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Design of Personalized Devices—The Tradeoff between Individual Value and Personalization Workload

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Featured Application: The method for the *Design of Personalized Devices* presented in this publication is aimed particularly at companies who are considering personalizing their products according to patient-specific needs.

Abstract: Personalized medical devices adapted to the anatomy of the individual promise greater treatment success for patients, thus increasing the individual value of the product. In order to cater to individual adaptations, however, medical device companies need to be able to handle a wide range of internal processes and components. These are here referred to collectively as the personalization workload. Consequently, support is required in order to evaluate how best to target product personalization. Since the approaches presented in the literature are not able to sufficiently meet this demand, this paper introduces a new method that can be used to define an appropriate variety level for a product family taking into account standardized, variant, and personalized attributes. The new method enables the identification and evaluation of personalizable attributes within an existing product family. The method is based on established steps and tools from the field of variant-oriented product design, and is applied using a flow diverter—an implant for the treatment of aneurysm diseases—as an example product. The personalization relevance and adaptation workload for the product characteristics that constitute the differentiating product properties were analyzed and compared in order to determine a tradeoff between customer value and personalization workload. This will consequently help companies to employ targeted, deliberate personalization when designing their product families by enabling them to factor variety-induced complexity and customer value into their thinking at an early stage, thus allowing them to critically evaluate a personalization project.

Keywords: product development; personalized product; design method; adaptation workload; variety-induced complexity; individual value; variety planning; product individualization; medical device; flow diverter

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1. Introduction

The personalization megatrend promises better, if not exact, fulfillment of individual needs. The trend is also finding its way into the health care system, where there is scope to improve individual patient care and thus improve the quality of the entire health care system [1,2]. One area of focus is the adaptation of the medical device in question to suit the patient's individual needs. While customized product families rely on fully predefined product variants consisting of predefined product modules and components with predefined attributes, the individual attributes for the properties of products in personalized product families can be defined according to the individual needs of a specific customer or patient (see Figure 1a,b). The term product family is used to refer to a set of

product variants that share similar functional principles, technologies, areas of application, or production processes [3–5]. The term product attribute refers to a specific design of a product property or characteristic that can be used to differentiate one product variant from another such as 3 mm or 4 mm for the characteristic diameter of a stent [5]. The deliberate distinction between product characteristics and product properties can be traced back to Weber, who states that a product property describes a product behavior that cannot be directly influenced by the designer such as the weight of the product [6]. Product characteristics, on the other hand, constitute the product behavior and can be defined directly by the designer. These include aspects such as the geometric dimensions and the material of the product [6]. Product characteristics are also known as internal or independent properties or design parameters, while product properties are also referred to as external properties or dependent properties [6]. Accordingly, the designer can only influence the attribute of a product property by modifying the attributes of the corresponding product characteristics. In contrast to the designer, the customer is often unaware of the technical product characteristics, noticing only the product behavior they cause. Differentiating properties is the term used to refer to those properties that are relevant for the customer when choosing or defining a product variant to suit their individual requirements.

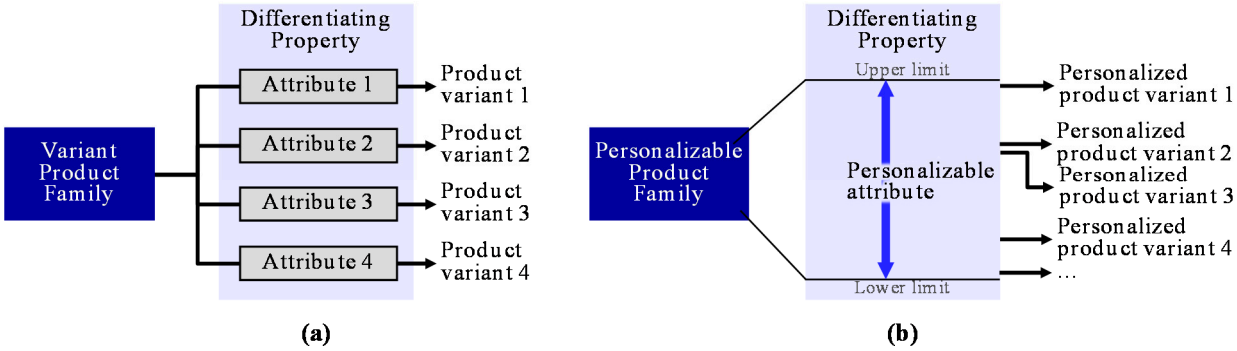


Figure 1. (**a**) Predefined, discrete attributes of a variant product family compared to (**b**) a personalizable product family with personalized attribute.

For personalized product families, almost any specific attribute design for a product property is possible within a defined attribute solution space (see Figure 1 b). This allows customer-specific requirements to be catered to exactly, thus minimizing the difference between the exact requirements and the attributes offered. This maximizes customer satisfaction and treatment success. For the purposes of this paper, the terms personalization/personalized and individualization/individualized are considered as synonyms. The physician and the patient are referred to collectively as the customer.

While the personalization of a medical device promises enormous potential for both patient and physician in terms of treatment success and product use, patient-specific product adaptation means that the company that provides the medical device in question needs to be able to handle a wide range of different process designs and components internally. Within the company, there is an increase in the variety-induced complexity caused by the repeated product individualization and the associated personalization workload (e.g., for design adaptation, production control, documentation, or quality assurance). In this context, the term variety-induced complexity is defined as the number of elements, together with their relationships and their variability over time [7,8]. An increase in the variety-induced complexity causes an increase in the complexity costs, the costs of implementing a large variety of products [9–11]. Suitable complexity reduction strategies must be developed as part of variety management in order to tackle this challenge [12]. Consequently, in the context of a personalization project, it is important to consider whether personalization is at all controllable and worthwhile for the company in question. The benefit of a medical device cannot be expressed in monetary terms and compared like-for-like with complexity costs. Instead, the increased product benefit must be viewed and evaluated

holistically in the context of the market and the treatment. Personalization only makes sense in situations where there is a great diversity of needs and the individually adapted attributes have the potential to significantly increase the product benefit [13]. As such, this paper was based on the following research question:

> *How can an appropriate variety level be defined for a product family, taking into account standardized, variant, and personalized attributes and focusing on medical devices?*

As described above, personalization plays a special role in medical technology. Despite this, it has been shown that complexity, or variety management, has not yet been associated with medical devices, nor has modularity or design for variety [14]. Thus far, the focus has mainly been on methods for the user integration and risk assessment of medical devices. With this in mind, the following section will describe some general variant management strategies.

There are a number of different strategies that are generally used to control variety-induced complexity. In addition to process-based strategies, which include postponement and process commonality, the product platform and modular design are used as product-based strategies for product portfolios with a large number of variants [5]. These offer the possibility of maintaining a comparatively large product portfolio, hereinafter referred to as external variety, while simultaneously reducing the internal variety, which describes the variety of components, parts, products and processes [5,12]. Different product variants can be created by configuring the modules accordingly, which takes place after the application of modularization or platform design methods such as those described in [12,15–17]. These may be standardized modules with standardized components that are used in each product variant of a product family, or also variant modules with at least one variant component, which evoke the differentiating product behavior of each of the product variants as perceived by the customer. Nevertheless, the personalization of product components and thus the determination of personalizable product attributes has not really been taken into consideration when designing modular product families. In addition to the definition of standardized and variant components, a personalizable/individualizable component with at least one personalizable attribute has to be determined [18,19]. Gräßler believes that the best way to implement personalized attributes is in a software-based setting and not in hardware components [20]. Koren et al. introduced *Open Architecture Products*, in which personalized modules with individual attributes are developed by different developers in collaboration with the customer before being integrated into a central platform using a standardized interface [21]. This idea requires a complete decoupling of the personalized module from the other product modules. This can be analyzed by using, for example, semantic networks and graphs in order to represent the product structure and its interconnections between the components. With the help of the graphs, an estimate of the adjustment workload required when changing one element can be done, taking into account the resulting changes to other elements [22,23]. Only after finally defining the product families' structure with standardized, variant, and personalized attributes, process-based approaches to reduce personalization workload can be applied, like the ones of Baumberger and Lindemann, who established a unified framework for evaluating the effects of individual customer needs and accordingly developed a coordinated adaptation process [24], or of Spallek et al., who recommend implementing a standardized individualization process for the repeated personalization of components [19,25].

The approaches presented have mainly focused on the decoupling of personalized components within the product structure. What is missing so far is support for the identification of components relevant for personalization within an existing product family to design the product structure accordingly. Furthermore, support for the determination of the characteristics relevant for personalization within the identified component is missing, taking into account the value provided by personalization against the personalization workload. A first approach to counter this problem is provided by Berry et al., who developed a product architecting algorithm for personalization [26]. However, the numerical solution requires the expression of any quantities as a number or function, which again requires a large

volume of data. This is considered as a very inflexible solution, since relation between life phases and with the customer are hard to model. A workshop-based, customer-integrative approach is preferred, since decision-making is regarded as an interactive process needing the opportunity for discussion and joint solution finding [27].

To sum up, attempts to determine the optimum level of variety have thus far concentrated solely on the differentiation between variants and standardized components for reducing internal variety. The targeted expansion of external variety by means of personalization has yet to be considered. The literature describes the properties that personalizable components must possess (e.g., decoupling). However, it does not provide a satisfactory answer to the research question, nor does it offer any assistance on how to identify where in the product personalized attributes should be considered, taking into account the adaptation workload and customer value. In order to change this, the goal of this paper was to present a method for defining an appropriate product concept with standardized, variant, and personalizable product characteristics for the components. Section 2 presents the research method for the development of the new design method. The method is described in detail in Section 3 and applied to the example product, the flow diverter. Finally, the results are discussed and summarized.

2. Materials and Methods

In order to ensure that personalizable product properties are specifically taken into account alongside standardized and variant product properties when defining the variety of a product family, particularly in the field of medical devices, a method for designing personalized devices was developed and applied to a flow diverter as an example product. In general, a design method describes a systematic procedure for structuring and improving the design process [28,29]. In the present case, a method was proposed to systematically and efficiently identify complexity aspects that may arise due to the repeated adjustments of individual attributes to find a solution for them at an early stage to ensure an efficient and controllable product personalization later on.

The research method for developing a method is explained in more detail in this section. The first part of the section explains the reasoning behind adapting and expanding upon an established method as a means of filling in the gap identified in the existing research, and how this is done. The next section explains the example product used for this paper, the flow diverter. The manufacturer of the flow diverters must consider whether personalization will be useful in preventing or reducing product complications during the handling of the implant and, if so, which attributes of the product should be personalized. In order to assist with the decision-making, the newly developed method was applied to the example of a flow diverter. The medical simulator HANNES (HANNES: Hamburg Anatomical Neurointerventional Simulator (see Section 2.3), development funded by the Federal Ministry of Education and Research as part of project ELBE-NTM (031 L0068A)) was used to validate individualized flow diverter designs. As such, the last part of this section provides an introduction to the simulator.

2.1. Research Method, Tools, and Visualizations

The new method was based on the existing methods developed at the Institute of Product Development and Mechanical Engineering Design (PKT) of the Hamburg University of Technology (TUHH), supervised by Prof. Dieter Krause. The existing methods were compiled in the method toolbox known as the *Integrated PKT approach for developing modular product families* [12,30,31]. This section provides a brief introduction on the methods relevant to this publication. These act as the basis for developing the new method. The new method incorporates both the established method steps and introduces new steps that take personalization specialties into account.

The *Design for variety* method is used as a variety-oriented approach to design a product family [12,32]. This approach maintains the existing external variety while reducing the corresponding internal variety by optimizing the product structure with regard to various

different ideals (see Figure 2) [12,30,33]. Different, variant attributes for a component are only justified if they are related to a differentiating property, and are thus perceived by the customer. Components that are variants but have no impact on the product behavior as perceived by the customer should be standardized. This is summarized within the ideal of differentiation between standardized and variant components. Furthermore, the scope of a variant component should be reduced as far as possible until it is simply the carrier of the differentiating property. Additionally, according to the one-to-one-mapping ideal, a variant component should ideally implement exactly one differentiating property. Finally, the variant components should be decoupled from other components. Figure 2 summarizes the ideals of variety-oriented product design.

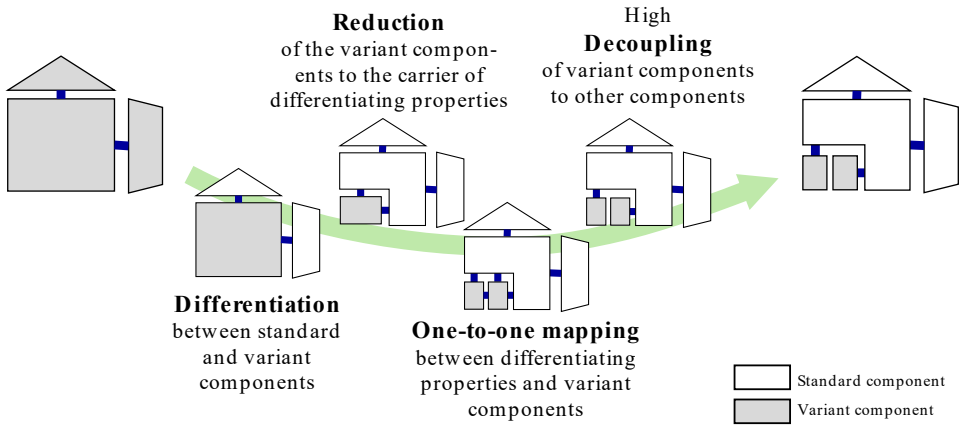
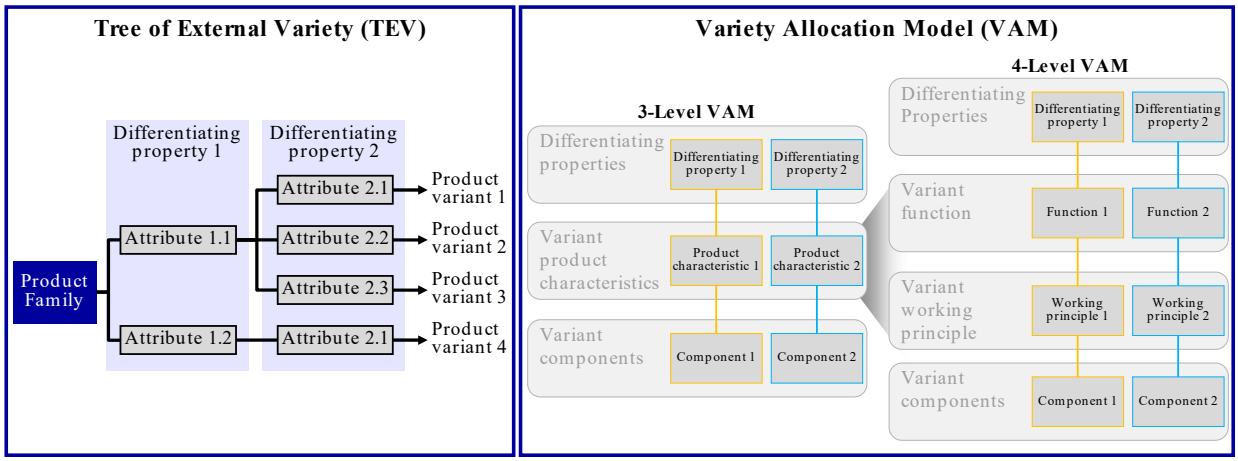


Figure 2. Ideals of variety-oriented product design.

In contrast to the existing design for the variety method, however, this work did not retain the external variety while focusing on the reduction of the internal variety. Instead, the expansion of the external variety to include personalized product variants was examined, and consideration was given to the idea of maintaining a suitable level of internal variety. Nevertheless, personalization can be understood as a more pronounced differentiation than variance. As such, the ideals of *Design for variety* still apply. Personalization of a component—in this case with a focus on the detailed design of defined components—might only be applied if the personalized component relates to a differentiating property in some way. In order to optimize personalization workload, personalization should be preplanned and restricted to those differentiation properties that are relevant for personalization from the customer's point of view. For this and other aspects, new method steps were introduced, as presented in Section 3.

The *Tree of External Variety* (TEV) tool, the structure of which is shown in Figure 3a, was used to illustrate an external variety. This tool breaks down the variants of a product family according to the attributes of the differentiating properties [12,30]. For the analysis and design of variety-oriented products, the *Variety Allocation Model* (VAM) was used [12,30], see Figure 3b. This shows the relationship between differentiating properties and variant components in order to ensure that the variant components are related to a differentiating property, and thus that the variance is justified from a variety management perspective. The VAM can be used as an aid for applying the ideals of variety-oriented product design and carrying out optimization. As shown in Figure 3b, a distinction can be made between the 4-level VAM according to Kipp [30,32] and the 3-level VAM based on this, which was presented by Gebhardt et al. [34]. In the 4-level VAM, the relationship between the differentiating properties and the variant components is established based on the development process by translating differentiating properties into variant functions, highlighting their working principles and illustrating their implementation in the components [12,30]. In contrast, in the 3-level VAM, the functions and working principles levels are replaced by a variant product characteristics level [34]. This shows how a differentiating

property is implemented using technical characteristics, and the component in which these characteristics can be found.



(a) (b)

Figure 3. (**a**) Structure of a TEV representing a product family with predefined product variants, and (**b**) structures of a 3-level and 4-level VAM.

2.2. Example Product Flow Diverter

For the purpose of clarifying each step of the new method and demonstrating how it can be applied, a flow diverter was used as an example product in the next section. A flow diverter is a braided stent that is implanted into the diseased vessel in order to treat intracranial aneurysms. The implant reconstructs the blood vessel and alters the blood flow so that the aneurysm can regress [35,36]. Flow diverters are produced using a braiding process. First, the mesh is created by weaving together thin, nitinol wires. It is then subjected to heat treatment, during which it is shaped so that it returns to its embossed form at body temperature after having been folded for implantation [37]. The flow diverter is implanted using a catheter treatment for minimal invasiveness. For this purpose, the mesh is advanced through the femoral artery, the aorta, and the carotid by using a system of access and catheters until it reaches the diseased vessel in the head. The position of the implant in the vessel is of crucial importance and has a significant impact on the healing of the aneurysm. One possible complication of the implantation process is an incorrect wall apposition of the flow diverter. The implant can migrate if the wall position is insufficient [38] and, in the worst-case scenario, may even prolapse into the aneurysm sac [39]. Sufficient wall apposition is crucial in order to prevent thrombus formation following deployment of the flow diverter, which can lead to thromboembolic complications [40]. Moreover, sufficient wall apposition along the treated vessel is significantly associated with complete aneurysm occlusion [41]. The position of the distal and proximal end of the implant is also very important. If the distal anchorage zone is too short, this can lead to migration of the implant after, or even during, treatment. If the proximal end is positioned incorrectly, for example, in a pronounced vascular curve, this can result in a fishmouth, which is the term used to describe when the proximal end of the implant does not open all the way.

To prevent these handling complications from occurring during implantation, it is essential to select the best-fitting implant variant from the product portfolio to suit the patient's individual anatomy. However, repeated mistakes in implant size selection indicate that medical staff do not receive sufficient assistance when selecting the best implant variant, and may even be a sign that the product portfolio is too small. In order to prevent the former of these issues, *Acandis GmbH* introduced the *Ankyras Sizing Tool* (Galgo Medical Inc., Barcelona, Spain), which allows patient-specific planning of the position of an implant variant in an individual patient blood vessel [42]. In order to improve the alignment of the

product portfolio, it is proposed that the mesh could be adapted to suit patient-specific needs and the product could be personalized. The method presented in this paper will be used to investigate whether product individualization is effective and can be implemented in a way that is manageable in terms of complexity.

In order to apply the newly developed method to the case of the flow diverter, it is advisable to work in an interdisciplinary team with the involvement of the user [14]. For this reason, an interdisciplinary team of researchers with experts from different fields has been put together to analyze and evaluate the product personalization for the flow diverter:

- Physicians—anatomy experts for the evaluation of individualized designs
- Development engineers—flow diverter product experts for the personalization of the design
- Method consultants—experts in the development and application of design methods

2.3. Evaluation Environment—The HANNES Medical Simulation Model

The impact of personalized designs on product performance for medical devices can be investigated using medical simulation models. These models realistically reproduce anatomical conditions in a targeted manner [43]. The following section will provide a brief introduction to the *Hamburg Anatomical Neurointerventional Simulator* (see Figure 4), *HANNES* for short, which can be used to evaluate individualized flow diverters. *HANNES* is currently used particularly for the training and further education of physicians in minimally invasive aneurysm and stroke treatment [19,44,45]. The relevant vascular tree from the inguinal artery, the aorta, the carotids, and the petrous segment of the skull base to the diseased cerebral vessel is reconstructed. In angiography, the vascular disease can be treated using x-rays and added contrast medium to create the roadmap. A fluid system consisting of a pump, a solenoid valve, a tank, and other elements such as tubes and connectors is connected to the vascular tree. This generates both a volumetric flow and a pulse, which can be adjusted between 0 and 150 bpm. A heating element in the tank ensures that the temperature of the blood replacement medium, which is usually water or a water–glycerol mixture, remains constant. The temperature is set to 37 °C to match the human body temperature. As a result, the medical instruments behave in the same way as the human body as the realistic anatomical reproduction means that original instruments can be used. Thanks to its modular design, *HANNES* enables physicians to configure different training scenarios by exchanging individual modules. Using specially developed adapters, individual sections of vessels can be exchanged and integrated into the vessel tree without an inner edge [46]. The aneurysm models were developed using a standardized individualization process in accordance with Spallek et al. [19], which uses patient-specific angiographic image data. The device is produced using an additive manufacturing process as this offers great freedom of geometry.

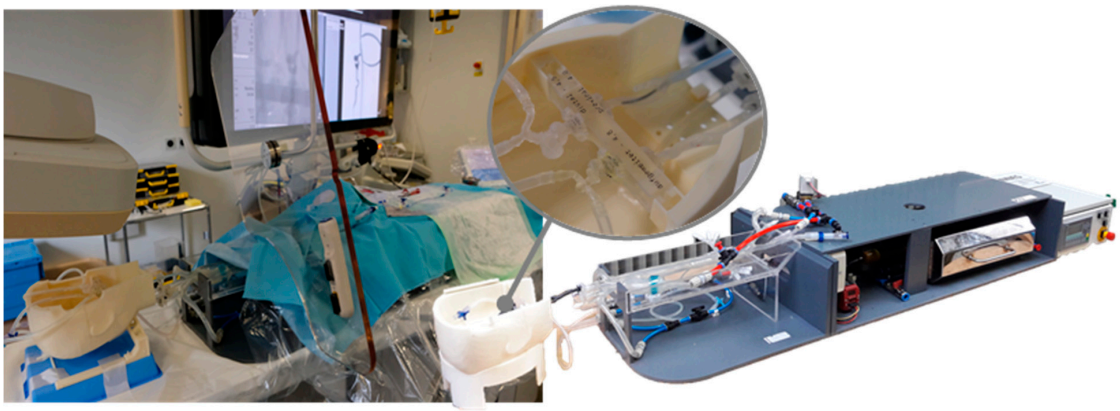


Figure 4. *Hamburger Anatomical Neurointerventional Simulator HANNES* with realistic replication of the relevant vessel tree for the evaluation of personalized flow diverter designs.

3. Results

The following section presents the new method for identifying where the product personalized attributes should be considered based on customer value and adaptation workload, and applied this method to the example product, the flow diverter. The customer value was evaluated by identifying the relevant product properties for personalization from the customer's perspective and determining the constituent product characteristics. The adaptation workload was evaluated by examining the processes for adjusting the attributes of relevant product characteristics to suit the individual's needs. Finally, the findings were compared and a product concept with standardized, variant, and personalized product characteristics was agreed upon.

Figure 5 summarizes the steps involved in the method developed. In the first step, the existing *Design for variety* method (see Section 2.1) was used to assess the current external variety and the corresponding internal variety, while documenting them using the TEV and VAM tools. This assessment forms the basis for the subsequent investigations. In the second step, the differentiating properties are verified and expanded upon. It is possible that product complications and individualization ideas will arise not from the non-exact attribute design, but rather from the standardization of the properties that are relevant for differentiation. Some of the differentiating properties relevant for the customer may not be considered in the variant design. This should be verified in this second step of the method, before a variety-oriented product design is verified in step three. In the fourth step, the differentiating properties are examined with respect to their relevance for individualization. This is a means of analyzing the impact of an individual attribute design on the overall product performance as compared to the impact of a variant attribute design. Subsequently, internal individualization effects caused by individual attributes were determined systematically. Finally, the findings were summarized in individualization profiles, which were used to assist with workshop-based decision-making regarding the implementation of product personalization.

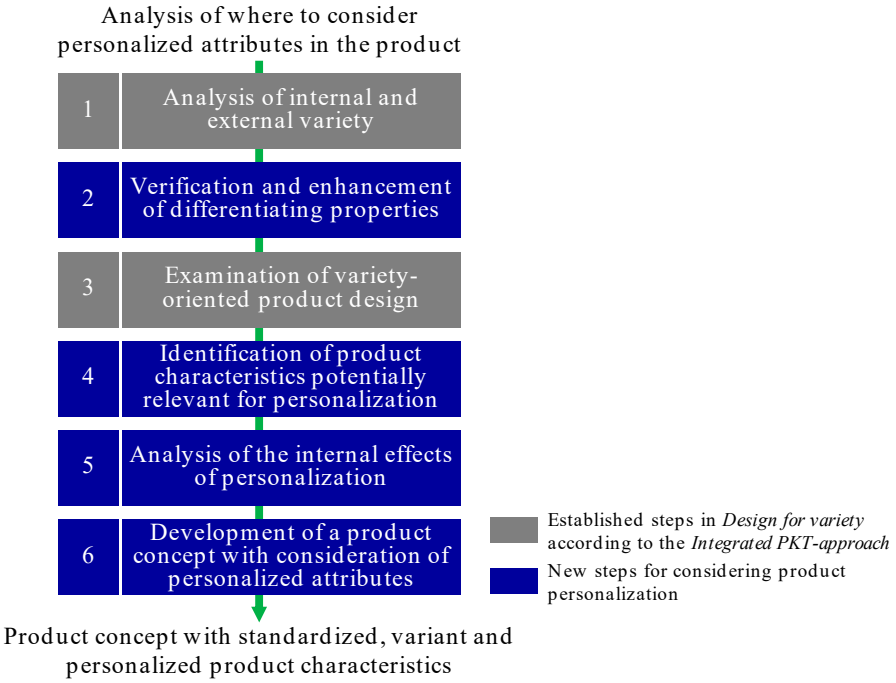


Figure 5. Method for the design of personalized devices including identification and investigation of product characteristics relevant to individualization as a means of dealing with the tradeoff between individual value and personalization workload.

The following section describes each of the method's steps in detail. The goal and the exact procedure for each step is explained, then applied to the flow diverter.

3.1. Analysis of External and Internal Variety

In the first step of the method, the current external and internal variety of the product family in question are analyzed. This investigation of the current situation serves as a basis for the analysis and evaluation of the product family's personalization potential.

The external variety currently on offer is presented in a TEV. The product variants are broken down according to the differentiating properties known internally within the company and the attributes offered for each of the differentiating properties are assessed.

From the company's current point of view, the *Wall apposition (proximal)* and the *Length of treated vessel* are relevant to the customer when selecting a flow diverter variant. The proximal apposition is relevant because this is where the largest vessel cross-section is expected in most cases. The variants of the *Derivo® flow diverter* offered by *Acandis GmbH, Pforzheim, Germany* therefore differ in terms of diameter (3.5 to 6.0 mm, in 0.5 mm increments) and implant length (15 mm to 30 mm, in 5 mm increments, plus lengths of 40 mm and 50 mm). Other mesh characteristics such as *Wire thickness*, *Number of wires*, and *Braid angle* are standardized in order to cause uniform hemodynamic behavior in the aneurysm. The number of wires is always 48, except for the flow diverter with the diameter of 3.5 mm, whose mesh consists of 36 wires. This is because using a smaller number of wires produces better mesh behavior in small vessels. However, the customer cannot select the number of wires as this is indirectly determined by the choice of diameter. The external variety is shown in the TEV in Figure 6a.

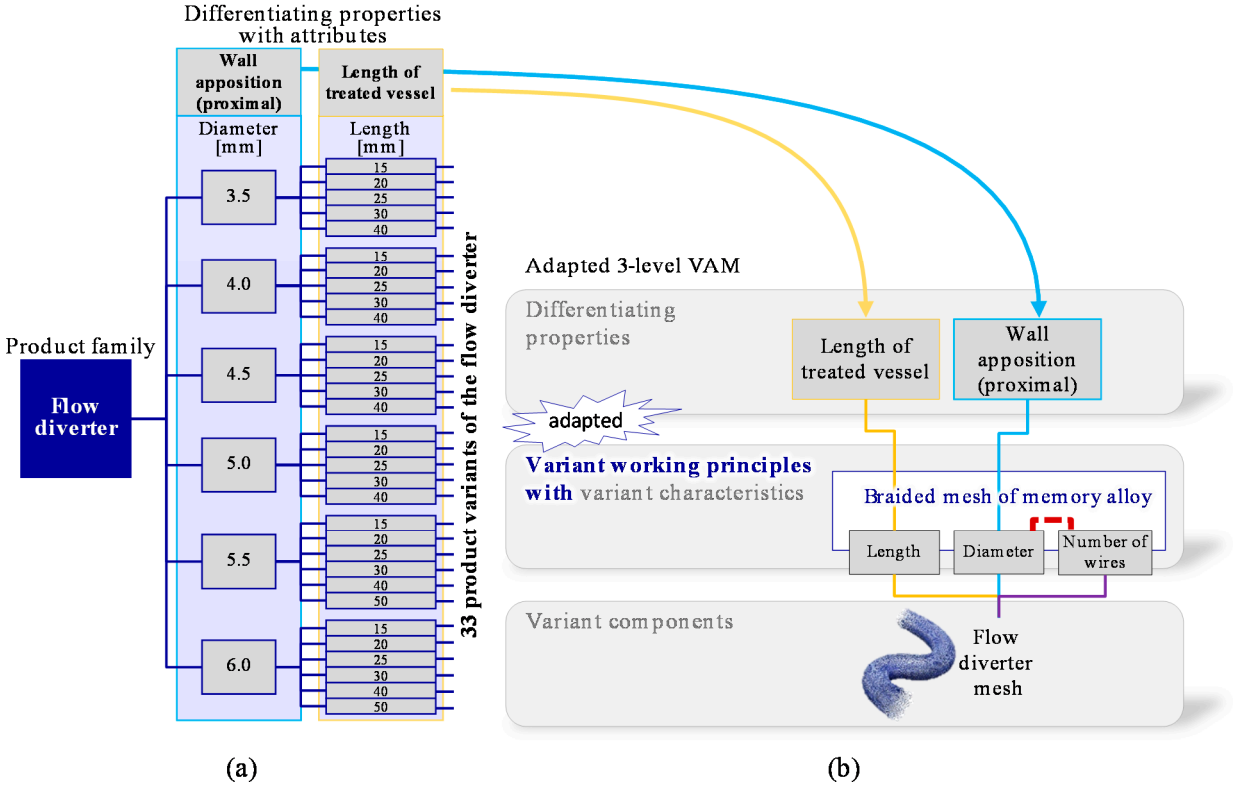


Figure 6. (**a**) External variety of the flow diverter presented in a *TEV*; (**b**) Internal variety of the flow diverter presented in a *VAM* with three levels.

The assessed internal variety can be represented in a 3-level VAM. The differentiating properties taken from the TEV are displayed on the top level. The second level, the level of technical product characteristics, can be derived in one of two ways. The first is to analyze all of the characteristics defined during the design. This process involves investigating which product characteristic causes which product behavior. It may also be necessary to carry out experiments to examine the relationship between a product characteristic

and the corresponding product behavior. In order to understand these relationships, a product characteristic must be varied with a focus on how the variations change the product behavior. The second option is to assess the internal variety using a 4-level VAM. In this scenario, the variant functions and the associated working principles are assessed. The results of this assessment can be used to determine the technical characteristics that play a significant role in implementing the working principle.

A combination of these two approaches was used for the flow diverter. The 3-level VAM was adapted, and the working principle was also included on the middle level, alongside the technical characteristics. The known differentiating properties *Length of treated vessel* and *Wall apposition (proximal)* are displayed on the first level. The length of the treated vessel was used as the basis for the length of the implant, while the proximal wall apposition was used as the basis for the implant diameter. All the product characteristics were used to design the component *Flow diverter mesh*. The internal variety of the flow diverter is shown in the 3-level VAM in Figure 6b.

Subsequently, an analysis of variety-oriented product design was carried out, applying the ideals of variety-oriented product design. Since the differentiating properties were implemented using different product characteristics, there was no conflict here. The only component that was adapted was the *Flow diverter mesh*. As such, the design can be regarded as sufficiently variety-oriented.

3.2. Verification and Enhancement of Differentiating Properties

In the next step, the differentiating properties are verified, and expanded upon if necessary. This step is not included in the variety-oriented product design defined in the *Integrated PKT-approach*, since the external variety in this process remains constant, rather than being reduced or expanded. Product individualization, on the other hand, aims to expand the external variety where this is relevant for the customer's use or purchase of the product.

It is assumed that the relevance of personalization only needs to be checked for differentiating properties, since this is the only area where the customer would notice any differentiation. In order to ensure that absolutely all of the differentiating properties are known, they need to be verified again, specifically as part of this method step. There is a chance that the company might have failed to recognize certain differentiating properties that are relevant for the customer, and has thus simply standardized these properties until now. Once this is done, checks can be carried out to determine whether a differentiating property is relevant for individualization, or whether an expanded variant portfolio without individual attributes will provide sufficient variety by adding variant attributes to differentiating properties. If product complications and unfulfilled customer needs can be satisfied adequately using a variant design with differentiating properties that were not considered previously, a predefined variance is usually preferable to product individualization from a complexity perspective.

In order to verify and expand upon the differentiating properties, close coordination with the product user is required. Different application scenarios and use cases must be analyzed and compared. User-centered design methods such as the Persona method or use case analysis can be applied here.

For the flow diverters, a survey was conducted and there was a close coordination with medical experts. These experts have a wealth of experience in different application situations, and can specify the differences between the aneurysm pathologies where the product behavior is required for each one. A flow diverter is used for the treatment of a variety of vascular anatomies and pathologies, which differ from one patient to the next. The exact diameter varies both between two patients and along the vascular pathway of one patient. The same applies to the curve and twist progression along the vessels (see Figure 7). Due to the individual pathology of the aneurysm, the vessel section that needs to be treated will also vary in length between different patients. Following close coordination with the physicians, the differentiating properties *Wall apposition (distal)*, *Wall apposition*

(twist), and *Wall apposition* (*curvature)* for twisted or curved vessel sections were obtained, in addition to the *Wall apposition (proximal)* and *Length of treated vessel*.

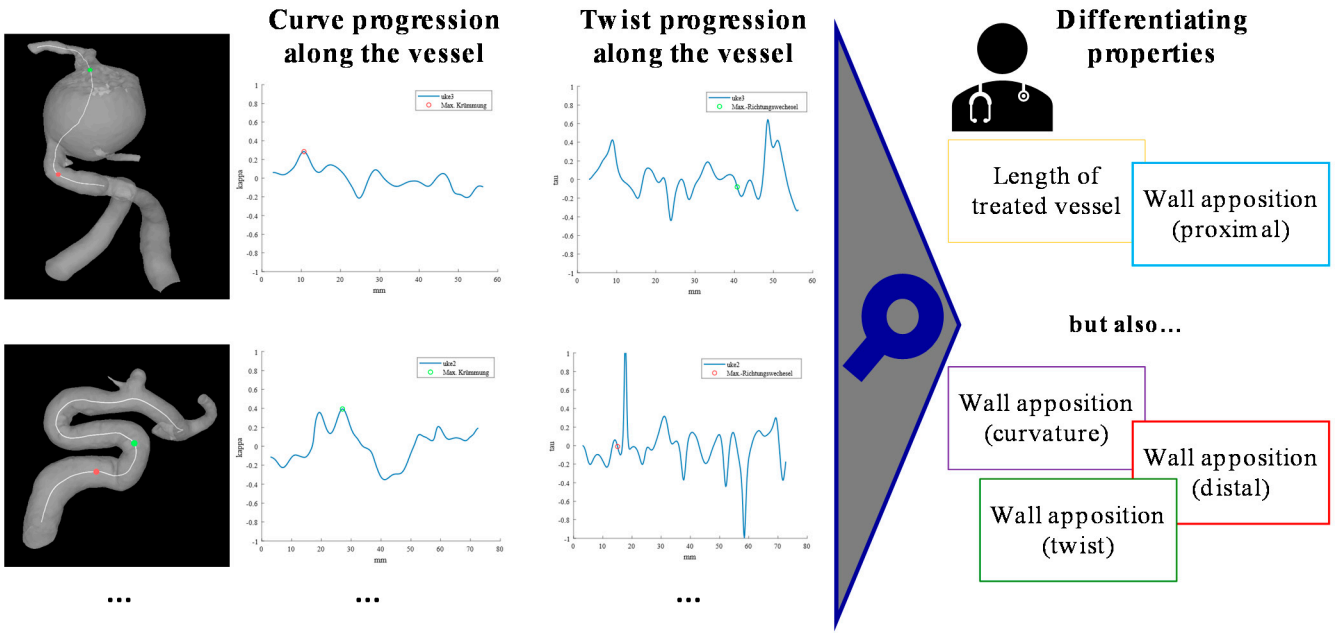


Figure 7. Verification and enhancement of differentiating properties relevant for the customer.

The added differentiating properties were assigned the constituent product characteristics (see Figure 8). For this purpose, internal tests are required within the company in order to establish the relationships clearly. For wall apposition in curved and twisted vessels, additional investigations have shown that the braid angle product characteristic is particularly effective in influencing this product behavior. Until now, the braid angle has remained at a constant 75° throughout the flow diverter mesh, since the hemodynamics at the position of the aneurysm are satisfactory at this angle. A local adjustment of the braid angle at the axial position of the curve or twist shows a positive effect on the wall apposition. The number of wires in the mesh and the wire thickness also play an important role with regard to the wall apposition in curved vessels. The distal wall position is used to determine the implant's diameter. As shown in Figure 8, these findings were added in the 3-level VAM.

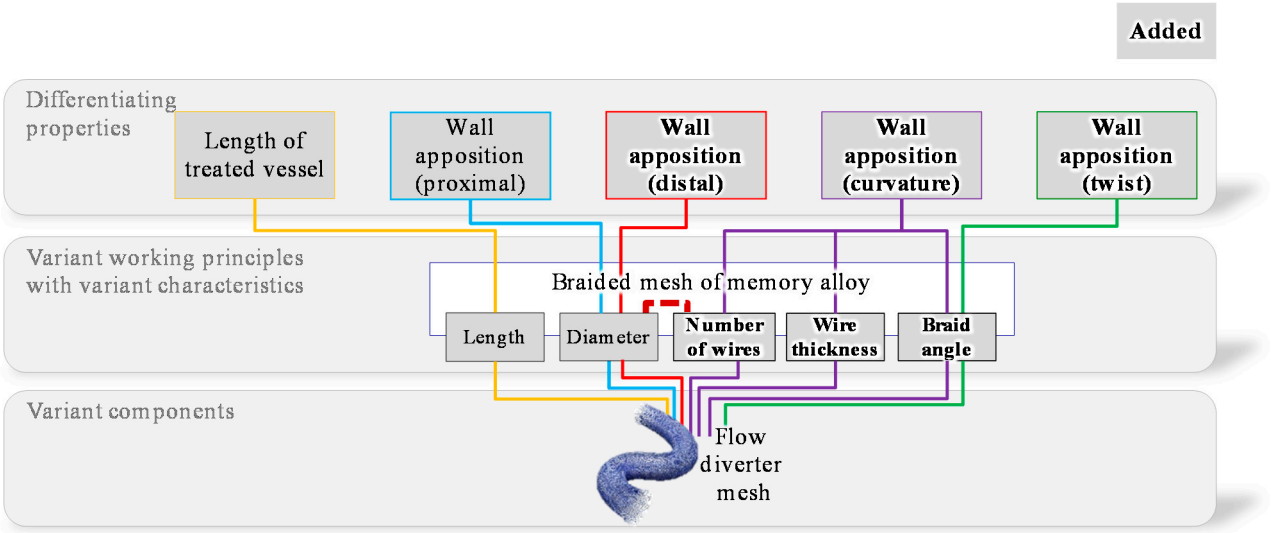


Figure 8. Revised 3-level VAM with added differentiating properties.

3.3. Examination of Variety-Oriented Product Design

Just as the analysis of the variety-oriented product design followed the assessment of the internal and external variety in Section 3.1, this section once again reviews the product's compliance with the ideals of the *Design for variety* method (see Section 2.1).

It is worth noting that the *Diameter* characteristic of the *Flow diverter mesh* covered two differentiating properties. Likewise, the *Braid angle* covered the wall apposition in both a curvature and a twist. Product tests conducted at the manufacturer's premises showed that the larger the braid angle, the better the compensation for a more pronounced twist. Targeted enlargement of the braid angle also has a positive effect on the wall apposition in pronounced curves. At the same time, up to a certain point, modifying the braid angle in this way has hardly any negative impact on the behavior when working with only a slightly pronounced curvature or twist. As such, the braid angle can be used to cover both differentiating properties without them contradicting one another. In terms of diameter, the attributes required at the proximal and distal ends often differ, which leads to a conflict when using just one characteristic in one component to deal with the differentiating properties *Wall apposition (distal)* and *Wall apposition (proximal)*. This conflict now needs to be solved using a variety-oriented product design.

Since the mesh is manufactured as a single component using a braiding process, it is not possible to break the *Flow diverter mesh* component down into several smaller components. However, it is possible to carry out a *virtual segmentation*, a process after which different technical characteristics can be selected for each segment (see Figure 9) while still allowing the mesh to be braided as a single component using a coherent braiding process. In order to enable both a distal and a proximal wall apposition with one-to-one assignment, the *Flow diverter mesh* component is divided into a *distal segment* and a *proximal segment*. The diameter, length, and braiding angle can be selected individually for each segment. However, the number of wires and the wire thickness can only be selected for the distal segment. This is due to the continuous braiding process and the fact that this attribute is dependent on the smallest diameter. The thickness and the number of wires cannot be varied across the length of the braid, since a continuous braiding process is required in order to manufacture the mesh. Both characteristics are closely linked to the smallest diameter of the braid, since together, they determine the porosity of the mesh, which is important for the hemodynamics of the blood for the healing of the aneurysm.

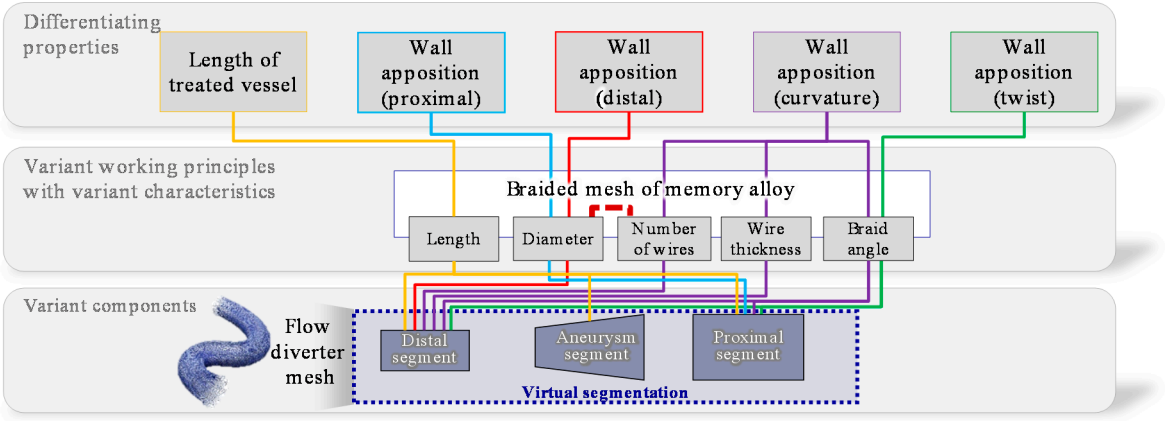


Figure 9. Virtual segmentation of the component *Flow diverter mesh* component into distal, aneurysm, and proximal segments in line with the ideals of variety-oriented product design.

An additional segment is required for the transition from the distal segment to the proximal segment. Studies by Ding et al. [47] have shown that positioning the transition segment at the same level as the aneurysm has a positive effect on blood flow, and thus on the healing of the aneurysm. As such, the *aneurysm segment* is defined in addition to the *proximal segment* and *distal segment* for the transition. It is only possible to vary the length

of the *aneurysm segment*. The other characteristics are derived from the other two segments. A segmented flow diverter can be created using a modular braiding mandrel, in which the segments of the tool can be plugged together [48].

3.4. Identification of Product Characteristics Potentially Relevant for Personalization

It is essential to determine whether a differentiating property requires a customer-specific, individualized attribute, or if a predefined variant attribute will be sufficient to fulfill the purpose of the product efficiently. With this in mind, it is necessary to evaluate the impact of an individual attribute design on the overall product performance as compared to that of a variant attribute design. Product surveys and evaluation tests conducted by the product user are particularly well-suited to this task. For medical devices, medical simulation environments can be used to investigate the individualization relevance of the product properties.

For this example, the *HANNES* medical simulation model with its patient-specific aneurysm models was used (see Section 2.3). The aneurysm models corresponded to patient pathologies that had been treated using a flow diverter and showed pronounced vascular characteristics such as a particularly pronounced curvature or small optimal anchorage zones for the distal and proximal ends. Four different anatomies were tested; two of these are shown as examples in Figure 10.

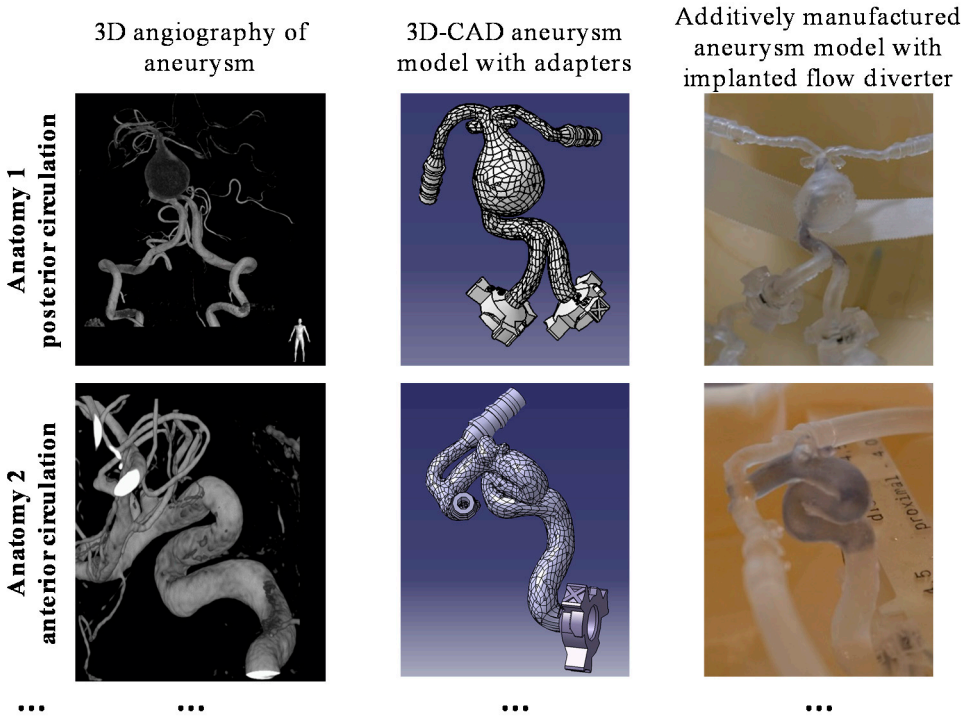


Figure 10. Using additively manufactured aneurysm models developed based on angiographic 3D images with different anatomical characteristics to implant personalized flow diverter variants in order to analyze the impact of specifically designed product characteristics on overall product performance.

The flow diverter prototypes were implanted by experienced senior physicians who were part of the interdisciplinary team investigating the personalization of the flow diverter. Different implant prototypes were released in each aneurysm anatomy, by each physician, and the product performance was evaluated. A System Usability Scale (SUS) questionnaire, as presented by Brooke [49], was used for this purpose. In this questionnaire, the physicians expressed their satisfaction with the product using a variety of statements. The questionnaire has already proven effective in measuring satisfaction in a number of previous studies [50]. The implantation time was also measured and compared. Furthermore,

the same implantation procedure was performed by two independent doctors. Tests at the premises of the manufacturer of the flow diverter were also added.

The flow diverter prototypes differed in one attribute of a product characteristic in an attempt to influence the performance of the corresponding product property. This ensures that any change in performance must be a result of the adaption to the attribute of the product characteristic in question. The testing of the personalized prototypes shows that ensuring that the implant length exactly matched the *Vessel length* determined by the physician has a positive effect on handling during implantation. At the same time, however, it was found that the physician could manipulate the length by pushing and pulling harder when releasing the flow diverter. If a uniform discharge—and thus a physician-specific manipulation of the length—can be prevented, personalizing the exact length of the implant will improve the product performance. Implementing the differentiation between the proximal and distal diameters alone led to an improvement in the *Wall apposition (proximal)* and *Wall apposition (distal)*. An exact, customer-specific attribute for the diameter based on the pathology of the individual in question led to an improvement in the result of the treatment. A personalized attribute for the braid angle at an individual position in the proximal segment also demonstrated a highly positive effect on implant performance in curves and twists. An individual attribute for the *Number of wires* and *Wire thickness* would also be conceivable for individual behavior in curves, but since the effects of adjusting the braid angle have been researched in more detail, it makes more sense to adjust the differentiating property *Wall apposition (curvature)* using the braid angle. A standardized attribute is sufficient for the *Number of wires* and *Wire thickness*. Figure 11 summarizes the results of the personalized prototype tests in the medical simulation model, and highlights the fact that that nearly all product characteristics are potentially relevant for personalization from a product performance perspective. As such, the figure does not show the SUS results with regard to how great the potential is for each product characteristic.

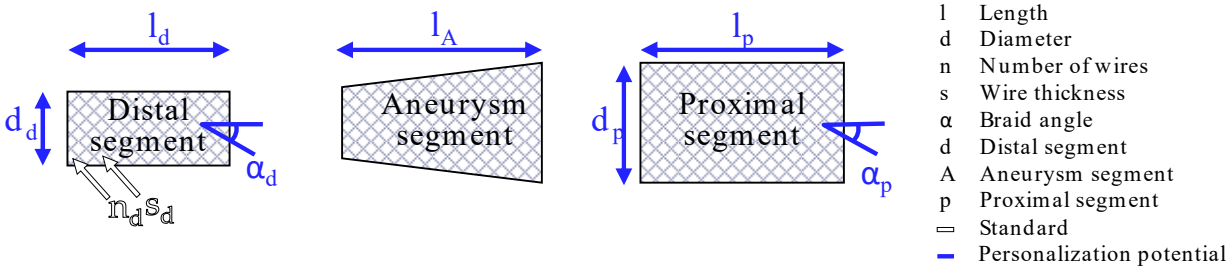


Figure 11. Segments of the flow diverter with product characteristics and their relevance for personalization.

3.5. Analysis of the Internal Effects of Personalization

In parallel with the examination of the relevance of product characteristics for individualization, the workload required for repeated adaptation of the characteristic's specific attributes based on the needs of the individual patient was also investigated. This process focuses on every phase of the lifecycle including product development, procurement, production, quality assurance, and sales [5]. This will allow manufacturers to consider variety-induced complexity at an early stage.

For each product characteristic, examinations were conducted to determine which of the processes in the various phases of the product's lifecycle influence the attribute in question. These examinations also consider which of these process steps need to be repeated for individual attributes—work that would not be required when using predefined variant attributes. Furthermore, this phase also needs to identify the processes that need to be added for personalization such as designing the adaptation once the individual requirements have been checked.

In order to achieve this, the processes were recorded hierarchically as described by Ross [51]. This means that the main processes of the lifecycle phases are recorded

first. Where there are connections or dependencies between a product characteristic and a process, the sub-processes are also taken into account. This adds increasing layers of detail to the process, potentially right down to the task step level. This facilitates the establishment of a relationship between a product characteristic and a process characteristic such as a tool size or program variable. Process characteristics that are particularly time or cost-intensive to modify such as the repeated customer-specific setup of machines and the procurement of attribute-specific tools are highly relevant here. During personalization, process or tooling costs that could otherwise be allocated to a large number of predefined variants may instead only be assigned to one specific product variant. The additional costs incurred through the use of personalized attributes as opposed to variant attributes are also examined and compared for each product characteristic.

For the example of the flow diverter, the processes were recorded accordingly and a relationship was established between the product and process characteristics. In some cases, one process characteristic affected multiple different product characteristics. For example, if the haul-off speed for the braiding process is changed in order to modify the braid angle, this also results in a change to the length of the flow diverter. As a consequence of this, the braiding time also has to be adjusted in order to ensure that the product characteristic *Length* is not affected. Therefore, recognizing the dependencies between the product characteristic and the process characteristic in terms of determining how a change will propagate if one process characteristic is adjusted is of great importance.

The process analysis showed that individualizing the diameter resulted in high costs because the product characteristic *Diameter* is heavily dependent on the process characteristic *Braid mandrel geometry*. A separate tool (braiding mandrel) would need to be procured for each individual diameter. When personalizing the diameter, the costs of one tool can no longer be split across a large number of parts, as they would be for predefined variants. Individually adjusting the diameter affects a wide range of processes in every phase of the lifecycle including tool specification during product development, tool ordering during purchasing, and installing the tool and adjusting the braiding program during production. As such, personalization of the diameter is not recommended from a complexity perspective. Instead, the best option is to use variant diameters for the proximal and distal segments so that there is no need to purchase individual braiding mandrels. This allows for the costs of one tool to be spread across a large number of parts, which is particularly useful for high-cost tools.

The *Product length* is strongly linked to the program variable *Braiding time* in the braiding process. An individual attribute of the length can be changed by means of a simple adjustment to the braiding time, thus can be implemented with relatively little effort. In addition to the documentation processes, an individual attribute will mainly affect the production process. Due to the three-way segmentation of the flow diverter into the *proximal segment*, *aneurysm segment*, and *distal segment*, the length for the distal and aneurysm segments become dependent on the length of the braiding mandrel. Here, the individualization workload has to be evaluated in the same way as the diameter. As such, individual lengths should only be used for the proximal segment, as this does not entail the cost-intensive adaptation of the braid mandrel. Variant lengths are recommended for the other two segments.

No specific tools are required to implement an individual attribute for the braid angle, so this can be adapted by means of adjustments during the braiding process, since there is a close link between the *Braid angle* and the braiding program variable *Haul-off speed*. However, changing the settings for individual haul-off speeds for individual braid angles takes a little more time than adjusting the braiding time for an individual proximal length.

From a workload perspective, there is no way of implementing an individual number of wires in the mesh while still maintaining some degree of control over the complexity. If the number of wires is changed, the braiding process can no longer be carried out in the same way as before. New braiding patterns—and thus new braiding programs—would need to be developed, and a new braiding machine may even be required. Likewise,

the determination and introduction of individual wire thicknesses is not viable. The least complex way of implementing differentiating properties for the wall position in curved and twisted vessels is by changing the braiding angle.

Figure 12 illustrates the procedure and compares the to-do list for a specific adaptation for all the product characteristics using the production phase of the lifecycle as an example.

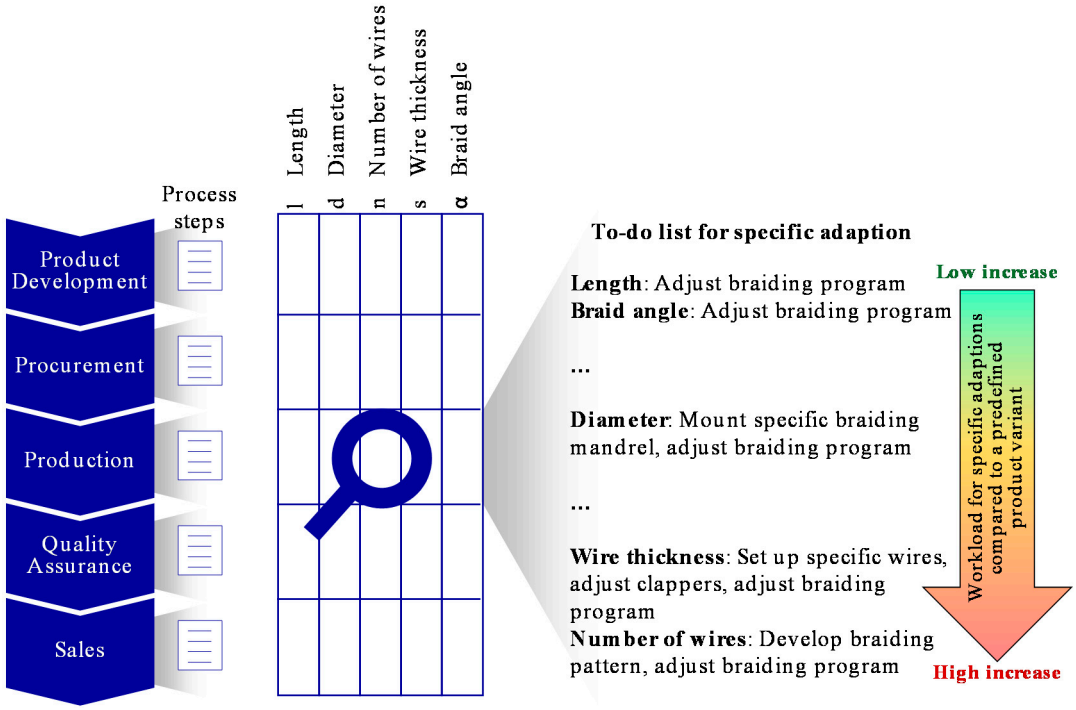


Figure 12. Analysis of the internal effects of individualization based on an examination of the to-do list for an individual design of the product characteristic in the different phases of the product lifecycle.

3.6. Development of a Product Concept with Consideration of Personalized Attributes

In the final step of the method, the analysis results are collected and compared. Taking into account the analysis results as well as the corporate strategy and other parameters for the individual phases of the product lifecycle, it is possible to develop a product concept with personalizable, variant, and standardized product characteristics. For this purpose, the value added by personalization for each product characteristic identified as relevant for personalization in step 4 is compared with the workload of personalization determined in step 5. Therefore, in order to summarize the results of the analysis, *individualization profiles* can be created for each product characteristic. The *individualization profile* of a characteristic contains clearly structured information on the following factors:

- Impact on product performance when personalizing the attribute of the characteristic;
- Individualization workload when personalizing the attribute of the characteristic; and
- Limitations when personalizing the attribute of the characteristic including attribute limitation due to anatomical conditions, manufacturing accuracy, and possibilities of certification issues.

In a workshop with representatives from every phase of the product's lifecycle including the customer of the use phase, and interdisciplinary departments, a decision was made regarding which of the product family's characteristics should be personalized, which will be variants and which should remain standardized.

Based on the results described in Sections 3.1–3.5, one way of structuring the product family for the flow diverter would be to use an implant consisting of three segments: aneurysm, distal, and proximal. The length of the proximal segment and the braid angles

of the proximal and distal segments would be defined individually for each customer. The diameters of the proximal and distal segments and the lengths of the distal and aneurysm segments would be varied in order to avoid the costly and time-consuming process of producing individual tools and tool modules. The number of wires and wire thickness would remain standardized for all variants of the flow diverter. The final evaluation of this concept is still pending, but will be done at *HANNES* in line with the procedure outlined in Section 3.4. Figure 13 provides a summary of one potential product personalization concept.

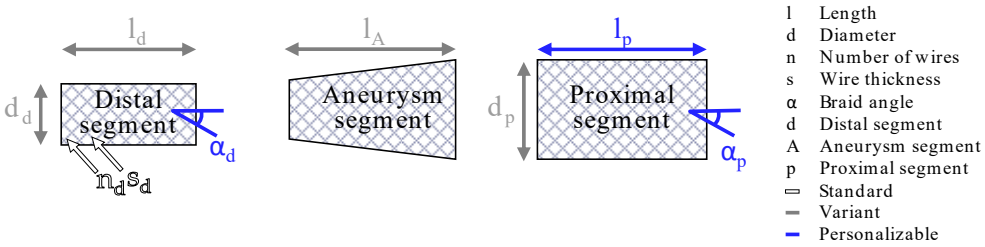


Figure 13. Potential flow diverter concept including three segments with personalizable, variant, and standard product properties.

4. Discussion

This article presents a method for defining an appropriate variety level for a product family, taking into account standardized, variant, and personalized attributes. The systematic procedure introduced here can be used to answer the research question formulated at the start of the article. The proposed approach of determining the customer value by examining the relevance of the differentiating properties for the individualization and evaluating the variety-induced complexity based on the individualization workload was proven to be suitable. The method was applied successfully to a flow diverter as an example product. However, no investigation was conducted into whether the method presented in this article is transferable to other medical—or even non-medical—products. As such, it is not yet possible to draw conclusions regarding the general validity of the method or any adjustments that may prove necessary.

The method comprises six different steps. This facilitates a comprehensive and targeted investigation that takes into account all the relevant aspects. The decision on whether or not to personalize individual characteristics is documented in a comprehensible manner while applying the method. The internal and external variety analysis and variety-oriented product design steps provide a solid foundation for the new personalization method. These steps have already been successfully applied to a wide variety of products (see e.g., [12]). The second step, which involves checking that all the differentiating properties have been recognized, provides a critical perspective on the personalization project. The analysis of the application scenarios presents a good opportunity to recognize the differences in requirements. Nevertheless, at this point, it is difficult to ensure that the application scenarios are complete. For medical devices, the process of determining the differentiating properties and assessing the benefits of personalization need to be carried out in close cooperation with medical professionals and, where necessary, the patient. The experience of these groups in using the product every day can help to determine what product behavior is required and how this varies depending on the specific use case. Medical simulation environments offer great potential for assessing individual attributes. However, the method presented in this paper offers little assistance in assessing the relevance of individualization for products in sectors other than the medical device sector. Further research is needed at this point. When analyzing the internal effects of individualization, the challenge is to recognize all the relevant sub-processes that will need to be repeated or modified for customer-specific attributes. Further research is required in order to characterize the processes that are affected by an individual product design.

Furthermore, it is important to note that the mesh of the flow diverter consists of only one component, which is segmented virtually. It is assumed that the method can be applied analogously for products with several components, since the method is based on the analysis of the differentiating properties. These differentiating properties should be implemented using product characteristics that are largely independent of one another, and whose attributes do not influence one another. Whether the independent product characteristics are then implemented in one component, as in the example of the flow diverter shown here, or in a variety of components is of secondary importance for the application of the method. The key factors to consider are the links between differentiating properties and product characteristics, the links between different product characteristics, and the links between these and the process characteristics. Nevertheless, the used product example is one key advantage as well as a main limitation. While the simple example clarifies the basic applicability and procedure of the method, the transferability and procedure for more complex products remain poorly explained. Further work is mandatory to fully validate the method and also show the applicability for more complex products.

The method can be applied to existing product families with tangible components, whose relation between product characteristics and product properties is fully investigated. Software solutions or services have been neglected so far. Further limitations are given by the use of the VAM as a basic tool. The VAM is preferably suitable for product families with a smaller number of variant components, as there is as yet no suitable software support for the fast and targeted generation and adaptation of the VAM. For the analysis and optimization of complex product families, model-based approaches should be implemented, like those suggested by Seiler et al. [52]. By applying the method for the targeted definition of medical products with standardized, variant, and personalized attributes, the economic position of a company can be strengthened. On one hand, it enables a company to consider the personalization workload at an early stage and not run the risk of variant-induced complexity getting out of control. On the other hand, taking personalized characteristics into account can create a competitive advantage as well as intensive customer loyalty.

In the specific case of the flow diverter used as an example product in this article, the extent to which the physician can influence the implantation result still needs to be discussed. An individual flow diverter design will help the physician in terms of handling the implant in a patient-specific vessel pathology. However, the flow diverter still allows the physician to manipulate the implantation result, both for individually designed devices and for predefined flow diverters. This potential manipulation includes influencing the opening and apposition behavior of the implant by varying the degree of pulling and pushing during discharge, thus causing greater compression or stretching of the implant, and subsequent modification of the mesh using a catheter so that the mesh can be pushed up further against the vessel wall. This physician-specific manipulation heavily impairs the implantation result. An individual flow diverter should make such manipulation largely unnecessary, thus minimizing dependence on the physician. However, it is not possible to completely rule out the possibility that the physician's skill and experience may affect the results.

5. Conclusions

This publication presents a method for defining an appropriate variety level for a product family, taking into account standardized, variant, and personalized attributes and focusing on medical devices. By analyzing and comparing the personalization relevance and personalization workload of the product characteristics that make up the differentiating product properties, it is possible to strike a balance between individual customer value and personalization workload. A deliberate distinction is made between differentiating properties, which are noticed by the customer, and product characteristics, which constitute product properties and can be defined by the designer. Analyzing the relationship between product properties and characteristics can be used as a way of immediately establishing the relationship between the customer's view of the product and that of the company.

The method was applied to a flow diverter as an example product in order to demonstrate and clarify the suitability and applicability of the method. The introduction of the method using a simple example clarified its applicability, but was also one of the main limitations of the article. The transferability of the method to more products and more complex products, remains to be examined as well as further research on making the method applicable for other products than medical devices.

As such, the method introduced in this article can help companies to design product families with standardized, variant, and personalized attributes and enable them to take both the personalization workload and the value to the customer into account at an early stage when critically assessing the potential of a personalization project.

6. Patents

Two patent applications relating to the neurointerventional training model have been filed at the *German Patent and Trademark Office*: file number 10 2019 008 058.0 [46] and file number 10 2020 003 786.0 [53]. The modular braiding mandrel for the manufacturing of the segmented flow diverter is protected under the patent with the file reference 10 2020 1012 50.0 [48].

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Conflicts of Interest: Outside of the submitted work, Fiehler reports grants and personal fees from Acandis, grants and personal fees from Cerenovus, grants and personal fees from Medtronic, grants and personal fees from Microvention, personal fees from Penumbra, and personal fees from Phenox; shareholder Tegus, CEO Eppdata. The other authors declare no conflicts of interest.

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