DECISION-MAKING AND FEEDBACK AS FOCI
FOR KNOWLEDGE-BASED STRATEGIES
SUPPORTING CONCEPT DEVELOPMENT

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Keywords: decision-making, design feedback, concept development, risk, robustness

1. Introduction
Performance attributes of the product, such as robustness, reliability and safety are widely acknowledged as relevant considerations through the design process. Yet they are more important in early design stages to ensure the feasibility of design requirements and reduce later design rework in the product lifecycle. This influence is due to the available room for making decisions, together with the cascading effects of these through downstream design activities [Andreasen and Olesen 1990]. Prior studies revealed the incompleteness of information from early stages for using current methods for robustness, reliability and safety, which also confirmed the problem of the extensive resource requirements in their use [Marini et al. 2010]. In response to this conclusion, a longitudinal study was performed in collaboration with the manufacturer of an insulin injection pen. This study followed the development of 20 solution alternatives for a new design of such device. This paper aims to describe the influence of design decisions and feedback originated from failures in solution alternatives during the concept development activity. It identifies the characteristics of the development process that influence practices in decision-making and feedback, and it discusses strategies to evaluate and mitigate failures in solution alternatives.

2. Background
This section presents the background for this study, comprising of engineering design knowledge management, and risks during concept development. Descriptions of the design process provide generic overviews on the design process [Pahl et al. 2007]; or they emphasize different views on engineering design activity: for instance, guidance to management as a nesting, multi-faceted set of activities [Hales 1993], and prescriptive methodologies to evaluate and verify a design, with focus on dealing with variation [Yang and El-Haik 2006]. Product design considerations need to accommodate competitive needs. Multiple-technology and multi-domain designs, and the need for their fast integration, have given birth to product architecture considerations [Ulrich 1995]. Modularity has particular importance, as it influences development management, design flexibility and product performance [Hölttä et al. 2005]. Considering the variety of solution alternatives and the uncertainty of their satisfying design requirements, concept development becomes a situation subject to uncertainty and ambiguity [Schrader et al. 1993]. This escalates the lack of awareness of designers about the knowledge which is available to them against the information requirements to assess and manage technical risks, which is only mitigated by experience [Bracewell et al. 2005].
Uncertainty and ambiguity pervade through the design process, cascading from the comparison of requirements against customer needs toward the development of a design solution with the aim of satisfying such requirements [De Weck et al. 2007]. The common reuse of past designs intuitively performed by engineers is understood to mitigate the uncertainty in novel developments, but may increase the ambiguity from conflicts in changed interfaces [Eckert et al. 2005]. The occurrence of failures is linked to the lack of scrutiny on solution alternatives, and the lack of awareness to the losses from past mistakes [Petroski 1994]. Four types of impediments preclude failure prediction: too much effort to process information, bias to avoiding commitment, isolation and lack of coordination, and lack of confidence on methods [Busby and Strutt 2001]. A major issue to assess and manage risks throughout the design process concerns methodologies that allow teams to build shared understanding of risks and uncertainties [McMahon and Busby 2005].

Experience plays a significant role when designers make references to prior facts they were told by their peers or experienced themselves [Visser 1995]. Designers engage in branching out issues and alternatives in decision discussions: criteria are updated along the emergence of situations, while previously considered factors may be forgotten upon this evolution [Dwakaranath & Wallace 1995].

Other characteristics of design decisions consider: short time given to discussing the importance of criteria; and little influence of formal methods on justifying the evaluations [Girod et al. 2003].

3. Knowledge strategies in the design process

This section presents the classification of design knowledge, the representation of design with models, the capture of design rationale, and the recognition of heuristics in design models and designers’ behaviour.

Design knowledge is classified in different types through ontologies, in order to facilitate the acquisition and retrieval of design information by indexing mechanisms [Ahmed 2005][Naay et al. 1992]. The derivation of these ontologies is to be carried out through empirical research with the aim of extracting generic types from information specific to individual design projects. Current knowledge in literature provides a basis for establishing prior definitions for the intended classification; this is complemented by the extraction of novel types from empirical data and their validation in dialogue with users [Ahmed et al. 2007]. A taxonomy for robustness, reliability and safety issues in product design attests the effectiveness of this framework in approaching complex issues, such as the evaluation of information requirements in current methods for robustness, reliability and safety [Marini et al. 2010].

Design rationale consists of relevant knowledge about the reasons designers define for engaging in specific courses of action through the design process. The capture and development of design rationale starts from generic frameworks guiding the identification and treatment of design issues toward recording decision chains for later retrieval and playback [Nagy, Ullman & Dietterich 1992]. This approach is implemented with a design rationale recording tool, DRed, that departs from a simplified issue-based framework to implement a fully functional design rationale tool that records the discussion of issues to defining conditions of further action [Bracewell et al. 2004]. A simplified approach based on sketches and interconnected statements about concept-configuration-evaluation triplets [Kroll and Shihmanter 2011] captures design rationale generated during concept design.

The use of heuristics consists of extracting ‘rules of thumb’ and strategies from observing models and activities in the design process. The meanings of visual and behavioural signs extracted from design models are then translated to guidance for designers when engaging with problems. One significant instantiation is the definition of design principles extracted from long-term experience [French 1992]. This approach is applied to modelling with the suggestion of heuristics for the modularization of product architectures starting from functional system models [Stone et al. 2000], which are recognized from the graphical interpretation of function structure models. Other way to use heuristics is to follow expert behaviour and recognize strategies that can be applied in order to improve communication among designers and solve design issues [Ahmed and Wallace 2004]. A fuzzier use of heuristics takes place when extracting design attributes of good examples as ‘rules of thumb’ to generate better solutions [Fu et al. 2010].
3.1 Our conclusions

Most propositions for engineering design address the engineering design tasks as the context of their use. They give support to engineering design in form of prescriptions and strategies to modelling solution alternatives and evaluating their performance. In our view, Knowledge management solutions have already been successfully applied to engineering design in order to support leveraging the intellectual capital inside manufacturing organizations.

However, current processes of concept development are still surrounded by uncertainty and ambiguity as the understanding about the intended solution is at best approximate and incomplete. Little scrutiny of solution concepts, attitudes that preclude failure prediction and the lack of methodologies to build common understanding about risks affect proper decision-making towards reducing technical risks. While knowledge management solutions work well in supporting the design task, there are significant issues: in the one hand, their effective use in decision-making is at best elusive as their support focuses the long-term design activity in modelling and generating knowledge; in the other hand, approaches for decision-making tend to focus on making records about the decision process rather than actually assisting designers, and taking advantage from their knowledge.

4. Research method and aims

This study was performed as an investigation of opportunities to improve the ability in managing technical risks during early design phases. This study aimed at finding out how current practice imposed obstacles to solving problems in regard to the attributes of robustness, reliability and safety in solution alternatives. The insulin injection pen is characterized as a precision-mechanics device integrated with electronic components whose performance is especially sensitive to robustness, reliability and safety attributes due to the life-threatening implications from performance shortcomings regarding the application of insulin in diabetic patients.

The study was performed as a longitudinal case study [Yin 1994] with the objective of investigating complex relationships in the use of design information to evaluate robustness, reliability and safety attributes and their implications to the course of action in concept development. As its objective is to find out and describe shortcomings with current practice in concept development, it can be understood as a first descriptive study within the design research methodology [Blessing and Chakrabarti 2007]. The research approach consists of collecting retrospective data about 36 months of concept development activity for developing the principle solution for the new device, along with interviews to explore the context and validate the findings on the information about the project. Four data collection approaches were used: document analyses, reverse engineering [Otto and Wood 1998], interviews (open-ended and semi-structured) and modelling/representation. Their use throughout the project is summarized in Table 1.

Table 1. Longitudinal case study [Marini et al. 2011]

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Document Analyses</th>
<th>Reverse engineering</th>
<th>Interviews with designers</th>
<th>Modelling and representation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case executed with actual project</td>
<td>17 partial/closure stage presentations</td>
<td>4 sketch sessions of work principles</td>
<td>5x open-ended on R3 development issues</td>
<td>9 function modules in all alternatives</td>
</tr>
<tr>
<td>Researcher observes project</td>
<td>5 technical risk stage reviews</td>
<td>20 alternatives of solution (concepts)</td>
<td>3 mechanical engineers, 1 system engineer and project manager</td>
<td>Several overview and close-up screenshots of alternatives</td>
</tr>
<tr>
<td>Longitudinal and retrospective study</td>
<td>14 feasibility reports on features</td>
<td>50 CAD variants with small changes</td>
<td>Not mediated, with video records. (45min each)</td>
<td>3 sequential/timeline development graphs</td>
</tr>
<tr>
<td>Comprehensive study of situation</td>
<td>4 matrices about set-based dev.</td>
<td>9 modules in system formulation</td>
<td>3x semi-structured on concept selection decisions</td>
<td>Total of 50 failure occurrences to reject</td>
</tr>
<tr>
<td>36 months from sketch to solution</td>
<td>Several reports from evaluations</td>
<td>61 work principles in all alternatives</td>
<td>Mechanical engineers: 2 veteran, 1 expert; Risk specialist</td>
<td>Total of 47 mentions to technical risks</td>
</tr>
<tr>
<td>Lead time launch in 6 to 8 years</td>
<td>Validated by interviews</td>
<td>Associated to interviews</td>
<td>Specialist as mediator, with video records (60 min each)</td>
<td>Developed upon interviews</td>
</tr>
</tbody>
</table>
Document analyses were carried out through the whole case, to understand when concepts were generated, which models were developed, which issues took place and when concepts were discarded. Reverse engineering was used to identify the functions performed by design alternatives, their working principles and similarity between these. The project team was composed by the project manager, three mechanical designers (two veterans), one risk specialist, and three electronics engineers (one veteran). Open-ended interviews were carried out with all mechanical designers, one system engineer and the project manager. Semi-structured interviews were carried out with mechanical designers only. Questions asked focused upon two types of issues: challenges and measures to manage technical risk (open-ended), and the rationale for selecting and rejecting design alternatives (semi-structured), to guide the search for information and validate the findings from documentation and reverse engineering, respectively [Marini et al. 2011].

5. Results

The data collected during the study was analyzed to understand the general approach to concept development, the solution alternatives and their working principles. The relationships between the alternatives and the reasons for their rejection were examined in the data. The first result is the description of the concept development process as executed. The study followed the development of solution alternatives up to the final choice of solution principle, concerning the scope of the internal mechanism of the insulin injection pen.

![Figure 1. Development of solution alternatives](image-url)
Figure 1 shows the phases and stages (Mx) for the development of solution alternatives of the medical device, from concept development up to testing and refinement, when a principle solution was selected. The developed alternatives are shown in the vertical axis, with the design stages shown in the horizontal axis. The legend in the figure indicates the development states of alternatives and the milestones of alternatives being rejected, put on stand-by, and passed.

The first phase, concept development, concerns the implementation of working principles and their integration in alternative mechanism formulations. These provide approximate descriptions of working principles and of their physical implementation in product architectures. In that context, their development focuses issues regarding the performance of mechanism designs in order to minimally satisfy design requirements. The development of alternatives is shown to continue through system and detailed design, which indicates the negotiation of interfaces between system functions. That reflects the adoption of a set-based approach [Ward et al. 1995], where solutions are explored and refined through a long period. Designers continuously negotiate design interfaces up to reaching agreeable strategies and converging values to establish the solution principle. Later alternatives are developed with increasing detail, reusing working principles used in previous alternatives. If some of them are rejected, new alternatives are designed with variations in architecture and changes in working principle. The changes in working principles reflect an exploration of possibilities in regard to satisfying requirements on given system functions.

The second result is the description of reuse and variants of working principles in solution alternatives. The study has obtained knowledge about the reasons to reject solution alternatives by interviews with engineering designers, performed when the solution principle was being refined.

Figure 2 shows the variety of working principles that was used and reused in solution alternatives, compared against the reasons found for the rejection of solution alternatives. The developed alternatives are shown in the horizontal axis, with the reasons to reject and the variety of working principles shown in the vertical axis. The occurrence of failures and the reuse of working principles are represented with arrows, with repeated failures are highlighted in red.

The figure shows that variety of working principles in adjacent functional units was found to be the highest in proportion to the complexity of function units in their number of physical interfaces. The Actuate displacement unit was found to have an average of eight interfaces through solution alternatives, and the export medicine unit was found to have an average of three interfaces. In that regard, the variety of working principles increases with the number of physical interfaces, as there are more degrees of freedom that need to be negotiated. Another characteristic found through the study was the repetition of reasons for rejection in parallel with the reuse of working principles from alternatives that were previously rejected for the same reasons.

While the reuse of past designs facilitates much of the design work as they incorporate knowledge which is already developed [Eckert et al. 2005], it becomes a problem when different solution alternatives fail because of the same problem. The repetition of failures indicates that not enough knowledge was collected from previous decisions. This takes place as decisions are taken through the development process without clear enough information on their motivations. At the same time as the available information enables designers to make decisions, repeated failures take place because of the failure to incorporate previous failure occurrences as feedback to further development work [Marini et al. 2011].

Repeated failures take place more often on function units that are more complex. This may be due to the fact that decision statements clearly described the performance failure that motivated the rejection of alternatives, but could not pinpoint where the failure took place or what was the issue so that to provide feedback to the development of further alternatives. The reuse of working principles that failed previously ended up consuming development resources that could be invested into implementing novel solutions from principles that worked well and needed improvement.

The third result consists in the identification of direct relationships between decisions on solution alternatives and the development of new ones. The study focused the development timing among solution alternatives, identifying the development of further solution alternatives from the need to create feasible options to implement the principle solution for the mechanism of the insulin injection pen.
Figure 3 shows the development timeline highlighting the relationship between the rejection decisions and the generation of new alternatives. The decision-making milestones are shown in blue, while the generation of new alternatives is shown in red. The decision–feedback loops are shown in red dashed squares, and identified from A to G. The first phase in the project shows several parallel alternatives on the run, with three feedback loops (A, B and C), which is the same number of feedback loops in all other subsequent phases.

It was shown that evaluation methods in concept development influence decisions and feedback on solution alternatives [Marini et al. 2011], and this illustration confirms the strong relationship between decision-making and feedback. The results on design reuse shown in this paper indicate there is a shortcoming in taking advantage from decisions made to avoid the repetition of reasons for rejection in further solution alternatives.

That consists of the failure in decision-making and feedback to learn from the first occurrence of failure – data collected from the study show that such repeated failures are only definitely corrected upon their second or third occurrence among several alternatives. The issue with failing to pinpoint the locations of failure derives very much from the ambiguity among the product architectures of solution alternatives in regard to the parameters in working principles.
It is difficult to make generic criteria applying to all possible variants, especially when they are to be compared at the component level. That generates the need for support to overcome such differences in comparing alternatives and identifying their failures [Schrader et al. 1993]. The chain of decisions through the project shows that the decision criteria not only evolve through single meetings [Dwakaranath and Wallace 1995] but mainly in the long-term through the evolution of issues in the design process. That takes place as the decision criteria evolve from a concept basis to a system basis. However, the study has shown that the reasons for rejecting solution alternatives stay mostly the same through early phases of the design process. That can be interpreted as result from overall functional and environmental parameters that make the general concept of the new design. These parameters operate at the technical process level, so they influence the kind of working principles that can be used. This could be used as cue to predict most of the issues with selected working principles.

6. Discussion
Current knowledge management approaches provide support to ongoing development tasks, but there is need to assess their effectiveness in supporting designers when they need to make decisions and take advantage from the knowledge they learn from issues in previous alternatives. Table 2 shows a comparison of approaches to identify and mitigate failures in product development. Set-based development is being increasingly applied through industry, as our case shows.
Table 2. Comparison of approaches to identify and mitigate failures in product development

<table>
<thead>
<tr>
<th>Industry/ref.</th>
<th>Medical device</th>
<th>Automotive</th>
<th>Oil &amp; Gas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size, no. parts</td>
<td>Small, n x 10^2</td>
<td>Medium, n x 10^3</td>
<td>Large, n x 10^2</td>
</tr>
<tr>
<td>Complexity</td>
<td>Low</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>R3 dependency</td>
<td>High</td>
<td>Medium</td>
<td>High</td>
</tr>
<tr>
<td>Focus area</td>
<td>Eng. Design, DFx R3</td>
<td>Product development</td>
<td>Eng. design, process</td>
</tr>
<tr>
<td>Duration</td>
<td>36 months</td>
<td>6 months (interviews)</td>
<td>38 months</td>
</tr>
<tr>
<td>Management framework</td>
<td>Set-based development</td>
<td>Set-based development, Mizenboushi</td>
<td>Risk assessment, compatibility matrices</td>
</tr>
<tr>
<td>Modelling approach</td>
<td>Whole product, system mechanism: virtual and physical prototypes</td>
<td>Components, subsystems, virtual and physical prototypes</td>
<td>Subsystems, whole product, virtual prototypes</td>
</tr>
<tr>
<td>Knowledge platform</td>
<td>Expert knowledge</td>
<td>Expert knowledge, KBE</td>
<td>Expert knowledge, KBE</td>
</tr>
<tr>
<td>Failure identification</td>
<td>Measurement + simulation</td>
<td>Measurement + simulation + DRBFM</td>
<td>Simulation + FORM/SORM + HAZOP</td>
</tr>
<tr>
<td>Evaluation and testing of alternatives</td>
<td>Brief tests on generic parameters, working principles earliest evaluated on tolerances</td>
<td>Single-domain (FEA) tests on partial modules linked by reciprocity on boundary conditions</td>
<td>Math calculations and simulation of design parameters, components on individual factors</td>
</tr>
</tbody>
</table>

The use of set-based development expands the horizon of design alternatives further from concept development, toward alternatives to system and detailed design. The use of past designs is more sensitive to changes, where the Mizenboushi technique [Shimizu et al. 2007] works, with DRBFM (Design Review Based on Failure Mode) as carrier of design considerations. Risk assessment plus methods such as FORM and SORM (First, and Second-order reliability method) is mostly performed in the oil & gas environment, where any issue could be critical threatening the success of the operation. [Busby 1998].

The involvement of designers through the product lifecycle determines the success in that effort. This is more critical at the decision-making process: there is lack of necessary information about critical problems; the information about the severity of most flaws (or the lack of it) does not justify their mitigation; and, there are doubts on whether the issues found make symptoms of flaws in product design [Gries 2007]. While heuristic strategies and taxonomies have shown success with aerospace design [Ahmed and Wallace 2004], [Ahmed 2005], there is more potential to evolve their application on other sectors, with significant role to support, discussion, decision and mitigation of design flaws.

7. Conclusions
Starting from a review of current knowledge about engineering management frameworks, support for knowledge management and issues in concept development and decision, this paper engaged in discussing the recognition of decision-making and feedback as core issues in the repeated failures observed during concept development. Results from a longitudinal study performed in collaboration with a medical device manufacturer demonstrate the need to support the evaluation of several options starting from concept design toward the choice of the principle solution, the failure of current practice to avoid the repetition of flaws in robustness, reliability and safety on solution alternatives, and the need to address decision-making and feedback with knowledge-based support.

Future work involves the development and validation of knowledge-based tools to address decision-making and feedback issues during concept development, considering the manifestation of design attributes and the use of such information by designers for decision-making and feedback.
Acknowledgement

We gratefully acknowledge the members of the project we followed in the medical company – mechanical engineers, system engineers, knowledge manager and risk specialist – for sharing their practice with us and giving us the opportunity to address their concerns. We also thank the CAPES Foundation, the Ministry of Education of the Federative Republic of Brazil, for sponsoring the project under which this study has been performed.

References


DRBFM – Design Review Based on Failure Mode
FORM – First-order Reliability Method
SORM – Second-order Reliability Method
FEA – Finite Element Analysis
KBE – Knowledge-based Engineering
HAZOP – Hazard and Operability Studies

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