INTERNATIONAL DESIGN CONFERENCE - DESIGN 2008
Dubrovnik - Croatia, May 19 - 22, 2008.

DESIGN 2008

DESIGN WITH MEDICAL INFORMATION

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Keywords: product design, methods, design with X, medical information

1. Introduction

Peter Hompes, head of In Vitro Fertilization (IVF) centre of the Vrije University Medical Centre in Amsterdam (VUMC), came with the question for a pump at the Advanced Product Project course. The course is planned in the first year of the master for all integrated product designs students and all the other master students can follow it as an elective course. The design method can be chosen out all taught methods in the bachelor (Hoog et al. 2007). A work method is also used by the students, which is mentioned in the syllabus Materialisation (Kandachar 2001). Embodiment design may be used for reducing design time or improving design quality (Langeveld 2006).
The question appeared simple but the problem was complex. A pump which soaks up 30 μL should be no problem, but which physical principle works best, that is more difficult to find out. A team of six first year master students have worked five months on it, 20 hours a week. The first question was 'what stuff should be pumped?' Another question was 'how should pumping be done, continuously or taking up 30 μL and driving it out again?'
Design with X improved the quality of design but medical information asks already explanation at the start of design process (Langeveld 2006). The first communication problem between the medical specialist and the design team came up in the beginning of the process. Therefore it was necessary to visit the IVF centre in Amsterdam, where explanation about the assignment could be given. The visual information with explanation about the assignment gave the designer a quick insight into the medical aspects. The medical specialist had big problems to understand the needs of the designer about medical facts. Communication is the base for understanding each others' profession, so a certain understanding grows between medical scientist and the designer.
The design team had designed a functional model first, to show the physical working principle. The functional model worked as expected, but it was unsuitable for an experimental IVF treatment (Alfen et al. 2006). Based on the functional model a patent application was done by VUMC, where the original idea came from.
During the patent application there was the possibility for seeking a graduate student who could make a product design from the functional model, which is developed out into a working prototype.
According to the medical specialist, the prototype works better, easier and is more accurate. Now they start medical tests with the devices on feasibility of a standard controlled embryo replacement. They hope to find a higher percentage of succeeding pregnancies and this result gives a kick for both parties.

2. Medical aspects

In short time the designer or design team should be deepening in the medical aspects of the concerning assignment. The designer or design team make use of three information sources:
Visual medical information
Written medical information

Scientific medical information.
Visual medical information should be gathered by attending an embryo replacement. The oocyte aspiration, fertilization cleavage and hormonal stimulation aren't directly needed information but it can indirectly stimulate the motivation and the inspiration source for an excellent product design.
Written medical information is mainly in the brochures with which the patient gets informed about the treatment, for this case it goes about in vitro fertilization. In figure 1 the IVF treatment is schematically indicated, where the visual information supports extremely the written text.

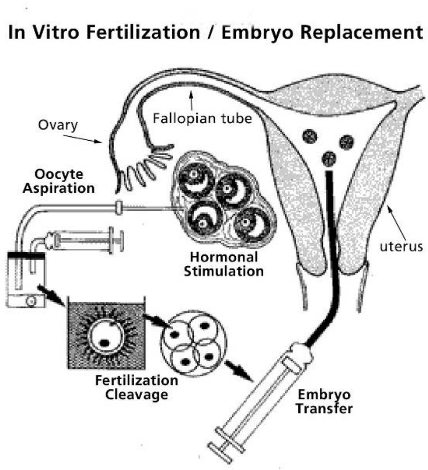

Figure 1. Schematic overview of the IVF treatment with the role of the embryo transfer device

The embryo transfer is the final step in the IVF treatment where one or more embryos are transferred back into the uterus. Replacing more than one embryo may increase the chance for pregnancy but it increases also the chance for multiple pregnancies. Multiple pregnancies are undesired because it gives health risk for mother and child. The law forbids a transfer of three or more embryos in the Netherlands for protection of mother and child.
Internet is also an important information source for written information on websites of:

- electronic magazines
- patient organisations
- IVF institutions

Scientific medical information gives the state of the art in the research in the form of congress papers and journal papers. Lambers (2007) published a congress paper about elective single embryo transfer.
Medical science papers proposed new boundaries of research, but also some requirements for new product design. The designer has to realise that the researcher has hidden wishes which must be found out in open discussion with all involved parties.
The designer or design team has to extract all medical information to find out the requirements and wishes from all medical parties involved in the IVF treatment to come to a product design. The extraction must take place in the beginning of the design process known as the orientation phase and overflows in the analysis phase.

3. Advanced product project

The master in Integrated Product Design offered by TUDelft has three graduation variants:

- Product Design
- Automotive Design
- Medisign

The master course Advanced Product Project offers the possibility for students involved in medisign to do an assignment in this area. Dr. Hompes, on behalf of the VU medical centre, brought in the assignment of the embryo transfer. This assignment was picked up by a group of six medisign students with a great result. The design team first started with gathering medical information about IVF treatment. They visited the IVF centre in Amsterdam directly after the communication problem showed up. There, a hormone pump was present, as a possible solution. It had two main problems:

1. The hormone pump can only inject
2. The syringe principle has uncontrollable friction problems.

They found a medical dilemma with two faces. First the gynaecologists of the IVF centre have difficulties with performing the IVF treatment, because the embryo transfer process is uncontrollable. Second, because of the uncontrollability of the embryo transfer, the infertile couples have to endure more emotional and time consuming consulting hours for a successful treatment.
The student design team has to find a product concept within the requirements and wishes for the IVF treatment. In particular, the uncontrolled embryo transfer asks attention for a new product design in which the embryo transfer should be controlled.

The design objectives of the embryo transfer pump are drawn up based on existing pumps. In figure 2 the problems are indicated and put in a scheme.

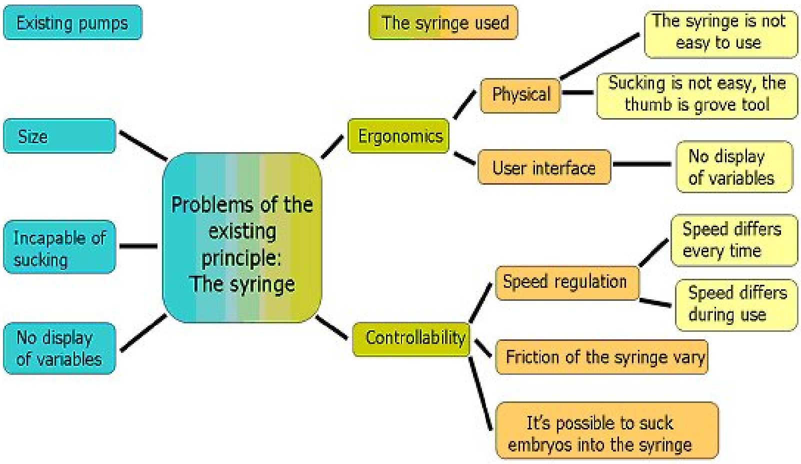

Figure 2. Scheme with indicated problems of existing pumps

The following design objectives should be investigated or researched:

Suction and Injection

Technical solutions to suck and inject
Calculate force needed to suck/ inject
Choose the best technical solution
Optimization and detailing for

- Prototype
- Product

Display

Gather information about the displays availability
Define what data to display
Choose the best display for the product concept

User interface

Gather information about what user will or want to do with the product design

- Brainstorming
- Product functionalities

Look at the different possibilities of the user interface

1. Controllability
2. Make it possible to set and control time
3. Make it possible to set and control volume
4. Through 1 and 2 the injection/suction speed is set and controlled

Make sure all of these aspects are done with the user in mind as well as the patient.

Features of the intended results:

1. Design a small product that can be handled with one hand
2. Design a product that is able to suck as well as inject
3. Display the variables

The research of the objectives had led to the peristaltic pump based on the indicated problems of existing pumps. The peristaltic pump solved all the problems related to controlled embryo transfer, but the solution is technical and medical aspects should be researched with a prototype.

The design team starts the concept development of the embryo pump after continuing consultation with medical specialists. In figure 3, a functional prototype of the embryo pump is shown.

Figure 3. The functional prototype of the embryo pump

The functional prototype is tested in the IVF-centre and they came to the conclusion, it works for the small amounts of 30 µL transfer liquid. They had a large list with remarks, such as: size is too big, thumb wheel turns only with hard push or pull, no display of any function and the time varies too much for sucking and injecting.

The functional prototype served as an intermediary between the designer or design team and the medical specialist. Both parties involved in the project have a visual representation of the embryo transfer pump now. In consultation with parties the program of requirements and wishes should be adjusted with the technical and medical remarks made as a result of testing the prototype.

4. Graduation project

After the result of the advanced product project, the next step in developing an embryo transfer pump was a graduation assignment formulated based on the functional prototype. The first part of the graduation assignment consists of research on the functional prototype. The goal of the research is to evaluate the requirements and wishes for the new product design of the embryo transfer pump. In the conceptual design phase the focus is on ergonomics, user interface and perfection of the functional parts. The aesthetics of the embryo transfer pump must fit in the context of the use in medical centres.

After the research of the functional prototype the graduate student also came up with the peristaltic pump as the most suitable one. He built and tested three functional models with different working principles of peristaltic pump (see figure 4):

- The linear type
- The classic type
- The unseen type, a patent from the seventies

The outcome was disappointing. The results were not reproducible. The pump of the classic type was bought in consultation with the medical specialists, with the prospects of a working pump which can be controlled.

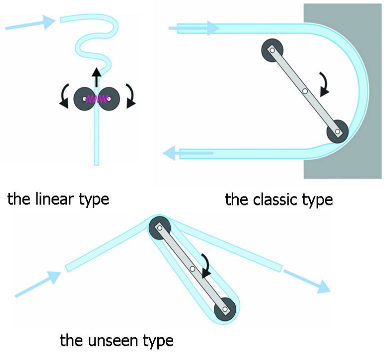

Figure 4. The working principles of peristaltic pump

The context influenced the mind setting during idea generation. The main aspects of the context had to be described, such as: flow cabin, the laboratory, IVF centre, and the time.
The flow cabin is used during the embryo transfer and the domain of the lab employee. The workplace must be equipped with the necessary devices for a successful transfer. The greatest ethic and medical attention should be given to the embryo. No damage or loss of the embryo should take place. This is a heavy responsibility for the designer or design team, every handling in the transfer process should be controlled in a standard way in the future.
The laboratory is the area where oocytes and semen are brought together for in vitro fertilization. The workplace requires good sight and overview; therefore the space is brightly illuminated by TL-lighting. One strict rule must be preserved: only human material of one patient couple is allowed on the workplace, before starting on the next couple the workplace must be cleaned with a 70% alcohol solution. No interchange of oocytes and semen of patient can be tolerated. Unnecessary talking and sounds in the laboratory should be avoided,
The IVF centre houses IVF-doctors, analysts, embryologist, assistants, administrative supporters, and cleaning workers. Its first IVF treatment started in the seventies and it is grown out to 1670 treatments in 2005. This is more than 10 % of all transfers in the Netherlands.
The centre operates seven days a week all year around, just different from normal out-patient institutions which are closed in the weekends.
The time of writing is at the moment that progress is made with the quality of IVF treatment. The percentage of pregnancies is in progress, the new product design has the opportunity to increase that, but 1 % increase should be a big step forward. If the embryo transfer device could guarantee a better chance for pregnancy with one embryo than this embryo transfer may be very popular.
Shape and interaction are explored with foam models. These foam models are used in series of user trials to observe the interaction device and user. During the observation the right shape and interaction can be archived with notes of the important features for each concept. In figure 5 the four different concepts in foam are shown:

- Linear concept
- Upside down pistol grip concept

- Pistol grip concept
- Ipod-wheel concept

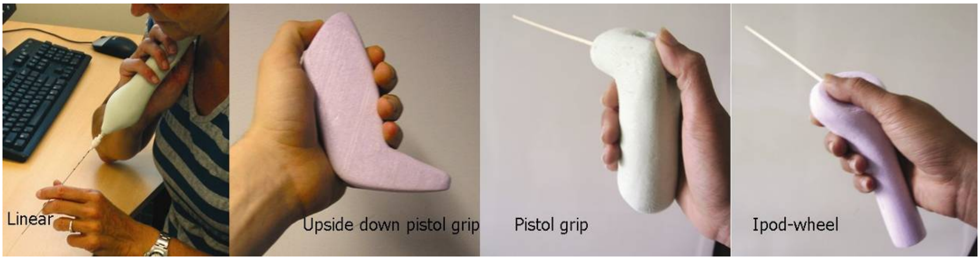

Figure 5. The different concepts in foam

In the trials it became clear that the gynaecological chair poses some restrictions for a design solution of the embryo transfer device. The IVF-doctor used a special pillowed platform for support of wrist or elbow. This can be an obstruction if the shape of the device is too big (Pheasant, 1988), (Singleton, 1982).
The pistol grip concept doesn't work because the platform is in the way.
When the staff tested the foam models there showed up an interaction that is almost the same as the syringe type for taking up and driving out. This led to real uncomfortable work positions. So they had to learn using another way of working. After showing the new working process they get convinced of the advantages of the new device.

Figure 6. The working prototype of the embryo transfer device

The interaction between medical process observation and designing led to a new embryo transfer device. The cooperation between designer and medical specialist isn't always as good as in this case. During the design process the designer needs regular moments of consultation with the medical specialist. When this is known at the beginning of a project the medical specialist doesn't have problems.
The final concept is realised after many consultations, but both parties are proud of the embryo transfer device which is excellent for the medical experiments. In figure 6 the working prototype is shown with all the features, the head is made movable for a better working position and it has a better interaction between users and device.

5. The new approach

Design with medical information has only sense as both parties involved in the design process have a good consultation from the beginning. In the fuzzy front, the designer needs the medical information for understanding the assignment. He has to filter the medical information to his need and guard from the working blindness of the medical specialists.
High tech medical devices can be split up into four main parts:

- Outside (mainly the housing , concerning aesthetics, interaction, ergonomics)
- Inside (mainly the physical part, concerning engineering)

- Electronics (hardware part with controls)
- Software (program for fulfilling the proper functioning and controlling of the product)

These product parts could be developed separately by specialist and assembled at the end. These assemblies have to fit and work correctly, which gives much stress and uncertainty whether each separate part will also function together. Otherwise the designer has to go back to the developing specialist of a product part. A product can be represented schematically with its main parts as depicted in figure 7.

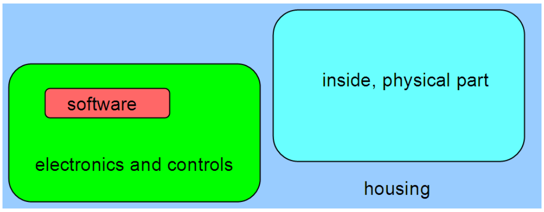

Figure 7. Scheme of the product with its main parts

The designer does not develop all the main parts by himself. Usually, he outsources the software, the electronics and the controls. This speeds up the design process when the outsourced parts are developed in parallel to the other main parts.

Every step in the design process should be deliberated with the involved parties. This deliberation is a necessity to get all the parties on the same engineering and medical level of understanding. Complex systems ask information on a higher abstraction level in the beginning of the design process, but the information goes still about engineering. This varies with medical information because the medical aspects influence the engineering information.

6. Discussion

Design with medical information means that in the fuzzy front the medical information must be absorbed by the designer or design team. This is earlier in the design process than the conceptual phase mentioned in Langeveld (2006). The designer filtered the medical information but he must be observant to bad habits in medical handling. During the tests with the foam model it appeared that the linear type is comparable with the syringe type but the attitude toward work was to exhausting.

High tech products such as the embryo transfer device should not be designed anymore by an individual designer, because then the design period gets too long. Instead, a team should be involved, consisting of a designer and specialists such as hardware engineer, software engineer, mechanical engineer and electronic engineer. The designer has to play the role of project manager in the team. This requires qualities other than those required for practicing the new task. The integrated product designer has to find his way in the management tasks of the design process.

The design assignments are getting substantial but also complex at the same time. Students doing such projects spend more time on deepening the design task. A good approach for this type of assignments is dividing the assignments into sub-assignments that are appropriate tasks for individual designers. An assignment can never be strictly divided, because overlaps are always present. The overlaps can stimulate the communication between designers to save a part of the time. The biggest advances are the discussions which stimulate and inspire the designer.
The acceptance of the design progress should be deliberate on a regular basis with the medical specialists. They have to know the progress and which medical requirements and wishes are met up to the moment. These meetings are also to verify the requirements and wishes and if necessary adjust them to knowledge of the day. Furthermore, the designer brings his vision into the discussion. Optimisation should always be an issue in the discussion to come up with the best product design.

7. Conclusions

In the fuzzy front end, designs with medical information asks special attention to the communication between designer and specialist, otherwise there could be lost opportunities for an optimized product design. The knowledge must be brought directly on the level of understanding and sharing the medical and technical information. The shared information should be known to all the involved parties for a successful project with an optimized product design or working prototype as result.

Projects with medical science as starting point require a new design approach to develop a design concept or a prototype. The new approach is doing of observation research in the orientation phase of the process by following a medical treatment and the medical steps forward which the medical researcher wanted to reach with the project. But the acceptance of design progress belongs also to this new approach. Shortly, communication and understanding the design progress by all involved parties motivate to come to a new product design or prototype. Models can really support the understanding and the communication.

The testing of the foam models was crucial in the whole design process of the embryo transfer device by the discovery of the uncomfortable work positions. The moving head has solved this problem, but the users have to learn new work procedure. The users are very enthusiastic about the prototype.

Acknowledgement

The author would like to acknowledge the 2006 first year master students of Industrial Design on the Delft University of Technology that had followed the Project Advanced Product from February to June. The assignments were concluded with a written report and a mini-lecture. Bram de Leeuw finished his graduation project with two prototypes of the embryo transfer pump based on the results of the earlier project (Leeuw, 2007).

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