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Process types of customisation and personalisation in design for additive manufacturing applied to vascular models

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Abstract

Manufacturing companies face high demand for products that fulfil individual customer desires. Recent improvements in additive manufacturing (AM) enable the fabrication of customer-specific components of a product.

This paper presents a categorisation of design processes for customised and personalised products through the use of AM in three process types: special design, specific adaptation, and standardised individualisation. The characteristics of design processes are examined in medical development of vascular models integrated into a modular neurovascular training setup. The paper considers how initial customer involvement and preplanning of customer-specification influence the design process for varying degrees of individualisation enabled by additive manufacturing.

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1. Introduction

Manufacturing companies are confronted with demand for products fulfilling individual customer needs. Additive manufacturing (AM), as a collective term for layer manufacturing methods, facilitates the fabrication of customer-specific products because of the elimination of tooling, which enables production directly from computer-aided design data [1]. Compared to conventional manufacturing, such as subtractive, joining, and formative processes, additive manufacturing is generally recommended for fabricating products with higher degrees of customisation and/or higher levels of geometrical complexity [2].

The object of this work is the impact of AM in product design when offering customer-specific products and in the resulting design processes. The capabilities of AM are well known and AM is already used for customisation and personalisation, e.g. 17 million customer-specific orthodontic aligners annually fabricated in the dental industry [3]. However, there is a lack of knowledge and methods in design for AM [4] and the potential remains unrealised, particularly in custom part production [3]. The aim of this paper is to

present the AM-specific influences on design processes for customisation and personalisation and to present three main process types of individualisation in design for AM. Based on an overview of AM and individualised design, the processes of individualisation in design for AM are described and applied to medical design of individualised vascular models showing the distinct design effort for individualisation.

2. Background

2.1. Additive manufacturing and its applications

Tool-less fabrication, due to the layer-by-layer fabrication of AM, has various possibilities in the product engineering process. Beside Rapid Prototyping and Rapid Tooling, AM is used more for direct manufacturing of end-use parts [1] with three main areas of application [1, 5]:

- High design freedom to either improve functionality and performance through the adoption of internal and external forms or to offer more aesthetics and design features
- Integration of functions and part consolidation to reduce the overall number of parts

- Individualisation and user-fit requirement to adopt unique shapes and to fabricate small lot sizes economically.

Principles of design for AM are summarized by Rosen, including design ideas that cannot be produced using conventional fabrication methods [6]. The various AM technologies offer their own material and geometry properties [7], with diverse restrictions [5], so that each requires different construction guidelines and design knowledge. It is assumed that the effects of different AM technologies on the design process are comparable, so this work assesses the implications of direct additive production of AM in design without focussing on one specific AM technology.

2.2. Customised and personalised product design

In a buyer's market there is a demand for products that fulfil individual customer needs. Manufacturing companies face the conflict of increasing the external variety demanded by the market while offering competitive prices [8].

The business strategy Mass Customisation aims to fulfil individual customer needs at a cost level that satisfies a large part of the market [9]. Common strategies for Mass Customisation present a compromise between standardisation and pure individuality. Product family design aims for sufficient external product variants combined with manageable internal variety to obtain economies of scale at the component level and to reduce complexity in the development and manufacturing capabilities [8]. It profits from reuse of design elements and modules that are specifically configured for the customer and assembled within a pre-defined product family [10]. One attribute of a modular product structure is "function binding" of each product function implemented within a specific component [11]. A variety-oriented product structure should obtain one-to-one mapping between differentiating properties and variant components, and a minimal degree of coupling of variant components to other components [8].

While the current Mass Customisation strategies have passive and limited customer participation, Mass Personalisation strategies aim to satisfy each customer as an individual with implicit needs [12]. Personalisation is enabled through a high degree of product change, user experience and co-creation, so that the final product as well as the basic design and product structure are changeable, adaptable, configurable [10] and consequently less predictable [12].

As per [10, 12], the term (mass) customisation is used in this work for a design for market segments and (mass) personalisation for regarding each customer as an individual. The term individualisation is further used in this work as a generic term of customisation and personalisation for customer-specific products that satisfy customer needs. It differs from other definitions, where individualisation is equated with personalisation [13]. It is particularly used for products not easily classifiable as one of the two terms. The degree of individualisation increases with early initial involvement of the customer, but has negative effects on delivery time and efficiency [9].

2.3. Design for customisation and personalisation through additive manufacturing

Flexible production technologies support the customer-task-oriented parts of production in allocating high performance and geometric complexity. Thus, AM is an enabler of customised product design [14]. There are multiple applications of AM in customer-specific products, such as patient-specific Aligners in the dental industry and plastic shells for custom in-the-ear hearing aids [3]. The potential of direct AM can be graded by lot size effects and the degree of customisation [15]. Most AM-facilitated customisations are based on user information for body-fitting or for user-relevant geometries [16], as in the customised design of protective face masks [17] and in the design method for the production of body-fitting customised seat profiles using three-dimensional laser scanning, reverse engineering and direct additive manufacturing [18]. Ko et al. argued that personalisation through AM needs to consider design requirements that include customer satisfaction. They proposed a formal framework for a design process for AM-facilitated personalisation that systematically categorises preferable affordances and user behaviours in a numerical way [16]. In another publication, Ko et al. introduced a new representation of design knowledge of Customized Design for Additive Manufacturing [19].

3. Process types of customisation and personalisation in design for additive manufacturing

Additive manufacturing is an enabler of customer-specific product design. The make-to-order environment is the main application of AM for individualisation containing high potential for companies [20]. AM makes it possible to offer high external variety while the internal processes remain lean and standardised. The self-customisation of components in the stock-to-order environment exists as a further personalised design. The customer designs components and fabricates them using AM [21]. The increased number of home-based machines and AM distributors enables the self-customisation of components, which is interesting for consumer products but only has minor influence on the design process.

In the make-to-order environment the levels of individualisation and customer involvement in product processes differs [20]. Three types of design processes are identified through the use of AM in make-to-order individualisation: (1) special design, (2) specific adaptation, and (3) standardised individualisation. The types of individualisation processes differ in degree of customer integration, preplanning of individualisation, and influence on the design process.

In *special design* as a one-off production, a single product is designed and fabricated bases on customer desire. The special design presents the implications of AM in customer-specific design, for example in lamps or medical modelling [21]. Special design is only slightly suitable for Mass Customisation as it is truly custom-made. It has the highest

degree of individualisation. Special engineering is not competitive with batch production. High external variety occurs because of unique parts, which are truly customised and fulfil all customer requirements.

The two other types of design processes for customer-specific products through AM have a gradual transition of their characteristics: the often applied pre-planned standardisation for customisation (called *standardised individualisation*) and the high level of individualisation and customer-specific, personalised design (called *specific adaptation*) [20]. Key differentiators of these two types are the frequency of true customer participation and the level of predictability.

Specific adaptation provides an individualised product with special requirements and functions. The adaptation is located within a fixed solution space without changing or new-designing the main product attributes, as in special design. This adaptability needs detailed product structure planning in the first step of the design process to define an individualisation scope that circumscribes the core product structure limits with changeable and adaptable features and open zones for personalisation (Fig. 1). After gathering the requirements of the individual customer, the product is adapted within this individualisation scope for specific adaptation. The design process is redone according to individual customer desire by influencing different steps within the design process. A customer co-creation [10] is also achievable, but is not detailed here.

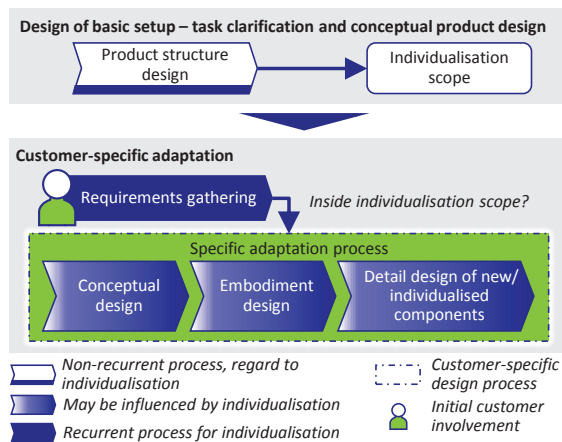


Fig. 1. Design process of specific adaptation

If there is a single point of individualisation where geometrical adaptation can increase product applicability or customer satisfaction, the customisation can be predefined by planning a *standardised individualisation* process. During the conception and design phases of the product, the constraints of individualisation are assessed without being performed (Fig. 2). The main part of standardised individualisation is the process for the detail design of the individualised component, and particularly its process development. The process

contains the special individualisation process from initial customer involvement to the final production data. The individualisation process is a recurrent process for each customisation and should therefore be standardised. Although the geometry of the component is customer-specific, there is no preceding requirements gathering through interaction with the individual customer. The product structure, part properties and functionality are not changed. The customer-specific component increases the user experience, and limited product change is realised. A product with customer-specific components can be achieved without performing true personalisation of the product.

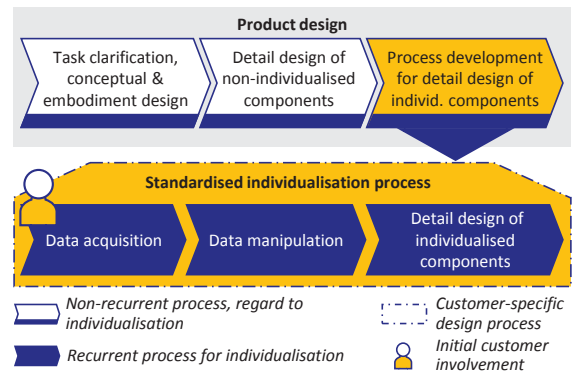


Fig. 2. Design process of standardised individualisation

The advantages of AM for an individualised design are enhanced by the other two application areas of AM (Section 2.1). High design freedom enables customer-specifically latticed designs and freeform surfaces, e.g. for user-fitting. AM facilitates the integration of several functions and their working principles in one part either consolidating parts with separated working surfaces or merging working surfaces and materials together. Functional integration is realisable in design for AM, but equally contrary to approaches of design for variety, where the product structure should obtain one-to-one mapping between differentiating properties and variant components. Multiplication effects may occur through functional integration of differentiating properties in one part.

The individualised component of a customer-specific product exists inherently in high variety and small numbers. As it is changed in any case for the individualisation-relevant property, e.g. a customer-fitting surface, the component can further adopted to other desires and differentiating properties. The functional integration through AM facilitates an appeal for variability to combine differentiating properties and their functions in the individualised component. An integral design using AM facilitates a direct mapping between differentiating product properties and variant working elements while coupling them in one additively manufactured component.

To avoid multiplications effects it is relevant that the functional integration doesn't unnecessarily increase the component's variety. The main cost and complexity driver for

production and subsequent processes must remain similar to the differential design structure. The part volume should not be scaled up compared to the differential design, because this affects the process time and costs of the additive manufacturing negatively. Due to the tool-less fabrication of AM, small lot sizes may be fabricated economically and an integration of function is enabled. Function sharing in the individualised component has minor multiplication effects as it is individualised in any case.

4. Design of individualised vascular models

A vascular replication system with patient-specific aneurysm models applied to train neurovascular interventions was developed and adapted to individual patient diseases and specific demands of physicians [22, 23]. The three types of individualisation processes are applied to the vascular replication system for various applications.

4.1. Vascular models

The freedom of design by AM has a big impact on the replication of branched cerebral blood vessels and their diseases. These replications help neuroradiologists to train for interventions and to get used to the various instruments. A *vascular model* replicates a vascular disease and the nearby vessels as a hollow space; here, it mimics a brain aneurysm, i.e. a bulging, weak area in the wall of a cerebral blood vessel. For the neurointerventional treatment technique, a flexible microcatheter is placed inside the aneurysm under fluoroscopy. During coil embolization of aneurysms, the risky blood flow into the aneurysm is reduced by packing the aneurysm with platinum coils. This catheter-based method requires a negative vessel replication, which means the vessel is replicated as a hollow structure, enabling introduction and navigation of devices. Fabrication with AM is ideal for these tangled geometries with inlying characteristics. Even though AM can theoretically produce any complex shape, there are restrictions when producing the hollow, branched vessel geometry. Powder-based procedures are not suitable, and Fused Deposition Modelling needs two dissimilar materials to solve the internal support structures [23].

4.2. Vascular diseases in standardised individualisation

The intervention of aneurysms is a patient-specific challenge for physicians. It is important to simulate the treatment at different geometries based on real patient data, because patient-specific vascular models offer the best training conditions. The component that has to be individualised is known (i.e. cerebral blood vessel with aneurysms) and represents one single point for customisation. The process of standardised individualisation is the type of individualisation to be used here. First, the whole training setup and its components are designed. The interfaces to the individualised vascular model are then defined. In the design process for standardised individualisation, the development of

the process for detail design of the individualised vascular model component is remarkable. This process (Fig. 3) is held up each time for a new patient-specific vascular model of cerebral aneurysms.

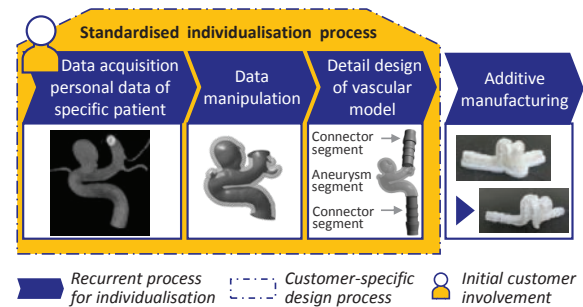


Fig. 3. Standardised individualisation process of vascular models

The design of customised vascular models of intracranial aneurysms is based on real angiographic patient data [22]. A workflow is defined for clinical 3D-rotational angiography data to be acquired, reconstructed and transformed in the volumetric model. The real vessel geometry is converted to a negative model with defined wall thickness and small vascular branches are removed. To integrate the models into the training setup, connector segments for silicone tubes are added as standardised interfaces at the major vessels. The vascular model contains standardised connectors and a patient-specific aneurysm segment. As this process is implemented in a standardised workflow, the detail design of the individualised vascular model does not require much time.

4.3. Modularity of the neurovascular training setup

The vascular models that replicate diseases of cerebral blood vessels, like aneurysms, are integrated into a *neurovascular training setup*. The final product feature of the setup depends on the planned aim, resources and target group of the training, and generates external variety. The variations have in common that they all replicate cerebral aneurysms to simulate neurovascular interventions for training of physicians, who are the user of the product and customer. The training setup is placed in an angiographic system, i.e. a medical imaging procedure outlining blood vessels on x-ray, in the same manner as the patient would be laid.

Customer-relevant distinctive variant properties of the neurovascular training setup are listed in the first line of Fig. 4. The Variety Allocation Model (VAM), adapted from the Integrated PKT approach for the development of modular product families to reduce the internal variety [8], considers the functions in the second line and the working principles of operation in the third. In the last line, the components influenced by variety are listed.

Differentiating property for the customer is the type of aneurysm geometry that might be either patient-specific or generically developed for targeted simulation of treatment.

Equally relevant is the wall feature of the vascular model, which is either rigid and opaque, rigid and transparent, or elastic. The rigid and opaque model is the basic feature. The transparency enables an optical proof of medical instruments, like coil in the aneurysm, and offers information additional to the angiographic measurement. The rigid models are recommended for exercising the procedure and getting to know the neurointerventional instruments. The behaviour of the instruments on the soft blood vessel wall is mimicked through the elastic wall of the vascular model. Force feedback of catheter and coil is thus enabled with the elastic model. It requires other interfaces to the rest of the system. The rigid male connector geometry is substituted by tube-like geometry. Of lower relevance to the customer is the sort of vessel tree, which is either simplified by silicone tubes or by a silicone model of a human aorta, and the type of blood flow, which is with or without a pump for a pulsatile flow.

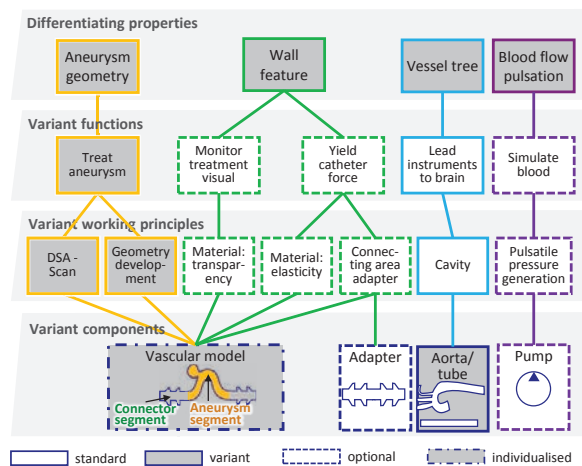


Fig. 4. Variety Allocation Model (VAM) of the neurovascular training setup

In the last line of Fig. 4 the components influenced by variety and the customer relevant properties are listed. The pump is an optional component that offers pulsatile flow. The vascular tree is either modelled with simple tubes or with an aorta model and its mounting. The product features of the aneurysm geometry as well as the wall property influence both the same variant component, i.e. the vascular model. Normally in design for variety, function binding is intended to minimize the effort of individualised influences. As described in Section 3, the advantages of AM to functional integration can relativise this aim, and the mapping of multiple functions that influence the individualised component is also conceivable. The type of aneurysm has an effect on the aneurysm segment of the vascular model, which is either an angiographic measurement or generically developed. The wall property influences the connector segments (male/ female) of the vascular model and the presence of the optional component adapter connecting the vascular model to the whole setup. The physical component vascular model

contains different segments that are additively manufactured as one part. The wall property influences the choice of AM technology further. Rigid vascular models are fabricated through Fused Deposition Modelling, Stereolithography or Material Jetting. The soft wall requires elastic material, for which Material Jetting at a Connex machine is most qualified. More information to this topic is described in [23].

The neurovascular training system is installed in an angiographic system (Fig. 5). The mounting for the vascular model of aneurysm is flexible, which means that most of the geometries can be fastened at the mounting. This standard component is realised by a box-shaped mounting with standard brackets that are aneurysm-independent.

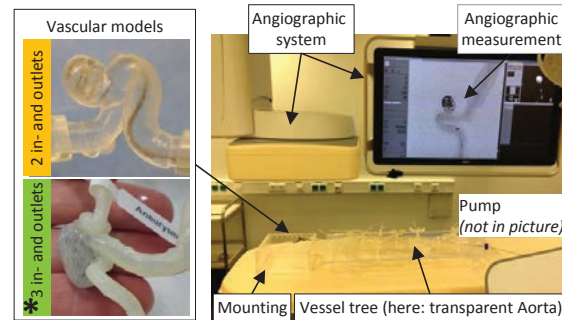


Fig. 5. Neurovascular training system installed in angiographic system

4.4. Personalised training setup in specific adaptation

The product family of a neurovascular training setup has the capacity to be personalised. Further customer-specific adaptations are possible in a defined individualisation scope. Two adaptations of the basic setup of the neurovascular training setup, explained in Section 4.3, are described.

The box-shaped mounting for the vascular model is not very realistic. A request from a customer resulted in the setup of the training system becoming more life-like, and the standard mounting was replaced with an individualised head-mounting. The head was constructed to hold one specific vascular model. Other models with different inlets and outlets cannot be positioned in this head-mounting.

Another customer wanted to realise three inlets and outlets in vascular models that depend on patient-specific vessel geometry. The change influences the detail design process with the workflow of the standardised individualisation. This desire is a typical example of progression of an isolated individualisation case to becoming the usual case. In the iteratively implemented standardised individualisation, if and how many connector geometries for elastic or rigid models are desired (see * in Fig. 5) were later selectable.

Two further personalised designs for transparency of the vascular model and wall elasticity were considered initially as specific adaptation. Since the high relevance for customers was recognized, they were implemented in the standardised individualisation and integrated into the product family (Section 4.3).

4.5. Special design of vascular models

Special design becomes relevant to customer requirements outside of the individualisation scope, where the effort of adaptation is high. Two special designs of the neurovascular training system have been required. A presentation object of neurovascular diseases is suggested as a positive model of the blood vessel (Fig. 6.a). The functionality of the presentation model, e.g. for teaching, is new but the data processing is similar to the standardised individualisation process for the negative vascular model. The second special design of vascular models should replicate neurovascular diseases other than aneurysms, such as stenosis, i.e. a narrowing in a blood vessel. Different intervention behaviour has to be replicated and needs new development in vascular models (Fig. 6.b).

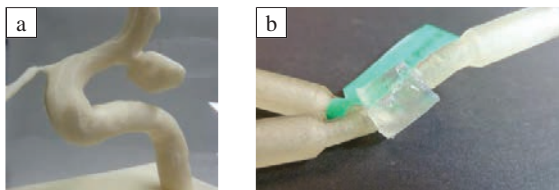


Fig. 6. Special design of vascular models:
a.) Positive model as presentation object; b.) Stenosis model

5. Conclusion

Degrees of individualisation and their corresponding processes are presented in this work categorised in three design processes for customised and personalised products through the use of additive manufacturing. Standardised individualisation is recommended if one defined component will be recurrently individualised and results in a defined degree of customisation for user involvement. Customer specific adaptation is reasonable in a predefined individualisation scope for adjustment development and influences the prior design process steps. Special design is necessary for customer requirements that need greater development effort. The types of individualisation are presented in vascular models of neurovascular diseases. Requested function binding in design for variety is relativized with AM because of the advantages of functional integration within the individualised component. The improvements in additive manufacturing facilitate the direct manufacturing of parts and the possibilities for individualised design increase due to tool-less fabrication.

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