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ECONOMIES OF MASS CUSTOMIZATION – VALUE CREATION VIA MASS CUSTOMIZATION

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Abstract: *3D printing offer may potentials for MedTech companies. 3D printing is nowadays much more common as well as relevant due to enhancements of printers and materials. As such, it provides opportunities for mass customized medical solutions. Specifically, it allows optimized personalized solutions for the patients. Additional advantages for patients include issues like diagnose improvements, diversified options of medical-devices or even entirely new solutions. MedTech companies, contrarily, can benefit from 3D printing due to its related profit as well as cost advantageous such as maximization of sales revenue, cost savings due to the elimination of material waste, the removal of tooling expenses, the reduction of labor costs as well as inventory levels, and the improvement in design complexity. Elaborating on this topic, this paper illustrates the diverse benefits of mass customization based on MedTech 3D printing concepts and its potentials for value creation.*

1. INTRODUCTION

Joseph Pine states that mass customization requires flexibility and the ability to respond quickly in order to succeed. This is especially relevant in today's constantly changing environment in which customer demands and corresponding reconfigurations are essential to survive in the long-term. Moreover, skilled individuals and an efficient management of the value added chain are highly relevant in this context since they mayorly influence the achievement of lower costs, highest quality, and personalized goods as well as services.

3D printing technologies provide an operating network in terms of adaptability for one-to-one personalized healthcare solutions and flexibility. Hence, 3D printing fullfils the basic criteria of successful mass customization. Although it is the goal to develop products based on customers' needs, they have to be linked to the front-end. In detail, there are two key medical customers who can potentially be involved in the adaptability aspect. The first is the healthcare specialist. An example could be an orthopaedist who gives the inputs for therapeutical design and materials. The other customer is the patient. (S)He might have some specific optical wishes besides his/her demand of a successful treatment. Consequently, an orientation on the demands of specialists and patients is necessary in order to meet the above stated objective. The required flexibility can be achieved via clearly defined systematical and unified operations which include the customers in the value creation chain in a way so that the latter have a say in term of definition, configuration and modification of any individual order. Flexibility, particularly in the form of responding quickly, is an important concept in the MedTech market. That is predominantly because it emcompasses several relevant aspects such as matching customers' needs and wants, and delivery on time. Moreover, it is essential in the context of mass customization because it represents the basis to supply the agreed quantity. The most crucial challenge of mass customization is, however, that it has to satisfy customers' demands and simultaneously reduce the producers' operating costs while increasing products' quality. All of the above dissucssed issues are in favour of 3D printing because it enables focusing on manufacturing for designs and implementing features that are required to obtain optimal functionality of the devices [1].

It is the aim of this paper to highlight the so called *economies of mass customization* in the MedTech industry. Specifically, economies of mass customization are concerned with cost and profit structures which occure while integrating costumers into the value creation of mass customization-based MedTech 3D printing.

2. MASS CUSTOMIZATION-BASED MEDTECH 3D PRINTING

Key Enabling Technologies (KETs) such as 3D printing technologies for production open new possibilities to design innovative supply chains for flexible, medical, specialist-driven, small series or and even personalized medical devices. Because of this, the MedTech industry, in particular, demands for 3D printing technologies. Moreover, 3D printing technologies are highly relevant for this market segment because of material and printers improvements which open up new options for personalized medical solutions. The patients' and production's benefits in the MedTech industry are indeed significantly as can be seen in the fact that 40% of all patent applications for 3D printing in the last two years are a result of the MedTech sector. Today orthopaedics and prosthetics 3D printing applications can be established in a shorter period of time and also offer opportunities to increase revenues and lower costs for othopaedists. A cost analysis of Arcam assumes that a hip, for instance, can be produced with a cost reduction of approximately 65% compared to the costs of traditional methods [1]; and this is only one example which shows the potential cost savings which are applicable for diverse segments of the highly diversified MedTech market segment. In the long-term, research on printing functional organs will be available, too. Yet, most commentators agree that it will be at least 10 years before technology is viable for these high complex medical fields [2]. In the short-term, opportunities of 3D printing - including high revenues and cost savings - will have an impact on dentistry, orthopaedic reconstruction, orthopaedic trauma and prosthetics, but also on corrective lenses, advanced wound care and stents [1]. 3D printing is mostly suitable because it facilitates the move away from design towards suit manufacturing. Moreover, it places emphasis on the patient already at the design stage. This is also helpful for expert costumers in order to implement their diverse demanded features and functionalities. Overall, this allows prducing optimal personalized solution or devices for the patients.

3. CUSTOMER-DRIVEN SUPPLY CHAIN-BASED MEDTECH 3D PRINTING

The following chapter of this articel, explaines the motives and incentives of integrating users into the value creation of mass customized products. Users are, in this context, regarded as medical experts who provide functional and design inputs. Additionally, patients are viewed besides their user position customers, too. Their focus lies, however, on comfort functionalities and likely on design. Furthermore, this chapter points out the factors which drive consumers to spend time on mass customization and their opportunity costs on using configurators. Finally, this chapter illustrates how companies in the MedTech area should implement these mechanisms to create fruitful business models.

At the beginning of introducing mass customization based MedTech 3D printing to medical customer and their patients, it is likly to bear additional psychological stress for the users. This is due to the uncertainty concerning the results of the solution and devices. More to it, this stress is expected to appear prior to purchase since there is no physical basis. Consequently, this situation forces companies to implement strong technology-based visiual presentations to connect both, the medical expert customer and their patient, via an user-friendly front-end. This customer centric solution space design should optimally present easy-in-use product templates for customization. Thus, front-end applications are the inter-linkage to the whole supply chain. This front-end could, for example, be a cloud-based collaboration platform for co-designers which allows new innovative business models to focus on flexible supply chains for the design and production of electronics as well as flexible parts - realised through modular services. Overall it can be stated that the above discussed customer integration has to be well designed and implemented in order to avoid that the orders from the front-end are impossible to manufacture (e.g. due to flaws in the fixed solution space in the backstream) [3]. Therefore, strong visualization and rich illustrations are crucial to reduce perceived risk and uncertainty [4]. Instant product visualization in 2D, 3D or 4D after configuration as well as the visualization of functionalities such as rotation, zoom, and other details, integrate the customer and their patients into the design task (Figure 1.). Moreover, it allows for more process enjoyment as well as higher certainty of product outcomes and thus, fosters the usage of web-based mass customization tools. Personalization is the process of screening and selecting objects based on individual-level information [5] which are therefore even more suitable fit a single patient's situation.

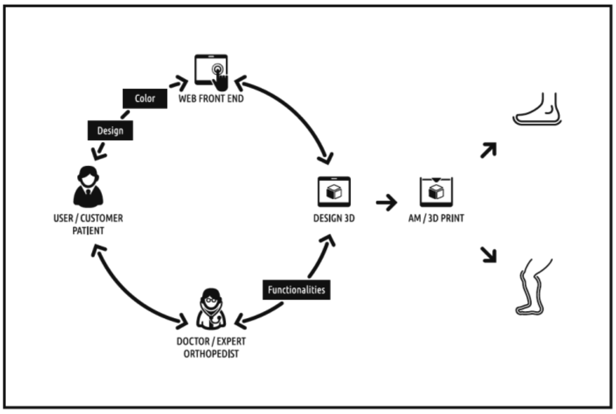

Figure 1. Product visualization

Hence, medical customers should create their individual user profile that reflects their preference information. Furthermore, profiling and archiving data makes even more sense in order to track patients' courses of disease. A good example is the use of a virtual gaitway analysis which has a direct influence on the front-end design and which can be integrated into the process of a new business model. A gait analysis of a stroke patient, for instance, which includes information on the current situation of a patient, can give direct input on how to design and how functionality changes have to be made from preceding solutions.

The following describes the process of how a personalized spasticity splint can be captured, designed and printed. In the first step, the data-base comprises CT, MRT or 3D-scan input-data of the corporal area that has to be treated - e.g. of an leg. This data is then remodeled or reconstructed by a medical expert in a web-space solution or via the help of 3D-operators. In the future, a computer will then assess the optimal pattern and structure for the splint. The 3D-model of a functional lower limb orthosis is designed to enhance the movements of an individual patient with neuromuscular disabilities. The device shows customized pattern jackets for legs that are 3D printed in durable ABS or multicomponent plastic to get strong as well as flexible parts. With time patient data can be re-captured via CT, MRT or 3D-scanning which helps to tracke the course of disease and to adapt solutions to new patients' situations. In every situation the medical expert, the therapist or physician can analyse how the solution is effecting the gait of a patient after stroke. Specifically, scientific precision can, in this context, be assued via other connected visualization technologies such as gait analysis tools.

In cases where a product is regularly manufactured, it cannot be adapted to changing customers' or patients' requirements in the usage phase. This is especially a problem if the course of a disease changes or even worse, if the disease is totally unstable over time. Likewise, it is a problem if the users' preferences are poorly defined. An example of such a situation includes a spasticity which requires modification in the therapeutical positioning via a personalized splint [6][7]. Put differently, the above discussion highlights that customers' wants or patients' needs at the time of purchase do not always match with what they require when they use their personalised product [8]. Furthermore, new medical solutions or devices often require radical adjustments when it comes to the first useage or in the patient corporal structure [9]. To mitigate the risk of non-matching requirements, experts recommend to implement embedded open toolkits for co-design steps which allow the customer or the patient to customize the solution or device according to his/her individual requirements in real time - even after it has been manufactured [10]. Such multi-functionalities and product adaptabilities via additional embedded toolkits qualify offerings as 'smart products' [11]. A good example for this is a personalized 3D printed cast to cover a fraction of an arm which is equipped with an ultrasound device to speed up bone healing [12]. Specifically, a low-intensity pulsed ultrasound device determines how much waves are giving to the patient and also in which intensity on a daily treatment basis. This reduces optimaly the healing time. Furthermore, removable silicon pads can be adjusted, removed or replaced via variants during fitting and therapy.

To introduce 3D printing technologies and thus, the possibility of mass customization in the MedTech market, customers like orthopaedists and other experts should firstly interact with company representatives in order to find out more about the technology and product offerings [13]. Other options for the MedTech sector concern knowledge-based systems. These link, interactively, customers to the supply chain, make proposals by matching similarities between customers' requirements, and may even suggest other recommendations. The latter especially refers to knowledge about specific customers' preferences for special product characteristics and complex needs. They can be categorised within a knowledge-based frame [14]. Overall, such recommendations represent value-adding services and foster higher sales revenues [15]. Moreover, recommender systems ease not only the customer-facing interactions and link customer inputs into backstreamed (back-end) product output specifications, but also allows configurations (following a product logic) which generate the required variants within the solution space (front-end) [16].

An online/web bases fosters collaboritve co-designs [17]. In the context of the medical area, this is particularly suitable to bring together co-design communitys of experts and 3D-operators. Especially the latter mentioned 3D-operators are essential because they translate the expert customers' functional and design requirements into 3D data dimensions and further into 3D-printable virtual objects. The online platform as such needs to grant that experts can perform the co-design task, give feedback, and inspire others throughout the process. Additionally, it could integrate other experts (e.g. people who have already made co-designing and ordering experience of a personlised product from a specific supplier) and facilitate communication with them. Several investigations show that peer group inputs of experts provide positive impulses for the evaluation of new developments and new design ideas. Thus, it leads to further problem solving possibilities which are important for complex MedTech solutions and highly valued by further medical experts [18][19]. The expert customers' co-designs and the integration of medical experts as well as their patients are key to mass customization in this market segment [20][21][22]. This can be achieved with the help of today's information technologies which enable customers to interact and become a critical element of the value creation chain - e.g. by defining, configuring and modifying the functionalities and designs of an individual product order. Customer co-design foster the establishment of personalized contacts between the manufacturers and the expert customers. This, in turn, opens opportunities to build sustainable relationships. Once the customer is satisfied with a personlised order, it increases the chance for repeated orders; also because they become more simplified [23]. An orthopaedist, for example, often faces similar stroke patient situations in arms and legs. Once the medical expert has saved previous orders and knows the combination of preferences for a new patient situation, the orthopaedist can order customer solutions at ease. Likewise, the seller gets rewarded based on the collected preference data.

On one hand, co-design activities are the basic requirement of mass customization. On the other hand, they are complex due to multiple (possible) combinations which require high efforts. Moreover, it is perceived as risky from the customers' perspective since it comes with uncertainty concerning the final visual and functional result. All of the previously discussed issues are burdens for the establishment of mass customization strategies. Specifically, the related confusion and the customers' mixed experiences of mass customization interactions [24] support the argument that customer co-design is not only a prerequisite, but also a major success factor of the implementation of mass customization technologies and offerings in the complex medical business area [24]. Co-design is also challenging because customers and manufacturers have differing information which needs to be reconciled for effective customization processes. The MedTech area is particulalrly suitable for such customer-centered co-design because the expert applier makes customization decisions by nature. At the beginning, manufacturers should allocate more efforts on explaining the technology to the co-design partners so that the latter effectively learn about the high amounts of options - i.e. the customers' choices. Simultaneously, the partners can stress the customers and their requirements since customers usually not have the knowledge on such products [25].

4. VALUE CREATION VIA THE USAGE OF 3D PRINTING IN MEDTECH-BASED MASS CUSTOMIZATION

A company might be regarded as market-oriented if it focuses highly on the profitable and permanent creation of superior customer value while also taking into account the interests of other key stakeholders [26]. Therefore, customer value and shareholder value are obviously coherent [27].

3D printing in the MedTech-based mass customization technology environment enables companies to create a cost efficient value chain and simultaneously to increase flexibility to respond to medical customers needs' and heterogeneous patients' demands. Against the background of the new concept of manufactural value creation, it is not surprising that companies which listen to their consumers [28] and take care of delivering high quality services [29] building long-term relationships with the existing client base [30]. Likewise, they should focus on acquiring new customers, too. Mass customization is a mean which leads to the fact that customers become partners of companies, who influence the value creation process to a certain degree [31]. To ensure that 3D printing is suitable for MedTech-based mass customization, it has to work in many areas which are related to mass production efficiencies. Therefore, companiess in the MedTech market have to find the optimal balance between the additionally created customer value and the necessary investments which are required to establish customization on a mass scale [3]. Personalization of medical solutions provides the potential to charge consumers higher premiums from incremental utilities. The added value due to the enhanced product characteristics and functions is highly likely to accurately meet the customers' and patients' needs [31]. Better fitting personalized products exceed existing alternatives - e.g. best standard products - for example, with respect to the repeal of their side effects. Because of this added value, it is not only health insurance funds which are more likely to pay for the more expensive customized product over the mass-produced generic alternatives, but private patients are expected to be more willing to accept the higher prices, too [32]. 3D printing in MedTech results in various mass customization opportunities. Especially the fact that the same amount of consumers can be served than in the traditional mass markets, makes it remunerative. Certain fields such as orthopaedics, dentistry, corrective lenses, and cardiovascular are more suitable to adopt these new technological advances. That is particualrly becuase they are able to maintain the ability to treat the custumer and patient nearly as individually as in the traditional and currently still state-of-the-art craft production [33]. Beyond state-of-the-art MedTech, mass customized solutions and devices increase, due to their fullfilment of personal needs as well as experts' and their patients' requirements, the level of product inimitability, especially compared to mass-produced . This co-creation does hand in hand with a value adding effect, which rests on the fact that ojective price comparisons are limited and thus, decrease pricing erosions [34]. However, the implementation of 3D printing technologies is likely to increase production costs. Yet, this does not seem to be a critical issues since customers in the MedTech sector are fairly willing to pay premium prices for personalized solutions. Moreover, there are three additional strategic approaches which help to counterbalance the trade-off for companies [31]:

- Companies achieve a competitive advantage due to improved value chain optimization such as more stable processes, planning and control systems, refined IT-systems, enhanced order tracking and better interacting customer-facing technologies [35].
- A price increase of personalized solutions or devices.
- The concept of “economies of integration” [36] grants cost saving potentials by using precise information provided by MedTech expert customizer and their patients. Based upon this, individual behavior needs and wants can be identified. Moreover, it allows to postpone unnecessary activities. Likewise, this direct interaction can also boost consumer loyalty [37] [36][38] and thus create value for the firm [31].

Mass customization delivers high value added products. This is especially the case for knowledge-intensive products such as in the MedTech area where experts give high value inputs for product development and design. The creation supported by medical experts and the inputs of patients represent high valuable information [31]. However, the value generation based on this information depends on the companies' ability to receive information on experts' costumers and the patient as well as their communicated needs. Furthermore, the respective company should spread such information along its value chain in order to translate it into personalised medical solutions and devices, and thus, to add superior value. The success of mass customization in the MedTech area ultimately depends on the ability to provide superior customer value through customization on a mass scale [3]. Especially first mover market entries in MedTech mass customization using 3D printing technologies allows companies to differentiate their offering from their competitors. Hence, they offer long-term potentials to boost corporate image towards a customer driven and innovative reputation [37].

5. ECONOMIES OF MASS CUSTOMIZATION VIA THE USAGE OF 3D PRINTING IN MEDTECH BUSINESS AREAS

The following chapter points out that mass customization and the already described customer integration result in new cost and profit structures which are also known under the term “economies of mass customization” [39][31].

In the MedTech technology it is crucial for a company to produce and deliver personlized products within a predetermined time frame and thus, without burdening a customer with long delivery times of mass-customized products [40]. Medical customers should be regarded as an integrated function of a technologised mass customization process especially because they do it today already. This fosters the reduction of cycle times while still developing, producing and delivering optimal personalised medical solutions [41]. 3D printing technologies enable medical experts of various MedTech fields to deliver not only faster but also the demanded functionalities and designs for their patients.

3D printing technologies offer several benefits for medical consumer like experts and their patients.

Patient benefits:

- Diagnosis & therapy choice – relying on digital diagnostic imaging methods in conjunction with 3D printing allows creating models which can be used to help physicians diagnose disease.
- Customized medical devices – the ability to custom-tailor patient-specific medical devices is highly likely to further expand in the future. This may include more customized solutions in dentistry, corrective lenses and orthopedics.
- Entirely new solutions – 3D printing provides entirely new features for patients, such as reproduction of personalized spasticity splints.

Manufacturer benefits:

- Low volume, High value – often medical devices productions are relatively low in term of volume, whereas sales value is high. Moreover, medical devices are mostly small but characterized by high design complexities. Thus, it is fairly suitable for small-scale 3D printing manufacturing.
- Stock reduction – just-in-time production by usage of 3D printing technology.
- Reduce waste – as 3D printing is precise and thus, saves materials.
- Other savings – 3D printing enables productions in a single step. Thus, it eliminates tooling and labor costs.
- Design complexity – 3D printing enables design flexibility as well as new features and functionalities. As such, it is able to produce products with a higher level of complexity than alternative (state-of-the-art) often-manual methods at ease. Furthermore, 3D printing can use advanced materials and hence, improve structures.
- New growth opportunities – 3D printing offers new growth opportunities for manufacturers as well as medical experts such as orthopedists because it can produce personalized solutions in a relatively short time.

3D printing in the MedTech industry is still in its infancy. Yet, its ability to offer more personalized patient solutions is cutting edge and can even be regarded as a disruptive technology which offers opportunities for others, too. Turning the focus to the benefits of 3D printing, it is interesting to initially point out how 3D printing can, potentially, impact the MedTech sector. Specifically, it is foreseeable that 3D printing provides two major benefits for the orthopaedic industry:

- Inventory management – being able to manufacture a customized spasticity splint on demand at short notice should allow MedTech companies' to lower its high inventory levels and release cash to shareholders. While acknowledging that customized cutting block solutions of visionaries (also 3D printed) have the potential to offer similar benefits, its impact on inventory appears so far rather immaterial.
- Cost reductions – an analysis produced by Arcam [1] compares the costing data of reconstructive implants productions. Specifically, they analyze the cost savings of producing an ace tabular cup via 3D metal printing instead of the traditional method using of cast metal and forging using CNC machines. The findings indicate that the cost saving of using 3D printing technology is between 60% and 70% of the original material which is scrapped. Furthermore, they save manual labor hours and time in many other production areas.
- Ortho COGS share – Based on the authors' market experience, it is assumed that orthopedics make about 50% of COGS in the industry.
- Ortho COGS reduction – A Morgan Stanley study states that companies' orthopedic reconstructive COGS can be reduced by approximately 25% by using 3D printing technology [1].

The discussion on economies of mass customization via the use of 3D printing technologies in the MedTech industry starts by questionning whether entire business segments which traditionally rely on mass production will be replaced by mass customization. Pine [41] hypothesizes that mass customization is likely to completely replace any other kind of value chain setups. For years, mass customization has not been able to establish itself for a wide range of customized offerings. That is because it is often argued to be too complex and cost intensive. Today, however, we are in a new age in which customers' rising expectations for personalisation can be met by three mayor trends. Firstly, there are state-of-the-art supply chain technologies which enable more efficient productions. Specifically, they allow a smooth connection between the customers' co-design inputs and the sustainable production fulfillments. Secondly, customer-oriented technologies are much cheaper and simpler to deploy than ever before; and in the future, customer- and patient-oriented technologies will be even more groundbreaking. In detail, customers and patients will be enabled to design their personalised product in an open and ulimited way. Thirdly, developed devices like the future Xbox Kinect will allow capturing exact body measures and gestural characteristics. As such, they can be used for new experiences in product configuration which are likely to be web-based dependent so that customers, patients and designer can interact no matter where they are situated [42].

KETs as 3D printing technologies are radically changing the standards of producing custom products [43]. 3D printing allows the fabrication of objects directly from a 3D model data set that is usually building up layer upon layer. Traditional subtractive manufacturing methods, contrarily, are cutting, drilling, and bending materials [44]. Thus, they waste materials. Alternatively, 3D printing allows - in a rich and plentiful way - customizing and makes economies of scale out-of-date. In term of production this means that reproduction to recover costs is obsolete since nearly any form can be printed from almost any material without high retooling efforts and thus, costs. Another main advantage of 3D printing is that it substantially decreases the time from design to productions [45]. Specifically, a long-term study on this matter shows that investments in flexible automation technologies - such as 3D printing - relate positively to performance enhancements. In detail, the investments are discovered to have an impact on higher sales growth, earnings and market shares already two years after the respective investments. Thus, the study's results indicate that organizations need to firstly adapt to new production concept and the related improvements before being able to take advantages [46].

6. CONCLUSION

Economies of mass customization for the MedTech industry represent an important area of research. Firstly, it is facile to calculatory give back the difference between backstreamed traditional production methods and 3D printing. However, is it more interesting to empirically evaluate (on a quantitative base) the impact of 3D printing on the whole mass customization processes. Moreover, the success and performance factors have to measure the different outcomes of mass customization systems. Currently, it is difficult for executives to decide on the economical benefit of the 3D printing usage in the MedTech industry because the total value chain is unclear. New technologies, which result from the introduction of 3D printing, do not only cause production costs [47] but also create value in various way - most commonly via designing and additional costs resulting from different and new degrees of customer-supplier interaction which are all not yet covered by actual reporting and accounting systems. Value based management-oriented systems like the balanced score card [48] provide a starting point to capture the economies of mass customization of this innovative MedTech segment. Most uncertain and difficult is, however, the value calculation of the customer relationship. That is, in particular, because the use of mass customization is most likely to increase if the customers' expected returns exceed the expected costs [49]. Drawbacks and stress factors of the integration of medical experts into the value creation during the configuration process (as discussed earlier) include, among others, risk, information overload, time and required efforts. Rewards for the medical customers and their patients relate to the design process and incorporate, for example, flow experience which in turn facilitate future customizations or satisfaction with the fulfillment of a co-design task. Another benefit concerns the value of customization. Specifically, it means that current customers can refer to former customers' experience and thus, are likely to get access to new functionalities and design possibilities which are better than the best achievable standard product [50].

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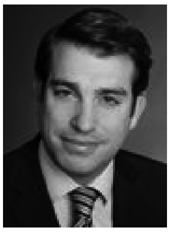

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