An Axiomatic Design Methodology for Manufacturing Process Selection Based on Multi-User Requirements Mapping

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Abstract. The fundamental principles of Axiomatic Design involve the systematic analysis, evaluation and transformation of customer needs into product functions with the scope of deriving a set of design parameters and process variables. This paper presents a novel methodology based on the application of axiomatic design theory, with the aim of supporting manufacturing process selection by considering the technological capabilities during manufacturing and the functional requirements of the artefact in hand. The proposed model integrates both functional and non-functional requirements by mapping various stakeholder needs. A case study for a release-buckle mechanism used in a rehabilitation device is presented. Results of an initial qualitative evaluation with medical device designers provide a degree of evidence that the proposed methodology is useful during process selection activities.

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1 INTRODUCTION

Poor design decisions often limit the functionality of the product in hand [21]. This often results in increased maintenance, re-design or disposal of the product. In areas such as healthcare, poor design can inconvenience patients, doctors or clinicians and might expose users to severe consequential risks upon product use [2], [3]. This highlights the importance of good requirements engineering, with Nam P. Suh stating that careful elicitation of customer needs is a must to properly define the demands of the product [23]. Through the identified requirements, designers can transform needs into specifications and functional requirements. The latter are consequently mapped onto design parameters, however, it often happens that designers start implementing design goals without fully understanding all requirements. Research shows that designers typically generate early design solutions which are not always congruent to what the customer wants [18]. Thus, time is

misused designing a product which is only successful if it reflects the solution the designer had in mind. This idea should be extended to emphasise user involvement within the designated design process [8]. Different methods exist to identify user requirements within the design process. These include Quality Function Deployment (QFD), Axiomatic Design (AD) and Theory of Inventive Problem Solving (TRIZ). In this paper, the original AD model [22] (depicted in Figure 1) will be used as the foundation upheld to support the transformation of multi-user requirements into good product design. The main scope of the AD model is to guide the design process from user needs to product functions whilst it is also beneficial providing guidance to designers to increase design efficiency by limiting repetitive tasks during product design. This is particularly useful in the medical device industry which often involves a high degree of time-consuming and laborious product development cycles. An effort is also made to address the mapping of *Non-Functional Requirements* (NFRs) onto DPs since the original AD model proposed by Suh is only limited to mapping *Functional Requirements* (FRs), but not NFRs. A refinement of the original AD method is therefore being proposed which integrates the identification and mapping of NFRs within the design process.

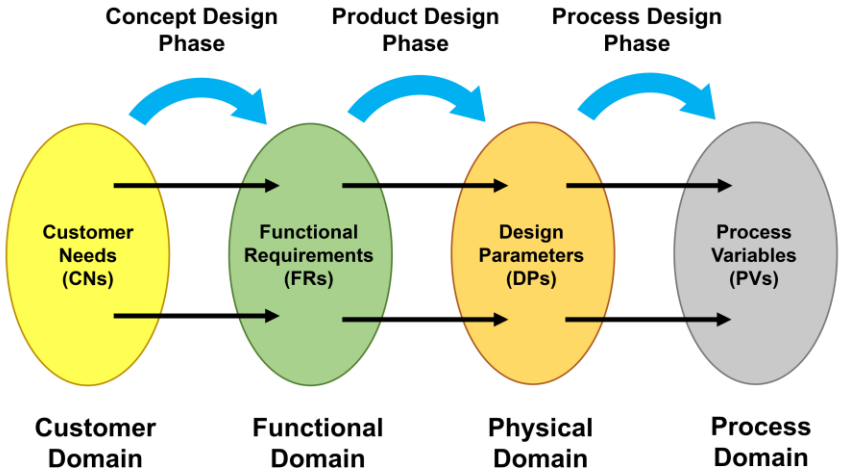


Figure 1: The original AD methodology as proposed by Nam P. Suh [22].

Suh's model transforms customer needs into numerical and measurable information to support the early development of conceptual designs [22]. Research shows that within User-Centred Design (UCD) activities, adopting a multi-user approach provides a more holistic requirements elicitation process [3]. Abela *et al.* showed that identifying requirements from a variety of stakeholders allows for a more useful and effective design process [3]. Thus, the current research study also incorporates multi-user requirements through defining a set of *Stakeholders Requirements Specifications* (StRS).

Numerous studies also stress that successful product design should be based on the consideration of the capabilities of the manufacturing technologies available [15], [17]. To address this requirement, the AD model is deemed an adequate strategy for assessing design ideas in terms of manufacturing capability as early as the task clarification stage. The research objective of this investigation is therefore centred around assisting the designer with selecting the most suitable manufacturing process in view of the identified collective user requirements. The methodology being proposed integrates the assessment of technological capabilities during the manufacturing process selection activity, as part of the AD method. This paper is structured in the following manner: Section 2 discusses the basic elements of the AD model whilst Section 3 discusses background literature concerning various existing models. Section 4 presents a novel AD model aimed towards incorporating manufacturing process selection within the design process. A set of results from an evaluation of the model with a cluster of designers working in *Research and Design* (R&D) are also presented. Finally, Section 5 lists the conclusions resulting from this study.

2 THE AXIOMATIC DESIGN MODEL

Suh describes the goals of AD as being the enrichment of design creativity and the creation of optimal design solution [23]. The AD model supports the designer in generating innovative and functional solutions in a highly efficient manner. Suh argues that the AD method guides designers in generating faster solutions based on *right-first-time* design decisions. Consequently, all possible outcomes converge into an optimal solution satisfying the user's requirements. This philosophy is based on the notion that Customer Needs (CNs) are mapped directly onto *Functional Requirements* (FRs), *Design Parameters* (DPs) and *Process Variables* (PVs) [22]. Solutions are systematically generated by formulating a set of constraints which eliminate poor design outcomes at the initial design stages. This allows designers to focus on the most promising design solution early during task clarification.

2.1 Overview of Design Domains and Axioms

Suh's model is composed of four domains which create the design world in AD (see Figure 1). These are the *Customer Domain*, the *Functional Domain*, the *Physical Domain* and the *Process Domain* [23]. The *Customer Domain* typically encompasses the CNs. In the *Functional Domain*, CNs are mapped onto FRs by means of constraints. The latter are restrictions and limitations placed on any promising solutions. For instance, in the field of rehabilitation an FR can take the form of "Hand Rehabilitation Exercise". FRs are subsequently mapped onto DPs. DPs characterise measurable factors which describe the design solution with the *Physical Domain* [9]. For the same example, the underlying DPs can be described as "Hand Rehabilitation Instrument". The designer is then guided to define a set of PVs. These define the manufacturing process and specify the DPs [9]. PVs can be defined through variables such as build envelope, minimum section and part resolution. The characteristics of each domain are determined by the mapping process between the previous and the consequent domain.

The AD model is also based on two axioms [22]. The first axiom – known as the *Independence Axiom* – is focused on defining only FRs which are independent of each other. The second axiom – known as the *Information Axiom* – is focused towards minimising the information content produced during product design [24]. For a viable solution, the independence axiom should always be preserved. This is possible by evaluating the design matrix which results from the mapping of the FRs. For any given matrix A, the mapping of functional requirements should satisfy the equation:

$$FR = [A] \times DP \tag{2.1}$$

where FR is the functional requirement vector, DP is the design parameter vector and [A] is the design matrix. Similarly, for any given matrix [B], mapping of DPs/PVs satisfies the equation below:

$$DP = [B] \times PV \tag{2.2}$$

3 LITERATURE REVIEW ON AXIOMATIC DESIGN (AD) MODELS

3.1 Incorporation of Non-Functional Requirements in AD Models

Mabrok *et al.* [14] define NFRs as a set of requirements with constraints on the manner that the product achieves the desired functionality. They argue that NFRs are important for consideration in the *Functional Domain* since they characterise the product's performance, quality and reliability. For instance, a rehabilitation device might include "easy to carry around" and "requires no maintenance" as NFRs identified from end-users. Other examples of NFRs are usability, aesthetics, performance, engagement and reliability. Previous studies have shown that Suh's original AD model is only restricted to mapping FRs [4], [7], [25], [26]. This is regarded as a limitation as NFRs are normally excluded from the mapping between domains. Various authors also highlight the importance of merging NFRs. Thompson [26] remarked that the lack of consideration of NFRs leads designers to describe all requirements as functional, or to discard NFRs altogether. Additionally, Delaš *et al.* [7] documented the utility of including NFRs in design, stating that these comprise features which are

indispensable to the user and which are typically excluded when defining FRs. To address the issue of including NFRS, Mabrok *et al.* [14] proposed a refinement of Suh's model based on mapping CNs directly onto both FRs and NFRs. The NFRs in this case are an addition to the requirement vector. In their model, the authors decompose NFRs into three constituent sets of requirements [14]. These are *Non-Functional Performance Requirements* (NFPRs), *Non-Functional System Requirements* (NFSRs) and *Non-Functional Implementation Requirements* (NFIRs). If we introduce these NFRs in the design case of a finger rehabilitation device, these could take the following forms: $NFPR_1$ – Operating time for finger flexion should be less than 60s; $NFSR_1$ – The design should be reliable; $NFIR_1$ – Palm support should be fabricated using additive manufacturing.

3.2 Application of the AD Model for User Experience

Foley and Harðardóttir [11] presented a creative AD approach to consider the feelings and experiences of users throughout the design process. They proposed the terminology of $\mathcal{FR}$ to denote Feeling/Experience requirements. In this case $\mathcal{FR}s$ are mapped directly onto the *Physical Domain* by defining the proper DPs as ordinarily achieved when mapping FRs. This model is intended to promote the creativity and innovation of the designer by providing guidance on interpreting user *feelings* and *experiences*, and defining DPs accordingly. In a separate study, Uang *et al.* [27] proposed a new approach to product design aimed at increasing design usability and efficiency during product development. This was possible by integrating AD principles with the *Theory of Inventive Problem Solving* (TRIZ). The study showed that by combining AD and TRIZ design tools, a number of usability issues can be eliminated during product design. Additionally, solutions can be easily generated with respect to the existing FRs. After generating a set of FRs and corresponding DPs, a set of inventive principles are applied to establish the improved and worsened design features of the artefact in hand. The designer is then guided to make decisions pertaining to such features as part of the inventive principles. For instance, in the design example of a hand-rehabilitation device, aesthetics can be a prerequisite to satisfy a specific user need. In this case, whilst the aesthetics are improved, manufacturability is worsened. TRIZ principles theory are applied to improve the latter. The principle of *Segmentation* (TRIZ Principle 1) is applied to segment the hand-extension mechanism into wrist-extension, palm-extension and finger-extension mechanisms to improve manufacturability.

3.3 Application of AD Model to Manufacturing Process Selection

The application of the AD model is convenient as it provides an opportunity to integrate functionality, specifications and manufacturing process. The original model by Suh involves three sets of mappings i.e., CNs/FRs, FRs/DPs and DPs/PVs. Two design matrices are generated when mapping FRs/DPs and DPs/PVs giving the designer an opportunity to make several early-stage *Design for Manufacturing* (DFM) considerations [23]. However, research reveals inconsistency in terms of when DFM principles should be applied during design. Several authors agree that DFM should start at the early conceptual design stages when specifying functionality and product specifications [20], [28], [29]. On the other hand, Pahl and Beitz [19] and Ferrer *et al.* [9] disagree with this rationale, as they regard the embodiment design stage as more appropriate to apply DFM principles. The authors of this paper deem it necessary to apply DFM prior to any process selection activity, as is also suggested by Ashby [5]. In this case, the selection activity is complemented by design changes to improve the manufacturability of the artefact in hand. The manufacturing process selection task is normally accomplished by mapping specifications onto process attributes. Process attributes (such as *material capability*, *machine tolerances* and *cost per part*) are characteristics of the manufacturing process which define the process capabilities in terms of material, tolerances, cost, shape and size [5]. Ferrer *et al.* [10] proposed an improved AD model which captures important manufacturing information such as critical process characteristics (such as *tolerances*, *surface finish*, *cost of components* and *part manufacturability*) to guide designers in making n decisions so as to fulfil the existing FRs.

The main intention of the approach is to make DFM information concerning the available manufacturing processes accessible to the designer. This is achieved by implementing a four-stage process structured as follows: (1) *Manufacturing Process Selection*, (2) *Identification of Process*

Parameters (PPs), (3) *Definition and Formalisation of PPs*, and (4) *Definition and Formalisation of Execution Variables (EVs)*. Within the first stage, a recommendation is made to use the theory of Manufacturing Process Selection Based on Quantitative Analysis (MPS-BQA). This involves using an off-the-shelf software tool aimed for process screening and selection, such as the CES Selector, originally proposed by Ashby [5]. The DPs are input in the MPS-BQA tool and a viable manufacturing process is output as a result. Subsequently, a set of DP/PP and PP/EV matrices are generated. Additionally, a set of tables are formulated based on industrial practices for the manufacturing process selected. This constitutes the DFM information. A major advantage of the approach developed by Ferrer *et al.* [10] is the integration of AD principles with process selection by directly using the output of the DPs as inputs to the DFM information database. A limitation is that the approach does not take into account NFRs as an input but is only constrained in mapping FRs.

From these reviewed AD-based models it can be concluded that a gap exists linking multi-user requirements elicitation involving both FRs and NFRs, *User Experiences* (UX) and incorporating manufacturing process selection within AD. A model is being proposed to aid in the design of artefacts based on the viability of the manufacturing processes or technologies available to them.

4 PROPOSED AD MODEL TO INCORPORATE MANUFACTURING PROCESS SELECTION

To address the gap identified in Section 3.3, an Axiomatic Design for Manufacturing Process Selection model (**AXI-DEM**) is being proposed (Figure 2). This is based on the critical appraisal of various research studies and a critical review of two other previous studies [2], [3].

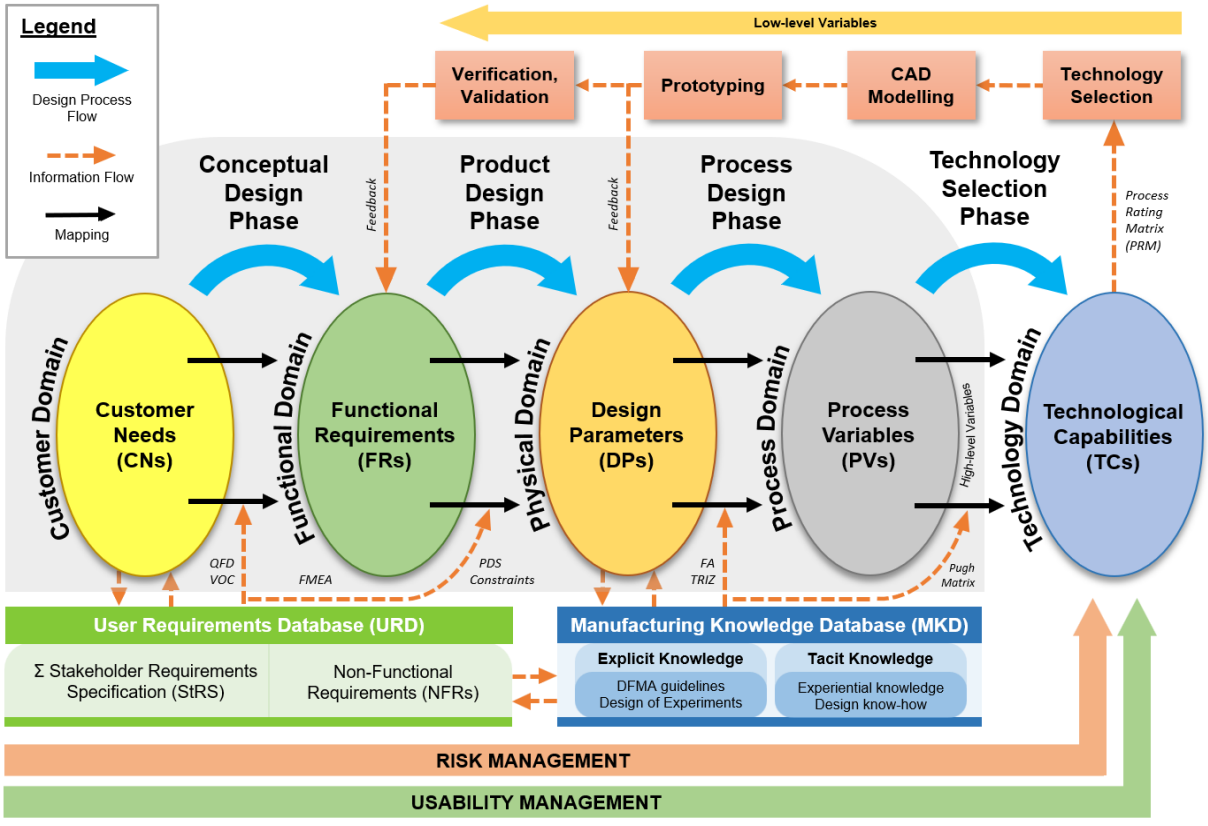


Figure 2: The proposed AD model for manufacturing process selection. Abbreviations: (QFD) Quality Function Deployment, (VOC) Voice of the Customer, (FMEA) Failure Mode and Effects Analysis, (PDS)

Product Design Specification, (FA) Failure Analysis, (TRIZ) Theory of Inventive Problem Solving, (DFM) Design for Manufacturing, (DFA) Design for Assembly.

4.1 Description of the Methodology

A *User Requirements Databases* (URD) is included in the model which feeds into the CNs/FRs and FRs/DPs mappings. The database incorporates a holistic set of requirements other than those related only to the end-user. This implies that a product is regarded as a multi-user system involving the participation of different stakeholders. For instance, a medical device which refers to *the patient* as the customer, might involve additional stakeholders within the *Customer Domain*, such as clinicians, doctors, relatives or community carers, all of which comprise the "user" of the product. These requirements are specified within the StRS. CNs are identified by means of the VOC approach whereby information regarding the user is obtained. This is achieved by interviewing different stakeholders, conducting a thematic analysis of the discussion, determining the importance ratings with respect to different user needs and using this information to initiate a QFD process. The latter is a method to analyse all CNs and map these to FRs. QFD uses a defined set of matrices and charts aimed at translating information obtained through the VOC and stored within the URD into measurable design targets. In parallel to the formulation of FRs, an FMEA is conducted to identify possible design failures with regards to its functionality. This supports the generation of DPs in an effort to reduce, prevent or eliminate failures in acceptable design solution. FMEA follows the QFD in the design process. All requirements and constraints are documented in a PDS document containing all specifications the product is expected to adhere to. The URD also seeks to incorporate NFRs within the database. In this case we are proposing that NFRs are directly mapped onto FRs by means of a requirements matrix [R] hereby acting as a transformation matrix. Consequently, for *n* number of NFRs, the requirements matrix is described through the equation below:

$$\begin{bmatrix} NFR_1 \\ NFR_2 \\ \vdots \\ NFR_n \end{bmatrix} = \begin{bmatrix} R_{11} & R_{12} & \dots & R_{1n} \\ R_{21} & R_{22} & \dots & R_{2n} \\ \vdots & \vdots & \ddots & \vdots \\ R_{n1} & R_{n2} & \dots & R_{nn} \end{bmatrix} \times \begin{bmatrix} FR_1 \\ FR_2 \\ \vdots \\ FR_n \end{bmatrix} \tag{4.1}$$

The model in Figure 2 contains a *Manufacturing Knowledge Database* (MKD). This includes a record of **Explicit Knowledge** (e.g., DFMA standards and guidelines) and **Tacit Knowledge** (e.g., lessons learned through design experience). The latter is integral to the MKD as it provides a basis for manufacturing considerations founded on previous design activities in view of the outcomes of past decisions taken by the designer. The MKD feeds directly into the DPs/PVs and PVs/TCs mappings. A *Failure Analysis* (FA) is useful in this case to realise the issues which may arise during manufacturing. FA typically involves an investigation of the acceptable solutions and allows for corrective action to be taken for mitigating failures during production or product-use. Additionally, as explained in Section 3.2, TRIZ tools are used to assist designers to analyse underlying problems and propose innovative design solutions with respect to the artifact in hand. Two other important aspects of the **AXI-DEM** model are *Risk Management* and *Usability Management*. With *Risk Management* it is ensured that all necessary measures are considered in order to identify, control and prevent failures which can be hazardous to users. This entails proper risk analysis and record-keeping associated with product design. With medical devices, these activities are generally conduced in line with ISO13485 and ISO14971. Proper *Usability Management* should also be followed to ensure that the required safety and efficacy of the product is met. This entails proper usability testing throughout the design process (under the guidance of IEC 62366) prior to placing the product on the market.

The model also presents the notion of *Technological Capabilities* (TCs) constituting the *Technology Domain*. These suggest a formal list of characteristics related to the manufacturing technology available to the designer for fabricating the artifact in hand. TCs can be regarded as attributes which rank different technologies to manufacture a product in terms of the capabilities of the technology accessible to the designer. Through the introduction of the *Technology Domain* another design matrix is generated to map PVs/TCs. The resultant ranking is attributed to each

manufacturing technology and is presented to the designer through a *Process Rating Matrix* (PRM). If [M] designates the PRM, then the PVs/TCs mapping is represented through the equation below:

$$PV = [M] \times TC \tag{4.2}$$

Equation (4.2) allows the designer to make decisions based on manufacturing attributes pertaining to different available technologies described through a set of High-Level Variables. These influence the manufacturing process selection and are independent of in-house technologies available to the designer. Material capability, surface roughness, machine tolerances, post-processing, build envelope, cost per part, minimum section and part resolution can all be considered as High-Level Variables. The PRM facilitates the decision-making process of the designer by establishing a list of weighted criteria to support the selection of a manufacturing technology. The designer then evaluates each option against the set criteria. The *Technology Domain* provides feedback directly into the *Physical Domain* which allows for the refinement of DPs in view of the selected manufacturing technology. Based on the output of the PRM, the designer is then able to define a set of Low-Level Variables and proceed with CAD modelling, prototyping and *Verification-Validation Testing* (VVT). Low-Level Variables are directly related to the manufacturing technology selected and are described in terms of flow-rate, manufacturing speed, part orientation, production time to mention a few.

4.2 Role in CAD Systems

The methodology presented is highly beneficial when modelled within a computer-based design tool. Such a tool could be merged in CAD systems to assist designers in understanding better the needs of the customer and to map these onto the appropriate design parameters. The benefit of the tool lies in its ability to make recommendations for various design tasks in view of multiple stakeholders involved. During the modelling stages, the tool can make manufacturing suggestions in terms of the capabilities of the fabrication technology available to the designer. The tool will therefore support the designer in selecting the most adequate manufacturing process for the artefact being designed. The suggestions made by the tool can be integrated in the model being designed in the CAD system.

4.3 Case Study: 3D-Printed Release-Buckle for an Upper-Limb Rehabilitation Device

An initial validation of the model was conducted through a case study related to a rehabilitation device designed to support upper-limb rehabilitation therapy. The mechanism being considered is a release-buckle which acts as a mechanical fastener. The latter joins a strap-harnessing module which fastens around the user's upper arm to secure the device with the patient's wrist and forearm during physical therapy (Figure 3). The release-buckle is fabricated with *Additive Manufacturing* (AM)

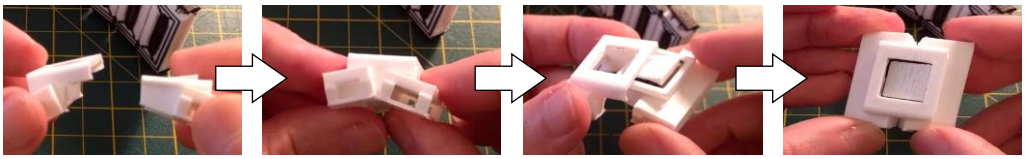
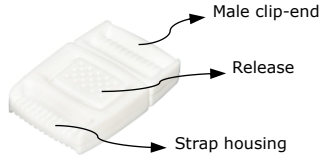


Figure 3: A functional prototype of the release buckle considered in the case study.

FRs and NFRs were initially identified. The FRs for the release-buckle include 'locking' – to fasten the harness with the upper arm; and 'releasing' – to unlock the connection from the secured position (Table 1). A single NFR was identified as 'durability', implying that the mechanism should sustain use over a prolonged period of time. This was translated into the appropriate FR – to withstand repetitive loading cycles. The prerequisite for the release-buckle to sustain loading for 10,000 cycles is required.

{CNs}	*Fastening mechanism*	
{FRs}	*Function*	*Object*
FR_1	Lock	To fasten harness
FR_2	Release	To release when open



FR_3	Withstand repetitive loading cycles	To resist damage

Table 1: Mapping of FRs/DPs for the case-study.

Equation (4.3) shows the matrix generated for mapping the FRs and DPs. Moreover, Table 2 shows the generated DPs as a result of the matrix in Equation (4.3).

$$\begin{bmatrix} FR_1 \\ FR_2 \\ FR_3 \end{bmatrix} = \begin{bmatrix} 1 & 0 & 0 \\ 0 & 1 & 0 \\ 0 & 0 & 1 \end{bmatrix} \times \begin{bmatrix} DP_1 \\ DP_2 \\ DP_3 \end{bmatrix} \tag{4.3}$$

{DPs}	*Parameter*	*Property*	*Information*
DP_1	P_i - Buckle mechanism	Tensile strength	1.5MPa
DP_2	P_i - Centre release	Shear strength	0.3MPa
DP_3	P_i - Stiff polymeric material	Modulus of elasticity	2.7GPa

Table 2: Generation of DPs and corresponding properties. Data from [16].

A set of PVs is consequently generated as shown in Table 3. Each PV constituent can be mapped directly onto the *Technology Domain*. Each PV is independent of the technology being considered.

{PVs}	*Variable*	*Information*	*{TCs}*
	Material capability	Nylon	TC1
	Surface roughness	30µm	TC2
	Machine tolerances	±0.2%	TC3
	Post-processing	Possible	TC4
	Build envelope	300 x 500 x 200mm	TC5
	Cost per part	€0.50	TC6
	Minimum section	1mm	TC7
	Part resolution	50µm	TC8

Table 3: Generation of PVs and mapping onto TCs.

A TC scoring for different manufacturing technologies is documented in Table 4. For the sake of the current validation, six AM technologies were specified. These are *Fused Deposition Modelling* (FDM), *Stereolithography* (SLA), *Digital Light Processing* (DLP), *Selective Laser Sintering* (SLS); *Selective Laser Melting* (SLM) and *Multi-Jet Fusion* (MJF). TCs are populated based on an understanding of the capabilities of each AM technology with regards to the presented PVs in Table 3. The selected PVs include *material capability*, *surface roughness*, *machine tolerances*, *post-processing*, *build envelope*, *cost per part*, *minimum section* and *part resolution*. This activity is facilitated through the MKD. A weighted average is generated from the matrix in Table 4. This provides a relative score for the applicability of the available technologies with regards to the artifact in hand, in this case the centre-release buckle mechanism. For the case study in consideration, SLA is the ideal candidate with a relative score of 8.0. Additional capabilities can be defined as deemed necessary and input as a basis to the manufacturing database.

Technology	*TC1*	*TC2*	*TC3*	*TC4*	*TC5*	*TC6*	*TC7*	*TC8*	*Score*
FDM	o	**x**	o	**x**	**x**	**x**	**x**	**x**	6.0
SLA	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	8.0
DLP	**x**	o	**x**	**x**	**x**	o	**x**	**x**	6.0

SLM	o	**x**	o	**x**	**x**	o	**x**	**x**	5.0
MJF	**x**	**x**	**x**	**x**	**x**	o	**x**	o	6.0
SLS	**x**	**x**	o	**x**	**x**	**x**	o	**x**	6.0

Table 4: Effective PRM following the constituent mapping of PVs/TCs.

4.4 Evaluation of the AXI-DEM Model

In order to evaluate the applicability of the model proposed (Figure 2), a qualitative research study with designers working in the medical device industry was conducted. The study was composed of an interview and a focus group with all participants. The aim of the focus group was to assess the usability of the proposed approach and to identify areas for improvement. Semi-structured interviews were also conducted individually with the scope of obtaining qualitative information on current design practices and opinions about the proposed method. All interviews were conducted by one researcher through an interview script and a set of predefined questions. A mixture of Likert-type scale questions and open discussions were conducted to allow participants to critically appraise the proposed approach. Key questions included the following: *To what extent are you familiar with the Axiomatic Design methodology?; What are the strengths and weaknesses of the proposed methodology?; If you had a tool to help you with selecting a manufacturing process in view of multi-user requirements would you use it? Please explain why.*" The questions were orally presented to each participant and the interviews were tape-recorded and transcribed verbatim. Interviews lasted an average of 60 minutes. Consequently, a thematic analysis was conducted by means of assigning codes to different phrases within the transcripts. Consistent codes were grouped into categories which facilitated the formulation of a set of core themes as part of the analysis. Codes generated from transcription included the following: **Usability**, **User Experience**, **Multi-user Requirements**, **Human Factors**, and **Manufacturing Processes**. The thematic analysis was based on the guidelines proposed by Braun and Clarke [6]. In addition, a pilot study was carried out with two researchers to reduce the bias factor of data collection and to review the layout and presentation of the interviews. The necessary improvements in wording, terminology and layout structure were implemented accordingly.

4.4.1 Participants

A total of 5 participants working at the *Austrian Center for Medical Innovation and Technology* (ACMIT Gmbh) were recruited. Table 5 provides a description of the participants.

Reference	*Occupation*	*Years of Experience*
P1	Senior R&D Engineer	15-20
P2	R&D Engineer	5-10
P3	Engineering Project Manager	10-15
P4	Team Leader, Sr. Project Manager	10-15
P5	Sr. Project Manager	15-20

Table 5: List of participants in this study recruited from ACMIT Gmbh.

Participant occupation and experience varied among designers. Focus groups and semi-structured interviews were conducted viva-voce. Designer occupations normally involved medical device design management, mechanical design development, testing and administration of clinical trials.

4.5 Results and Discussion

The advantages of the **AXI-DEM** model are numerous. The model can incorporate both FRs and NFRs identified from a combination of stakeholders and map these onto parameters which designers can implement to realise the desired tasks. This is possible by means of the URD. The implementation

of the MKD is also a beneficial element of the model in that DFMA considerations can be made which incorporates information from any relevant *Design of Experiments* (DoEs) and lessons learned during design and prototyping. Usability and risk management are also included to ensure that proper risk-mitigation actions and usability testing are conducted prior to product launch. The model also ensures that the manufacturing process selection is based directly on the DPs/PVs and PVs/TCs mapping. Hence, the designer can rely on the methodology to obtain a score for the optimal technology ideal for fabricating the artefact in hand. As a matter of fact, the proposed methodology was regarded as highly useful for mapping stakeholder requirements into FRs. *P3* remarked that this approach has the potential to assist designers in developing robust solutions in a faster and more efficient manner. Furthermore, *P5* remarked that the proposed model guides the designers to follow a formal structured way of conducting the design activities. 66.6% of respondents commented that selecting a manufacturing process based on multi-user requirements is continually a challenging task. In particular, *P4* stated that the manufacturing process is not dependent only on the requirements of users, however this is directly related to other aspects such as production quantity, lead times, cost and design restrictions. Early design decisions (e.g., material requirements) inevitably dismisses individual manufacturing technologies. In this regard, the selected manufacturing technology is not strictly bound to user requirements. Participants also disagreed on which stakeholder should be responsible to select the fabrication technology, with *P1*, *P2*, *P4* and *P5* saying that this role should be fulfilled by the designer, whilst *P3* argued that the stakeholder responsible for process selection should be different than the designer, such as a manufacturing specialist or a production engineer. It can be argued that this activity is ideally conducted by the designer, as is also shown in various studies investigating the relevance of supporting designers when selecting the appropriate manufacturing processes [1], [12], [13].

The idea of incorporating NFRs was highly esteemed by all designers. *P2* stated that this methodology "*could offer a basis to distinguish between alternative ways to manufacture a product*". Designers also highlighted some limitations worth mentioning. As it stands, the methodology does not address the implications imposed by the *Medical Device Regulations* (MDRs) and the *Food and Drug Administration* (FDA). This is generally useful for documentation and CE marking. 80% of participants agreed that the main underlying concept of the presented AD model is easy to understand. Designers (80% of respondents) also agreed that they would use the methodology in the design of medical devices as long as this is validated and it does not require additional time to understand or implement. *P4* remarked that implementing this methodology is a challenging task due to the restrictions imposed by ISO13485 which requires the compliance of manufacturers and developers. *P4* also remarked that even though the AXI-DEM model cannot replace the *Quality Management System* (QMS) in place for the company, it can be easily incorporated in the company's QMS. 80% of participants commented that the methodology is a good basis to address multi-user requirements, as long information flow is traceable. This means that information concerning risk and usability management, quality control and compliance should be tracked and traced during the design cycle for the sake of transparency and accessibility. Moreover, all designers agreed that the proposed model complements the design process they currently adopt. In general designers also remarked that this model can be applied to other design areas, not just rehabilitation. However, it should be stressed that certain risk management restrictions could apply to other specific areas of design.

Participants had mixed responses on whether the proposed model is useful in the selection of manufacturing technologies during design. Whilst 25% of participants agreed that this is the case, another 25% of participants disagreed. 50% of the respondents took a neutral stance to the question. *P2* and *P3* agreed that the model can support process selection however the ultimate decision should be left to the designer. *P5* disagreed with this comment arguing that often designers embrace a particular technical solution which is not always the best decision in view of the manufacturing technology available. This is based on designer bias towards particular technologies which may not be worthwhile in the long run. Designers can also be predisposed to use in-house equipment or to opt for processes they are most familiar with. In this case, the model can serve as a good basis to support the decision-making process of the designer in terms of manufacturing technology selection. This provides a good basis to develop a design-support tool which assists

designers during the manufacturing process selection and which incorporates the requirements of multiple stakeholders during the early stages of design. A tool based on the proposed model will assist in rationalising the designer's decisions, however it is argued that designers should not rely entirely on it for decision-making but should make final decisions themselves. One major limitation of the methodology is the financial aspect of product development. Manufacturing costs, service costs and operational costs are not considered in the proposed model. These pose a key influence on the time-to-market and also impact the manufacturing technology selected and hence the TCs defined. Given that costs can be considered as NFRs, this can be investigated in future work as it would possibly require a dedicated database to map costs onto design implications. Another limitation of the study is a small sample size of five participants. In order to offset this limitation, it was ensured that a good mix of participants with varying experience in medical device and rehabilitation design were interviewed.

5 CONCLUSION

It is concluded that the main contribution of this paper lies in the formulation of an AD approach which seeks to incorporate NFRs together with various elements of UX and which directly informs the selection of manufacturing technologies based on multi-user requirements. It was observed that NFRs are rarely considered when implementing traditional AD methods. The same was observed in the incorporation of manufacturing process selection as part of AD. The proposed methodology bridges the gap between axiomatic design, process selection and requirements elicitation during product development. Through the case study it was demonstrated that by considering the capabilities of manufacturing processes, conclusions could be made on the applicability of selecting a technology to fabricate a release-buckle mechanism using AM. An evaluation with R&D designers working in the field of medical and rehabilitative devices was also conducted in order to evaluate the applicability of the proposed methodology. Based on the feedback obtained from the participants several improvements were implemented whilst the need to extend the methodology into a design-support tool was also highlighted. A design-support tool is currently being developed with the aim of improving the design process of designers by assisting them in taking various considerations regarding manufacturing and process selection. It is planned that the support tool will be validated with design engineers. Future work also includes the application of the proposed methodology onto assembly and sub-assembly modules rather than on individual components.

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