ON THE TYPES AND ROLES OF DEMONSTRATORS FOR DESIGNING MEDICAL DEVICES

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ABSTRACT
Unlike many fields that make the most of advances in numerical modeling and simulation, actors involved in medical technologies R&D have more and more recourse to demonstrators when designing a product. These concrete materializations are a handy support at certain stages, but an inadequate use of mock-ups and prototypes can lead to tackling the problem in a roundabout way, at the risk of ending with an unsuitable product that does not meet the users' needs. Based on our own experience in research projects in close collaboration with clinicians, this paper tries to sort out the different types and characteristics of demonstrators, regarding their potential uses at the successive stages of the design process. The general discussion is clarified by several illustrative examples that underline the important roles demonstrators play to help designers finding the right way on the winding path towards an innovative and useful medical device.

Keywords: Model, mock-up, prototype, design for medicine, clinicians-engineers collaboration

1 INTRODUCTION
"One day a young surgeon entered the office of a professor of mechanical engineering, holding a wood model […] of a robot structure of approximately 66 degrees of freedom (DOF). He asked the engineer: *Could you build this robot for me?*" [1]. The intention of the surgeon, a specialist in maxillofacial surgery, was to have a robot build that would help him make complex operations by displacing with high precision up to five fragments of maxilla inside the patient's mouth. As depicted in Figure 1, the final solution proposed by the engineering team is very different from the initial wood model (which is in fact a mock-up, as explained in section 2). A prototype with 6 non-actuated DOF was built after several months of problem analysis and 4 more years of collaborative research and design. The project ended with the successive phases of verification and validation.
According to FDA and EU recommendations [2], verification is the confirmation that "specified requirements have been fulfilled", while validation is the confirmation that "particular requirements for a specific intended use can be consistently fulfilled". Verification testing of the device was rather encouraging and was followed by a first clinical trial. This last validation step demonstrated that, although the requirements were met, the proposed device was not as efficient as expected, because it did not solve the actual problem! As designers say, we built the *thing right*, but not the *right thing*…

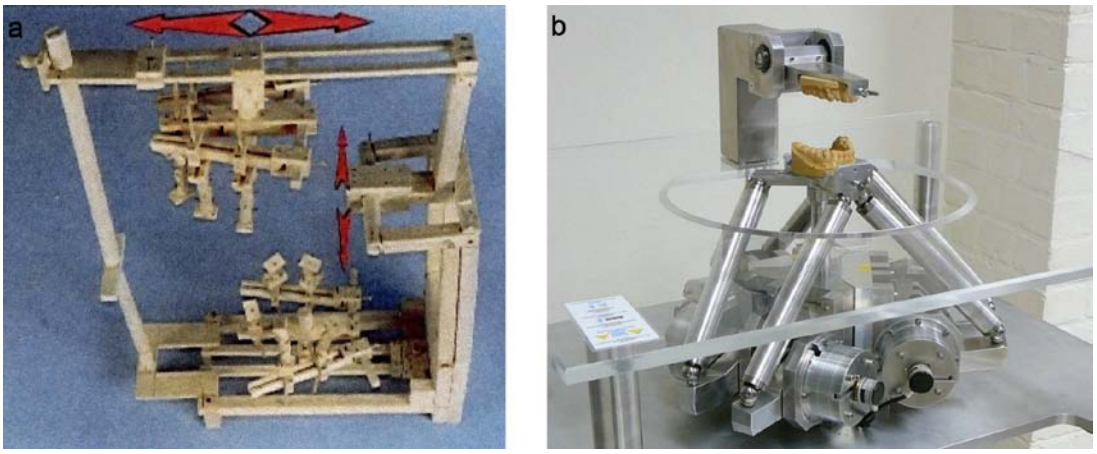

Figure 1. (a) Initial wood mock-up of maxillofacial robot presented by the surgeon [1] and (b) prototype of the solution proposed by the engineering team

The initial problem statement (the *design brief*) given by the surgeon was described with a wooden mock-up that presented a solution. This problem can be regarded as *ill-defined* or *ill-structured* because its formulation was solution-dependent [3]. Edward and Monika Lumsdaine [4] pointed out the problem of an expert who can be narrowly focused on what he/she knows so well. As a consequence he/she "tends to look beyond the familiar to new horizons". Such an approach often leads to slow refinement procedure [5] but very rarely to paradigm shifts. In [6], Barker introduced the concepts of paradigm paralysis, paradigm shifts and paradigm pioneers: "a paradigm is a model or pattern based on a set of rules that defines boundaries and specifies how to be successful at and within these boundaries" [7]. A paradigm shift occurs when a novel idea replaces the old one. A paradigm paralysis means that the designer is frozen with an idea that was successful in the past, and thinks that it will continue to be successful in the future if the idea is merely refined. On the other hand, a paradigm pioneer is someone who breaks existing rules, and as a consequence is ready to take some risks. It is important to notice that performing a paradigm shift depends not only on people but also on circumstances. When designing a medical device, minimizing the risk is of upmost importance – *primum non nocere*. As a consequence, there is a natural tendency to paradigm paralysis, or at least to a slow refinement of the well-established medical procedure.

Our example of the maxillofacial robot is clearly a case of paradigm paralysis attitude. The surgeon was convinced that with the device he wanted, he would do much better without having to change the whole surgical procedure. The presentation of the wooden mock-up has an unintended influence on the problem description, as it focuses the discussion between the clinician and the engineering team on the desired solution and not on the real problem to solve.

The first clinical trial was the trigger to a deeper and broader analysis of the limitations of the current surgical procedure. Patients and surgeons global wishes were established: reduction of muscular pain, mastication disorders, and aesthetic troubles (main indications to surgery), better and more precise planning of bone cutting and displacement, increase of post-operative bone stability, and diminution of surgery duration. This new problem formulation seemed much more ambitious but thanks to the increased freedom for designers, a better solution was proposed. Several novel and less complex ideas were imagined and verified with partial mock-ups and prototypes (see Figure 2), and finally included in a completely redefined surgical procedure. Validation clinical trial successfully demonstrated feasibility and advantages for both patients and practitioners, and a spin-off company is currently being launched to market the new technology.

Through this example one can see that models, mock-ups and prototypes, or more generally *demonstrators*, were used all the way through the design process with sometimes a positive impact but sometimes a more adverse influence. The key purpose of this paper is to analyze and discuss the roles of demonstrators in the particular case of medical design in close collaboration with clinicians.

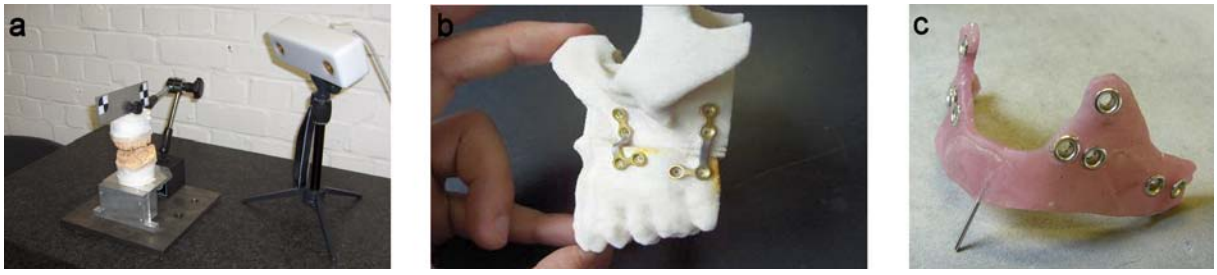

Figure 2. Verification mock-ups and prototypes of the novel solution after re-establishment of patients and surgeons needs: (a) localization device to measure the required bone displacements, (b) rapid prototyping full-size model of the desired displacement after CT-scan based simulation, and (c) template to guide gestures during procedure.

2 DEMONSTRATORS: WHAT FOR AND WHAT FORM?

Models, mock-ups and prototypes can take many forms: scaled or full-size, functional or not, representing the product itself or its environment. But obviously, all forms cannot play the same role during the design process. Therefore, we postulate that each step of this process requires a particular type of demonstrator with specific characteristics.

This section first sorts out materialization purposes in function of the design stage. Based on our own experience, required demonstrators characteristics are deduced subsequently. This classification is summarized in Table 1, which follows a design process adapted from Cross [3] that falls into the concurrent engineering methods class [8]. This taxonomy of demonstrators types is in accordance with most authors of engineering design books, such as [9]. Our analysis below shows that a particular type of demonstrator can be used during some successive steps. We therefore divided the Cross's steps into 3 main stages, close to French's descriptive model [10]: Needs analysis, Conceptual design, and Detail design.

Table 1. Main purposes and subsequent type and characteristics of demonstrators during the design process of medical devices

Stage in the design process		Materialization purposes	Type and characteristics
Needs analysis	Clarifying objectives Establishing functions	Illustration of a medical problem Description of anatomy Description of medical technique/gesture Vocabulary exchange	Scaled or full-size anatomical/pathological model Solution-independent!
	Setting requirements Determining characteristics	Performance quantification for a specific requirement	Full-size anatomical/pathological model
Conceptual design	Generating alternatives	Feasibility assessment of an original solution	Partial functional mock-up
	Evaluating alternatives	Experimental comparison of technical (sub-)solutions Global solution(s) presentation Check of mutual understanding Check of adequacy to objectives and user's needs	Partial functional mock-up of technical solutions for specific functions Passive scaled mock-up of complete device(s)
Detail design	Proving the concept	Preliminary in vitro trials Early in vivo/preclinical experiment	Partial functional prototype (implementation of all main functions)
	Improving details Finalizing the product	Technological transfer for industrial production Improvement of ergonomics Clinical trials Filing of regulatory procedures (e.g. CE certification, FDA approval)	Pilot prototype Batch of industrial prototypes

2.1 Needs analysis

As the introductive example shows, understanding a clinician's need is no small task for a design engineer or a researcher. Unfortunately, an incomplete identification of the problem to solve can have serious consequences, leading sometimes to a non-efficient product. Tanzillo [11] states that nearly half of all costs in design projects of medical devices are spent to correct inadequate features or even add ones that were not initially translated into requirements.

Several well-known tools, such as Cross's objectives tree or a careful functional analysis along with a matrix checklist [2], can be used during brainstorming discussions to help the clinician to express and objectify the medical needs. However, these design methods cannot guarantee completely that the essential problem will be discovered and fully described. Indeed, many communication issues often occur between clinicians and engineers during this initial stage [1]: vocabulary problems, especially words that are used by both clinicians and engineers but with different meanings, information that seems obvious for clinicians and remains untold, mandatory steps of a surgical procedure that are in fact imposed only by the use of a specific device or technique that could be avoided etc.

Scaled and full-size *anatomical/pathological models* (e.g. plastic bones and organs, dummies, see Figure 3) can be useful complements to the methods mentioned above, that can reinforce exchanges and discussions during the objectives clarification. By focusing on the anatomy, the clinician can

explain more easily the medical need – *what* the device must do – without drifting to ideas of solutions – *how* it has to be done, or *how* it is done currently with existing tools – that can lead to a non-efficient local optimum, as in the introductive example.
Models are also teaching aids for engineers to become rapidly familiar with the basics of the medical specialty. Of course, they cannot completely replace immersion into the real practice (e.g. discussion with patients, attendance to several surgical procedures). However, they are a good material support for discussions in an office, where clinicians do not have to give explanations while performing a difficult task on a patient.
When it comes to putting values on requirements, models can again play a helpful role. For example, orthopedic surgeons and mechanical engineers have different subjective interpretations of the accuracy of a planar cut. Performing experimental measures of the quality of a surgical gesture on full-size plastic bones allows a more objective quantification of requirements [12], as direct *in situ* measurements are not always possible. Bulkiness has also a different meaning for an engineer and a surgeon. A discussion about the maximum size of a device can rapidly become a subjective and sterile negotiation. Bringing cardboard boxes in the operating room to "simulate" this maximum allowed size can be by far more cost-effective.

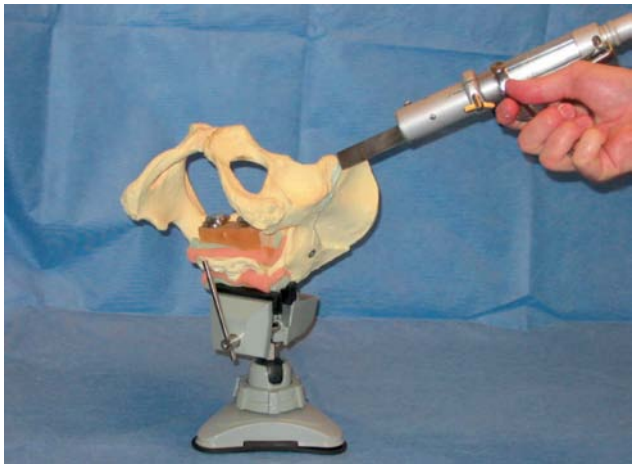

Figure 3. Plastic model of bone used for experimental quantification of cutting accuracy [12]

2.2 Conceptual design

In the early creative phase, designers are encouraged to propose and explore as many ideas as possible. Sometimes, the best solution will emerge form an idea that first seemed impossible or harebrained. This is true especially in the case of research projects on completely novel devices, in opposition to the refinement of an existing product. Originality is obviously of high importance to differentiate from competitors in niche markets such as medical technologies. Nevertheless, engineers must also ensure soon enough that their innovative solution is feasible in order to detect a potential deadlock as early as possible. At the stage of solution generation, building a partial functional *mock-up* of an original alternative for a key function of the device can help engineers in objectifying its feasibility.
Functional mock-ups are also an interesting tool during the following step of solutions evaluation. Experimental comparison of several rival solutions for a (subset of) function(s) is sometimes more efficient than computation or numerical simulations, as illustrated in section 4.2 below. It should also be emphasized that the ongoing diffusion and democratization of rapid prototyping technologies can accelerate the materialization of mock-ups.
At the end of the conceptual design phase, engineers are generally rather confident in their solution. But morphological charts, preliminary sizing calculations and weighted comparison tables are less decisive arguments to convince clinicians. The latter are more sensitive to seeing and touching tangible objects than to a 100-pages technical report. In a way, a passive mock-up is the privileged pedagogic support for an engineer to explain technical issues to a clinician, like the anatomical model used by a therapist in the first phase. It helps the end-user to verify that the proposed product answers actually his/her hopes and expectations, and that all faces of the initial problem have been identified

and solved. Iteration at this moment is really less harmful for the project than after the building of a first functional device.

2.3 Detail design

The proof of concept step focuses on the implementation and verification of the solutions for the main functions of the device. In particular, ergonomics and specific safety issues that depend on the outer embodiment are left aside at this stage. A first partial functional prototype is designed and produced, with as few custom parts as possible and using rapid and low-cost prototyping processes. After adjustment trials, it is used to perform the demonstration of pertinence and performance of the solution selected at the end of the conceptual design with clinicians. The latter are again involved in the experimentations, performed *in vitro* on benchmarks and plastic models, or even on animal organs, bones, or pieces of meat. It is not unusual that one or more design iterations and prototype update are required, in order to meet the specifications stated during the needs analysis.

The next step intends to shift from a rough prototype to a fully functional device that would satisfy the severe requirements of a first clinical use, with the mandatory agreement of the hospital's ethics committee. More than detail improvements, most of the device is generally redrawn and optimized with specific attention paid to safety, ergonomics and usability. Components with clearance for medical use must now be preferred. The fully-functional pilot prototype enters then the validation process with a first clinical trial.

Finally, certification procedures (e.g. FDA approval, CE marking) have to be fulfilled for being allowed to bring the product to market. A batch of industrial prototypes must be built so as to perform certification trials in parallel with a wider randomized clinical trial. Minor improvements are usually required to lead to this nearly finalized product.

3 DISCUSSION

Our definition of a demonstrator is close to what Hubka and Eder call a *model*: "A *model of a technical system* is a complete or partial picture of an original (Urbild, prototype) of the reality, visualization or idea. The degree of similarity (analogy) between original and model can extend from similarity (analogy) in only one property, up to identity (complete similarity)" [13]. Most of the usages that we proposed in section 2 are in accordance with the 4 common purposes of their models for designing:

- To demonstrate the properties of a technical system;
- To optimize the organization;
- To test an hypothesis or a constructive solution of the device;
- For concrete planning, projecting, designing.

In many fields (e.g. automotive, aircraft, architecture and civil engineering) the ongoing tendency is to replace *concrete* demonstrators by *virtual* demonstrators (which fit also with Hubka and Eder's definition of *models*), especially during the conceptual design and the early steps of detail design using computer-aided design, computer-aided drafting and virtual reality software [14]. For example, assessment of functionality and ergonomics of a car dashboard can be conducted using a virtual reality simulator. However, the medical domain is an exception to this general digital trend for three main reasons. The first one is linked to the key role of demonstrators in the communication between clinicians and engineers. Both have their own codes and habits to represent the real world and these representations are not easily understandable by the other team. For example, the understanding of anatomic drawings or mechanical sketches requires deep knowledge in the particular domain. Our experience is that it is difficult to have a good discussion with medical teams and to avoid misunderstanding without a demonstrator. As stated in section 2, these are very precious tools to engage the discussion at different levels. The second reason is economical: medical applications require a "no-risk" solution but, at the same time, offer a generally low production volume with respect to many industrial fields. As a consequence, there are at the moment very few virtual reality and simulation platforms available for developing medical devices. In addition, each medical application is rather specific, and the virtual modeling of all interactions between the clinician, the patient and the device makes the development of suitable software difficult and expensive. The third reason lies in the fact that prototypes are required for certification. A wide majority of products can be sold after a phase of self-certification in accordance to well-known general norms and quality management procedures. Medical manufacturers are more closely supervised. A series of prototypes

must generally be sent to independent organizations for testing (e.g. electromagnetic interferences, sterility, behavior in case of electrical surge, risk in case of fall) in order to get the indispensable FDA approval or CE mark. This is similar to car crash tests performed by Euro NCAP on a new model before the manufacturer can sell it in many European countries.
We should also highlight the fact that models, required for identifying and discussing the problem at the clarification stage, can become a complement to the (written) specifications and so be used to start the conceptual design stage. In the same way a mock-up used during the conceptual design stage should be used as a basis for the detail design stage. Thus, in addition to their usefulness during specific steps, demonstrators are also complementary outputs that pave the way to the next phase.
Finally, we drew another lesson from the maxillofacial project. Through the Simplified Waterfall Model [2], the FDA states that verification loops have to be performed during the design process while the validation (clinical) trial comes only when the final output, namely the medical device, is built. Our example shows that this first confrontation with the user needs should not come that late in order to avoid wasting time and money in designing and building a product that works perfectly but does not bring any useful improvement for the user or the patient. Engineers should check as early as possible that the needs *expressed* by clinicians are close to their *actual* needs. As suggested in section 2.2, mock-ups of the proposed solution can be used during the conceptual design phase to perform a preliminary validation loop, as depicted in Figure 4. Indeed, even a partial and non-functional materialization put in the users' hands can help them to project themselves into clinical routine using the device, so as to detect possible weaknesses and, if necessary, refine the demand with key points that were not identified yet.
In summary, concrete demonstrators play 4 main roles for designing medical devices: communication support, thinking aid, cost-effective verification tool, and validation and certification material.

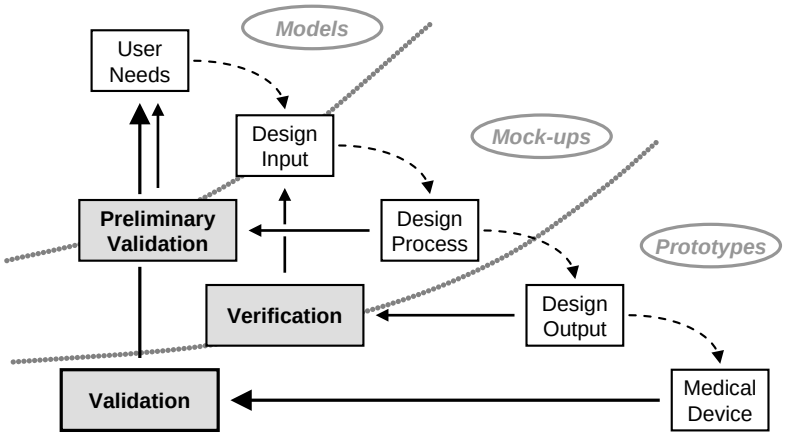

Figure 4. Simplified Waterfall Model with successive use of models, mock-ups and prototypes during the design process and the verification and validation steps; models and mock-ups can serve in a preliminary validation at the end of the conceptual design (adapted from [2])

4 ILLUSTRATIVE EXAMPLES

The above reflections will now be set back in practical context, through several examples from two research projects being carried out currently in our research centre, in close collaboration with practitioners. Both projects stem from the fact that many areas of medicine perceive in the progress of robotics, data processing and multimedia, an opportunity of developing robotic assistance tools to improve the therapist working conditions and to provide more efficient care to patients.
The first project deals with physical and rehabilitation medicine. Its purpose is to provide assistance to the therapist during upper limb rehabilitation for hemiplegic patients. Our solution consists in an original exoskeleton made of five modules governing the movements of the shoulder, elbow, and wrist and a novel control algorithm that uses an admittance virtual system to reproduce a compliant behavior (like a real therapist, in contrast to most existing robots that impose a trajectory to the arm) through different operating modes [15]. The algorithm and the electromechanical structure were devised and optimized separately through specific experimentations, as presented in sections 4.1 and 4.2 respectively, and integrated subsequently.

The second project aims at developing a robotic endoscope positioner for minimally invasive abdominal surgery [16]. It is an assistant that holds the camera and moves it when the surgeon asks with a remote control. As the robot works in the operating room just next to the patient and the surgical team, compactness, safety, sterility and ergonomics are important features, as well as ease of installation. Key verification and validation steps are summarized in section 4.3.

4.1 Preliminary validation of a control algorithm for the rehabilitation robot

To develop and validate the usefulness and efficiency of the control algorithm, we implemented it on a first *functional mock-up* (see Figure 5a). It is a planar 2 DOF robot whose end-effector supports a handle mounted on a force sensor via a free revolute joint. We preferred to work on this type of basic planar robot (instead of on an exoskeleton) for 3 main reasons. The first one is of practical nature, as it is simpler and easier to write the mathematical model and the resulting control law in a plane than in space. Secondly, it is closer to the exercises (e.g. moving objects on a table) that patients perform nowadays in clinical routine. The last reason is strategic. This approach allowed us to implement, tune and validate our control scheme without having to wait for the end of the electromechanical design of the modular exoskeleton. This first mock-up allowed us to *assess the suitability of the main objectives*, in terms of compliant control, in relation to the needs of patients and therapists.
After this first encouraging phase, we built a more *detailed functional prototype* depicted in Figure 5b. In addition to the main function (i.e. compliance), it fulfils the performances of comfort, ergonomics and safety required for conducting the first clinical trials. The external appearance is now improved, and most of the electromechanical components are encapsulated and out of reach of both patient and therapist, for obvious safety reasons. The prototype also comprises a screen placed in front of the patient's seat to display instructions and several simple video games, to make the physiotherapy sessions more attractive. In the foreground of the picture, we find the control station of the physiotherapist, from which the robot parameters can be configured.
A third version of this device is currently under development. The aim of this latest version is to be *clinically validated* and CE marked. To carry out this action, a *technological transfer to industrial production* has to be made to ensure the robustness of the device and *ergonomic improvements* must be made to the human-machine interfaces.

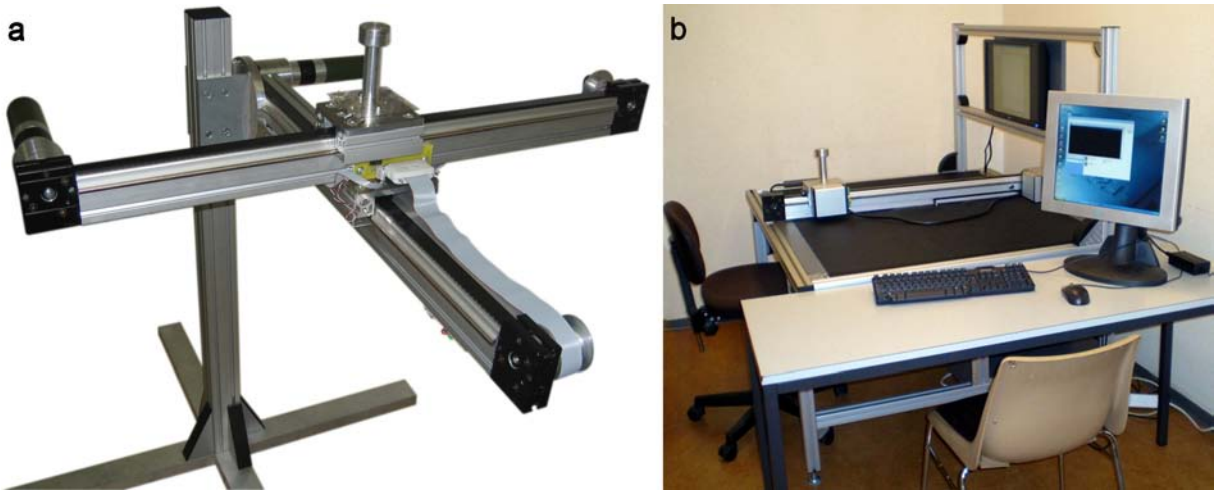

Figure 5. Evolution of the planar robot developed to prove the efficiency of the control scheme that ensures active compliance during manual manipulation: (a) initial partial mock-up and (b) detailed functional prototype

4.2 Experimental comparison of solutions for the shoulder module

The 6 DOF robot takes the general shape of an exoskeleton whose action principle on the patient does no longer require any tedious and accurate alignment between the robot's and patient's joints. The shoulder module is made up of a poly-articulated structure whose actuation is deported and whose transmission is ensured by so-called Bowden cables commonly used in bicycle brakes. It assists two of the three rotational movements of the shoulder – antepulsion/retropulsion and abduction/adduction (see Figure 6). Quite light and compact, its proximal end is embedded in a backpack-type structure that can be tightened to the patient. The distal end is connected to the arm through free joints and a

splint guaranteeing the robot action principle, i.e. the application of a force perpendicularly to the patient's arm, whatever its configuration.

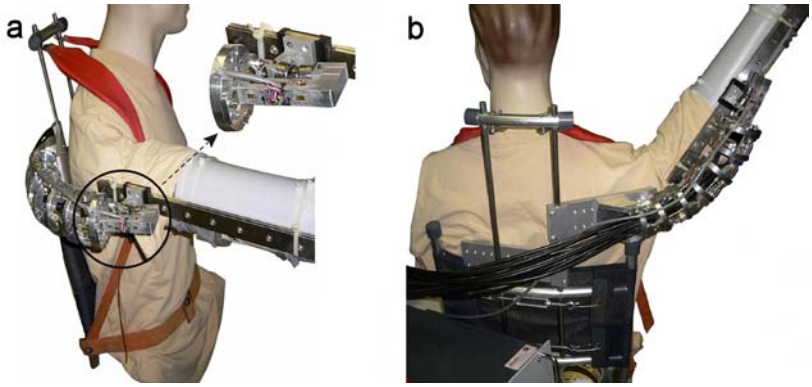

Figure 6. Shoulder module of the 6 DOF exoskeleton in (a) antepulsion and (b) abduction movements

During the evaluation step of the conceptual design, three possible solutions of module structure were in contention to be the best one. Mechanical requirements (e.g. actuability, singularity, working volume, compactness) are so strong that it was impossible to choose a particular technology without an experimental comparison of these solutions. Therefore we decided to undertake the realization of *partial functional mock-ups* (including the structure and the transmission with manual actuation) to make a final choice (see Figure 7). This materialization phase allowed us to verify the feasibility of these technological solutions and to quantify their performances regarding the mechanical requirements. Thanks to this experimental step, we managed to identify the most viable solution (see Figure 7c). Indeed, trials and measurements have revealed that it was better than the others in terms of actuability, accuracy, precision, curvature radius, and other more technical parameters.

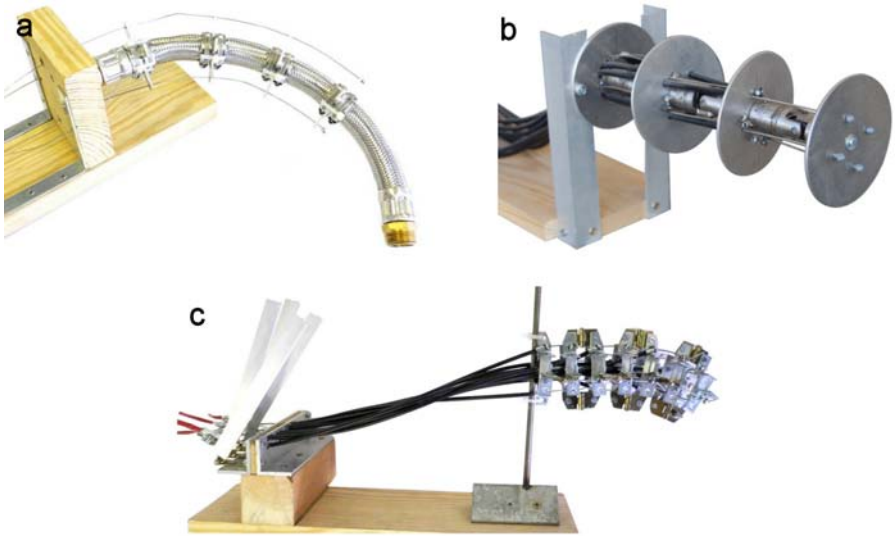

Figure 7. Functional mock-ups for experimental comparison of technological solutions

4.3 Active laparoscope holder for minimally-invasive surgery

The problem of manual camera handling by an assistant in minimally invasive laparoscopic surgery has been described for more than 30 years. Several robots have already been designed and marketed but several ergonomics problems remain. Based on our knowledge of existing solutions we managed to identify main objectives with medical collaborators. We drew up a list of requirements including working volume, compactness (in function of the robot placement above the patient, on the table side or on the ground) and maximum installation time.

Using a classic comparison of solutions with criteria and weights coming from a previously established objectives tree, we rapidly converged on a proposition. We submitted it to the surgeons by

means of a 3D virtual view of the robot in surgical environment (depicted on Figure 8a). Although they found the solution rather interesting and innovative, they could not form an opinion on the actual size and bulk of the robot and asked for a mock-up. Doctors are used to judging devices during exhibitions or demonstrations of the actual device and are less confident in virtual reality.

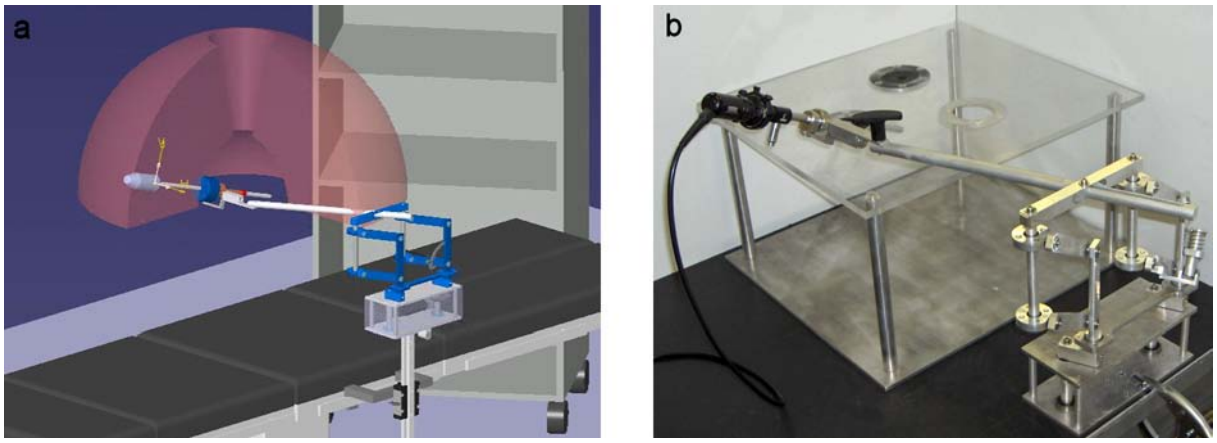

Figure 8. (a) Virtual model and (b) passive mock-up of the active laparoscope positioner

We built rapidly a full-scale mock-up of the virtual model (see Figure 8b). With this materialization, questions and suggestions arose and few complementary requirements were stated by the surgeons: in addition to the remote control, the robot should be back-drivable to allow manual manipulation of the laparoscope. A gravity compensation mechanism was added to facilitate this manual handling. Several in vitro trials were performed on a training test-bed to ensure that the presence of the robot did not restrict the surgeon's gestures. The duration of the installation and setup procedure was also measured. Those preliminary validation trials confirmed the choice of robot architecture.
A functional proof of concept prototype was then built (see Figure 9), using the mock-up as a preliminary design. Several tuning and verification trials were performed on test-bed and after some minor adjustments, a first clinical trial was performed. The prototype was then presented to a manufacturer and the technological transfer is under progress.

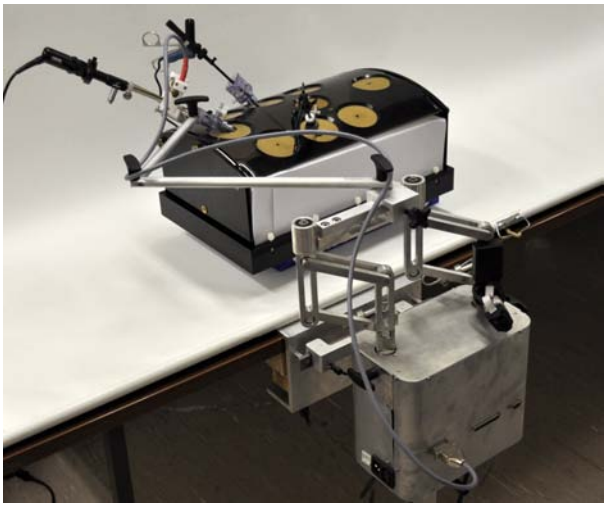

Figure 9. Proof of concept prototype of the laparoscope positioner

5 CONCLUSION

Models, mock-ups and prototypes constitute valuable tools throughout the design process of a medical device. First of all, they facilitate the discussion among a multidisciplinary team where everyone has his/her own references, methods and vocabulary. They are a good support to describe a medical problem or to depict a technical solution. Furthermore, demonstrators contribute to characterization, performance assessment and comparison of solutions during the conceptual design phase. Prototypes

are an essential element for the long validation and certification phase, which is compulsory prior to marketing. When more and more industrial fields abandon them and turn to the expanding virtual world, demonstrators will definitely keep playing decisive roles in designing medical devices, making profitable use of emerging rapid prototyping technologies.

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