 4.4).

4.3.2.2 New framework for evaluation in emulations

So far in the literature the analysis of the conversational interaction is identified as a generally accepted method to study the design activities and interactions. In this method, conversation is transcribed from the meeting recordings. Then, the analysis will be done on the corpus, commonly called verbalization analysis. Verbalization, expressing something in words, is what actors say during a happening. This subject is highly developed in a large number of language studies and Pragmatics in main subjects of the argumentation and the dialogue.

However, the verbalization analysis method ignores non-verbal interaction, such as manipulation, facial expression, etc. As mentioned before, the analysis seeks to find out about what (activities during the emulation), who (actors) and how (details of action) questions. Moreover, the analysis tries to trace the information exchange among the actors to understand the evaluation of the logic and the decision-making. This information and exchanges are not limited to verbal expressions, and could be found in other activities.

Reviewing the literature, I couldn't find any design study concerning the integration of non-verbal activity. On the other hand, many studies on surgeons and OR workflow employed hand gesture analysis for studying surgeon's activity. (e.g. learning surgical

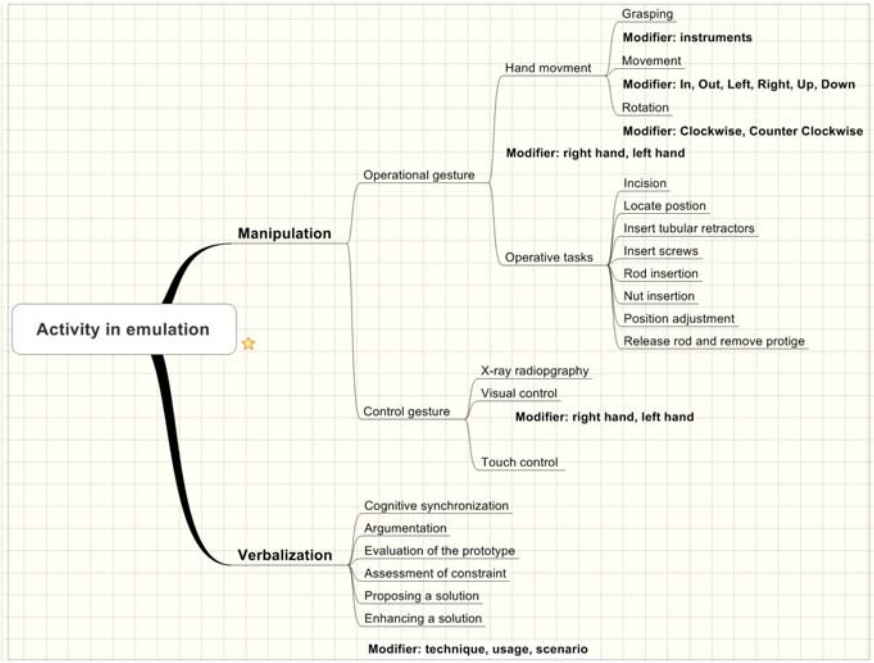


Figure 4.4: Analytical framework for activity classification in emulation

techniques). As a first idea, it seemed important to me to integrate the non-verbal activity of surgeon into analysis. For this reason I developed an analytical framework to annotate the additional information. Figure 4.4 represents this framework, adapted for observation in the OR. I used this framework for analyzing the emulations of the Protige experience, and thus the framework is improved by the practice of annotation.

In this framework surgeon's activity is divided to two main branches: verbalization and manipulation. The verbalization coding scheme is almost the same classification as what mentioned in Table 4.4. The small modification is to employ "evaluation of prototype" instead of "evaluating solution" which is according to the main goal of the emulation. Manipulation of surgeon is divided to operational gesture and control gesture. Operational gesture is roughly what the surgeon does to perform the operation. Accordingly, this framework helps to annotate the operative tasks (in general following the scenario) and also to annotate the surgeon's hand movement. The importance of following hand movement of surgeon is to study how and in which position he uses the surgical instruments and how he manages to have many instruments on the operation site.

On the other hand, control gesture is used to classify and annotate what the surgeon does in order to identify, verify and control the visible and non-visible situations (e.g. verify the screw position in the vertebra). Control gestures are not mentioned in the operative scenario, and vary from one surgeon to another. Based on my observation, I proposed the classification of control gesture into X-ray radiography, visual control, and touch control.

The new term *modifier* in Figure 4.4 is a specific term used in annotation. An activity is considered as a behavior with different levels. A behavior takes a modifier to indicate more data about the behavior. For example surgeon (subject), moves (behavior) his right hand (modifier) and engineer (subject) proposes new solution (behavior) for technical (modifier) issue. I come back to this subject, behavior, modifier classification later when explaining the annotation software (see Figure 4.5).

4.3.3 Annotation and annotation software support for analysis

Based on this framework, a coding scheme has been developed to categorize and classify the happenings. Annotation consists of adding data synchronized with the video stream and allows analysis of the happenings captured by the video recording[3].

Annotation process consists of building a framework and coding the corpus. Before starting the annotation some concepts should be defined. For example, a happening can be defined as an event by an occurrence time, or as an interval by the start and stop times. Usually, frameworks present spontaneous happening through the subjects, objects and the actions. For example, commonly in design studies, such a framework presents typical elements including actors, intermediary objects, and interaction between actors. This categorization can be as detailed as the research needs, and is supposed to follow a logical classification.

We call the setting up of a coding scheme in software as configuration. In other words, configuration is the act of modifying the software options to their nature, number and chief characteristics to realize the framework classification. The result of configuration provides a guidance table called coding scheme. The coding scheme characteristics depend on the annotation software including the level of details, the interrelation between the elements, and being flexible or predefined. This step is the most essential and conceptual step for annotation. However, the annotation process is iterative, because rarely a first coding scheme is capable to classify and distinguish all the happenings of an observation.

Coding in a manual or software means to assign a defined happening from the coding scheme to the video stream. Thus, by coding, the user marks – event or interval – on the stream and adds the appropriate data. Technically, the coding is performed by stopping the stream, and entering a comment or clicking on the coding scheme to assign an item.

For this study and in view of the expected analysis of the video stream, a particular

[3]Numerous studies have demonstrated that annotation is an important part of human reading behavior in both printed and digital environments (Fu et al., 2006). Annotation in the electronic environment requires special support due to limited media features. Many tools were developed to support the requirements of researchers and some studies were carried out to evaluate the functionality and advantages of their annotation tools (Bernsen et al., 2003; Harrison and Baecker, 1992). An increasing demand concerning better tools for handling and analyzing video requires special attention, thus the new tools would have appropriate functionalities and meet users' needs.

selection criterion was set up, except that it should be possible somehow to develop and to enrich the observation from different aspects. With this exception, a survey was performed to review the accessible software in two research center partners G-SCOP and LIG. The result of this survey and a comparison between some annotation software was proposed in form of a paper, and has been accepted as an oral presentation in ICED 2009 conference (Rasoulifar et al., 2009). Because of the importance of the subject in the design interaction studies, I decided to assign Appendix 3 of this dissertation to the concept of annotation and analysis, and the appropriate software tools.

Finally, from this study, The Observer XT®(from Noldus Information Technology) was chosen for data annotation and analysis. The Observer is a professional software package for collection, analysis and presentation of the observational data with capability of defining independent variables and linking them to an observation.

One of my aims in annotation of the surgical operation observation was to gather feedback from the surgeon about the surgical instrument in the usage situation. Moreover, as described in the beginning of this section, the argumentation and discussion between the engineer and the surgeon is also important to be captured and be added to the framework of analysis. For this reason, the audio stream of the discussion during the surgical operation was separately transcribed into text and added to the analysis stream. In the literature, such analytical frameworks are better known as product validation, or usability testing, and have been used for two well-known way of development: engineering and ergonomics.

Performing the annotation on video stream is a difficult task. Thanks to the eye tracker, the movement identification is more accurate, and the use of software slows the stream to facilitate pin-pointing the start and the end of an act. However, the annotation does not cover all details in the video stream, but the results are acceptable for tracing the instrument manipulation. Although the annotation process is very time consuming and deals with some technical problems, the annotated stream is very useful for focusing on both the use aspects and the design aspects of the instrument.

The coding scheme that I developed in the software is a representation of the analytical framework explained in Table 4.4. However, as it will be shown in Figure 4.5 and also later in the results, the level of classification in the framework and in the coding scheme is not the same. Due to the software's design requirements, the parallel activities need to be at the first level. For example, when annotating the right hand and left hand movements, they should be on the first level, and not the subcategory of hands movement, or even manipulation. The elements of the argumentation (description, critic, proposition, question and answer) are at the first level for the same reason. As a result, an observation file (result of the annotation task) contains the movement of the surgeon's hands, his control and his verbalization.

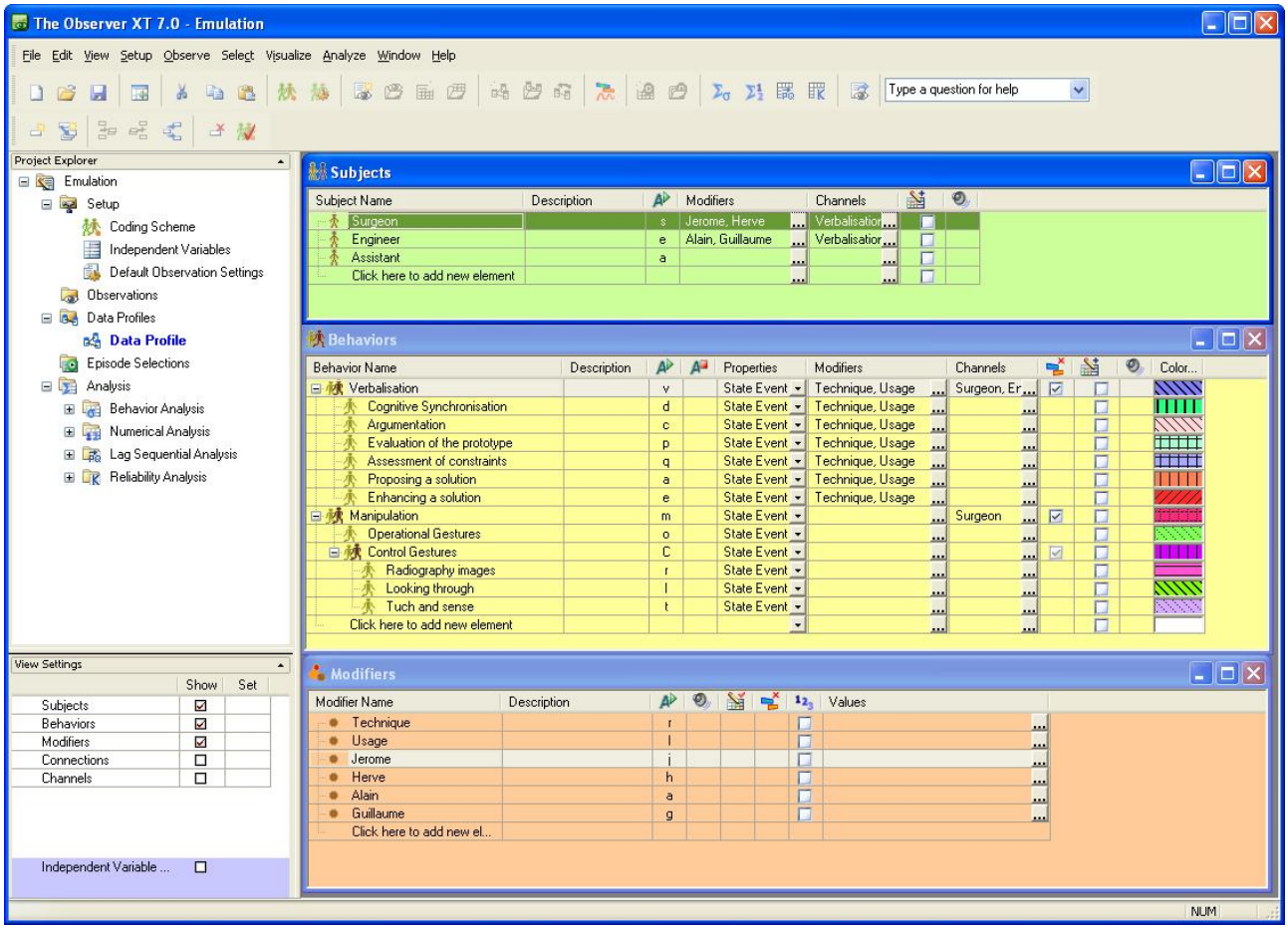


Figure 4.5: Configuration of the coding scheme in The Observer XT®

4.4 Analyzing the Protige experiment

I chose to divide the analysis into (or based on) two scales: macroscopic analysis and microscopic analysis. In the macroscopic level, I look at the whole design process to analyze which design moves and strategies have been used, and how I could determine the aspects of the design specification. Two main discussions are presented in this section. First discussion is about the nature and the type of the design process, according to the existing literature in design studies. The major part of this work was presented at two international design conferences: 'Expert user-centered design' at TMCE Conference (Rasoulifar et al., 2008b) and 'Scenario based design approach in medical application' at CIRP Design conference (Rasoulifar et al., 2009). Second discussion is about a specific moment in the observed design process, called emulation. In chapter 3, I explained the concept of emulation and the importance of such a moment in collaborative design. The section is based on a former publication in ICED conference (Rasoulifar et al., 2007) which is explained in more detail here with the demonstration of the Protige Project examples.

On the other hand, the microscopic analysis focuses on tangible traces of information exchange, design interaction, the designer interactivity with other designers, users, design objects, etc. For microscopic analysis, not only a good observation capture method is needed, but also one or more analysis methods should be employed. In our study I tried different analysis methods such as scenario analysis, argumentation analysis and interaction analysis, with different objectives. However, according to the specific situation of the study the interaction analysis method seemed to provide a better result, but not complete in different aspects. I explained the idea of an analytical framework for studying design interaction in a CIRP conference paper (Rasoulifar et al., 2008b).

Following the text, two microscopic analyses on the Protige project corpus are explained. First analysis is in the objective of investigating the role of the user (surgeon) in the design process. For this reason two design meetings –one with and the other without the user– have been selected and analyzed to find out the influence of the expert user in decision making. The second analysis is on the data coming from an emulation in the OR, in which the communication and interaction of engineer and surgeon is analyzed.

4.4.1 Analysis of two design meetings, with and without the user

As mentioned earlier, observations for this study have been focused on two successive design evaluation meetings. The first one has occurred between the engineering team members, where the participants have validated a series of issues concerning the solution. A software tool called Annot'Action has been used by the engineering team before and during the first meeting. This tool provides an environment for asynchronous communication by putting comments about the 3D model of the product. To find out more about this tool please see Appendix 4. In the second meeting, the modified solution has been reviewed and discussed by the surgeon and the engineering team. Both meetings were captured in video.

To investigate the role of the expert user, I was interested in the question: how does the presence of the surgeon influence the design activities, particularly on the decision making? I consider a design decision to be any and all intentional declaration of information as valid for the design problem. For example first meeting, 31:30, "the contact couple between the rod and the instruments grip should be maximum possible."

Two analyses are proposed in this part. The first analysis (section 4.4.1.1) aims to identify the influence of the user on the design meeting through the meeting statements, extracted from Annot'Action tool in the first meeting. Then, I follow these statements in the second meeting (with the surgeon).

The second analysis (section 4.4.1.2) examines the design activities to understand how the absence and presence of the user influence the design meeting. For this reason, I used annotation-analyse method to code the activities on the corpus (video recordings). The framework detailed in the previous section (see Table 4.4) is used for this analysis.

4.4.1.1 Analysis of decisions in two meetings

As explained before, the Annot'Action software was used between engineers before and during the first meeting. This tool allowed the engineers to access the 3D model of the instrument before discussing it during the meeting. Furthermore, this tool allowed designers commenting on different design issues in the software, by putting an arrow on the target part of the instrument and then entering their comments or questions. Thanks to the argumentation tree functionalities, engineers have also responded to each other's comments. This asynchronous activity happened during two weeks before the meeting. Then, during the meeting the engineers reviewed all the raised issues about each part of the instrument and took some decisions. Those decisions were entered in the software as the final branches of the argumentation trees. Then, the status of the argumentation trees have been flowingly switched by the engineers to reject (the content of the annotation is not to be considered) or closed (the content is to be considered when elaborating the next version). Table 4.6 below shows the arguments extracted from Annot'Action. Some of these statements carry decisional characters; while others announce a need to gather more data for making a design decision.

As Table 4.6 shows, during the meeting, every issue that has been raised and discussed by the engineers through the tool has been reconsidered, in order to reach a final statement. When faced with a usage-related issue, participants followed three successive strategies. They first tried to consider the previous user feedbacks in order to find a similar case. A decision was made when the participants were convinced of the compatibility between the previous feedback and the current issue. When this strategy failed to bring participants to a decision, they tried to elaborate a usage hypothesis by putting themselves into the user's place. When the hypothesis lead to have an agreement, a decision was made and entered in Annot'Action. Otherwise, participants decided to do nothing before having the feedback from the user.

Table 4.6: The statements of design evaluation meeting, extracted from Annot'action

		No decision, need for surgeons opinion	Need to be verified vs usage	Finalized Decisions
1	Verifying the compatibility of the size and form of the rod and screw nuts		✓	
2	Minimizing the number of turns for rod plug			✓
3	Find compromise on rod smoothness, between sterilization and fabrication costs		✓	
4	Handle orientation to be validated by surgeon	✓		
5	Improving the contact site between the rod and the grip			✓
6	Exterior diameter of the grip 15 mm			✓
7	Ask surgeon if he needs a support system on the patient's back	✓		
8	Prepare two grips: round and Allen		✓	
9	Using sudden Inox (Material) for long life cycle			✓
10	Exterior diameter of grip's body: 7,52			✓
11	Add a groove of 0.2 mm, inside, verify with sterilization process	✓		
12	Increase the interior diameter up to cover empty space and verify to be compatible with connecting part			✓

As a result, these statements are classified into three categories: finalized decisions, decisions need to be verified with a usage issue (e.g. sterilization procedure), and non-decision statements to be verified by the surgeon. Statements are presented in Table 4.6. Out of 12 collective statements in this meeting, 6 have been finalized (50%), and the rest needed to be verified by usage process (25%) and by the surgeon (25%). The distribution is shown in Figure 4.6.

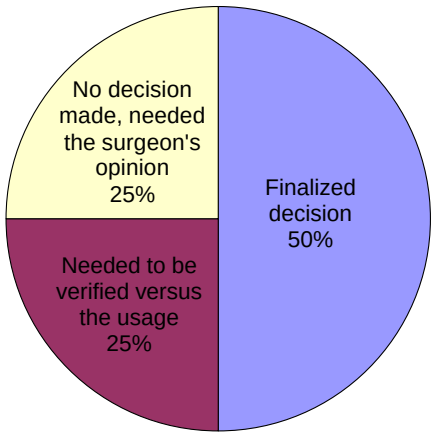


Figure 4.6: Statements distribution during the design evaluation (first) meeting

The data showed that although the objective of the meeting was to validate technical issues on the solution, the designers were needed to consider a large number of usability-related issues. In other words, usability problems have been inevitably involved, even for the technical validation of the design solution.

Furthermore, in the absence of the surgeon, the engineers have had serious problems for dealing with these issues. In one fourth of the cases, they have not had satisfying amount of user feedback to refer to for making a decision. For a quarter of those cases, they were not able to develop satisfying usage hypothesis, and had to close out the issue without any decision. The engineers therefore concluded that those issues should be discussed again in the presence of the surgeon.

In the next step of the analysis, I looked through the second meeting, in which the surgeon was present, to find out the evaluation of the surgeon on the design decisions. To do that for each subject, first the concerning argumentation in the recorded video was identified, and then made in transcripts. The second meeting did not follow the same order as the first one, however, the design was improved since the last meeting and though a large proportion of the time was spent on the presentation and discussion around the new model of solution. Most of the finalized decisions were approved by the surgeon, but for example the decision number 6 which was very important for the technical design was somehow rejected by the surgeon and a lot of time was spent on argumentation and finding new design alternatives. In Table 4.7 the three categories of statements are shown (left

column). In the right columns the status of each statement according to the discussion during the second meeting is classified.

Table 4.7: The status of the decisions made in the first meeting during the user evaluation meeting

	Decision number	Discussed in the second meeting	Evaluation (+/-/No)	Need design modification	Need emulation
Finalized decision from the first meeting	2	●	+		
	5	●	+		
	6	●	-	●	
	9				
	10	●	-	●	●
	12				
Needed to be verified versus the usage	1				
	3				
	8	●	No		●
No decision made, needed the surgeon's opinion	4	●	+		
	7	●	No		●
	11	●	No		●

Although the first category decisions from the first meeting contained technical issues and was estimated as finalized, as Table 4.7 shows, two out of four discussed issues were not positively evaluated by the surgeon and needed more design refinement. Only one statement from the second category was discussed in the second meeting, and was evaluated negatively. In the third category, one decision was evaluated positively by the surgeon, and two other statements were left out without evaluation, to be examined in an emulation.

This result shows that some finalized decisions, even if they are related to the technical issues, may be questioned again by the designers when they receive the surgeon's evaluation. The reason is that the specific expert point of view of the surgeon often opens new insights to designers. I can thus conclude that the designers lack of this insight when they think about the usage in isolation, and the presence of the surgeon offers benefits for every type of design issue (even to the technical ones).

4.4.1.2 Analysis of activities in two meetings

How does the interaction during meetings change with the presence of the surgeon? In the previous section I analyzed the declared statement in order to follow the decision making trends in design evaluation meetings. In this part, I propose to extend the analysis to the design activity, on the video capture of the meetings.

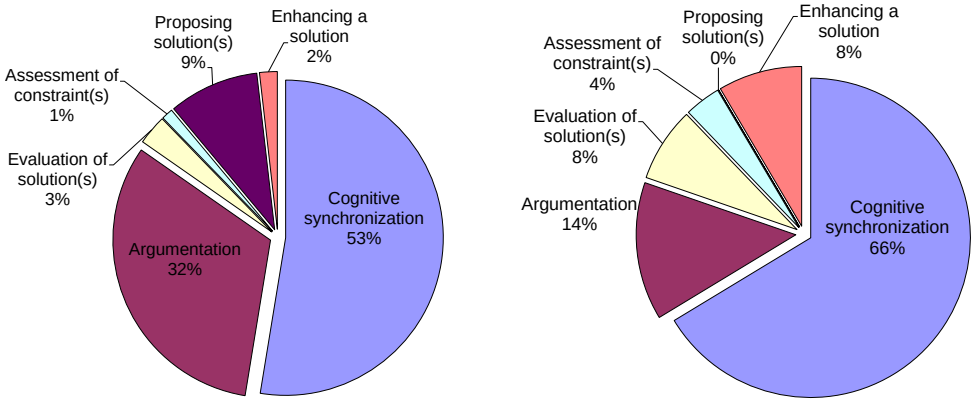
The distinction of usage versus technique showed that the interaction proportion on the usage and the technical aspects of the design are similar in both meetings. Though, the usage-focused interactions remain important no matter with or without the expert user. Therefore, the user is as much needed during the product development as for the phases of validation.

Coding design activity allows to put emphasis on the 'communication features' of the two meetings. This also helps us to argue that the asynchronous communication can be useful for carrying out a part of the latter (e.g. line of argument, assessment or solution suggestion) in asynchronous. That is why I investigate design activity analysis.

Based on the activity categories defined in the previous section (Table 4.4), both meetings were annotated using annotation software and the data were extracted in form of time/activity. The first meeting, (technical design meeting) was a face-to-face situation, where engineers have sought to validate the design modifications regarding the mechanical, ergonomic and manufacturing constraints, prior to the next meeting with the surgeon. The result of activity analysis is shown in Figure 4.7.

The comparison of these two meetings shows interesting results. In both meetings participants spend more than the half of the time on the cognitive synchronization activity, which is quite normal in such meetings. In the second meeting this share is even more, because of the presence of the surgeon and question and answer around the usage aspects.

The argumentation activity is decreased in the second meeting, because the focus of this



(a) First meeting, engineering design evaluation

(b) Second meeting, evaluation with user (surgeon) of the user evaluation meeting

Figure 4.7: Design activity classification in evaluation meetings

meeting was design validation with the user, and no design modification. In the same way, there is no proposition solution activity in the second meeting and the share of enhancing solution is augmented considerably from the first meeting. Finally, the direct evaluation activities, evaluation of solution and assessment of constraint are increased in the second meeting.

Let's look at the focus of design activity in these meetings. This comparison made on the percentage of each activity category, divided to usage and technique focus. The result is presented in Figure 4.8. The left side of the graph shows the first meeting, and the right side the second meeting.

As the figure shows, cognitive synchronization, argumentation and evaluation of solution activities have almost the same focus distribution. The share of usage in evaluation of solution is increased in the second meeting, which is a expected, due to the presence of the surgeon. The other effect of the surgeon participation is the considerable increase of usage focus in the assessment of constraint activity in the second meeting. As explained before there was no new proposition in the second meeting, and the enhancing a solution activity has a share of usage focus.

According to these results, I could conclude that the presence of the surgeon provided the possibility for enhancing solutions from usage point of view (see Figure 4.8). It also brings the group to propose new solutions on usage procedure. The last point to add is that the time spent on the assessment of solution has a great focus on the technical issues, which is in line with the objective of this meeting.

In conclusion, the results presented in this section clearly show that in design of products like surgical instruments, where the users are expert, user's know-how plays an important

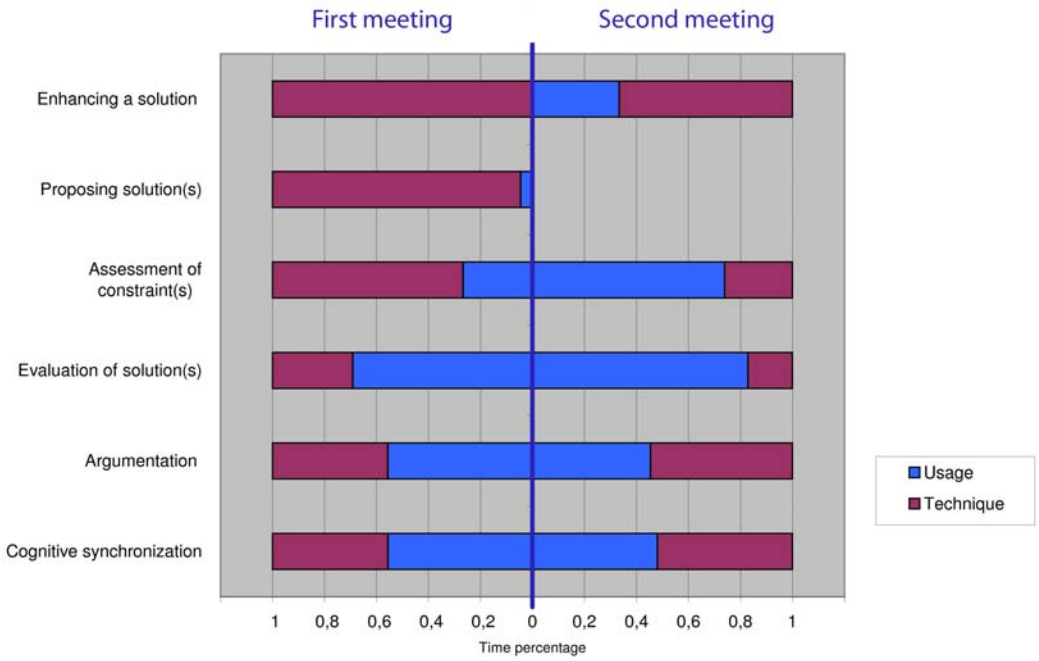


Figure 4.8: Comparison between design evaluation meetings, first without and second with the surgeon

role on the efficiency of design solutions. They also show that designers benefit from the active presence of the user in every step of the design process, even when they face technical issues. Asynchronous annotation of the proposed solution has allowed engineers to discuss and establish an issue list of the meeting before the session. Moreover, asynchronous discussion on these issues helped them to reach a common understanding about them. Sharing the solution before the meeting allowed to detect design failures earlier, and to give the designers enough time to search for solutions. The annotated solution helped also to ensure a systematic communication during the meeting. The explicit list of issues during the meeting helped participants to achieve a better time management and a better orientation of the discussions towards the decisions.

The distinction of usage versus technique showed that the interaction proportion on the usage and the technical aspects of the design are similar in both meetings. Though, the usage focused interactions remain important with or without the expert user. Therefore, the user is as much needed during the product development as for the validation phase.

4.4.2 Analysis of emulation: Confrontation of technique and usage

The word emulation was introduced in chapter 3, and it was mentioned that this choice was to make difference from simulation. Simulation, for instance in surgical studies, is subject of virtual reality and has an increasing reputation in surgical studies such as training and

intervention. In contrary, emulation deals with physical objects and occurs in the operation room with necessary surgical devices. This concept was initiated from our preliminary contact with the industry in surgical instruments domain (see section 3.2.1). According to the discussions, an environment providing facilities for surgeons to evaluate the design prototype and discuss around had a principles role in the design process. Here in this part, I present my coding (annotation) and analyses on the emulations of the project. The first objective of this coding and analysis was to investigate whether or not the coding scheme is reliable. This objective was studied as follows in the section 4.4.2.1. The second objective was to examine whether or not it is important to analyze in detail the surgeon's manipulation behavior parallel to the surgeon-engineer interactions. This issue is explained in the section 4.4.2.2, and a detail analysis of the discussion and decision making during the last emulation (test on cadaver) is presented.

4.4.2.1 Analysis of four emulations of project

As mentioned in section 4.3.1, a new framework was needed in order to analyze both verbal and non-verbal aspects of the emulations. The framework was proposed in Figure 4.4. Based on this framework, I created the coding scheme in The Observer (annotation software) and coded those four emulations from the Protige project. Figure 4.9 shows an example of the coding in The Observer.

Once the coding is done, The Observer can visualize the segmentation of activities on time axis. This visualization helps to have the first image of the distribution of activities during the observed session. For example as it is shown in Figure 4.10, for two subjects of this annotation (surgeon and engineer) there are two activity distributions. Two behavior channels of the surgeon are verbalization and manipulation. In this example, it can be seen that in the beginning his main behavior is cognitive synchronization and while approaching the end, other behaviors appear. On the operational gesture, the distribution of the time that he took for each operative phase is shown. The verbalization distribution of the engineer's activity is shown below in Figure4.10. However, further analysis and interpretation need to export annotation data and so exploit and visualize with other methods.

Evolution in emulations

I may remind from the last chapter that a trend of evolution was observed on successive emulations during the project. In other words, the first emulation was the simplest one and was performed only for the concept validation of the new instrument. By the progression of the project, the instrument design and the usage scenario advanced in parallel. As a result, each new emulation had a more advanced situation. This evolution is demonstrated in Figure 4.11 by the duration on emulation and through the manipulation procedures.

As it can be understood, the fourth emulation contains all the activities while the other ones are limited to some manipulation activities. Although the last three tasks (rod insertion, nut insertion and release the rod) were at the center of our design project, as

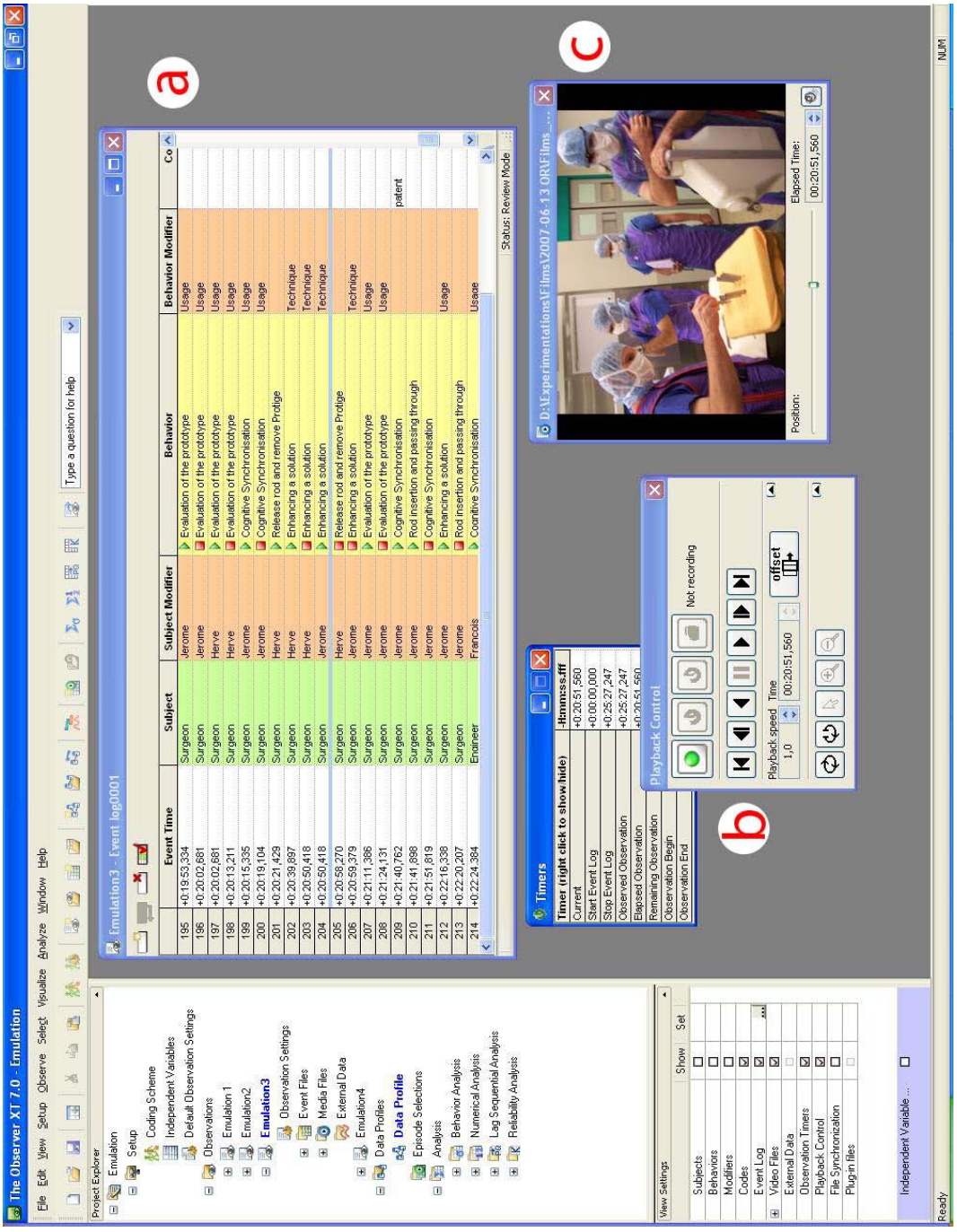


Figure 4.9: Coding the observation in The Observer

a) Coding space, b) video stream, c) playback control. Once the coding scheme is defined, in order to start coding process the operator opens the observation video stream(s) (there is a synchronization control for multi stream). The green button on playback control starts playing the movie. To code and event should: stop the playing (to conserve time), and then enter subject, behavior and modification. In this Figure the underlined event coded as: time 0:20:50, 410 subject surgeon (Jérôme), has the behavior enhancing a solution (technique).

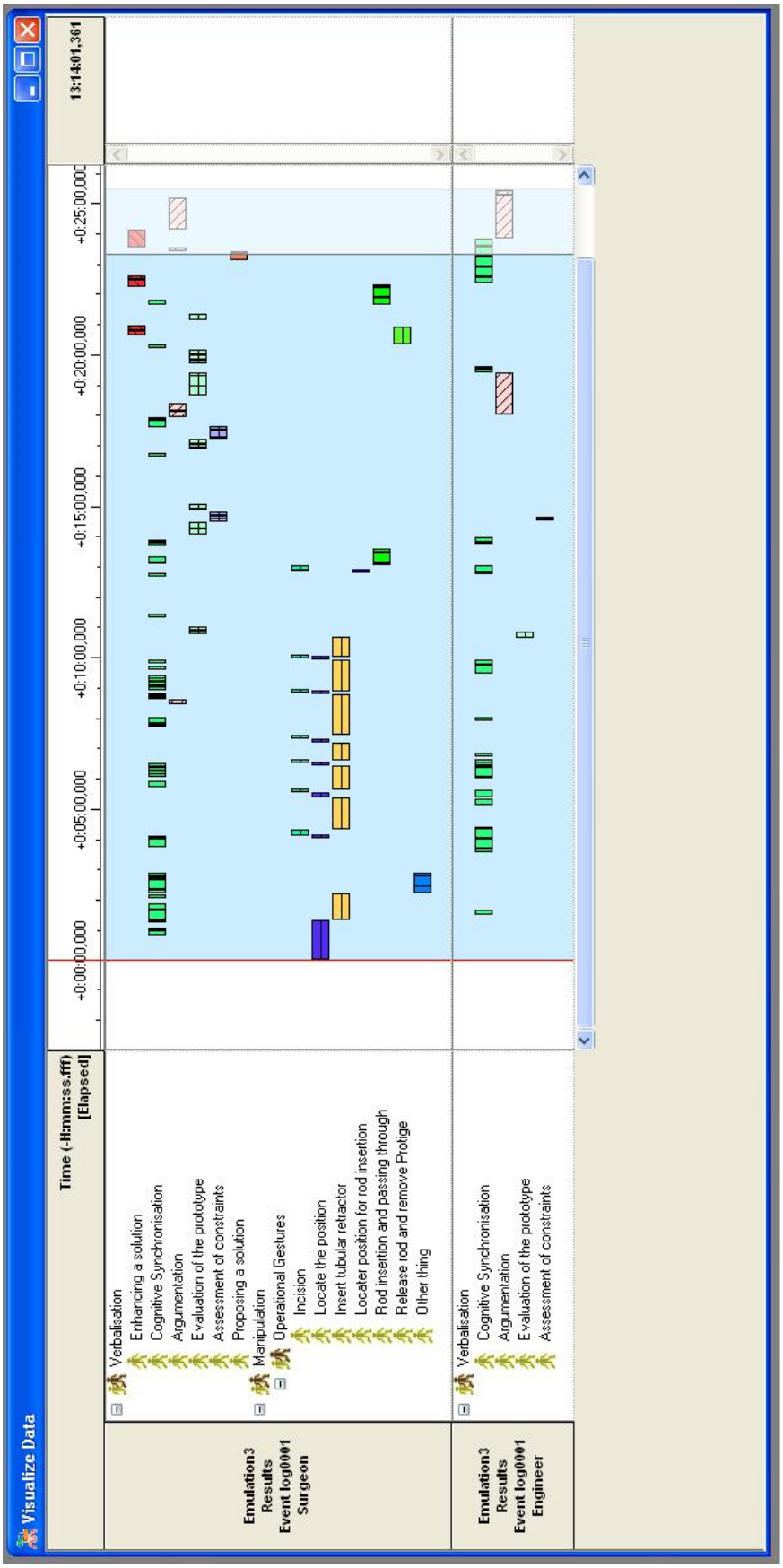


Figure 4.10: Visualization of the analysis of the third emulation, corpus of the Protige project

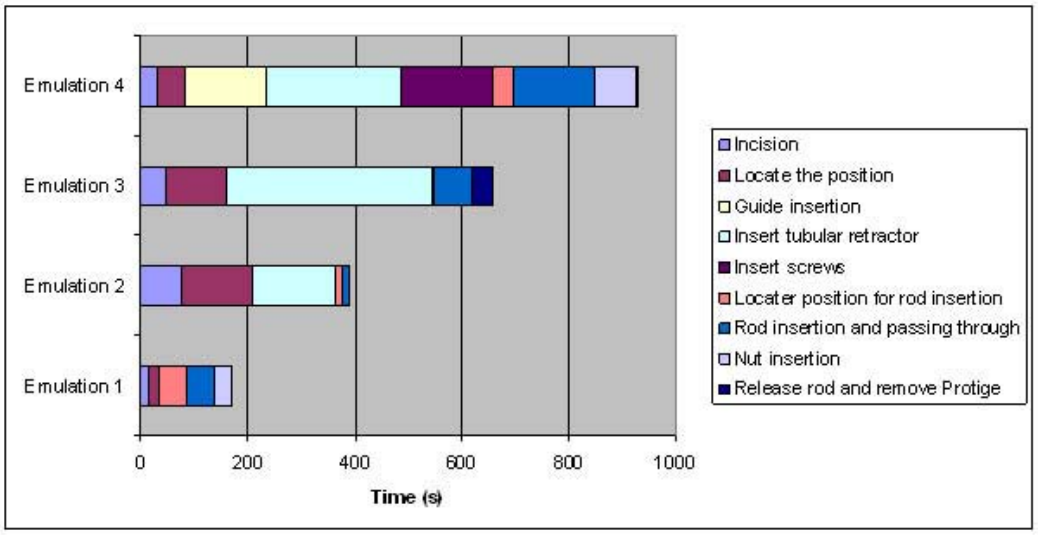


Figure 4.11: Evolution of the scenario and manipulation in four emulations

the analysis shows, other activities are needed in order to prepare the situation for rod insertion. Moreover, as a modified tubular retractor is proposed, clinical evaluation of this modification was also necessary.

The last quantitative characteristic of an emulation is the duration and the number of X-ray images taken during the operation. Table 4.8 shows the summary of (scenario) operation time and number of X-ray images of four emulations from the Protige project. The time here is the duration of performing the scenario, extracted from video observations. The number of X-ray images implies the time of radiation, which is a very important factor in evaluation and comparing surgical protocol. In my analysis however I'm not using this number for evaluating the operation, but as a factor of surgeon manipulation (control gesture) and an index for differentiation of the evaluation of an expert in the real situation. Just to remind, in the second emulation the phantom had the radio transparency problem, and this problem prevented the surgeon to use X-ray images. To have a comparison with real operation, according to my observation in the OR, the number of X-ray images are between 15 and 25 for the similar spinal procedure operation.

Table 4.8: Scenario operation and control in emulations

	Time (s)	**Number of images**
Emulation 1	465	25
Emulation 2	1762	16[a]
Emulation 3	1527	60
Emulation 4	1986	65

[a]X-ray radio transparency problem, see section 3.5.2

Let's look at the verbalization activity during the emulations. The result of coding activity shows how these activities are distributed in each emulation. Here I propose three graphical representations created from the analysis results. The first graphic shows the distribution of design evaluation activities in time percentage. Then I bring the attention to the focus of the activity and so the second and the third graphics compare the contribution of activities considering the focus of the activity.

a) Distribution of design evaluation activity in emulation At the first place, the distribution of activities shows the objectives obtained in each emulation. The numerical results from coding of design evaluation activities based on coding scheme (see Table 4.4) are presented in Figure 4.12. As it can be understood from the figure, a considerable part of the time is spent on the cognitive synchronization between surgeons and the engineers. There is no much room for new propositions, and as it will be explained later, the proposition on the enhancement of solutions containts usage aspects. On the other hand, evaluation of the prototype and assessment of the constraints coming from the surgeon side are very important for engineers to understand the problems and looking for new solutions.

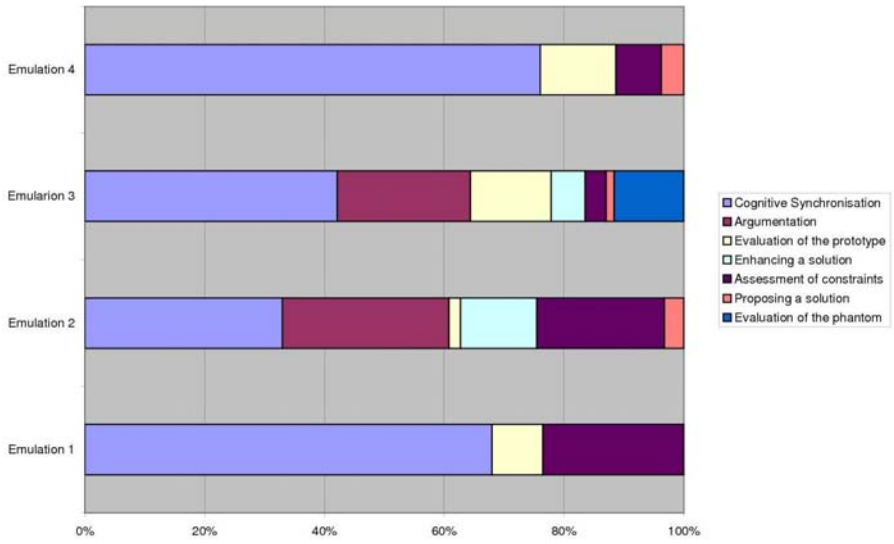


Figure 4.12: Distribution of design evaluation activity in emulation

There is a new class added to the coding scheme "evaluation of the phantom". Normally the verbalization out of the classified activity is not subject of coding. The reason why this part is present here is to show that in practice, there is a discussion on the reliability of the phantom. In our experience, during two first emulations these discussions took place before

starting the operation. In the third emulation, the surgeon evaluated the used phantom during the operation, so there exists an annotated part (color blue in Figure 4.12). For the last emulation on cadaver, so naturally no comment addressed the phantom evaluation.

b) Distribution of activities according to the focus

As discussed in section 4.3.2.2, I proposed to analyze the design evaluation activities by their focus (technique, usage and scenario). To be mentioned, in the primary coding scheme and annotation the activity focuses was technique and usage. The first stands for technical and functional aspect of prototype and the second standsfor surgical operation. During the project, I realized that with a third focus on scenario of operation, a better refinement can be obtained. The reason was that a considerable part of surgeon verbalization and the question/answer between the surgeon and the engineer was not really focused on usage (the future operation), but on the actual emulation scenario. So, I decided to add this focus to the coding scheme.

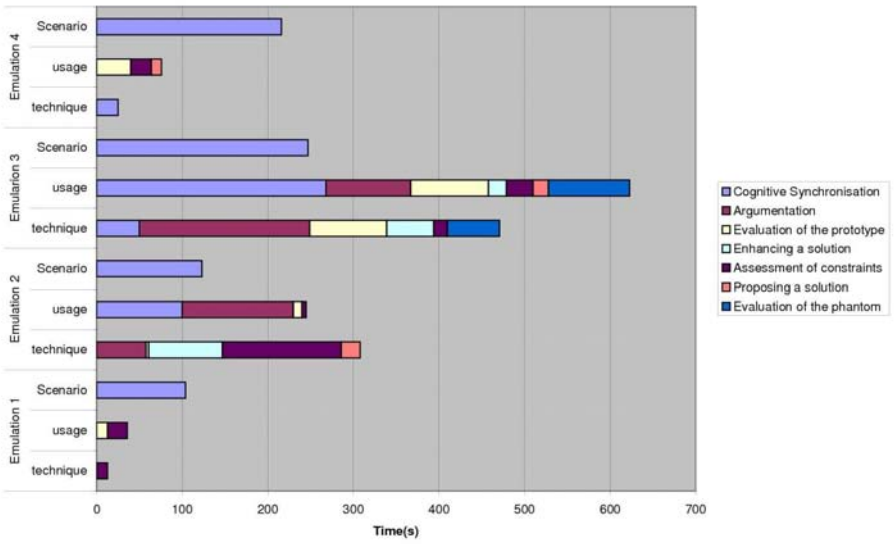


Figure 4.13: Design evaluation activity distribution by focus in four emulations. The time shown in the figure is the duration time of the activity, annotated by the software.

Figure 4.13 shows the distribution of the design evaluation activities in four emulations in time scale. These results are in agreement with the design process of Protige project. Since the two first emulations were an opportunity for observing the usage environment and situation and discussing on the principles, the third emulation was in fact the first design evaluation. Both prototype and phantom have been carefully prepared, and as a result,

much discussion happened concerning both technique and usage aspects of the design. The fourth emulation was the beginning of the clinical validation. Therefore, as the result shows, the discussion centered more on usage aspects than technical.

To look at the analysis from another angle, I normalized the time scale of the results by dividing each time period by the whole time of each emulation. The emulations total time was given in Table 4.8. Figure 4.14 below shows the new results.

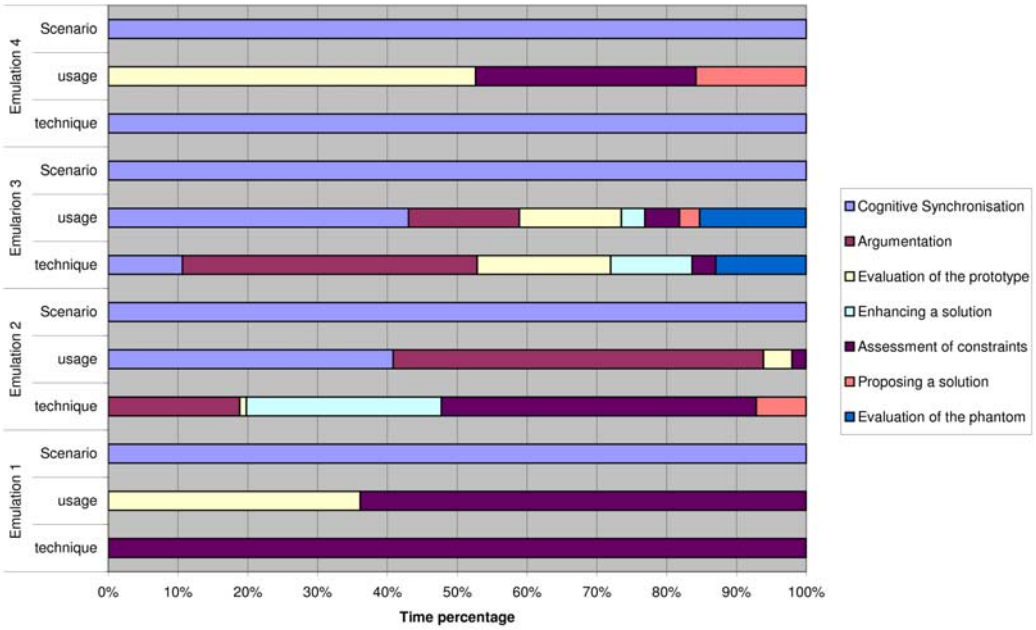


Figure 4.14: Normalized design evaluation activity distribution by focus in four emulations

As the diagram shows, scenario is the main subject of cognitive synchronization activity in all four emulations. This result somehow confirms the important role of scenario as a communication tool between surgeon and designer, and also shows the guiding role of scenario to organize an emulation.

Argumentation activity is more present in the second and third emulations, on both technical and usage issues. Considering the most communication about the concept of new solution has took place in those periods, this result is totally understandable.

Evaluation of the prototype by the surgeon is one of the main expectation of each emulation, and as it can be seen is present in all emulations (in the second emulation the same prototype of the first emulation was used). Interestingly, this evaluation is not limited to usage issue, and in the third emulation there are some technical evaluation from the surgeon.

Enhancing a solution activity is observed in second and third emulations, when the solution was in progression. Moreover, this activity is more associated with the design

meeting and evaluation meeting, not with emulations.

Assessment of constrain activity shows a very interesting evolution in the diagram. In the beginning the focus is mostly on technical issues, in the third emulation we can see an equal share for both technical and usage issue, and then in forth emulation the focus is only on usage issues.

Proposing a solution has the technical focus in the second and usage focus in the forth emulation. From the observation, the technical proposition was made by the engineer (for the instrument), and the usage proposition was made by the surgeon on the operation protocol.

In conclusion, according to what I observed, there is a particularity of design evaluation activity once it happens in the usage situation and in presence of the expert user. The observation on the surgeons of our team in four emulations showed that in almost all the time they commented on the design, they were manipulating the instrument.

From this point on, I suspected whether the manipulation of the surgeon has the same importance for understanding his evaluation as what he commented. To investigate this hypothesis I decided to go through the verbal exchange between the surgeon and the designer and to analyze these activities parallel to the surgeon manipulation. For this study the corpus of the third emulation was selected, because it was the most debating emulation. This study is presented as follows.

4.4.2.2 Importance of analyzing both verbal and non-verbal observation

One of the outcomes of using the framework of analysis in Protige project was understanding the importance of analyzing both verbal and non-verbal observation particularly in evaluation situation such as emulation. In most of design studies the analysis of design activity is based on what captured from the verbalization between actors. In the situations like emulation in which the manipulation evaluation is important, and also the user does not necessarily explain his logic of evaluation, consideration of the non-verbal observation has a particular importance. I explain this issue by an example of one of the emulations from the project.

For the third emulation, the usage scenario was prepared and a functional prototype of Protige was fabricated for being examined. Since the surgeon was asked to comment and to criticize while using the prototype, and his verbalization provided a source of information beside the manipulation, I made my analysis firstly by listing the activities and phrases of the surgeon. Table 4.9 shows an extract of the operation phase (manipulation) and verbalization.

Surgeon made some remarks and critiques on the prototype, and concluded that the bottom-up rod insertion was not acceptable. Afterwards he proposed a new solution, to insert the rod top-down. Then he tried his solution and made his comments. As shown, the

Table 4.9: An extract of analyzed observation – Emulation in the OR

Manipulation coding			**Verbalization**	**Coding**
Positioning screws	Control	X-ray	The screw positioning is not perfect because of lack of a tool	Assessment of constrain
Insertion the rod (bottom-up)	Incision	Right hand	The handle is not ok	Evaluation of solution
	Rod insertion	Right hand Left movement	It is not heavy-set It turns I'm pushing and it turns	Evaluation of solution
	Control	X-ray Left hand: hold/Right hand: push down	I can not guide it on Can not we have a gritty ending for better grasping? Change the insertion direction	Cognitive synchronization Proposition of solution
	Change rod			
Insertion the rod (top-down)	Incision Rod insertion	Right hand Left hand: right movement	It is good It was with the direct control, not necessary the X-ray	Evaluation of solution Evaluation of solution
	Control	X-ray	I like it, because I could make it without the direct X-ray	Argumentation

surgeon's first critique in this case is about the handle of the prototype, "the handle is not ok". The designer asked why, but the surgeon's answer was not clear: "it is not heavy-set".

However, by analyzing the manipulation of the surgeon from the observation capture, it will be known that the problem surgeon mentioned is not the handle, but the instrument's grippe. This is a simple example, but based on the idea I could demonstrate the added value that my proposed framework brings to the activity analysis studies.

4.5 Conclusion

In this chapter, the Protige project experiment was reviewed and analyzed in order to locate design phenomena in the particular situation of the design of surgical instruments. This chapter also addressed the methods used for observation, annotation and analysis of design evaluation activity. Two types of design evaluation situations were observed in the project, design meetings (with expert user) and emulations. Both of these situations are new to the subject of activity analysis, so I built-up my methodology provided by examples for better understanding of this analysis.

To conclude, analyzing design activity needs not only a reliable framework, but also reliable coding and interpretation technique. After creating a modified and appropriate analytical framework for analysis evaluation activity in both verbal and non-verbal behavior, I have analyzed both evaluation situations of the project by using annotation technique and video annotation software, The Observer XT. As a result, various graphical representations of the distribution of activities were obtained. Using the annotation software for the activity analysis is not new in design studies, but it is almost rarely justified why such a tool has been chosen. In my study, I spent plenty of time on trying different software and comparing the functionality. The result of this study together with explaining the annotation process is published in (Rasoulifar et al., 2009), and can be found in Appendix 3.

The corpus analysis of the Protige project took the hypothesis of a particular characteristic for design in the context of surgical instruments: the role of the expert user. This hypothesis was examined by analyzing the design activity during evaluation meetings and emulations. Here is what I concluded from the analyses:

1. Role of the expert user in design

It has been observed that the presence of the expert user in the design meetings has an important impact on the organization and quality of the meeting. Even in the advanced design phase many discussion issues needed to be verified by the surgeon, and therefore it is almost worthless to finalize the design and start prototyping without confirmation from the surgeons.

2. Role of the expert user in evaluation

Evaluation in some design project has a particularity: only the expert user can perform

the evaluation. Complexity and experimental know-hows are the particularity of usage, and as the studies of aviation and surgery confirm, designers could never put themselves in the place of user for the evaluation. As a result, the design process has to provide situation and facilities to acquire the expert user evaluation. It means go much further than using questionnaires or making interviews, and go forward to physical manipulation in the real usage environment. This evaluation situation is what I called an emulation.

3. Coevolution in design process

The other result of this analysis is to highlight the interdependence of design activities in moving forward from problem to solution, which are categorized to instrument and usage sides. In macroscopic view, the design prototype which is representing the technical knowledge coevolves with the usage scenario, the representation of usage. In microscopic view, this coevolution happens in the small problem solving activities, during meetings and emulations. Considering three categories of pure technique, pure usage and instrument-usage classes, the last class seems to be the best source to be studied for design activity analysis.

To sum up, expert-user integration and design evaluation in emulation are the moment I consider the new design phenomena were observed. This finding can help to better explain the design process of surgical instruments, and also to prescribe as a model for helping design projects in this field. The descriptive and prescriptive models of design process, which build at the same time the reflection part of my action research study, are presented in the next section.

Chapter 5

Propositions for the design process of MIS instruments

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In this chapter you will find :

- *Propositions for describing the design process*
- *A prescriptive model for the design process of surgical instruments*
- *Validation of the design model in an application case*
- *An informatic structure to support the design model*
- *Lessons learned from observation in the OR*

5.1 Introduction

In the last two chapters (chapters 3 and 4) of this dissertation, I followed the three steps of action research approach: Plan, Action, and Observation. The observation took the whole chapter 4, because there were a lot of issues to analyze and to discuss in detail. Now, is the time for the last step: Reflection. Reflection, according to Swann, means "reflecting" on the result of the evaluation and on the whole action and research process, which may lead to the identification of a new problem or problems and hence a new cycle of planning, acting, observing and reflecting. I interpret the reflection as two main activities, one inside the other. First the internal reflection is on the action, which means here the design process of the surgical instruments. In this step by using what has been observed, analyzed and learned, I can describe, evaluate, justify or propose the modification for the strategy of the action (here the preliminary design process). Then, on the external reflection, I look out the whole approach of action research and in the same way justifies or proposes modifications.

The present chapter concerns the reflection on the design process: I describe and explain the design phenomena in this specific field of design (section 5.2), and then make a proposition for the process model in a prescriptive way (section 5.3). The proposed model is the claim of this chapter, and like any other process model needs to be validated. I discuss this issue in section 5.4 and then propose a case validation: application of the model on a new surgical instrument design project.

To go further, I propose to investigate the possibility to have a software tool to support the proposed model. This subject brings the discussion to the proposition of an informatic structure for the design process managing tool in section 5.5. Last but not the least, section 5.6 puts together some recommendations for observation and capture in the OR, lessons learned from Protige experience.

5.2 Propositions for descriptive models

I may remind from the second chapter that most of design research studies are seeking to better describe the design phenomena, through the various observation and analysis techniques. In this PhD study, the observation and analysis of the Protige project progression

was the opportunity to investigate and identify new characteristics for the design process, in the context of new instruments for innovative surgery. This study came up with two key concepts: the coevolutive nature of the design (particularly in the emulation phase) and the expert user integration in the design process. In this section, these two concepts are described.

5.2.1 Coevolution of product - usage

In Merriam-Webster dictionary coevolution is defined as: "evolution involving successive changes in two or more ecologically interdependent species that affect their interactions". Therefore, what we mean by the coevolution in design is the parallel development of two or more design interdependent objects, in which the progression of one affects the others and their interactions[1].

In the context of our research, such a phenomenon has been observed: the coevolution of the new instrument prototype, and the new operation procedure throughout the design progression. In other words, the evolution of the instrument prototype showed interdependency with the evolution of the usage scenario.

Prototype brings together all of the requisite knowledge appropriate to a specific usage scenario, and is a tangible trace of what the designer have understood from the requirement of the user. On the other hand, the user examines the prototype to evaluate whether or not, the design solution satisfies what he desires. Naturally, the user evaluation is not limited to planed usage scenario, and he tries to find out what is possible to do. This moment is very similar to what the designers do in producing design alternatives. In this way, a modified usage scenario appears from user's idea and discussion with the designer. As a result, prototype and usage have a coevolution during the project.

In Figure 5.1, this concept is shown with the examples from the Protige project. For each emulation, solution was already realized in the form of a prototype and a usage procedure demonstrating the response to the last expression of the problem. During the emulation, the surgeon validates the functionality of the instrument by manipulating. Even if he

[1] We derived the term coevolution in design from the quotes in software engineering by Fisher as "coevolution of specifications and implementation" (Fischer and Schneider, 1984). The coevolution later was used by Maher as the design formalization by representation of the requirements and the solution within the genotype (Maher and Wu, 1999). It is shown that the support for the coevolutionary design style in software engineering and HCI is strong (Gould, 1998; Jacobson, 1992). Brown suggested that the design artifacts coevolve, and the informal artifacts such as textual scenarios can be usefully linked to the other design artifacts. (Brown and Marshall, 1998). In engineering design the coevolutionary nature of the design process was recently discussed in the literature, such as a zigzagging between disciplines (Suh, 2001), cycles between the questions and the options (MacLean et al., 1991), loops to develop the solutions that fit the problems (Pahl et al., 2007), and the activities between solution definition and problem reformulation (Lonchampt et al., 2006).

follows the written procedure task by task, what he does - his activity - is different from the procedure. Therefore, the present mechanical solution (the prototype) is being verified by a new problem expression which is not totally different from the last version, neither totally the same. After the emulation, the problem expression is somehow implicit, in the form of the mentioned points and critics of the both actors, as well as the result of some engineering data capture (for example force measurement on the handle of the instrument). However, the tacit part of the problem expression remains in the form of the actors' knowledge and is not traceable.

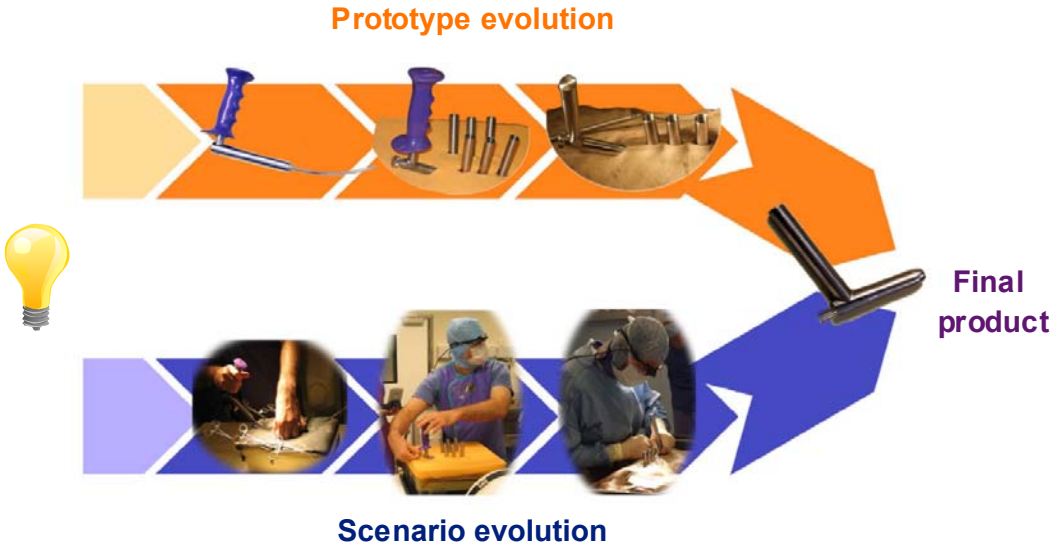


Figure 5.1: Evolution in prototype and scenario in Protige project

In this coevolutive process, the emulation plays an important role in communication, knowledge exchange, evaluation, decision making and so on. For this reason, I propose to have a closer look at this step.

Conceptualization of emulation

Since our first contribution, we have considered the emulation as a design step in the design process. The idea was firstly presented at the ICED conference 2007(Rasoulifar et al., 2007). In the same paper, we identified the user validation step as a necessary step for both engineering and clinical progress in design of the surgical instruments. Here, I explain how the emulation step is an adequate user validation situation.

The *raison d'être* of emulation is to help the designers to validate their design ideas and concepts by their user, in the situation that they could not play the user's role. Thus, I define the emulation in design process as the situation in which the user evaluate a physical prototype through the manipulation under usage conditions. Therefore, the emulation step in design process is where the confrontation takes place between known/unknown needs, and proposed technical solution.

Accordingly, organizing an emulation is possible when a prototype (simple or advanced) is fabricated to be tested and evaluated by the user, under a usage scenario. What happens during an emulation is the knowledge exchange between the engineer and the user concerning the instrument and the usage. Although the knowledge is tacit and there is no access to it, there are some representing objects for tracing this exchange. For example the question/answer between the actors is a traceable object through observation and capture. Moreover, modifications of prototype or usage scenario between two emulations indicate the changes according to the previous agreement.

I conceptualize the emulation with these factors: identification, objective, actors, entry, body, and output. These factors are adapted from Moment theory in participatory design (Caelen et al., 2005). The detail list with an example is shown in Table 5.1.

Table 5.1: Conceptualization of emulation

Identification	**Example**
Number	3
Date	13/06/2007
Place	Grenoble hospital
Objective	Proof of concept
Actors	Dr. Vouaillat, Dr. Tonetti, G. Thomann, A. Didinato, F. Villeneuve, R.Rasoulifar, B. Meillon
Entry	Second Protige prototype, operation scenario
Body	Evaluation through manipulation of the prototype following the scenario
Output	Capture of observation, notes, documents

With this definition, the emulation became the connecting step for design development. Since the design artifact subsumes both product and usage, the emulation step is the moment in which designer and user evaluate both product and usage. Figure 5.2 shows a schematic of emulation and component. Emulation is a repeatable step, until reaching the final objectives of instrument and usage.

Emulation should be followed by a debriefing or review meeting, in which designer and user could communicate about their evaluation and make decision for the next development. Our experience showed this meeting can happen during and right after the emulation, when a general agreement exists and some development is needed before any new decision and meeting. Finally emulation is a repeatable step, until reaching the final objectives of instrument and usage. The analyses of the Protige project showed some sort of evolution exists in emulations during the project. I think this evolution is coming from the nature of collaborative design and would not be limited to our project. Nonetheless, being aware of this characteristic helps the designer to better organize the emulation steps. I come back to this subject in section 5.3.1 by the concept of Extended Scenario.

Therefore, I can go through the description of the design process, and propose my

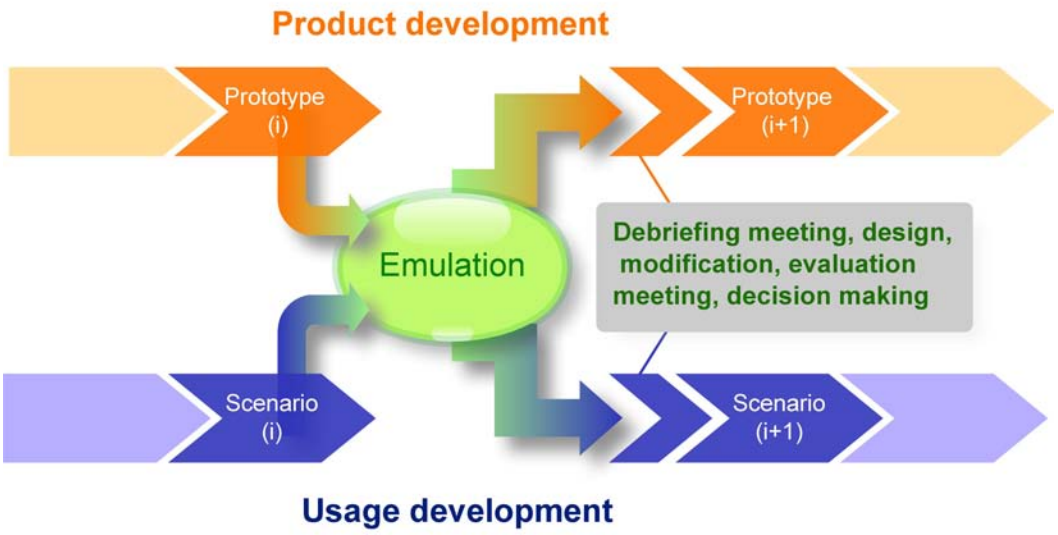


Figure 5.2: Emulation step in the coevolutive design process

descriptive model of design process. Previous studies (e.g. Cross in section 2.2.4) described the design process in this way: the problem divides into sub-problems and sub-problems find sub-solutions, and then the convergence of the sub-solutions creates the final solution. However, the problem in the context on my work has two series of components: product (engineering), and usage (surgery). In result, the design problem here does not follow the conventional approach of proposing technical alternatives for a given task list. In addition, the usage, which is the reference for defining the tasks and functions is not, and can not be clearly given in the beginning of the project.

In my description of design, by the progression of the project the problem divides into sub-problems. These sub-problems have technical, usage or both properties, which create three categories: pure technical problems, pure usage problems, and instrument-usage problems. Solving the pure technical problems is the responsibility of the engineers. There are many studies on how designers design, some of them are explained in the second chapter. Solving pure usage problems is the responsibility of surgeons. In chapter 1, I discussed briefly how surgeons "design" new technique for new operation. Finally, solving the instrument-usage problem is the responsibility of both engineer and surgeon, but mainly the job of the designer. Thus, the designer should have an adequate understanding of the design process and also vision on the whole project to be able to solve these problems. Figure 5.3 shows this description in schematic presentation.

As the figure proposes, from the beginning the problem has both technical and usage components, and theses dual characteristic remains in the sub-problems. Then, in the collaborative space of product and usage coevolution, engineer and user produce technical

Figure 5.3: Progression from problem to sub-problems, design evolution in technical and usage components which produce sub-solutions, and progression from sub-solutions to solution

and usage solution which are in strong interaction through the emulation. Finally sub-solutions progress to the final solution, which still has both components. To give an example, look at the problem we dealt with during the Protige project. From the beginning, to be able to perform a MIS procedure (problem - usage), we are looking for an instrument with certain functionality (problem - technical). Scenario helped us to divide the usage problem to tasks (subproblem - usage), and accordingly the technical problem divided to different functions of the instrument (subproblem - technical). The design process provides the technical sub-solutions for the usage scenario, and the tasks of scenario evolved in order to propose usage sub-solutions, both in interaction through some emulations. In final, the Protige and the operation procedure together formed to final solution.

In the following, I would like to bring the discussion to the role of the user, and look at the design process from user-centered point of view.

5.2.2 Proposition of expert-user integration

The analyses of the Protige experiment showed the importance of the surgeon integration in the project, particularly for design evaluation in meetings and in emulations. I may remind from the chapter 2 section 2.5 that the primary design process of the Protige project had some inspiration from UCD methods. Although the UCD processes have more descriptive nature like “how it is” than prescriptive nature like “what to do”, they provide a good basic structure for the design development. In this section, I propose an evolution of the UCD model, that enables me to obtain a modified model for user integration, I called Expert-UCD. This idea was presented in the TMCE 2008 conference, and was pre-selected for journal publication (Rasoulifar et al., 2008c).

The main reason to go from a UCD model to Expert-UCD model is the difference made by dealing with expertise of user and the consequence of designing a product for non-ordinary usage. I discussed this subject in section 2.3.1. In brief, the designer has three challenges in this context:

First, the usage is not completely known to the designer, thus a description of usage is

needed, generally called scenario. This scenario can not be prepared by the designer lonely, and need the participation of the expert user and validation from him.

Second, designer can not put himself in the place of the expert user to evaluate whether or not the designed product satisfies the requirements (otherwise than design of ordinary usage product). In fact, the designed solution needs to be evaluated by the expert user, and in the usage situation.

Third, the usage is a part of the problem and through the solution. Thus, the expert user's participation is needed not only for the requirement definition, but also for making detail design decisions and technical choices.

Moreover in the UCD model, the user is not considered as a design collaborator, which seems very important in my research context. Collaborative design implies the collaboration of distinct individuals with different areas of expertise or knowledge to work towards the accomplishment of common goals, simultaneously or chronologically, and co-locationally or remotely. Accepting this insight of collaboration, we have considered the expert user as a collaborator in the whole or some main steps of the design process.

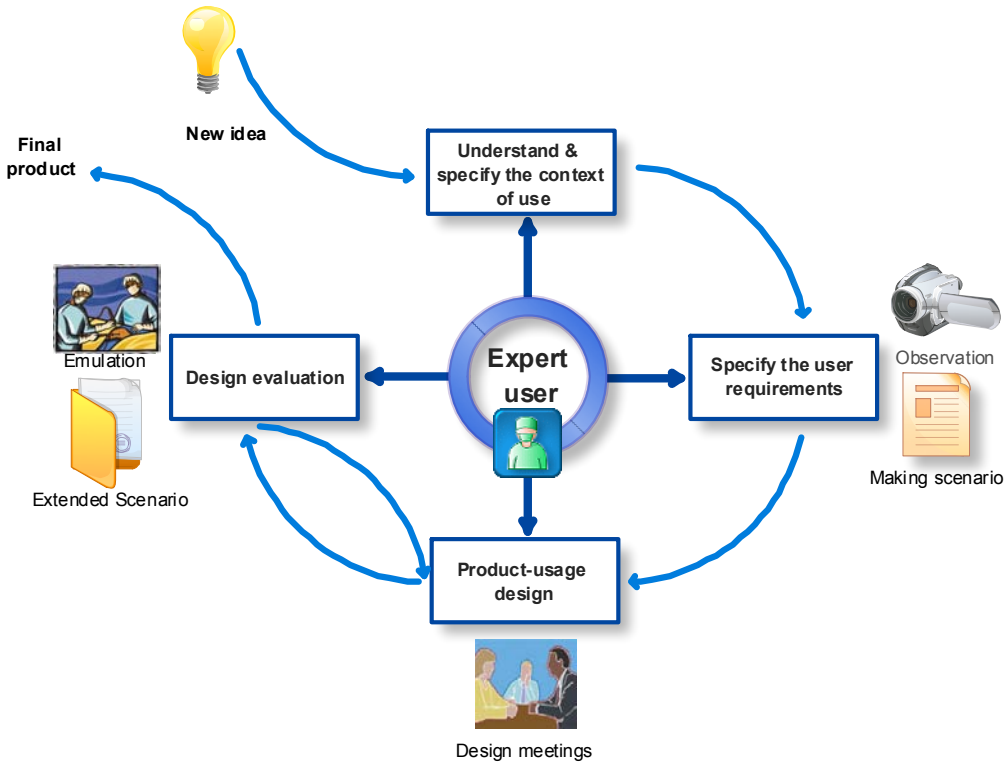


Figure 5.4: Expert user-centered design model

As a result, I propose a modified model for user integration, putting effort on the expert user. This model is shown in Figure 5.4, and the details are explained as follows. The model starts with a new idea and an interest to start the design project. This is were we enter

the process. The first step, understand and specify the context of use is almost the same as what proposed in the UCD. In this step designers meet expert user and discuss about the problem and make the first shared understanding about the goal of the design process.

Specify the user requirements The purpose of this step is to specify the usage and the usage environment. The usage is defined in form of the task description, how the user should use the design artifact to achieve the goals is determined from the previous step. This design phase is where the usage of user is defined. The scenario of use is created here to make the proper relation between the user and the design artifact. The scenario not only explains the usage procedure, but also provides the adequate information about the usage situation and environment. This design phase realized generally by the discussion between the designer and the user, but in specific context it needs using the intermediates of explanation, like a simulator (physical or virtual). For instance, in case of a surgical instruments design, a phantom is always needed in order to clarify the discussion between the user and the designer. The outcome of this step is a written report, a scenario, which explains the usage, the environment, and the interaction of the design artifact with other instruments.

Product-usage design The purpose of this step is to produce a coupled design artifact; product and usage. Here, the usage is basically the scenario from the previous step, but the modification and the details concerning the product proposition should be added. These details include the user interface, user documentation, user support, and user training. Many knowledge exchange took place in other steps, in parallel to development of the product-usage, the engineering and technical solutions confront the usage constraints. The organization of this step includes a collaborative session, the separate solution development in technical and usage aspects, and the prototype development. Supportive tools are needed to facilitate the collaboration, such as CAD software, elements of usage situation, etc. The outcome of this step is the prototype of the solution, and the usage procedure which should be provided in parallel. This step and the next step are iterative. The designed artifact would be evaluated and the result would come back for necessary modifications.

Design evaluation The main purpose of this step is to evaluate the designed product-usage in a real situation. This step addresses the evaluation of the usability by the expert user's performance. The term emulation here is to put emphasis on the physical real element of the situation. The emulation needs a setup. The new term Extended Scenario (ES) here is a tool to help preparing the emulation. Extended Scenario (ES) is explained later in section 5.3.1. As an example, one of the elements of the ES is setting up the video recording (video capture of emulation is very useful, in order to remind the discussion, critics, new solutions and whatever happened during the session). The outcomes of this step are the evaluation results, in form of notes, documents and mainly the recordings. As figure 5.4 shows, the results of evaluation would return the design activities to the previous step to redesign or modify the solutions.

This model makes clear the integration challenge of the expert user integration. Product design needs the usage design, which is not the entry of the procedure. The challenge of

design specialist in this case is to provide an organization to understand, clarify and evaluate the usage of expert user parallel to the product design progression. As widely recognized, this is a true challenge in many cases. This model has been proposed based on my main experience, the Protige project, and is valid to explain other project demarche, such as those I observed at Delft University.

To conclude this section, it has been discussed that the scenario could help the medical and healthcare designers to integrate the professional user needs into the design step. The user integration in the design process has been introduced to the design studies by different approaches. The user-centered design models and methodologies led us to infer that the design activities should understand the user's needs and evaluate the design solutions against the user requirements. This study, however, proposes a more essential and collaborative role for a certain group of users, called expert users. The investigation of surgeons, as a role model of an expert, showed that the presence and integration of these users in the design progression is not inconsiderable. In this way, the next step is to build a prescriptive model which can help the designers to pursue the expert user needs and their usage specifications. In the next section I explain my prescriptive model of the design process.

5.3 Proposition for a prescriptive model

Designers can use any design method for their design process. This include the designer of surgical instruments as well. Here, I propose a prescriptive model for designing innovative surgical instruments, that takes into account the specific aspects of the design process I have explained in the previous section. The complexity of design in this field, and also the coevolution of the product and the usage often appear to be diverting progress from the central task of designing. Nonetheless, this is the importance of using a method for design. A qualified method proposes the strategies and moves on the way in which the problem is being under taken.

In this dissertation, for planning and running the Protige project, I proposed a process model, which has been inspired from the various proposition of the literature in design (see Figure 2.12). The application of the method in a real case of design was the opportunity to understand more about the design steps and strategies. Taking into account the reflection for the case application, I propose an evolved model for the design process, from the preliminary model (see section 3.5.1). Before going to the detail of the new model, I propose to discuss the role of scenario and scenario-based approach, presented as follows.

5.3.1 Extended Scenario-based approach

Can the design projects like Protige be considered as a scenario-based design? And, in case of positive answer, can we generalize the experiment and imagine a scenario-based approach for design in the domain of the surgical innovation?

Historically, medical engineers tried to bring new technical solutions to the medical applications. Design and development of the new healthcare devices needs the participation of the health agents, from the innovation phase at the beginning to the medical validation at the end. Scenario has been introduced as a designer tool, to demonstrate the usage, task analysis, and communication inside the design team and with users. (see the literature review on scenario and scenario-based design in chapter 2, section 2.3.1).

The Protige experience showed other aspects of using of a scenario for the design process, in the particular context of the surgical instruments. In the project, by creating the scenarios, the designer formalized the desired usage tasks, and also initiated the preparation for the evaluation step in a proper way. A scenario describes the required actions for the artifact in use. It describes the usage situation, which is important for the user's activities. However, the experience showed that a scenario is dependent on the functionality of the prototype, and the emulation situation (for example the OR facilities). Moreover, according to the scenario, the observation and capture setup may need changes.

Consequently, I came up with the proposition of using an improved concept from the scenario, and use it in order to proceed in the design process. I called this document an Extended Scenario (ES). Here is the definition: An ES is a document (paper or informatic) that provides the explanation on four subjects:

1. Scenario of usage (operative protocol)
2. Main functions of the future product, that are realized in the present prototype
3. Emulation situation: tools and facilities
4. Observation setup

Table 5.2 shows an example of an ES in the context of design of a new surgical instrument. In this example, a new instrument is needed to perform a new operation, in order to transform an open surgery to MIS.

In the design of a medical device, the surgeon-designer cooperation is the most important issue. Basically, a scenario is a tool to improve the communication and to facilitate the decision-making. Considering that, in the context of the innovative surgical instruments, the usage (operation techniques) is a part of the design artifact and starts from an idea and evolves step by step vis-à-vis the prototype, ES as a report shows what the prototype was supposed to have and what the user is supposed to do. As a result by using ES, the designers can trace the evolution of the prototype and the usage.

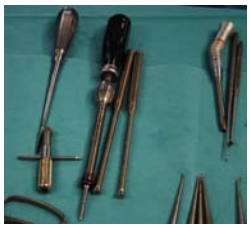
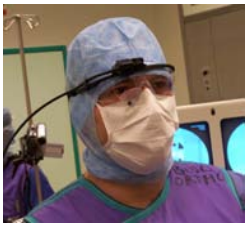
Finally, some advantages of the ES-driven approach for user-centered medical application are:

- Data accumulation of the progression of the prototype-usage
- User participation and integration in the design process

- Analysis of the decision-making based on the tasks and the criteria
- Organization and facilitating the communication

To sum up, ES-based approach supports a fluid exchange of reasoning between the prototype functions and the usage implementation, so that the user know-how can inspire the new product and the new product can extend the expert user manipulation. Our research focused on the surgical instruments in which the user is professional or expert and the design artifact is a combination of instrument and usage (operation). Nonetheless, the discussion is valuable for other medical devices and systems in which the user validation passes through the physical evaluation (having a prototype of the product) in the usage situation.

Table 5.2: An example of an ES from the Protige experiment

Scenario (operation procedure)		**Instrument prototype**	
Identifying the fractured vertebra *Incision (1-2 cm)* *Insertion tubular retractor* *Position screw* *Incision (0.5 cm)* *Insertion rod by rod holder* *Fix the rod in screws head* *Release the rod holder*		*Receive the rod (swerving mechanism)* *Hold the rod during insertion* *Release the rod* ***Evaluation criteria*** *Ergonomic of the handle* *Weight of the prototype* *Size of rod housing part* *Feasibility of manipulation in presence of tubular retractor*	
Emulation situation		**Observation**	
Operating room at hospital *C-arm radiography* *Phantom: spine model with a fracture on L1, positioned in a box, filled by synthetic plastic granules, covered by artificial tissue*		*A general camcorder on operation site* *A frontal camcorder on surgeon's head, capturing where he looks* *Sound recorder*	

5.3.2 Design process model for surgical instruments design

In view of the central responsibility of designers for the technical and economic properties of a product, it is important to have a defined design procedure that finds good solutions, in the particular nature of surgical instruments design. This procedure should be flexible and at the same time be capable of being planned, optimized and verified. It includes intermediate objects that link working steps and design phases according to the content

and organization. It also includes strategies, rules and principles to achieve general and specific goals as well as methods to solve individual design problems and usage tasks.

Engineering design methods - commonly regarded as rational methods - encourage a systematic approach to design. In the literature review on design methods and prescriptive processes in chapter 2, I tried to demonstrate the existing works, and also to picture what theoretical bases are needed to describe and prescribe a design process. Nevertheless, these methods often have similar aims to the technical design, such as creating a function list based on requirement list and producing alternative solutions to satisfy functions and constrains.

On the other hand, user-centered and participatory methods, reviewed in chapter 2 (section 2.3.1) often have similar aims to bold the user anticipation approach such as widening the requirement definition to users and facilitating teamwork and participation in decision making. So it is not necessarily true that user-centered methods are always applicable methods for product design or technical product design.

Many engineering designers are suspicious of user-centered methods, fearing that they are superficial, or that they do not lead to a CAD model and a functional prototype. This is a misunderstanding of the intentions of systematic design which is meant to guide the whole design process from the idea to the end. User-centered methods and participatory methods are complementary aspects of systematic approach to design. Rather than some superficial techniques of team working, they should be bridges, helping the designer to overpass the gap between technical world and user world.

In this way, a design methodology in our context should therefore foster and guide the abilities of designers and surgeons, encourage creativity and collaboration, and at the same time drive home the need for objective evaluation of the results. Only in this way it is possible to raise the innovative design in which a new technical solution helps the surgeons performing a new surgical operation.

I propose a design process model including the aspects I explained in the descriptive design model section (section 5.2). This model contains the most relevant and applicable methods, covering the whole design process starting after the definition of the project and rising up to the clinical validation, the obligatory passage before beginning the production. Figure 5.5 shows the schematic of this process model. For each main step there is a title, the explanation of the aim, the procedure and tools and techniques for performing the procedure, which are explained as follows.

As Figure 5.5 shows, the six steps of design process are classified in three main phases. The reason of making phases is coming from managerial issues of design project. In one hand, there are many iterations between design steps that help the enrichment of the data. On the other hand, progression in the projects requires the clarified input and output and defined decision points. For instance, in the proposed design process the two steps of clarifying design objectives and defining clinical problem are two steps that could be completed in parallel and with iteration. But, there should be an exit point from this phase

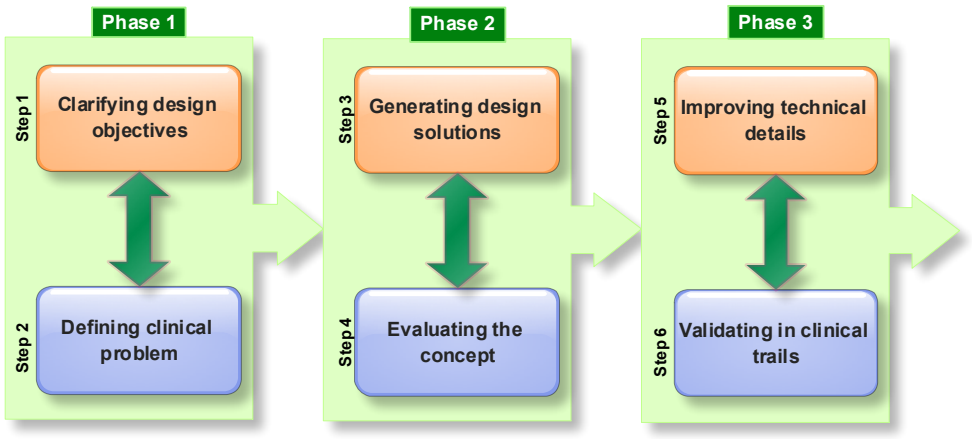


Figure 5.5: Six steps of the design process positioned in three phases

to go forward for the next phase. This passage is essential in project management, and usually is characterized with the deadline and certain documents. In the following I explain the phases and their internal steps.

5.3.2.1 Phase one: Understanding and identification of problem

This phase starts by the beginning of the project. The main guideline for the two steps of this phase is that the designer should be able to establish the communication with surgeons and should have good understanding of the clinical problem and clinical situations. OR observation is the key approach. At the end of this phase, design should come up with a clear definition of problem in terms of requirement list and usage scenario. Procedures of these two steps are explained as follows.

Step 1: Clarifying design objectives The aim of this step is to clarify design objectives in terms of new product and new usage, and sub-objectives in both terms.

Procedure:

- Expressing the overall usage protocol in terms of successive steps
- Breaking down the steps into a set of tasks
- Setting requirements list according to the task list
- Establishing functions (functional analysis/FBS/...)
- Breaking down to sub-function to correspond the tasks
- Drawing the system boundary to have the functional limits, according to the clinical limits and constrains

Output:

- Requirement list
- System limitation

Step 2: Defining the clinical problem The aim of this step is to define the clinical problem, the objective of expert user for new usage and new product

Procedure:

- Definition of the current situation of operation/intervention/ cure : protocol
- Clarifying the clinical problem
- Identifying the interactions with other devices and instruments during the protocol
- Listing clinical limits and constraints
- Formulating the desired usage protocol

Output: scenario of the desired use

As one can find out, the procedures in these two steps show that it is not possible to take over the first step and then go to the second. The design activity has a zigzag manner between clarifying objectives and defining clinical problem. The internal organization in this phase depends on the problem nature, project management and timing, and many other non-design issues. Observation of the clinical situation is suggested for a better understanding of the problem situation. Figure 5.6 demonstrates this phase in details.

5.3.2.2 Phase two: Conceptual design

The second phase of the design process is where the innovation happens, new solutions would be found for solving the problem which was identified and characterized in the previous phase. The solution involves both the instrument and the usage procedure. The design progresses in parallel to technical and clinical steps. Procedures are explained below:

Step 3: Generating design solutions The aim of this step is to generate alternatives solutions.

Procedure:

- Generate idea and solutions
- Select the best alternative(s)
- Evaluate against limitations

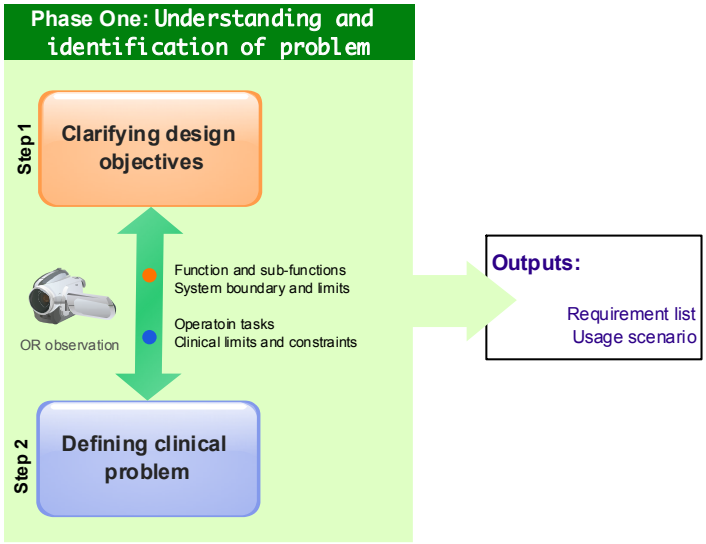


Figure 5.6: Phase one of the design process: understanding and identification of problem

- Prepare preliminary communication with user
- Prepare functional prototype
- Improve/modify the functions according to user evaluation

Output: Functional prototype

Step 4: Evaluating the concept The aim of this step is to evaluate the design by the user, in an emulation.

Procedure:

- Prepare the phantom or mannequin for the emulation
- Prepare the emulation situation (OR) use of scenario
- Emulate with the expert user
- Improve/modify the usage scenario

Output: Operation protocol

These two steps include the famous "make and evaluate" loop of the design process. There should be as necessary iteration as the surgeon confirms the concept. However, using certain techniques may help to optimize the design activity. The use of ES as a tool helps the designer to manage and organize the emulation. ES provides also a tracking base for

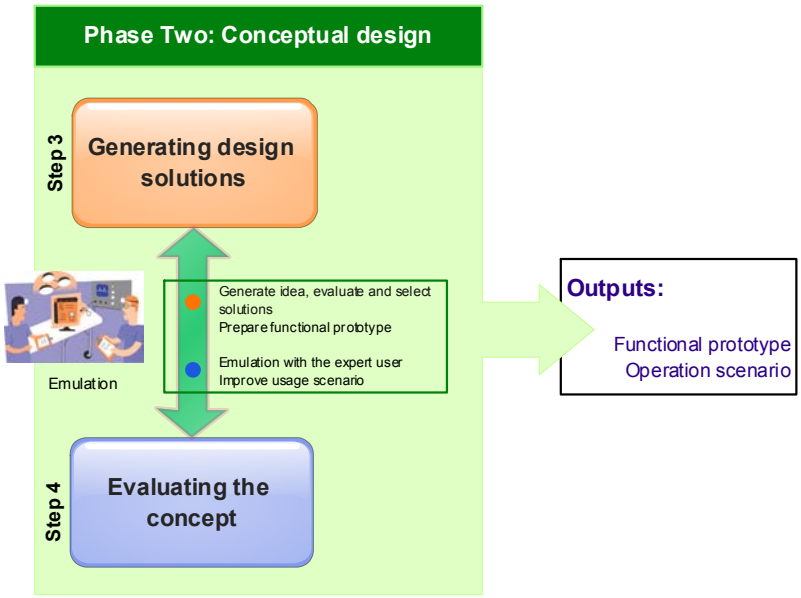


Figure 5.7: Phase two of the design process: conceptual design

different versions of prototype and usage scenario. Depending on the project, one or some prototypes will be prepared. It is suggested not to limit the design to the technical and functional issues. The choice of material and considering the ergonomic issues have a non negligible effect on the acceptability of the new instrument from the expert users. The observation of emulations helps further review and analysis. It is obvious that surgeons are very busy persons, and accessing the OR is not always easy, so the emulation should be optimized. Figure 5.7 illustrates the details of phase two.

For the last point, at the end of this phase the design is supposed to be matured enough and the solution is supposed to be found. Therefore it is the best time for starting the patent process. Nowadays patents of surgical instruments involve both new technical innovations and operative innovations. Following the proposed model, it offers the opportunity to document the emulations and provide enough data on the procedures as well as on the instrument.

5.3.2.3 Phase three: detail design and clinical validation

This phase is the last design phase, before starting the production. Having the results of the last steps, in this phase the engineering design of the instrument finalize the details and end-up with the prototype(s) which can be clinically authorized and can be used for clinical validation. On the other hand, in this phase surgeons establish an operative scenario, called operative protocol which is the precise and detailed operation tasks and techniques. Clinical

validation itself has an important and complex job description. The number of operation, variety of surgeons, variety of patients and many other issues should be defined. Once this study is designed, it may take several months (even years) to report the clinical validation.

Step 5: Improving technical details The aim of this step is to develop a fully defined product design from a clear set of requirements while creating deliverables and documentation appropriate for product manufacturing.

Procedure:

- List the product component and functions
- Identify function-component relation
- Review evaluations and select improvements
- Create detail CAD model
- Apply clinical standards and limitations
- Prepare the prototype plan for fine fabrication
- Search for the ways of cost reduction
- Consider the production guidelines

Output: Clinically authorized advanced prototype

Step 6: Validating in clinical trials The aim of this step is to compile and to evaluate the final solution through clinical examination.

Procedure:

- Design the clinical study
- Establish Statistical hypothesis
- Define Statistical method(s) and sample size
- Prepare detailed description of the protocol (e.g. refer to "NCCLS Document from FDA)
- Prepare ethical issues and hospital authorization
- Use the new instrument in the controlled situation
- Report problems/difficulties by sample cases be used for design improvement

Output: clinical validation report

Figure 5.7 illustrates phase three in detail.

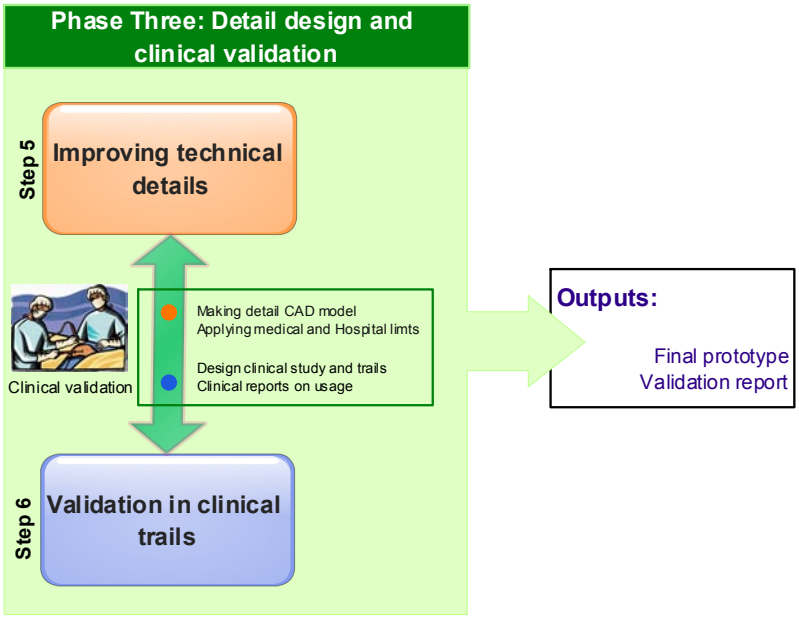


Figure 5.8: Phase three of the design process: detail design and clinical validation

If one considers the clinical evaluation as a pure medical step, there would be no place for feedback of surgeon on the design of the instruments. This model however proposes not to eliminate this feedback, and by using the ES trace the clinical validation and provide information for final design refinement before the production planning. The reason is naturally once the surgeons use the instrument in the real usage situation (surgical operation on the patient) they probably modify and upgrade their usage techniques. These modifications may have effects on design and necessitate final refinements.

The other point is any medical device including surgical devices and instruments need a certificate from international organizations such Food & Drug Administration (FDA) and International Organization for Standardization (ISO). Therefore, it is highly recommended for the designers or project managers to be aware of the official procedure for standardization and design the clinical study accordingly.

Finally, I would like to come back to the coevolutive description of the design process (section 5.2.1), and try to put together both descriptive and prescriptive propositions. From the descriptive point of view we discussed the coevolution of product and usage during the project progression. The prescriptive design process model proposes the steps and tasks to move forward from the idea to the final solution. Although in this model the evolution of the design artifact is considered, by recalling the double product usage characteristic a better understanding can be acquired. I put together both coevolutive description and process model in Figure 5.9. This figure shows how the prototype as a representation of product, and scenario as a representation of usage coevolve, behind the successive steps of

the design process.

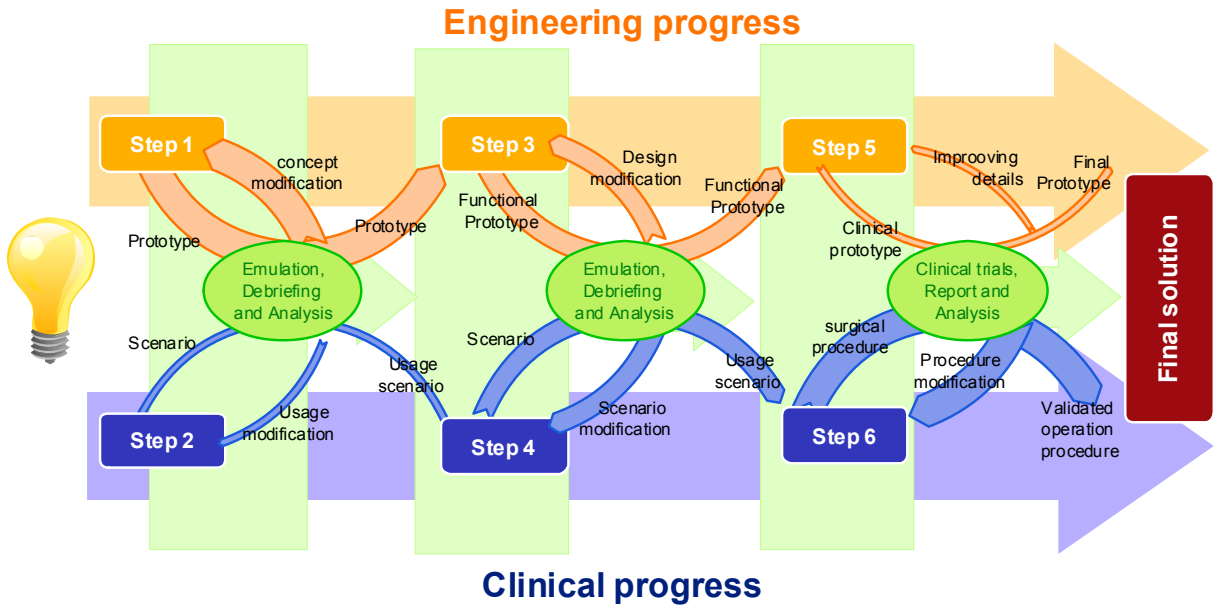


Figure 5.9: Coevolutive design process model for surgical instruments

Some issues in this model need to be pointed out:

1. In the beginning of the design, in the first phase the designer tries to understand the usage and to generate ideas. The collaborative space including emulation, debriefing meeting, and analyses help to find the best concept for the solution. At this level, the feedbacks are more on the technical issues and not the scenario. But, as the design progresses, the emulation and the following meeting and analysis include more feedback on the usage and thus scenario modification. My analyses of the emulations during the Protige project confirms this proposition (see 4.4.2.1). In phase three, during the clinical trials there is a few design modification for the technical issues and on the contrary much feedback and modification on the usage to validate the best usage procedure.

2. Steps 1, 3 and 5 are where the most engineering tasks are situated. Similarly most clinical tasks are situated in the steps 2, 4 and 6. However, as the details of each step contains different tasks and many iteration exist between two steps in a phase. In Figure 5.9 these iterations and main input and output of each step is shown. The coevolution arrows schematically pass through the odd and even steps, where a prototype or scenario is presenting the design progression.

To conclude, the proposed model takes a step forward to the describing the design process and also to formalize the design activity and collaboration, in order to provide a help for the designer in the field of surgical instruments. The particularity of this proposition

is considering the expert user, surgeon, as a principal actor in the design process, not only for the requirement definition but also in detail design decisions. Since the design process model is made for designers and engineers, the expert user integration happens through the collaborative task and situations (e.g. emulation). Moreover, this model considers the coevolution of product and usage during the design, and provides the organization which allows such coevolution take place in an efficient way. In the following section, the validation challenge of the proposed model is discussed.

5.4 Validation: Case study application

The validation of design methods and models is a bizarre work. On one hand a general model of actions such as design process can never been considered as "validated" in the same manner of validation of a physical equation, or an algorithm in informatic. Design is a social activity and just from this point any design process differs from the other in application. On the other hand, the experimental effort can be made to examine whether or not a process method is suitable for guiding the activities needed for a project. In this case, even various positive feedbacks on using a method for design do not conclude the validation of the method. However, it seems there is no better way to model validation. Searching in design literature for validation of methods (not methods for design validation), I figured out the number of the studies is very few. For example I found two studies that investigated the methods validation: methodology validation by application in industry (Rzevski et al., 1980), and validation using the methods in hospitals (Jalote-Parmar and Badke-Schaub, 2008). Although it is rare but not impossible to show the design method efficiency by making comparison between the quantitative parameters (product life cycle time, total cost of project, etc.) before and after method application, but in most of the case studies are limited to the positive feedbacks from the users.

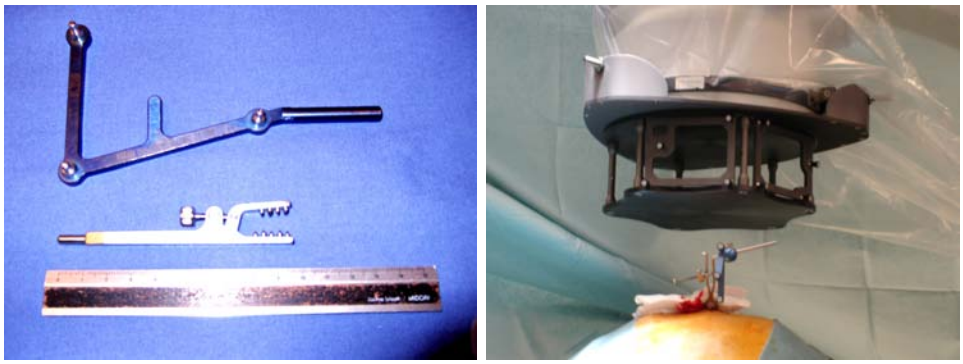
For the design process model that I have proposed, it could have been very useful to have the opportunity to apply the method in a surgical instruments enterprise and extract the quantitative results to examine the efficiency of the method. However, it was almost impossible to do such a work, because of the lack of the time in three years of a PhD (in France), and also the complexity of going to such a confidential and competitive industry.

Nonetheless, I had the opportunity to apply this model to another project of surgical instrument design. In following section I first explain the design project and objective (section 5.4.1), and then present the project progression under the process model.

5.4.1 SpineRef: a system for fixing Rigid Body in spine surgery

Rigid Body is an essential instrument to realize surgical operations In fluoronavigation. A Rigid Body and it's fixation grip is shown in Figure 5.10(a). The spine intervention of this project requires the installation of the Rigid Body related to the spinal column of

the patient. This typical MIS intervention is done without direct visibility of the surgeon to the vertebra. A virtual environment is created to visualize the tools in a radiological representation of the vertebra on a screen. The Rigid Body is optically localized in space by infra-red camcorders. Placed on the vertebra, the Rigid Body is connected to the reference frame of the radiological image generator, the gauged tools used by the surgeon. It must stay in place during all the intervention to preserve a precision of displacements of the tools in the representation of the vertebra visualized on a screen. The stability of the fixing of this Rigid Body to the vertebra is fundamental for the precision of the system. Figure 5.10(b) shows the usage of Rigid Body in the current operation.



(a) Rigid Body and the fixation grip

(b) Fluoronavigation procedure using the Rigid Body

Figure 5.10: Fluoronavigation using Rigid Body

Because of this typical MIS intervention, the system for fixing the Rigid Body must fix itself at the bones of the vertebrae in a percutaneous way, through the skin. This device mustn't disturb the movements of surgical instruments. It has to be radio transparency not to obstruct the realization of the fluoroscopic photos and sterile answering the standards anti prion.

Currently, this fixing system is inserted into the thorny process of the vertebra using a small grip with teeth (see Figure 5.10(a)). Although the fluoronavigation procedure is meant to be minimally invasive, nothing but insertion of the Rigid Body need a not so small incision. The innovation of this invention includes first to fix the Rigid Body in a percutaneous way, that is to say without incision, which already decreases the traumatism of the patient. Second, to extend the osseous catches on several adjacent thorny processes, in order to increase the stability of fixation.

5.4.2 Project progression

I demonstrated the three steps of the project progression of SpineRef in Figure 5.14, following the prescriptive model explained in the previous section. In the following, I review

each step separately and in more detail.

In the first phase, the designer team was supposed to prepare a requirements list and a usage scenario through a series of meetings, observation, etc.

In order to define the clinical problem, a meeting with the surgeon held on 03/10/2008. Having pre-defined the problem, the team prepared for an observation in the OR took place on 28/10/2008, in the hospital of Grenoble. Through this observation the designers observed the operation and gathered information on the surgical instruments and devices needed for the surgery. The desired system should receive the Rigid-Body, so the information gathered about this instrument by contacting the manufacturer.

The requirement list was prepared during design meeting, using methods such as functional analysis. The usage scenario was prepared and confirmed by the surgeon. Figure 5.11 shows a photo of OR observation with surgeon using the Rigid Body. This step ends with the requirement list and the usage scenario. For more detail of the functional analysis and the requirement list of SpineRef see Appendix 5. A simple prototype was prepared and the end of this step, shown in Figure 5.12(a).

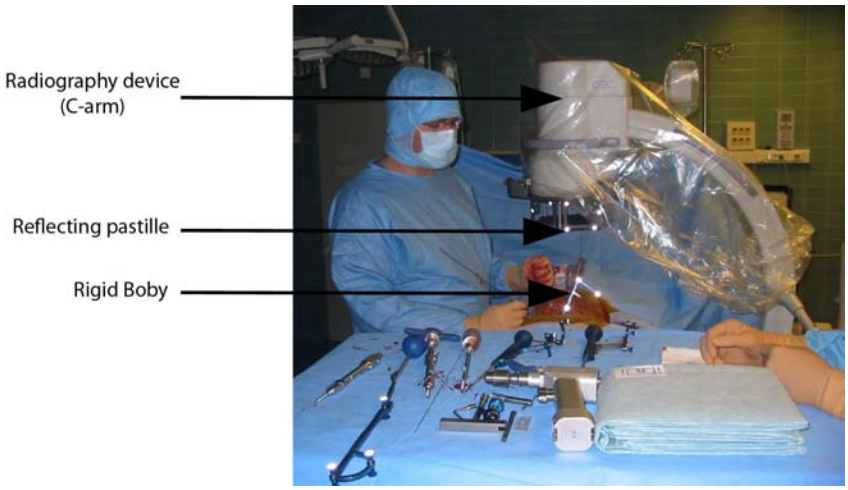
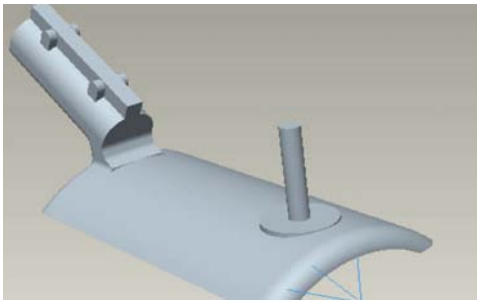


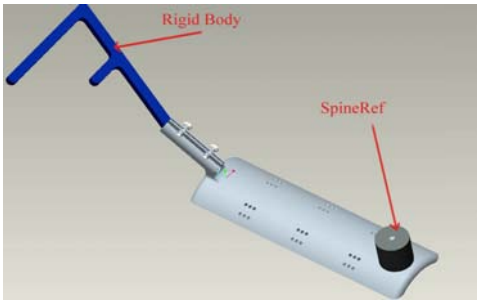
Figure 5.11: Observation in the OR

In the second phase, the design group worked on various ideas and developed some to find the possible solution. They also had many discussion with the surgeon. Finally they came up with a selected solution that seemed to serve the functions required by the requirement list. The next step was to evaluate the concept of the solution with the surgeon. For this reason a functional prototype was made to be shown to the surgeon. Accordingly, after some discussion and idea exchange the design was modified and became ready to be used in an emulation. The emulation took place on 15/12/2008 and many important comments and precisions came from the surgeon, that let the design advance. Figure 5.12 shows the first prototype, and the alternative solutions in form of CAD models.

(a) First prototype made by the students



(b) 3D model of a primary solution



(c) Rigid Body assembled in the SpineRef

Figure 5.12: SpineRef Prototypes and alternative solutions

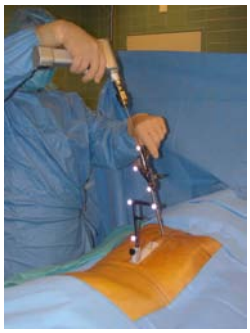
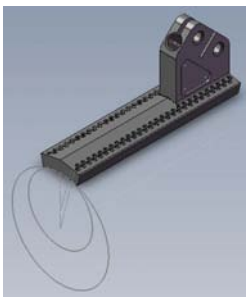
Preparing and organizing an emulation need many attentions, particularly for the first time. ES tool has been proposed to help engineer preparing and managing the emulation steps. For the SpineRef project the ES has been used, and was going to be used until the end of the project. An example of ES is shown in Table 5.3.

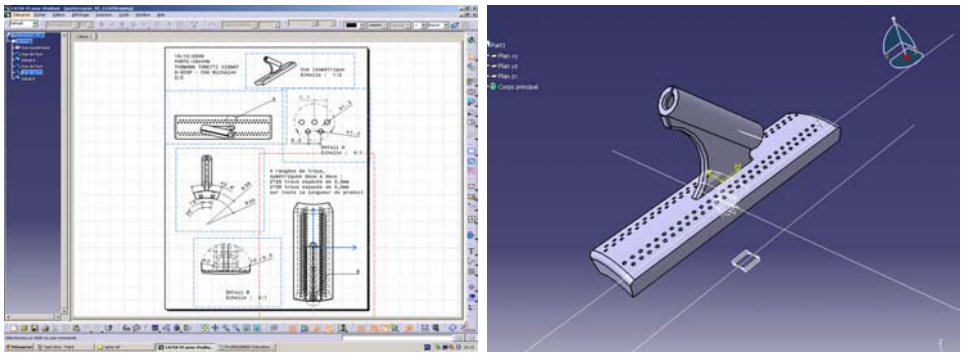
In the third phase, the team worked on the details of the design. The modification was made and a detail 3D CAD model was prepared for advanced mechanical analysis of deformation. The model also served for a fine prototype production that could be used for clinical validation. In this step the properties of the instrument were finalized by the team, such as exact dimensions, final cost, etc. The final solution is shown in Figure 5.13. In this step the design was matured enough, and was positively evaluated from the clinical partner. Accordingly the patenting process of SpineRef was started and succeeded in a short time. For the patent information please see (Tonetti et al., 2009b).

Because the instrument is designed as single use, a series of 20 prototypes was fabricated for the clinical validation. It was also needed to provide the sterilization procedure together with the usage scenario. The clinical validation process started in February 2009 and is in progress at the moment of writing of this dissertation.

In conclusion, the usage of the proposed design method has positive reflection from the design team and also from the surgeons. As a matter of fact, the SpineRef project was established in the same organization as the Protige project, though the clinical partner

Table 5.3: An example of an ES from the SpineRef project

Scenario (operation procedure)	Instrument prototype
Locate the fractured vertebra *Place the SpineRef on the back on the patient* *Fix the SpinRef by insertion of Kirshner pin into spinous process (4 times)* *Insert Rigid Body into SpineRef* *Fix Rigid Body inside by turning the handwheel* 	*Be positioned comfortably on the back* *Be fixed by passing the Kirshner pins* *Receive the Rigid Body* *Fix and Hold the Rigid Body during the operation* *Release the Rigid Body* ***Evaluation criteria*** *Ergonomy of the SpineRef* *Biocompatibility of material* *Size, number, and the orientation of small holes* 
Emulation situation	**Observation**
Operating room at hospital *Fluoronavigation system* *Operation on patient*	*A general camcorder on operation site* *Sound recorder* *The X-ray imaging record of the mail device*



(a) (b)

Figure 5.13: SpineRef detailed CAD model of final solution

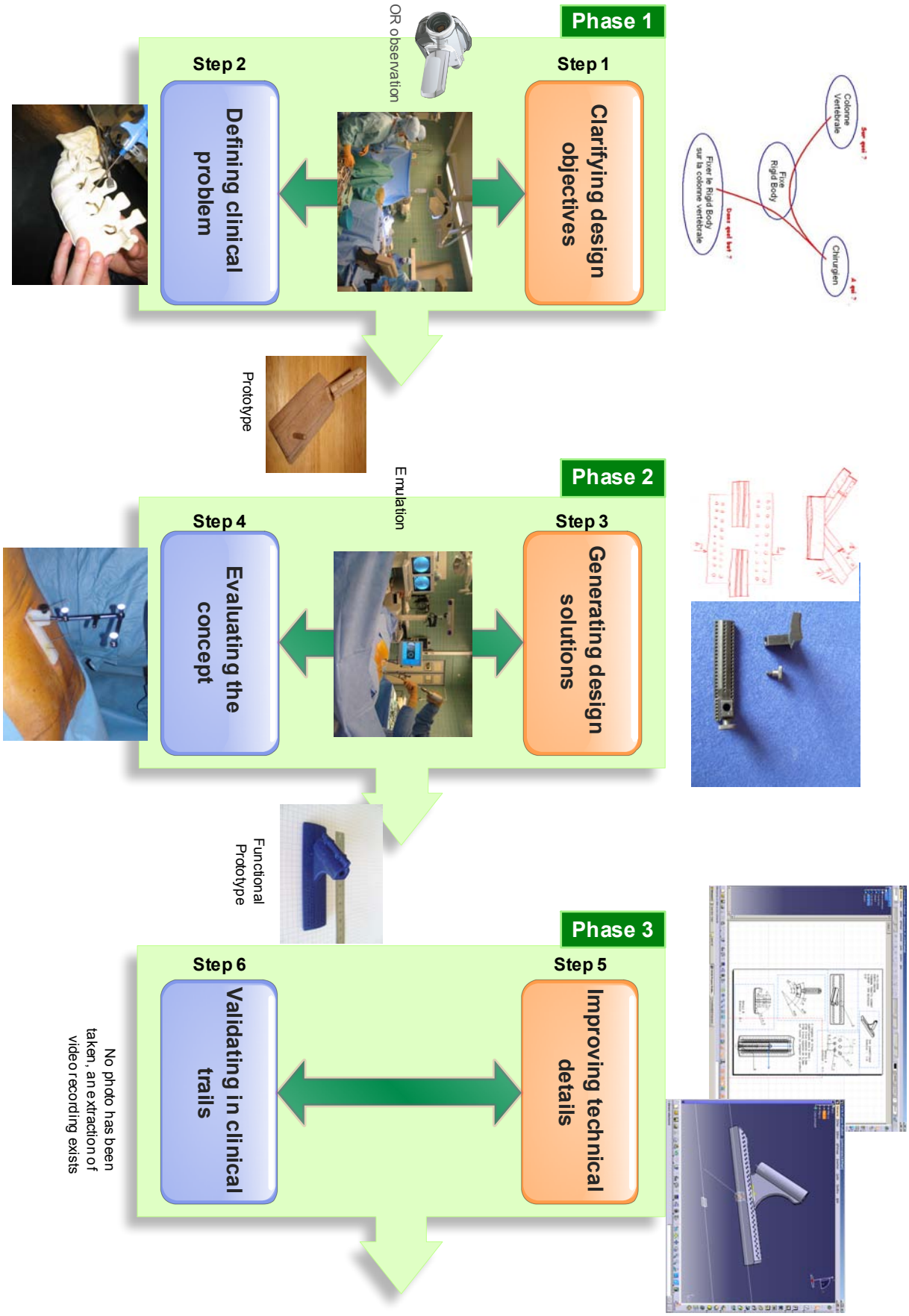


Figure 5.14: The design process model of SpineRef

were Prof. Tonetti and Dr. Vouaillat from the hospital of Grenoble. Feedbacks showed that the SpineRef has a more organized progression than the Protige, not only because of its simplicity, but also due to having a method to follow the design steps. The need for a software tool to help to organize the design activity and to provide knowledge accumulation was noticed. This was the motive to go deeper through this subject. In the next section, I propose an informatic architecture as a support of the design model.

5.5 Proposition for an informatic architecture

I would like to finish this research on design methodology by a short discussion on the informatic supports for the design methods, and proposing an architecture for a software tool that can help the designer in the field of medical and surgical products.

To the time, there are many attempts to create software tool that can help designers to manage a design process. Many of these propositions can be categorized in workflow management software. There are also many software dedicated to a particular phase in design, such as requirement and function analysis, detail design, etc. The new generation of software was developed considering the need for asynchronous and collaborative design. However, the research on a software that can handle all design aspects as well as being compatible with the existing tools is ongoing. A design methodology is also a prerequisite for flexible and continuous computer support of the design process using product models stored in the computer. In this vision it is possible to develop knowledge-based systems; to use stored data and methods; link separate programs, especially geometric modelers with analysis programs; ensure the continuity of the data flow; and to link data from different company divisions. Having a systematic architecture makes it easier to divide the work between designers, users and computers in a meaningful way.

At the end of this PhD we were thinking about the subject of designing a software tool to provide help for design actors in the design project of surgical products. Fortunately this subject was interesting for the department, and a master student in informatic joined me to work on this issue. Together with Yassine Chaoufe, we proposed an architecture for a software tool that can support the design method I proposed. In following section, I present an extraction of this work, which can be found in his master thesis (Chaoufe, 2009). A basic knowledge of UML is needed for this section.

5.5.1 Workflow and the actors

The workflow contains information about the process and the actors. Here we specify the workflow by these definitions:

- Name: for identification
- Description: presentation of the context
- Date of creation
- Date of expiration
- Name of different actors
- Name of workflow creator
- Number of workflow states

- Actual state of the workflow
- Workflow identification in the data base

The main actors of the workflow are the designer and the surgeon. Surgeon in the role of the expert-user has the responsibility and though should have the authority. The use case definition for designer role and surgeon role is shown below (Figure 5.15).

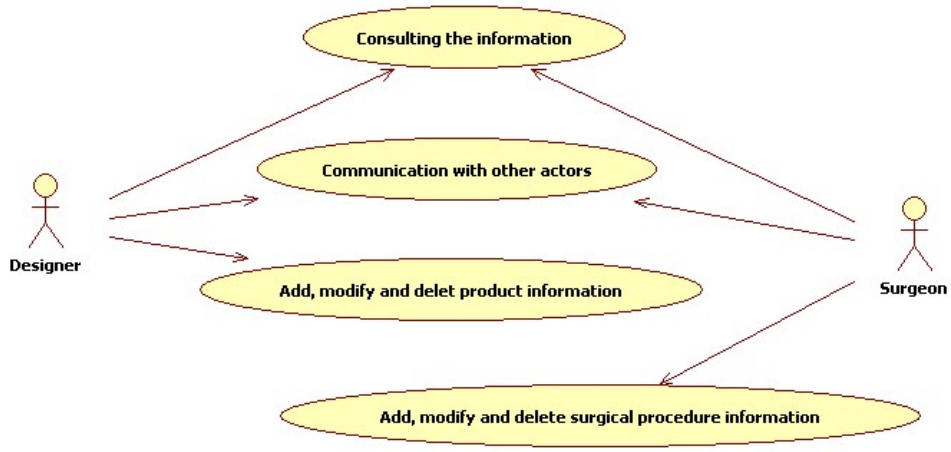


Figure 5.15: Use case diagram for designer and user (surgeon)

5.5.2 Selection of the engine for workflow

The complexity of the engines for workflow and time limit drove us to privilege the second choice. After some research (e.g. review in the master thesis) on the web it appeared that there is a number of available engine software, in various programming languages, some are free the others should be paid. Java is a language having access to numerous advantages: it is multi-platform, adaptable and has access to an API [2] offering all the basic services. Also, several units of the platform are already written and accessible. So the final choice is to use Java. Accordingly, the engine should be chosen from the available options. After consulting many web sources such as java-source.net, and comparing the proposed options, the jBMP was chosen between the final list of Apache ODE, Bonita, Bossa, jBPM.

JBPM uses the language jPDL for the definition of a workflow. Therefore, to create a workflow, it is necessary to create a file using this language from certain data, the name of the workflow, the documents and prototypes to be analyzed and validated, the names of the surgeons and designers. When the creation of the workflow is validated, it results in the creation of several detailed files below (Figure 5.16). First of all a file processdefinition.xml is generated, it contains the definition in language jPDL of the workflow. One can generate it from a graphic outline of the plugin jBPM jPDL of Eclipse.

[2] Application Programming Interface

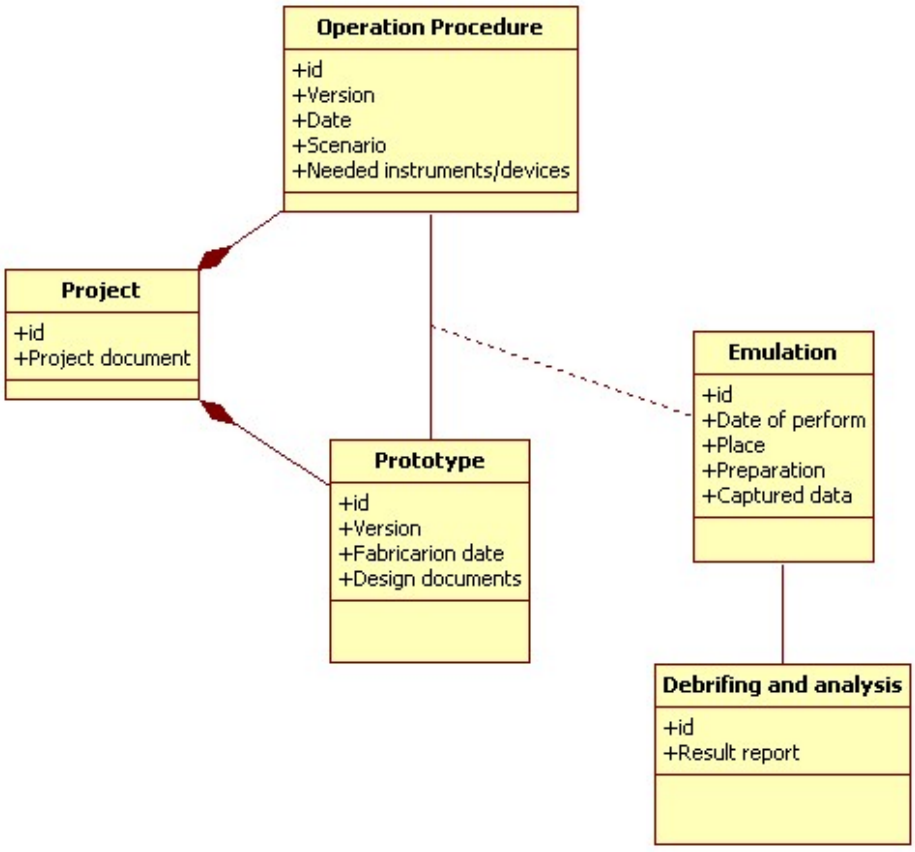


Figure 5.16: The class diagram of the data base

The language jPDL presents a workflow in a continuation of knots linked between them by transitions (one can assimilate that to a robot), the first knot is called departure state (start-state) and the last state of end (end-state). Certain knots can be special as for example the task knots (task-node), these knots assign a task to a user and are blocking, it means that it is impossible to take a transition to go to another knot as long as the task is not finished.

5.5.2.1 The deployment of workflow

When the actor decides to deploy his workflow, a definition of process is created going through the file jPDL. Afterwards, an instance of process is created from this one. This process instance receives then a signal that provokes the advancement of a state of the process (workflow), the workflow leaves therefore the departure state to arrive in the first knot of task. In the end, the context is closed therefore the state of advancement of the workflow is safeguarded in the database.

When a surgeon authenticated himself, he ends up with an interface which can show the body of the workflows at which he must carry out an action and if it is not him to carry out the action, it cannot do anything more on a workflow. In the opposite case a button allows him to execute his action (to validate), the task is then closed, and the workflow advances to the next state.

Figure 5.17 shows the class diagram of our data base. We used the hibernate framework to manage the object persistence in relational database. We created the classes with their attributes through java then the hibernate framework created automatically the tables in the database. The management of the database (update, insert) is also done by this framework through a class where all the methods of the management of the data base are defined.

In conclusion this architecture provides the possibility to manage a design process, considering the activity of the designer and the surgeon. I would like to have the possibility to connect this programming to an interface, and to use it in a project to find out the positive and negative points. Unfortunately it was not possible to focus on this subject at the end of my PhD research. I hope this work to be continued by first designing and connecting an interface to this program, and then using the program in action of design.

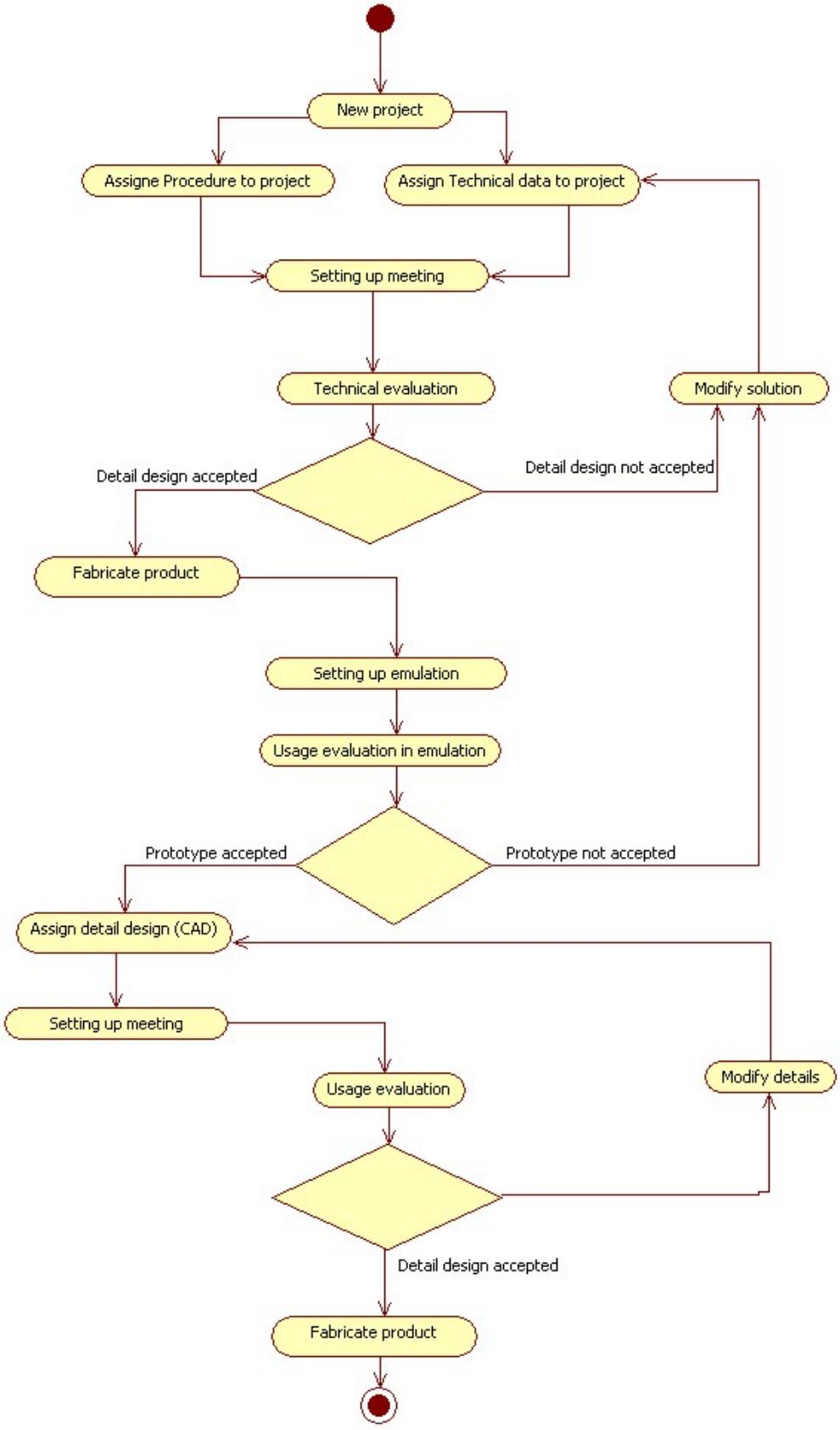


Figure 5.17: The process of workflow

5.6 Notes on observation and capture in the OR

To be able to capture the information concerning the design interactions, different observation techniques were used, among which video recordings have been used more extensively in experience. Accordingly, many tools and software were developed to facilitate the manipulation of the streams, and also to provide some digital annotation on videos. The method and consequently tools for collecting and capturing the data bring new approaches to this research. A short literature review is provided in the footnote[3]. Here in this part I explain the experience and what I have learned during the Protige project.

For the Protige project I started the observation and capture from a single ordinary camcorder, to record how the surgeon prepared the phantom and inserted the screws. For the first emulation I used two camcorders in the OR to capture both right and left views. However, the problem I faced was that as a matter of fact, in the MIS operations, surgeon guide himself by the radio images and his next decision depends on what he had seen. Though, I needed to find a way to capture the images from C-arm device monitor. The simplest way was to put a camcorder and film continuously the monitor. The second and the wiser solution was proposed from one of our colleagues; he found a solution to download the images directly to a Macbook.

Moreover, reviewing the captured movies I found out that the side camcorders are too far to capture very details of surgeon's gesture. So I tried to use a frontal camcorder (positioned on the surgeon's head) to capture what he is seeing. This solution worked much better because I could also have the radio images when the surgeon was looking at.

In the final experimentation I used an eye tracker. The reason was to see where exactly the surgeon was looking during the operation. Considering different regions such as operation site, instruments table, C-arm device, etc., I was interested to see whether analysis of the trajectory of surgeons view could help to understand about the surgeon's action.

Here is a summary of what I have learned from the Protige experience:

[3]Video recording and analysis have been used in the design studies on surgical instruments, OR workflow, etc. and some examples which are shown in the first chapter. Almost all researchers used a framework of analysis which explains the classes of the phenomena and their interrelations (Dybkjaer and Bernsen, 2002). Based on this framework, a coding scheme should be developed to categorize and classify the happening. Annotation is the process of adding data to the video stream. It allows the analysis of the happenings captured by the video recording. Numerous studies have demonstrated that annotation is an important part of the human reading behavior in both printed and digital environments (Fu et al., 2006). Many tools were developed to support the requirements of the researchers and some studies were carried out to evaluate the functionality and the advantages of their annotation tools. Since the field of video annotation and analysis is growing rapidly both in scope and importance, there is an increasing need to expand, further develop and professionalize annotation tools for the design research. Evaluating existing tools and the reported experiences in the design context and embracing what exists currently and what will be available could be useful in this process.

1. **Camcorder**

   For the OR observation and capture, high definition-high capacity camcorders with autonomy of 2-3 hours are needed, because there is not possibility to connect power wires and it is very difficult to change the battery or storage (cassette or memory) during the operation.

2. **Camcorder setup**

   Although the tripod is the basic solution for setting up camcorders, I suggest the use of ball heads (see Figure 5.18(b)). Ball heads utilize a ball and socket joint to allow movement of all axes of rotation from a single point. Some ball heads also have a separate panoramic rotation axis on the base of the head. The head has two main parts, the ball, which attaches to the camcorder and the socket, which attaches to the tripod. The camcorder is attached to the ball via quick release plate, or a simple 1/4"-20 screw. The advantage of using ball heads in the OR is that they can be attached to the illumination systems and though provide a good capture angle.

3. **Frontal camcorder / Eye-tracker**

   These systems provide a very good capture on the operation site, and most of them have an integrated microphone for capturing of the surgeon's comments and verbalization for further analysis. However, wearing such an extra facilities is not always in favor and not all surgeons accept to do so particularly during a real operation.

4. **Synchronization**

   An important issue when there is more than one capturing device is the synchronization. It is suggested to make a certain sound (like a clapper board for movies) to have a synchronization point.

(a) (b) (c)

Figure 5.18: Observation setup in the OR (a) Two general camcorders and the eye tracker worn by the surgeon (b) Ball head camcorder installation on the illumination system, (c) Configuration and calibration of the eye tracker

5.7 Conclusion

In this chapter, I have proposed the descriptive and prescriptive models for the design process of surgical instruments. Emulation step was introduced and conceptualized as a design moment in the process. A new role for surgeons in design process was identified: the expert-user. This proposition of E-UCD helps to end the struggle between user and designer role. It was discussed that the design artifact cannot be considered as one of the products (surgical instruments) or usage (operative protocol), but the combination of both. Accordingly, the design process is explained in a coevolution of product and usage. Finally, based on the new description of design process, a prescriptive model was proposed, including ES, a tool for emulation preparation.

For an appropriate design methodology, the action research method proposed to plan, action, observe (and analyze) and then reflect on the action. The observation capture analyzed in the previous chapter provides me with some interesting results based on which I reflect on the design process. This reflection had two parts: reflecting on the design process of surgical instruments, the subject of the action, and reflection on the action research method. In the section 5.2, I described the design process with two newly introduced issues: the expert-user integration, and the coevolution of product-usage in the design process. Both propositions were demonstrated in the form of process models. afterwards in section 5.3, I formalized the activities of design to provide a rational sequence of tasks, steps and phases to help the designer in performing the design of surgical instruments. This design process was explained in detail, and a model was proposed. Like any process proposition, this model needs to be verified. I brought this discussion in section 5.4 and introduced a case study on designing a surgical instrument using the proposed model.

So, having finished the reflection on the action, the tendency of having software support for design method brought the study to investigate the subject of informatic architecture for the design process. With technical assistance of an informatic engineer, an architecture was proposed to support the design progression of surgical instruments, based on the proposed process model (section 5.5). Finally, I came back to the Protige project experience and put together some recommendations for observation in the OR, the lesson learned from the practice (section 5.6).

Finally, in the next chapter together with the general conclusion of this dissertation, I will discuss the second part of the reflection: reflection on the research method.

Conclusion

Design research is fantastic. Not so many years from the first appearance of design in the scientific community, the 17th International Conference on Engineering Design (ICED) was held at Stanford University, California, in which I enjoyed presenting my contributions. So I would like to begin my conclusion with the conference slogan: "Design has never been this cool".

With regards to Hubka's classification of design sciences (design objects and design process), for me the design research has two divisions: First, research on the design artifact or system (the subject of design) and second, research on the design actors (designers, engineers, users, etc.). Although in my opinion these two divisions can not really be separated from each other, most design studies have focused on either the technical object, or the human aspects. What I tried to do in this PhD dissertation was to make a bridge between these two approaches, and propose a design model that helps engineers dealing with the expert users.

My PhD was a fascinating experience of working together with engineers and surgeons. It was a "practice-based PhD", and as a research scholar, I tried to problematize aspects of practice, inquiring into issues related to creative practice and partly using the results of creative practice as evidence for my proposition arguments. The problematic of this dissertation was formulated as "what design methodology is needed to design innovative surgical instruments?". In other words, how could I provide some help (e.g. models, methods, tools) for design team including engineers and surgeons, to design innovatively, and together? Let me insist that my problematic was not how to help surgeons perform a better operation, as it is for almost all studies which deal with surgeons and surgical instruments. What I did was studying the design process, design roles and relations, and design elements in a specific context. In result, I came up with new contribution to the design process: the coevolutive character of the design, the concept and application of emulation step in design, the role of expert user in the design process. I also proposed a prescriptive model for innovative surgical instruments. In this model the Extended Scenario (ES), a tool for organization of emulations steps was explained and demonstrated with examples.

I chose the action research demarche as my research demarche, and followed the steps: Plan, Action, Observation, and Reflection. There is no much left to say other than what have been explained in chapter 3, the plan and the action of Protige project, in chapter 4, the observation and analysis of the project corpus, and in chapter 5, reflection on design process. But, what is left is how can I reflect on the action research approach itself?

I found the action research a very useful method for performing a practice-led design study. In fact, the action research provides a logical and trusty framework in which a design study can advance. I suppose the action research can be considered as dominant method for the design PhD research, particularly when the project involves the action of

design. However, without knowing the action research one can define his own plan and apply a generic method. This dissertation may show the advantage of having a well defined research method together with an application to study design process and design activity[4]. This dissertation may show the advantage of having a well defined research method together with an application.

I complete my contribution to the action research method by adding what I have experienced and learned during the case study, which I think will ameliorate this method.

1. **Research objectives and design objectives**

   The action in the action research method is usually a design project, a part or the complete process, and is supposed to be directed by the researchers who take action research method for their research study. On the other hand, the design projects need to have well defined and clarified objectives. For this reason, I propose to set up separately the research objectives and the design objectives in the plan step of the action research method. An example for this proposition is the research and design objective I have explained in the chapter 3.

2. **Observation and Analysis**

   When a design project is in action, naturally the observation should take place simultaneously during the project. In other words, once the project is finished there is no room for observation. For this reason, I suppose the observation step in the action research implies more analysis meaning than what observation means.

Therefore, I suggest the action research to provide some observation guidelines in the beginning of the action step, and then rename the observation step by the analysis step. In the new analysis step the researcher should define the analysis objective, make the analytical framework, analyze the observation captures and then evaluate the action according to the analysis results. Accordingly, I propose a modified schema for the action research, shown in Figure 5.19.

In terms of results, this PhD research provided two types of contributions: analytical and methodological. First, following the field of design activity analysis, focusing on design evaluation meeting (an important but overlooked design situation), I identified two classes of evaluation, expert-user meeting and emulation. For both classes an analytical framework was proposed and explained. Then, two design meetings and four emulation situations were annotated and analyzed, using a video annotation software. The analysis results showed interesting design phenomena due to the study hypothesis:

- Integrating expert user in the design process of Protige had considerable effect on design activity, particularly the evaluation meeting. Moreover, activity analysis of

[4]Very recently I heard of and have a chance to browse the valuable book of Blessing and Chakrabarti titled "DRM, a Design Research Methodology" published by Springer. I would highly suggest this book for further discussions on the subject of design research methodology.

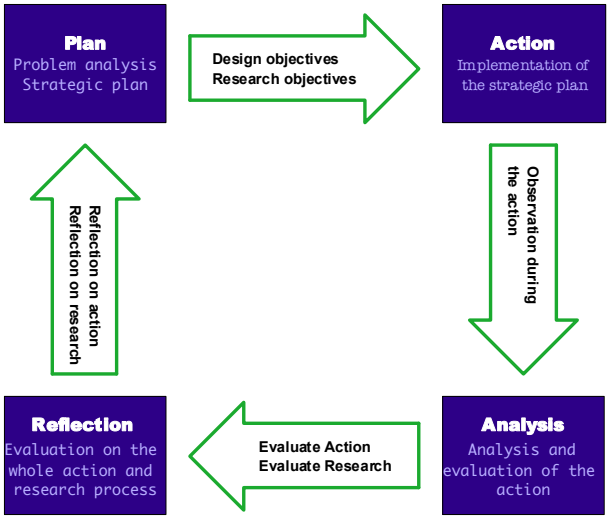


Figure 5.19: New proposition for action research

user evaluation is prepared situation, which I called emulation, showed a dynamic communication between the user and the engineer, and indicated the evolution of these situation.

- Design activity analysis also demonstrated that the technique-usage characterization of the activities helped to have a better understanding of communication dynamics. This classification provided the first evidences for product usage coevolution proposition.

Second, concerning the design methodology, this dissertation brought following contributions:

- A primary hybrid model of engineering and human-centered approaches
- Formalization of this model and applying it in a design case (Protige project)
- Reflection on design process in descriptive and prescriptive way

In descriptive modeling of the design process, I conceptualized the emulation moment, and explained how the product and usage coevolve through the emulation. Besides, I proposed an expert user-centered design model, a modified form of UCD from ISO, which was adapted to integrating and centering the design around a user with expertise.

In prescriptive modeling, I formalized the design activity in form of phases, steps and tasks and proposed a process model for design of innovative surgical instruments. This model was explained in detail, in "what to do" format, as it is common in prescriptive models. Nonetheless, one particularity of this proposition is in order to consider the iteration and interchange of tasks between two steps in a phase.

In the next step, I tried to validate the proposed model. Going through the discussion of "whether or not the validation is possible", I proposed to apply the design approach to a similar case: a new instrument for MIS. The case application seemed promising, and even encouraging for further development.

This work, however, had some limitations both in method and in application. One can argue the choice of the action research approach, instead of case study (in large number), patent analysis, industrial observation, etc. To defend my methodological choice, I may remind that this PhD thesis was originated in an engineering design focus infrastructure, and was the first research approach to the medical and surgical application domain in the our research center. Accordingly, there was no access for me to observe various surgical instrument design cases. Neither was any possibility to observe surgical instruments industry from this level, mainly because of confidentiality. The lack of observed design cases was one of the reasons that brought me to my scientific visit at TU Delft, where I observed some projects closely. However, I figured out that surgical instruments design project in university takes at least four or five years, and so it would be impossible for me to picture it in my three-year PhD.

On the other hand, as an engineer and not from biomedical engineering background, not only I could not do a design project by myself, but also I needed to be familiar with the dominant knowledge of the project (e.g. anatomy vocabulary). Though, I myself was looking for the opportunity to work in a surgical design project.

Altogether, the action research method suites well enough to provide a scientific approach to self participation in the action of design, and have observation and reflection. To go further, I suppose the action research method is the best research method in a situation which researcher participation in the action of project is necessary.

This work also has some application limit. At the first place, my best wish was to validate the proposed model in theory and in practice, by applying the model in as many design projects as possible, to have feedbacks on the structure and details of the proposition. Nevertheless, the validation case explained in the dissertation showed the encouraging feedbacks. Particularly the need for a software tool to help managing design process was reported. Another limit of this research was the fact that the focus of study was only on the surgeon role. Nonetheless, it opens the perspective for further research on the integration of other user (roles) into the design process.

In perspective, I suppose the first goal would be to improve the design process model. To do this the best way is to apply the model in various design cases of surgical instruments, and have their feedbacks. Moreover, since what characterizes the surgeon from a novice user in this model is the expertise and the knowledge about the usage which the designer does not have, this model can be extended to all other user with this characteristics. Famous examples are pilots, air traffic controller, specific or extreme sport athletes, etc. There is another type of users in order to serve them this design process model can be very helpful to the designers: specific users, such as disabled people. These users also have a usage

protocol which is unknown, and maybe never describable (e.g. handicapped children) to the designers. In this situation, the process which looks for designing a product to help a handicapped child needs firstly to provide methods and techniques in order to understand, clarify and formalize the user requirements. In such situations, the proposed process model can play an important role[5]. Working on the aspects that facilitate the model application, such as software tools, would be in primary priorities for the future works. There is also a particular perspective for the Protige, to go through the clinical validation step and then to be fabricated and commercialized.

[5]In fact, we have started to work on the application of some findings of this thesis on the design for handicapped children, and we found very interesting and promising feedbacks. However, this subject was decided to be exclude from the dissertation. Some of the related publications can be found in the Personal contribution section.

Glossary

Asteric sign indicates the contribution from this dissertation.

C-arm C-arm or Fluoroscope in medical settings, is a highly complex piece of equipment which uses x-rays and produces a 'live' image feed which is displayed on a TV screen. The letter C stands for the hemicycle shape of the device, where x-ray source and plumb plaque situated on the ends.

Coevolution * (see section 5.2.1) evolution involving successive changes in two or more ecologically interdependent species that affect their interactions. Coevolution in design is the parallel development of two or more design interdependent objects, in which the progression of one affects the others and their interactions

CT Scan Computed tomography scan. A medical imaging method employing tomography created by computer processing. Digital geometry processing is used to generate a three-dimensional image of the inside of an object from a large series of two-dimensional X-ray images taken around a single axis of rotation.

Emulation * (see section 3.5.2.4 and 5.2.1) is the act of imitating the behavior of some situation or some process by means of something with physical properties. Emulation in design process is the situation in which the user evaluate a physical prototype through the manipulation under usage conditions.

Endoscopy looking inside and typically refers to looking inside the body for medical reasons using an instrument called an endoscope.

ES Extended Scenario * (see section 5.3.1) is a support document for planning and organization of an emulation. ES includes four parts: 1. Scenario of usage, 2. Product functions, 3. Emulation situation, and 4. Observation setup.

E-UCD * (see section 5.2.2 Expert User Centered Design, is a modified UCD method which put efforts on the expertise of the user and proposes the techniques and tools for better integration of the expert in the design cycle. Four steps of E-UCD are Understand and specify the context of use, Specify the user requirements, Product-usage design, and Design evaluation.

Fluoronavigation Fluoroscopy navigation, is an imaging technique commonly used by physicians to obtain real-time moving images of the internal structures of a patient through the use of a fluoroscope. In its simplest form, a fluoroscope consists of an x-ray source and fluorescent screen between which a patient is placed. However, modern fluoroscopes couple the screen to an x-ray image intensifier and CCD video camera allowing the images to be recorded and played on a monitor.

ISO International Organization for Standardization is the world's largest developer and

publisher of International Standards. ISO is a non-governmental organization that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government.

Laparoscopy direct visualization of the peritoneal cavity, ovaries, outside of the tubes and uterus by using a laparoscope. The laparoscope is an instrument somewhat like a miniature telescope with a fiber optic system which brings light into the abdomen. It is about as big around as a fountain pen and twice as long.

MIS Minimally Invasive Surgery, is any surgical procedure that is less invasive than open surgery used for the same purpose. A minimally invasive procedure typically involves use of laparoscopic devices and remote-control manipulation of instruments with indirect observation of the surgical field through an endoscope or similar device, and are carried out through the skin or through a body cavity or anatomical opening. This may result in shorter hospital stays, or allow outpatient treatment.

MRI Magnetic Resonance Imaging, is primarily a medical imaging technique most commonly used in radiology to visualize the internal structure and function of the body. MRI provides much greater contrast between the different soft tissues of the body than CT does, making it especially useful in neurological (brain), musculoskeletal, cardiovascular, and oncological (cancer) imaging.

NOS Natural Orifice Surgery is an experimental surgical technique whereby "scarless" abdominal operations can be performed with an endoscope passed through a natural orifice like mouth, nose, urethra and vagina.

OR Operating Room, know also as operating theatre, the room within a hospital where surgical operations are carried out.

Phantom visible representation of something abstract. Here in surgical context phantom is a mannequin of human body, used for clinical test and education.

Trocar is a hollow cylinder with a sharply pointed end, often three-sided, that is used to introduce cannulas and other similar implements into blood vessels or body cavities. Trocars are also used as ports in laparoscopic surgery.

UCD User-Centered Design is a design method and a process in which the needs, wants, and limitations of end users of an interface or document are given extensive attention at each stage of the design process. User-centered design can be characterized as a multi-stage problem solving process that not only requires designers to analyze and foresee how users are likely to use an interface, but also to test the validity of their assumptions with regards to user behaviour in real world tests with actual users.

Personal contribution

2009

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Appendix 1 - Spine anatomy and spinal operations

Source:
ORTHOPEDIC SPINE SURGERY
Lumbar Spine
REGIONAL ORTHOPEDIC CENTER
Poudre Valley Hospital
Fort Collins, Colorado
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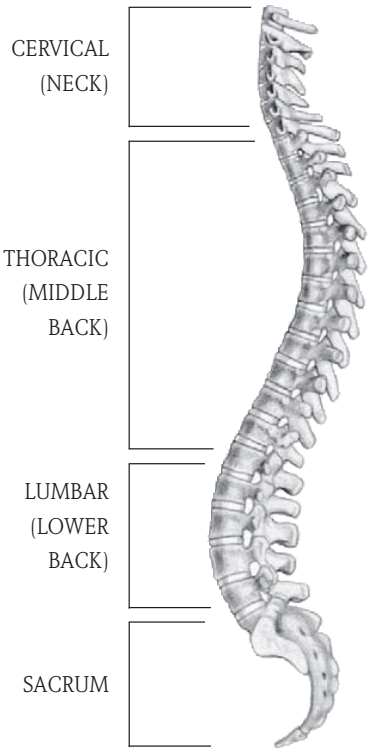


SIDE VIEW OF SPINE

HOW THE SPINE WORKS

The spine, or the spinal column, is the central pathway for the spinal cord. The spine serves as a mechanical connection between the arms and legs. Muscles are attached to all levels of the spine. These muscles help maintain proper posture and spinal alignment.

Composed of a large strand of nerve tissue, the spinal cord extends from the brain down along the spine. At each level of the spine, individual nerves branch off from the spinal cord. These nerves provide the brain with information about the body, and allow the brain to control the movement and function of the body

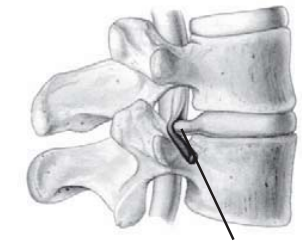
The spine is divided into four main sections:

- the cervical spine or neck is composed of seven vertebrae. Nerves in this area generally control the arms and hands.

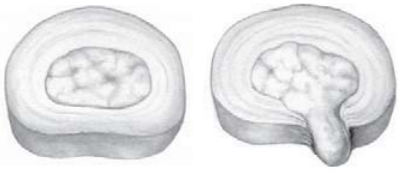
Degeneration of the spine is usually related to damage to the disc. This puts pressure on the spinal nerves, which in turn causes pain or weakness in the arms, legs, or spine.

DIAGNOSING SPINAL PROBLEMS

Spinal problems usually show up as pain in the back, arms, or legs. Your physician asks exactly where you have the pain, how long you've had it, and what makes it better or worse. X-rays are usually taken. Depending on your symptoms, a magnetic resonance imaging (MRI) scan may be done. The MRI gives a much better picture of the discs and spinal nerves. Sometimes a myelogram with a CT scan is done. This also gives a good picture of any pressure on the nerves. Occasionally, discography is performed to assess whether a degenerated disc is the source of your back pain. During this test a dye is injected into the disc through a small needle. X-rays and a CT are then taken of the disc.



PROTRUDING DISC



TOP VIEW OF NORMAL DISC

TOP VIEW OF RUPTURED DISC

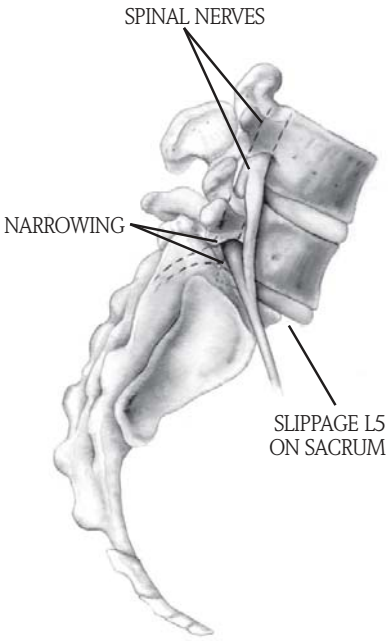
COMMON SPINAL PROBLEMS

Herniated Disc

A disc herniation occurs when the center of the disc bulges through the outer layer of the disc and puts pressure on the spinal nerves. This can occur in any part of the spine.

Spinal Stenosis

Spinal stenosis is a narrowing of the spinal canal. This occurs as a result of gradual wear and tear on the spine. The intervertebral disc bulges and the facet joints grow bone spurs. This results in pressure on the spinal nerves. This can occur in any region of the spine, but is most common in the lumbar spine and less common in the cervical spine.

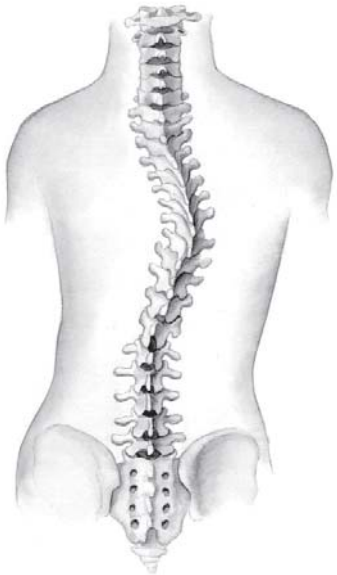


Spondylolisthesis

Spondylolisthesis is a slippage of one vertebrae on another. This often causes narrowing of the spinal canal and leads to leg or back pain. This is most common in the lumbar spine.

Scoliosis

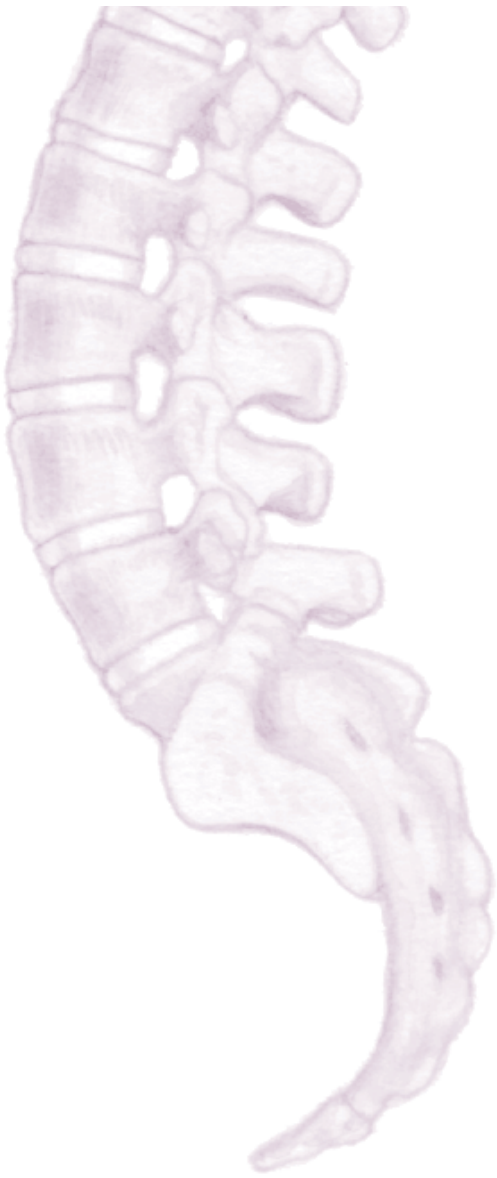
Scoliosis is an abnormal curvature of the spine. This can lead to increased back pain and pressure on the spinal nerves.



SCOLIOSIS

NON-SURGICAL TREATMENT OF SPINAL DISORDERS

Most spinal problems can be treated without surgery. Treatments include medicines, physical therapy, chiropractic manipulation, massage therapy, acupuncture, and spinal injections.

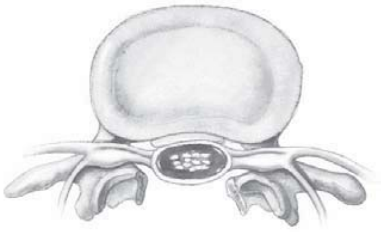


COMMON SPINAL OPERATIONS AND POST-OPERATIVE CARE

The following are some of the most commonly performed operations on the lumbar spine. Your particular surgery may be a modification of one of the following or may not be included below.

Lumbar Discectomy

This surgery is performed when part of the disc bulges and presses on the spinal nerves. Patients usually have severe leg pain and some back pain. The surgery is performed from the back side of the spine. A small piece of the back covering of the spinal canal is removed (laminotomy) so the fragment of disc that has bulged can be removed. A fusion is usually not needed. This surgery can be performed as an outpatient or you may stay overnight.

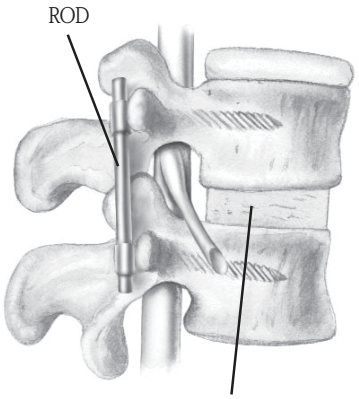


SPINOUS PROCESS AND
LAMNIA REMOVED

Lumbar Laminectomy

This surgery is done when the spinal canal becomes narrowed (spinal stenosis). Once again, this surgery is performed from the back of the spine. The back covering of the spinal canal is removed (laminectomy). Bone spurs are removed from the facet joints on the left and right side of the spine. This makes more room for the nerves to run down the spinal column and exit the spine.

LUMBAR FUSION AFTER SURGERY



Lumbar Fusion

This operation is performed when the spinal column has become unstable or when a lumbar disc has become degenerated and painful. The fusion can be performed several ways:

Anterior Lumbar Interbody Fusion (ALIF)

This surgery is performed from the front side of the spine. A small incision is made on the left side of your abdomen. The abdominal contents (peritoneal cavity) and great blood vessels are pulled out of the way and the degenerated disc is removed. The disc space is then distracted and a piece of bone graft or a spacer called a cage is placed. Bone from your hip or the bone bank may also be used. Often your surgeon will make a separate incision on your back to place screws and additional bone graft to further stabilize the spine.

Posterior Spinal Fusion

This surgery is performed from the back of the spine. It is usually done along with a lumbar laminectomy. A bone graft from your hip and allograft (donated) bone are placed between the transverse processes of the spine. This allows the vertebrae to grow (fuse) together. Often, metal screws and rods are used to stabilize the spine while the bones fuse together.

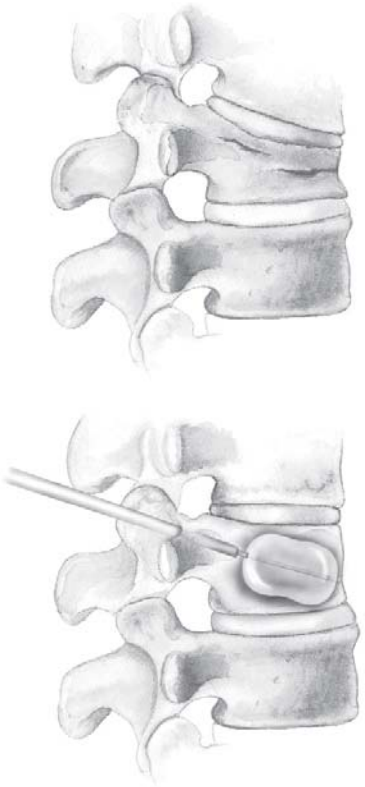
Posterior Lumbar Interbody Fusion

This surgery is also performed from the back of the spine. A partial or complete laminectomy is performed. Spacers called cages filled with bone graft are placed between the vertebral bodies. This allows your surgeon to help restore the normal height of the degenerated disc. Often metal screws and rods are used to stabilize the spine while the bones fuse together.

Kyphoplasty

This surgery is performed for people who have a painful compression fracture of a vertebral body as a result of osteoporosis. The surgery involves placing balloons into the vertebral body to help restore the height of the vertebrae. The balloons are then removed and the vertebrae are filled with bone cement. The hospital stay is usually one night.

KYPHOPLASTY



Appendix 2 - Minimally Invasive Posterior Instrument Sets

Source: Synthes GmbH Instruments and implants - MIS instruments series

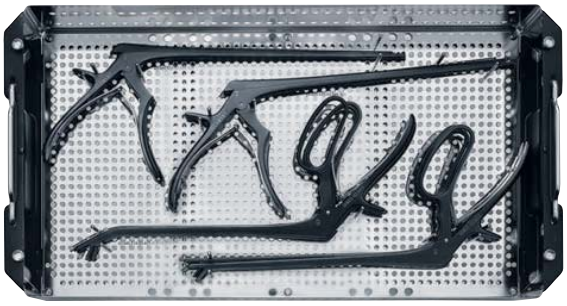
Sets

01.605.903	Set for Minimally Invasive Posterior Instruments

Instruments in Case 68.605.900

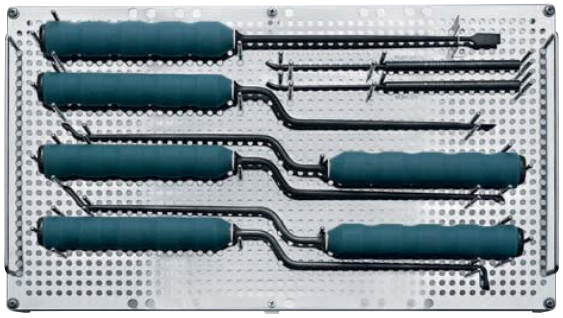
1. Level 68.605.901

03.605.513	Rongeur, curved, 2.0 mm, black
03.605.514	Rongeur, curved, 4.0 mm, black
03.605.515	Rongeur, curved, 6.0 mm, black
03.605.520	Laminectomy Punch, 40°, 4.0 mm, black
03.605.521	Laminectomy Punch, 40°, 2.0 mm, black
03.605.522	Laminectomy Punch, 90°, 4.0 mm, black
03.605.523	Laminectomy Punch, 90°, 2.0 mm, black
03.605.526	Rongeur, straight, 2.0 mm, black
03.605.527	Rongeur, straight, 4.0 mm, black
03.605.528	Rongeur, straight, 6.0 mm, black
03.605.502	Endplate Elevator, bayoneted, black



2. Level 68.605.902

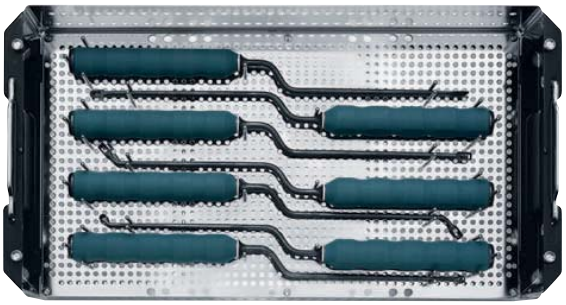
03.605.504	Bone Curette, 5.5 mm, bayoneted, black
03.605.505	Bone Curette, 45° angled, 5.5 mm, short, bayoneted, black
03.605.506	Bone Curette, 45° angled, 5.5 mm, medium, bayoneted, black
03.605.508	Osteotome, straight, black
03.605.509	Bone Curette, 90° angled, 5.5 mm, bayoneted, black
03.605.524	Dissector, blunt, 4.0 mm, black
03.605.525	Dissector, blunt, 2.0 mm, black



Instruments in Case 68.605.910

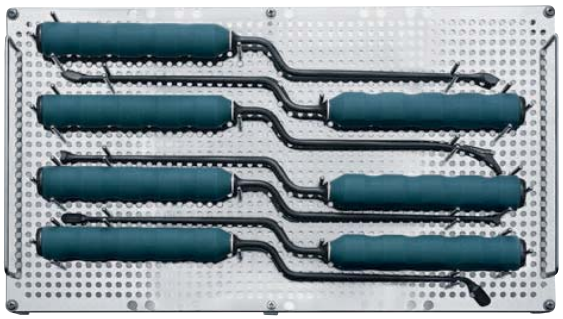
1. Level 68.605.911

03.605.503	Curette, rectangular, left, bayoneted, black
03.605.510	Ring Curette, straight, bayoneted, black
03.605.529	Curette, rectangular, angled, right, bayoneted, black
03.605.530	Curette, rectangular, angled, left, bayoneted, black
03.605.534	Ring Curette, curved, bayoneted, black
03.605.536	Curette, rectangular, right, bayoneted, black
03.803.054	Curette, rectangular, bayoneted, black



2. Level 68.605.912

03.605.500	Impactor, standard, bayoneted, black
03.605.501	Implant Pusher, bayoneted, black
03.605.507	Rasp, dual-sided, bayoneted, black
03.605.511	Rasp, dual-sided, angled, bayoneted, black
03.605.531	Impactor, large, bayoneted, black
03.605.532	Impactor, curved, standard, bayoneted, black
03.605.533	Impactor, curved, large, bayoneted, black



Appendix 3

OBSERVATION, ANNOTATION AND ANALYSIS OF DESIGN ACTIVITIES: HOW TO FIND AN APPROPRIATE TOOL?

Reference of this paper:
Rasoulifar, R., Meillon, B., Thomann, G., Villeneuve, F., 2009. Observation, annotation and analysis of design activities: how to find an appropriate tool? ICED 09, Stanford, CA

ABSTRACT
Recently design researchers have been interested in observation-analysis approach to study design activities. In this way the annotation and annotation tools have been introduced to the design research. This paper describes the annotation process as an approach in design activity studies. It presents several design research in the context of collaborative design and user-centred design, using video annotation tools, and explain how these tools have been employed. We describe the evaluation criteria for annotation tools, and provide a functional comparison on the explained tools. We explored the existing functionalities of different software, to extract a list of desired characteristics of an ideal annotation tool for the design research and studies.

Keywords: video annotation, design activity, observation, analysis, annotation software

1 INTRODUCTION
Observation of design activities takes a holistic view of the relationship among designer communication, designed artifacts, the socio-cultural context of the design situation, the position of the observers and the technique they use for the observation. While the observation-analysis studies are developed outside of the design studies and mainly in psychology and natural interactivity sciences, their approaches and results did interest the design researchers in different aspects like argumentation analysis and human machine interactions. To be able to capture the information concerning the design interactions, different observation techniques were used, in between video recordings has been used more extensively in experiences. Accordingly, many tools and software were developed to facilitate the manipulation of streams, and also to provide some digital annotation on videos.

Unlike the natural interactivity community, design interaction fully recognizes itself as a "design discipline", in that the objective is to create new and change existing interactive systems for the better [1]. There is an increasing interest in design community to observe and analyze design activities in industrial situations, student experiments, and international research workshops. Although there is no generally accepted approach or research methodology, each group typically uses an "observe - hypothesize - analyze – verify" method to obtain results. Analysis is generally done through the additional information and the interpretation is annotated on the video. *Annotation* and *coding* are the terms generally used for this process in the community.

Since the field of video annotation and analysis is growing rapidly in scope and importance, there is an increasing need to expand, further develop and professionalize annotation tools for the design

research. Evaluating existing tools and the reported experiences in the design context and embracing what exists currently and what will be available could be useful in this process. Moreover, a guide comparing software programs' capabilities and performances and tool limits could provide researchers useful information when they select a tool for future research.

In this paper, we will explore the background of observation, annotation and analysis, then review four annotation tools, and their usage in a design project. In section four, we define the main evaluation criteria of an annotation tool, and compare the above-mentioned tools. Finally, in section five we discuss an ideal tool according to the identified design research requirements.

2 VIDEO ANALYSIS AND THE DESIGN PROCESS

Observation, annotation and activity analysis originated from the cognitive sciences such as psychology, sociology, and natural interactivity. Observation used to be direct, placing the researchers in the environment, and their observation tools were simply pens and notebooks. The development of new technologies changed observation: video recording and analysis become the principal observation method of many scientific researchers in these fields. Design as a human activity includes social aspects, so the observation has become an important technique in design studies. Many design observation studies are published in various subjects such as: design communication [2], knowledge interaction [3, 4], validation hypothetic models [5, 6], and design education [7, 8].

Design activity as a data source provides a multitude of information about the design phases including design-thinking, decision-making, collaboration using intermediate objects, and design evaluation. Externally activities can be observed, recorded, archived for analysis, etc. whereas externally imperceptible activities are far harder to capture [9]. Researchers used to collect the design project archiving and reports. They used questionnaires, interviews and other types of surveys to communicate with the designers. The deeper and more complex the research question was, the more data were needed. The method and consequently tools for collecting and capturing the data bring new approaches to this research.

Tang proposed recording design activities in his Observe-Analyse-Intervene methodology [10]. Video recordings provide maximal data of the subject and the situation. It can be replayed and reinterpreted, and provide the access to behaviors and interactions that could have been missed by direct observation. It can reduce observer bias and better corroborate the results [11]. Thus, video recording is being used widely for research on design in research workshops. Technology advancement facilitates the use of video streaming. Real-time audio and video recording, known as protocol analysis, have widespread use in academic research. For instance, in an international workshop held in Delft, The Netherlands, researchers analyzed video recordings of designers working on an engineering product design [12]. Also a workshop held in Lulea, Sweden was about capturing the design-activities of a group of students in various situations and various practices.

Video recording analysis requires an analytical framework. That framework is based on a theory which explains the classes of phenomena and their interrelations [13]. Based on this framework, a coding scheme should be developed to categorize and classify the happening. Annotation is the process of adding data to the video stream, and allows analysis of the happenings captured by the video recording.
Numerous studies have demonstrated that annotation is an important part of human reading behavior in both printed and digital environments [14]. Annotation in the electronic environment requires special support due to limited media affordances. Many tools were developed to support the requirements of researchers and some studies were carried out to evaluate the functionality and advantages of their annotation tools [15, 16]

Increasing demand for better tools for handling and analyzing video requires special attention to, so the new tools have appropriate functionalities and meet users' needs. However, comparatively little research has been conducted to understand the specific needs of researchers for annotating videos, so as to develop tools to support their needs.

Surprisingly, there are too many tools developed for video annotation, since almost all the tools were created, used, tested and augmented without concerning design research. For video analysis tools to succeed in the design context, they must support a wide variety of design tasks and analysis styles, and support design objectives. We need to gain new insights into the way the designers' progress in the design process. Little is known about the use of such tools in specific behavioral contexts, and more still needs to be explored. The annotation process is explained in the next section.

3 CONFIGURATION, CODING AND ANALYSIS

In its very basic form, the annotation process consists of three steps: configuration, coding and analysis. One can claim that the analysis is not an internal annotation process, but what we are explaining here is the process used to learn more about the design actors, objects and activities during a design situation.

While the observation is the entry of this process, we argue that the observation can be influenced by the researcher knowledge and experience in annotation. Observation provides raw material for the research; the richer the video capture is, the more profound the analysis could be.

1. Configuration (the analysis framework)

Based on what kind of data an analysis seeks to show, the type of input data and its categorisation should be defined. This categorisation has two main parts: spontaneous happening and their interpretation. A happening is a set of actor, activity and object that can be recognised evidently, like "Alain draws a sketch" or "Bob asks a question". On the contrary, an interpretation comes from the study hypothesis like "problem explanation" or "understanding new solution". In other words, this classification called the *framework* includes explicit and implicit classification.

A happening can be defined as an *event* by an occurrence time, or as an *interval* by the start and stop times. Framework presents spontaneous happening through the subjects, objects and actions. For example, commonly in design studies such a framework presents typical elements including actors, intermediate objects, and interaction between actors. This categorisation can be as detailed as the research needs, and is supposed to follow a logical classification. Figure 1 shows the typical examples of classification.

<table>
<tr><td>Actor 1</td><td rowspan="3">Activity 1, Activity 2, Activity 3</td><td>Phase 1</td><td rowspan="3">Happening 1, Happening 2, …</td></tr>
<tr><td>Actor 2</td><td>Phase 2</td></tr>
<tr><td>Actor 3</td><td>Phase 3</td></tr>
<tr><td>Activity 1</td><td rowspan="3">Actor</td><td rowspan="3">object</td><td>Object 1</td><td rowspan="3">Actor</td><td rowspan="3">Activity</td></tr>
<tr><td>Activity 2</td><td>Object 2</td></tr>
<tr><td>Activity 3</td><td>Object 3</td></tr>
</table>

Figure 1-Various types for coding scheme, according to the observation focus

Configuration is the act of modifying the software options to their nature, number and chief characteristics to realise the framework classification. The result of configuration provides a guidance table called *coding scheme.* The coding scheme characteristics depend on the annotation software including the level of details, the interrelation between elements, and being flexible or predefined.

This step is the most essential and conceptual for the annotation. However, the annotation process is iterative, rarely a first coding scheme is capable to classify and distinguish all the happenings of an observation.

2. Coding

Coding is the software facility to assign a defined happening from the coding scheme to the video stream. Thus, by coding, the user marks – event or interval – on the stream and adds the appropriate data. Technically, the coding is performed by stopping the stream, and entering a comment or clicking on the coding scheme to assign an item. Depending on the annotation software, coding could be

restricted to the coding scheme or be open to create and add a new class. Some software let the coding scheme be changed once the coding is started while the others don't. This capability helps the annotation evolve during the process instead of each time restart.
By the way, sometimes the annotation tool provides a space for adding non-categorised data during the coding. For example, in the case of verbal annotation, the user may prefer to write down the whole sentence or to extract a phrase expressed in the film.

Almost all annotation software use a time line to provide the coding space. This idea is coming from the video edition software like Adobe Premiere or Windows movie maker. In some cases, there is no horizontal visualisation of the timeline, but the coding appears vertically one after the other on below. Once the horizontal presentation is simpler to understand and ergonomic, some finds the other one more functional in practice.

The other important concept in coding support is what we call *coding channel*. Coding channel is the coding dedicated to one category of coding scheme. It means the user can decompose the happening to different independent channels (naturally following the coding scheme) and focuses only on one category. For instance, the user defines the verbalisation channel, and codes the subcategories of the verbalisation such as asking a question, answering a question, making a suggestion, aside from the other happenings. Thus, with the coding channel support, the user can decompose the annotation into different channels (like verbalisation, hands movement, use of objects, etc.) and code them separately.

The main advantage of the coding channel is that such a support provides the possibility of annotation using several people with different expertises. This lets to go deeply into subcategories and to code the happening as much as possible.
Only a few annotation software provides such a facility. Technically, this option also allows coding the same channel by different persons, which can evaluate the reliability of the coding procedure. Few recently promoted software has a feature about this aspect and shows the agreements and disagreements of the different user coding.
By the way, this step is the most time consuming part of the process. Coding a five minutes movie, even a low detailed coding scheme can take almost a week for the coding. As mentioned, it is very common to start with a first coding scheme and evolve it during the coding. It costs a lot of time and patience, particularly when the annotation software doesn't support the coding scheme modification and forces to restart the coding.

3. Analysis

Once the coding is done, all annotations are recorded in a log file, with each item placed in a different column identified by the time code and added comment. This makes possible the analysis to have the outputs like tables of frequencies, duration, interaction matrix and transition matrix. The log file may be directly viewed, exported to the data analysis software (eg. SPSS), or can be manually modified.
Only a few software have some basic statistical analysis tools (like graphs) while the others just make an export of data. The export format is very different from one software to another, and there is no standard on this issue. In most of the cases, the user needs to manipulate the data himself to extract some analytical results.
Qualitative analysis has been used in design study issues much more than quantitative analysis, which somehow explains the lack of motivation in tool development. In most of studies, a graphical representation of the annotation or a result table has been supposed adequate.
Reliability analysis is the solution to avoid observer bias. According to the study goals, the annotation should be done by 3 or 5 different persons, and a certain percent of agreement supposed to be reached. A few software provides systematically this facility by comparing records of different coders and list the agreements and disagreements between them.

One excellent type of export provided by one annotation tool is the video extract export. This means the user can select a coding type, like actor A uses blackboard and the software export a video file of the montage of all scene where the Actor 1 was coded as using the blackboard. This software provides also a multi-criteria selection like actors A uses blackboard and actor B takes note, and so extract a movie of these scenes together. This facility is very helpful in qualitative studies and analysis.

These three successive steps build the body of the annotation process. The entry to this process is the observation capture, in different form of recordings. Since the focus of this paper is on video recordings, the last issue to discuss here is the data import function of annotation software.

4. Data entry

One of the biggest inconvenient of many of annotation tools is that they are very limited in data import and accept one or very few video formats. Considering the movie format converting and encoding configuration as a professional knowledge which the researcher is not supposed to deal with, the data import is a serious limitation for usage.
Moreover, most of annotation tools does not support multi-streaming and can import just one video. This limit is also important, because more and more the researchers need to have multiple views on the design session to capture more about what is happening.

4 OBSERVATION ON DESIGN STUDIES

In this section, four experiences of annotation in the context of design study are reviewed. The studies have been selected from the different contexts, such as collaborative design and user-centred design. The cases have been selected due to their relevance to the design research in the regional design community. Thus, each annotation tool is explained through a study case to provide a clear picture of how and why the tool was used. Some advantages and disadvantages are listed. The goal of this review was not comparing these software and nominate the best one, which by the way is not possible, but to show the capabilities and limits in design research. Nonetheless, explaining the annotation tools through the annotation experiments seems to provide a good overview of tools' capabilities and possibilities.

1. VideoGraph

Videograph is a free tool, windows platform, which enables the construction of observation categories and rating scales which the viewer can use as a "measuring instrument" to analyze the contents of the video.
In the usage presented here, the study follows the scope of the international workshop DTRS7, which is held on London on September 2007 [17]. The data obtained from the workshop includes: DVDs of four meetings, transcriptions, materials used during the meetings, role description of all participants along with the seating plan. The aim of this research was to see if it is possible to keep the trace of the design meetings by intermediary objects. As the first objective, researcher needs to become familiar with the data and to have an overview of the meeting. Then, a deeper analysis was realized in order to identify the intermediary objects and their activity level.
Videograph was selected for this project. A coding schema of all objects observed during the meeting was developed. Each object was labelled "active" as long as it was used or produced by any of the participants. By coding the video, it became possible to see the object types which were more active than the others, at different phases of the meeting.

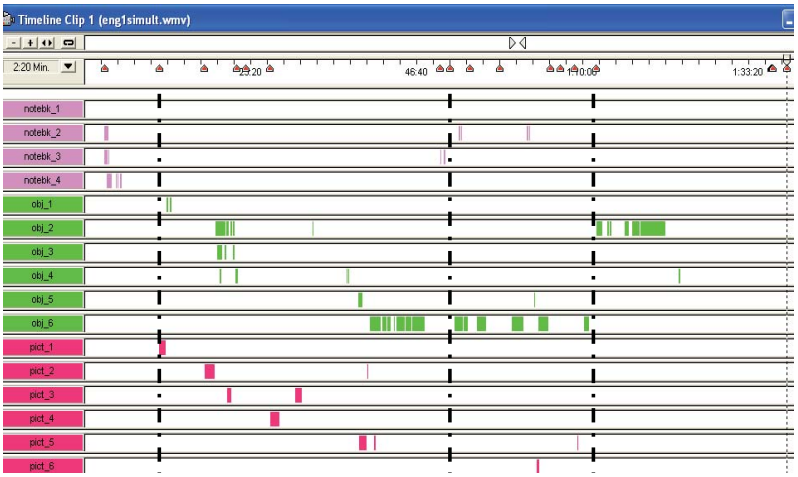


Figure 2 - Videograph report of the coded observation

Videograph was also used for a detailed analysis of a relevant meeting sample to identify all kinds of visible interactions that engineers could have with an object. So, there were two analyzing axes. The first one is the objects which are active on the analyzed period and the interactions of the actors with those objects.

From this experiment, Videograph is easy to use; it is possible to redefine, modify or delete coding variables within the program while it is running. Using different colors for each category makes the coding and also analyzing process easier. It is possible to put some notes on the time interval, which helps the practice of coding. Once the coding finished, the data sets are shown graphically on the screen and can be transferred to spreadsheet software like Excel. This Excel format gives start and End point of coding sequences. However, there is no possibility to make sub-categories. The software does not support the multi-streaming. The extracted data are not easy to manipulate.

2. Anvil

Anvil is a research tool for audio video annotation, written in JAVA language by Michaël Kipp in 2001 [18]. This tool has been implemented to study multimodal information such as gesture, speech or any other visual or auditory signal coming from a digitized audiovisual stream. Anvil's overall design is object oriented. The coding scheme has to be written in an XML specification file, according to a formal description of the tracks, elements, attributes and their possible values.
In a research project on design of a surgical simulator in Laboratory of Informatics of Grenoble (LIG), Anvil was selected for annotation and analysis of the surgeon's hand movements. The goal of the research was to decompose the operational techniques into the simple hand gestures and movements.

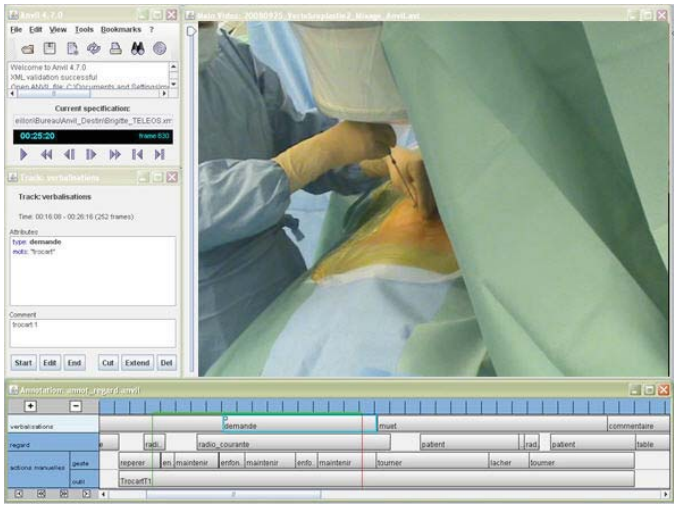


Figure 3 - Anvil coding screen

In Anvil, the concept of coding is defined by temporal "tracks", for instance a gesture, verbalizations, and gaze. Tracks can be independent or related to a "reference track". Each track contains several "elements" (e.g. question, request, order for the verbalization track) and each element can hold a number of "attribute" value-pairs. It's also possible to define non temporal tracks (called "sets"), to provide a list of objects, which can be linked to an element. For example, the Object "set" (such as radio, patient, table, colleagues) can be linked to the Gaze "element" in an operating room. Figure X shows an extraction of the Anvil.
As it was mentioned, the coding scheme should be developed separately in an XML file. Although some templates are provided in the software library, the XML coding is not obvious to make for a design researcher. The graphical user interface of Anvil is very user friendly and it's quite easy to perform annotations through guide windows, once the specification file is written.
An important feature of Anvil software is the possibility to gather several annotation files in a project (the concerned annotations files must have the same coding specification file) and search for a specific

track over all the files. The output file resulting from an annotation process is called the “annotation file” and is provided in XML language.

Anvil is a very convenient tool for video annotation. It is platform independent and based on XML, so that people can use all the free tools provided for the manipulation and conversion of XML files to analyze their annotation data. Anvil gives the possibility to register external “plug-in” and some of them are available on the Web.
However, the input video format in Anvil is very limited and unfortunately the common MPEG format is not supported. During the annotation phases, a small ergonomic problem exists that affect assigning the coding to the relevant time line track.

3. Actogram (Kronos)

Actogram is a Windows software for chronologic observation treatment. In this software, the events are considered like the state generator for a class, thus the categorization is up to the user based on the description protocol (framework) [19]. Actogram is selected for a research project in ICAR research center, Lyon, France, in which the dynamics of argumentation was investigated in a design situation. The main goal of the project was to identify the convergence factors to a new solution. The corpus of a design experiment was selected for the annotation and analysis.

Actogram was used in this research aiming to find the interaction between different kinds of objects like people, tools, in order to describe what is happening during the session. Thus, by making the coding scheme and the coding, Actogram helped to decompose the complex situation into the detailed description. Once the coding completed, the researchers made some hypothesis about the patterns of happenings. They used the Actogram for first analysis for the hypotheses evaluation. Figure 4 shows an example of the software workspace.
This software is simple to use, and very much likely for the coding scheme making. In the coding phase, the right-click function helps the process to be fast. The software supports the multi streaming and showing the coding scheme categorization during the coding is handy. For the analysis, the result presentation is very easy to parameterize, and is not restricted. The software is very useful is pattern research.

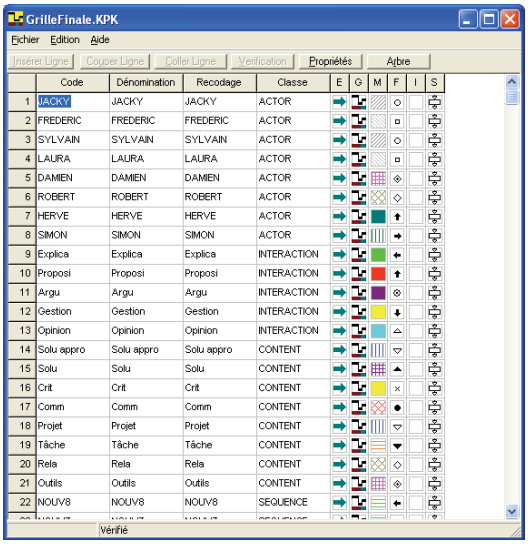


Figure 4 - Actogram coding screen

However, the software didn’t show enough stability and happened to close suddenly some times. Stream entry has a strict format, and coding scheme entry has some difficult obligations. The video is not linked up to the coding, thus the user should replay manually and find the appropriate time to see the happening. The coding page doesn’t have the timeline presentation which can be considered as a lack.

4. The Observer XT

The Observer XT® is a commercial product from Noldus Information Technology, The Netherlands. This software is a professional software package for the collection, analysis and presentation of observational data and has the capability to define independent variables and link them to a specific observation. In a research project on design process of innovative surgical instruments, the surgeon-designer collaboration was studied during the development [20]. That study passed through the observation in the operating room, data capturing, and analysis and interpreting of the recordings. The main goal of the study was to extract and analysis of the communication between surgeon and engineer in the operating room, for which the discussion, use of design artifact and use of operating room equipments should be annotated.
The Observer XT was selected according to the primary qualification criteria of multi-stream support and analyzing capabilities.

Coding scheme in The Observer has three categories: Subject, Behavior, and Modifier. There are no limits in making subcategories, and the (sub)category elements can be grouped, as shown in the Figure 5. For example, “Dr. Smith moves his right hand down during the operation pushing down a screw” can be coded as the following:
Dr. Smith > Surgeons > Subject
Push down > Right hand movements > Hand movements > Behavior
Screw > surgical tools > Modifier

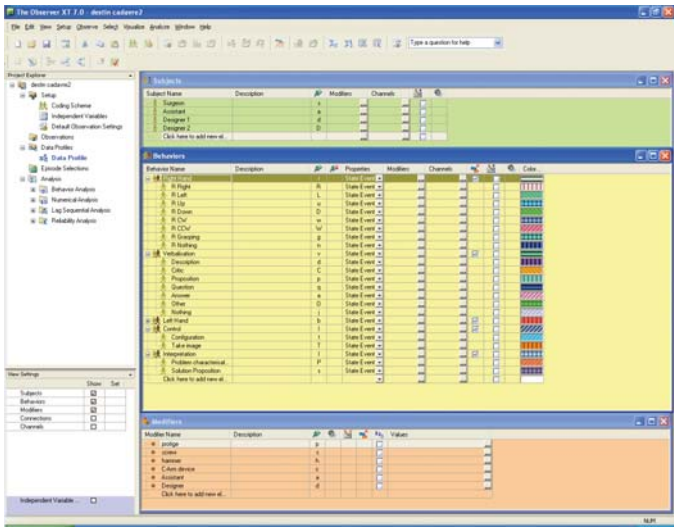


Figure 5 - The Observer coding scheme configuration

In order to annotate an observation from an emulation in the operating room, an analytical framework has been developed and the software was accordingly configured. Subjects were divided into surgeons and engineers, so the persons’ name entered in the subcategories. Behavior was divided into gestural movements, control movements, and the surgeon’s verbalization. Thus, a grammar of possible gesture in detail was developed for the first category. Control gesture was subcategorized into visual and tangible. And the verbalization was subcategorized into description, critique, proposition, question and answer.
The observer provides some facilities for coding, by simple keyboard shortcuts or by clicking on the coding scheme table while the movie stream is playing. Nonetheless, coding in this level of detail took a large amount of time.

For analysis part, the observer generates descriptive statistics and graphs instantly, formatted the way it is needed which is very helpful. It calculates statistics and creates transition matrix. A system called filtering provides the possibility of analyzing group of annotations, totally free in configuration.
One very interesting feature of this software is to make clips of those parts of video and data on demand. This extract feature has a great value in working as a team and takes an intermediate tool role

in group. However, having many functions makes the usage complex and depending on the very correct configuration. The commercial price of the software makes it high and not accessible for any research group, and as there is no trial version, it is not easy to make the decision to buy and base the research on The Observer XT.

Reviewing these cases helps to see the big picture about an annotation process in a design research. In the next section, the general evaluation criteria for an annotation tool is provided and accordingly, the software explained above are compared by their functionalities.

5 DISCUSSION AND SUGGESTIONS

At the time of this research, several interesting video annotation software were found, among them some selected to be presented in the paper. Although selecting an annotation tool for a research is highly depending on the focus and the objectives of the research, having some evaluation criteria could help finding the best match. In this section, a list of evaluation criteria for annotation tools is presented in five main categories: Configuration, Coding, Analysis, Data entry, and General characteristics of the software. Table 1 shows these criteria and typical values in detail.

A qualitative comparison of the software explained in the section four is provided using the mentioned evaluation criteria. The evaluation is based on the two researchers per software opinion, which has gathered by interviewing and simple questionnaires. Figure 6 shows the evaluation graph.

Table 1 - Annotation criteria range for existing software

Main criteria	Sub-criteria	Negative	Positive
Configuration	Subcategory level	2-level limited	Unlimited
	Modifiability during the coding	Not possible	Real-time
Coding	Coding shortcuts	No shortcuts	Keyboard and mouse
	Time line demonstration	Not available	Dynamic
	Punctual event coding	Not possible	Possible
Analysis	Data export	Struggle numbers	Standard format
	Integrated analysis tool	Not available	Graphs, tables, etc.
	Coding reliability	Not available	Multi-user reliability control
Data entry	Video format and codec	Limited	Various format
	Multi-stream entry	Not available	Up to 8 streams
General characteristics	Software stability	Unstable	Stable, data recovery
	Operating system limitation	Limited to Mac OS	Windows and Mac OS
	Usage ergonomics	Non standard	Standard
	Sample version	Not available	Available
	Price	High price	Free

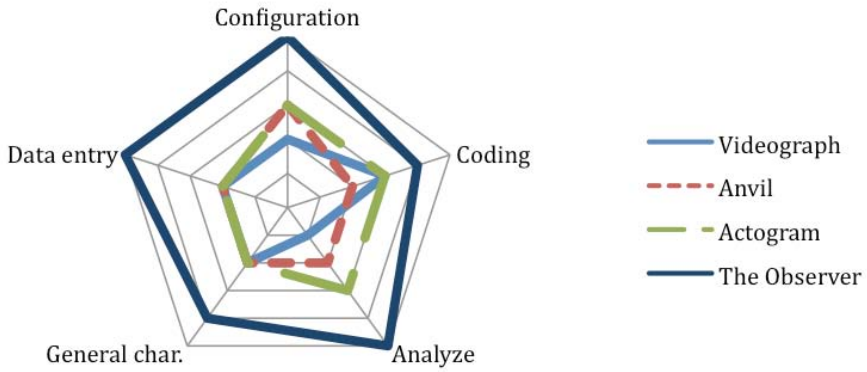


Figure 6 - Comparison of four annotation software

So far, video annotation software used for different design research objectives, but any study explored the specific requirement of design research of an annotation tool. Such a study should investigate the user requirements and the technical capabilities of software developments. Meanwhile, there are some functions listed below as result of our experiments in this field. Nonetheless, listing these requirements could demonstrate an image of the ideal software for the design studies, and can be evaluated and improved by the researchers in this field. Here is a list of design requirements, shown in table 2.

Table 2 – Main criteria for an ideal annotation tools

Configuration requirements
Flexible and non-limited level of subcategories Standard for coding scheme Library of coding scheme that can be used for different annotation Modifiability of coding scheme during the coding with trackback the evolution
Coding requirements
Simple and ergonomic interface, improvement in specific hardware Extended techniques for linking the coding to the video stream Automatic coding (ex. using pattern recognition)
Analysis
Features for reliability control of coding process (different persons, different channel) Tools for simple analytical reports like graphs, tables, etc. Export data compatibility with the common statistic analysis software

6 CONCLUSION

This research has attempted to explain the annotation process by the definition and by looking through the design studies where an annotation tool has been used. The aim of this study was to determine the characteristics of existing annotation software through the design studies, and to explore about the possible functions of an ideal annotation tool for design research.

We review different annotation tools and extract a list of evaluation criteria for the functionality of these software. It seems clear that selecting an annotation tool is highly depended on the project objectives, researchers expects and qualifications and also on the financial support of the project. Making the technical comparison in this various tools wouldn't have provided any better information than what can easily found on the internet. Nonetheless, in this study we tried to make a functional

comparison of selected annotation tools, aiming to provide a decision making help for researchers in this field.
Finally, since there are too many annotation tools, our selection was limited on the authors' former experiences and studies from the regional design community. We therefore look for several usage experiences on the same annotation tool, to find out more about the tool functionality and relevance.

In our future work, we will firstly extend our selection chamber to have more design research cases using annotation, and then we investigate the possible evolution to reach a well defined architecture for ideal annotation software.

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Appendix 4

Annot'Action tool

Notice: *This text has been extracted from this paper:*
Hisarciklilar, O., Rasoulifar, R., Boujut, J.-F., Thomann, G., Villeneuve, F., 2009. User - designer collaboration in the design process of surgical instruments: New aspects for annotation as a communication tool. In: ICED09. Design Society, Stanford, CA.

Like practitioners in other disciplines such as chemistry or architecture, engineering design actors often use 3D artifacts to communicate complex concepts. 3D artifacts are effective to provide common representations of design solutions to participants from different disciplines (such as between technical and non technical actors). Therefore, these artifacts are more and more set out to support the design communication, specifically the discussion of artifact-centered design issues. Lightweight versions of CAD representations, such as VRML[1] format, have been proven to be effective to share and manipulate 3D design information over distributed actors. Lightweight representations provide an easy way to share and manipulate versions of CAD models. Their usage becomes common, especially to communicate 3D representations to external partners or to users.
Several software tools have been proposed in research in order to facilitate annotation practices in lightweight 3D representations across distributed teams. For instance, (Jung, Gross et al. 2002) has developed the Immersive Redliner software for asynchronous communication between designers and users around lightweight representations in architectural design context. (Craig and Zimring 2002) proposed Immersive Discussion Tool (IDT) for synchronous annotation of architectural 3D models. IDT allows users to leave arrows to designate specific points of the design to point out specific information or evaluate models. In engineering design context, (Aubry, Thouvenin et al. 2007) developed a textual annotation tool on 3D lightweight representations with ontology support for increased search functionalities.
In the research presented in this paper, the Annot'Action tool has been used. Annot'Action[2] has been designed to create virtual workgroups for asynchronous annotation of VRML models. Participants in a workgroup are represented by their expertises. The tool allows the annotation of co-constructed argumentation trees to 3D representations. Each node of an argumentation tree contains a textual message and metadata on the textual content.

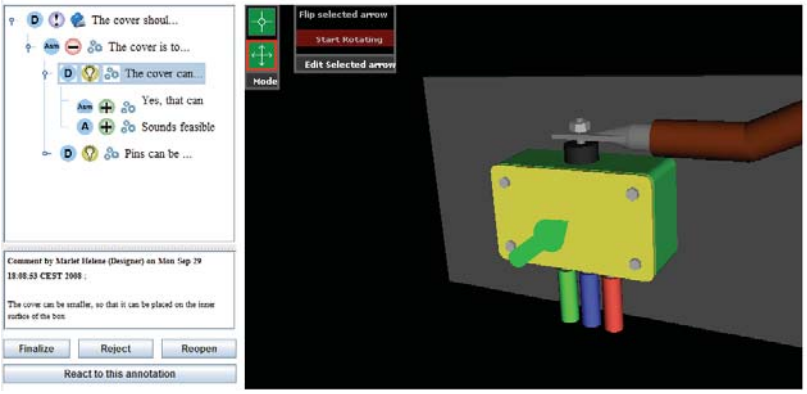
Annot`Action is a web 2.0-based annotation tool of VRML representations, developed in University of Grenoble, 2008 (Hisarciklilar 2008). The tool has been designed to support asynchronous communication of cross-functional design teams. The tool allows designers to create workgroups around specific design tasks (projects). Each project is divided into milestones, which represent a different version of the design solution. A series of VRML objects (views) can be shared in a milestone.

[1] Virtual Reality Mark-up Language
[2] http://annotaction.g-scop.fr/www/index.php

The asynchronous collaboration is achieved through annotations related to the views. The first level of the annotation structure consists of the 3D symbol attached (anchored) to a particular point of the VRML object, pointing to the problematic zone. The second level is a tree consisting of nodes (interventions) and links connecting them to each other. The intervention nodes are connected to each other, forming a tree-like argumentation structure. Participants communicate through co-constructing these argumentation trees. The objective of this structure is to have a conversational dimension by allowing participants to interact each-others.
Each node on an argumentation tree has a semantic structure, which is represented by a combination of three symbols. This semantic structure aims to enhance the textual core of each node, in order to facilitate the recognition of the textual content and the conversational flow on an argumentation tree. The three symbols consist of:

- The role of the participant in the project,
- The intent of the author (clarification, evaluation or proposition)
- The purpose of the textual content (a project requirement or problem-related constraint, a domain-specific constraint or the current solution)

This structure has been presented in (Hisarciklilar and Boujut 2007) illustrates an example of an annotated VRML object. The pointing arrow on the VRML object (right side) refers to the argumentation tree (left side).



An annotated VRML object in Annot`Action

Using Annot'Action in the Protige project

Observations for this study have been focused on two successive design reviews. The first one has occurred between the engineering team members, where the participants have validated a series of issues concerning the solution. During the second review, the modified solution has been discussed by the surgeon and the engineering team. The Annot`Action tool has been used by the engineering team before and during the first review.
Our observations have been focused on two main points. We have investigated whether the early sharing and discussion of the solution through an annotation tool may aid to achieve a more systematic cooperation between the participants.
The second point of interest of our observation was to see how engineers have acted when faced with design issues concerning the usage of the product during the solution development phase. We more particularly observed how accurately the usage requirements were perceived by the designers and whether the solutions they produced according to theses perceptions satisfied the needs of the user.
Through these observations, we tried to find out whether the integration of the user in the development phase facilitates the convergence towards a more satisfying solution, and how an annotation tool could help to fulfill this integration. Our observations related to the process are presented in the following. Annotations functionalities for user integration are discussed in the fifth section.

Asynchronous design phase

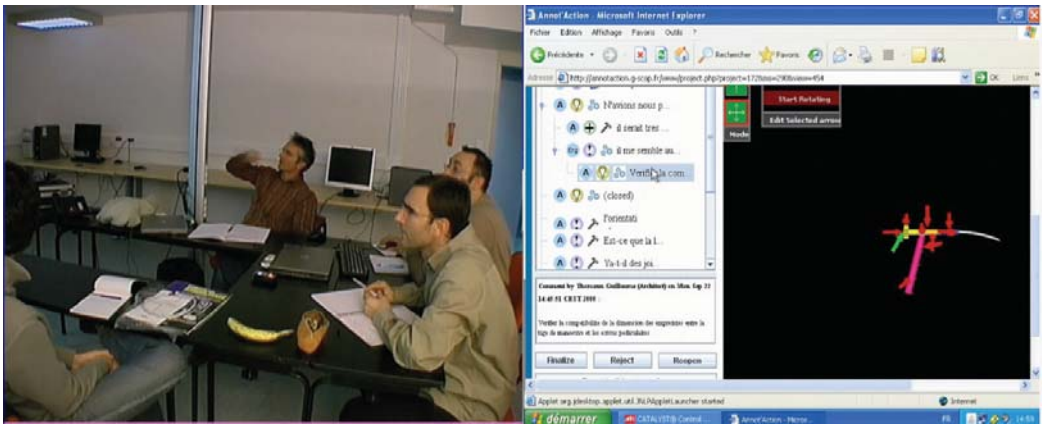
Prior to the review, the engineering team has shared a lightweight version of the CAD model through the Annot'Action tool. The shared model contained the latest modifications proposed by the designer following the last design review session.

The participants had the opportunity to review the model first to obtain information on the ongoing design prior to the review in order to construct their personal point of view before the review. Second, the participants have annotated the model for storing and sharing their comments and proposals initiating a preliminary discussion. Their objective was to acquire further understanding of the respective points of view and elaborating the issues list of the next design review.

Technical design review

Technical design review was a face-to-face situation, where engineers have sought to validate the design modifications regarding the mechanical, ergonomic and manufacturing constraints prior to the next review with the surgeon.

Participants have used the annotated version of the model as the shared artefact during the review. The issues raised during the asynchronous annotation session have been reviewed and discussed. When an issue was concluded an agreement or a corrective action, then the participants added further nodes on the argumentation trees to record them shows a capture of the recorded video (left side) and the shared screen (right side) during the review.



Engineering team discussing on annotated comments

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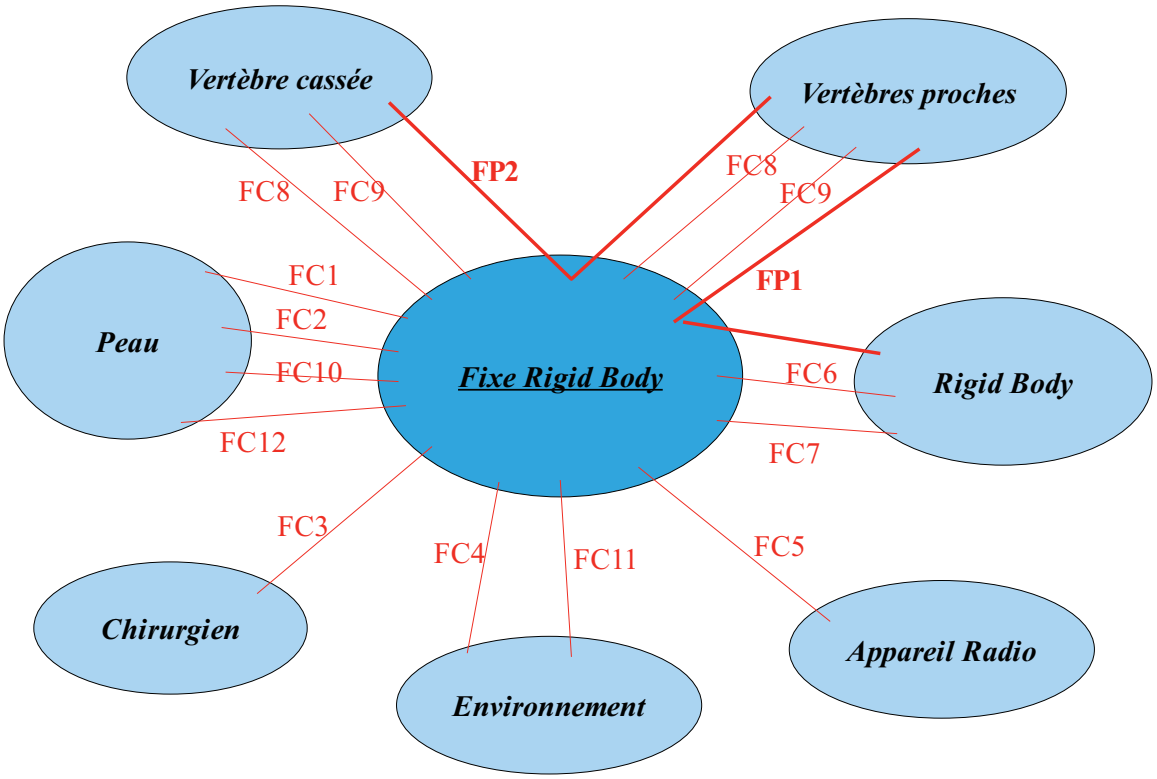
Appendix 5 - Spine Ref functional analysis



FP1 : Fixer le *Rigid Body* à la colonne vertébrale

FP2 : Rigidifier la colonne vertébrale durant l'opération

FC1 : Être à l'extérieur du corps humain

FC2 : Minimiser les incisions sur le patient

FC3 : Limiter l'encombrement pour ne pas gêner le chirurgien

FC4 : Être à usage unique

FC5 : Être radio–transparent

FC6 : Incliner le *Rigid Body* entre 30° et 60° par rapport à l'horizontale

FC7 : Se fixer de façon démontable au *Rigid Body*

FC8 : Se fixer de façon démontable aux vertèbres

FC9 : Limiter les contraintes sur les vertèbres

FC10 : S'adapter à toutes les morphologies

FC11 : Être stérile

FC12 : Utiliser des matériaux adaptés au corps humain

FONCTIONS, CRITÈRES ET NIVEAUX DE CRITÈRES :

Nom de la fonction	*Objet de la fonction*	*Critère*	*Niveau*	*Flexibilité*
FP1 : Fixer rigidement le *Rigid Body* à la colonne vertébrale	Le *Rigid Body* doit être lié de façon rigide aux vertèbres, afin de réaliser un repère fiable	jeu	jeu nul	0
FP2 : Rigidifier la colonne vertébrale durant l''opération	La ridification de la colonne permet de limiter les mouvements et d'améliorer le repérage	jeu	jeu nul	0
FC1 : Être à l'extérieur du corps humain	La chirurgie mini-invasive est beaucoup moins traumatisante pour le patient			
FC2 : Minimiser les incisions sur le patient	Idem	Taille des broches	1,5 mm	
FC3 : Limiter l'encombrement pour ne pas gêner le chirurgien	Le *Rigid Body* doit être placé de façon à ne pas gêner le chirurgien	Volume	Dimensions restreintes	
FC4 : Être jetable	L'usage unique est intéressant pour le chirurgien et d'un point de vue commercial	Fabrication en polyéthylène		
FC5 : Être radio-transparent	Le *Fixe Rigid Body* ne doit pas interférer avec la radiographie	Radio transparence		Parasites
FC6 : Incliner le *Rigid Body* entre 30° et 60° par rapport à l'horizontale	L'inclinaison facilite le repérage par le software	Angle	57°	30°
FC7 : Se fixer de façon démontable au *Rigid Body*	Le *Rigid Body* est standard et est réutilisé pour chaque opération	Liaison démontable		0
FC8 : Se fixer de façon démontable aux vertèbres	Le patient ne gardera pas le *Fixe Rigid Body* sur son corps	Liaison démontable		0
FC9 : Limiter les contraintes sur les vertèbres	L'ensemble *Rigid Body* et *Fixe Rigid Body* ne doit pas exercer un couple ou une force trop importante sur la colonne vertébrale	Forces, couples		
FC10 : S'adapter à toutes les morphologies	Le *Fixe Rigid Body* doit être standard et doit donc s'adapter à tout type de patient	Épaisseur de la peau, taille des vertèbres	Dimensions limites	
FC11 : Être stérile	Le *Fixe Rigid Body* ne doit pas infecter le patient			0
FC12 : Utiliser des matériaux adaptés au corps humain	Le corps humain doit accepter le *Fixe Rigid Body* sans le détériorer	Polyéthylène		

DIAGRAMME FAST :

Fonctions de services	*Fonction technologiques*	*Solutions Technologiques*
FP1	Liaison encastrement	Broches + Trous pré-percés, Serrage à oreilles
FP2	Liaison encastrement	Broches + Trous pré-percés
FC1	Liaison adaptée	Fixe RB posé sur le patient
FC2	Eléments de liaisons petits	Broches 1,5 mm
FC3	Taille restreinte	Dimensions adaptées
FC4	Usage unique	Fabrication en polyéthylène
FC5	Radio-transparence	Fabrication en polyéthylène
FC6	Liaison adaptée	Fixation inclinée par rapport à la base de la pièce
FC7	Liaison adaptée	Serrage à oreilles + vis
FC8	Eléments de liaisons adaptés	Broches retirables
FC9	Limiter les contraintes, bras de levier etc	Centre de gravité au milieu de la pièce Trous répartis symétriquement
FC10	Etre utilisable sur différents types de colonnes vertébrales	Nombre et positions de trous pré-percés
FC11	Stérilité	Fabrication en polyéthylène
FC12	Non détérioration du corps par le matériau	Fabrication en polyéthylène