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MEDICAL DEVICE DESIGN PROCESS: A MEDICAL ENGINEERING PERSPECTIVE

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1. Introduction

This paper presents an approach for the planning phase of a medical device design. Challenges during this process are discussed and a strategy to identify all required specifications is proposed. Hereby, the interdisciplinary collaboration of engineer, patient and clinician will be examined. As an exemplary case a shortened version of the development of an instrumented tissue expander is illustrated. This subject bases on a previous thesis, which was elaborated during a research stay at Stanford University. The research study was in collaboration with the Design Education Lab, the Living Matter Lab as well as the Department of Medicine at Stanford University.
The research was initiated by a mechanical engineer who found out about tissue expansion during his study. His intention was to provide the physician quantitative feedback during the procedure. He focused on the use case for infants with giant congenital melanocytic nevi. For a certain diameter this birthmark increases the risk of cancer and therefore will be removed. To replace the removed birthmark extra skin is needed. Therefore a tissue expander device is implanted into a subcutaneous pocket underneath the epidermis and dermis. In this procedure, saline solution is injected into the implant located around the birthmark under the skin. Filling the expander with saline solution over a couple of weeks gradually stretches the skin to trigger growth. Ideally, this initial injection would be followed by a protocol at home, similar to a procedure that is common practice for tightening braces. It is assumed that the therapy was non-ideal for three reasons. First, parents do not feel comfortable injecting fluid into an expander implanted in their baby without any quantitative feedback. Second, due to an obligatory safety margin, the achieved stretch is not maximal and growth is not ideally triggered. Third, the injection intervals are not optimized. This leads to an unnecessary long treatment and a discomfort for both the patient and the parents [Zöllner 2012].
To meet their needs, a first attempt of an instrumented tissue expander providing quantitative feedback has been designed. Using the proposed method, the planning phase of the medical device design process will be outlined. This paper only presents a shortened version. Giving a short overview of the medical background, existing devices and current limitations. In addition interdisciplinary basic approaches in other fields are considered. The aim of this paper is to demonstrate the importance and challenges during the process of information procurement.
Existing medical device design methods are summarized and supplemented with details ensuring a successful treatment. It is also considered how the collaboration in medical device design process can be improved. Based on the exemplary case, the impact of the adapted approach is discussed and how the results add to design process improvement approaches. Besides, the goal of this exemplary process is to be certain that a product can be developed more easily by including a clinician with his knowledge and experience into the engineering process.

2. Medical Device Design Process

A design process usually starts with the concept phase, followed by the development, the manufacturing and the distribution. In general, the concept phase starts with the product planning, which is done by a design engineer with knowledge of the market. The issues to be considered are the determination and documentation of the customer requirements [Gilman 2009].
At the outset of this step it is critical to speak with physicians, observing their procedures and to understand the limitations of existing devices and methods [Privitera and Murray 2009]. To fully understand the specific need that is to be addressed, someone is needed who is frequently faced with this problem. In medical devices this understanding is acquired most often by the physician specializing in this area [Aitchison et al. 2009]. Besides finding the right experts it is also all-important to critically use one's own judgment in weighting and prioritizing the various opinions heard. Moreover it is important to consult with the end user on the intended product [Grocott et al. 2007]. In addition, one must undertake a literature research. This search is designed to extend one's knowledge and to find out about existing products. Solving the current limitation and pleasing the unmet needs a complete knowledge of the current product sector is necessary. For methodological support mainly checklists [Ehrlenspiel and Meerkamm 2013] and main feature lists [Pahl et al. 2013] are used [Jung 2006]. Subsequent to the determination of the problem reviewing ones' observations and conclusions with the specialist is recommended. In the end the concept phase is completed with identified target problems or products [Gilman 2009].
Critical tasks in the areas of clinical testing, regulatory or governmental clearances, and reimbursement strategy are included in the subsequent development phase.

3. Approach for Planning Phase

In the understanding of the author, the planning phase is a single phase, before the concept phase. Within the planning phase the user requirements specification ("URS") are worked out among others. Whereas subsequent to the planning phase a functional device concept is generated. It bases on the URS and focus on the technical solution space within the medical framework. This second phase will be followed by a design phase where a real feasibility prototype is built.
It is assumed that the product planning of a medical device is performed by a design engineer with knowledge of the market. Of course having knowledge of the market facilitates the first steps into the process, but it is not a necessary qualification. However, such a gap of knowledge only is manageable for engineers, since medical background can easier be learned than understanding the technical basics.
According to Jung [2006] and J. Ward [2003] there are a lot of potential deficits possible, during the planning phase, especially regarding the requirement specifications. The main challenges during the planning phase are:

- Requirement specifications are not recognized
- Specifications are recognized but unnecessary
- Misleading formulation of the requirements
- Unspecific requirements were not adapted to greater knowledge

In the following a structure to support the planning phase of a medical device design process is presented. This is a result of several medical device design processes. The interdisciplinary collaboration is challenging for many reasons. A great degree of interdisciplinarity implies that the disciplines are technically apart, which results in a more difficult cross-domain communication and cooperation [Jung 2006]. Based on organization and communication difficulties the clarification and manipulation of requirements are challenging. According to [Jung 2006] there are no systematic procedures that guide the developer when working with requirements, especially for interdisciplinary development processes.
The key questions during the planning phase are illustrated in Figure 1. First oneself needs to understand the medical background. Second, learning about existing medical devices is necessary to conceive the treatment. Based on those two knowledge domains potential limitations regarding the treatment procedure as well as medical devices are realized. On top of that basic approaches in other (e.g. interdisciplinary) areas may be helpful to improve existing devices or to design a new one.

Figure 1. Key questions during the planning phase

The circuit matrix in Figure 2 is designed as a dynamic process and therefore has no starting phase. It is an iterative process that should be passed through several times. With each iteration a more specific level of abstraction is achieved.

In general the phase begins with a conversation with a specialized physician, learning about the disease and the treatment. One main problem during this step is that the surgeon has a very focused point of view. In medicine there are a wide variety of treatment types and various views. This is why it is extremely important to push the physician with questions about the type of treatment and other procedures. Even in cases when the medical doctor talks other treatment options down, oneself gets to know about the alternatives and the associated disadvantages. In addition, there are different types of treatments worldwide. It is recommended to speak to at least two different experts before forming an opinion on the situation.

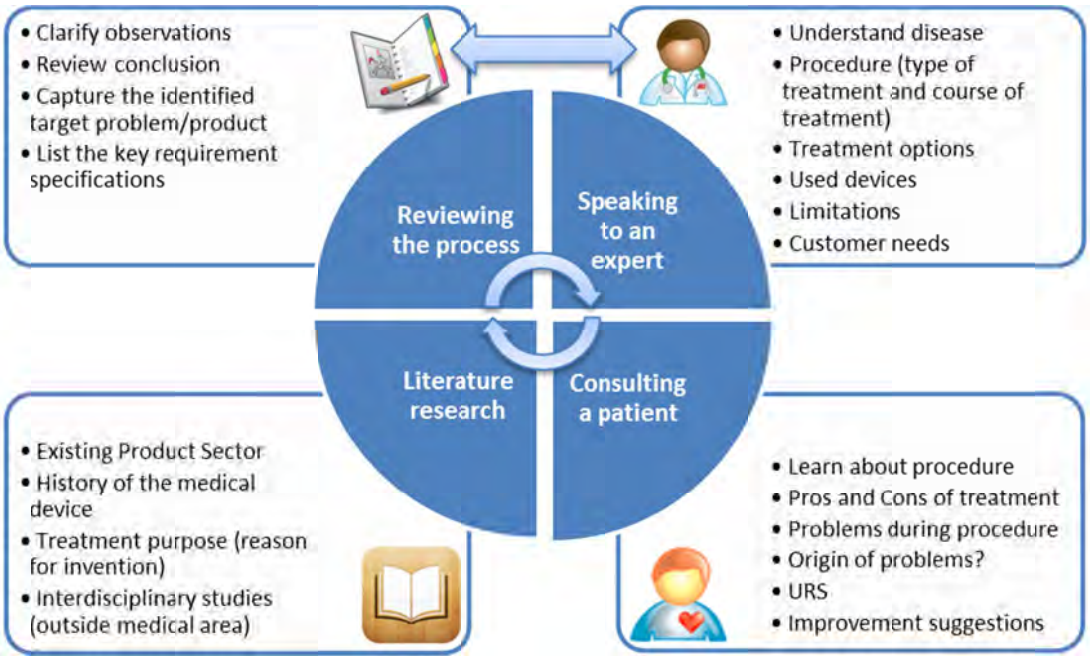

Figure 2. Circuit matrix illustrating the iterative approach during the planning phase

Talking to a physician about the used medical devices is a challenging process for several reasons. Most surgeons are not short of technical understanding, which leads to misunderstandings and confusing ambiguities. It is recommended to listen to the physicians' explanation, but should carefully be scrutinized.

Comparing the customer needs stated by the physician with the URS indicated by the patient is important. It may be redundant, but the experience has shown that there are some divergences. A patient can tell you his situation at first hand. The treating surgeon has rarely received the same treatment himself, which is why his version usually is a subjective observation or narration of the patients' courses. Moreover, a medical device should satisfy both, the surgeon and the patient.

Sometimes the treated person has a technical background, which may cause synergy effects. The main questions the patient should be asked are the pros and cons of the procedure, as well as possible complications. In the case of a noted complication the patient can state the potential origin or solution possibility. Nevertheless the creation of the URS should be an essential element of the conversation.

A literature research is self-explaining. It is evident that an engineer needs a broad knowledge of the existing product sector. The history of a used medical device is very helpful as it reveals room for improvement and already tested samples. The treatment purpose is a key question during the literature search. Having this question in mind, oneself focuses on the main objective regarding a new or redesigned medical device. A very important and easily missed factor is to look for research outside one's field. Especially interdisciplinary areas, like biomechanics or biomedical engineering, provide helpful indications.
The following reviewing step is extremely important and should always be discussed with a physician. The observations, that base on the previous steps will be clarified. Meaning a weighting and prioritizing of the different statements, treatment methods, and a structuring of the product sector. Taking the various perspectives into account the acquired conclusion will be discussed with a physician. This prevents nonconformity and ensures the achievement of the objectives by considering the marginal conditions. It also helps to detect misleading formulations of the requirement. At the end of this step there is a precise list of the key requirement specification capturing the target problem or product. In the case of an inconsistency oneself should go over the matrix once again to clarify the facts and circumstances.
The consultation of the physician, the patient and the literature in combination with the reviewing step shall minimize the risk of ambiguous or unperceived requirements. The clarification of the observations and the various opinions heard will help to filter unnecessary requirements. Finally, the iterative character of the circuit matrix leads to an adaption of unspecific requirements to the greater knowledge.
In the following an exemplary case of a medical device design planning phase is presented. All above-mentioned product planning steps are included. Using the iteration method, oneself will be given an overview and finally the key requirements are specified. Figure 3 pictures the constitutive character of the process.

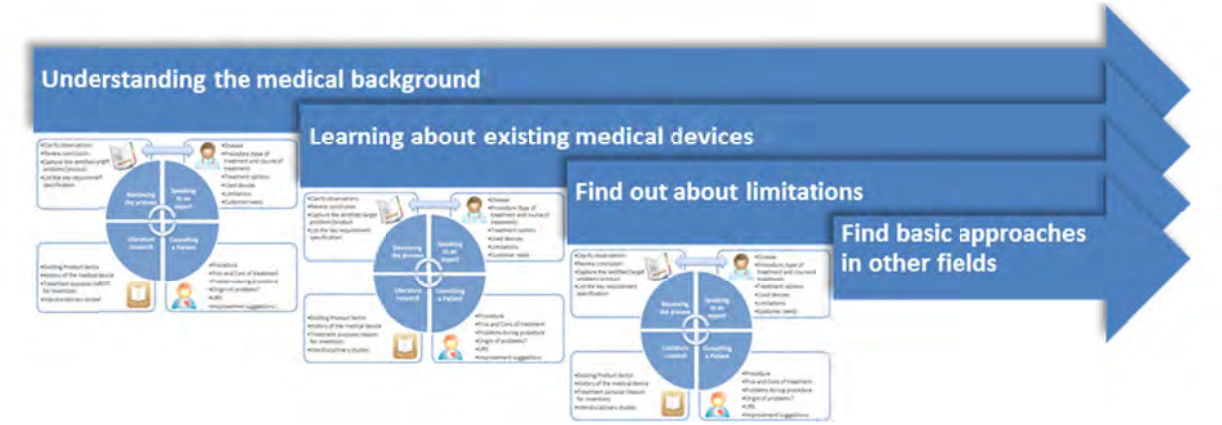

Figure 3. Iterative process during the planning phase regarding the key questions

For illustrative purposes the investigation of the instrumented tissue expander is used to analyze the device design process phase. Originally, the investigation was extremely detailed. This demonstrated the complexity of an apparent simple device. This paper only presents a shortened version. The exemplary case will be followed by an analysis of the approach, outlining the challenges during the phase.

4. Medical Device Design Planning Phase: Exemplary Case

4.1 Short understanding of the medical background

Tissue expansion (TE) is a natural process, that enables the body to grow extra skin through controlled mechanical over-stretch. Tissue expansion procedure bases on skin responding to a mechanical loading through a net gain in skin surface area. For a TE treatment, a hyper-elastic silicone balloon

expander is inserted near the area to be repaired. TE creates skin that matches the color, texture, and thickness of the surrounding tissue [Zöllner et al. 2012b].
Tissue expansion is applied for the development of needed flaps in many areas of the body: scalp, face, neck, trunk and extremities [Radovan 2002]. Birthmarks larger than 10 cm in diameter place the child at an increased risk to develop skin cancer [Gosain et al. 2001]. To prevent cancer, surgical excision is the standard treatment [Zöllner et al. 2012b]. Figure 4 illustrates a clinical case of tissue expansion in pediatric scalp reconstruction. Three expanders have been implanted around the birthmark to grow additional skin. All implants were inflated over several weeks to encourage the body to grow new skin. The expanders were removed, when the implants measured an appropriate size and therefore enough skin was grown. After removal, the birthmark was cut out and the skin flaps were sewn together. Tissue expansion has also been successfully used for the rehabilitation of selected burn victims [Argenta et al. 1983].

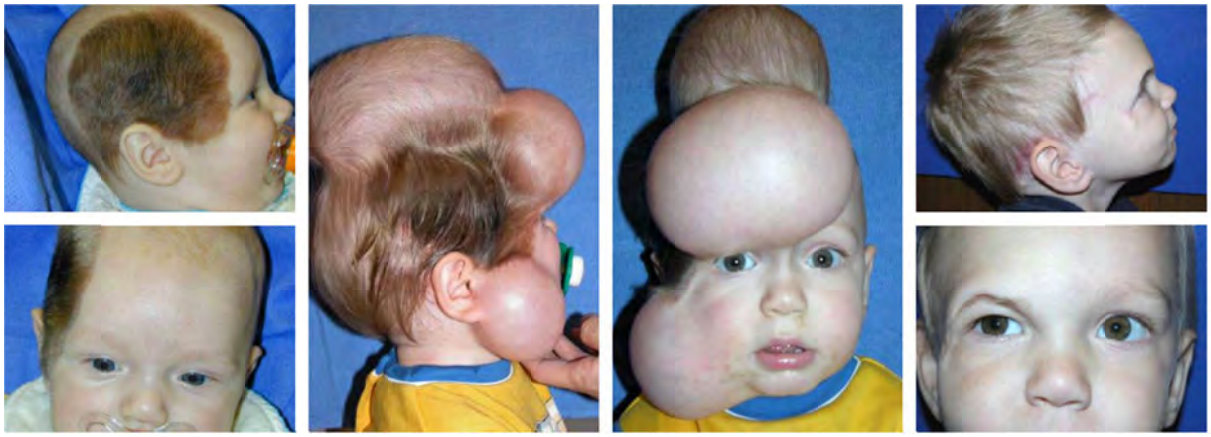

Figure 4. Patient with a giant congenital melanocytic nevi. Three expanders are implanted around the birthmark to grow additional skin for reconstruction [Zöllner et al. 2012b]

4.2 Short insight into existing product sector

Expanders are available in a variety of shapes, sizes, and backing configurations. Some companies provide custom-made expanders. Expanders are also available in various volumes ranging from 2 ml up to more than 2,000 ml [Eisenmann-Klein and Neuhann-Lorenz 2008]. The infusion is usually accomplished through a self-sealing inlet valve arrangement that is directly or indirectly connected to the tissue expander [Bark et al. 1991] (see Figure 5).

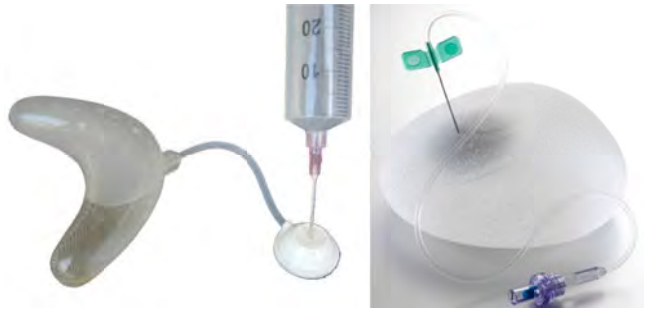

Figure 5. Tissue expander with a self-sealing injection port arranged indirectly and directly [drgallego.com 2013]

Most common available expanders are filled with saline solution. Based on its incompressible characteristic, the implant increase is related to the filling volume. The newly established company, AirXpanders Inc., has evaluate a gas-filled device as a possible alternative to standard tissue expansion [Jacobs et al. 2012]. The AirXpander expands by using compressed carbon dioxide that is gradually released through a small internal valve. This needle-free procedure reduces patient anxiety and the risk of percutaneous transmitted infection (See Figure 6) [Jacobs et al. 2012].

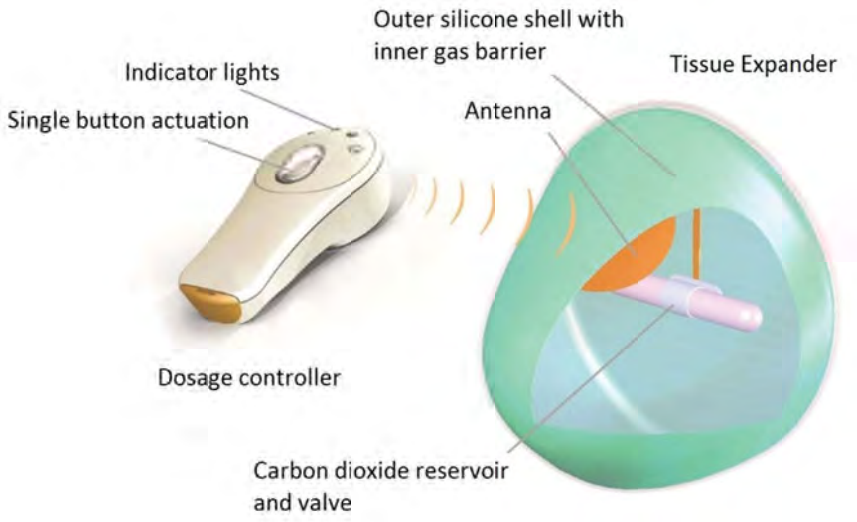

Figure 6. AirXpander that is inflated with carbon dioxide from a reservoir (AirXpander, Palo Alto in California). Using a dosage controller a predefined amount of carbon dioxide is released. [Jacobs et al. 2012]

4.3 Short summary of limitations

A serious problem in tissue expansion is the selection of an appropriate implant [Rappard et al. 1988]. Another difficulty in tissue expansion is to calculate the gained tissue area. Most often, the choice of the tissue expander is arbitrary. Usually surgeons select an expander based on clinical judgement and experience as well as size and location of the skin defect.

To date, the main problems are the lack of feedback during inflation and the suboptimal inflation timing leading to an unnecessary long treatment. In case of a leak the treatment involves removal and replacement performed typically as an outpatient surgical procedure [Dirbas 2011].

For breast reconstruction the tissue expansion procedure is non-ideal as well. Regarding injection volume, injection interval and optimal skin growth there is a clear uncertainty. In contrast to the aforementioned, the injection volume is customized by the surgeon. The treating surgeon adjusts the saline solution volume in relation to the sense of pain and subjective measurements of the skin (e.g. skin color and texture). The surgeon observes the skin color during the filling. When the skin turns white, perfusion is prevented. To restore blood circulation, saline solution is removed from the expander. The injection interval is based on the sense of the patient. This results in less pain, but less-than-ideal skin growth. In addition most surgeons repeat the inflation procedure in a weekly or biweekly interval. The injection intervals vary according to tissue tolerance, and the schedules of both the patient and the doctor [Antonyshyn et al. 1988].

Most surgeons circumvent the potential problem of leakage by selecting the largest expander that can reasonable be inserted beneath the region of expansion [Margo 2012]. Furthermore the use of two or more expanders is considered to gain the needed tissue.

During the filling, surgeons do not have any quantitative feedback. In addition marginal conditions like the maximum pressure applicable on the skin, without causing ischemia, are not evaluable.

The new AirXpander enables a continuous treatment at home, which is practical and increases the skin growth over time. Nevertheless many surgeons are critical of this treatment. Tissue expanders are made of silicone rubber, which is permeable for oxygen and carbon dioxide [Coady et al. 1995], [Jacobs et al. 2012].

Although the treatment is based on patient sense of well-being it is not assumed that the skin surface pressure is at an appropriate level (e.g. just below capillary blood pressure). Additionally it is not ensured, that the inflation interval is at exactly the right time. To grow skin at maximum velocity, the skin growth state needs to be considered. Assuming that the skin growth is always the same, a constant contact pressure on the skin may result in a constant skin growth.

4.4 Basic approaches in another field

In biomechanics, the modeling of tissue behavior is a central research topic. In this context a very interesting correlation of the tissue growth is discovered. In addition the finite element (FE) simulation gives valuable insights into the biomechanics of skin growth. For example it is found, that the use of rectangular expanders provides the greatest net area gain when compared to circular, square or crescent expanders [Zöllner et al. 2012a].

Based on the correlation of the skin area and the expander pressure, presented by [Zöllner et al. 2012a], a potential trigger for the next inflation time point is investigated. The increase in expander volume at the beginning of each filling step is associated with an increase in expander pressure and an increase in skin area stretch [Zöllner et al. 2012a]. It is believed that the skin growth is a strain-induced process, for what reason the skin grows as a result of a certain inflation volume. As the skin grows, the skin stress decreases accordingly, since the stresses in the skin are a function if the elastic strains alone. On this account, the expander pressure, caused by the filling volume, decreases over time (see Figure 7).

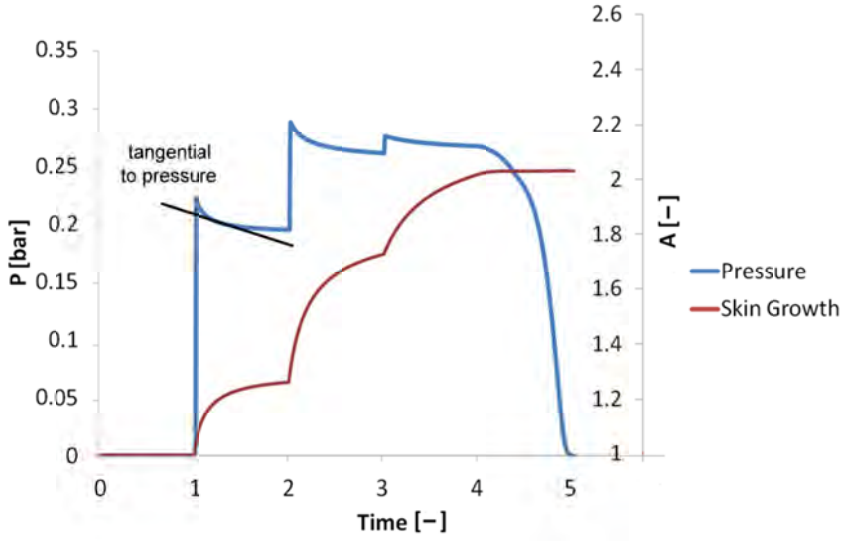

Figure 7. Skin growth modeled as a strain-driven process: Correlation between skin area gain and expander pressure. As the skin grows, the skin stress and the expander pressure decrease

The moment when the pressure curve converges towards an equilibrium state it is associated with a stagnating skin growth and a stress relaxation [Maequardt 2002]. The treatment time could be decreased and the procedure optimized when minimal skin growth over time is avoided. Skin growth, skin stress, and strain are not measurable in vivo without a surgical procedure. For that reason, the decrease of the skin growth is triggered by the concurrent expander pressure decrease. Therefore the first derivative of the expander pressure curve is calculated. The moment the first derivative of the pressure curve converges to zero, both, the pressure curve and the fractional area gain remain constant.

5. Challenges in Medical Device Design

Main problem in medicine is the extreme specialization of the medical doctors. For the instrumented tissue expander the initial contact partner was a surgeon treating babies with giant nevi. During literature research it has been found out that there are several types of treatments using tissue expansion. Therefore another expert, specialized in plastic and reconstructive surgery, was contacted. He mostly did know about tissue expansion in the context of breast reconstruction after mastectomy. Of course there are a lot of correlations, but also various limitations for each type of treatment. In this context, not only the interdisciplinary cooperation but also the knowledge of the physician and the engineer is all important for the planning phase of a medical device.

Tissue expansion is a procedure, that only a few surgeons are practicing worldwide. Since it is a very experienced-based treatment, the procedure is hard to learn for an inexperienced doctor. The literature

only gives some indications of how to perform tissue expansion procedure. From an engineering perspective, the review of the literature revealed that most of the published standards are inaccurate. Every physician has his own advice how to proceed during the tissue expansion. Meaning the frequency of the injections and also the injection volume. The inflation protocol is triggered by subjective measures like the skin color. The only control variable during the following inflation is the volume of saline solution injected into the expander. Not even the loss of volume because of a leakage is measurable. Collecting various opinions and approaches, judgment was required to filter out non-reproducible courses of treatment. This judgment was based on the insights given by the finite element simulation.

Moreover most physicians are very judicial regarding new developed devices. The start-up AirXpander designed a TE, which is inflated with carbon dioxide. Nearly every surgeon rejected this approach because of the assumption that the expander is gas-permeable. Actually the device is nearly impermeable due to an additional skin. Furthermore, this method includes a user interface and period self-inflating feature to maximize the tissue growth. For an engineer this fact is highly relevant. The absence of an injection port makes this a much more user-friendly device.

Another key factor of the collaboration is the communication process. Due to questions outside one's field the perspective and the wording are different. For the presented exemplary case the surgeon talks about over-expansion, but is not able to explain the causal chain that causes leakage. Therefore the physician is not able to prevent potential leakage at its technical origin. He can only minimize the risk using his experience or published empirical values: Using several expander and implants that are as large as possible. From an engineering perspective there are two main risks of failure. The expander devices are designed to stretch until a certain value. In contrast the injection port is designed to resist a predefined pressure. When the physician was talking about “over-expansion”, he actually meant overinflation. This could cause leakage because of a ruptured surface. When the pressure exceeds a certain limit the injection port will spring a leak. A physician can observe the pressure applying onto the skin, but this value does not state the pressure inside the device. In this context a pressure signal could help to minimize the risk of leakage.

Usually, in medical device design the engineer initiates the process [Kaplan et al. 2004]. Most likely doctors are no experts in the field of technology. Therefore the doctors are not primary interested in the new technological innovation. A medical doctor’s motivation is intrinsic or involves a gain in reputation. Sometimes monetary aspects also motivate doctors to invent something. But especially in hospitals, it is difficult to gain short-term profits from in-house generated innovations [Bohnet-Joschko and Kientzler 2010]. That’s why sometimes hesitate to support them. Nevertheless, for medical technology user-generated innovations are not only profitable but also indispensable. Mostly innovative medical doctors act as lead users and improve patient care with medical technology innovations. The Medical Device Design Process (MDDP) can be advanced by offering adequate support through cooperation models. A support for knowledge transfer facilitates the engagement of the medical engineer and increases the involvement of the physician.

According to [Medina et al. 2013], the first phase of the MDDP involves the identification of a particular clinical need. This presupposes the cognizance of a need for improvement by the physician and also a clinical solution. Since this procedure only describes the limited medical point of view, it is proposed to involve the medical engineer *ab initio* for cross-disciplinary knowledge.

Corresponding with [Grocott et al. 2007] a lot of medical devices are generated in isolation of the ultimate users. User involvement is very important and not considered in most Medical Device Design Processes. [Syed et al. 2009] revealed that the main benefits of user involvement were an increased access to user experiences and ideas. As a consequence thereof the functionality, usability and quality of the devices are enhanced.

An other challenge in medical device design is the complexity of medical background, treatment and devices. It is hard to get an overview of the whole situation, including its limitations and opportunities. In the same way, the design of a medical device is a very complex procedure. Usually research studies in other areas are unattended although they give great indications that are impossible in vivo. Especially for the following Concept Phase this step is relevant since it broaden the solution space.

Based on the detailed planning phase oneself now can structure the filtered key requirements. For medical device design there are usually three categories: The device properties, the physician needs and the patient requirements. Major questions to be answered are:

- What are the limitations?
- What are the physician's needs?
- Why needs it to be done?

The following graphic illustrates the given relationships, influences and needs during TE treatment. Usually oneself can classify various categories, including the major questions.

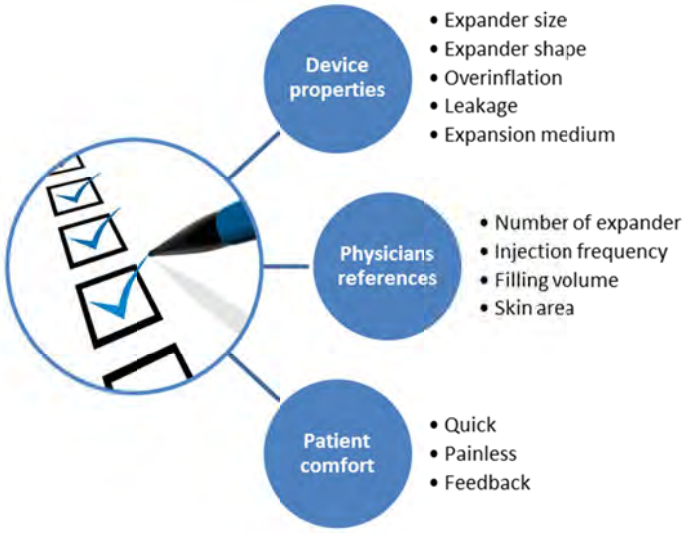

Figure 8. Various relationships, influences and needs during Tissue Expansion procedure

This visualization enables a holistic approach for the Concept Phase, where a range of solutions will be found. Based on these categories the solution space can be filtered. So that in the end one or two design concepts are found, which cover most of the listed needs of every category.

6. Conclusion

Despite the progress of the reconstructive treatment, there are some limitations. Both, the inflation protocol and the filling volume vary for every patient. A first attempt of a sensor featured tissue expander has been addressed. This so-called instrumented tissue expander provides the treating surgeon a sensory feedback to enhance a successful procedure. A pressure sensor, inserted inside the TE, displays both, the current expander pressure and the pressure over time. Based on the progress of the pressure curve, the inflation time points are triggered. This new way of tissue expansion was simulated with a finite element model to facilitate the communication with the surgeon.

The proposed procedure for the planning phase gives a profound knowledge of the medical background, existing devices and resulting limitations as well as their correlations. On this basis new aspects of other (e.g. interdisciplinary) fields are included, giving a new attempt. All concerned parties are taken into account and their opinions are regarded and compared. Cross-linkages are detected, supported by the iterative process. The completeness is intended by cognition of various requirements. Consulting all parties, the verbalization of the requirements is reconsidered. Finally, a first attempt of simple structuring the key requirements is presented.

The procedure model for innovative medical technology can be fully harnessed to contribute to establishing an optimal collaboration. It has the potential of significantly reducing the burden of disease through a good interdisciplinary cooperation. The quality of medical technology is improved by accurately analyzing and designing solutions to limitations in medicine.

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