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EMPIRICAL STUDY OF ILL-SUPPORTED ACTIVITIES IN VARIATION RISK IDENTIFICATION AND ASSESSMENT IN EARLY STAGE PRODUCT DEVELOPMENT

Bjarklev, Kristian (1); Mortensen, Niels Henrik (1); Ebro, Martin (2)
1: Technical University of Denmark, Denmark; 2: Novo Nordisk A/S, Denmark

Abstract

The purpose of this paper is to present findings from an industrial case study about the support of activities related to identifying and assessing variation-related issues in the design during the concept- and embodiment design stages. The case study investigates a large world-leading mechanical medical device company by interviewing six key employees that work in the variation risk identification and assessment process. It is found that there are several ill-supported activities, and that the project teams rely heavily on tolerance experts' assistance and experience in order to identify and assess the variation risk. Ill-supported activities are found to be: Balancing hardness of requirements and the screening; communicating mechanism understanding; predicting user input and internal component movement; documenting and communicating tolerance analysis; implementing robustness in the early definition of the projects; and implementing statistical information in the calculations. It is suggested these areas should be supported further.

Keywords: Tolerance representation and management, Robust design, Early design phases

Contact:
Kristian Bjarklev
Technical University of Denmark
Department of Mechanical Engineering
Denmark
krbjar@mek.dtu.dk

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1 INTRODUCTION

The purpose of this paper is to present findings from an industrial case study about the support of activities in relation to identifying variation-related issues in the design during the concept and embodiment design stages. The findings point out several activities that are ill-supported and gaps for new tools or processes that may aid the identification and assessment of variation risk in industry in general.

Variation in product functional performance and design parameters is often a problem in industry. This type of variation leads to a degradation of quality perception, and can in many cases have serious consequences for the users of the products (Ebro et al., 2015; Taguchi et al., 2005).

Variation sensitive products lead to a high amount of late stage redesigning, which increases the development time. They further lead to higher scrap rates and lower yields for the companies, narrower tolerances and more in-market failures (Ebro et al., 2015). It is thus crucial for industry to be able to reduce the variation sensitivity of their products. This paper seeks to assess the support used for the variation risk identification and assessment (as a part of the variation risk management (VRM) process, described by Thornton (2003)) in a specific large high-volume mechanical medical device company. This paper particularly investigates the variation risk identification and assessment early in the product development processes.

This paper furthermore looks into how the insights from the identification and assessment processes are used in the design process. The chosen company is among the world leaders within its field and has already done a lot for implementing robust design and variation risk management.

Investigations of the implementation of VRM in industry have been described (particularly in USA) by Thornton et al. (2000). This showed that a proactive approach had not been implemented sufficiently in the companies investigated. The main reason for this was a lack of quantitative models for making quick and accurate decisions. I.e., there was a lack of support for the variation risk identification and -assessment activities during the design process in the investigated companies. Similarly, Gremyr and Hasenkamp (2011) also described a lack of support in identifying noise factors, and that explicit Robust Design practices were missing in industry.

Three projects (Ertan, 1998; Padgalskas, 2007; Parkins, 2004) analysed the implementation of variation risk management in different case companies. They described cases of inefficiency in linking capabilities of production, customer requirements, and the consequences of exceeding these, to the variation risk management process. They also described a lack of management support and support structures for the VRM processes studied. They suggested an earlier implementation of VRM in the development process. Parkins (2004) further noted existing inefficiencies in the expert-to-team communication, due to a complex information format.

Consequently, the main research question for this paper is: **Which activities are ill-supported in the process of identifying and assessing the variation-related issues in the product design during the early product development process?**

The underlying hypothesis is that important activities in the variation risk identification and assessment during the concept- and embodiment design stages of the product development process are ill-supported, reducing the efficiency of these and rendering the process largely dependent on expert knowledge and -experience.

In the next sections, the theoretical background for this paper is described, the research approach and the case study are elaborated and the results of the interviews are presented. Finally the findings from the interviews are discussed, topics for further work are suggested, and the conclusion is presented, answering the main research question of this paper.

2 THEORETICAL BACKGROUND

2.1 Framework

Thornton's framework (2003) is used as a basis in this paper for analysing the process of identifying and assessing the variation-related issues at the investigated company. The framework provides a holistic view of the entire VRM cycle and considers the three steps of risk management: Identification, Assessment and Mitigation (Danish Standards Foundation, 2009). Inspired by Thornton et al. (2000), the term variation risk is adopted here for denoting the risk of serious impact on the key productfunctionality from variation-related issues in the final product due to variation sources affecting the product design parameters.

Thornton (2000) defined three main elements of the VRM: Variation risk identification, -assessment, and -mitigation. In this paper, the focus is mainly on the process of identifying and assessing the variation risk particularly when creating new designs, as opposed to the process of identifying and assessing variation risk on existing products in production. Thereby, speed and timeliness are important factors, as the design will be in continuous development while the variation risk is identified and analysed. The design undergoes much iteration along the development process and the process of identifying and assessing the variation risk focuses on single particular iterations. Thus, the identification and assessment process cannot take longer than the timespan of that single iteration. Furthermore, it is investigated how the insight gained in these two steps is used in the product development process, hereunder also investigating if the knowledge has been used for prioritizing concepts - which is a type of mitigation.

We define early product development as the stages before the Definitive Layout is determined (as defined by Pahl and Beitz (2007)) in the particular company investigated. The investigation focussed on the stages of concept design and embodiment design (as defined by Pahl and Beitz (2007)). These stages are similar to the Concept Synthesis and Product Synthesis stages described in Andreasen et al. (2015). This is where the foundation of the robustness of the product is defined and where it is important to find any issues since few changes are possible in the later stages such as the detail design stage (He et al., 2009).

'Support' is investigated in two different categories: 1) Tools - that are used in order to retrieve, obtain or structure insight, 2) Processes - specific ways of working with data that lead to greater insight in the product. These categories are inspired by Blessing & Chakrabarti (2009) who list these as involved factors in designing.

'Activities' are here meant as product development process steps towards a launch-ready design. 'Ill-supported activities' are defined in this paper as activities that currently do not have a systematic and standardized aiding process or tool meaning that the people working with the activities have to either do the activities unaided or with a 'home-made' tool, invented by themselves either on the spot for each situation or locally stored. E.g. the activity of identifying sources of variation would be well-supported if there was a company-official list of possible sources of variation found in earlier products launched. In an ill-supported situation no company-official tool would be available and the designers would have to know the sources through experience or have them written down on a local list.

2.2 Factors for the Identification and Assessment Process

In variation risk identification the important steps are to identify the Key Characteristics (KCs) and creating the Variation Flowdown (Thornton, 2003, chap. 3), i.e., identifying the variation sensitive performance parameters that are important for the user and linking the part variation to these. Thornton (2003) describes that several information types should be available when creating this overview. In this paper these information types are sorted in three main categories according to what kind of information they provide. This paper investigates how the product development teams at the specific company acquire insight for these three main categories:

- System KCs: **Insight in the user-requirements**, especially those that are critical and probable of varying.
- Product Architecture and Functional Structure: **Insight in the mechanism and the interfaces and links between parts and modules.**
- Manufacturing Processes, Critical Suppliers, Previous or Current Products, Quality Control Plans and Data, Scrap/Rework Data, Failure Modes and Effects Analyses (FMEAs), Customer Complaint and Warranty Data, and Statistical Process Control (SPC) Data: **Insight in variation sources and the probability of failures/variation.**

For the variation risk assessment, the main elements of focus in this paper are how the development team acquires: a) **Insight in the contributions of part and process variation**, and b) **Insight in the risk and cost of exceeding the tolerances of the important system requirements**, inspired by Thornton (2003).

Finally, this paper investigates how the insights from the variation risk identification and assessment are **used in the design process**, specifically how the insights affect the choice of concepts.

3 RESEARCH APPROACH AND INDUSTRIAL CASE STUDY

3.1 Respondents

In order to assess the variation risk identification and assessment process, in the early stages in the company, interviews were the main source of information. Interviewing has the advantage of being able to dive into insights and issues from several projects in a very short amount of time. The product development process usually takes several years for each project, so direct observation of the process only acquires a small sample of the total process. The disadvantage of interviewing is that the input is subjective, so the respondents are able to highlight issues and answer according to their roles in the process.

The interview-guide was semi-structured and six key employees in the variation risk identification and assessment process were interviewed. There were two tolerance experts, two lead engineers and two project (mechanical team) engineers. The inclusion criteria were that they had participated and contributed to the process of managing variation and tolerances in past or current development projects at the company in question. The respondents had been working with different projects and they were selected for interviews so that each respondent only had to remember and describe the process for maximum three different projects, and so that most of the projects had at least two respondents, so that their answers could be used to verify each other.

The six respondents have been working at the case company for many years, and have thus been involved in the process of managing variation in several development projects. Therefore, they collectively have a profound experience in the applied methods used at the company, and how these methods influence the concepts along the development process.

3.2 Interview Form

In order to acquire both qualitative and quantitative answers the interview had five questions and five statements (presented below). The questions and statements were asked alternately and the progress of the interview was aided by a timed slideshow with one question or statement pr. slide. The respondents were asked to state to which extent they agreed with each statement according to a 5-step Likert Scale (Likert, 1932) and asked to explain why. The scale was presented as a visual horizontal scale on the respective slides. The respondents were asked to give examples and answer the questions specifically with regards to the projects they had participated in (maximum three projects). The statements were also answered according to their opinion for each of the highlighted projects.

The questions for the interviews were the following:

1) "How did you identify and assess the influence of variation in the design parameters on performance of key product functionalities?" 2) "Which specific tools did you use and how did you work with these tools in the project? Give examples." 3) "How did you use the output of the identification and assessment of variation-related issues in the concept development?" 4) "If any, how did you identify and deal with coupled and conflicting requirements? Give examples." 5) "Describe any deviations in the anticipated issues or surprising insights that emerged over the course of the projects? Give examples."

The statements for the interviews were the following:

1) "The variation-related issues in the concept designs were identified and assessed efficiently (in terms of speed and performance)." 2) "The tools used in the variation identification and assessment process were efficient." 3) "The variation-related issues in the concepts were overcome efficiently in the projects." 4) "The way coupled and conflicting requirements were handled in the projects was efficient." 5) "The way variation was dealt with in the projects was adequate for finding all variation-related issues."

3.3 Description of the Case Study Company

The case study company produces compact handheld medical devices and the accuracy of the products key functionalities are of high importance for the safety of the customer. At the same time, due to the large scale of the production, and in order to keep costs reasonable, very narrow tolerances cannot be obtained. For most of the part features, IT13 is specified as the tolerance.

Consequently, the company has already been implementing robust design methods and is aware that the variation and tolerances have to be analysed and monitored during the entire development process.

4 DATA ANALYSIS AND RESULTS

4.1 Qualitative Input

The statements from the six respondents were compared and issues that were mentioned several times by different respondents were gathered and sorted into the chosen framework:

4.1.1 Support for Insight in the User Requirements:

The main support stated, for obtaining insights in the user requirements, was the Product Specification (PS) Requirements, i.e., the top level system requirements. These are typically defined in the beginning of the project - during the stages equivalent to the Planning and Task Clarification Stage (Pahl and Beitz, 2007) - but are updated slightly throughout the project, when the solution is concretized. A respondent gave an example where the requirements had to be interpreted further, because the solution showed that the initial requirement was not specific enough. The interpretation was adjusted to what was technically possible in the given concept.

Several respondents mentioned that the initial requirements were stated relatively vaguely but cascaded into technical requirement with measurable ranges during in the project. An example was that a sound from the product had to be audible for the user and this was then translated into a decibel range based on recommendation from literature. According to one respondent the hardening of the requirements (i.e., cascading the PS into technical requirements) lead to a lot of discussions and they were aware of being careful not to spend too much time on analysing solutions for requirements that could be softened. The settlement of the requirements comes from discussion between the different disciplines (such as manufacturing, assembly, material selection, structural stability, etc.).

The common practice at the company is to keep track of the PS requirements by making functional descriptions for each, describing the fulfilment of given functions and assessing them in terms of company-defined robustness Key Performance Indicators (KPIs). The issues identified are managed and prioritized in a grid that places the issue according to the level of certainty of fulfilling the requirement vs. the amount of time the issue is likely to delay the project. The prioritization is done by the project lead engineer in weekly meetings with the group of mechanical engineers and specialists.

Besides this, all of the respondents said that identifying the target of tolerancing and variation risk management work was primarily founded on intuition based on experience with previous devices. Some of the respondents stated that they look into calculation sheets of previous devices and that they write down a gross list of calculations that may be relevant. Many of the respondents mentioned that they have 'standard calculations', meaning that certain issues are likely to be similar to previous projects.

Some of the respondents mentioned that the severities of the consequences of not fulfilling the requirements are thought of when identifying core-functionalities. Since the company design medical devices the accuracy of the product is always of high importance, both regarding user-safety and approval by medical authority, but it was also stated that the degree of severity of exceeding the tolerances of the low level requirements is not communicated clearly to the tolerance experts when identifying and assessing the impact of variation.

4.1.2 Support for Insight in the Mechanism and Interfaces

All of the respondents mentioned that a deep understanding of the mechanism structure and interfaces is crucial for identifying variation-related issues. The tolerance experts mention that they thoroughly go through the CAD-model in order to understand the mechanism of the design. The designers have a good understanding of the mechanism, since they have been part of designing it, but communicating how the mechanism works to the tolerance experts takes a long time. The products are highly integrated meaning that many parts have several functions at several states, making it difficult for outsiders to quickly understand the mechanisms.

Dialogue between the tolerance experts and the designers is the main way of identifying the variation-related issues. The experts state that the team members know what is important to investigate and the designers state that the experts typically find further issues than they are able to find themselves. Therefore, the tolerance expert has to know the design and the requirements very well, since the designers rely very much on the experts to find all the hidden issues. The dialogue between the experts and the designers works as a way of sharing the experience of variation-related issues and the understanding of the mechanism structure, interfaces and requirements. The tolerance experts bind the structure of the mechanism together with the important user requirements and the expected variation and thereby produce a list of tolerance stack-ups that have to be calculated in order to ensure proper functioning of the concept. Therefore, it is crucial for the experts to have a deep understanding of the mechanism and the requirements.

Tools used for communicating and illustrating the mechanism function - and also the calculated tolerance stack-ups - are mainly simplified 2D-sketches, either by hand or by computer and screenshots of the CAD-model. A new initiative in the company is for the designers to produce swim-lane diagrams that illustrate the different states of the mechanism, along the use.

Several respondents have stated that prototyping has shown many cases of unpredicted interfaces, where the use of the product, or the internal behaviour and movement of the components, have been different than anticipated. E.g., this could be unanticipated issues appearing when dialling a button in the opposite of the intended direction, or activating the mechanism in certain sequence, or simply by dropping it on the floor.

4.1.3 Support for Insight in the Variation Sources and Probability of Failure/Variation

The designers obtain knowledge about the variation in manufacturing and assembly, thermal variation and structural variation in collaboration with experts in the different fields. Together they produce analytical models and simulations that predict the geometrical part-variation well.

IT grades are highly used as a rule of thumb where guidelines are used according to the material and the manufacturing process. The specific IT grades are used in the tolerance stack-up calculations.

Most respondents expressed that the prediction of user variation and internal movements of components is challenging and estimations are usually based on gut-feeling, built on years of experience with similar mechanisms. Studying the CAD-model and drawing 2D-sketches is the usual support for obtaining this understanding.

A respondent stated that determining the acceptance criteria of the initial screening process was difficult, since applying 'too hard' requirements would not let any concepts through and applying 'too soft' requirements would let variation sensitive concepts through. Sometimes estimations of variation impact give results borderline to the limit of what is acceptable. In these cases it is difficult to argue against or for a given concept, due to uncertainty of the calculations.

4.1.4 Support for Insight in the Contribution of Part and Process Variation

The main tool used at the company for assessing the part and process variation is a validated spreadsheet that includes: 1) a list of tolerance stack-up calculations needed for the examined concept, 2) all the specific calculations, and 3) a parameter list with the measurements of the geometrical features used in the tolerance stack-up calculations. The list of calculations is specified by the tolerance experts in dialogue with the project team, summing up the identification of variation-related issues. The parameter list has to contain measurements from the technical 2D-drawings of the parts, where the measurements are annotated and given a parameter number. This means that for using the tool correctly, the designer has to update the 2D-drawings with datum planes and annotations and update the parameter list accordingly and then calculate the tolerance stack-up (See Figure 1). It was stated that annotations done during the official tolerance stack-up calculations are often not configured correctly, so that reviewers have to redo many of the annotations, and thereby they also have to redo many of the tolerance stack-up calculations. This requires much extra work.

Some respondents stated that it is time-consuming and sometimes impossible to setup the intricate calculations of the internal movement of the components, caused by clearances, in the official calculation tool. These calculations are often hard to understand afterwards, resulting in a tedious review process.

Some of the respondents noted that only one person at the time is able to work on the master files. This creates a lot of work of version control, since the solution is sometimes to create local copies of the parameter list. Some of the challenges are to be sure that the parameters are up to date, and that it takes much time to annotate the part-files. Furthermore, the spreadsheet is not very useful for communicating the tolerance stack-up calculations and the learnings from these. A respondent stated that the designers often get stuck with trivial software-related issues, and that they often have to ask the tolerance specialist for help in these situations. Therefore, the designers use their own 'home-made' spreadsheets and sketches for doing quicker calculations and communicating easier to the other team members, but also because the design iterations happen a lot faster than what the official tolerance tool is geared for. The respondents claim that not much spreading of these tools happen in the organization.

4.1.5 Support for Insight in the Risk and Cost of Exceeding the Tolerances of the Important System Requirements

No respondents mentioned estimation of cost of exceeding tolerances. A respondent mentioned that the measurement data from production was used in previous projects to calculate the probabilities of exceeding part tolerances. This feature is not included in their validated tolerance calculation spreadsheet, and updating this sheet is a long process, since the tool will have to be revalidated. The validation is required by authorities since the company produces medical equipment. Thus, the risk and cost of exceeding the tolerances of important system requirements is not done explicitly. The tolerances are set on part level and production is expected to produce the parts within these limits.

4.1.6 Use of Insight in the Design Process

The respondents answered that often only minor design corrections resulted from identifying and assessing the variation-related issues. Often the solution is to narrow the tolerances for the production, and in some cases even finding or inventing new manufacturing techniques for producing within the narrowed tolerances. In some cases the designs have been sensitive to variation on a conceptual level, but yet large conceptual changes are only done reluctantly after the very early stages when the project has been defined. Some of the respondents stated that the initially chosen concept defines the project itself. So if the concept is changed radically the project loses its reason of being, since it will then be a different product. A respondent stated the concepts are so highly integrated that it is rarely possible to take out a sensitive part of the design, without changing the entire concept. Other respondents (primarily the tolerance experts) claim that there is not enough focus on targeting variation-related issues in the beginning of the project, resulting in sensitive concepts.
Figure 1 below is a flowchart illustrating the variation risk identification and assessment process as-is in the specific company. Particularly the step of identifying the features of interest (which are the features that have to interface in a specific way in order for the product to function) and their requirements is a difficult step which is largely based on experience. The process of annotating the 2D-drawing is a time consuming task. The results of the assessment are typically fed back to the embodiment design stage, meaning that the concept design stage is not always supported with regards to variation risk management.

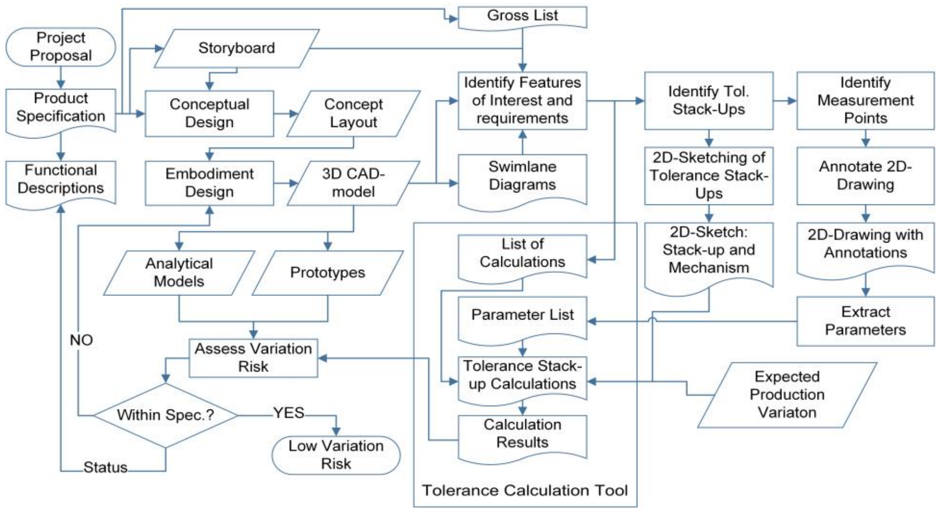

Figure 1. Flowchart illustrating the variation risk identification and assessment process in relation to the product development process.

4.2 Quantitative Input

Table 1 below shows the degree of agreement of the respondents with the five statements. In order to process the input, the degree of agreement was numbered from 1-5, lowest for strongly disagree (1) and highest for strongly agree (5). The mean of the answers are calculated for the tolerance experts (T) and for the development team engineers (P).

Note that for Statement 2 regarding the efficiency of the tools used in the variation risk identification and assessment is one degree higher for the tolerance experts. This difference support that tolerance analysis tools are difficult to use for the project engineers while the experts have an advantage, since they work with it every day. Furthermore, the tolerance experts are responsible for developing the tool, so they will tend to say that the tool is sufficiently efficient.

The mean for Statement 3 regarding the efficiency in mitigating the issues has a difference of half a degree; higher for the team engineers. This illustrates the point of the tolerance experts stressing that variation risk is not mitigated sufficiently, while the project engineers feel that they need to continue on a specific concept layout. Furthermore it is the project engineers' task to mitigate, so they will tend to say that they perform well.

Table 1. Chart with the degree of agreement (1-5) of the respondents (1-6) for each with the statements (1-5) for each of the projects (A-H). Indicated: Project Engineers (P) and Tolerance Experts (T)

Statement:		Statement 1: Efficient Assess. and Ident.								Statement 2: Efficient Tools								Statement 3: Efficient Mitigation								Statement 4: Efficient Handling of Coupled Req.								Statement 5: Adequate proc. - finding all issues							
	Project:	A	B	C	D	E	F	G	H	A	B	C	D	E	F	G	H	A	B	C	D	E	F	G	H	A	B	C	D	E	F	G	H	A	B	C	D	E	F	G	H
Respondents	1 (P)		3						4		3						3		2						4		2						3		3						4
	2 (P)			3			4	5				3			5	3				4			5	5				4			4	4				3			5	5	
	4 (P)				4		2						3		3						4		3						5		2						4		2		
	6 (P)			4	4							2	4							3	4							3	3							5	4				
	3 (T)	5						3	4	4						3	4	5						4	4	4						4	4	4						4	4
	5 (T)	5	2			2				4	5			5				5	1			1				5	1			1				4	4			4			
Mean (P)		3.7								3.2								3.8								3.3								3.9							
Mean (T)		3.5								4.2								3.3								3.2								4.0							
Strongly Disagree=1, Disagree=2, Neutral=3, Agree=4, Strongly Agree=5																																									

5 DISCUSSION AND PERSPECTIVES

5.1 Ill-supported activities

The main ill-supported activities in this specific case study are:

5.1.1 Balancing hardness of requirements and the screening

The balance of the softness of the user requirements and the roughness of the robustness screening is done today by gut-feeling from experience and discussions in the project teams together with the tolerance expert. These are lengthy processes, which should be supported further.

The degree of softness/hardness of the user requirements often depends on the safety of the user and consideration of other stakeholders, and risk assessments are typically made, but communicating the consequences of exceeding the boundaries and including these when designing the concept and assessing the impact of variation was not done sufficiently well at the time of the study.

The uncertainty about the roughness of the robustness screening may be attributed to the uncertainty about the exact degree of variation, and that the design is often on the edge of what is technically possible.

5.1.2 Communicating Mechanism and Tolerance Calculation Results

Currently, the team-to-expert communication of the concept mechanism is done by 2D-drawings, Swim-lane diagrams, and dialogue. Yet it takes long time for an outsider, such as the tolerance experts, to get to know all the details of the mechanism, partially due to the high complexity of the designs. This process seems to need further support.

Furthermore the designer-to-designer and expert-to-designer communication of the tolerance stack-up calculation findings is difficult with the official tolerance stack-up spreadsheet. Therefore, designers develop their own simplified tools, but these are not spread out through the organization, and no official light-weight tool is available.

5.1.3 Predicting User Input and Internal Component Movement

It is difficult for the designers and the tolerance experts to imagine all the ways the user may use the device, and related to this, how the internal components of the mechanism interact outside of the intended scope. This has to do with mechanism understanding as well. Currently prototypes help in finding unpredicted issues, but they are more costly and take more time to make than using virtual tools. The process of identifying the problems related to these issues relies very much on the experts' and the designers' imagination and experience.

5.1.4 Documenting Tolerance Analysis

Today the designers are prompted to annotate the measurements used for the tolerance stack-up calculations on the 2D-drawing of the parts involved in the stack-up. This is a very lengthy process, and requires thorough version control, so that part-annotations and parameters in the parameter list are updated. Software has been implemented for extracting the parameters from the drawings, but still it takes much time to set up. It is noted, that the annotations, and therefore the calculations, have to be redone, because they are typically not done properly by the designers in the concept- and embodiment stages. This may be due to lack of training or lack of time. A more light-weight official tool for calculating the tolerance stack-ups could be a solution for this.
Furthermore, setting up the intricate trigonometric calculations in the spreadsheet tool is cumbersome, and the resulting calculation sheet is difficult to review because the layout makes it difficult to comprehend the calculation steps. Because the tool is heavy to work with, the designers often need assistance from the tolerance experts, for teaching them how to use it, for helping them out with technical problems, and for version control.

5.1.5 Implementing Robustness in Early Definition of the Projects

In some cases the definition of the projects, done in the task clarification stage, confines the project to a variation sensitive concept. This particular design constraint becomes the identity and reason of being for the project, and combined with the typical highly integrated nature of the products produced at the company, there is only room left for minor design changes. Since the projects become driven by a variation sensitive target, a trade-off has to be done regarding variation related issues, and the team will try to make a variation sensitive concept work anyways, typically by narrowing tolerances in the production. It is observed from the interview answers that variation risk management is mainly done in the embodiment design stage today and it is mainly in this stage that the tolerance experts are included in the projects.

5.1.6 Implementing Statistical Information in the Calculations

Neither the validated tolerance stack-up calculation tool nor the current homemade light-weight tools have the feature of including statistical information about the production processes. Previous projects have been including it, and it was beneficial for estimating the error rates. Thus, this would be a relevant additional feature to the official tool used.

5.2 General Applicability

The chosen company for this case study is one of the world leaders within its industry, and has for several years been working with implementing variation risk management, such as robust design principles, and variation analysis. The company has a high-volume in-house production at several sites around the world, and has a lot of knowledge and control of production related variation sources. The medical application of the devices forces the company to have particularly much control over the variation that the end-user experiences, because malfunctioning products may have very negative consequences for the user. Furthermore, as mentioned earlier, the tolerances cannot be specified too narrowly, due to cost considerations.
The findings in this study does not conflict with the findings of either Thornton (2000), Gremyr and Hasenkamp (2011), Ertan (1998), Parkins (2004), or Padgalskas (2007) described in the introduction.
Of course, the limited amount of respondents is a weakness in the method here, and thus further investigation should be conducted. However, the findings in this paper are found from a high-performance, world leader within VRM, and some of these findings are similar to previous works. Issues illustrated in this paper may therefore be likely to occur in other similar companies as well.

5.3 Further work

An area of further research will be to develop support for the abovementioned ill-supported areas, by either by introducing new tools or new processes and testing them in the same company and in similar companies. From the abovementioned ill-supported activities, it is suggested that tools are developed for: 1) Including consequences and probability of exceeding tolerances of requirements, 2) Rapid screening of variation risk and tolerances and communication of learnings during the embodiment design stage, 3) Communicating, understanding and predicting of how the product works (sequences, internal components, mechanism). A process is needed for earlier engagement of variation risk management, during the early concept design stage.

6 CONCLUSION

The purpose of this paper was to answer the question of which activities are ill-supported in the process of identifying and assessing the variation-related issues in the product design during the early product development process. By conducting interviews with six key stakeholders in the variation risk management process at a case study company it was found that during the concept- and embodiment design stages, the main ill-supported activities are: 1) Balancing hardness of requirements and the screening, 2) Communicating Mechanism and Tolerance Calculation Results, 3) Predicting User Input and Internal Component Movement, 4) Documenting Tolerance Analysis, 5) Implementing Robustness in Early Definition of the Projects, and 6) Implementing Statistical Information in the Calculations. The process is described as being largely based on gut-feelings and mechanism experience, and relies heavily on the tolerance experts to identify and assess variation-related issues by binding knowledge and experience of requirements, mechanical structure and variation sources together, and for technical support of the related analysis tools. This confirms the original hypothesis, that the processes are ill-supported, and that the design teams rely heavily on the tolerance experts during the variation risk management process.

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