Workflow Analysis as Tool for Development of Medical Devices, a white Paper

A. Boese, K.-H. Grote

***Abstract*— At present, workflow analysis is frequently used in medical applications for the optimization of the patient flow, the equipment utilization and human resources. As a tool for the development of medical devices, e.g. for the generation of optimized requirement lists, this technique has not been applied so far.**

Advancement and technical innovations within the medical range are driven by the ideas and desires of physicians involved. These try to pass on their requirements to the product developer. In fact, it is necessary that the developing engineer deals with the medical field of activity and the procedures and expirations in order to understand the task. Global players in industry operate large development departments employing special staff with medical and engineering background. Research is practiced by working on experimental fields for test and verification goal-oriented. This possibility does not exist for small and medium-size enterprises. In this publication the method of the workflow analysis as a tool for the development of medical devices is presented and demonstrated giving a first example.

***Index Terms*— engineering process, medical devices, workflow**

I. Introduction

The success of a medical device utilized within operations depends on its medical value, on the costs and also on the handling characteristics. The medical value strongly is affected by the handling characteristics. Both success criteria should be defined during the product development as accurately as possible. Therefore it is necessary to find a common language between the physician involved and the developing engineer. A methodical approach during the product development reduces the development time and the development cycles substantially. This includes the creation of a product requirement list where the specifications of the product to be developed are categorized and described [1]. Commonly the product developer immensely profits on his experience when generating the list of these requirements. However, in the medical, and especially in the operational, range this is very difficult. The product developer does not have a direct experience in handling the operation tool in the human organism.

Manuscript received March 22, 2010. This work was supported by the Federal Ministry of Education and Research (BMBF) in context of the 'INKA' project.

A. Boese is project leader of the INKA research project on the Otto-von-Guericke-University Magdeburg, Boulder, PF 4120, 39016 Magdeburg, Germany (phone: 0049 391 67 20094; fax: 0049 391 67 11182; e-mail: axel.boese@ ovgu.de).

K.- H. Grote, Department of Mechanical Engineering - Engineering Design, Otto-von-Guericke-University Magdeburg, PF 4120, 39016 Magdeburg, Germany (e-mail: karl.grote@ovgu.de).

They lack the feeling for leading the tool, the handling, the haptical feedback, the reasons and criteria for decisions and the interaction of the persons and devices taking part in an intervention. For the skilled physician operating these issues are a matter of course and difficult to explain. That leads to the fact that newly created products often do not achieve the expected goal and must be adapted throughout further development cycles. Development time, resources and costs are increasing and a successful, i.e. profitable, product introduction renders more challenging. By analysising the operational sequences, the handling of the operation tools and the application of additional devices and a person's decision-making different ways can be outlined. The analyst or user of the data gets a logical comprehension of the working routine. During a later discussion with the operating surgeon a list of high-quality product specifications can be provided on this database.

II. Background

In 2002, medicine-technical goods having a value of € 72.9 billion were produced in the US, followed by Japan with € 15.3 billion and Germany with € 12.6 billion. Hence, the structural composition of the medical technology industry is very similar in the US, Europe and Asia. Several very intensively researching and globally acting enterprises, in particular from the range of electrical medical devices and instruments, are confronted with a multiplicity of small manufacturers. Small enterprises which offer new technologies and products have usually a narrow product spectrum and produce predominantly for the respective national market or act primarily on niche markets. They depend on the conditions of the national market access and the restrictions of health systems. Decisive factors for the potentials of these producers are the constellation of interests of the national healthcare sector, the financing by the health system and the international adjustment of standards of medical technology products. However, for technological pioneers in the medical sector even the acceptance on the home market and the implementation of innovations in application is of importance for economic survivability [2].
The market access of small businesses is based strongly on personal contacts into the medical community and positive experiences in the co-operation of a physician and the developing enterprise. Long and frequent development cycles for products are not accepted. The expectation is high. While global players can rely on a stable workforce of physicians who cooperate actively in the forming of an opinion and evaluation of new product ideas, small and medium-sized companies are dependent on a fast and successful transfer of innovations. Applying a workflow analysis can contribute to reaching this goal.

ISBN: 978-988-18210-8-9
ISSN: 2078-0958 (Print); ISSN: 2078-0966 (Online)

Workflow analysis within the medical division is not a new issue. The method is frequently used for the optimization of the intervention times and the patient flow or the staff requirements. Here, the economic value is the most important figure for hospitals, like for instance better equipment utilization, higher patient throughput, savings regarding personnel and non-personnel costs [3],[4]. In addition, quality increase can be a motivation for the use of workflow analysis. In that way operational sequences can be compared, in order to determine the potential of improvement. Also the comparison of workflows of analog operations can lead to improving work methods [5].

In the range of engineering of medical technology the procedure was not used yet. Here, the developer often tried to set up a list of describing requirements by discussing and explaining the problem to the physician. For specifying the requirements the engineer frequently has to rely on him/herself, since the temporal integration of the active physician does not permit to deal intensively with the problem. A high level of time and hidden costs on search and systematization must be invested. As a result the developer receives a requirement list that describes the problem in a way that he or she finds it logical but the conceptions of the physician does not correspond necessarily. The practice of the workflow analysis helps the developer to better understand the approach of the physician and to determine and document difficulties, e.g. with the handling of assigned tools. Furthermore, problems become not only visible but also quantifiable by means of an analysis of expenditure of time or accuracy. From here on, not only precise requirements can be derived, but also a definite improvement by the using new equipment. A measurable medical use or time saving leads to a higher acceptance and thus to a more successful product introduction.

III. Method

A. *Engineering in the context of INKA research projects*

In the research project „INKA - intelligent catheters“, components and overall systems for minimal invasive operation techniques are developed. In these medical interventions, not allowing a direct optical control of the application area and only to be accomplished under a medical imaging, x-ray with 3D functionality is most frequently applied. A new, but still rare method is the execution of minimal invasive operations controlled by magnet resonant imaging (MRI).

For both procedures guidance and/or basis catheters, diagnostic and therapy options on the catheter tip will be developed in the INKA project. These must be compatible with the imaging systems, so that navigation, detection, therapy and control of the catheters are made possible. The INKA team defines problems regarding minimal invasive operations in medical applications, and analyzes and improves them by means of technical developments. Thus interventions supported by magnet resonance represent an apparent challenge for the product development. For this application only a few tools and devices exist that are compatible with the MRI. Frequently the MR compatibility leads to restrictions with the usefulness of the equipment [6]. Also, within the range of the therapy of neurovascular illnesses a high demand for suitable functional and - above all - very small tools exists to conduct fast and successful interventions. The INKA team compiles solutions for these proposals, which are converted from the technical bases to prototypes. The results are then taken up and marketed by regional small and medium-sized companies. The experience in INKA's commitment to engineering medical devices has led to the necessity of optimizing the process of information reception. In the following, the first steps of the production development process using workflow analysis are demonstrated by introducing an example.

B. *First steps of engineering process of a steering of a micro catheter applying workflow analysis*

Due to the brain-supplying arteries the region of the artery cerebri media is most frequently (approx. 80% of the arising cases) affected of lack of blood circulation. Blood clots replaced by the bloodstream settle there and cause an apoplexy, which may then cause the impairment of the movement apparatus or disturbances of the apprehension [7]. Several studies revealed that each minute of the blood circulation of the brain being impaired is harmful and therefore a treatment must taking place as early and fast as possible [8]. In order to treat the neurological losses the physician inserts a catheter into the vessel system to the place of illness and conducts an appropriate therapy. The treatment takes place with the support of a rotation x-ray system that points the x-ray-close catheter and the vessel tree visualized by an additional injection of contrast agent.
For moving the catheter into the correct vessel branching, the tip is preformed defined and navigated by manual rotation and careful forward pushing. Additionally, the use of a guide wire is necessary, which is pushed through the catheter and affects its form (Fig. 1).

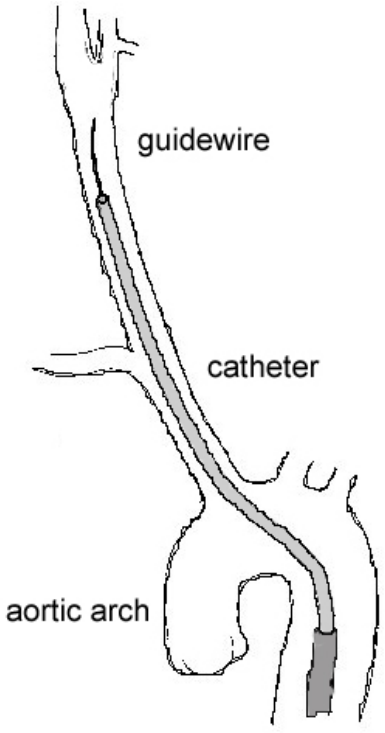

Fig. 1 - Selective catheterization technique

ISBN: 978-988-18210-8-9
ISSN: 2078-0958 (Print); ISSN: 2078-0966 (Online)

For very small vessels and complex branching this approach becomes very complicated and time-consuming, since the guide wire or catheter must be changed frequently and/or readjusted. As a consequence, the operation time and concomitantly the risk of irreversible damage rises. To avoid this, a possibility for the external controlling of the catheter tip is to be developed. Fig. 2 shows an angiographic image of a neurovascular therapy.

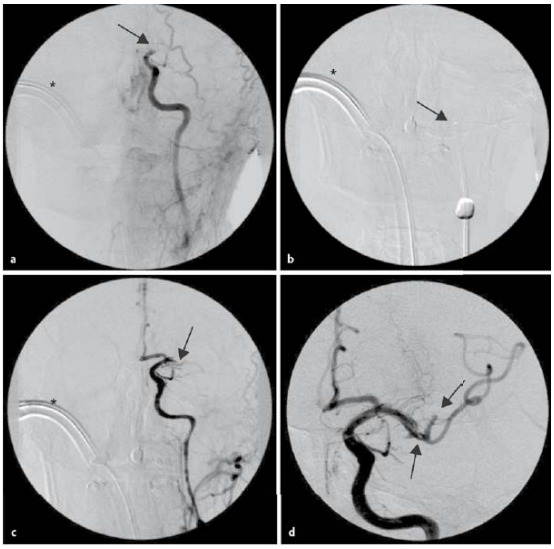

Fig. 2 - Angiographic image of a therapy of acute aphasia on right hemiparese [9]

The engineering process was accomplished in the classical methodical way (Fig. 3): discussions with the operating physician, searching the approach in principle, investigating the assigned devices and tools.

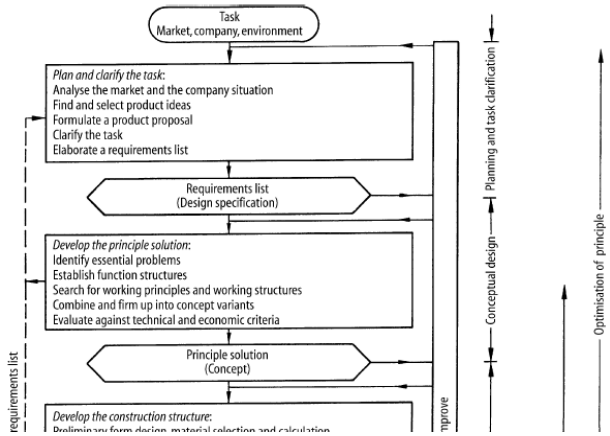

Fig. 3 - Steps in the planning and design process [1]

But in fact the actual problem definition could not be detected by the developer. For an example, the requirement was expressed that turning at a certain vessel branching must go „better“. This “better” can be defined as faster or simpler, since it concerns a rather subjective impression. However, the requirement could not be specified more clearly by the physician. Also haptical impressions of the operator experienced during the intervention cannot be comprehensibly explained in the discussion. A try out and experiencing of the problem by the developer is inconceivable regarding this medical development with direct application in the patient. Also the observation of several operation processes did not bring satisfying results. Hence, the information capturing process changed over to document and measure temporally the operation processes. For a start, the actual conditions were recorded. In addition to that, the interventions were observed and documented temporally. The number of persons actively taking part in the intervention and their respective tasks, the intervention goal, the assigned tools and the temporal operational sequence of the operation was recorded. As a support, data collection sheets (Fig. 4) were provided, which were filled in by the observer. The sheets were created based on the examination in principle, as it is represented in [10].

Collector:		Schulz					
Date:		08.02.2010					
Intervention:		A.cerebri Media					
Timeline	**Steps**	**Interventionist 1**	**Interventionist 2**	**Anesthesiologist**	**MTRA 1**	**MTRA 2**	**Counter**
Start 0:00	Preparation Patient				x		1
							2
							3
05:10	Local Anesthesia	x					4
							5
							6
06:20	Aspiration	x					7
							8
							9
07:30	Insertation Wire	x					10
07:50	Contrast agent						11
							12
08:10	Insertation Catheter	x					13
08:30	Contrast agent	x					14
							15
							16
							17
							18

Fig. 4 - Data collection sheet

The analysis of the data collection sheets revealed that the operation time depends much on individual patient anatomy. Elongation of the vessels or calcification and plaque partially make it more difficult to penetrate to the region of interest. . The most difficult part of the intervention was bending into the arteria cerebri media. For this section, most of the attempts and readjustments were necessary. Different strategies were pursued here. On the one hand, a micro catheter with extremely soft tip was inserted and directly placed at the vessel branching over a rigid preformed guide wire. On the other hand, a soft preformed guide wire was inserted into the arteria cerebri media from a micro catheter below the vessel branching. Both variants are very time-consuming and dependent on the experience and skill of the interventionist. Thanks to the documentation and the following discussion with that interventionist precise requirements concerning the size, attitude, handling, management, and geometrical boundary condition are set up.

C. Results

The workflow analysis during the engineering process is a simple and a helpful tool. The documentation of complex procedures and the processing is made possible in order to purposefully create a requirements list. The complexity is comparatively small using an appropriate data collecting sheet of the operation process. Based on the documentation the actual state of art can be archived for the purpose of comparison. Also, procedures automated by daily routines are represented giving a comprehensive picture of the operation conducted. Using the dataset made it is possible to

ISBN: 978-988-18210-8-9
ISSN: 2078-0958 (Print); ISSN: 2078-0966 (Online)

generate optimization scenarios and in such a way to find a "better" solution. The cooperating physician finds himself understood and can contribute in developing a product corresponding to his conceptions. The developer is able to pass on information or use it as a quantitatively underlain basis for discussion. Workflow analysis in the engineering process has the potential to reduce costs and generate optimized products. Especially for small and medium sized companies acting in the medical range this method can be an effective tool for placing successful new innovations.

IV. CONCLUSIONS

The application of the workflow analysis during the engineering process of a medical device is helpful for documenting complex procedures. The understanding for not self executed procedures is improved. It was shown that even a documentation using simple recourses leads to an optimized solution. Depending upon complexity of the interesting procedure and the temporal resolution of the expiration the method can be extended, e.g. by using professional documentation tools. These possibilities and their pro and cons are subject to a continued examination in the context of the product development processes within the INKA project.

ACKNOWLEDGMENT

The authors would like to thank their colleagues at the Otto-von-Guericke-University of Magdeburg. This research was financially supported by the Federal Ministry of Education and Research (BMBF) in context of the 'INKA' project.

REFERENCES

[1] G. Pahl, et al., "Engineering Design : A Systematic Approach," 2007.
[2] R. Farkas et al., "Situation der Medizintechnik in Deutschland im internationalen Vergleich Studie im Auftrag des BMBF," 2005.
[3] E. Rödler, "Workflow und Prozeßmodellierung – Instrumente der Workflow-Analyse in der Praxis," 2000.
[4] M. Greiling, Chr. Marschner, "Nutzeneffekte von Prozessoptimierungen - Workflow-Management im Gesundheitswesen," 2007.
[5] T. Neumuth, G. Strauß, J. Meixensberger, H. U. Lemke, O. Burgert, "Acquisition of Process Description from Surgical Interventions," 2006.
[6] D. Weishaupt, V. D. Köchli, B. Marincek, "Wie funktioniert MRI?," 2009.
[7] M. Trepel, "Neuroanatomie : Struktur und Funktion," 2008.
[8] W.G. Barsan et al, "Urgent therapy for acute stroke. Effects of a stroke trial on untreated patients," 1994.
[9] C. Brekenfeld et al., "Thrombolyse der Arteria cerebri media," 2009.
[10] G. W. Kauffmann, W. Wenz, "Röntgenfibel," 2001.

ISBN: 978-988-18210-8-9
ISSN: 2078-0958 (Print); ISSN: 2078-0966 (Online)