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Additive manufacturing for standard parts in the healthcare supply chain: What are the available performance improvements?

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ABSTRACT

Additive Manufacturing (AM) has established itself as a manufacturing technology for customised and personalised parts in healthcare applications. More recently its use in healthcare applications has been extended to also include standard parts, albeit to a limited degree. In our case study of small and medium-sized manufacturers of medical devices, we investigate how extending the scope of AM from customised parts to standard parts brings opportunities for additional operational improvements. These additional improvements build on the benefits of using AM for customisation, constituting an opportunity for cumulative performance improvements. Identifying the specific operational mechanisms of performance change through the use of AM in healthcare applications, our cross-case analysis identifies the available cumulative improvements based on widening the scope of AM from customised to standard parts. The contribution to research is the identification of a sequence of improvements available through wide-scope AM: the simplification of flow through kitting-based solutions and cost reduction through capacity sharing, affecting multiple performance dimensions.

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1. Introduction

The switch-over from tool-based to direct digital production technology is constrained by trade-offs along specific performance dimensions, such as quality, delivery, cost, and flexibility (e.g. Khajavi, Partanen, and Holmström 2014). However, sometimes a change of production technology enables further operational changes, making a sequence of cumulative improvements available (Hallgren, Olhager, and Schroeder 2011; Wurzer and Reiner 2018). In this study, we examine in the operations of eight medical device manufacturers how extending the use of Additive Manufacturing (AM) beyond customised products to standard parts makes available cumulative product and supply chain innovations and performance improvements.

The distinguishing feature of AM is flexibility, ena bling design customisation. Several authors (Durach, Kurpjuweit, and Wagner 2017; Holmström et al. 2010; Khajavi, Partanen, and Holmström 2014; Tuck and Hague 2006; Walter, Holmström, and Yrjölä 2004) have argued that AM has a disruptive effect on conventional supply chains as its introduction enables additional improvements, such as shorter supply chain and simplified operational processes. According to these researchers, AM, as a driver of digital supply chain transformation can deliver any digitalised product on-demand and on-site, without the highly specialised tooling, processes, and inventories required by traditional manufacturing for each new product.

The low cost for design modifications drives the application of AM for customised parts, with conventional manufacturing remaining the preferred solution for standard parts due to lower unit costs in production (cf. Tuck and Hague 2006). However, more recently spare parts (cf. Heinen and Hoberg 2019; Khajavi, Partanen, and Holmström 2014) and bridge manufacturing (cf. Khajavi et al. 2015) have emerged as AM application areas for standard parts. This widening of scope is based on seeking available improvements along the strategic performance dimensions of cost, delivery, and flexibility enabled by the manufacture of both customised and standard parts directly from digital models (Lyly-Yrjänäinen et al. 2016), and conceptualised as a new mode of operations – build-to-model manufacturing (Hedenstierna et al. 2019; Holmström, Liotta, and Chaudhuri 2017).

In this paper, we examine the operational reasons why standard parts should, and should not, be produced using AM in the operations of eight medical device

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manufacturers. Based on this examination we theorise how wide-scope AM creates opportunities for product and supply chain innovation in healthcare. By standard parts we refer to those parts with a fixed or non-changing digital design that can be tested and improved – the opposite of customised (changing design), tailored, bespoke.

We focus on the healthcare sector and medical device manufacturers and examine in a multi-case study of eight companies that already use AM for customised parts what are the drivers and constraints for widening AM's scope, presenting an empirically grounded opportunity assessment for further academic research and practical implementation of wide-scope AM. We address the question how the available benefits of AM can be realised in the form of cumulative operational improvements and discuss how extending the scope of AM from customised parts to standard parts changes the cost–flexibility trade-off. We contribute by identifying how operational practices based on wide-scope AM change performance trade-offs into cumulative performance improvements.

2. Literature review

The literature review begins with AM in healthcare, and identifies healthcare as an application area on the leading edge. We then proceed to examining the scope of AM production and the operational reasons for widening the scope for customised parts to standard parts. The literature review concludes with identifying a gap in current understanding.

2.1. Additive manufacturing in healthcare

Applications of the technology in the healthcare sector can be classified into five major areas: (i) medical models, (ii) surgical implants, (iii) surgical guides, (iv) external aids, and (v) bio-manufacturing (Tuomi et al. 2014). Recent advancements can be found in pharmaceuticals where AM can be used for the delivery and production of individualised dosing and personalised treatments (Içten et al. 2017), printed scaffolds that delivered a uniform microstructure and further validated the process (Zhong et al. 2017), prosthetic devises for wounded warriors (Liacouras et al. 2017), and pre-operative planning and surgical simulation with the possibility to produce different parts of the human anatomy with high accuracy in short periods (Yap et al. 2017).

There are several advantages that AM can bring into the healthcare sector when compared with conventional manufacturing methods. The technology can reduce surgery time and cost, reduce the risk of post-operative complications, reduce lead-time, reduce repair cost, and improve process flexibility (Javaid and Haleem 2018). Conversely, Ghomi et al. (2021) highlight that still challenges remain to address inadequate mechanical properties in AM, scaling up of the AM products for mass production, and developing smart printable biomaterials. Moreover, vascularisation in AM bioprinting demands innovations.

It is evident from the aforementioned considerations that healthcare providers are constantly seeking opportunities to reduce costs while at the same time maintain the quality of patient care. However, operational improvements are required to implement the aforementioned prospects. Applications of AM in healthcare supply chains can assist healthcare providers to decrease their inventory levels by manufacturing on demand and hence save on inventory costs (Verboeket et al. 2021).

2.2. Impact of widening the scope of AM on supply chain performance

Next, we examine the available benefits of AM in supply chains and the motivations for widening the scope of AM to also include standard parts. The research gap addressed in this study is then summarised in detail in the following section.

Most studies examine the impact of AM on supply chain performance, supply chain innovation, and supply chain design aspects. Kunovjanek, Knofius, and Reiner (2022) examine the adoption of AM in supply chains based on the supply chain operations reference (SCOR) framework and find strong evidence on design aspects. Naghshineh (2024) considers how different features and barriers of AM technology adoption affect supply chain agility (SCA) dimensions and macro-level SCOR processes. Oberg (2022) indicates how disruption occurs at multiple positions in the supply chain and provides important insights on how AM changes or will change the circumstances for firms positioned along a supply chain. Peron et al. (2022) indicate that when AM is adopted as an emergency solution to support supply chain resilience, it can deliver benefits in terms of service level and lead time, as exemplified by Salmi et al. (2020) for the fast response to increased demand for personal protection equipment at the onset of the COVID-19 pandemic. Naghshineh and Carvalho (2022) suggest that although AM could improve supply chain resilience by enhancing supply chain capabilities, it can also cause certain supply chain vulnerabilities. Ivanov, Dolgui, and Sokolov (2019) through a conceptual framework examine the relationship between digitalisation and AM and how the technology can mitigate risks in the supply chain. Rodríguez-Espíndola et al. (2020) look at applications of emergent

technologies and AM in humanitarian supply chains and propose a framework to address available improvements in relation to the flow of information, products, and financial resources. Ahmed, Heese, and Kay (2023) suggest that when AM is employed for some demand points for part shortages or as a primary dedicated source, it can result in reductions in back orders, inventory holding, and transportation costs. Kunovjanek and Reiner (2020), through a dynamic evaluation model, investigate the availability of AM to alter established manufacturing and supply chains. Strong et al. (2019) propose a hybrid-AM supply chain that integrates AM with traditional manufacturing post-processing to assist Small and Medium-sized Enterprises (SME). Durach, Kurpjuweit, and Wagner (2017) conclude that decentralised manufacturing and the rise of AM printing services are associated with a strong potential to come true. Friedrich, Lange, and Elbert (2022) examine the make-or-buy decision of manufacturing firms to implement industrial AM in their supply chains and conclude that in-house manufacturing is more likely to remain the preferred choice of manufacturing firms due to intellectual property issues, re-evaluation of their core competencies, and commitment to internal learning. Delic, Eyers, and Mikulic (2019) examine the relationships among different dimensions of supply chain integration, supply chain performance, and firm performance from the perspective of AM adoption and conclude that AM adoption positively influences supply chain performance and, as a consequence, firm performance. Luomaranta and Martinsuo (2020) conclude that innovations in business processes, technology, and structure as well as supportive changes in the business environment are all required to enable fully leveraging AM at the supply chain level.

A number of studies examine the impact of AM on spare part supply chains. This is a particularly important issue since spare parts are known, because of their scope for obsolescence, to be a major source of concern with regards to environmental sustainability.

Demiralay et al. (2023) develop a decision support system (DSS) that covered transportation and production phases to determine the most environmentally friendly AM spare part production strategy. Cantini et al. (2024) develop a DSS for spare parts to assist companies with centralised or decentralised inventory management when AM is employed. Sgarbossa et al. (2021) examine when AM should be employed for spare parts inventory management over traditional manufacturing methods. Heinen and Hoberg (2019), by taking a holistic view of the entire spare parts portfolio, identified the possibility of a systematic shift in spare parts manufacturing from conventional manufacturing processes to AM. Sirichakwal and Conner (2016) examine how AM affects the management of spare parts inventories and develop a model to analyse how inventory-related benefits can be derived from reductions in holding cost and production lead time.

Other studies look at the application of AM as a manufacturing technology over conventional manufacturing methods and address challenges in terms of optimisation and management.

Dohale et al. (2024) evaluate suitable manufacturing systems for organisations – traditional or AM – based on different process choice criteria to further assist researchers and practitioners to choose one over the other. Top et al. (2023) investigate the benefits of AM for sustainable production processes and redesigned products. Jarrar et al. (2023) propose a knowledge-based framework to assist information management and critical decisions along the AM product realisation. Zhang, Yao, and Li (2020) develop an improved evolutionary algorithm for application to AM to address AM scheduling-related issues. De Antón et al. (2022) offer a framework to formalise the production planning problem in AM at the operational level. Lolli et al. (2022) develop a DSS to address implementation issues of preventive maintenance policy that includes either AM or conventional manufacturing (CM) parts. Gardan (2016) in his study took a global overview to examine new trends through the review of different AM technologies.

Table 1 summarises all the aforementioned studies in relation to their main focus.

AM and other direct digital manufacturing are limited in current applications of the technology to customised products and small-scale production of spare parts. Fully achieving the proposed benefits for AM in the supply chain indicates a need to extend the scope to also include production of standard parts.

2.3. Operational practices available through widening the scope of AM

The characteristic of AM that has been emphasised as a mechanism for changing operational practices is direct digital manufacturing (DDM) (cf. Holmström et al. 2019). DDM enables innovative operational practices in product design, distribution, use, and after-sales services, presenting opportunities to improve the performance of both products and processes (Holmström, Liotta, and Chaudhuri 2017). DDM can be incorporated in current practices for prototyping, tooling, on-demand parts manufacturing, and customised parts manufacturing. However, it can also be used as the basis for novel practices for incremental product improvement (Friesike et al. 2019), and for collaborative delivery processes improvement (Hedenstierna et al. 2019). Furthermore, the available impact of product and delivery process improvement is

Table 1. Studies on impact of AM on supply chain – optimisation and management of AM.

AM in supply chains	References
Supply chain performance, supply chain innovation, supply chain design aspects, supply chain resilience	Kunovjanek, Knofius, and Reiner (2022), Naghshineh (2024), Oberg (2022), Peron et al. (2022), Naghshineh and Carvalho (2022), Ivanov, Dolgui, and Sokolov (2019), Rodríguez-Espíndola et al. (2020), Ahmed, Heese, and Kay (2023), Kunovjanek and Reiner (2020), Durach, Kurpjuweit, and Wagner (2017), Friedrich, Lange, and Elbert (2022), Delic, Eyers, and Mikulic (2019), Luomaranta and Martinsuo (2020)
Performance of spare parts supply chain	Demiralay et al. (2023), Cantini et al. (2024), Sgarbossa et al. (2021), Heinen and Hoberg (2019), Sirichakwal and Conner (2016)
Optimisation and Management of application of AM	Dohale et al. (2024), Top et al. (2023), Jarrar et al. (2023), Zhang, Yao, and Li (2020), De Antón et al. (2022), Lolli et al. (2022), Julien Gardan (2016)

amplified when complete assemblies and products can be produced using DDM.

A breakthrough operational practice, direct digital kitting (Lyly-Yrjäninen et al. 2016; Stark et al. 2023), combines DDM with product-centric control in the preparation of customised assembly kits. Direct digital kitting reduces handling costs and improves response time and flexibility in planning by replacing batching with directly manufactured kits. Experimental research suggests that direct digital kitting can be introduced in an operation with many AM machines to control post-processing activities, eliminating batching, the handling of batches, and inventory management (Khajavi et al. 2018). Operations can further leverage digital encapsulation for the integration of product design information with additional information on how that design is to be translated into a physical object, delivered to the customer, and used (Holmström et al. 2019).

The systematic use of DDM and digital encapsulation provides the basis for build-to-model manufacturing, as a novel mode of manufacturing. Alongside the familiar to-order production modes, build-to-model manufacturing provides a justification for more wide-scope AM (Hedenstierna et al. 2019). By taking advantage of the AM technology, build-to-model manufacturing can delay the choice of manufacturer and the location of production until close to the customer delivery date. Digital encapsulation of control and processing information, and the use of general purpose AM technology, eliminates the need for set-up and prior development of product-specific delivery capabilities with suppliers, as manufacturing is based wholly on the information provided by the digitally encapsulated model. The build-to-model mode of manufacturing enables flexible outsourcing arrangements, where peak demand is outsourced, and slack capacity is offered to other firms (Hedenstierna et al. 2019).

Baumers and Holweg (2019) suggest that in AM there is an important relationship between capacity utilisation and throughput. Their findings in relation to capacity utilisation suggest that the unit cost reduces as the pre-committed build space is filled with parts. These parts can be both alike and different, as the unit cost decreases with each additional part that is committed to the available build space. Thus, the total unit cost in AM is inversely related to production quantity, up to the point where the build volume capacity is fully utilised.

2.4. Cumulative performance improvement and trade-offs: drivers and constraints for wide-scope AM

The effect of introducing AM operationally can differ in distinct ways, depending on whether AM is introduced on its own or in combination with other practices. A hybrid model of manufacturing performance (Wurzer and Reiner 2018) recognises the possibility of both cumulative improvements and trade-offs. Trade-off theory (Skinner 1969) argues that operational change fundamentally constitutes a trade-off, such that introducing AM improves flexibility, but increases costs. However, if introducing AM enables the introduction of further new practices, the effects can be cumulative (Ferdows and De Meyer 1990; Hallgren, Olhager, and Schroeder 2011). An example of a cumulative effect avoiding the trade-off is the introduction of AM for customised parts that improves flexibility, followed by the addition of kitting that also improves cost efficiency and delivery.

While it is clear that AM is particularly effective for producing customised parts, and the healthcare sector is at the leading edge for using the technology for this purpose, conventional manufacturing has been seen as more competitive for standard parts due to the higher manufacturing cost of AM. However, as our literature review indicates there are available advantages for widening the scope of AM also for producing standard parts. Current literature lacks in understanding of how different AM-related practices drive or constrain the widening of the scope. What are the available improvements building on the extension of AM to standard parts, and what are the constraints to the extension?

3. Methodology

Our research seeks to assess the available improvements based on wide-scope AM in the healthcare supply chain. As wide-scope AM supply chains do not exist yet, but

developments in AM for customised parts are ongoing, the time is right for research exploring available opportunities and identifying promising new research directions. For this purpose, we look at the relevant operational drivers and constraints in the current operations of eight medical device manufacturing units using AM for customised products. Our access to these leading-edge operational settings allows us to develop our understanding of the drivers and obstacles empirically.

3.1. Preliminaries

We employ a multiple case-based methodology, combined with existing theory on widening the scope of AM in healthcare supply chains to collect data and develop propositions that are useful for the participating organisations (Voss, Tsikriktsis, and Frohlich 2002; Yin 2014). We do not work towards generalisability, although the number of cases considered does enable us to extend our discussions beyond these organisations. We return to this issue in the last section of the paper.

Our research within the context of healthcare supply chains examines the supply chain of medical device manufacturers and the operational drivers and constrains for widening the scope of AM to also produce standard parts. Within a typical healthcare supply chain for medical device manufacturers, the organisation procures the material and equipment from suppliers and then, based on the data received form healthcare centres or the patients' consultants, produces a customised medical device to fit the needs of individuals. Thus, a typical healthcare supply chain for medical device manufacturers consists of suppliers, medical device manufacturers, and healthcare centres. For our research and within the context of healthcare supply chains, healthcare centres will be the customers for all the products produced by medical device manufacturers. Our research does not examine the operational drivers and constrains for the end user and individuals who are in need of treatment.

For this purpose, a pilot case study facilitated the collection of initial data which, upon analysis and in conjunction with the theoretical backdrop in this area, led to the development of the research instrument. The pilot case study was conducted at a U.K. manufacturer of orthopaedic medical devices that has employed AM methods and specialises in the fabrication of custom-made and small range of standard parts for foot orthoses. It was found that extending digital design to DDM also for standard parts using the same digitalised design methods and tools as for customs could further validate the process for a wide-scope of AM.

The pilot case results, coupled with contributions from the existing theory and DDM, were used as a guidance to provide focus on the relevant operational drivers and constraints identified for wide-scope AM and inform the choice of selected case studies. As it can be seen from the sample (3.2), all selected case studies relate to medical devices as the selected cases have moved towards producing a small range of standard parts. Therefore, our research does not examine other parts of the healthcare supply chain such as drugs as currently the evidence is not present to support a movement towards standard parts.

Semi-structured interviews were used to collect primary data from eight medical device manufacturers, which, upon analysis and triangulation, leads to the development of an empirically grounded assessment of the opportunity for wide-scope AM.

3.2. Sampling

We look for applications of the technology for standard AM parts in the healthcare sector and medical devices. Within this sector, and as it can be seen from the examined sample, there are available applications of the technology not only for customised but also for standard AM products.

The sample consists of eight medical device manufacturers the names of which cannot be disclosed (Figure 1). Their main characteristics are as follows: (a) they are all based in U.K., although they are geographically dispersed within the country; (b) they are all small –medium-sized enterprises (SMEs); (c) they all produce a small range of standard AM parts; and (e) they all have similar healthcare supply chains in terms of main parties involved as it was previously noted (3.1).

The companies were recruited and information was collected over a $3\frac{1}{2}$ year period.

3.3. Unit of analysis

The initial research questions provide guidance for selecting the appropriate unit (Yin 2014). The central research question of this study is the following: 'Why use AM for standard parts?' For this purpose, the unit of analysis for this study was based on products and parts of the case companies (Table 2). The interview process covered themes on operations management, supply chain, procurement, and logistics. The interviews were recorded and transcribed and, when required, follow-up discussions were conducted to further explore specific issues. Prior to the interviews, background research on the organisations took place to enhance the quality of the interview process. Summary information on the case companies and the interviewees is presented in Table 2.

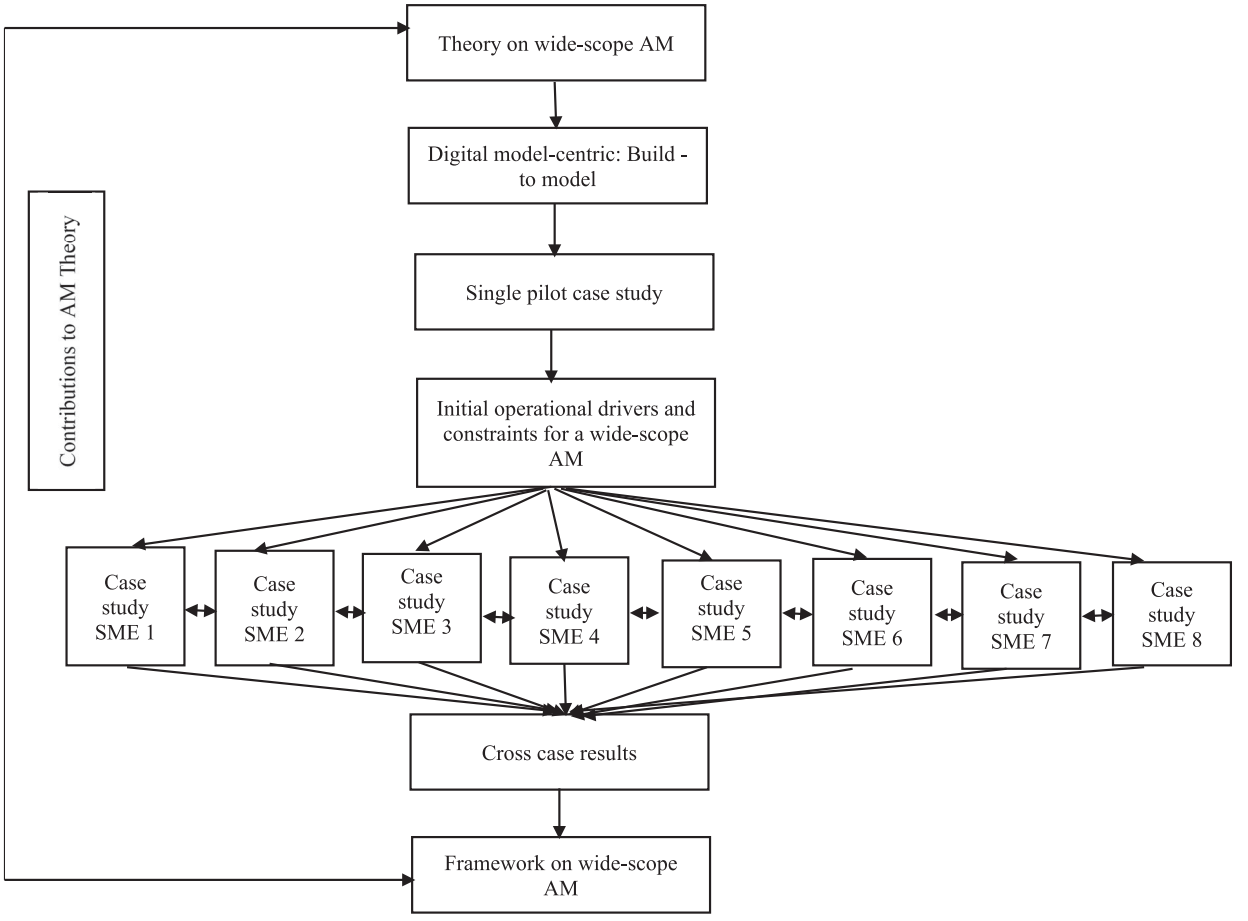

Figure 1. Research methodology employed.

Table 2. Information on case companies.

Company	Products	Informants/ position
Company A	AM standards and customised insoles	AM Operations Manager, Company Director
Company B	AM standards and customised insoles	AM Operations Manager, AM Process Engineer
Company C	AM standards and customised wheelchair parts	Company Director, AM Process Engineer
Company D	AM standards and customised dental products – crowns, implant bridges	AM Technical Director, AM Production Engineer
Company E	AM standards and customised dental products – crowns, implant bridges	AM Operations Manager, AM Process Engineer
Company F	AM standards and customised hearing aids	AM Technical Director, AM Operations Manager
Company G	AM standards and customised joint replacement, repair, and reconstruction	Company Director, AM Production Engineer
Company H	AM standards and customised joint replacement, repair, and reconstruction	AM Production Manager, AM Operations Manager

3.4. Data sources

To enhance 'data triangulation' (Eisenhardt 2007) and increase validity, a number of supplementary data collection processes were employed that revolved around the review of pertinent documents and direct observations by the researchers. The following documents were reviewed, where available: purchasing of the AM machines and materials, production performance measures – inventory reports, and service levels reports related to the various hospitals those companies serve. To ensure verification of the information collected through interviews and relevant documents, a visit took place to all AM facilities to obtain further physical evidence and information and relate that back to the collected data.

3.5. Data analysis

The analysis of the data collected was carried out on two levels: (a) within-case, and (b) cross -cases.

Within-case analysis took place immediately following each case study. The pilot case results, coupled with contributions from the existing theory, were used as a guidance to provide focus on the relevant operational drivers and constraints identified for wide-scope AM. The purpose was to proceed to the next case study with enhanced knowledge on widening the scope of AM in healthcare supply chains. The analysis began with open coding and the transcription of the interviews, which involved reading through the data to identify operational drivers and constraints towards such wider scope.

Miles, Huberman, and Saldaña (2014) highlight that it is important for the transcripts to be completely broken down into codes, because a code is considered the smallest unit of data in thematic analysis. Then axial coding was employed to identify groups based on similarities of the operational drivers and constraints identified and establish valid correlations between them (Vaismoradi, Turunen, and Bondas 2013). Once the operational drivers and constraints were categorised, the analysis process was repeated until saturation was reached where no new operational drivers and constraints could emerge.

The second level of analysis, cross-case, compared the issues/activities, identified for each operational driver and constraint. The evidence from the analysis was compared with the organisation's documentation and observations to further increase validity. The outcome of this analysis was the development of the opportunity assessment for wide-scope AM.

4. Results: cross-case analysis

The cross-case analysis focuses on the operational issues/activities that help and hinder widening the scope of an AM process in the studied healthcare supply chains. The analyses are conducted along functional performance dimensions: procurement, design, production, distribution/logistics, and customer operations. This analysis is then used to inform the development of an opportunity assessment for wide-scope AM presented at the end of this section. During the analysis, AM is often compared to conventional production processes that are all the same (injection moulding) for the selected case studies.

4.1. Procurement for wide-scope AM

The case organisations G,H (AM standards and customised joint replacement, repair, and reconstruction) emphasised that one of the main challenges that hinder the application of AM for standard parts can be found in the complexity of the industry. The healthcare industry is highly regulated, including standards related to patient and device safety. Consequently, when introducing a new device in accordance with the parameters of AM, the relevant steps followed are quite tightly controlled and very demanding. Within this industry there are certain materials and AM metals, which are biocompatible and relatively new in their use as compared with the evolution of AM. Therefore, supply of materials and knowledge need to evolve together to contribute towards a wider scope of AM, also for standard parts, which means that AM and traditional supply chain relationships needs to be re-examined to further incorporate a two-way flow of information.

The case organisations D, E (AM standards and customised dental products – crowns, implant bridges) noted that it is an extremely competitive industry and material selection varies by AM machine, where more advanced AM machines are required to produce complex models and thus further developments are required in relation to materials and processes to enable production of a wide range of AM standards. It was highlighted that still some machine suppliers limit attempts to scale up production through controlling what materials can be processed and restricting adjustability of machine parameters.

The case organisation C (AM standards and customised wheelchair parts) is a comparatively new space where a lot of materials are still being developed. The case organisation works with a number of suppliers to develop appropriate products for this sector in collaboration with hospitals, surgeons, and clinical laboratories to gain a better understanding of patient requirements. At the moment, it was highlighted that there are a number of problems associated with customised parts where most suppliers seem to lack the expertise to operate with the right materials and validate their process related to the required standards, which makes production of standard parts even more challenging.

> Of course, we would like to use the technology more for standards parts but at the moment there is lack of experience from both parties' suppliers and manufacturers, to validate the process and scale up the technology. We need to focus on improving customized products and once we have the 'know how' then we can start thinking of how to widen the scope of standard parts. (Company Director, Company C)

The case organisation F (AM standards and customised hearing aids) highlighted that the supplier market is dominated by only a few large firms and the industry is quite consolidated. Thus, in terms of capital equipment there is little growth for new systems largely as a result of the maturity of the AM hearing aid shell market suggesting that capacity may already have been reached. The case organisation stressed that this might be the reason why prices have increased over time.

The case organisations A, B (AM standards and customised insoles) emphasised that another issue that hinders wider-scope AM can be found on investing in highly innovative machines that can produce standard parts on a sufficient scale to make it commercially viable. Here, it was stressed that most AM machines are not ready yet for production of volumes of standard parts. Therefore, before a company invests in one of those machines, it needs to examine whether this investment will deliver its promise for production of standard parts

and produce them on an efficient economic scale. Collaboration with suppliers and healthcare professionals can assist the implementation of the above.

> Yes, we have looked at expensive AM machines but is it worthwhile? We are not convinced yet that they can produce volumes of standard parts and even if they do it is still more expensive compared to conventional manufacturing methods. (AM Process Engineer, Company B)

The case organisations D, E (AM standards and customised dental products – crowns, implant bridges) agreed that when examining production-type volumes, the supplier must have the capacity to guarantee both supply and process management. This is particularly evident when examining volume manufacturing of standard AM parts, where raw materials need to be stocked in advance based on lead times and capacity constraints. However, the case organisations emphasised that this area is still quite limited and applied only for certain range of products as costs remain a prohibiting factor that would further allow adoption of technology for volumes of standard parts. Nevertheless, it was noted that products designed to a generic shape can still find applications, as for standard products made of conventional manufacturing, but the challenge remains to scale up the technology.

The case organisation F (AM standards and customised hearing aids) suggested that outsourcing AM demand could potentially be an alternative when capacity is the general purpose and there are many available suppliers. Then capacity can be better managed also for improving lead times and reducing transportation costs.

> Yes, I do believe that potentially volume manufacturing of standard AM parts could lead to capacity constraints but at the moment applications are only limited for certain range of parts and I cannot see that being a problem. (AM Technical Director, Company F)

All case organisations have recognised that co-development of their own materials and improvements in process efficiencies could potentially scale up the volume for AM standards.

A summary of procurement issues and activities in the case organisations for wide-scope AM is presented in Table 3.

4.2. Design for wide-scope AM

All studied case organisations design AM products in-house. Three-dimensional (3D) Computer Aided Design (CAD) software, and in particular *SolidWorks*, is often employed in medical applications (G, H – AM standards and customised joint replacement, repair, and reconstruction) to produce both patient-specific and standard parts. It was highlighted (G, H) that for both custom and standard parts, software selection needs to be carefully planned as existing CAD systems are not at all suited for exploring the design freedom of AM processes, and when a 3D print file is developed for one printer, it is not necessarily viable for use on a different one. Successful production of customised and standard parts depends on the extent to which an organisation can manage existing CAD modelling systems, including compatibility issues related to software and hardware.

The case organisation C (AM standards and customised wheelchair parts) recognised that AM is the most appropriate and powerful technology available to capture each individual's unique body shape. Here, it was pointed that their principle for designing the right product is placing the end-user at the beginning of the process. Therefore, once the particular needs of the end-user are identified, then a decision is made with regard to an appropriate software solution. This can only be implemented successfully when, within the supply chain, the customer, the designer, and the manufacturer work closely together.

> Once we've found the right technology and the right platform, the right capital equipment, and then perhaps identify the right supplier, we'll look at, 'Okay, how do we establish data transfer? What do we do? (AM Process Engineer, Company C)

The case organisations A, B (AM standards and customised insoles) noted no difference with traditional

Table 3. Summary of procurement issues and activities for wide-scope AM in case organisations.

Operational drivers/ constraints	Procurement issues/activities for wide-scope AM
Supplier selection	• Highly regulated industry – standards relating to patient and device safety. Cases G, H • Supply of materials and knowledge to include standard parts. Cases G, H • Some machine suppliers limit attempts to scale up production through controlling what materials can be processed. Cases D, E • Problems with AM customs delay production of standard parts. Case C. • Maturity of AM hearing aid shell market. Case F
Vendor supply chain (AM machine vendors – close relationships between suppliers and organisations to scale up AM through technical knowledge, ability to solve problems, support, and back-up services)	• Limited ability to produce standard parts on an efficient economic scale. Cases A, B • Applicable for a small range of standard parts. Cases D, E
Supplier acquisition/integration	• Potential partnership with suppliers could enhance the scaling up of standard parts. Cases A, B • Outsourcing demand for standard parts if capacity becomes general purpose. Case F
In-house AM co-development	• Improvements in process efficiency to include standard parts. All Cases

manufacturing in data acquisition, foot shape, and other clinical information but only on the model physical geometric designs – based on a process of reduction and elimination of waste material. It was strongly highlighted that the mechanical integrity of the AM standard in terms of its durability and robustness cannot be supported or informed by any sort of data.

With regard to patient-specific products, all case organisations usually rely on the patients' consultant or hospital to obtain the relevant data. In particular, all case organisations depend on computerised tomography (CT) files to acquire 3D information about a patient's anatomy to make custom products. Then the data are translated into 3D CAD and through reverse engineering are transferred into Magic software as for example in the case of organisations G and H (joint replacement, repair, and reconstruction) to produce patient-specific custom implants.

On the contrary, for standard parts, which are not patient specific, the case organisations G and H (joint replacement, repair, and reconstruction) noted that scanning is not required as the parts are designed to a generic shape, design, geometry, and anatomy. Here, the software allows the case organisations to design standard parts that can then be produced with AM.

It was strongly emphasised (D, E – AM standards and customised dental products – crowns, implant bridges) that the need to hold physical inventory for standard parts (except for raw materials) can be significantly reduced as everything can be stored in the form of digital data and produced as required. This can also be useful for customised products where the digital inventory of standard parts can be adjusted to meet specific customer requirements and thus any changes in the product can be postponed to the latest possible moment. The case organisations D and E have implemented a digital workflow integrating technology, patients' needs, and dentists' requirements, but they stressed that accuracy of the final product still remains the main challenge that further hinders the production of standard parts.

> We can now design standard parts to a limited range and are looking at the possibility of holding digital inventory if demand is increased; that might allow as to produce more volume but we need to overcome technological constraints before investing heavily on capital equipment. (AM Production Engineer, Company D)

The case organisation F (AM standards and customised hearing aids) emphasised that DDM has significantly improved the digitisation of medical procedures and clinical workflows and potentially this digital model-centric way of organising supply chains could also enhance production of a wide range of AM standards. They can now expand on product modelling and produce parts directly on demand that are based entirely on the digital model, and without the need for tooling up and setting up they can further incorporate DDM into their operations for general capability to produce standard parts.

> We found that direct digital manufacturing can help us not only to produce patient-specific but also a small range of standard parts; we are still looking for ways to improving our capability for general purpose equipment. (AM Operations Manager, Company F)

All case organisations agreed that further software improvements are required to address the particularities of the healthcare industry and challenges related to standard parts.

A summary of design issues and activities in the case organisations for a wide-scope AM is presented in Table 4.

4.3. Production for wide-scope AM

All case organisations underlined that manufacturers need to address all those challenges associated with the selection of the appropriate process, including limitations and post-processing requirements. They all agreed that by using AM processes they can create customised and standard parts, which would be impossible with traditional manufacturing methods.

Table 4. Summary of design issues and activities for wide-scope AM in case organisations.

Operational drivers/constraints	Design issues/activities for wide-scope AM
Software selection	• Design customs and standard parts in-house. All Cases
	• Compatibility issues related to software and hardware for customs and standard parts. Cases G, H
Software integrated solution	• AM is the most powerful technology available to capture each individual's unique body shape. Case C
	• Integration of CAD and AM technology to enable production of standard parts. Case C
	• Differs on the model physical geometric designs – based on a process of reduction and elimination of waste material. Cases A, B
	• No data can inform or support the mechanical integrity of a product in terms of its durability and robustness. Cases A, B
	• Standard parts: Scanning is not required as the product is designed to a generic shape, design, geometry, and anatomy. Cases G, H
Direct Digital Manufacturing (DDM)	• Produce a small range of standard parts based directly on a digital model. Cases D, E
	• Accuracy of the final product hinders the production of standard parts. Cases D, E
	• Eliminate the need for tooling and setting up – available for standard parts. Case F
	• Digital model-centric way of organising supply chains. Case F
Software development	• Improvements in software to address challenges for standard parts. All Cases

The case organisations G, H (AM standards and customised joint replacement, repair, and reconstruc tion) found that flexibility is one of the main advantages of the AM technologies, which enables them to build a combination of different products at the same time. It was highlighted that the utilisation of an appropriate AM technology can assist them to reduce overall cost of production and total lead times.

> So, if we want five of one product and three of another product and ten of a third product and one of a fourth product, we can build those all in one go without having to swap out tooling or machine time or, you know, processes and become very efficient. (Company Director, Company G)

The case organisations G, H highlighted that limitations of the technology concerning AM powder bed processes can be found in residual powder, where devices need to be made free from residual organics and inorganics if they are to be placed into a patient's body. It was noted that each product in the industry is different and therefore when a process works for one product, it does not necessarily mean that it can work for every product and produce the same results and surface finishes. This also constrains the production of AM standards.

The case organisations A, B (AM standards and customised insoles) employed Extrusion-based Systems and in particularly Fused Deposition Modelling (FDM) with the potential to achieve production of AM standards and high-volume manufacturing. It was noted that the cost for producing insoles by using FDM can be many times higher compared with conventional methods and a lot of the build cost depends on the height of the object that is to be produced. Thus, taking into consideration that traditional methods have been in place for many years and improved a lot, the opportunity for AM to add value to the existing digital supply chain can be quite limited for the particular sector. The case organisations A, B present a strong example of the technology constraints in relation to materials and processes and therefore when an AM technology is particularly good for certain applications, it does not necessarily mean that it can be beneficial for others.

The case organisation C (AM standards and custo mised wheelchair parts) stressed that AM methods and FDM in particular have enabled the company to produce more customised wheelchair parts in less time and in a cost-effective time. The case organisation noted that the production of standard parts can offer similar advantages to traditional manufacturing methods; however, the technology constraints that are evident for customised products are also associated with the applications of the technology for standard parts. It was pointed out that limitations, except the build time for high volume, associated with the processes and strength of materials and the fact that every single part is completely different make the production of standard parts quite challenging. It was underlined that materials used in AM are commonly found in traditional manufacturing processes where standards related to storage, handling, and transportation are relatively well articulated. However, the cost and availability of materials, sustainability issues as with the case of polymers that cannot be recycled, and the challenge to source new materials pose significant barriers for wide-scope AM and standard parts, particularly when considering volume manufacturing for standard parts.

When examining post-processing requirements, it was noted (G, H – AM standards and customised joint replacement, repair, and reconstruction) that AM processes can be quite complicated as they involve various stages till the product is ready. Most of the products require some other post-machining – traditional machining functions and other processes such as cleaning, packaging, laser marking, and sterilising. In the case of standard parts this remains a constraint, particularly when thinking of scaling up the technology. It was highlighted (A, B – AM standards and customised insoles) that this is a challenging area where traditional manufacturing methods still seem to have an advantage as they have also been advancing and becoming very efficient in terms of savings, including labour and other costs. Nevertheless, it was noted that for a small range of standard parts the application of the technology can still deliver similar benefits as for customised products.

> We found that the application of AM for a small range of standard parts can still be beneficial but when looked at ways of scaling up the technology for volume manufacture, we faced several issues concerning build platform, cost of materials and still have to use traditional manufacturing for post processing. (AM Operations Manager, Company A)

The case organisation F (AM standards and customised hearing aids) stressed that it can now make hearing aids far faster than before and can produce 50 custom AM hearing aid shells or moulds in an hour that are more accurate with less material used compared to traditional silicon moulds. This can have significant implications when considering production of a wide range of AM standards; nevertheless, as previously noted (case organisation C) limitations of raw materials and AM processes still hinder the growth of standard parts. The case organisation strongly agreed that DDM has a great potential to eliminate some of the constraints associated with the production of standard parts, also found for customised products, such as improving operational practices for products and services by looking at optimal

designs to further improve sustainability within the supply chains.

> I think the capabilities of DDM has not yet fully been explored; if we improve designs of DDM when applied for standard parts or demand parts manufacturing and make the process more sustainable then we might look of ways of scaling up the production of standard parts. (AM Technical Director, Company F)

The case organisations D, E (AM standards and custo mised dental products – crowns, implant bridges) highlighted that by using a number of AM machines and stereolithography (SLA), they can produce higher volumes compared with conventional methods without compromising on the quality. The case organisations have considered the scenario to make standard parts in parallel production, which would considerably speed up the process. It was highlighted that parallel fabrication by using multiple devices parallel to fabricate portions of the model could significantly accelerate the processing speed and scale up the technology for standard parts. It was stressed that when it comes to the production of standard parts and particularly for high volume, there is a need for comprehensive costs models that will incorporate production costs within the total cost of the supply chain. It was underlined that further evidence is needed to establish a positive relationship between production quantity in AM and unit cost before investing in parallel production as capital costs can be very high.

> We are not ready for parallel fabrication yet although we have looked at potential benefits. This could be very good for standard parts and even if we benefit from cost per unit the technology needs to be widely accepted within healthcare supply chains; We still have way to go for this to happen. (AM Process Engineer, Company E)

A summary of production issues and activities in the case organisations for wide-scope AM is presented in Table 5.

4.4. Distribution/logistics for wide-scope AM

All case organisations follow an in/house-centralised approach to AM. It was noted (G, H – AM standards and customised joint replacement, repair, and reconstruction) that in-house manufacturing offers adva ntages that cannot be replicated by other means such as distributed manufacturing. The case organisations G, H highlighted that when a product, customised or standard, is manufactured in-house, they can develop an in-depth knowledge and understanding, which would not be acquired if the product was outsourced.

It also became apparent that emerging technologies and markets do introduce many opportunities for manufacturing to be outsourced. Companies can choose from a wider specialist supplier base and take advantage of the emerging economies to produce in a more cost-effective manner. The case organisations A, B (AM standards and customised insoles) noted that the only AM insole products that are on the market are a combination of a printed part and a traditional manufactured part. Thus, production of a wide range of AM standards can be feasible only if an AM product does not require support from traditional methods. As AM is a relatively new technology, the supply chain around spare parts and materials is not as established as it is for the traditional milling process and thus it is important to invest in both technologies, in traditional methods as well as in AM methods, among which the first one offers more security but is less innovative compared to AM. The case organisation B highlighted that although the idea of outsourcing appears to be appealing, they tend to 'focus on how to overcome daily problems rather than introducing new technologies' (AM Operations Manager, Company B). Nevertheless, it was suggested (H-AM standards and customised joint replacement, repair, and reconstruction) that companies 'will probably look for alternative ways to outsource their

Table 5. Summary of production issues and activities for wide-scope AM in case organisations.

Operational drivers/constraints	Production issues/activities for wide-scope AM
Process selection	• Produce standard and custom products that would not be possible through traditional manufacturing. All cases
	• Flexibility of manufacturing: build a combination of different products at the same time. Cases G, H
Process limitation	• Different AM processes produce different results and surface finishes. Cases G, H
	• A process can work for one product but not necessarily for every product. Cases G, H
	• Cost for producing insoles can be many times higher compared with conventional methods. Cases A, B
	• AM adds limited value to the existing digital supply chain for the particular sector. Cases A, B
	• Every single part is completely different and that makes the production of standard parts quite challenging. Case C
	• Cost, availability, strength of materials, sustainability issues for standard products. Case C
	• Traditional processes have become very efficient in saving labour and other costs. Cases A, B
	• DDM to improve operational practices and sustainability for standard parts. Case F
	• Parallel fabrication for standard parts to speed up process. Cases D, E
Post-processing	• Various stages involved till the product is ready. Cases G, H
	• Production of standard parts will require further post-processing. Cases G,H
Process cost	• Need for comprehensive costs models – establish a positive relationship between production quantity in AM and unit cost for standard parts. Cases D, E

technology if treatment becomes more patient-specific' (AM Operations Manager, Company H).

The case organisations D, E (AM standards and customised dental products – crowns, implant bridges) pointed out that outsourcing was a lengthy process, taking up to two weeks for models to be returned resulting in extra costs to their operation. It was indicated that for standard AM parts, the possibility of outsourcing may become feasible in the future if they take on more orders than in-house capacity permits. However, safety critical parts are a very important element in the medical industry and one of the main barriers related to outsourcing for both customised and standard parts. The case organisations D, E suggested that they may then opt for partial outsourcing or bidirectional partial outsourcing where the company can keep the critical operations in house and outsource other noncritical work to selected subcontractors to cope with demand surges.

> At the moment we don't consider the possibility of outsourcing our products; maybe in the future if we face capacity constraints, we can look at this scenario but again probably only for standard AM parts. (AM Technical Director, Company D)

The case organisation F (AM standards and customised hearing aids) highlighted that currently in-house manufacturing capacity covers the existing needs and outsourcing may not be the best pathway currently as products are very light weight and thus transportation costs are less compared with outsourcing manufacturing costs. Nevertheless, the significant world-wide growth of the AM hearing market may drive medical manufacturers towards outsourcing.

An interesting possibility appeared to be that of distributed manufacturing near the hospital or the patients themselves. The case organisation C (AM standards and customised wheelchair parts) highlighted that this scenario cannot yet be considered for standard parts as current cases require custom-made devices for patients. It was noted that the time taken to manufacture a custom device from the point of CT scan to the manufacturer and back to the patient can be a matter of days or a week. In that respect, there is no urgent need to manufacture devices in close proximity to the hospital or patient, as the product can be delivered in a short time. However, it was suggested that as technologies develop, this is likely to change. Technologies and materials need to grow with the patient to be applied in a more effective way, and therefore in emergency cases manufacturing next to the patient will be more applicable.

> Now there may be technologies and materials available in the future that are better applied or made maybe even in the theatre or with the patient. So, I don't think there's a lot of need for distributed manufacture at the point of treatment at the moment, but I think it will probably go that way. (Company Director Company C)

In relation to inventory levels, and as it was previously mentioned, there are two categories of products within the case organisations: (i) customised, and (ii) standard AM parts. Examining the customised products, there is no need for stock as they are predominantly demand driven. When it comes to standard parts, the case organisations G, H (AM standards and customised joint replacement, repair, and reconstruction) noted that the same rules of inventory apply as for normal products. Therefore, there are certain lead times based on capacity constraints and how many units are shipped out in a year.

> Standard parts made of additive manufacture doesn't make as much difference because we'll need to stock everything, we'll still need to stock the whole size range of a range of products, and there is still a lead time associated. (AM Production Engineer, Company G)

It was previously noted (Section 4.2, Case D, E – AM standards and customised dental products – crowns, implant bridges) that everything can be stored in the form of digital data and produced as required and therefore when examining standard products, the case companies are looking at the possibility of holding digital inventory if demand is increased.

A summary of distribution/logistics issues and activities for wide-scope AM in the case organisations is presented in Table 6.

4.5. Customers (healthcare centres) for wide-scope AM

The case organisations G, H (AM standards and customised joint replacement, repair, and reconstruction) stressed that in the healthcare sector decision making regarding the appropriate technology for treatment is complex while there is pressure on hospitals and the National Health Service (NHS, U.K.) budget. Therefore, although surgeons have a direct interest in the technology of the product, they are not involved in the decision-making process. As a result, decisions on choosing a technology are based mainly on cost rather than the technology itself, which makes the case for a wider range of standard parts very challenging. It was highlighted that in the healthcare industry it is quite difficult to justify that a device that uses a better technology produces better long-term patient results. Therefore, when a new technology is introduced with the potential to produce better results over a long period, it may not be easily adopted, especially when it is more costly (More in Section 4.6).

> Yes, we would like to see hospitals using more of the technology; but at the moment when it comes to a new

Table 6. Summary of AM distribution/logistics issues and activities for wide-scope AM in case organisations.

Operational drivers/constraints	Distribution/logistics issues/activities for wide-scope AM
Centralised manufacturing	• In/house-centralised approach to AM for standards and customs. All cases • Develop an in-depth knowledge for standards and customs. Cases G, H
Outsourcing (Outsourcing, transportation costs, and delivery times)	• Feasible only if an AM product does not require support from traditional methods. Cases A, B • Outsource technology if treatment becomes more patient-specific. Cases G, H • Products are light weighted: transportation costs are less compared with outsourcing manufacturing costs. Case F • Bidirectional partial outsourcing for standard parts if the companies take on more orders than in-house capacity permits. Cases D, E • Safety critical parts. Cases D,E • Distributed manufacturing near the hospital or patient is not considered yet as products can be delivered in short times. Case C
Logistics (Inventory issues)	• Standard products: AM manufactured products – same rules of stock and inventory as for regular products. Cases G,H • Digital inventory of standard parts if demand is increased. Cases D,E

> technology, they mainly look at costs and not the long term benefits, that's why I cannot see them thinking of standard parts – not now anyway. (AM Production Manager, Company H)

The case organisations G, H have pointed out that they could further collaborate with healthcare centres to create both standard and patient-specific devices. It was argued that implications in the implementation of this scenario can be found in the various costs, as they are expected to increase, and regulations and standards that may delay this process; however, if both parties within this manufacturing portfolio prioritise innovation within their strategic agenda, then manufacturing costs could become less of a consideration (More in Section 4.6). It was stressed that this scenario can be possible in the long run since it is already implemented for customised products and the same principles also apply for standard parts in terms of operations.

The case organisations A, B (AM standards and customised insoles) pointed out that the biggest barrier is to initiate some early adoption into clinical practice to then establish a proper feedback loop as at the moment the technology can be found on printing bureaus or people who have the printers and the material manufacturers, and they do not engage actively with clinicians to support this innovation. Other barriers within hospitals involve attitude to risk and safety, which has to do with every new technology.

The case organisation C (AM standards and custo mised wheelchair parts) noted that currently it is mainly the health-tech companies that are assigned to work within the healthcare centres and not so much the medical device manufacturers and filament producing companies. It was highlighted that regulations tend to be quite outdated when considering wheelchair fabrication.

A very interesting use was found to be the possibility of physically locating machines in the hospitals. However, a number of considerations were put forward (F – AM standards and customised hearing aids) that render this solution not that easy to implement. In particular, decisions need to be made regarding the validation of the process. A clear allocation of responsibilities to the different parts such as hospitals, suppliers, and manufacturers for the different parts of the process needs to be established including the liability, the training, and the skill level.

> It's not an easy thing to do because some of these machines have to be run in a controlled environment. The process has to be validated. Who's going to do that? Is it the hospital, is it the supplier or is it the manufacturer? (AM Operations Manager, Company F)

Conversely, as it was previously noted (A, B – AM standards and customised insoles) conventional manufacturing methods will not be easily replaced since they have proved to be cost effective and efficient. It was pointed out that many AM standard parts require some sort of support from traditional machining and thus the possibility of a hybrid scenario including both AM for standard parts and traditional manufacturing may arise. This will further challenge the possibility of integrating AM technology within hospitals.

> I could see in the possibility of producing a wider range of standard parts but not in the near future; standard parts will still require support from traditional methods. So even if this happens, they can only be used in conjunction with conventional manufacturing methods. (Company Director, Company A)

The case organisations D, E (AM standards and custo mised dental products – crowns, implant bridges) recognised that the healthcare centres are making efforts to get involved in the whole process; however, they need to collaborate more with the community to validate the process. Here the cases D, E noted that they could take advantage of the web technologies and engage with healthcare centres to a much greater extent by sharing the available

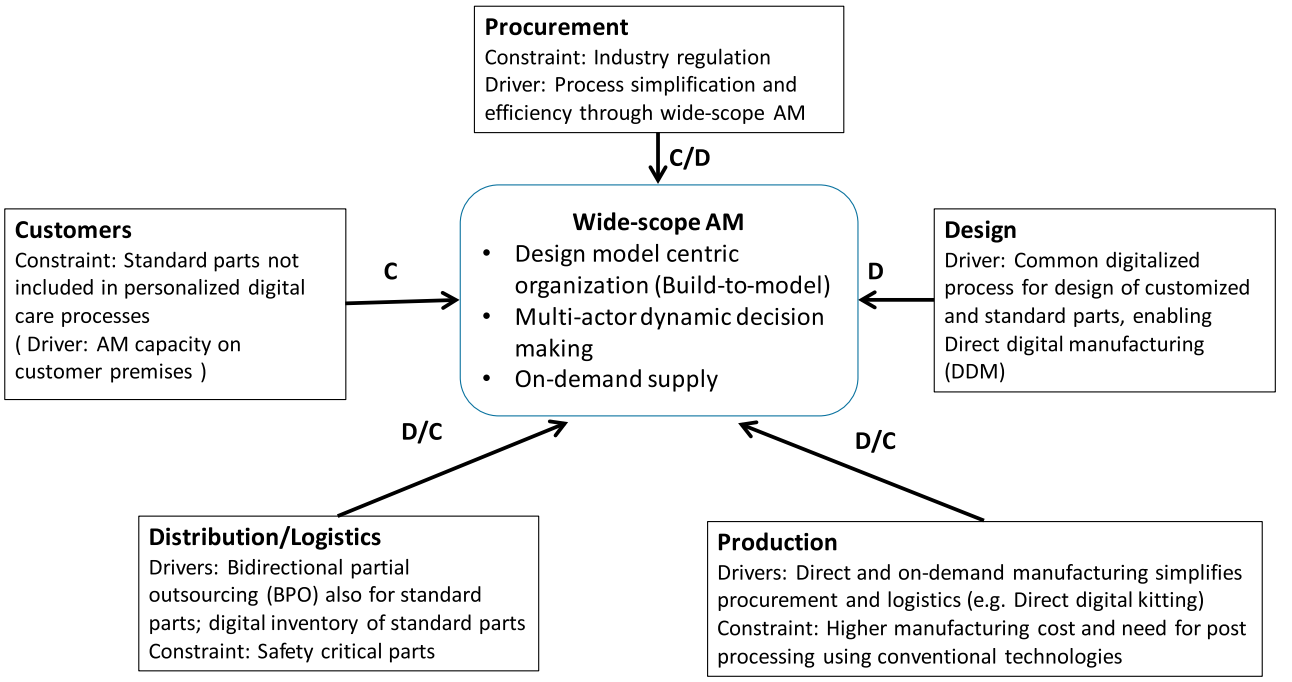

Figure 2. Opportunity assessment for wide-scope AM in healthcare supply chains. Drivers designated (D) and constraints (C).

data and improving standard parts or sub-assemblies or implants customised per patient.

> We are aware that there are many web technologies like cloud-based design and manufacturing to help us accelerate the technology – we could also take advantage of an open source software to share ideas with hospitals for customs and why not also for standard AM parts, but we haven't done much towards this direction. (AM Operations Manager, Company E)

Hence, the extent to which hospitals utilise the technology propositions should have a fundamental impact on the evolution of the healthcare supply for wide-scope AM. A summary of customers' issues and activities for wide-scope AM in the case organisations is presented in Table 7.

5. Opportunity assessment

Next, we assess the opportunity for widening the scope of AM to include standard parts taking into account the operational drivers and constraints identified in our cross-case analysis. The assessment takes a supply chain perspective and seeks to identify the available cumulative improvements through increased scope of AM in procurement, design, production, distribution/logistics, and customer (Healthcare centres) operations. We conceptualise cumulative performance effects based on the identified drivers and trade-offs based on the constraints from the cross-case analysis mentioned previously. We summarise the opportunity assessment indicating the main drivers and constraints and their interrelationship in Figure 2.

Table 7. Summary of customer issues and activities for wide-scope AM in case organisations.

Operational drivers/ constraints	AM customers issues/activities for wide-scope AM
Collaboration of medical manufacturers and hospitals	• Limited utilisation of AM technology within healthcare canters. All cases. • Technology decisions are based mainly on the cost rather than the technology itself. Cases G, H • Cost hinders production of standard parts. Cases G, H • Main barrier: Implementation and adoption in clinical settings. Cases A, B • Other barriers: Attitude to risk and safety, sharing electronic data, security and clearance. Cases A, B • Regulations tend to be quite outdated when considering the wheelchair fabrication. Case C
Integration of AM within hospitals	• New departments and practices for production of customs and standards parts. Case F • Decisions regarding the validation of the process and allocation of responsibilities. Case F • AM standard parts will still require support from traditional methods. Cases A, B
Web 2.0 technologies	• Sharing available data to improve standard parts, sub-assemblies, customised products. Cases D, E
Cloud-based design and manufacturing (CBDM)	• Patient data to create parts or sub-assemblies for the device and ship them to the point of use. Cases D, E
Open source software and maker culture	• Create new devices for increased design participation. Cases D, E

We identify the digitalisation of design in the medical device organisations as a primary driver for wide-scope AM in the healthcare supply chain. When medical device manufacturers increasingly design customised and standard parts using the same digitalised design methods and tools, the available next step is extending the use of digital design and AM to standard parts. Here, we find the practice of remixing (Friesike et al. 2019) in product design for AM (i.e. reuse of standard designs through remixing) as a mechanism for cumulative improvement and for increasing the use of AM for standard parts.

Production is both a driver and a constraint of wide-scope AM. When AM is used for direct and on-demand manufacturing of individual parts and assembly kits, the widening of the scope of AM to standard parts simplifies procurement and logistics. The parallel production considered by some case organisations (e.g. D, E – dental) is a first step. The cumulative outcome is faster responses to customer demand, and more predictable cost outcomes for procurement, driving the extended scope of AM. However, production is also a constraint to wide-scope AM due to high manufacturing costs and the need for post-processing using conventional technologies.

Similarly to production, distribution and logistics are more drivers than constraints for wide-scope AM. The technology allows for more dynamic and responsive decision making in terms of both the timing and location of part production and inventory. This decision making can involve the customer (Healthcare centres), as well as multiple suppliers, logistics centres, and production locations. In such dynamic networks, collaborative practices and bidirectional partial outsourcing (Hedenstierna et al. 2019) can drive a wider scope of AM based on available shared AM capacity. However, regulations for safety critical parts are a constraint for wide-scope AM from a perspective of distribution and logistics in the healthcare supply chain.

Procurement and customer operations (Healthcare centres) are primarily constraining wide-scope AM in the healthcare supply chain. For procurement, the constraint is first and foremost strict regulations that make it challenging to take advantage of wide-scope AM to simplify and streamline processes. On the customer side, a further constraint is the limited digitalisation of care processes. Whereas processes for customised and personalised parts are highly digitalised, this is not yet the case for many care processes requiring standard parts. In contrast to design in the medical device organisations, where customised and standard parts are equally digitalised, the processes for standard and customised parts in customer organisations are not equally digitalised. Schneller and Abdulsalam (2022) note that healthcare providers will need to pay greater attention to supply chain expenses as the utilisation of medical supplies and suppliers is a key factor to achieving financially sustainable outcomes along with high clinical quality. Here a constraint is limited information transparency between the procurement and the clinical staff, with physicians choosing the medical device based on purchase cost as main selection criterion, neglecting supply chain, life cycle, and transaction costs. Furthermore, a potential customer driver of wide-scope AM is investment in AM capacity in healthcare centres. However, few such investments have yet been made.

The opportunity assessment posits that a wide-scope AM supply chain in healthcare is enabled by the increased use of the digital design model by the manufacturer, more dynamic decision making involving multiple supply chain actors, and the procurement and supply of both custom and standard parts closely aligned to patient requirements. Currently, this development is constrained primarily by regulation, and the lack of integrated (digitalised) operational processes for standard parts in healthcare centres and hospitals.

While wide-scope AM enabled by digitalisation is poised to simplify operations of the medical device manufacturers in healthcare supply chains, the current reality is very different in the customer operations (healthcare centres and hospitals). Digitalisation in personalised care processes has made significant progress and enables AM for customised parts. However, for standard parts the processes are to a significant degree not yet digitalised. For fit-dependent standard parts, physicians rely on physical access to part inventories and physical fitting. We find this situation is similar to that in the retail supply chain, where the digitalisation of product fitting for standard products (Gustafsson, Jonsson, and Holmström 2019) provides an opportunity for reducing reliance on physical inventory, but is constrained by current operations. As in retail, we see a need for research in healthcare supply chains to investigate how the supply chain and operational processes for both standard and customised products can be re-organised around the digital representations of products and customers. This research is needed for enabling a move towards a digital design-centric way of organising supply chains and the build-to-model manufacturing mode.

6. Discussion

Our multi-case study investigated the use of AM for standard parts and contributes to research on how the available benefits of AM can be cumulated operationally. Our cross-case analysis and empirically grounded opportunity assessment identify the operational drivers and constraints for widening the scope of AM and specify a

sequence of operational practices to cumulate the available opportunity for performance improvement. Furthermore, we point to topics in need of further study in digitalisation of the healthcare supply chain.

In the following, we position our opportunity assessment to the operations and supply chain management literature on performance improvement. The high-level operational performance dimensions, quality, delivery, cost, and flexibility are affected by extending the scope of AM from customised to standard parts. In the assessment frameworks of Ferdows and De Meyer (1990) and Hallgren, Olhager, and Schroeder (2011), quality is identified as the primary driver of cumulative improvement. The frameworks differ in their view of flexibility (Wurzer and Reiner 2018): is flexibility a driver of increased cost or is flexibility and cost trade-offs in terms of performance? Our study indicates how AM significantly differs from conventional manufacturing in terms of available cumulative improvements. In AM, flexibility is a primary driver of cumulative performance improvement, enabling cost reductions through the possibility to simplify flow with kitting-based solutions and through capacity sharing. The role of quality does not emerge as an enabler of cumulative improvements across different performance dimensions, as in conventional manufacturing. Quality appears strictly as a constraint to the wider application of AM, not as an enabler of innovative practices enabling cumulative improvements in delivery, flexibility, and cost dimensions. Instead, digital design and digital encapsulation serve as the basis for available cumulative improvements across several performance dimensions. Furthermore, in the studied healthcare setting, the lack of digitalisation in customer processes emerges as a major hurdle.

We can now address the question how the available benefits of AM can be realised in the form of cumulative operational improvements. Based on our study of extending the scope of AM in the healthcare supply chain, we find that AM is only one component of a more systemic solution. To realise available performance improvements, AM needs to be introduced in a combination of other solutions. In the healthcare supply chain, the digitalisation of design, on both the manufacturer and customer side, is the foundation for the flexibility required for customised parts. However, digitalisation of design is also available for standard parts. Building on digitalisation of design, the practices of direct digital kitting and dynamic capacity sharing become available, enabling cumulative cost and delivery improvements for AM of standard parts. Thus, extending the scope of AM from customised parts to standard parts changes the cost–flexibility trade-off through a sequence of available improvements resulting in cumulative performance outcomes along multiple performance dimensions.

The performance improvements are available already at low volumes, making wide-scope AM particularly interesting for innovative small and medium-sized companies, as in the companies of our study. For small and medium-sized companies, the immediate benefits available from introducing AM for customised parts reduces the barriers for entry for standard parts through wide-scope AM. The cumulative benefit of digitalising both design and production reduces the need for the type of systematic operational capabilities development often required to switch-over from conventional manufacturing to AM in large organisations (Roscoe et al. 2019). Furthermore, the possibility of cumulative benefits is interesting from the perspective of investment risk (Gunasekaran et al. 2024), through the effects on the business case for investments in AM technology.

Our opportunity assessment builds on previous conceptual research and initial propositions on the available benefits of producing all parts direct from digital models from the perspective of the medical device manufacturers, driven by a digitalised design process (Verboeket et al. 2021). Through interviews and observation of practice, we have been able to outline how different operational practices build on each other and identify apparent trade-offs. However, as the case companies have implemented AM for standard parts to a very limited degree, we have not been in a position to empirically observe the relationship between the proposed drivers and constraints in wide-scope AM operations.

The managerial implication of this study is to emphasise the role of the customer's digitalisation in enabling wide-scope AM in the healthcare supply chain. Medical device manufacturers who seek to increase the use of AM in their own operations need to recognise the challenges faced by their customers in digitalising operational processes and reducing the need for accessing a physical inventory. While we found clear indicators that healthcare providers are considering a move towards AM-enabled operations that include standard parts as well, the challenges and path forward are not well understood. Current research is focused on customised parts (Verboeket et al. 2021).

The main limitation of this research is that although a multi-case approach can increase validity of results (Eisenhardt 2007), for explorative research topics, where practice is only emerging, we cannot draw generalisable conclusions. Nevertheless, this research is the first of its kind and therefore it provides a valuable first insight into the operational drivers and constraints for extending the scope of AM in healthcare supply chains. These insights point towards a hybrid model of manufacturing

performance dimensions (Wurzer and Reiner 2018). Further research, such as investigating operational drivers and constraints for widening the scope of AM in other sectors where AM is widely used for customised parts, and the impact of different types of digitalisation in healthcare centres on wide-scope AM, are required. This research would contribute to the theoretical understanding of the role of technology in operations management.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Data availability statement

The anonymised research data associated with the paper is available upon request from the first author.

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