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Additive Manufacturing in the medical sector: from an empirical investigation of challenges and opportunities towards the design of an ecosystem model

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Additive Manufacturing in the medical sector: from an empirical investigation of challenges and opportunities towards the design of an ecosystem model

Abstract

Purpose

This works provides a thorough understanding of the challenges and opportunities associated with Additive Manufacturing (AM) adoption in the medical sector. Through this analysis, we aim to better understand when to adopt AM, how to do so, and how such adoption might change in the future.

Design/methodology/approach

This research first conducted a systematic literature review (SLR) to identify AM challenges and opportunities in the medical sector, which were then validated through a Delphi study. The 18 Delphi study participants were also asked to suggest countermeasures for the challenges and help identify future AM adoption scenarios. Finally, these findings were analyzed according to the ecosystem pie model to design an ecosystem model for AM in the medical sector.

Findings

Among the 13 challenges and 13 opportunities identified, the lack of a skilled workforce and the responsiveness achievable via AM were by far the most relevant challenge and opportunity. Moreover, the participants identified countermeasures for 10 challenges, as well as three future AM adoption scenarios. Finally, leveraging these findings, an ecosystem model was developed.

Originality

This work contributes to the limited understanding of the AM challenges and opportunities in the medical sector. It helps medical practitioners to better understand the challenges and opportunities associated with AM and AM manufacturers to better identify where to focus their R&D efforts and how this would impact future AM adoption levels. Furthermore, this work extends current theory supporting the design of an ecosystem model for AM in the medical sector following the ecosystem pie model.

Keywords: Additive Manufacturing (AM); medical sector; challenges; opportunities; ecosystem model; systematic literature review (SLR); Delphi study.

1. Introduction

The interest in Additive Manufacturing (AM) has continuously increased in recent years. In fact, AM allows to produce complex products easily and quickly (Akmal *et al.*, 2022) by manufacturing objects layer-by-layer without needing of any tooling or set-ups (Patil *et al.*, 2023). This has revolutionizing implications for supply chains, like being able to consolidate multi-part assemblies, produce products on-demand and close to the point of use (i.e. decentralized production), and produce highly customizable products (Caviggioli and Ughetto, 2019; Dwivedi *et al.*, 2017). Thanks to these benefits, AM is applied widely in different sectors, with the aerospace and automotive sectors being the precursors and currently accounting for almost one-third of AM applications worldwide (Wanke, 2019). However, in the next years, the medical sector will lead AM adoption, with one of the highest compounded annual growth rates (CAGR) (almost 22% from 2021 to 2030) and a market that in 2030 will be worth almost $US 10 billion (Precedence Research, 2021). In comparison, the sectors currently leading in the use of AM – the aerospace and automotive sectors – show a CAGR equal to 18% and 19%, respectively (SNS Insider, 2022; Maintworld, 2022).

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Medical implants and devices, in fact, are a good fit for the highly customizable products achievable via AM: each patient's anatomy is unique, and patient-specific implants increase the likelihood of implant success and the reduction of patients' discomfort (Chaudhuri *et al.*, 2021). So far, AM-produced custom implants have been used for a variety of applications, including dental implants, maxillofacial implants, knee and hip joints, with productivity sometimes even higher than with Conventional Manufacturing (CM) technologies (Emelogu *et al.*, 2019). Moreover, as proven during the COVID-19 pandemic, distributed and remote on-demand production opportunities are also beneficial for the medical sector. In this way, apart from lowering inventory and distribution costs and cycle times, AM can fulfill a sudden health-saving demand in any remote location (Choudhary *et al.*, 2021). An example is that of Siemens, which was able to shorten the cycle time of hearing aids by up to 80% and significantly reduce labor, inventory and distribution costs by adopting such AM-enabled decentralized production (Cortez *et al.*, 2004).

However, despite such advantages and benefits, some challenges continue to limit AM adoption in the medical sector. These include high initial investment costs for purchasing AM machines, the need for post-process operations (AM products may require surface cleaning or other treatment after the manufacturing process), and limited material selections (Emelogu *et al.*, 2016; Friedrich *et al.*, 2022). Furthermore, Willemsen *et al.* (2019, p. 163) found that policies and regulations in the medical sector "*tend to be restrictive*" and limit AM adoption. Finally, as Emelogu *et al.* (2019, p. 18) have suggested, AM's unknown impact on the medical sector does not favor its adoption: medical practitioners need to be fully aware of all the challenges and opportunities associated with it to be able to make "*decisions pertaining to the enhancement of their expansion and maintenance of their marketplace competitiveness*".

Therefore, a thorough understanding of the challenges and opportunities involved is crucial to boosting AM adoption in the medical sector and allow it to reach its full potential. Nevertheless, this is still overlooked in the literature. Indeed, contrary to other sectors, to the best of the authors' knowledge only one paper addresses the topic (Choudhary *et al.*, 2021). However, Choudhary *et al.* (2021) consider only the challenges associated with AM adoption. For the first time, this paper goes beyond mere challenges to also consider opportunities. We provide not only theoretical data (as in Choudhary *et al.* 2021) but also, for the first time, empirical data. The latter, currently missing in the literature, is crucial for understanding the challenges and opportunities involved in the use of AM in the medical sector and boosting its adoption. Therefore, this work aims to empirically answer the following research question:

RQ: What are the challenges and opportunities associated with the use of AM in the medical sector?

We adopted a two-step methodology to identify the challenges and opportunities for AM use in the medical sector. First, through a systematic literature review (SLR), we identified from the literature the challenges and opportunities associated with AM adoption in the medical sector. These have then been proposed to practitioners working in the medical sector to validate them and to establish their relevance leveraging a Delphi study. In this way, this study not only provides a mere list of challenges and opportunities but also identifies the different degrees of relevance attributed by medical practitioners to such challenges and opportunities. Moreover, for the first time, medical practitioners have also been asked to suggest potential countermeasures for the challenges identified and to support the identification of future AM adoption scenarios. In this way, this work aims to benefit two groups. First, it aims to help medical practitioners to better understand AM-related challenges/opportunities in the medical sector and to understand how AM adoption could vary in the future. Second, it aims to support AM manufacturers during their R&D activities to better align with

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the medical end-users' needs. Indeed, as stated by Villapún *et al.* (2022, p. 207), "*manufacturer advancements tend to favor engagement with larger scale industries such as automotive or aerospace yet align less closely with the medical device market*". Finally, this work also aims to contribute to the existing theory. Specifically, for the first time in the literature, it aims to support the design of an ecosystem model for AM in the medical sector. To do so, the results obtained in terms of challenges, opportunities, countermeasures and future AM adoption scenarios have been analyzed according to the ecosystem pie model. This, indeed, provides a theoretical lens suitable for extracting from such results the information required to establish a successful ecosystem model for AM in the medical sector. More details about the information and the ecosystem pie model can be found in Section 2 together with the specifics of the SLR and the Delphi study. Section 3 summarizes the challenges and opportunities identified from the SLR, while Section 4 reports the results of the Delphi study. These are then analyzed with respect to the theoretical lens of the ecosystem pie model in Section 5. Finally, Section 6 discusses the results and Section 7 concludes the work.

2. Methodology

This Section describes the methodology adopted in this work. First, Section 2.1 provides the specifics of the SLR that identifies the challenges and opportunities reported in the literature. Then, Section 2.2 describes the Delphi study performed (i) to validate the challenges and opportunities identified through the SLR and to establish their relevance and (ii) to identify potential countermeasures to the challenges and possible AM future scenarios. Finally, Section 3.3 describes the ecosystem pie model used to support the design of an ecosystem model for AM in the medical sector.

2.1. Systematic Literature Review

We chose SLR as methodology to identify the challenges and opportunities associated with the use of AM in the medical sector since it ensures the replicability, validity and reliability of the results (Sudusinghe and Seuring, 2022). In this work, we adopted the three-step methodology of Tranfield *at al.* (2003).

Step 1 – Planning the review

This first step consists of identifying the need, preparing the proposal and developing the protocol for the SLR. The need and proposal for the SLR were previously described in the Introduction, while the PRISMA protocol was adopted as SLR protocol (Moher *et al.*, 2010).

Step 2 – Conducting the review

We aligned with preceding research in following the PRISMA protocol, e.g., Moher *et al.* (2010), Amrutha and Geetha (2020), Correia Loureiro *et al.* (2021), and Peron et *al.* (2022). We used Scopus as database to collect relevant articles due to its broad coverage of relevant journals (Ahi and Searcy, 2015).

The search consists of a three-groups keywords structure using keywords selected to cover the literature on AM adoption in the medical sector (Table 1). The first group (Group A) consists of the keywords defining AM, while the second group (Group B) consists of keywords defining application areas of AM. The third group (Group C) consists of keywords related to the medical sector.

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Group A	Group B	Group C
"Additive Manufactur*"	"Supply Chain*"	"Medical*"
"Additive Technique*"	"Value Chain*"	"Biomedical*"
"3D Print*"	"Supply network*"	"Health*"
"3D Object*"	"Logistic*"	
"Rapid Prototyp*"	"Transport*"	
"Layer Manufactur*"	"Production*"	
"Freeform Fabrication*"		

Table 1. Keywords' groups

The logical operators 'AND' and 'OR' were used to generate the search strings within 'Title, Abstract and Keywords'. The search was limited to articles in English, published in the subject areas 'engineering', 'business, management and accounting', 'decision science', and 'economics, econometrics, and finance', resulting in 1338 articles.

These articles were screened according to the following inclusion criteria:

i. Journal articles.

ii. Full text availability.

iii. Detailed and narrow focus: Only articles explicitly reporting challenges/opportunities associated with the use of AM in the medical sector were considered.

Following Seuring and Gold (2012), (iii) was carried out independently by two authors to ensure the reliability and objectivity of the results. At the end, the article set was reduced to 106 articles.

The same two authors screened the full text of the remaining articles to confirm their relevance, resulting in a total of 34 articles (cf. Appendix A for the detailed list).

Step 3 – Reporting and dissemination

This steps usually consists of a descriptive and a content analysis. However, for the sake of brevity and since the goal of the SLR in this work is to derive the propositions for the Delphi study, here only the content analysis was carried out. The papers were divided in inductively derived categories, where each category corresponds to a specific challenge/opportunity identified. This is common practice when the literature on the topic is scarce (Seuring *et al.*, 2021). Moreover, to ensure reliability and objectivity in the categorization, we applied the same approach adopted in *Step 2* for the categorization.

We then used the results of the content analysis to derive the propositions that represent the starting point of the Delphi study.

2.2. Delphi Study

We selected the Delphi study as appropriate methodology to validate and establish the relevance of the challenges and opportunities identified since it represents a systematic iterative method for obtaining agreement on a particular topic (i.e. consensus) from a heterogeneous panel of experts (Okoli and Pawlowski, 2004; Saporiti *et al.*, 2023). The Delphi study consists of three steps.

Step 1 – Identification and Selection of Experts

The first step is to identify the panel of experts participating in the study. This step must be rigorous to improve the reliability of the research (Gbededo and Liyanage, 2020). First, the experts must be experienced individuals who can clearly provide in-depth knowledge to the research (Dohale *et al.*, 2021). Therefore, we selected experts with 5+ years of experience. Specifically, only practitioners were selected, excluding researchers since we assumed that their opinion was already collected through the SLR. Then, the panel of experts needs to be heterogeneous to ensure to foster different opinions to avoid biased results (Culot *et al.*, 2020). To achieve panel heterogeneity, two main actions were pursued. First, the experts were selected from different companies working with AM in the medical sector. Second, both manufacturers and end users were selected. This resulted in a panel of experts composed by 18 practitioners (cf. Appendix B), in line with the recommendations in the literature (Diamond *et al.*, 2014; Moeuf *et al.*, 2020).

Step 2 – Delphi study design

We presented the expert panelists with the identified challenges and opportunities to collect their opinion on their relevance. To do so, we developed and distributed a questionnaire using an Internet-based survey tool (Microsoft Forms) to guarantee results anonymity and independent judgements. We distributed the questionnaire (cf. Appendix C) iteratively, until achieving either consensus or the maximum number of rounds. Dealing with the former, following Saporiti *et al.* (2023), we evaluated the consensus through the inter-quartile range (IQR) method based on a five-point Likert scale: at IQR ≤ 1, we considered that consensus had been reached. Then, we followed Diamond *et al.* (2014) in setting the maximum number of rounds to three. The propositions not reaching the consensus in three rounds were eliminated. It is worth mentioning that, before sending the questionnaire to the panelist, we conducted a pre-test with three practitioners to validate it, ensuring its consistency and comprehensiveness (von der Gracht, 2012). The pre-test was carried out in three steps: (i) informing the experts about the research aims, (ii) sending out the questionnaire, and (iii) interviewing the experts about the clarity and appropriateness of the questions. We modified the questionnaire according to the insights received. The final version of the questionnaire was reviewed one last time by the experts involved in the pre-test and by the research team. The experts that took part to the pre-test were not part of the final panel of experts.

Step 3 – Delphi study rounds

Each round consisted of a closed-ended questionnaire where the experts were asked to evaluate the relevance of the challenge/opportunity described in the proposition using a five-point Likert scale ranging from 'not relevant' to 'very relevant'. At this stage, we evaluated the consensus on challenges/opportunities and every round resulted in a two folded output, i.e. the identification of the consensus/dissensus on every challenge/opportunity and the evaluation of the relevance attributed to the challenges/opportunities. In each round, only the challenges/opportunities not reaching consensus in the previous round were submitted to the experts. When doing so, following the literature (Kache and Seuring, 2017; Saporiti *et al.*, 2023), each expert also had access to a customised report showing the positioning of their own personal answers with respect to the panel of experts. In this way, each expert was encouraged to reflect on answers clearly outside the consensus, therefore driving the development of the Delphi study. Figure 1 reports a block diagram describing the Delphi study process.

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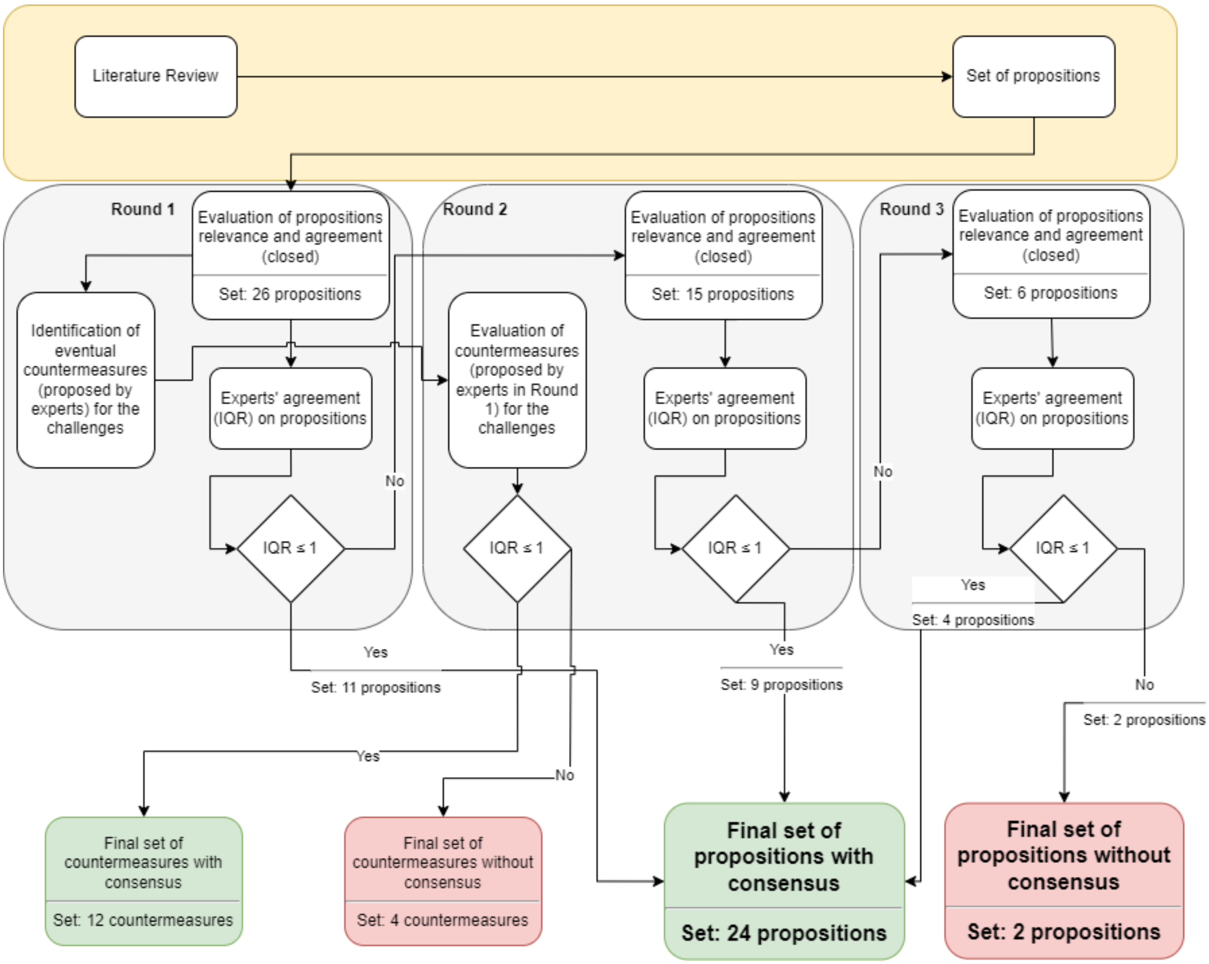

Figure 1. Delphi study process description

Moreover, in round 1 experts were asked to suggest potential countermeasures for the challenges identified. The proposed countermeasures were then included in round 2 to be evaluated and verify whether or not consensus could be reached.

Finally, following De Lima and Seuring (2023), we presented the results of the Delphi study at two online workshops, one for AM manufacturers and one for end users (physicians and surgeons). Here, for each challenge reaching consensus, end users were asked to discuss and estimate how much AM adoption in the medical sector could increase by 2030 if such challenge was to be mitigated; manufacturers were asked about the ease of mitigating such challenge by 2030. We asked the end users and manufacturers different questions because end users are expected to better understand how challenges mitigation might affect the final AM adoption while manufacturers to better understand how easy it would be to mitigate such challenges. More in detail, we asked the end users to rate the AM adoption increase as “low increase (i.e. up to 10-15%)”, “medium increase (i.e. from 10-15% up to 25-30%) or “high increase (i.e. higher than 25-30%)”; we asked the manufacturers to rate the ease of challenge mitigation as “low easiness (i.e. high investments necessary, achievable only with governmental bodies support and funding)”, “medium easiness (i.e. high investments necessary but available within the firm)”, or “high easiness (i.e. low investment necessary)”. By doing so, we aimed to derive some potential future scenarios for AM adoption in the medical sector; this would support not only physicians and surgeons in understanding how AM adoption in the medical sector could vary in the future, but also AM manufacturers and researchers in understanding the efforts required to overcome the different challenges and what they could provide in terms of increased AM adoption (and hence increased market shares).

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2.3. Theoretical Lens: the Ecosystem Pie Model

As discussed above, to support the design of an ecosystem model for AM in the medical sector, we analyzed the results obtained (challenges, opportunities, countermeasures, and future AM scenarios) according to the theoretical lens provided by the ecosystem pie model. The ecosystem pie model (Figure 2) was developed by Talmar *et al.* (2020) and it represents a qualitative strategy tool for designing ecosystem models. They developed it by following Adner's (2017) structuralist approach.

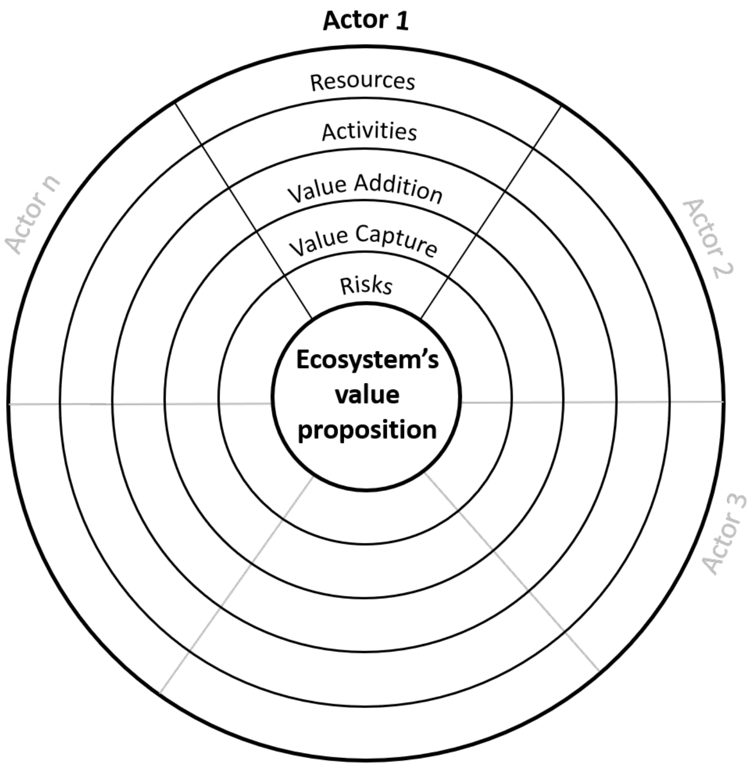

Figure 2. Ecosystem pie model (adapted from Talmar *et al.* (2020))

The ecosystem pie model is composed of two circles, which needs to be filled to support the design of an ecosystem model. The inner one is home to the *ecosystem's value proposition*, while the outer one represents a pie chart. Each slice of the pie chart corresponds to a certain *actor* involved in the ecosystem. Each slice is then further divided into different elements, i.e. *resources*, *activities*, *value addition*, *value capture*, and *risks*, the content of which varies from slice to slice (and hence from actor to actor). The so-called *constructs* of the ecosystem pie model (i.e. the *ecosystem's value proposition, actor, resources, activities, value addition, value capture,* and *risks*) are described in Table 2 from a general point of view (i.e. they are not linked to this work).

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Constructs	Definition
Ecosystem's value proposition	The *ecosystem's value proposition* represents the output of the whole ecosystem, as targeted to end users. To better understand this concept, one can see it as "what is accomplished for the end user" or "what is the problem that is solved for the end user".
Actor	*Actors* are the different entities involved in performing distinct activities within the ecosystem. In addition to the end users, these can be entities such as companies, service providers, governmental bodies, … For sake of clarity and simplicity, some *actors* can be grouped together on the basis of similarity.
Resources	This describes the most important assets to be used by a specific actor for value creation. *Resources* include not only tangible assets but also intangible assets, capabilities, knowledge, … available for value creating *activities*.
Activities	These are the *activities* an *actor* puts in place to use the *resources* available for generating value (i.e. *value addition*). In other words, *activities* are the (sets of) activities by which the *actor* generates v*alue addition*, ensuring that it earns sufficient returns in the process.
Value addition	Each *actor* contributes to the *ecosystem's value proposition* through a particular contribution: this particular contribution represents the *value addition* of that *actor*. In other words, *value addition* incorporates the products/services/financial supports/other kind of support provided by the *actor* to accomplish the *ecosystem's value proposition*.
Value capture	In exchange for their support to the ecosystem, *actors* are interested in receiving a benefit of some kind. This benefit can be either financial or non-financial (e.g. citizen welfare for a government), and it represents the *value capture* construct.
Risk	This construct includes all the challenges that might hinder or limit the accomplishment of the *ecosystem's value proposition*.

Table 2. Ecosystem pie model constructs

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As can be understood and as proven in the literature (Helman, 2020; Moerchel *et al.*, 2023), this model is suitable for designing a successful ecosystem model since, given a certain goal (i.e. the *ecosystem's value proposition*), it supports the identification of the *actors* involved and provides information on the *resources* that each actor should put in place, on the *activities* that each actor should carry out, and on the contribution (i.e. *value addition*) required by each actor to ensure that the goal is achieved. Specifically, the required *activities* and contributions (i.e. *value addition*) often need to be linked to the *risks* (i.e. challenges) that might hinder the achievement of the goal. Furthermore, this model ensures the design of a successful ecosystem since it enables all the *actors* to visualize the benefits (*value capture*) achievable by taking part in the ecosystem.

3. Challenges and Opportunities

The challenges and opportunities associated with the use of AM in the medical sector, together with the corresponding propositions later used in the Delphi study, have been inductively derived from the SLR. It is worth mentioning that in doing so we have included all the challenges and opportunities associated with the adoption of AM in the medical sector, without distinguishing between challenges and opportunities that are characteristics only of the medical sector and those that are general, i.e. applicable also to other sectors. For the sake of brevity and aiming to prioritize the discussions of this work, we summarize the findings in Table 3 and Table 4 (the former for the challenges and the latter for the opportunities). Full details can be found in Appendix D (for the challenges) and E (for the opportunities).

Challenge	Code	Proposition
Dependency on Supplier	C1	Only few suppliers are able to procure suitable AM raw materials and/or parts, causing a lack of alternative suppliers
High Production Costs	C2	Producing medical devices in AM has production costs which are much higher than those of conventional manufacturing techniques
High Investment Costs	C3	The investment costs necessary to purchase AM machines are very high
High Material Costs	C4	The costs of AM raw materials are very high
IP Issues	C5	The use of AM for producing medical devices is accompanied by issues related to IP infringements and data breaches
Social Sustainability	C6	AM requires less workforce than conventional manufacturing techniques and hence employees are reluctant to its adoption
Standardization and Certification	C7	There is a lack of standards and certification processes that complicates the use of AM for medical devices
Material Limitation	C8	There is a limited variety of materials producible via AM
Specialized Workforce (Design Phase)	C9	AM requires specialized workforce during the design phase to exploit design benefits such as those achievable through topology optimization procedures
Specialized Workforce (Production Phase)	C10	AM requires specialized workforce to operate AM machines with proper knowledge on key decisions such as production parameters to be adopted, post process operations, …
Production Limitation	C11	Production speed is limited and lower than conventional manufacturing techniques
Need for post-process operations	C12	AM parts need to undergo to post-process operations (heat treatments, polishing, …) after production
Quality	C13	AM medical parts are characterized by low quality

Table 3. Summary of the challenges identified and corresponding propositions

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Opportunity	Code	Proposition
Hedged Sourcing Strategy (Demand Risks)	O1	Integrating conventional manufacturing and additive manufacturing can minimize demand-related supply chain risks
Hedged Sourcing Strategy (Supply Risks)	O2	Integrating conventional manufacturing and additive manufacturing can minimize supply-related supply chain risks
Resilient Supply Chain	O3	Adopting AM can reduce and/or mitigate the impact of supply chain disruptions since it allows to produce on demand and close to the point of use
Environmental Sustainability	O4	The possibility provided by AM to produce parts close to the point of use reduces the environmental footprint of the supply chain since shorter transportation routes are required
Reduced Need of Employees	O5	AM requires less workforce than conventional manufacturing techniques (an operator can operate more than one AM machine)
Customization	O6	AM enables a higher degree of customization than conventional manufacturing techniques, derived mainly from a higher design freedom (e.g. topology optimization procedures)
Responsiveness (On-Demand Production)	O7	AM assures quick responses to new orders due to the on-demand production
Responsiveness (Geographical Convenience)	O8	AM assures quick responses to new orders due to the production close to the point of use
Waste Reduction	O9	AM assures a buy-to-fly ratio of almost 1:1, thus drastically reducing waste compared to conventional manufacturing techniques
MTO Production	O10	AM enables the possibility to switch from make to stock (MTS) to make to order (MTO) and hence to lower inventory levels (and hence costs)
Simpler Supply Chain	O11	AM simplify the supply chain since it encompasses less actors in the supply chain
Part Consolidation	O12	AM enables to consolidate existing part assemblies made from many components into a single part
Shareability	O13	AM allows to easily share products design as they only need to be shared via STL files to be ready to be printed

Table 4. Summary of the opportunities identified and corresponding propositions

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4. Delphi Study Results

This section presents and discusses the findings of the Delphi Study: at the conclusion of the three rounds, 24 of the 26 identified propositions reached consensus (Table 5).

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Challenge/Opportunity	Code	Round 1			Round 2			Round 3		
		IQR	Mean	St.Dev.	IQR	Mean	St.Dev.	IQR	Mean	St.Dev.
Dependency on Supplier	C1	1,5	3,27	0,90	1	3,36	1,03			
High Production Costs	C2	1	3,00	1,10						
High Investment Costs	C3	1	3,36	1,12						
High Material Costs	C4	1	2,91	1,22						
IP Issues	C5	2,5	2,73	1,42	1,5	3,27	1,19	1	3,27	0,90
Social Sustainability	C6	2,5	2,36	1,29	1	2,36	0,92			
Standardization and Certification	C7	2	3,91	1,04	0,5	3,91	0,70			
Material Limitation	C8	0,5	3,91	0,70						
Specialized Workforce (Design Phase)	C9	1	4,27	0,79						
Specialized Workforce (Production Phase)	C10	1	4,27	0,79						
Production Limitation	C11	2,5	3,09	1,58	2	2,91	1,30	0,5	3,18	0,87
Need for post-process operations	C12	2	3,82	1,17	1,5	3,73	1,10	1	3,82	1,08
Quality	C13	2	2,73	1,35	1	2,73	1,10			
Hedged Sourcing Strategy (Demand Risks)	O1	1,5	2,73	1,10	2	3,18	0,98	1	3,36	0,81
Hedged Sourcing Strategy (Supply Risks)	O2	1,5	3,00	1,18	1,5	3,36	1,03	1,5	3,36	1,03
Resilient Supply Chain	O3	1,5	3,82	0,98	1	3,91	0,94			
Environmental Sustainability	O4	1,5	3,36	1,29	0,5	3,64	1,21			
Reduced Need of Employees	O5	2	2,91	1,45	2	3,00	1,18	1,5	2,73	1,01
Customization	O6	0	4,82	0,40						
Responsiveness (On-Demand Production)	O7	0,5	4,55	0,93						
Responsiveness (Geographical Convenience)	O8	1	3,82	1,08						
Waste Reduction	O9	1,5	3,45	1,29	1	3,55	1,04			
MTO Production	O10	1,5	3,36	1,03	0,5	3,82	0,60			
Simpler Supply Chain	O11	1,5	3,36	1,29	1	3,45	0,93			
Part Consolidation	O12	1	3,18	1,08						
Shareability	O13	1	4,18	0,87						

Table 5. Delphi study results per each round in terms of IQR, mean and standard deviation per each proposition

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As can be seen, consensus has been reached in a widespread way in all the three rounds. Indeed, in the first round, eleven propositions reached the consensus (six challenges and five opportunities), in the second round, nine of the remaining propositions reached the consensus (four challenges and five opportunities), and finally, in round 3, four propositions (three challenges and one opportunity) reached the consensus. The panel of experts did not achieve consensus on Opportunities *"Hedged Sourcing Strategy (Supply Risks)"* (O2) and *"Reduced Need of Employees"* (O5).

Moreover, in round 1, experts were asked to propose potential countermeasures to the challenges. Table 6 reports the countermeasures reaching consensus in the study according to the challenge in question.

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Challenge	Code	Countermeasure	Mean	St. Dev.
Supplier Dependency	C1	Higher efforts on public investments/fundings on AM to further incentivize the AM adoption. With the increase of AM market the number of suppliers will increase and supplier dependency will lower	3,82	0,60
High Investment costs	C3	More research funding to decrease the prices of AM machines (particularly for metallic ones)	3,45	1,04
		Wider use of shared AM machines	3,55	1,13
Social Sustainability	C6	Shift of workforce to other operations related to AM such as post-processing operations	3,55	1,04
Standardization and Certification	C7	Higher effort required from certification entities (ASTM, ISO, DNV, …)	4,10	0,83
Material Limitation	C8	More fundings to develop additional AM raw materials	3,64	1,03
Specialized Workforce (Design Phase)	C9	Higher focus from higher education institutions in providing students’ knowledge on AM design	4,36	0,81
Specialized Workforce (Production Phase)	C10	Use of training groups to train more employees (also of different companies) simultaneously	3,09	0,94
		Focus of educational bodies on teaching their students how to operate AM machines	3,45	0,82
Production limitation	C11	Act on the design phase to reduce the volume of material needed so the printing process is faster	3,64	0,81
		Provide more research funding to improve AM machines performance	3,45	0,93
Need for post-process operations	C12	Act on the selection of AM machines and/or design strategies that minimize the need for post-processing	3,82	1,08
Quality	C13	Time and resources from AM manufacturers to find the optimal production process parameters	3,36	1,12

Table 6. Countermeasures suggested by the experts. Only those reaching consensus are reported

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To support the discussion of the Delphi study, we have followed the literature (Saporiti *et al.,* 2023) in grouping the challenges and opportunities reaching consensus based on the relevance the experts attributed to each (evaluated through the mean value of the replies) and on the consensus dispersion (evaluated through the coefficient of variation of replies). In this way, it was possible to develop a relevance – consensus dispersion matrix (Figure 3); this provides a concise summary of the overall impact of the major challenges and opportunities, as well as a possible prioritization among the challenges and opportunities. Indeed, the matrix can be divided into four quadrants using the median value of coefficient of variation of replies (Y axis of the matrix) and median of replies (X axis of the matrix), leading to the identification of four major groups of challenges and opportunities: low-relevance and low consensus-dispersion, low-relevance and high consensus-dispersion, high-relevance and low consensus-dispersion and high-relevance and high consensus-dispersion. Before proceeding with the discussion, it is worth clarifying that such relevance – consensus dispersion matrix does not represent a result but rather a tool used to support discussions.

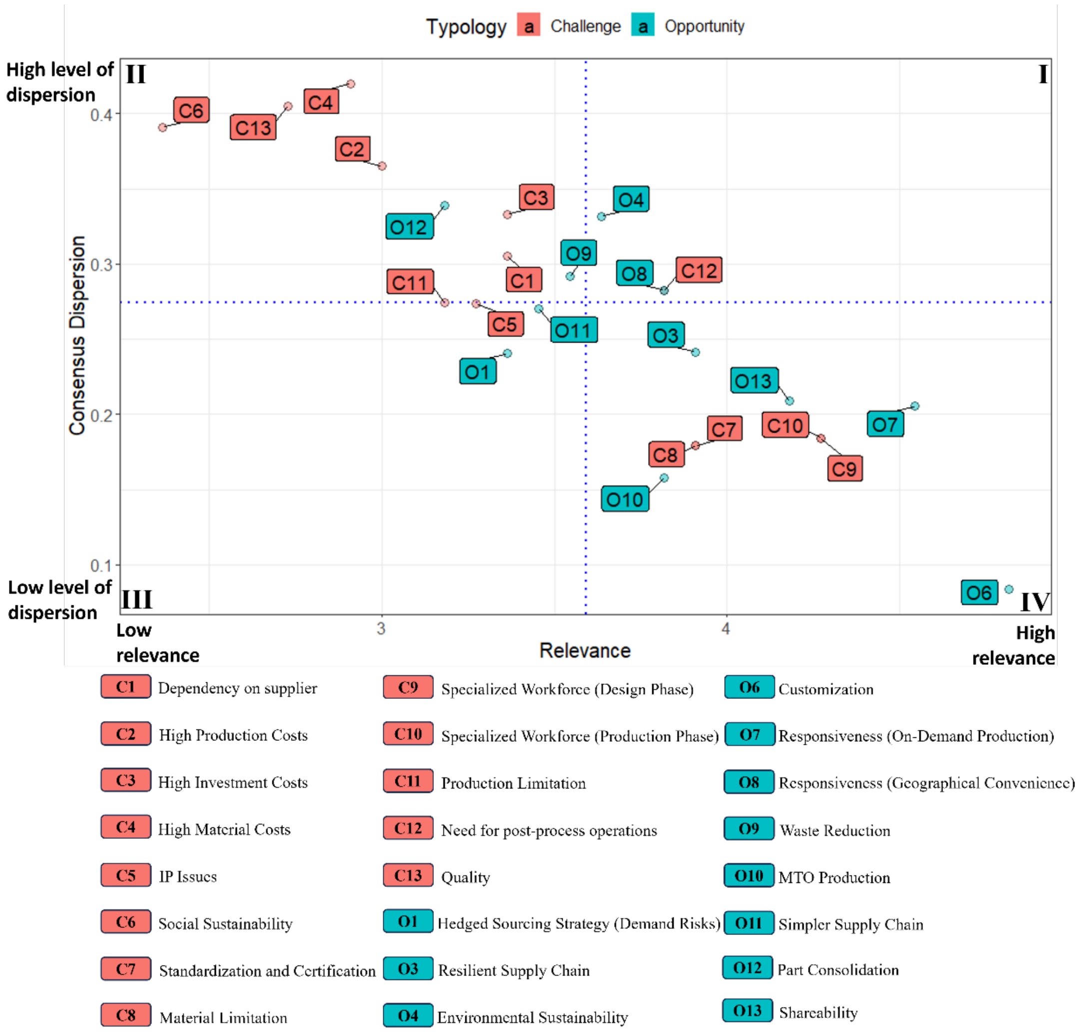

Figure 3. Relevance – consensus dispersion matrix of challenges and opportunities

In the matrix's first quadrant, i.e., high relevance and high level of consensus dispersion, one challenge and two opportunities can be found: *"Need for post-process operations"* (C12), *"Environmental Sustainability"* (O4), and *"Responsiveness (Geographical Convenience)"* (O8). Practitioners attributed high relevance to these challenges and opportunities, but with a quite high level of consensus dispersion, meaning that, although reaching consensus, the variability among practitioners' opinion is

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higher than the mean. This may be attributable to the fact that the relevance of these challenges and opportunities highly depends on factors like the specific industry, the AM machine/material adopted, etc., as exemplified by the challenge *"Need for post-process operations"* (C12). This challenge affects all AM parts, but its relevance might be perceived differently according to the AM machine/material used (some AM machines can provide better surface quality than others, cf. countermeasures in Table 6) and the application (less affected are applications without aesthetic functions or load-bearing requirements). As an example, one practitioner stated that "*the relevance of post-process operations depends on the material being used, with polymers being overall much less affected*", while another stated that "*if I consider AM for medical models, I barely care about post-process operations and how these have been carried out, while if I am dealing with AM for protheses, that's totally different*".

The matrix's second quadrant (low relevance and high level of consensus dispersion) includes seven challenges and two opportunities, i.e. *"Dependency on Supplier"* (C1), *"High Production Costs"* (C2), *"High investment Costs"* (C3), *"High Material Costs"* (C4), *"Social Sustainability"* (C6), *"Production Limitation"* (C11), *"Quality"* (C13), *"Waste Reduction"* (O9), and *"Part Consolidation"* (O12). These challenges and opportunities are deemed of low relevance by practitioners, meaning that their effects on AM adoption in the medical sector are limited. However, the relatively high consensus dispersion implies that such effects might be influenced by different factors, e.g. industry, AM machine/material adopted, etc. Exemplary of this are the challenges related to high costs (i.e. *"High Production Costs"* (C2), *"High investment Costs"* (C3), *"High Material Costs"* (C4)). Although a plethora of evidences exists about high costs associated with AM (cf. Appendix D), their relevance is often low when it comes to the medical sector since this is a sector driven mainly by the need for responsiveness rather than economy. Indeed, as one medical practitioner pointed out "*our goal is to save people and we need to be responsive rather than cost-effective to do so*". However, as one AM manufacturer put it "*if you are interested in protheses or other niche products, you might forget about costs, but if you are looking for every-day medical products, at the end of the day, it is a competition based on costs, and AM might not always be the most economic solution*". Thus, this perception favoring responsiveness might change depending on the products being considered and on the boundary conditions, explaining the relatively high level of consensus dispersion here. For example, during COVID-19 pandemic, AM face masks were highly required despite their higher costs since availability was low; now that their availability is high, AM face masks demand dropped. Other reasons behind the consensus dispersion are the materials being used (metals are more cost-sensitive than plastics) and the type of products in question (it was possible to produce cheaper nasal swabs in AM than in CM due to the possibility to print multiple nasal swabs with a single print job (Salmi *et al.*, 2020)). Furthermore, it is interesting noting the very low relevance of *"Social Sustainability"* (C6), meaning that employees do not consider AM as 'job killer': "*AM is definitely not a threat for our employees; actually, it is a potential source of improvement*", stated a participant. This is in line with the lack of consensus on the opportunity *"Reduced Need of Employees"* (O5).

One challenge and two opportunities, then, belong to the matrix's third quadrant (low relevance and low level of consensus dispersion): *"IP issues"* (C5), *"Hedged Sourcing Strategy (Demand Risk)"* (O1), and *"Simpler Supply Chain"* (O11). According to the practitioners, these challenges and opportunity only marginally influence AM adoption in the medical sector. Moreover, considering the relatively low level of consensus dispersion, this holds regardless of considerations such as the industry or AM machine/material adopted. The low relevance can be justified given the current AM applications in the medical sector. AM is used mainly for producing personalized implants, medical models, tools, instruments, medical aids, supportive guides, and prostheses. These applications are all characterized by very low production volumes (personalized implants are manufactured in a one-off production),

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which are hence less affected by the negative impact of *"Production Limitation"* (C11) and by the positive impact of *"Hedged Sourcing Strategy (Demand Risk)"* (O1). The low production volumes further justify the low relevance attributed to *"IP issues"* (C5). Indeed, this challenge has arisen mainly during extraordinary circumstances like COVID-19 pandemic where the production volumes of medical parts (mainly PPEs) were high. However, under normal circumstances, IP rights infringements are highly unlikely to happen since AM medical parts are often a one-off production. Indeed, as specified by one medical practitioners, "*when it comes to hospitals, cyber-attacks and data breaches concern patients' data like social security numbers or other similar info, AM medical products are not the target, and IP issues are not a problem since AM prostheses differ from one another*". Finally, it is interesting to underline that the demand risk represented by the opportunity *"Hedged Sourcing Strategy (Demand Risk)"* (O1) reached a consensus, while the supply risk represented by the opportunity *"Hedged Sourcing Strategy (Supply Risks)"* (O2) did not reach a consensus. This may lead to the consideration that supply risks are perceived as more influenced by the changes in the expert industrial sector or by the expert role (manufacturer or end user).

Finally, the fourth quadrant of the matrix include four challenges and five opportunities, i.e., *"Standardization and Certification"* (C7), *"Material Limitation"* (C8), *"Specialized Workforce (Design Phase)"* (C9), *"Specialized Workforce (Production Phase)"* (C10), *"Resilient Supply Chain"* (O3), *"Customization"* (O6), *"Responsiveness (On-Demand Production)"* (O7), *"MTO Production"* (O10) and *"Shareability"* (O13). These are characterized by a noteworthy relevance as well as a low degree of consensus dispersion, meaning that the experts consider them to have the biggest impact on the AM adoption in the medical sector. While some of them are intuitive and widely known from the literature (*"Material Limitation"* (C8), *"Customization"* (O6), and *"MTO Production"* (O10)), others are instead overlooked by the literature but of high concern for practitioners: *"Specialized Workforce (Design Phase)"* (C9), *"Specialized Workforce (Production Phase)"* (C10) and *"Standardization and Certification"* (C7). These are indeed the most relevant challenges identified by the Delphi study participants, especially those related to Specialized Workforce (C9 and C10) that have the highest relevance among the challenges. From participants' comments, it emerged how these are very concerning: one participant, for example, stated "*take one hundred machine workshops at random, there might be only one or two experts on AM*", while another stated that they "*do not have enough in-house experience or knowledge to fully exploit AM potentials*" (cf. below for some solutions proposed by Delphi study participants).

Finally, aiming to derive for the first time some potential future AM adoption scenarios in the medical sector, the Delphi study results were presented to the practitioners that had undertook it in two online workshops, one for end users and one for AM manufacturers. For each challenge, the former were asked to rate the potential AM adoption increase if such challenge was to be mitigated as "low increase (i.e. up to 10-15%)", "medium increase (i.e. from 10-15% up to 25-30%)" or "high increase (i.e. higher than 25-30%)", while the latter to rate the easiness of challenge mitigation as "low easiness (i.e. high investments necessary, achievable only with governmental bodies support and funding)", "medium easiness (i.e. high investments necessary but available within the firm)", or "high easiness (i.e. low investment necessary)". The results are reported in Figure 4.

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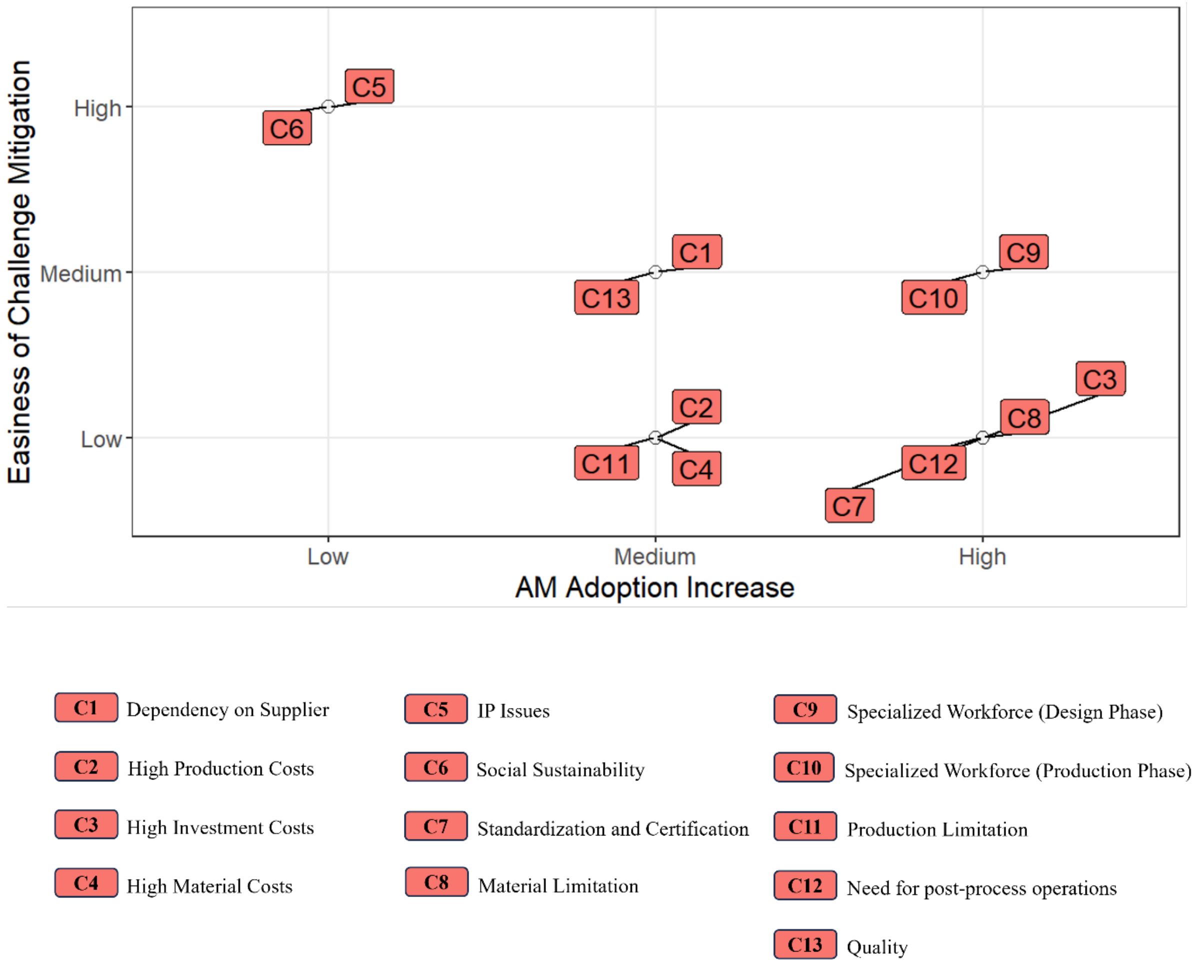

Figure 4. AM adoption increase – challenge reduction easiness matrix

As it can be seen, end users rated "*IP issues*" (C5) and "*Social Sustainability*" (C6) as "low increase": indeed, as it emerged also from the Delphi study results, they believed that AM adoption is very limitedly affected by these challenges, particularly by "*Social Sustainability*" (C6) since AM is not perceived as a 'job killer' but rather as an opportunity. Then, "*Dependency on Supplier*" (C1), "*High Production Costs*" (C2), "*High Material Costs*" (C4), "*Production Limitation*" (C11), and "*Quality*" (C13) were rated as "medium increase" since not all AM applications in the medical sectors are affected by such challenges. For example, end users highlighted how orthopedics protheses and implants are one-off productions – hence, unaffected by production limitation – and that high materials and production costs are not relevant since the main focus when producing protheses and implants is on improving patients' quality of life and less on costs. Ultimately, "*High Investment Costs*" (C3), "*Standardization and Certification*" (C7), "*Material Limitation*" (C8), "*Specialized Workforce (Design Phase)*" (C9), "*Specialized Workforce (Production Phase)*" (C10), and "*Need for post-process operations*" (C12) were rated as "high increase". Aligned with the results of the Delphi study were "*Standardization and Certification*" (C7), "*Material Limitation*" (C8), "*Specialized Workforce (Design Phase)*" (C9), "*Specialized Workforce (Production Phase)*" (C10), and "*Need for post-process operations*" (C12). These were found to be particularly relevant in limiting AM adoption (especially C9 and C10), unlike "*High Investment Costs*" (C3). Indeed, in the Delphi study results this challenge fell within the second quadrant (i.e. low relevance and high level of consensus dispersion); however, here practitioners rated it as "high increase" since they recognized that a decrease in investment costs could incentivize more hospitals and other medical entities to invest into purchasing an in-house AM machine to produce not

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only protheses and final medical devices, but also medical models. However, practitioners pointed out that for this it is crucial to have access to specialized workforce (as discussed above).

For their part, the AM manufacturers rated "*High Production Costs*" (C2), "*High Investment Costs*" (C3), "*High Material Costs*" (C4), "*Standardization and Certification*" (C7), "*Material Limitation*" (C8), "*Production Limitation*" (C11), and "*Need for post-process operations*" (C12) as "low easiness". Indeed, the manufacturers believed that overcoming these challenges (except "*Standardization and Certification*" (C7)) would require some key technological developments beyond their internal R&D capabilities: advanced R&D activities (ideally in collaboration with research centers and higher education institutions) are necessary, requiring a commitment from governmental bodies and funding agencies to support and drive such research. For example, one participant stated that "*more research funding is needed to decrease the prices of AM machines*"; similarly, another participant said that "*national and inter-national funding opportunities should be given to support AM diffusion by reducing the high costs associated with AM*". For "*Standardization and Certification*" (C7), then, no technological developments are required, but there remains the need of very high commitment from certification entities (ASTM, ISO, …): according to one participant "*current standards for AM are a disaster. It is not clear what should be done and this complicates the adoption of AM; this should be solved as soon as possible if we really want AM to become common practice in the medical sector*". "*Dependency on Supplier*" (C1), "*Specialized Workforce (Design Phase)*" (C9), "*Specialized Workforce (Production Phase)*" (C10), and "*Quality*" (C13) were rated instead as "medium easiness". Indeed, manufacturers believed that these challenges can be overcome without the need for external funding from governmental bodies and funding agencies, but that a high commitment from each AM manufacturer or cooperation with higher education institutes would suffice. Indeed, specialized workforce (C9 and C10) could be trained internally and/or through internships offered to students in higher education institutions. For example, one participant suggested using "*training groups, also between different companies, to train more employees*", while another suggested that "e*ducational bodies should teach how to design for AM and how AM machines should be operated*" and that this could be done "*by establishing internship or supporting the establishment of dedicated study programs*". "*Quality*" (C13) could then be improved dedicating time and resources to find the optimal production process parameters. These would require high commitment in terms of investments from the AM manufacturer, but it is considered doable within each AM manufacturers' capability. Finally, "*IP issues*" (C5) and "*Social Sustainability*" (C6) were rated as "high easiness" since AM manufacturers believed that few investments would suffice to overcome these challenges; they suggested that few investments in ICT infrastructure would significantly reduce data breaches risks and that rotating jobs could mitigate employees' reluctancy.

As can be seen from the development of the "AM adoption increase – challenge reduction easiness" matrix reported in Figure 4, and as it has been just discussed, some challenges are of "low easiness" to mitigate, others are of "medium easiness" to mitigate, and others are of "high easiness" to mitigate. As described above, to each level of "easiness" corresponds different requirements in terms of investments and commitment from the actors involved. It is possible, therefore, to assume that in future there could be three different AM adoption scenarios: one with low investments and commitment from the actors involved where only the "high easiness" challenges are mitigated; one with medium investments and commitment from the actors involved where both the "high easiness" and "medium easiness" challenges are mitigated; and one with high investments and commitment from the actors involved where all the challenges are mitigated, regardless the level of "easiness". Clearly, each of these future AM adoption scenarios increase AM adoption at different levels, which have been quantified through discussions with practitioners (cf. above "low increase", "medium

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increase", and "high increase"), as illustrated in Figure 5. Notably, the three future AM adoption scenarios and their implications for adoption were quantified considering as reference what we refer to here as "current scenario" or also "benchmark scenario" (the red line in Figure 5). This corresponds to the current prediction of the AM market in the medical sector. As discussed above, this reports almost a 22% Compounded Average Growth Rate from 2021 to 2030 (with a market that in 2030 will be worth almost 10 billion U.S.D.) (Precedence Research, 2021).

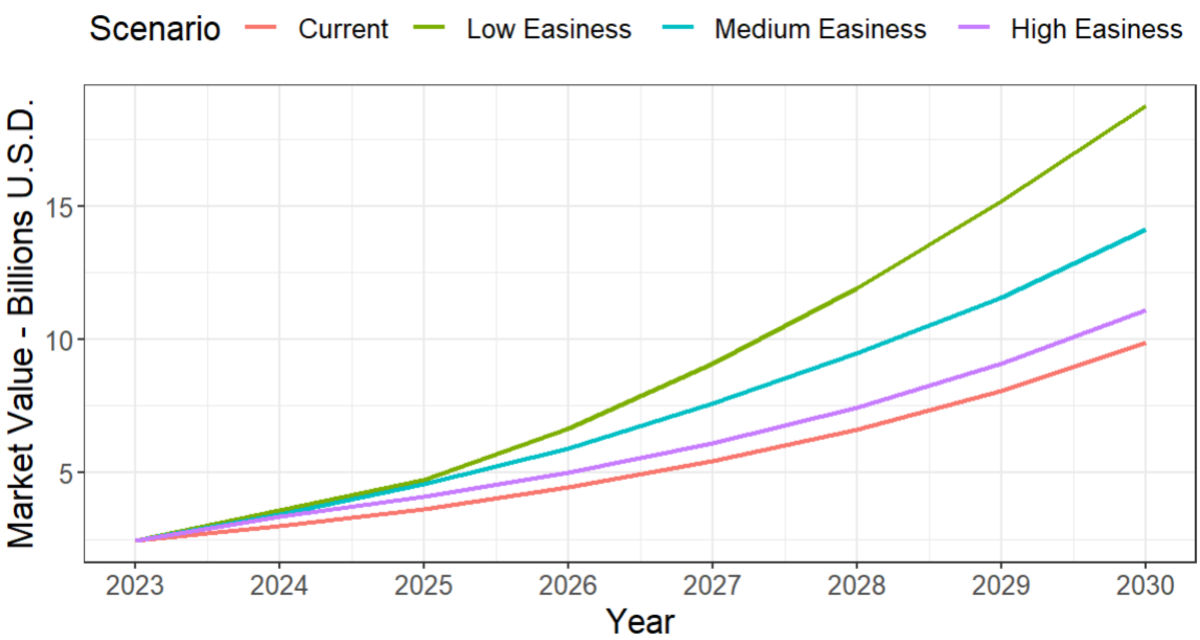

Figure 5. Schematic representation of the potential future AM adoption scenarios in the medical sector

As can be seen, the increased AM adoption of the "high easiness" scenario (which, after discussing with practitioners, has been assumed as the average of the corresponding "AM adoption increase" reported in Figure 4) with respect to the benchmark scenario appears with a very limited time delay. This is because the actions required have an immediate effect. Such is not the case for "low easiness" and "medium easiness" scenarios, which require instead some time before showing differences in AM adoption levels increment. Indeed, for the "medium easiness" scenario, AM manufacturers require some time to improve the quality of their part (finding the optimal production process parameters requires printing and testing several parts before finding the optimum one). The time lag for the "low easiness" is even higher since here, e.g., new AM machines need to be developed. For these two scenarios, increased AM adoption has been assumed as the average of the corresponding "AM adoption increase" reported in Figure 4. Using this analysis, AM manufacturers, governmental bodies, and funding agencies can have a better overview of how their efforts in R&D activities and investments might increase AM adoption (and consequently, their market shares) allowing them to estimate an expected return on investments and assess which intervention is profitable and which not.

5. Ecosystem Model

As a practitioner suggested, the design of an ecosystem model for AM in the medical sector will help to boost AM adoption in the medical sector *("We need an ecosystem model to understand who should do what and what would be the benefits and challenges")*. This view aligns with what of Salmi and Peron (2023, p.4746): "*it is crucial to understand the possible business models adoptable by the medical sector and the corresponding challenges*". Therefore, we analyzed the results (challenges, opportunities, countermeasures, and possible future AM adoption scenarios) through the ecosystem

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pie model theoretical lens developed by Talmar *et al.* (2020). As described above, this represents a useful tool to support the design of ecosystems, making it possible to identify all the constructs necessary to design an ecosystem model for AM in the medical sector. From the analysis of the countermeasures, it has been possible to identify all the a*ctors* involved in the development of such an ecosystem, as well as the *resources* the required a*ctivities* needed per actor. The analysis of the opportunities and future AM adoption scenarios helps to identify the *value addition* to be put in place and the *value capture* (or benefits/opportunities) generated by each actor. Finally, analyzing the challenges helps to identify the *risks* (or challenges) (for the sake of brevity, the detailed description of how the constructs have been identified is reported in Appendix F). Therefore, all the constructs necessary to design an ecosystem model for AM in the medical sector are known, and hence, such an ecosystem model can now be designed following Talmar *et al.*'s (2020) ecosystem pie model. We clarify that we decided not to adopt the traditional graphic representation of the ecosystem pie model: as can be seen in Talmar *et al.* (2020), the graphic representation can become quite hard to understand when there are too many constructs. Therefore, we decided to summarize all the findings in Table 7, where we report the *actors* involved, and, per actor, the *resources* needed, the required *activities*, the *value addition* to be put in place, the *value capture* (or benefits/opportunities) generated, and the r*isks* (or challenges) to be faced. This can be used as a reference by those interested in adopting AM in the medical sector since it provides all the information required to fill the ecosystem pie model and design a successful business model.

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	Actors					
	Governmental bodies	Certification entities	HEIs	AM manufacturers	Hospitals/medical practitioners	Patients
Resources	- Funding	- Regulation power	- Knowledge on AM - Training facilities & equipment - Staffs	- Knowledge on AM - Staff - AM machines - Supply chain	- Equipment for medical services - Knowledge in providing medical services - Staffs	- Money
Activities	- Provide funding opportunities - Support HEIs	- Develop new standards	- Develop AM-related study programs/course - Establish internship - Provide lifelong learning programs	- Cooperate with HEIs on internship & lifelong learning programs - Commit to find optimal production process - Develop new AM solution/processes (with HEIs if necessary) - Provide intra- and inter-organizational trainings	- Support lifelong learning of their staffs - Prefer AM products - Improve IT systems	- Provide demand for medical services
Value addition	- Funding for research/innovation projects - Funding for HEIs	- New AM standards	- Establishment of internship, courses & lifelong learning programs - Graduation of AM market-oriented students	- Databases for optimal production process - New AM machines/ solutions - AM products of lower costs and better quality	- AM-informed staffs - Demand of AM products - Improved IT systems	- Surgeries with AM products - Money inflow

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Value capture	- Better welfare and wellbeing of population (O4, O6, O9, O13) - Higher tax income	- High satisfaction on AM standards - Certification-related income	- Support for AM-related research activities - New and attractive study programs/course - New AM-skilled staffs - Closer connection with companies - Increased student satisfaction	- Simpler supply chain (O11) - Reduced inventory levels (O10) - Reduced waste (O9) - Part consolidation (O12)	- High customers' satisfaction (O1, O3, O6, O7, O8) - Simpler supply chain (O11) - Reduced inventory levels (O10)	- Improved wellbeing (O6) - Adequate and timely healthcare (O1, O3, O7, O8) - Better air quality (O4, O13) - Easily access to healthcare (O13)
Risk (challenge causing it)	- High healthcare costs if healthcare is public (C2, C3, C4)	- Fail to overcome/mitigate identified challenges	- Fail to overcome/mitigate identified challenges	- Low supply chain responsiveness and resilience (C1, C11) - Increased inventory level (C1, C11) - Low demand for AM medical products (C2, C3, C4, C7, C11, C12, C13) - Inability to produce parts/optimal parts/economic part (C9, C10) - Employees' reticence (C6)	- Reduced healthcare level (C8, C13) - Low supply chain responsiveness and resilience (C1, C11) - Increased inventory level (C1, C11)	- High healthcare costs of healthcare is private (C2) - Personal data theft (C5) - Reduced healthcare level (C8, C13)

Table 7. Ecosystem model for AM in the medical sector: actors involved and resources, activities, value addition, value capture (benefits/opportunities), and risk (challenge) per each actor.

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6. Discussion

As described in the introduction, this work is the first in the literature to deal with (i) the identification of both challenges and opportunities of AM in the medical sector from both a theoretical and empirical point of view and (ii) the design of an ecosystem model for AM in the medical sector. Starting from (i), in the literature there is only one work on the topic (Choudhary et al., 2021), which however focuses only on the challenges associated with AM adoption and considers only theoretical data. The literature available on the medical sector is thus limited to enable an extensive comparison of the results of our work with those in the literature. For this reason, we considered more fruitful to compare the challenges and opportunities of AM in the medical sector with those in other sectors. More in detail, due to the extant literature available (Blakey-Milner *et al.*, 2021; Kanishka and Acherjee, 2023; Delic *et al.*, 2019; Dwivedi *et al.*, 2017; Gao *et al.*, 2015; Chekurov *et al.*, 2021), we focused on the comparison with two leading sectors for AM, i.e. automotive and aerospace. For the sake of brevity, however, we elaborate in details only on the main interesting findings. For the comparison of all the challenges and opportunities, the reader can refer to Appendix G.

Starting from the challenges, it is interesting starting the discussion focusing on probably one of the most widely known AM limitation, i.e. its high costs ("*High Production Costs*" (C2), "*High Investment Costs*" (C3), "*High Material Costs*" (C4)). When it comes to the medical sector, these challenges have been rated by Delphi study participants as of low relevance. On the contrary, Dwivedi *et al.* (2017) reported them to have a high relevance on hindering AM diffusion in the automotive sector, with similar findings reported by Blakey-Milner *et al.* (2021) for the aerospace sector. To justify this difference, we followed Lagorio *et al.* (2021) who justified the low relevance of such challenges in the medical sector explaining that the medical sector is driven mainly by the need for responsiveness rather than low costs. It is also interesting to discuss the two other major differences in terms of relevance attributed to the different challenges between the medical and the aerospace/automotive sectors, i.e. "*IP issues*" (C5) and "*Production Limitation*" (C11). The former is ranked low in relevance in the medical sector, while it is deemed high in relevance in the aerospace and automotive sectors (Kanishka and Acherjee, 2023; Dwivedi *et al.*, 2017). Indeed, in these latter sectors, information on designs of different components are of high interest for, e.g., competitors. In the automotive sector, car manufacturers such as BMW, Toyota, and Honda have been recently sued for patent infringement (Karkaria, 2019; NikkeiAsia, 2021). This is due to the intrinsic nature of these sectors, where fierce competition exists and where the volumes sold are high. The medical sector is completely different and is characterized by a one-off production type of manufacturing. For this sector, "*Production Limitation*" (C11), then, represents a challenge in terms of low production speed, which might hinder the responsiveness of the supply chain (which has emerged to be the main focus of the medical sector). On the other hand, the aerospace and automotive sector are concerned about AM limitation in achievable sizes and dimensions since some AM technologies can only produce small and medium parts (Blakey-Milner *et al.*, 2021; Dwivedi *et al.*, 2017; Gao *et al.*, 2015). Notably, this has not been identified for the medical sector, neither in the literature nor in discussions with the practitioners. This can be due to the limited products dimensions required by the medical sector compared to those used in the, e.g., aerospace sector, which requires parts even up to two to three meters' long (Blakey-Milner *et al.*, 2021). Furthermore, Specialized Workforce (C9 and C10) also represent interesting challenges to discuss. In both the medical and aerospace/automotive sectors, these are deemed as relevant, suggesting that this lack of knowledge should be urgently filled by higher education institutes and through industrial training. However, only a few researchers discussed this challenges for the medical sector (Choudhary *et al.*, 2021; Prashar, Vasudev and Bhuddhi, 2022), while this found much more space in the literature related to the aerospace/automotive sectors (Chekurov *et al.*, 2021; Gao *et al.*,

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2015; Blakey-Milner *et al.*, 2021; Dwivedi *et al.*, 2017). This variance may be related to the fact that the medical sector started implementing AM only very recently, whereas the aerospace and automotive sectors are seen as leaders in AM, and have therefore recognized this lack much before the medical sector. Nevertheless, the lack still exists, and there remains a great need to educate workforces to be knowledgeable in AM, even though the ''2009 Roadmap for Additive Manufacturing'' urged "*the development of university courses and programs for educating the general population to enhance the interest in AM applications and generate some societal 'pull' for the technologies*" (Gao *et al.*, 2015, p. 81). Finally, one last interesting difference among the challenges is that in the aerospace and automotive sectors the lack of governmental support was identified as a relevant challenge (Blakey-Milner *et al.*, 2021; Dwivedi *et al.*, 2017; Gao *et al.*, 2015), with Dwivedi *et al.* (2017) even reporting that governmental support would be a driving power in the diffusion of AM in the automotive sector. This challenge was not even identified in the medical sector literature, but governmental support widely emerged as important in the discussions with the Delphi study participants. Indeed, governmental support was reported as a countermeasure for many of the challenges (cf. Table 3), and it was also reported to lead to high increase in AM adoption (cf. Figure 3). This discrepancy between the literature on the medical and on the aerospace/automotive sectors highlights the current low knowledge of researchers on AM in the medical sector and further confirms the relevance of this work.

Regarding AM opportunities, it is interesting starting from the opportunity deemed of the highest relevance in the medical sector, i.e. "*Customization*" (O6). As previously discussed, the medical sector is attracted by the design flexibility and freedom of AM to produce customizable medical parts that would improve patients' wellbeing and quality of life. For the automotive and aerospace sectors, instead, opportunities lie in design flexibility and the freedom AM offers in producing lighter components. Indeed, in this way industry professionals can achieve substantial savings during operations (e.g. fuel consumption reduction) (Blakey-Milner *et al.*, 2021; Delic *et al.*, 2019; Gao *et al.*, 2015). For example, reducing the weight of a Boeing 787 by 20% would reduce the fuel consumption by 10-12% (Blakey-Milner *et al.*, 2021). To explain the different interest in the design flexibility and freedom of AM, we can rely on the different goals between these sectors, with the automotive and aerospace sectors being more interested in reducing costs, while the medical sector is more interested in the patients' wellbeing. Another interesting opportunity difference between the medical and aerospace/automotive sectors concerns the opportunity "*Simpler Supply Chain*" (O11). This opportunity is considered of low relevance by the medical sector and of high relevance by the aerospace and automotive sectors. The inherently different characteristics of the supply chains can explain this difference, with aerospace and automotive sectors being characterized by a much higher number of tiers of suppliers, manufacturers, distributors and service providers, which are even spread around the world. This is also linked to the different number of components constituting the final product, with cars containing anything between 15 000 and 25 000 components. "*Part Consolidation*" (O12) constitutes another interesting difference between the two sectors. It is deemed of low relevance in the medical sector because medical products are often single products not requiring any assembly. In contrast, aerospace and automotive products very often involve the assembly of many components, explaining why this opportunity is deemed so relevant for these sectors. To illustrate, the Ariane 6 rocket injector head built via AM reduced the number of components from almost 250 to a single one (EOS, 2018). Similarly, NASA produced rocket engine in AM reducing the number of components from 115 to 2 (NASA, 2013). Finally, comparing our results with the literature on the aerospace and automotive sectors, we have identified two opportunities that are characteristics of the aerospace and automotive sectors but that are not of interest for the medical sector. The first deals with "parts sustainment": aging aircrafts or cars might be affected by the lack of available spare

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parts if these are produced in CM. However, if spare parts are managed with AM, these can be printed on-demand based on the CAD file stored online (Blakey-Milner *et al.*, 2021). This constitutes a common AM opportunity in the aerospace and automotive sectors since these are characterized by aging products (aircrafts, cars, …) that run out of production and require spare parts to continue functioning; such is never the case for medical products since these are not operating products like cars or aircrafts. The second opportunity that concerns only the aerospace and automotive sectors is the possibility of AM to repair components and/or products. Again, due to the intrinsic characteristics of the medical sector, this is not considered an opportunity here since medical parts, in the unlikely event of a failure, are substituted with new ones with improved performance to avoid another failure.

From this comparison between the challenges and opportunities of AM in the medical and the aerospace/automotive sectors, some main differences have emerged, especially in terms of relevance. However, what is interesting noting from such comparison is also the novelty of the literature on AM in the medical sector, which is lacking a comprehensive analysis of the challenges and opportunities involved (cf. governmental support), contrary to leading sectors such as the aerospace and automotive. This paper contributes to filling this gap. Moreover, the analyses of countermeasures and ecosystem model design allow us to identify new perspectives on challenges and opportunities, further complementing those found from the literature.

Furthermore, the ecosystem model herein designed, to the best of the authors' knowledge, represents the first of its kind and it is expected to support a boost of AM in the medical sector by ensuring informed decisions. Indeed, as Talmar *et al.* (2020, pp. 7-8) affirmed, the ecosystem model developed following the ecosystem pie model "*empowers managers to make informed decisions about their strategies*", helping them in their strategical decisions through a systematic analysis of the situation where the different actors to be involved are identified, the linkages between these actors and their activities are highlighted, and critical factors likely to determine the success of an ecosystem, as well as the risks and challenges, are exposed. According to Jarzabkowski and Kaplan (2015) and Wright *et al.* (2013), these represent all the required information for the development of a successful ecosystem model since it allows to develop the strategic insights necessary. More in detail, thanks to such information, the ecosystem model herein developed provides insights both in a prospective outlook (for establishing future ecosystems) and in a retrospective outlook (for reflecting upon an existing ecosystem and then, eventually, redesigning it according to the insights gained). Considering the results herein obtained, it emerged clearly that it is pivotal to have governmental support. Indeed, most of the countermeasures identified to mitigate the challenges required some form of governmental support (cf. Table 6). This, in turn, would result in a considerable increase in the adoption of AM in the medical sector (cf. Figure 5). As mentioned above, however, the stringent need for governmental support is not completely understood when it comes to the medical sector: for example, contrary to the aerospace and automotive sectors, the lack of governmental support was not even identified as a challenge in the literature on the medical sector. This lack of awareness about the importance of governmental support is further confirmed when considering the funding opportunities provided by the different national and international funding agencies: the majority of the AM-related projects awarded by the European Commission deal with sectors other than the medical one (e.g. aerospace, automotive, energy, …) (European Commission, 2024). Likewise, out of the 75 projects that the European Commission short-listed for the final year of Horizon 2020 Health societal challenge, none were on AM (European Commission, 2021). Similar observations can be made about the involvement of higher education institutions. As shown above, both the literature on the medical and other sectors (e.g. automotive and aerospace) report the lack of knowledge on AM as a relevant challenge, with, however, the literature on the medical sector being far more limited than

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that in the other sectors. This has repercussions on the knowledge developed and provided by higher education institutions. Although these are still lagging in filling the gap between theory and practice (Gao *et al.*, 2015), they are working to close it. For example, various universities have recently put into place specific courses on AM (e.g. EiT Manufacturing, 2023; University of Nottingham, 2023; TUM 2023), but their focus is not on the medical sector. Although one might say that a specific focus on the medical is not needed, the comparison of challenges and opportunities of AM in the medical sector with those in the aerospace and automotive sectors have shown that there are differences. Just to recap one, the medical sector is interested in designing products that matches the human physiology, while the aerospace and automotive sector in designing products with reduced weight, with hence very different aspects and boundary conditions to account for in the design phase. Moreover, the funding availability in sectors different from the medical also influences the AM manufacturers and their R&D activities, which will hence align towards solving challenges of sectors other than the medical one. This is an already visible phenomenon, as reported by Villapún *et al.* (2022, p.207): "*manufacturer advancements tend to favor engagement with larger scale industries such as automotive or aerospace yet align less closely with the medical device market*". However, as shown by our ecosystem model, the commitment of AM manufacturers is also a crucial aspect to ensure a successful spread of AM in the medical sector, and the benefits arising from such commitment would be considerable (especially for pioneers) due to the high increase in the market value potentially achievable.

As can be seen, the major actors involved in the ecosystems have very limited experience with and knowledge on the medical sector. Just to repeat some examples, higher education institutions have recently developed courses not focusing on AM, AM manufacturers are aligning their R&D activities with the need of sectors completely different from the medical, etc. However, considering the increasing interest in AM for the medical sector, especially after the COVID-19 pandemic (cf. CAGR in the Introduction Section), these actors will soon have to deal with the specific characteristics of the medical sector, and currently, they are unprepared for it. The ecosystem model herein developed is meant to guide them through this process, identifying clearly what they should do, which resources they should place, which detailed activities should be implemented, which challenges they should face, etc.

7. Conclusions and Contributions

Although the use of AM has the potentialities to revolutionize the medical sector, this breakthrough has not taken place yet, and AM adoption in the medical sector has yet to reach its potential. The use of AM in the medical sector is quite recent, and hence, the associated general knowledge is low and lacking. This, in turn, limits the adoption of AM in the medical sector. With this work, we aim to fill this literature gap and thus boost the adoption of AM in the medical sector. To do so, we first focused on filling the lack of knowledge about the challenges and opportunities associated with the use of AM in the medical sector, providing a thorough analysis. To do so, we adopted a two-steps methodology, i.e. an SLR and a Delphi study. Specifically, the SLR was performed to identify the challenges and opportunities associated with AM adoption in the medical sector reported in the literature; these were then proposed to practitioners working in the medical field to validate them and establish their relevance through the Delphi study. From the results, it has been possible to identify the most relevant challenges and opportunities. As an example, the most relevant challenges are those related to the lack of employee knowledge on AM, while the most relevant opportunity is that related to the possibility to produce customized medical products that would fit better patients' needs. In addition, this work has investigated the potential countermeasures for the challenges identified and how the mitigation of such challenges is expected to influence AM future adoption scenarios. To do so, we

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performed online workshops with Delphi study participants, from which we identified three main possible AM future adoption scenarios, whose occurrence depends on the commitment of different entities. In particular, we identified that the widest spread of AM in the medical sector requires a strong commitment of governmental bodies, who can support the mitigation of the most relevant challenges, mainly through funding opportunities. Finally, to further boost AM in the medical sector, we designed an ecosystem model for AM in the medical sector. In this way, it was possible to identify all the actors (organizations, governmental bodies, …) that should be involved in such an ecosystem for a successful adoption of AM in the medical sector. Moreover, per each actor, we identified what they should do (in terms of resources to be invested and activities to be performed), what they would achieve (in terms of benefits) and what challenges thy might face. To design such an ecosystem, we analysed all the obtained results (challenges, opportunities, countermeasures and possible AM future adoption scenarios) using the theoretical lens of the ecosystem pie model, which has been proven satisfactorily in the literature in designing clear and successful business models.

Due to the diversity of results, our work contributes to both theory and practice. We list the following main contributions to theory:

- State-of-the-art expansion with respect to the challenges and opportunities of AM in the medical sector: this represents the first work to provide a thorough understanding of the challenges and opportunities of AM in the medical sector. Moreover, this work provides not only theoretical, but also empirical data. Furthermore, thanks to this work it is also possible to understand which are the most relevant challenges and opportunities, which countermeasures should be adopted to mitigate the effect of the challenges and how this will affect AM adoption scenarios in the future. All these aspects are currently missing in the literature;
- Ecosystem model design: for the first time in the literature, an ecosystem model for AM in the medical sector has been designed by building on the ecosystem pie model. In addition to further proving the effectiveness of the ecosystem pie model to support the design of ecosystem models, it provides a sound theoretical support for the design of a successful ecosystem model, identifying all the actors to be involved, describing what their contribution should be, what benefits they might expect to achieve, and the challenges they may encounter.

We contribute to practice in the following ways:

- Physicians and surgeons and AM manufacturers: through access to a complete list of challenges and opportunities with their corresponding relevance, physicians, surgeons, and AM manufacturers now have a clear overview of the positive and negative implications of adopting AM in the medical sector;
- AM manufacturers: AM manufacturers further benefit from this work because they can identify the most relevant challenges and consequently align their R&D activities with physicians' practice. Further, the development of three different potential future AM adoption scenarios helps AM manufacturers to understand what their efforts in R&D activities and investments could provide in terms of increased AM adoption;
- Governmental bodies and funding agencies: our identification of the countermeasures help these actors to understand more clearly what they can do to boost AM in the medical sector. Moreover, the development of three different potential future AM adoption scenarios equips them with an overview of what their efforts in investments could provide in terms of increased AM adoption;

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- Researchers: the identification of the challenges involved and the relevance attributed to each challenge also benefits researchers, who can now focus their efforts on mitigating the most relevant challenges. In doing so, they can further leverage this work given that possible countermeasures to the different challenges were collected from the Delphi study. Further, the three different potential future AM adoption scenarios enable them to understand how their activities would impact AM adoption;
- All the actors involved in the ecosystem: the design of the ecosystem model facilitates a better understanding of which actors are needed to design and develop a successful ecosystem and provides a clearer idea of what the contribution of each actor should be, which benefits they can expect to achieve, and the challenges they may encounter.

This work is however not without limitations, opening up potential for future research:

- This study performs a Delphi study, which enables access to a significant but limited number of practitioners' perspective. Therefore, this work could be extended by broadening the panel of experts through surveys or other methodologies more suitable to collecting opinion from a wider panel;
- Our work refers to practitioners operating in more than one country but with limited geographic origin. Future works might extend this aspect and carry out a comparison between, e.g., developing and developed countries;
- The Delphi study participants contacted in this work are lead users and pioneers in the adoption of AM in the medical sector. Therefore, it could be interesting in future to investigate whether practitioners having just adopted AM might have different perceptions on the topics herein investigated;
- This work does not delve into details about the dispersion of the relevance attributed to the different challenges and opportunities. Therefore, future works might try to better analyze how different factors such as the business industry, the AM machine/material adopted, etc. affect the perception of practitioners on the relevance of the challenges and opportunities.

Appendices

Appendices can be found at https://github.com/XY122492/Appendix-Delphi-AM-Medical. Please note that files need to be downloaded for being visible.

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